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

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	)	**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. 130
(Memorandum Opinion and Order on MMO's Motion for Class Certification, MMO's *Daubert* Motions, and Defendants' *Daubert* Motions 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 brought personal injury lawsuits against defendants, who are 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.

Presently before the Court is a different case within the MDL. Plaintiff Medical Mutual of Ohio (MMO), an Ohio mutual insurance company, has sued on behalf of a

putative class of third-party payors (TPPs) who allege that they suffered economic injuries when—as a result of defendants' fraudulent marketing schemes—they made reimbursement payments for 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, Lilly, and Endo; for conspiracy to violate the Act, 18 U.S.C. § 1962(d), against defendants AbbVie, Auxilium, Lilly, Endo, and Actavis; and against defendants AbbVie, Auxilium, Lilly, and Endo for negligent misrepresentation under Ohio common law.

MMO has moved to certify a nationwide class of TPPs and an Ohio state sub-class of TPPs. In addition, MMO has moved to exclude the expert opinions of Dr. Diane Giaquinta and Dr. Eric Gaier, which defendants rely upon in opposing MMO's motion for class certification. Defendants, for their part, have moved to exclude the opinions of MMO's experts: Dr. Meredith Rosenthal, Mr. Roy Wilkinson, and Dr. Jeffrey Harris.

The Court grants in part and denies in part defendants' motion to exclude Mr. Wilkinson's opinion; denies MMO's motion to exclude Dr. Giaquinta's opinion; and terminates as moot the motions to exclude the opinions of Dr. Rosenthal, Dr. Harris, and Dr. Gaier. The Court denies MMO's motion for class certification because MMO has not demonstrated that it can adequately represent the class, Fed. R. Civ. P. 23(a)(4), and because it has not met Rule 23(b)(3)'s predominance requirement.

Legal Standards

1. Rule 702 and *Daubert*

"[W]hen an expert's report or testimony is critical to class certification . . . a district court must conclusively rule on any challenge to the expert's qualifications or submissions prior to ruling on a class certification motion." *Am. Honda Motor Co. v. Allen*, 600 F.3d 813, 815-16 (7th Cir. 2010).

Rule 702 and the principles set forth in *Daubert* govern the admissibility of expert testimony. *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Together, Rule 702 and *Daubert* provide that for an expert's testimony to be admissible, (1) he or she must be qualified; (2) the reasoning or methodology underlying the testimony must be reliable; and (3) the testimony must be relevant, meaning that it would "assist the trier of fact to understand the evidence or to determine a fact in issue." *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007); *see also Hartman v. EBSCO Indus., Inc.*, 758 F.3d 810, 817 (7th Cir. 2014) (expert testimony must "fit the issue to which the expert is testifying [and be] tied to the facts of the case" (internal quotation marks and citation omitted)). *Daubert's* "gatekeeping" requirement is in place "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The court's inquiry is "a flexible one," but it should focus on the expert's "principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 594-95; *see also C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 834 (7th Cir. 2015) ("[T]he key to the gate is not the ultimate correctness of the expert's conclusions," but rather "the soundness and

care with which the expert arrived at her opinion" (internal quotation marks and citations omitted)). Nonetheless, an opinion must be "connected to the existing data" by more than "the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). A court may exclude expert testimony if "there is simply too great an analytical gap between the data and the opinion proffered." *Id.*

2. Class Certification

"[T]he primary purposes of the class action mechanism" are "judicial economy and efficiency." *Andrews v. Chevy Chase Bank*, 545 F.3d 570, 577 (7th Cir. 2008). To be certified, a proposed class must satisfy all four requirements of Rule 23(a): "(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a); *McCaster v. Darden Rests., Inc.*, 845 F.3d 794, 800 (7th Cir. 2017). In addition, a party seeking class certification must establish that the proposed class satisfies one of the requirements set forth in Rule 23(b). *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 614 (1997); *McCaster*, 845 F.3d at 800. MMO requests certification of the proposed class under Rule 23(b)(3), which requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3); *see also McCaster*, 845 F.3d at 800.

The party seeking class certification has the burden of establishing by the

preponderance of the evidence that class certification is proper. *Priddy v. Health Care Serv. Corp.*, 870 F.3d 657, 660 (7th Cir. 2017). In assessing whether the movant has met this burden, the district court need not accept the allegations in the complaint as true. *See Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 675 (7th Cir. 2001). The court should instead "make whatever factual and legal inquiries [that] are necessary under Rule 23." *Id.* at 676.

Background

The Court takes the following facts from its prior orders on defendants' motions to dismiss, the Third Amended Complaint (TAC), and the parties' class certification briefing, including their expert reports.

MMO filed this action in November 2014. MMO alleges that the United States Food and Drug Administration (FDA) has approved TRT drugs for the treatment of a relatively rare condition, called "classical hypogonadism," which encompasses conditions that cause insufficient secretion of the testosterone necessary for the body to perform normal functions. MMO contends that although the FDA has 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. Defendants' off-label marketing scheme allegedly included a "disease awareness" campaign that promoted the existence of a nonexistent disease, called "Andropause" or "Low T," which defendants invented and for which they claimed TRT drugs were a safe and effective treatment.

MMO asserts 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, those sales have begun to decrease, despite "continued rampant promotion," in response to recent revelations of the drugs' safety risks. TAC ¶¶ 19-21.

