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

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LIGITATION	)	**MDL No. 2545**
	)	**Case No. 14 C 1748**
This document relates to:	)	
MEDICAL MUTUAL OF OHIO,	)	
Plaintiff,	)	
v.	)	**Case No. 14 C 8857**
ABBVIE INC., et al.,	)	
Defendants.	)	

CASE MANAGEMENT ORDER NO. 146
(Memorandum Opinion and Order on Defendants' Motion for Summary Judgment in *Med Mutual of Ohio v. AbbVie Inc.*, No. 14 C 8857)

MATTHEW F. KENNELLY, District Judge:

In this MDL proceeding, thousands of individual plaintiffs have filed personal injury lawsuits against manufacturers, promoters, and sellers of testosterone replacement therapy (TRT) drugs. The individual plaintiffs allege that defendants' TRT drugs caused them to suffer serious cardiovascular and venous thromboembolic injuries.

Medical Mutual of Ohio (MMO), an Ohio mutual insurance company, has also filed a lawsuit that is part of the MDL proceeding. MMO has sued AbbVie, Inc., Actavis, Inc., Auxilium Pharmaceuticals, Inc., Eli Lilly & Company, Endo Pharmaceuticals, Inc.,

and affiliated entities.[1] MMO alleges that it suffered economic injuries when, as a result of defendants' fraudulent marketing schemes, it made reimbursement payments for what it alleges were medically inappropriate TRT prescriptions.

The Court previously dismissed some of MMO's claims but allowed others to proceed. *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 159 F. Supp. 3d 898 (N.D. Ill. 2016) (*MMO I*); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, Nos. 14 C 1748, 14 C 8857, MDL No. 2545, 2016 WL 4091620 (N.D. Ill. Aug. 2, 2016) (*MMO II*). MMO's surviving claims are made under the federal RICO Act, 18 U.S.C. § 1962(c), against defendants AbbVie, Auxilium, Endo, and Lilly; for conspiracy to violate the Act, 18 U.S.C. § 1962(d), against defendants AbbVie, Auxilium, Endo, Lilly, and Actavis; and against defendants AbbVie, Auxilium, Endo, and Lilly for negligent misrepresentation under Ohio law. In July 2018, the Court denied MMO's motion to certify a putative class of third-party payors (TPPs) asserting these same claims. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, Nos. 14 C 1748, 14 C 8857, MDL No. 2545, 2018 WL 3586182 (N.D. Ill. July 26, 2018) (*MMO III*). And in September 2018, the Court granted MMO's motion to amend its third amended complaint (TAC) to delete allegations regarding Auxilium's TRT drug Testopel but denied the motion in all other respects. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, Nos. 14 C 1748, 14 C 8857, MDL No. 2545, 2018 WL 4333625 (N.D. Ill. Sept. 11, 2018).

Defendants have moved for summary judgment on all of MMO's remaining claims. The Court grants defendants' motion, concluding there is insufficient evidence

[1] MMO originally sued GlaxoSmithKline LLC and Oscient Pharmaceuticals Corp. as well, but there are no remaining claims against those defendants.

from which a reasonable jury could find that defendants' alleged misrepresentations regarding the safety or efficacy of their TRT drugs proximately caused MMO's alleged injuries.

Background

The Court takes the following facts from prior orders in MMO's case, the TAC,[2] and the parties' summary judgment briefing, including their Northern District of Illinois Local Rule 56.1 statements and responses. The Court notes which facts are disputed.

A. Defendants' TRT drugs

In males, testosterone is the primary androgenic hormone responsible for normal male physical and sexual development. Male hypogonadism is an absence or deficiency of testosterone resulting from a pathological condition of the testes, the hypothalamus, or the pituitary. It is generally characterized as "primary" or "secondary" hypogonadism. Primary hypogonadism is the result of testicular failure to produce adequate levels of testosterone. Secondary hypogonadism results from a disorder of the pituitary gland or the hypothalamus. Hypogonadism in adult males can result in decreased sexual interest and desire, erectile dysfunction, benign breast enlargement, decreased muscular strength, sparse body hair, and reduced bone mass. Primary and secondary hypogonadism are sometimes called "classical" hypogonadism.

When the Food and Drug Administration (FDA) approves a drug, it is deemed safe and effective for certain medical conditions. The use for which a drug has been approved is referred to as an "indication." A label for an approved drug—including both

[2] MMO has not filed a version of the fourth amended complaint that complies with the Court's order granting in part and denying in part MMO's motion for leave to amend. The parties cite to the TAC in their summary judgment briefing, so the Court does the same in this Order.

the physical label and the package inserts for physicians and patients—may indicate use only for the approved indications. A drug manufacturer may not include a new indication on its labels without receiving prior approval from the FDA. Doctors, however, are permitted to prescribe drugs for "off-label" uses, meaning uses outside the approved indications.

The FDA has approved testosterone "as replacement therapy only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause . . . hypogonadism." Defs.' Reply in Support of Mot. for Summ. J. (Defs.' Reply), Ex. 37 (FDA March 2015 Drug Safety Communication) at 1. FDA-approved testosterone formulations include topical gels, transdermal patches, buccal systems (applied to the upper gum or inner cheek), and injections. At issue in the present case are defendants' topical testosterone formulations (topical TRTs): AndroGel, manufactured by AbbVie; Testim, manufactured by Auxilium; Fortesta, manufactured by Endo; and Axiron, manufactured by Lilly.[3]

On January 31, 2014, the FDA issued a drug safety communication to announce its investigation of risks potentially associated with use of testosterone products, including defendants' TRT drugs. The FDA stated, in relevant part:

> The U.S. Food and Drug Administration (FDA) is investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. We have been monitoring this risk and decided to reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events

[3] MMO has also asserted claims relating to Auxilium's TRT drug, Striant, and Endo's TRT drug, Delatestryl. The parties, however, do not discuss these drugs in their summary judgment briefing. Likewise, MMO has asserted claims relating to Actavis's TRT drug, Androderm. Although the Court has dismissed all claims against Actavis based on the sale and marketing of Androderm, MMO maintains that evidence regarding Androderm is relevant to its conspiracy claims against Actavis.

among groups of men prescribed testosterone therapy. . . .

> At this time, FDA has not concluded that FDA-approved testosterone treatment increases the risk of stroke, heart attack, or death.

MMO's Opp. to Defs.' Mot. for Summ. J. (MMO Opp.), Ex. 171, at 1. The FDA also stated that "[n]one of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition." *Id.*

In September 2014, the FDA convened an advisory committee to discuss the investigation into adverse cardiovascular outcomes potentially associated with TRT use. That same month, the advisory committee voted to recommend a change to the labeling of drugs in the TRT class. The FDA announced the required label changes in a drug safety communication in March 2015. The changes required TRT manufacturers, including defendants, "to clarify the approved uses of" TRTs and "add information . . . about a possible increased risk of heart attacks and strokes in patients taking testosterone." FDA March 2015 Drug Safety Communication at 1. In the drug safety communication, the FDA reiterated the approved uses for testosterone as a replacement therapy and stated that it had "become aware that testosterone [was] being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging." *Id.* The FDA further stated that "[t]he benefits and safety of this use have not been established." *Id.* The FDA-mandated labeling changes did not formally go into effect until May 2015.

B. MMO's drug formulary

MMO is an Ohio mutual insurance company that provides prescription drug benefits to patients covered under its insurance plans. According to MMO, if it provides drug benefit coverage for a patient's TRT prescription, it will pay most of the

prescription's cost, and the patient will pay the remainder. Whether MMO will cover the cost of a TRT prescription depends on the drug's status on MMO's formulary, meaning its list of covered drugs.[4]

It is undisputed that MMO "relie[s] on the expertise of" a separate corporation—its pharmacy benefit manager (PBM)—to decide which drugs are included on its formulary. MMO Opp. at 21; *see also* Defs.' L.R. 56.1 Stat. ¶ 13; MMO L.R. 56.1 Resp. ¶ 13. Medco was MMO's PBM from 1998 until April 2012. In April 2012, Express Scripts (ESI) acquired Medco and became MMO's PBM. According to John Shoemaker, MMO's designated Rule 30(b)(6) corporate representative, MMO's formulary during the time relevant to this lawsuit was "put together by the PBM." Defs.' Mot., Ex. 6 (Shoemaker Dep.) at 83:20-21; *see also id.* at 295:20-22 ("Medical Mutual could not make any formulary decisions because we didn't have the right to make those decisions."); Defs.' Mot., Ex. 8 (Dep. of Dr. Timothy Colligan, MMO's former Director of Pharmaceutical Care Management and Prescription Drug Program) at 179:23-24 ("We did not alter—we did not deviate from Medco's formulary."); Defs.' Mot., Ex. 4 (Canaday Dep.) at 230:11-14 (testifying that MMO does not customize ESI's formulary).[5] The parties agree that AndroGel has been on MMO's formulary since "at least" 2001, *see* Defs.' L.R. 56.1 Stat. ¶ 77; MMO's L.R. 56.1 Resp. ¶ 77, but as far as the Court can tell, they have not specified how long the other defendants' drugs have been on the

[4] MMO has more than one formulary. *See, e.g.*, Defs.' Mot. for Summ J. (Defs.' Mot.), Ex. 4 (Dep. of Dr. Kathryn Canaday, MMO's Pharmacy Director) at 230:8-14. The parties, however, do not distinguish between the formularies. For ease of reference, the Court refers to MMO's formulary in the singular.

[5] Dr. Canaday testified that in 2017, MMO customized "for the ACA High Performance formula to meet Ohio benchmark rules," but that "Basic Plus, Basic, National Preferred, [and] National Preferred Plus are not customized." *Id.* at 230:11-14. Neither MMO nor defendants have argued that the ACA-related customization is relevant to this action.

formulary. Medco and ESI's corporate representative, Jason Dohm, testified that he did not know when either PBM first put a TRT drug on its formulary and did not know the basis for either PBM's decision to do so. Defs.' Mot., Ex. 25 (Dohm Dep.) at 51:3-7; Defs.' Reply, Ex. 38 (Dohm Dep.) at 48:16-19, 49:3-6.

According to Dohm, ESI uses two committees to decide which drugs should be included on its formulary: a Therapeutic Assessment Committee comprising pharmacists and physicians, and a Pharmacy and Therapeutics (P&T) Committee comprising "thought leaders and academics." Defs.' Mot., Ex. 25 (Dohm Dep.) at 24:9-24, 25:1-6, 27:1-9, 28:20-29:11. The Therapeutic Assessment Committee conducts an annual review of the "top . . . 100 therapy classes of drugs" and conducts ongoing research to identify new science. *Id.* at 25:13-26:5. It makes formulary recommendations to the P&T Committee, which in turn makes "the ultimate binding decision[s]." *Id.* at 24:14-24. Both committees consider resources including press releases, scientific literature, clinical studies, drug labels, and information provided by drug manufacturers' medical science liaisons. ESI also has a Drug Evaluation Unit that is "responsible for the Therapeutic Assessment Committee" as well as prior authorization policies, step therapy policies, and other clinical policies. *Id.* at 41:6-14. The Drug Evaluation Unit consists entirely of pharmacists who "live and breathe in the medical literature," work with the P&T Committee, and report to ESI's Chief Medical Officer. *Id.* at 41:13-24. Dohm testified during his deposition that ESI's P&T Committee "would not accept information from a manufacturer at face value without doing [its] own due diligence." *Id.* at 35:1-4; *see also id.* at 162:4-11 (testifying that ESI would consider pivotal trial data while making formulary decisions, but that ESI's "job is to scrutinize the

heck out of it"). MMO argues, and defendants do not dispute, that "Medco and ESI followed the same general approach to formulary and drug coverage recommendations to clients such as MMO." MMO Opp. at 21; *see* Defs.' Reply at 11 n.10.

C. MMO's management of its drug formulary

Although MMO relies on its PBM to determine which drugs are on its formulary, it manages the formulary "with the implementation of utilization management tools, such as step edits and prior authorizations." MMO L.R. 56.1 Resp. ¶ 13; *see also* Defs.' L.R. 56.1 Resp. ¶ 6; Defs.' Mot., Ex. 6 (Shoemaker Dep.) at 390:17-391:2 (testifying that MMO had the ability and authority to impose utilization management restrictions for on-formulary drugs throughout the time relevant to this action). A prior authorization rule requires prescribers to receive pre-approval before prescribing certain drugs. If a drug is subject to a prior authorization requirement, it will not qualify for coverage until the pre-approval is in place. Dr. Marko Blagojevic, MMO's Manager of Clinical Pharmacy Programs, testified during his deposition that "[t]he main purpose of a PA[6] is to make sure that drugs are being used in clinically appropriate circumstances, that they're going to be effective for the conditions that they're being used for." MMO Opp., Ex. 35 (Blagojevic Dep.) at 141:3-9. A step edit rule (also called a step therapy rule) requires a patient to try one or more on-formulary drug(s) in a therapeutic class before an insurer will cover a prescription for another drug in that class.

MMO's Pharmacy Quality Management (PQM) Committee, comprising physicians and pharmacists, is responsible for deciding whether to impose prior authorization rules, step therapy rules, and other utilization management restrictions.

[6] PA refers to prior authorization.

Medco and ESI sometimes make recommendations to MMO about utilization management restrictions, but MMO makes the final decision regarding whether to follow the recommendations. *See, e.g.*, MMO Opp., Ex. 44 (Dep. of Dr. Milap Nahata, a chairperson of MMO's PQM Committee) at 67:2-10 (agreeing that after Medco shared utilization management recommendations with MMO, "MMO made the decision about whether to apply it"); MMO Opp., Ex. 37 (Dep. of Dr. Shaleen Joshi, a former MMO pharmacist) at 63:14-25 (testifying that MMO would not automatically accept ESI's prior authorization policies, but rather would evaluate and make decisions about them at PQM Committee meetings). According to Dr. Blagojevic, MMO's PQM Committee uses many sources of clinical information to make its decisions, including "professional journals, professional guidelines, publications that we receive from industry, drug reps, publications, the trade publications that come out, experts that we have, physicians. Anything really that's peer-reviewed also is included[.]" MMO Opp., Ex. 35 (Blagojevic Dep.) at 172:4-14; *see also* MMO Opp., Ex. 42 (Canaday Dep.) at 170:17-19 (agreeing that MMO's pharmacy department "stay[s] on top of what a [drug's] package insert" says). Furthermore, Dr. Canaday testified that she has never relied solely on what a drug manufacturer has told her in making a utilization management decision; does not know anyone within MMO who has; and does not think it would be ESI's practice to do so.

1. MMO's prior authorization rules for testosterone

MMO did not establish any prior authorization requirement for topical TRTs until July 2016. The prior authorization requirement MMO established at that time "limit[ed] coverage of topical TRT drugs to only those uses that are FDA approved or have

sufficient clinical evidence in the literature that is supportive." *See* MMO Opp., Ex. 52 (July 2016 PQM Minutes) at 2. Although MMO established the prior authorization requirement in July 2016, it did not go into effect until late 2017. *See* MMO L.R. 56.1 Stat. ¶ 30 (stating that "the prior authorization did not take effect until 2017"); Defs.' Mot., Ex. 4 (Canaday Dep.) at 356:1-20 (testifying during her November 29, 2017 deposition that she talked to someone at ESI "three weeks ago" to "understand . . . how it was missed that the edit wasn't placed").

Both parties have offered evidence regarding MMO's consideration of prior authorization rules for topical TRTs prior to July 2016. The Court provides the following summary of that evidence.

On January 13, 2004, Medco sent a memorandum to its P&T Committee for review in advance of its January 29, 2004 meeting. The memorandum contains attachments including a "Summary from the Second Annual Andropause Consensus Meeting" of The Endocrine Society. Defs.' Mot., Ex. 95, at MMO_TRT_00163802, -840. The summary contains mixed information about the safety and efficacy of TRT drugs. On the one hand, for example, it states that "[t]he members of the Consensus Conference were aware that data are limited or lacking on the long-term benefits and risks of TRT in older men." *Id.* at -840. On the other, it states that "[t]here are several potential benefits of TRT" including "improvements in libido, energy level, lean body mass, strength, and bone mineral density[.]" *Id.* On January 29, 2004, Medco's P&T Committee "reviewed new prior authorization criteria for select androgens." Defs.' Mot., Ex. 91 at 8. The P&T Committee approved "[t]he clinical basis for the criteria . . . with the modification that coverage not be provided for the treatment of signs or symptoms of

andropause." *Id.* MMO alleges that andropause, also called age-related hypogonadism or Low T, is a condition that defendants "invented" to "transform the male aging process into a curable disease state." TAC ¶ 4.

Defendants suggest that Medco sent the P&T Committee's recommendation to MMO's PQM Committee in 2004. By contrast, MMO contends that "[d]efendants fail to present any evidence that any employee of MMO ever saw this document." MMO Opp. at 53. MMO's corporate representative, however, testified, "I know that Medical Mutual received a document from Medco—because there wasn't a date on it, but in the attached article with it, I believe it was somewhere in 2004—that Medco did have a prior authorization function available." Defs.' Mot., Ex. 6 (Shoemaker Dep.) at 296:6-10. He continued, "Obviously at that particular point in time, we made a decision not to institute a prior authorization because we did not." *Id.* at 296:10-12; *see also id.* at 272:7-273:6 (when asked during his deposition when MMO first became aware that TRTs were being used and/or promoted for off-label conditions, Shoemaker testified, "The first document that I can recall seeing was a recommendation from Medco sometime in 2004 referencing their own—Medco's own prior authorization requirements for the use of testosterone in male hypogonadism"). Shoemaker also testified that he did not know which MMO employee(s) decided against establishing a prior authorization requirement in 2004, nor did he know the reasons for the decision. MMO does not dispute that it did not establish any prior authorization requirement for topical TRTs in 2004.