For example, on January 31, 2014, the FDA issued a drug safety communication (DSC) announcing that it was "investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products" as well as the "link between TRT use and cardiovascular adverse events." TAC ¶ 23. On March 3, 2015, the FDA announced that it was "requir[ing] label changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use." *Id.* MMO alleges that defendants were "[u]ndaunted" by these and other warnings and "continue[d] to claim that TRT drugs are safe and effective" for off-label use. *Id.* MMO also alleges that defendants' own research, even prior to these warnings, put them in a position to be aware of the risks TRT use poses. Nonetheless, defendants continued to target TPPs, 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. RICO claims and Ohio negligent misrepresentation claims

Based on these and other facts, MMO alleges that defendants AbbVie, Auxilium, Lilly, and Endo[1] engaged in marketing schemes by forming four "complementary and mutually reinforcing" fraudulent enterprises: a TPP "formulary access" enterprise, which targeted TPPs directly; "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, and that defendants conducted the affairs of the enterprises through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

In its motion for class certification, MMO places great emphasis on the "formulary access enterprise." According to MMO, TPPs are the entities "directly reimbursing most, if not all, of the cost of TRT drug prescriptions." TAC ¶ 1077. TPPs, therefore, were the primary and intended victims of defendants' marketing schemes. *Id.* Typically, if a TPP provides drug benefit coverage for a patient's TRT drug prescription, the TPP will pay approximately 80 to 90 percent of the prescription's cost, and the patient will pay the remainder. Whether a TPP will cover the cost of a particular drug depends on the "formulary status" the TPP has assigned to that drug. MMO explains that "[o]nce a drug is on formulary, payment by TPPs for the drug is largely seamless." Pl.'s Mot. at 3. TPPs can thus use formularies to give patients incentives to make more economical

[1] The AbbVie defendants include AbbVie Inc., Abbott Laboratories, Abbott Products, Inc., Solvay Pharmaceuticals, and Unimed Pharmaceuticals, LLC. The Lilly defendants include Eli Lilly and Company, Lilly USA, Inc., Acrux Commercial Pty Ltd., and Acrux DDS Pty Ltd.

prescription choices.

To determine the appropriate formulary status for prescription drugs, TPPs typically establish committees of experts, called "pharmacy and therapeutics committees" (P&T committees), to review clinical evidence and evaluate the drug products under consideration for formulary placement. In conducting these reviews, P&T committees sometimes consult "dossiers," which are "summar[ies] of the objective clinical evidence in support of a drug" and are prepared by drug manufacturers. Defs.' Opp., Ex. 44 (Declaration of Dr. Diane Giaquinta (Giaquinta Decl.)) ¶ 99.

MMO alleges that to ensure favorable formulary status for their respective TRT drugs, defendants formed fraudulent marketing enterprises that engaged TPPs and their P&T committees directly through deliberate misrepresentation of their respective TRT drugs' safety and efficacy, submission of false and misleading materials, and concealment of unfavorable medical evidence. Notably, some TPPs contract all or portions of their pharmacy benefit management responsibilities to entities called "pharmacy benefit managers" (PBMs). Pl.'s Mot., Ex. 2 (Declaration of Roy Wilkinson (Wilkinson Decl.)) ¶¶ 40-43. MMO contends that defendants directly engaged PBMs and their P&T committees just as they did TPPs.

By MMO's account, defendants "used common means and methods" when they engaged directly with TPPs and/or PBMs to obtain formulary access—meaning they used "standardized marketing" and clinical materials that were rife with misrepresentations regarding safety and efficacy, were "explicitly intended for TPPs," and, for all practical purposes, were scripted. Pl.'s Mot. at 9. For example, MMO points to an AbbVie "'Value Proposition' slide deck for Androgel" that allegedly "sought to

create an equivalence between hypogonadism" and "Low T." *Id.* at 10-11. MMO similarly highlights AbbVie's "Pinnacle" materials, which focused on men's health and, among other things, allegedly overstated the incidence of hypogonadism.

MMO alleges that "[o]nce [d]efendants obtained formulary access for their products, they initiated a variety of marketing initiatives to increase prescription sales by disseminating information regarding the formulary access of their drugs, typically described as 'pull-through' efforts." *Id.* at 3. And although "the lynchpin [sic] of [d]efendants' schemes was maintaining and expanding formulary access," MMO urges, defendants used "common messaging to deceive" consumers and physicians as well, thus "engag[ing] in . . . interlocking efforts . . . to maximize" profits. *Id*. at 13-14.

MMO's claims against defendants AbbVie, Auxilium, Lilly, and Endo for negligent misrepresentation arise out of many of these same facts.

2. RICO conspiracy claims

MMO also alleges that defendants AbbVie, Auxilium, Lilly, Endo, and Actavis[2] violated 18 U.S.C. § 1962(d) by conspiring both with third-parties—namely, the physicians, marketing firms, and other vendors with whom they worked to carry out their respective enterprises—and with each other to violate 18 U.S.C. § 1962(c). MMO's allegations regarding defendants' conspiracies with each other focus primarily on their alleged unbranded direct-to-consumer marketing campaign. According to MMO, defendants believed that by engaging in an unbranded campaign, as opposed to brand-specific campaigns, they could sidestep FDA regulations that prohibit off-label

[2] The Actavis defendants include Actavis plc, Actavis Pharma, Inc., Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Anda, Inc.

marketing. MMO contends that defendants "knowingly conspired" to exploit this perceived regulatory loophole to create belief in a new "curable disease" (Low T) and to boost TRT drug sales. TAC ¶ 891. By participating in the unbranded campaigns, each defendant "jointly adopted the philosophy of 'making a bigger pie,'" recognizing that increased overall sales of TRT drugs would likely lead to increased sales of their individual drugs. TAC ¶ 1076.