MMO also agrees that Medco's May 2008 position statement on oral androgens, injectable androgens, and anabolic steroids was "provided to" MMO. MMO L.R. 56.1 Resp. ¶ 75. The May 2008 position statement, which appears to set forth a prior

authorization policy for non-topical TRTs, states:

> An increased number of prescriptions are being written for testosterone products in older or elderly men for the treatment of 'andropause.'
>
> . . . . [A]ndropause is a term used to describe the gradual decrease in bioavailable serum testosterone as men age. A decrease in testosterone is associated with signs and symptoms such as loss of libido, erectile dysfunction, depression, lethargy, osteoporosis, and loss of muscle mass and strength.

Defs.' Mot., Ex. 92 (May 2008 Medco Androgens Position Statement) at 1. It also states, "No benefit was shown in a recent randomized, double-blind, placebo-controlled, trial studying testosterone supplementation in healthy males over 60 years of age with serum testosterone levels on the lower end of normal." *Id.*

In September 2008, MMO established a prior authorization requirement for non-topical (*i.e.*, oral, buccal, and injectable) testosterone products and anabolic steroids. According to the September 2008 PQM Committee minutes, the use of these products "for the enhancement of athletic performance or bodybuilding are not approvable conditions. The purpose of the proposed rule is to prevent misuse." MMO Opp., Ex. 70 (September 2008 PQM Minutes) at 2. The minutes also mention topical TRTs. Specifically, they state that Dan Resetar, a Medco account executive, "reported that Topicals and Transdermal Preps account for 70 percent of usage and have rebates. D. Resetar reported that the injectables are the most abused and suggested that we target injectables, tablets and buccals." *Id.* It is undisputed that MMO did not establish any prior authorization requirement for topical TRTs in 2008.

Medco and ESI's corporate representative agreed during his deposition that "ESI updated its prior authorization policies to reflect . . . information concerning age-related

hypogonadism" "after the FDA issued a notice of some sort in 2015." MMO Opp., Ex. 41 (Dohm Dep.) at 168:13-20. And as previously referenced, MMO first established a prior authorization policy for topical TRTs in July 2016. Medco and ESI's corporate representative testified that although he "could assume" MMO's decision to establish the prior authorization policy for topical TRTs was based on a recommendation from ESI, he does not know for sure. Defs.' Mot., Ex. 25 (Dohm Dep.) at 126:2-9. He further testified that he does not know whether ESI even made a recommendation to MMO in 2015 about the prior authorization requirement. The record contains no documentary evidence that it did.

2. MMO's step therapy policy for topical testosterone

In February 2014, MMO approved ESI's step therapy policy for topical TRTs. The policy requires "the patient to try one of the Step 1 products [AndroGel and Axiron] prior to the approval of a Step 2 product [Fortesta, Testim, and Striant]." MMO Opp., Ex. 38 (January 2014 ESI Step Therapy Policy) at 1; *see also* MMO Opp., Ex. 39 (February 2014 PQM Minutes) at 4 (approving the rule).[7] MMO does not argue that its approval of the policy caused any topical TRT drug to be added to its formulary. Nor does MMO argue that it gave preference to AndroGel and Axiron via the policy because it believed those drugs were safer or more effective than the Step 2 drugs.

D. MMO's claims and allegations

MMO filed this action in November 2014. It alleges that although the FDA has

[7] The Court notes that ESI's step therapy policy also requires "the patient to meet criteria in the ESI Standard Testosterone (topical) Products Prior Authorization Policy." January 2014 ESI Step Therapy Policy at 1. But MMO does not argue it approved the prior authorization aspect of ESI's rule in 2014. Rather, as previously referenced, MMO maintains that the first time it established any prior authorization requirement for topical TRTs was in July 2016. *See* MMO L.R. 56.1 Stat. ¶¶ 27-30.

not approved TRT drugs for the treatment of conditions other than classical hypogonadism, defendants have marketed the drugs as being safe and effective for the treatment of off-label conditions and symptoms, such as erectile dysfunction, diabetes, AIDS, cancer, depression, and obesity. According to MMO, defendants' off-label marketing scheme allegedly included a "disease-awareness" campaign that promoted a nonexistent disease called "Andropause" or "Low T," which defendants invented and for which they claimed TRT drugs were a safe and effective treatment. *See, e.g.*, TAC ¶¶ 4, 890

MMO further alleges that no competent medical evidence demonstrates that TRT drugs are safe or effective for treating "Low T" or other off-label conditions. Rather, MMO contends, medical evidence shows that off-label TRT use is associated with increased incidence of adverse cardiovascular and thromboembolic (blood clotting) events. MMO also alleges that the safety risks TRTs pose are particularly high for aging men, who are most likely to experience symptoms of "Low T" and at whom defendants' marketing scheme was largely aimed. Though increased off-label marketing coincided with an "astronomical spike" in TRT drug prescriptions and sales, MMO contends, those sales have begun to decrease, despite "continued rampant promotion," in response to recent revelations of the drugs' safety risks, such as the FDA's January 2014 and March 2015 drug safety communications referenced above. TAC ¶¶ 19-21. MMO asserts that even in the face of these safety concerns, defendants continued to target TPPs (including MMO), physicians, and consumers with fraudulent marketing schemes that affirmatively promoted the drugs' safety and efficacy for off-label use and actively concealed unfavorable evidence.

1. Substantive RICO claims

MMO alleges that defendants AbbVie, Auxilium, Endo, and Lilly each engaged in marketing schemes by forming four "complementary and mutually enforcing" fraudulent enterprises: a TPP "formulary access" enterprise, which directly targeted TPPs (including MMO); "peer selling" and "publication" enterprises, which targeted prescribing physicians; and a "direct-to-consumer" enterprise, which targeted consumers. TAC ¶¶ 225-29. MMO alleges that the planning and coordinating of each fraudulent enterprise "required extensive use of the wires and mails," *id.* ¶¶ 246, 276, 325, 340, and that defendants conducted the affairs of the enterprises through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

2. Ohio negligent misrepresentation claims

Based on many of the same allegations underlying MMO's substantive RICO claims, MMO has asserted claims for negligent misrepresentation under Ohio common law against AbbVie, Auxilium, Endo, and Lilly.

3. RICO conspiracy claims

MMO also alleges that AbbVie, Actavis, Auxilium, Endo, and Lilly violated 18 U.S.C. § 1962(d) by conspiring with each other to violate 18 U.S.C. § 1962(c). Specifically, according to MMO, defendants conspired to advance an "unbranded" marketing campaign in order to grow the market for TRTs (the "inter-company" conspiracy). *See* TAC ¶ 886. MMO contends that "[d]efendants coordinated their actions by engaging in common endeavors to facilitate" this "fraudulent objective[.]" MMO Opp. at 33. The alleged common endeavors include funding the same "Astroturf organizations" (organizations that "mask" their sponsors "to make it appear as though"

grassroots participants support their messages). TAC ¶ 911; MMO Opp. at 33. They also include training personnel to use the same marketing tools; supporting the same key opinion leaders (physicians that tout drug benefits and who are paid by drug manufacturers in connection with their efforts); engaging the same third-party consultants; and collaborating to make a presentation at the September 2014 FDA advisory committee meeting. MMO Opp. at 33-34; *see also, e.g.*, TAC ¶¶ 886, 897, 903, 910, 997, 1053. MMO alleges that defendants' conspiracy "involved the commission of overt acts in furtherance of the conspiracy" that caused MMO to "pay for excessive prescriptions of TRT drugs and related medical services." TAC ¶ 1078.[8]

MMO separately alleges that AbbVie and Actavis each violated section 1962(d) by entering into a co-promotion agreement providing that an Actavis entity (Watson) would promote AndroGel to urologists (the "AbbVie-Actavis co-promotion" conspiracy). MMO's Opp. at 40; *see* TAC ¶¶ 1085-88. MMO contends that this co-promotion conspiracy caused it to "pa[y] millions of dollars . . . for the TRT drugs that [it] would not have paid had Defendants not engaged in" the conspiracy. TAC ¶ 1092.

Discussion

A party is entitled to summary judgment only if it shows that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). There is a genuine issue of material fact, and summary judgment is precluded, "if the evidence is such that a reasonable jury could return a verdict for the

[8] MMO has informed the Court that it will not pursue its theory that each defendant conspired with its respective vendors "to create and propagate their fraudulent Low T messaging" (the "intra-corporate" conspiracy). MMO Opp. at 33 n.11. MMO contends, however, that "evidence of Defendants' interactions with their vendors remains probative of" its other conspiracy claims. *Id.*

nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In ruling on a motion for summary judgment, a court examines the record in the light most favorable to the non-moving party and draws all reasonable inferences in that party's favor. *Id.* at 255; *see also, e.g.*, *Diedrich v. Ocwen Loan Servicing, LLC*, 839 F.3d 583, 591 (7th Cir. 2016). Nonetheless, "to defeat summary judgment, [a] plaintiff must present something beyond bare speculation or a scintilla of evidence." *Zuppardi v. Wal-Mart Stores, Inc.*, 770 F.3d 644, 650 (7th Cir. 2014) (internal quotation marks omitted); *see also, e.g.*, *Skiba v. Illinois Central R.R. Co.*, 884 F.3d 708, 721 (7th Cir. 2018) ("[W]e make only reasonable inferences, not every conceivable one. . . . [O]ur favor toward the nonmoving party does not extend to drawing [i]nferences that are supported by only speculation or conjecture." (second alteration in original) (internal quotation marks and citations omitted)).

A. Substantive RICO claims (18 U.S.C. § 1962(c))

MMO alleges that AbbVie, Auxilium, Endo, and Lilly have violated 18 U.S.C. § 1962(c), which makes it unlawful for a person or entity associated with an enterprise engaged in interstate commerce "to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . ." 18 U.S.C. § 1962(c). The RICO Act authorizes "[a]ny person injured in his business or property by reason of a violation of section 1962" to bring a private cause of action. 18 U.S.C. § 1964(c); *see also, e.g.*, *Armada (Singapore) PTE Ltd. v. Amcol Int'l Corp.*, 885 F.3d 1090, 1093 (7th Cir. 2018) (section 1964(c), "colloquially referred to as 'civil RICO,' empowers private parties to bring lawsuits against those engaged in racketeering activity when that activity has caused them harm"). To prevail on its section 1962(c)

claims against each defendant, MMO must demonstrate that the defendant engaged in "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Roppo v. Travelers Commercial Ins. Co.*, 869 F.3d 568, 587-88 (7th Cir. 2017) (internal quotation marks omitted). MMO must also demonstrate that it was (1) "injur[ed] in its business or property (2) by reason of (3) the defendants' violation of section 1962." *DeGuelle v. Camilli*, 664 F.3d 192, 198 (7th Cir. 2011); *see also Armada*, 885 F.3d at 1093. The Supreme Court has interpreted the Act to require a civil RICO plaintiff to show that defendants' section 1962 violations were both the but-for and proximate causes of the plaintiff's injury. *See, e.g.*, *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 9 (2010); *Holmes v. Sec. Investor Protection Corp.*, 503 U.S. 258, 267-68 (1992); *DeGuelle*, 664 F.3d at 199.

For RICO purposes, proximate cause "requires 'some direct relation between the injury asserted and the injurious conduct alleged.'" *Hemi Grp.*, 559 U.S. at 9 (quoting *Holmes*, 503 U.S. at 268). In ruling on defendants' first motion to dismiss MMO's section 1962(c) claims, the Court determined that "RICO claims generally survive where TPPs allege that defendants made direct misrepresentations to them and fail where they do not." *MMO I*, 159 F. Supp. 3d at 919; *see also id.* at 913 (comparing, among other cases, *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) ("Crucially, the TPPs do not allege that *they* relied on Lilly's misrepresentations—the misrepresentations at issue were directed through mailings and otherwise at doctors." (internal quotation marks omitted))). Because MMO had alleged "that the defendant drug manufacturers made misrepresentations *directly* to" it, the Court observed, MMO's case "falls in the former category." *MMO I*, 159 F. Supp. 3d at 913, 919; *see, e.g.*,

Second Am. Compl. ¶¶ 832-33 (alleging that defendants "falsely promoted TRT drugs as safe and effective directly to TPPs" and that TPPs "relied on the Defendants' misrepresentations of TRT safety and efficacy when placing TRT drugs on formularies" and "in reimbursing and/or paying for prescriptions of TRT drugs for their members").

In ruling on defendants' second motion to dismiss MMO's section 1962(c) claims, the Court reiterated these principles; determined that MMO's claims against AbbVie, Auxilium, Endo, and Lilly could move forward because MMO had plausibly alleged that those defendants made direct misrepresentations to it; but dismissed MMO's claims against GlaxoSmithKline and Actavis because MMO had not plausibly alleged the same for those defendants. *MMO II*, 2016 WL 4091620, at *3-5. Subsequently, in affirming the dismissal of a TPP's section 1962(c) and section 1962(d) claims in a separate case, the Seventh Circuit recognized that "a RICO recovery is possible when a wrong against" one person "directly injures" another, but held that "improper representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence." *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 576, 578 (7th Cir. 2017).

The First Circuit has reached a different conclusion about the directness requirement for proximate cause under RICO. *See In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 39-40 (1st Cir. 2013) (concluding that TPP "met [RICO's] proximate causation requirement" with evidence that drug manufacturer "fraudulently marketed to physicians with the intent that those physicians would write prescriptions paid for by" the TPP, and that the "scheme worked as intended"). But in *Sidney Hillman*, the Seventh Circuit addressed and diverged from *In re Neurontin*. *See Sidney*

Hillman, 873 F.3d at 578 ("The implication of *Neurontin* may be short of a holding, but to the extent there is a conflict the Second Circuit has this right."); *id.* (citing cases in which the Second Circuit determined that the "causal chain" "between promotion and payment" was "too long to satisfy the Supreme Court's requirements"). The fact that the First Circuit recently followed its own 2013 decision does not alter the proximate causation analysis in this case. *See In re Celexa & Lexapro Mktg. and Sales Practices Litig.*, Nos. 18-1146, 18-1147, 2019 WL 364019, at *8 (1st Cir. Jan. 30, 2019) (citing *In re Neurontin* and reaching the same conclusion concerning proximate cause).[9]

The governing principles in the Seventh Circuit require MMO to show, in order to survive summary judgment, that there are genuine disputes on whether it (1) received direct misrepresentations from defendants and (2) relied upon them to make formulary-related decisions about defendants' TRT drugs.

MMO argues it can also survive summary judgment if a reasonable jury could conclude that its PBMs received and relied upon defendants' alleged misrepresentations to make formulary-related decisions, and that MMO, in turn, relied on those same decisions. *See* MMO Opp. at 17-28; *see also*, *e.g.*, TAC ¶ 201 ("At all times relevant hereto, MMO has, along with its PBM partner Medco/ESI, made decisions, based on FDA approvals, manufacturer-supplied information and clinical studies, to include or exclude new or existing prescription drugs from its formulary, or to implement tools to control utilization or to modify coverage criteria."). In its response to

[9] On February 8, 2019, defendants filed a notice of supplemental authority concerning *In re Celexa & Lexapro Marketing and Sales Practices Litigation*. MMO filed a response on February 11, 2019. The Court addresses only the parties' arguments regarding RICO's proximate causation requirement. The remaining arguments concern issues that the Court need not reach.

defendants' notice of supplemental authority, MMO argues that the First Circuit's decision in *In re Celexa & Lexapro Marketing and Sales Practices Litigation* supports its position. *See In re Celexa & Lexapro Mktg. and Sales Practices Litig.*, 2019 WL 364019, at *8 (crediting evidence that drug manufacturer "specifically targeted" PBM in determining that whether manufacturer's off-label marketing caused TPP's financial injury was a disputed factual issue).

In its order denying MMO's motion for class certification, the Court left open the possibility that MMO could satisfy RICO's proximate cause requirement this way. *See MMO III*, 2018 WL 3586182, at *17 (assuming without deciding that TPPs could show proximate causation "using evidence of misrepresentations to PBMs"). The Court will assume for purposes of discussion that this theory is viable, because it does not change the outcome. As the Court will explain, no reasonable jury could find that MMO relied on defendants' alleged misrepresentations to make any formulary or utilization management decision about defendants' TRT drugs. Likewise, no reasonable jury could find that MMO relied on any formulary or utilization-management decision that Medco or ESI made on the basis of defendants' alleged misrepresentations.

1. Misrepresentations to MMO

a. AbbVie and Lilly

Defendants admit that MMO employees "met or exchanged e-mails with AbbVie and Lilly representatives over the years." Defs.' Reply at 3. According to defendants, however, "[t]here is no evidence that MMO received a single representation from any Defendant—false or otherwise—about the safety or efficacy of TRT, let alone in relation to any allegedly off-label uses." Defs.' Mot. at 3. In response, MMO argues that as a

general business practice, MMO met with and received clinical materials from pharmaceutical sales representatives. Dr. Blagojevic, for example, testified that sales representatives "come and present about the clinical efficacy or safety of their drug, talk to us about their products, pipeline, answer questions, give us study data." MMO Opp., Ex. 35 (Blagojevic Dep.) at 173:14-17. No reasonable jury, however, could conclude from general testimony about MMO's business practices that AbbVie and Lilly misrepresented the safety or efficacy of their TRT drugs to MMO.

MMO has also provided the Court with e-mails, business plans, and other documents that it contends show that it received direct misrepresentations from AbbVie and Lilly. The Court has carefully reviewed these documents and has determined that most of them show that AbbVie and Lilly representatives communicated with MMO but lack meaningful information about what was discussed. For example, MMO cites an undated monthly report by a vice president of sales at Solvay, AbbVie's predecessor organization, that states, "Lisa Garofoli reviewed Solvay Cares with Medical Mutual Disease Mgmt team on April 21." MMO Opp., Ex. 17 at ABBVIE-MMO00270278. In addition, MMO cites a 2008 monthly report by Jed Cicak, a Solvay national account manager, that states, "Jed joined [regional account manager] Lisa Garofoli on Medical Mutual meeting with Ben Zelman, Chad Hendricks and Stephen Harry to discuss contracting and pull through opportunities with AndroGel[.]" MMO Opp., Ex. 14. MMO likewise cites a March 2013 e-mail from Paul Titus, a Lilly account manager, announcing that MMO "upgraded Axiron on their 2013 commercial book of business." MMO Opp., Ex. 36. In the e-mail, Titus writes, "Thank you for your help and coaching throughout my work with Shaleen Joshi, PharmD, Clinical Director at Medical Mutual of

Ohio." *Id.* No reasonable jury could conclude from documents like these that AbbVie and Lilly misrepresented the safety or efficacy of their TRT drugs to MMO.