3. Formulary status of TRT drugs at MMO

During the class period, MMO contracted with a PBM (Medco, and later Express Scripts (ESI)) to manage its formularies. John Shoemaker, MMO's corporate designee, testified during his deposition that MMO adopted its PBMs' formulary choices "as-is" for much of the class period. Defs.' Opp., Ex. 7 at 109:17-110:19, 125:5-126:12. MMO, however, retained control of other "utilization management" tools to contain drug costs. Giaquinta Decl. at A-9; Defs.' Opp., Ex. 21 (Deposition of Dr. Kathryn Canaday, MMO's Vice President of Pharmacy (Canaday Dep.)) at 30:4-31:13. One such tool is "prior authorization," which requires "prescribers to receive pre-approval for prescribing certain drugs." Giaquinta Decl. ¶ 29, A-7. If a drug is subject to a prior authorization requirement, it will not qualify for coverage by a TPP until the pre-approval is in place. *Id.* at A-7.

In August 2008, MMO's PQM committee, which is similar in concept to a P&T committee, tentatively decided to impose a prior authorization requirement for "oral, topical, and injectable androgens," or testosterone agents. Giaquinta Decl. ¶ 177. The committee had been concerned about androgen use for "enhancement of athletic performance or bodybuilding" and wanted to cover androgens only for FDA-approved

"conditions associated with deficiency or absence of testosterone, such as primary and secondary hypogonadism and delayed puberty." *Id.* ¶ 176. In September 2008, the committee decided to exempt topical and transdermal TRTs—the type of TRT drugs at issue in this litigation—from the prior authorization requirement. *Id.* ¶ 178. The committee reasoned that "injectable testosterone was the most abused form" and that "topical/transdermal forms of TRT 'have rebates.'" *Id.* (citation omitted).

In December 2008, a PQM committee member received an e-mail discussing this prior authorization requirement. The e-mail contained an attachment that discussed (1) increasing prescriptions for TRTs in older men "for the treatment of 'andropause'" and 2) a clinical trial whose results showed "no benefit" from TRT use in men over 60 years of age "with serum testosterone levels on the lower end of normal." *Id.* ¶ 179 (citation omitted). MMO, however, did not modify its prior authorization requirement at that time. Nor did MMO do so in February 2014, when Dr. Canaday and her colleagues discussed the "irony" of having just "recommended," in close proximity to the FDA's January 2014 DSC, two TRT drugs "for a step therapy program"—meaning that patients wanting to use TRTs had to choose those two drugs before others in order to qualify for reimbursement. Defs.' Opp., Ex. 35; Giaquinta Decl. ¶ 55. It was not until July 2016 that MMO's PQM committee voted to expand the existing prior authorization requirement to include topical and transdermal TRTs. And then, due to an administrative oversight, MMO did not actually implement the prior authorization requirement until late 2017. Notably, when asked during her deposition how MMO discovered that the prior authorization had not been implemented as planned in July 2016, Dr. Canaday testified that MMO "learned through [this] lawsuit." Canaday Dep. at

354:18-355:6.[3] Anecdotal evidence indicates that in contrast to MMO, several TPPs and PBMs implemented prior authorization requirements on some or all topical and transdermal TRTs during some or all of the class period, dating as far back as 2001.

4. Expert opinions

The following opinions from Dr. Rosenthal, Mr. Wilkinson, and Dr. Giaquinta are critical to the Court's class certification decision. Opinions from Dr. Gaier and Dr. Harris, by contrast, are immaterial, so the Court does not address them.

a. Plaintiff's expert Dr. Rosenthal

Dr. Rosenthal is a professor of health economics and policy at the Harvard T.H. Chan School of Public Health. She earned a Ph.D. in health policy on an economics track in 1998. MMO offers Dr. Rosenthal's opinion as a "common basis to establish" that defendants' alleged fraud caused the putative class members' injuries, and to establish damages. Pl.'s Mot. at 32. Dr. Rosenthal uses standard regression models to "estimate[] effects of promotion on [TRT] prescribing levels, controlling for other determinants of prescriptions for TRT drugs." Pl.'s Mot., Ex. 1 (Declaration of Dr.

[3] According to Dr. Giaquinta, "[t]here is some indication that" MMO imposed prior authorization requirements on defendants' TRTs "for its Medicare population" in 2007 and 2008, but Dr. Giaquinta could not locate any documents to confirm when the requirements went into effect. Giaquinta Decl. ¶ 183. Neither MMO nor defendants discuss this evidence, however, and MMO concedes that it did not implement a prior authorization for defendants' TRT drugs until "after the FDA-mandated class label change in 2015." Pl.'s Reply at 15 n.39. Along similar lines, while testifying in her deposition about MMO's failure to timely implement the July 2016 decision to impose a prior authorization requirement, Dr. Canaday stated that the "prior authorization hadn't been put on two of the agents," AndroGel and Axiron, "like it was supposed to be." Canaday Dep. 355:2-24. Dr. Canaday's testimony suggests that MMO may have timely implemented its July 2016 decision for other TRTs. Again, however, neither MMO nor defendants discuss this possibility, and even if true, it would not change MMO's concession that it failed to implement any prior authorization for TRT drugs until after the class period.