MMO highlights, in particular, a 2005 e-mail chain between a Solvay account manager, Lisa Cooper, and MMO's Manager of Pharmacy Services, Chad Hendricks. In one of the e-mails, Cooper writes that she wants to schedule a meeting with MMO to discuss "AndroGel and Pinnacle our Men's Health Program." MMO Opp., Ex. 5 (2005 Cooper e-mails), at 2. In another, she writes that "we have done all the research" and "only used top line references that if you had the time or a staff pharmacist it would be of that quality." *Id.* at 1. Hendricks replies that he "forwarded all of [Cooper's] info to the director of Disease Management and will let [Cooper] know if she and/or others would like to discuss this program." *Id.*

MMO argues that the 2005 Cooper e-mails "reveal[] exactly what Solvay said to MMO and when." MMO Opp. at 6 n.2. But the e-mails contain no clinical information or attachments and do not show that any meeting ever actually occurred. *See generally* 2005 Cooper e-mails. MMO also contends that in one of the e-mails, Cooper writes that "AndroGel had 'unlimited uses,' including for the treatment of depression[.]" MMO Opp. at 6 n.2 In fact, however, Cooper writes not that AndroGel has unlimited uses but rather that "Pinnacle, our Men's Health Program has unlimited uses," including "a comprehensive look" at disease states like hypogonadism and depression. 2005 Cooper e-mails at 1. Even considering these e-mails in combination with testimony that MMO sometimes received clinical materials from drug representatives, no reasonable jury could conclude they show that AbbVie made false or misleading statements about the safety or efficacy of AndroGel. The same is true of testimony from Drs. Blagojevic

and Joshi that they recalled meeting with a Lilly account representative (Titus) who had a memorable personality. *See* MMO Opp. at 11.

MMO's best evidence that AbbVie misrepresented the safety or efficacy of AndroGel directly to MMO is testimony from MMO's corporate representative that, according to MMO pharmacy employees, AbbVie representatives at some point told them that "AndroGel was safe and effective in the treatment of male age-related hypogonadism." Defs.' Mot., Ex. 6 (Shoemaker Dep.) at 284:6-11, 284:23-285:4.[10] In addition, there is evidence suggesting that Mark Hollinden, an AbbVie managed care account manager, presented a version of the AndroGel Value Proposition Deck to MMO's former pharmacy director, Dr. Sonny Borja, in 2012. The document MMO cites for this proposition—an AbbVie database listing calls in which the "discussion topic" was "AndroGel Value Prop," *see* MMO L.R. 56.1 Resp. ¶ 33(d) (citing MMO Opp., Ex. 77 (AbbVie Call Database))—does not support it, because the database does not list any calls with Dr. Borja or MMO. But in a July 2011 e-mail, Hollinden informs a colleague that he has "a request in with MM to discuss the Value Prop deck." MMO Opp., Ex. 24 at 1. And in a July 2012 e-mail, Hollinden writes, "[t]he Pharm Director liked the presentation." MMO Opp., Ex. 28. MMO contends that AbbVie's AndroGel Value Proposition Deck misrepresents the safety and efficacy of defendants' TRT drugs.

The Court will assume for purposes of discussion that based on this evidence, a reasonable jury could conclude that AbbVie directly misrepresented the safety or efficacy of their TRT drugs to MMO. But even if AbbVie did so, there is insufficient

[10] That said, the Court questions whether a party can affirmatively admit testimony by its own designated 30(b)(6) witness in which the witness is relaying, for their truth, statements made by other corporate representatives.

evidence to permit a reasonable jury to find that MMO relied upon the alleged misrepresentations to make any formulary-related decision regarding AndroGel. The Court will address this point in section 2 below.

MMO also argues that all defendants' pre-2015 product labels were misleading, including because they omitted known information about safety and efficacy concerns. *See* MMO Opp. at 28-31. Dr. Canaday, for her part, testified that MMO keeps itself apprised of the package inserts for products on its formulary. In the same vein, the record contains a June 2011 e-mail from a Lilly sales representative to Dr. Borja attaching a flyer that appears to contain information from Axiron's product label. MMO Opp., Ex. 34. Defendants contend that MMO's label-based arguments are improper attempts to predicate RICO claims on "the failure to comply with FDCA labeling duties[.]" Defs.' Reply at 9. The Court declines to reach this question. Instead, for the reason just discussed, it will assume that based on evidence suggesting MMO reviewed product labels for AndroGel and Axiron, a reasonable jury could conclude that AbbVie and Lilly directly misrepresented the safety or efficacy of their TRT drugs to MMO.

b. Auxilium and Endo

MMO appears to argue that Auxilium and Endo made misrepresentations to it about the safety or efficacy of Testim and Fortesta only by omitting information from the drugs' product labels. *See* MMO Opp. at 4, 6-11 (discussing evidence of direct misrepresentations only from AbbVie and Lilly); *id.* at 28-31 (discussing label-based omission theory without reference to any defendant). For the reasons just discussed, the Court will assume for purposes of discussion that Auxilium and Endo made direct misrepresentations to MMO via their product labels.

2. Reliance by MMO

Even if a reasonable jury could find that defendants made false or misleading statements to MMO about the safety or efficacy of their TRT drugs, it could not find that MMO relied on them to make any formulary or utilization management decision regarding the drugs.

First, MMO does not argue that it added any TRT drugs to its formulary in the first instance because of defendants' alleged misrepresentations. Rather, MMO admits that it adopted its formulary without modification from Medco and later ESI. According to Dr. Canaday, adopting a formulary does not require MMO to conduct any "clinical oversight," and to this day, MMO does not customize its formulary. *See* Defs.' Mot., Ex. 4 (Canaday Dep.) at 230:8-21 (testifying that customizing a PBM's formulary "would require us doing our own rebates and us doing our own clinical oversight, and I have not convinced MMO executives that that would be an advantage"). For these reasons, no reasonable jury could conclude that MMO added defendants' TRT drugs to its formulary in reliance on alleged safety- or efficacy-related misrepresentations that defendants made to MMO.

According to MMO, however, it relied on defendants' alleged misrepresentations to make utilization management decisions. Defendants contend that MMO has offered no evidence of such reliance. As a result, defendants maintain, no reasonable jury could find in MMO's favor. For the following reasons, the Court agrees.

a. Testimony from MMO employees

Defendants argue that no MMO employee "with formulary-related responsibilities dating back to 2000 could identify even one decision that MMO made with respect to

any TRT on the basis of information from defendants." Defs.' Mot. at 5; *see also* Defs.' L.R. 56.1 Stat. ¶ 12. Defendants, for example, cite the following deposition testimony:

- MMO's corporate representative testified that he did not know whether MMO ever decided against establishing prior authorization requirements in reliance on conversations its pharmacy employees allegedly had with AbbVie sales representatives. *See* Defs.' Mot., Ex. 6 (Shoemaker Dep.) at 296:24-297:20.
- Former MMO pharmacist, Dr. Joshi, testified that she had no specific knowledge of actions she took as a result of communications with Lilly or AbbVie sales representatives. *See* Defs.' Mot., Ex. 9 (Joshi Dep.) at 113:5-18. She also testified that she could not recall relying on information from AbbVie to make clinical evaluations of TRTs and could not recall anyone at MMO relying on such information to make coverage-related decisions concerning TRTs. *Id.* at 269:12-23.
- MMO's Manager of Pharmacy Services, Hendricks, testified that if he had conversations with AbbVie sales representatives about AndroGel, they "wouldn't have led to how we covered that drug." Defs.' Mot., Ex. 5 (Hendricks Dep.) at 291:20-292:2. He added that he does not "make clinical decisions." *Id.* at 292:4.
- MMO's Pharmacy Director, Dr. Canaday, testified that she has never solely relied on what a manufacturer has told her in making utilization management decisions and does not know anyone at MMO who has. Defs.' Mot., Ex. 4 (Canaday Dep.) at 233:11-19.

Dr. Canaday's testimony arguably suggests that MMO might rely partially on information from manufacturers in making utilization management decisions. But

neither Dr. Canaday nor any other witness cited by MMO identified any utilization management decision MMO made about defendants' TRT drugs in reliance on safety or efficacy information from defendants.

In response, MMO cites deposition testimony tending to show that in general, MMO's pharmacy employees received and considered information from drug manufacturers. *See* MMO Opp. at 12; MMO L.R. 56.1 Resp. ¶ 12. For example, MMO's Manager of Clinical Pharmacy Programs, Dr. Blagojevic, testified that in making formulary-related decisions, MMO considers sources including information from drug manufacturers. *See* MMO Opp., Ex. 35 (Blagojevic Dep.) at 172:4-11. Ben Zelman, a former member of MMO's pharmacy department, testified that it was "entirely possible" he met with an AbbVie sales representative while he was at MMO; it was possible that PQM Committee members received written materials from drug manufacturers; and his practice was to "scan" at "a fairly high level" materials he received from drug manufacturers. MMO Opp., Ex. 45 (Zelman Dep.) at 184:2-6, 190:3-13. Dr. Joshi, for her part, testified that she would review materials that drug manufacturers provided and then pass them along to her supervisors. *See* MMO Ex. 37 (Joshi Dep.) at 92:8-17. MMO also cites deposition testimony tending to show that on one occasion, Hendricks might have received materials from a drug representative about a "men's health" program regarding diabetes, hypertension, and depression and given them to MMO employees with clinical responsibilities. *See* MMO Opp. at 12 (citing MMO Opp., Ex. 6 (Hendricks Dep.) at 96:11-24); *see also* Defs.' Reply, Ex. 9 (Hendricks Dep.) at 97:1-9. MMO then argues that there is no evidence it "inexplicably broke from its established practice when it came to AndroGel, or any other TRT drug." MMO Opp. at 12.

None of MMO's cited testimony fills the evidentiary gap defendants have identified. Specifically, no MMO employee with formulary oversight responsibilities could point to any utilization management decision MMO made in reliance on defendants' alleged misrepresentations regarding TRTs.

The same is true of other evidence MMO cites in its Local Rule 56.1 response, although not in its brief in opposition to defendants' motion. Specifically, MMO cites deposition testimony from Dr. Joshi that in reviewing its "coverage management programs," MMO would assess "new safety markers for a drug class," and that in general, it would discuss safety alerts "internally and then possibly at our PQM meeting." MMO L.R. 56.1 Resp. ¶ 14 (citing MMO Opp., Ex. 37 (Joshi Dep.) at 184:5-13, 248:2-6). But the cited testimony does not shed light on any discussions MMO might have had about TRT safety markers, nor does it address whether MMO made utilization management decisions about defendants' TRT drugs in reliance on alleged misrepresentations from defendants.

In its Local Rule 56.1 response, MMO also contends that Dr. Joshi "conducted an analysis of certain aspects of the safety and efficacy of TRT drugs, and even enlisted the assistance of an outside clinician." MMO L.R. 56.1 Resp. ¶ 14. In support of this argument, MMO cites March 2014 e-mails between Dr. Joshi and Dr. Kyle Gustafson, a pharmacist at an Ohio hospital. *See* MMO Opp., Ex. 49 (Dr. Gustafson e-mails). MMO also cites March 2014 e-mails from Dr. John Kim, an ESI pharmacist, to Dr. Joshi. *See* MMO Opp., Ex. 50 (Dr. Kim e-mails).

MMO does not contend, however, that Dr. Joshi's analysis of TRT drugs led to any utilization management decision. *See* MMO L.R. 56.1 Resp. ¶ 14. And no

reasonable jury could draw such an inference from the March 2014 e-mails that it did, let alone that MMO made any such decisions in reliance on misrepresentations from defendants. First, although one of Dr. Kim's e-mails shows that he asked someone whether MMO had ever established a prior authorization requirement for topical TRTs, the e-mail does not contain any information about why he did so or what became of his inquiry. *See generally* Dr. Kim e-mails. The closest Dr. Kim comes to discussing clinical information is by writing that he was "awaiting [an] NEJM article" about the "14 years of age cutoff for the testosterone." *See* Dr. Kim e-mails at MMO_TRT_01386808. MMO, however, does not identify the article in question or argue that defendants had any role in authoring it. Furthermore, MMO does not argue that defendants' alleged misrepresentations related to a minimum age requirement for using TRT drugs.[11] Dr. Joshi's e-mails with Dr. Gustafson also lack information that could permit a jury to conclude that MMO made utilization management decisions based on misrepresentations from defendants. The e-mails appear to concern "Androgen/Anabolic steroids," not topical TRTs, *see* Dr. Gustafson e-mails at MMO_TRT_01400552, and MMO does not allege that defendants provided the

[11] Dr. Joshi testified during her deposition that she researched the use of TRT drugs for delayed puberty. MMO Opp., Ex. 37 (Joshi Dep.) at 262:3-7. She further testified that, based on her research, and because "the FDA did not list an age in their label," she recommended that MMO "not put an age restriction on the products for delayed puberty." MMO Opp., Ex. 37 (Joshi Dep.) at 262:10-13. According to Dr. Joshi, Dr. Canaday agreed. *Id.* at 262:14-16. MMO makes no reference to this evidence in its brief. That aside, no reasonable jury could conclude that Dr. Joshi's recommendation constitutes a utilization management decision relevant to this case. This is because MMO does not argue that defendants misrepresented the safety or efficacy of TRT drugs for treating delayed puberty or that it was injured by reimbursing for TRT drugs prescribed for that purpose. *See, e.g.*, MMO Opp. at 45 ("MMO was injured because it reimbursed claims for prescriptions that were unsafe and ineffective in treating the signs, symptoms and comorbid conditions associated with Low-T.").

information discussed in the e-mails, *see* MMO L.R. 56.1 Resp. ¶ 14.

b. PQM Committee meeting minutes and decisions

Defendants next emphasize that on the occasions when MMO's PQM Committee discussed androgens during the time period at issue in this case, the meeting minutes do not say anything about information defendants provided. *See* Defs.' L.R. 56.1 Stat. ¶ 15 (citing PQM minutes from 2001, 2004, 2008, and 2010). MMO disputes this argument only as it relates to the 2008 minutes. *See* MMO L.R. 56.1 Resp. ¶ 15. Specifically, MMO argues that Medco presented its May 2008 position statement on oral androgens, injectable androgens, and anabolic steroids to the PQM Committee. It points out that the statement cited (1) product labels for AndroGel, Testim, Androderm, and Testopel and (2) clinical guidelines funded by defendants, including Solvay.

PQM minutes from August and September 2008 show that Medco indeed presented its May 2008 position statement to MMO. *See, e.g.*, September 2008 PQM Meeting Minutes at 2 (stating that Medco representative Resetar presented Medco's "Androgens and Anabolic Steroids UM Modeling report"). And the August 2008 PQM minutes refer to certain FDA-approved uses for androgens, some of which could have been taken from topical TRT drug labels. *See* Defs.' Mot., Ex. 100 at 6. But neither the August 2008 minutes nor the September 2008 minutes contain any indication that MMO made any decision regarding topical TRTs based on any clinical data. Specifically, the PQM Committee did not make any utilization management decision about TRTs in August 2008. *See id.* at 6-7. And the minutes from the September 2008 meeting—when the committee decided to establish a prior authorization requirement only for oral androgens, injectable androgens, and anabolic steroids—do not reference any

information from defendants or discuss any safety or efficacy information regarding topical TRTs. Indeed, the only reference to topical TRTs concerns rebates. *See* September 2008 PQM Meeting Minutes at 2 ("D. Resetar reported that Topicals and Transdermal Preps account for 70 percent of usage and have rebates.").

Furthermore, although the September 2008 minutes explain why MMO decided to establish a prior authorization requirement for *non-topical* TRTs, they are silent on why MMO did not also establish a prior authorization requirement for topical TRTs. *Id.* The minutes lack this information even though Medco's May 2008 position statement mentioned an uptick in testosterone prescriptions "for the treatment of 'andropause'" and a clinical study showing "[n]o benefit" from "testosterone supplementation in healthy males over 60 years of age with serum testosterone levels on the lower end of normal." May 2008 Medco Androgens & Anabolic Steroids Position Statement at 1. No reasonable jury assessing either the August 2008 or September 2008 PQM minutes could find that they tend to show that MMO relied on defendants' alleged misrepresentations to decide that it would cover topical TRT drugs without restrictions.

MMO separately argues that its decision in 2014 to approve ESI's step therapy policy shows that it "relied on the information that was being provided to it about the safety and efficacy of the drugs." MMO Opp. at 12. MMO also argues that it approved the policy "thanks to the efforts of AbbVie employee Craig Geikie." *Id*. Likewise, MMO suggests that it approved the rule due to Hollinden's presentation of the AndroGel Value Proposition Deck to Dr. Borja in 2012. Each of these propositions is a stretch. For example, although the record contains an e-mail showing that Geikie "spoke to" Dr. Borja about the step therapy policy in 2012 and that she was "fine with adding" it, the

same e-mail also states that MMO's "Medical Directors" and "Quality Committee" had to provide "final sign-off." MMO Opp., Ex. 175 (June 2012 Geikie e-mail). Furthermore, there is no documentary evidence linking Hollinden's alleged presentation of the AndroGel Value Proposition Deck to MMO's approval of the step therapy policy approximately two years later. Indeed, the minutes from the February 2014 PQM meeting, in which MMO approved the policy, say nothing about the reasons for MMO's decision. *See* February 2014 PQM Minutes at 4 ("ESI's new Preferred Step Therapy Policies for Topical Androgens and Fenofibrates were reviewed and approved.").