Meredith Rosenthal (Rosenthal Decl.)) ¶¶ 76, 78. Dr. Rosenthal regresses data regarding "total prescriptions of each drug . . . on a set of explanatory variables" that, like prescription levels, "vary over time." Rosenthal Decl. ¶ 77. "The key explanatory variables" in Dr. Rosenthal's models "are the levels of Defendants' spending on promotion of TRT drugs *to physicians and consumers*." *Id.* ¶ 78 (emphasis added).

Dr. Rosenthal conceded during her deposition that her regression models do not measure promotion to TPPs. *See* Defs.' Opp., Ex. 1 (Rosenthal Dep.) at 82:14-84:24 (agreeing that "all of the promotional activity that [she] include[s] in [her] regression model consists either of promotion to doctors, including sampling, or promotion to end consumers," and that "none of [it] consists of promotion directly to third-party payors"); *id.* at 68:21-22 ("I did not attempt to measure direct contact between TPPs and the defendants."). Dr. Rosenthal also conceded during her deposition that her analysis does not measure whether defendants' promotion injured physicians in the form of lost business or revenue, whether it injured TPPs' beneficiaries, or whether TRTs were medically beneficial for TPPs' beneficiaries. *Id.* at 73:16-74:19; 75:8-21; 275:10-17.

According to Dr. Rosenthal, her regression models "indicate that in economic terms there is a causal relationship between Defendants' promotion and prescriptions of TRT drugs so that if [MMO's] allegations are proven true, impact on the Class can be inferred." Rosenthal Decl. ¶ 86. She uses the relevant values from the regression models to "simulate what the level of prescribing would have been if Defendants had not engaged in the alleged misrepresentation[s]," *id.* ¶ 87, and concludes that the "challenged conduct" caused the putative class members to pay for an estimated number of extra prescriptions. *Id.* ¶ 102. The estimated extra prescriptions translate

into an estimated range of monetary damages.

b. Plaintiff's expert Mr. Wilkinson

Mr. Wilkinson has twenty-seven years of experience as a "pharmacy benefit consultant" and has expertise in areas including "health care claims analysis" and "administrative services management and contracting." Wilkinson Decl. ¶¶ 1, 6. He earned a Bachelor of Science and is expected to earn a Master's of Health Administration in 2018. Mr. Wilkinson testified during his deposition that he has not served on a P&T committee and does not have the expertise to evaluate drugs' risks and efficacy. Similarly, he testified during his deposition that he does not have the expertise to assess whether clinical studies are reliable, and that he would not know how someone with clinical expertise would interpret clinical information.

In his report for this case, Mr. Wilkinson provides background information on the managed care industry, including on how TPPs manage drug benefits and make formulary decisions. He opines, for example, that although it is "common" for TPPs and PBMs "to rely upon a variety of sources for the scientific evidence on which they base their decisions," "[m]any of these sources are directly controlled (or heavily influenced) by drug manufacturers." Wilkinson Decl. ¶ 10. He also opines that drug manufacturers, including defendants, use "standard marketing materials"—many of which must be presented "verbatim"—and "various common strategies" to teach "TPPs and/or their contracted PBMs" about their drugs, "influence formulary access," and increase pull-through once their drugs are on formularies. Wilkinson Decl. ¶¶ 11, 12, 85, 187-207. Mr. Wilkinson bases this opinion on MMO-specific documents and contends that defendants' interactions with MMO and/or its PBMs "are the same type of interactions

that [defendants] had with other TPPs and/or their contracted PBMs." *Id.* ¶ 11. Mr. Wilkinson also states that between July 2012 and December 2015, "AbbVie employees made at least 741 calls to TPPs and/or to their contracted PBMs to discuss the AndroGel Value [Proposition] Deck," a promotional tool that MMO contends contained misleading clinical information regarding TRTs. *Id.* ¶ 118 & Ex. E (listing call notes from AbbVie's "iREP database"). Nonetheless, Mr. Wilkinson agreed during his deposition that he "would need to know the totality of . . . considerations that were in play at a particular time [to] . . . evaluate whether a third-party payor would have changed its treatment of a particular drug in response to a particular piece of information." Defs.' Opp., Ex. 6 (Wilkinson Dep.) at 308:3-11. He also testified that he deems defendants' marketing strategies to be common "regardless of [their] specific content." *Id*. at 202:17-203:8.

In addition, Mr. Wilkinson opines that "TPPs and/or their contracted PBMs would generally make strict changes to their formularies to limit a particular therapeutic category of drugs only once they receive notice from the FDA concerning potential safety and efficacy concerns." Wilkinson Decl. ¶ 14. And he states that in his opinion, "TPPs and/or their contracted PBMs would not have been on notice of the serious safety and efficacy issues associated with the TRT Drugs sufficient to implement strict Topical Androgen class-wide pharmacy controls until FDA's Safety Announcement dated January 31, 2014." *Id.* ¶ 256.

c. Defendants' expert Dr. Giaquinta

Dr. Giaquinta is a licensed pharmacist who has thirty-seven years of experience "working in managed care pharmacy" for entities including a PBM, a hospital, a

pharmaceutical manufacturer, and a managed care consulting practice. Giaquinta Decl. ¶ 2. She has served on P&T committees and has drafted drug monographs, which are similar in concept to dossiers, for P&T committees' review.

Like Mr. Wilkinson, Dr. Giaquinta provides background information on how private payers in the United States cover and pay for drugs. Based on this information and her industry experience, she opines that TPPs and PBMs are diverse entities that make formulary and utilization management decisions in many different ways. For example, the amount of clinical research that a TPP or PBM can conduct in making formulary decisions depends on the entities' resources. Some health plans have "different lines of business," such as HMOs and PPOs, and might cover drugs differently in each line of business—such as by imposing prior authorization requirements in HMOs but not PPOs. Giaquinta Decl. ¶¶ 5(a), 212. Many, but not all, TPPs contract with PBMs to help them manage pharmacy benefits. Some health plans control their own formulary selection, "[o]thers delegate full control to their PBMs," others may "customize" their PBMs' formularies, and others may "make their own utilization management decisions" even after accepting their PBMs' formularies. *Id.* ¶¶ 5(a), 213. Similarly, "some health plans simply accept a PBM's utilization management programs," such as prior authorization requirements, "while others do not." *Id.* ¶ 213. For some TPPs and PBMs, "[f]inancial incentives" such as rebate agreements "can play a critical role in formulary coverage, placement, and restrictions." *Id.* ¶ 5(a). According to Dr. Giaquinta, for many of these same reasons, whether defendants' marketing efforts influenced a given TPP or PBM will vary by entity. Dr. Giaquinta is insistent, however, that regardless of these differences, TPPs and PBMs "do not make coverage

decisions based solely, or even primarily, on what a pharmaceutical manufacturer told them." *Id.* ¶ 214.

In addition, Dr. Giaquinta discusses MMO's coverage of TRT drugs during the class period as garnered from MMO's documents and from MMO employee testimony. Likewise, based on third-party documents produced in discovery, she provides examples of TPPs and PBMs that took different approaches to TRT coverage. Similarly, she provides examples of TPPs and PBMs that had different "[a]wareness and knowledge of concerns" regarding TRT drugs' indication and alleged off-label use during the class period. *Id.* ¶¶ 5 (c), 197-206.

Dr. Giaquinta also opines that "MMO was an outlier during the class period" with respect to its pharmacy management practices, including because for many years during the class period, (1) MMO's PQM committee did not include "a member pharmacist employed by MMO;" (2) MMO did not have a pharmacist managing its pharmacy department or working anywhere else in the organization; and (3) MMO did not conduct clinical literature reviews. *Id.* ¶¶ 5(d), 159, 221-22. According to Dr. Giaquinta, the composition of MMO's PQM committee and pharmacy department was significant because although MMO relied on contracted PBMs for formulary placement decisions, MMO's PQM committee "ostensibly served to review the [PBMs'] formulary selections" and decide whether to adopt PBMs' recommendations to implement utilization management restrictions. *Id.* ¶¶ 5(d), 158, 175. In addition, after noting that MMO provides pharmacy benefits to approximately 750,000 policy members, Dr. Giaquinta states that she is "not familiar with any other pharmacy departments of a similar size of that of MMO that do not employ a single pharmacist somewhere in the

organization." *Id.* ¶¶ 157, 159. And although MMO's PQM committee "relied . . . on a pharmacist from its PBM" for part of the class period, Dr. Giaquinta opines that this practice, too, was "not typical for a health plan of MMO's size." *Id.* ¶ 159. Based on the composition of MMO's PQM committee and pharmacy department, as well as on Dr. Canaday's testimony that MMO did not "do its own research regarding drugs," Dr. Giaquinta opines that "MMO's pharmacy benefit management program was not as rigorous as other managed care organizations of similar size and geographic coverage." *Id.* ¶ 158-60. Dr. Giaquinta also states that MMO's "botched implementation of its [TRT] prior authorization criteria in 2016" further supports her conclusion that MMO "did not have rigorous operational controls in place." *Id.* ¶ 222.

5. Proposed class definitions

MMO defines its proposed nationwide and Ohio state sub-classes as follows and contends that putative class members number in the thousands:

> **Nationwide Class**
> All third-party payors ("TPPs") in the United States and its territories from January 1, 2000 through January 31, 2014, that have (1) covered the cost of one or more of Defendants' TRT drug products through insurance or employee benefit programs, and (2) included one or more of Defendants' TRT drug products on a formulary. TPPs include insurance companies, healthcare benefit plans, health maintenance organizations, union health and welfare plans, self-funded employer health and welfare plans, and employee or retiree health plans. Excluded from the class are:
>
> a. The Defendants and their officers, directors, employees, predecessors-in-interest, successors-in-interest, assignees, affiliates and subsidiaries;
> b. All governmental entities, except for government-funded employee, retiree and Medicare Part D plans provided through private insurance companies;
> c. All pharmaceutical wholesalers or distributors that purchased one or more of the Defendants' TRT drug products for purposes of resale; and
> d. Pharmacy Benefit Managers.
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> **Ohio State Sub-Class**
> All third-party payors ("TPPs") in Ohio from January 1, 2000 through January 31,