Even if a jury were to assume that Geikie or Hollinden convinced MMO to approve the step therapy policy, no jury could reasonably conclude that MMO made its decision based on safety or efficacy criteria provided by the defendants. MMO does not argue, for example, that it gave preference to AndroGel or Axiron (which were already on the formulary) because they were safer or more effective than the other TRT drugs on the formulary. Geikie's June 2012 e-mail does not say that he presented any clinical information to MMO, nor does a related e-mail in the record. *See* June 2012 Geikie e-mail; MMO Opp., Ex. 174. Additionally, although the reference section in ESI's 2014 step therapy policy lists the labels for defendants' TRT drugs, it does not discuss safety, efficacy, or any other rationale for the policy—nor do the minutes from the February 2014 meeting in which MMO's PQM Committee approved it. Finally, Hollinden testified during his deposition that he believes he spoke to Dr. Canaday about the policy in 2014 and that their discussion was "only from a business perspective." Defs.' Reply, Ex. 13 (Hollinden Dep.) at 206:24-207:10.

In its Local Rule 56.1 statement, MMO also contends that "[a]ccording [to]

AbbVie's Vice President of Managed Health Care and Policy, Jeff Haas, 'ultimately, the [marketing materials used with managed care plans] led them to a decision.'" MMO L.R. 56.1 Stat. ¶ 17 (citing MMO Opp., Ex. 130 (Haas Dep.) at 60:3-61:9). No reasonable jury could rely on this testimony to infer that MMO made utilization management decisions regarding AndroGel based on AbbVie's marketing materials. Haas's testimony does not address specific marketing materials or draw a connection between marketing materials and any specific decision that MMO made. To infer reliance from his testimony would require "speculation or conjecture." *Skiba*, 884 F.3d at 721.

For the foregoing reasons, no reasonable jury could conclude that MMO relied on misrepresentations from defendants in making utilization management decisions regarding their TRT drugs.

3. MMO's PBM-based causation theory

MMO argues that even if a jury finds it did not directly rely on defendants' alleged misrepresentations to make utilization management decisions about defendants' TRT drugs, it can nevertheless prevail on its RICO claims because ESI and Medco relied on those misrepresentations. This causation theory requires evidence from which a jury could reasonably conclude that (1) ESI and Medco relied on misrepresentations about the safety or efficacy of defendants' TRT drugs to make utilization management decisions, and (2) MMO relied on clinical aspects of the decisions ESI and Medco made in order to make its own utilization management decisions. *See, e.g.*, MMO Opp. at 22 ("[B]ased in part on Defendants' misleading TRT drug labels and other information, both PBMs recommended to MMO that each Defendant's TRT drug be covered without

restriction."); *id.* at 23 ("Defendants made deception the cornerstone of their promotion and expansion, first to Medco, and later to ESI. That conduct, in turn, led Medco/ESI to recommend favorable, unrestricted placement for the Defendants' TRT Drugs on MMO's formularies."). The Court assumes for purposes of discussion that MMO's causation theory would satisfy RICO's proximate cause requirement. Based on the evidence, however, no reasonable jury could find in favor of MMO on this theory.

a. Direct misrepresentations to Medco or ESI

Defendants contend that "there is no evidence that ESI received . . . direct misrepresentations from any Defendant" about the safety or efficacy of TRT drugs. Defs.' Mot. at 12. Defendants' main support for this argument is deposition testimony from Medco and ESI's corporate representative that he was not aware of Medco or ESI receiving any substantive information from defendants about TRT drugs' risks, safety, or efficacy. *See id.*; Defs.' Mot., Ex. 25 (Dohm Dep.) at 53:10-22. The record, however, contains the following evidence:

- An AbbVie sales representative (Cicak) e-mailed an AndroGel Value Proposition Deck to Medco in November 2007. *See* MMO Opp., Ex. 61. MMO contends that the deck misrepresents AndroGel's safety and efficacy.
- Another AbbVie sales representative (Geikie) called or met with Medco on August 17, 2012, to discuss "AndroGel Value Prop." *See* AbbVie Call Database at 2.
- An Auxilium sales representative met with ESI employees, including a pharmacist, in 2012 and discussed "Value Proposition and Testim Positioning[.]" *See* MMO Opp., Ex. 164 at AUX_MMO0414654.

- In response to a request from ESI in February 2011, Lilly sent ESI clinical information from the Axiron pivotal trial. *See* MMO Opp., Ex. 75; MMO Opp., Ex. 76 (ESI July 2014 Clinical Summary of Testosterone (Topical) Products (ESI 2014 Clinical Summary)), at 13 n.15 (citing "[d]ata on file. Axiron . . . . Eli Lilly and Company; February 2011").

The Court will assume for purposes of discussion that each of these documents conveyed false or misleading information about defendants' TRT drugs to Medco and ESI. The Court will do the same for defendants' TRT drug product labels, each of which ESI cites in its July 2014 and May 2015 clinical summaries of testosterone products, and in its August 2013 prior authorization policy for topical TRT drugs. *See* ESI 2014 Clinical Summary at 13 nn.4-7, 9; MMO Opp., Ex. 55 (ESI May 2015 Clinical Summary of Testosterone (Topical and Nasal) Products) at 15 nn.4-7, 9; MMO Opp., Ex. 54 (ESI August 2013 Prior Authorization Policy) at 7 nn.2-3, 5-6, 13.

b. Reliance by Medco or ESI

Defendants argue that "there is no evidence that ESI . . . relied on direct misrepresentations from any Defendant in making any formulary decision that was subsequently adopted by MMO." Defs.' Mot. at 12. MMO, on the other hand, appears to argue that Medco and ESI relied on defendants' alleged misrepresentations in deciding to add at least Fortesta and Axiron to their formularies. *See* MMO Opp. at 21-22. MMO also argues that ESI relied on defendants' alleged misrepresentations in adopting the 2014 step therapy policy. *See id.* at 26-27. Finally, MMO appears to argue that ESI formed its pre-2015 prior authorization policies for topical TRTs in reliance on defendants' alleged misrepresentations. *See id.* at 23.

Turning first to formulary inclusion decisions, the Court concludes that no reasonable jury could find that Medco or ESI relied on defendants' alleged misrepresentations in deciding to add any defendant's TRT drug to its formulary. Although Medco and ESI consider drug labels, package inserts, and other information from drug manufacturers and their medical science liaisons when making formulary inclusion decisions, Medco and ESI's corporate representative testified that he did not know when the companies first put a TRT drug on their formularies and did not know the basis for their decisions to do so. In addition, when asked during his deposition whether he had "any reason to think" that ESI did *not* consider information from defendants in making TRT formulary placement or inclusion decisions, he testified that he did not know one way or the other. Defs.' Mot., Ex. 25 (Dohm Dep.) at 156:23-157:6. Finally, the representative testified that he was not aware of Medco or ESI receiving any substantive information from defendants about TRT drugs' risks, safety, or efficacy. *Id.* at 53:10-22. For a jury to conclude that Medco or ESI added defendants' TRT drugs to their formularies in reliance on information provided by defendants, based only on Dohm's testimony that ESI and Medco consider such information as a general practice, would require guesswork.

MMO argues that Endo "made its case directly to ESI for inclusion on its formularies, and an agreement was reached that Fortesta would be included with no step edit on coverage." MMO Opp. at 22. The only document MMO cites for this proposition, however, is an Endo presentation marked "for internal training purposes

only." MMO Opp., Ex. 166 at 1.[12] And the only page MMO cites from the presentation is titled "Recent wins that present an opportunity for pull-through"; states that "[w]here Fortesta has unimpeded access, Endo must have successful implementation of pull-through to win"; and suggests that Fortesta has "preferred" status on Medco's formulary. *Id.* at 20. A reasonable jury certainly could infer from this document that Endo communicated with Medco about Fortesta at some point. But the document contains no information from which a reasonable jury could infer that Endo communicated false or misleading information about Foresta's safety or efficacy, which in turn caused Medco to add Fortesta to its formulary "with no step edit on coverage." MMO Opp. at 22.

MMO also contends that ESI's Therapeutic Assessment Committee relied on the Axiron pivotal trial information it received from Lilly "in making [a] recommendation about the drug." *Id.* MMO, however, does not specify what recommendation the committee allegedly made. *See id.* ESI's July 2014 clinical summary of topical TRTs and May 2015 clinical summary of topical and nasal TRTs do cite the pivotal trial information. But neither summary makes or refers to any formulary inclusion (or utilization management) decision. MMO has not even informed the Court when it alleges Medco and/or ESI added Axiron to their formularies.

With respect to utilization management decisions, which are distinct from decisions to place a drug on a formulary, the Court will assume for purposes of discussion that Medco and ESI relied on defendants' alleged misrepresentations in adopting the 2014 step therapy policy. The Court makes this assumption because the

[12] In its opposition, MMO cites Exhibit 164, but that is an Auxilium document regarding Testim. The Court assumes MMO meant to cite Exhibit 166. *See* MMO L.R. 56.1 Resp. ¶ 33(k).

record contains an e-mail in which an AbbVie employee writes that "[a]s the result of significant negotiations throughout 2013 by" Geike and a colleague, "AndroGel . . . ha[s] been maintained on [ESI's] 2014 National Preferred Formulary." MMO Opp., Ex. 78 at ABBVIE-MMO00081473. Relatedly, the record contains a document showing that Geike and other AbbVie employees won an award in 2013 for their "Express Scripts Business Performance," including their efforts to "uniquely position[] AbbVie's Value Propositions[.]" MMO Opp., Ex. 79 at AbbVIE-MMO00053774. And as previously referenced, there is evidence that Geikie presented an AndroGel Value Proposition Deck to Medco in 2012.