> 2014, that have (1) covered the cost of one or more of Defendants' TRT drug products through insurance or employee benefit programs, and (2) included one or more of Defendants' TRT drug products on a formulary. TPPs include insurance companies, healthcare benefit plans, health maintenance organizations, union health and welfare plans, self-funded employer health and welfare plans, and employee or retiree health plans. Excluded from the class are:
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> a. The Defendants and their officers, directors, employees, predecessors-in-interest, successors-in-interest, assignees, affiliates and subsidiaries;
> b. All governmental entities, except for government-funded employee, retiree and Medicare Part D plans provided through private insurance companies;
> c. All pharmaceutical wholesalers or distributors that purchased one or more of the Defendants' TRT drug products for purposes of resale; and
> d. Pharmacy Benefit Managers.

Pl.'s Mot. at 20.

Discussion

1. *Daubert* rulings

a. Plaintiff's expert Dr. Rosenthal

Defendants move to exclude Dr. Rosenthal's causation opinion.[4] They do not challenge Dr. Rosenthal's qualifications but rather argue that her opinion is irrelevant and unreliable. The Court finds that Dr. Rosenthal's opinion does not support MMO's causation theories on an individual or class-wide basis because it does not measure the effects of misrepresentations made directly to TPPs. The Court therefore does not rely on Dr. Rosenthal's opinion and thus need not go so far as to exclude the opinion under *Daubert*.

The Court's ruling requires an understanding of the causation doctrine governing

[4] Defendants also move to exclude Dr. Rosenthal's damages opinion, but the Court need not address damages because it has determined that class certification is inappropriate regardless of whether damages questions will require individualized proof. Likewise, because the Court has determined that it will not rely on Dr. Rosenthal's causation opinion, it declines to address defendants' arguments that the opinion is unreliable.

MMO's RICO and Ohio negligent misrepresentation claims. As this Court has previously explained, 18 U.S.C. § 1964(c)—the vehicle through which MMO brings its RICO claims—requires MMO to show it was "injured in [its] business or property by reason of a violation of section 1962." 18 U.S.C. § 1964(c); *see also MMO I*, 159 F. Supp. 3d at 910 (same). The Supreme Court has interpreted this statute as requiring a civil RICO plaintiff to show that defendants' section 1962 violations were both the but-for and proximate causes of the plaintiff's injury. *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 v. Camilli*, 664 F.3d 192, 199 (7th Cir. 2011).

After surveying the case law concerning TPP RICO claims against drug manufacturers that are similar to those MMO asserts, this Court "concluded that whether a TPP [can] satisfy RICO's proximate cause element largely depend[s] on whether the drug manufacturer's alleged fraudulent marketing included the communication of misrepresentations directly to the TPP." *MMO II*, 2016 WL 4091620, at *2; *see also MMO I*, 159 F. Supp. 3d at 919 ("RICO claims generally survive where TPPs allege that defendants made direct misrepresentations to them and fail where they do not."). MMO has tailored its allegations accordingly. *See, e.g.*, *MMO II*, 2016 WL 4091620, at *5 (dismissing MMO's § 1962(c) claims against GSK and Actavis because MMO did not plausibly allege that those defendants "made direct misrepresentations to [MMO]"). Since that time, the Seventh Circuit has weighed in on the issue and has reached the same result. *See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (holding that "improper representations made to physicians do not support a RICO claim by Payors, several

levels removed in the causal sequence"). This Court has applied the same causation principles to MMO's Ohio negligent misrepresentation claims. *See MMO II*, 2016 WL 4091620, at *7.

MMO now argues that interpreting *Sidney Hillman* as requiring proof that defendants made direct misrepresentations to TPPs and that TPPs relied on them (*i.e.*, first-party reliance) is "absurd." Pl.'s Reply at 9. According to MMO, this reading of *Sidney Hillman* runs afoul of *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 641-42, 647 (2008), where the Supreme Court held that first-party reliance is not an element of a civil RICO claim predicated on mail fraud. Pl.'s Reply at 9. The Court disagrees. In *Sidney Hillman*, the Seventh Circuit recognized that under *Bridge*, "a RICO recovery is possible when a wrong against A directly injures B." 873 F.3d at 576. The Seventh Circuit, however, concluded that the plaintiff-TPPs were not the "directly injure[d]" parties. *Id.* Furthermore, in *Bridge*, the Supreme Court itself recognized that "the absence of first-party reliance may in some cases tend to show that an injury was not sufficiently direct to satisfy § 1964(c)'s proximate-cause requirement." 553 U.S. at 659. Likewise, in discussing both but-for and proximate causation, the Supreme Court stated that "it may well be that a RICO plaintiff who alleges injury 'by reason of' a pattern of mail fraud" must show that "*someone* relied on the defendant's misrepresentations." *Id.* at 658-59. For purposes of MMO's claims—which are "nearly identical" to those in *Sidney Hillman*, *see MMO I*, 159 F. Supp. 3d at 911—that "someone" must be a TPP. *Sidney Hillman*, 873 F.3d at 578.