The Court will also assume for purposes of discussion that Medco and ESI relied on defendants' alleged misrepresentations in developing pre-2015 prior authorization policies regarding defendants' TRT drugs. The Court makes this assumption because ESI cites defendants' TRT drug labels in its August 2013 prior authorization policy for topical TRT drugs. And according to Medco and ESI's corporate representative, ESI updated the policy to reflect information about age-related hypogonadism "after the FDA issued a notice of some sort in 2015." MMO Opp., Ex. 41 (Dohm Dep.) at 168:13-20.

For the reasons that follow, however, these assumptions do not assist MMO.

c. Reliance on Medco or ESI's utilization management decisions

As previously discussed, no reasonable jury could conclude that Medco or ESI added defendants' TRT drugs to their formularies in reliance on defendants' alleged misrepresentations. Accordingly, MMO cannot have indirectly relied on defendants' alleged misrepresentations merely by adopting Medco's, and later ESI's, formularies without modification. Furthermore, even assuming Medco and ESI adopted the 2014

step therapy policy and developed pre-2015 prior authorization policies based on defendants' misrepresentations, no reasonable jury could find that MMO made its utilization management decisions in reliance on any clinically-based decision Medco and ESI may have made.

First, even assuming ESI relied on defendants' alleged misrepresentations in adopting the 2014 step therapy policy, the Court has already determined that no reasonable jury could conclude that MMO approved the policy for clinical reasons. The Court made this determination because, among other things, all TRT drugs subject to the rule were already on-formulary. Furthermore, MMO does not argue it approved the policy based on an understanding that the preferred drugs (AndroGel and Axiron) were safer or more effective than the others, and the minutes from the February 2014 PQM meeting in which MMO approved the policy do not discuss safety or efficacy. MMO does not even argue that ESI developed the policy because the preferred drugs were superior from a safety or efficacy standpoint, and ESI's policy itself does not discuss safety or efficacy. To conclude that MMO approved the step therapy policy based on clinical decisions ESI made, a jury would have to ignore that the record lacks evidence suggesting that MMO adopted the policy for clinical reasons. A jury would also have to rely on conjecture. Specifically, it would have to speculate about the clinical basis, if any, for ESI's decision to adopt the policy. It would also have to speculate about whether MMO—which makes final decisions about establishing utilization management restrictions—knew about and considered the clinical basis for ESI's decision.

Second, even assuming Medco and ESI relied on defendants' alleged misrepresentations in developing their pre-2015 prior authorization policies, no

reasonable jury could conclude that MMO relied on Medco and ESI in declining to establish any prior authorization policy for topical TRTs until July 2016. The record, for example, contains evidence that in 2004, Medco's prior authorization criteria for androgens restricted coverage for treating signs and symptoms of andropause. Additionally, according to MMO's corporate representative, MMO received a document from Medco "somewhere in 2004" stating that "Medco did have a prior authorization function available." Defs.' Ex. 6 (Shoemaker Dep.) at 296:6-10. But MMO, which conducts its own review of and makes final decisions regarding utilization management restrictions, did not establish a prior authorization policy for topical TRTs in 2004. In addition, the record shows that MMO did not establish a prior authorization policy for topical TRTs in 2008. MMO declined to do so despite receiving a May 2008 document from Medco that, among other things, noted an increase in TRT prescriptions to treat andropause. Finally, Medco and ESI's corporate representative testified that he did not know whether MMO's decision to implement the prior authorization policy for topical TRTs was based on a recommendation from ESI. He also testified that he did not know whether ESI advised MMO in 2015 that it should establish a prior authorization requirement. No reasonable jury assessing this evidence could conclude that MMO relied on ESI, rather than its independent judgment, in deciding whether to establish a prior authorization requirement for defendants' TRT drugs.

MMO argues that before 2015, "both PBMs recommended to [it] that each Defendant's TRT drug be covered without restriction." MMO Opp. at 22. In support of this argument, however, MMO cites only ESI's August 2013 prior authorization policy; ESI's May 2014 clinical summary of injectable testosterone products; ESI's May 2015

clinical summary of topical and nasal testosterone products; and deposition testimony by Medco and ESI's corporate representative (Dohm). *See* MMO L.R. 56.1 Resp. ¶ 17. In the cited portion of his deposition, Dohm testified primarily about the differences between the cited references in each of these documents. He testified, for example, that unlike the May 2015 clinical summary, the 2013 prior authorization policy lacks references to studies that arguably cast doubt on TRT drugs' safety and efficacy. None of Dohm's cited testimony pertains to whether MMO relied on (or even reviewed) ESI's 2013 prior authorization policy or 2014 and 2015 clinical summaries. MMO also cites February 2014 e-mails between MMO pharmacy employees and deposition testimony from Dr. Canaday, but none of these sources mentions ESI, let alone advice MMO received from it.

MMO next argues that ESI did not advise it to restrict coverage for TRT drugs "because of cardiovascular risks until the FDA mandated a class-wide label change in 2015," suggesting that ESI provided such advice after the label change. MMO Opp. at 23. The only documents MMO cites for this argument are the February 2014 PQM minutes (reflecting MMO's approval of ESI's 2014 step therapy policy), the July 2016 PQM minutes (reflecting MMO's approval of a prior authorization policy for topical TRT drugs), and MMO's 2016 prior authorization policy. *See* MMO L.R. 56.1 Resp. ¶ 16. None of these documents contains any evidence that ESI provided, or refrained from providing, coverage advice in connection with TRT drugs' cardiovascular risks. Finally, MMO contends that Medco used the AndroGel Value Proposition Deck "in its recommendations with its customers like MMO." MMO Opp. at 26. But MMO cites no evidence for this proposition, and the Court has found none.

Considering the evidence in the record, no reasonable jury could conclude that MMO relied on defendants' alleged misrepresentations in making any utilization management decision regarding defendants' TRT drugs. Similarly, even assuming Medco and/or ESI made certain utilization management decisions in reliance on defendants' alleged misrepresentations, no reasonable jury could conclude that MMO relied on clinical aspects of those decisions to make its own utilization management decisions. For these reasons, no reasonable jury could conclude that MMO can satisfy RICO's proximate causation requirement. The Court therefore grants summary judgment in favor of defendants on MMO's section 1962(c) claims.

B. Ohio negligent misrepresentation claims

The elements of a claim for negligent misrepresentation under Ohio law are as follows:

> One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their *justifiable reliance* upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Abboud v. Liberty Mut. Ins. Grp., Inc., 711 F. App'x 773, 776-77 (6th Cir. 2017). This Court has previously applied RICO's causation principles to MMO's Ohio negligent misrepresentation claims. *See, e.g.*, *MMO III*, 2018 WL 3586182, at *9; *MMO II*, 2016 WL 4091620, at *7. In their summary judgment briefing, the parties have done the same.[13] The Court therefore grants summary judgment for defendants on MMO's Ohio

[13] Defendants have argued, and MMO has not disputed, that an Ohio negligent misrepresentation claim cannot be premised on omissions. Defs.' Mot. at 14 n.38; Defs.' Reply at 8 n.7. As the Court has already determined, however, MMO's omission theory fails even for its section 1962(c) claims.

negligent misrepresentation claims, for the reasons previously discussed.

C. RICO conspiracy claims (18 U.S.C. § 1962(d))

To prevail on a RICO conspiracy claim, a civil RICO plaintiff must demonstrate that it suffered an injury caused by an overt act that violates the RICO statute. *See Beck v. Prupis*, 529 U.S. 494, 505-07 (2000); *see also, e.g.*, *MMO II*, 2016 WL 4091620, at *5 (citing *Beck*, 529 U.S. at 507). The plaintiff must also demonstrate that the overt act proximately caused his injury. *See, e.g.*, *DeGuelle*, 664 F.3d at 204, 205; *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 192 F. Supp. 3d 963, 972 (N.D. Ill. 2016) ("Because the Funds have not adequately pleaded proximate causation, the Court dismisses the RICO claim. This means their RICO conspiracy claim under 1962(d) fails as well."), *aff'd*, 873 F.3d 574 (7th Cir. 2017). Because no reasonable jury could conclude that defendants' alleged misrepresentations proximately caused MMO's injuries, the Court grants summary judgment in favor of AbbVie, Auxilium, Actavis, Endo, and Lilly on MMO's RICO conspiracy claims.[14]

Conclusion

For the foregoing reasons, the Court grants defendants' motion for summary judgment [413, 427]. All other pending motions are terminated as moot, except for the motion to withdraw the appearance of attorney Redi Kasollja, which is granted [463]. The Clerk is directed to enter judgment in favor of defendants and against plaintiff.

MATTHEW F. KENNELLY
United States District Judge

Date: February 14, 2019

[14] Defendants also argue that the Court should grant summary judgment in their favor on all claims because no reasonable jury could conclude that MMO can prove other essential elements of the claims, and on all claims against AbbVie, Auxilium, and Actavis because they are time-barred. The Court need not reach these arguments.