MMO makes a related argument that the focus of proximate cause is whether a plaintiff's injuries were the "probable," "expected consequence of the defendant's

wrongful conduct." Pl.'s Reply at 1, 9 (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011)). According to MMO, because defendants targeted TPPs, TPPs' injuries were expected. But as the Court has previously explained, TPPs are "direct victim[s]" of defendants' fraud, and their injuries the expected consequence of defendants' conduct, *when* they receive direct misrepresentations. *MMO I*, 159 F. Supp. 3d at 919 (discussing *BCS Servs.*, 637 F.3d at 758). Direct misrepresentations to TPPs, and TPPs' reliance on them, are thus crucial "links" in what MMO calls an "interlocking" causal chain. Finally, the Court notes that MMO has not provided any authority in its briefing to suggest that the RICO causation requirements should not apply to its negligent misrepresentation claims. *See MMO II*, 2016 WL 4091620, at *7. MMO does argue that a negligent misrepresentation claim requires proof that defendants' false statements were "aimed at a 'limited class of foreseeable persons,'" Pl.'s Mot. at 37, but without more, this argument is unconvincing for the reasons just discussed.

The Court now turns to Dr. Rosenthal's report. As an initial matter, the Court notes that although MMO periodically labels the report as bearing on "but-for" causation, *see, e.g.*, Pl.'s Mot. at 32, the Court reads it as first addressing proximate causation and then, assuming proximate causation, calculating damages in "but-for" scenarios where the promotional conduct allegedly driving causation did not occur. More specifically, Dr. Rosenthal contends that the Court can "infer[]" "impact on the Class" from the "causal relationship" between promotion and prescriptions that the regression models, controlling for other potential causes, purport to show. Rosenthal Decl. ¶ 86. Dr. Rosenthal then "use[s] the models to simulate what the level of

prescribing would have been if [d]efendants had not engaged in the alleged misrepresentation[s]." *Id.* ¶ 87. The Court need not address the second step of Dr. Rosenthal's analysis because the first step fails under *Sidney Hillman*. There, the court rejected the idea that a proposed regression model—which was nearly identical in principal to Dr. Rosenthal's—could show proximate causation, finding that it did not account for a number of causal "layers." 873 F.3d at 577-78. During her deposition, Dr. Rosenthal conceded that her regression models do not measure those very same "layers." *See* Rosenthal Dep. at 73:16-74:19; 75:8-21; 275:10-17.

MMO argues that Dr. Rosenthal's regression models differ from the proposed model in *Sidney Hillman* because they "capture[] the effect of Defendants' pull-through efforts aimed at doctors and consumers," which in turn "increased [the] number of TRT prescriptions paid by TPPs." Pl.'s Reply at 17. This line of reasoning echoes MMO's argument that because TPPs' injuries were the "expected consequence" of defendants' alleged misconduct, MMO can satisfy the proximate cause requirement without evidence of direct misrepresentations to TPPs. As the Court has just explained, MMO is incorrect. Finally, although regression analysis can be a "valid means to establish causal effects on a class-wide basis," Pl.'s Reply at 12, the regression analysis that MMO offers in this case falls short. Here, because Dr. Rosenthal's "means [of] establish[ing] causal effects" do not account for direct misrepresentations to TPPs, neither MMO nor any putative class member could use Dr. Rosenthal's analysis to establish causation.[5] *Cf. Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046

[5] MMO also contends that Dr. Rosenthal's opinion finds support in (1) Lilly's internal analysis in 2015 of the size of the "on-label" TRT market, and (2) Lilly's decision to stop promoting Axiron to primary care providers after the FDA-mandated label change in

(2016) (stating that if "each class member could have relied on" a "representative sample" to "establish liability if he or she had brought an individual action," the sample "is a permissible method of proving classwide liability"). Because Dr. Rosenthal's opinion does not support MMO's causation theories, the Court does not rely on it and terminates as moot defendants' *Daubert* motion.

b. Plaintiff's expert Mr. Wilkinson

Defendants argue that the Court should exclude Mr. Wilkinson's opinions because he is not qualified to offer them and because they are irrelevant and unreliable.

Although Mr. Wilkinson admits that he lacks the expertise to assess clinical data and has not served on P&T committees, he has extensive professional experience in the managed care industry. The Court is satisfied that Mr. Wilkinson's background qualifies him to teach a fact-finder about the industry, including by opining on the types of information TPPs "view[] as important to their formulary decision-making" and by opining that the FDA's January 2014 DSC *could* have put TPPs on notice of safety and efficacy concerns regarding TRTs. Defs.' Opp. at 55-56; *see* Fed. R. Evid. 702 (witness can be "qualified as an expert by knowledge, skill, experience, training, *or* education"

2015. *See* Pl.'s Reply at 12 n.30, 18 (citing Pl.'s Reply, Exs. 192, 205, 206). The Court understands MMO's argument as one that seeks to rebut defendants' attacks on the reliability of Dr. Rosenthal's methodology. More specifically, defendants argue that Dr. Rosenthal makes an unsupported assumption "that on- and off-label marketing drove prescribing at identical rates." Defs.' Opp. at 51. As the Court has already stated, it need not and does not address the reliability of Dr. Rosenthal's methodology. If, however, MMO has offered Exhibits 192, 205, and 206 to support the relevance of Dr. Rosenthal's regression models, the exhibits do not change the Court's conclusion that the models do not support MMO's causation theories. One defendant's estimate of the on-label market size and that same defendant's decision to change its sales strategy do not cure the fundamental relevance problem with Dr. Rosenthal's regression models: that they do not measure direct promotion of any kind to TPPs.

(emphasis added)).

The Court excludes, however, Mr. Wilkinson's opinion that TPPs usually make formulary changes "*only* once they receive notice" from the FDA about safety and efficacy concerns. Wilkinson Decl. ¶¶ 14 (emphasis added); *see also id.* ¶ 255. To be sure, Mr. Wilkinson has extensive business experience in the industry, and he has a sufficient basis to opine that an FDA safety alert may trigger a TPP to make a formulary change. But the discussion in his report does not support his conclusion that it is *only* when a TPP receives such an alert that it will make a formulary change. To put it another way, Mr. Wilkinson has not offered the necessary support for the leap from an opinion that an FDA safety alert is a *sufficient* basis for a formulary change to an opinion that such an alert is a *necessary* basis for a formulary change.

MMO argues, and it is certainly true, that Mr. Wilkinson can base his opinion "on the totality of the evidence," Pl.'s Reply at 19 n.48 (quoting *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, MDL No. 2545, 2017 WL 1833173, at *9 (N.D. Ill. May 8, 2017)). But an opinion must be connected to the existing data by more than "the *ipse dixit* of the expert." *Gen. Elec. Co.*, 522 U.S. at 146. An expert's opinions may be inadmissible because "there is simply too great an analytical gap between the data and the opinion offered." *Id.* That is the case here. Mr. Wilkinson does discuss evidence tending to show that TPPs will remove a drug from their formularies if the FDA "deems [it] unsafe," Wilkinson Decl. ¶¶ 218-23, but he does not provide an explanation for why or how this excludes the possibility that information and events other than FDA safety warnings could cause TPPs to implement formulary restrictions. In fact, Mr. Wilkinson concedes that "other clinical evidence that calls the

drug's efficacy or safety into question" can prompt a TPP to change its formulary. *Id.* ¶ 227; *see also id.* ¶ 55 (stating that most P&T committees conduct annual reviews of "all classes of formulary drugs" and consider "new, relevant information about the medications listed on the formulary"). For all of these reasons, the Court excludes Mr. Wilkinson's opinion on this point.

The Court also excludes Mr. Wilkinson's opinion that TPPs "*would not* have been on notice" of safety and efficacy concerns regarding TRTs until the FDA's January 2014 DSC. Wilkinson Decl. ¶ 256 (emphasis added). In support of this opinion, Mr. Wilkinson cites language from the DSC regarding then-recent TRT clinical studies and states that in his view, the DSC "contained enough substantive information to warrant a change in the TPP's [sic] formularies." *Id.* ¶ 231. This assessment, however, amounts to a clinical assessment that Mr. Wilkinson is not qualified to make. Mr. Wilkinson also supports this opinion with a February 2014 Auxilium document attributing a drop in TRT sales to the DSC; an Auxilium document demonstrating that one TPP implemented a prior authorization policy for all topical TRTs in July 2014; and a May 2014 AbbVie document discussing physicians' complaints about "widespread use of prior authorization" for AndroGel. *Id.* ¶¶ 232-33. Again, however, Mr. Wilkinson does not explain how this evidence excludes the possibility that sources of information besides the FDA's January 2014 DSC could have put TPPs on notice of safety and efficacy concerns.

Finally, based on the record before the Court, the Court excludes as unreliable Mr. Wilkinson's opinion that defendants interacted with all putative class members in the same way they interacted with MMO—*i.e.*, using the same common promotional

strategies. In finding the opinion unreliable, the Court is persuaded both by defendants' argument that Mr. Wilkinson "formed conclusions before even beginning work" and by actual indications that there is a significant mismatch, or "analytical gap," "between the data and the opinion proffered." Defs.' Opp. at 56; *Gen. Elec. Co.*, 522 U.S. at 146.

First, Mr. Wilkinson's opinion relies heavily on a compilation of materials "summarizing Medical Mutual's interactions with" defendants. Wilkinson Decl. ¶ 95 (citing Decl., Ex. D). As defendants point out, however, much of Exhibit D "copies allegations verbatim from" the complaint. Defs.' Opp. at 57. During his deposition, Mr. Wilkinson testified that he does not view this as problematic because he asked MMO's counsel for relevant materials; MMO's counsel selected the materials for Exhibit D; and MMO's counsel is "way more familiar with the materials than I am." Wilkinson Dep. at 280:5-24. This testimony indicates that Mr. Wilkinson did not make an investigation of the evidence sufficient to render an admissible expert opinion. Second, although Exhibit D purports to give "a chronology of interactions each [defendant] had with MMO aimed at influencing formulary access for their TRT drugs," the cited examples for Auxilium and Endo (with one possible exception) reflect only discussions *about* MMO, *plans* to contact MMO, or, in two instances, contacts with MMO's PBM. Wilkinson Decl., Ex. D at 1, 6-14. Furthermore, none of the entries in Exhibit D provide enough detail about the communications' substance to permit an inference that defendants made similar, let alone standardized, representations to MMO (or, by extension, to all putative class members). Mr. Wilkinson's concession that the "specific content" of defendants' promotional strategies have no effect on his opinion that those strategies are "common" to the putative class members lends further support to the Court's conclusion that there

is a gaping hole in Mr. Wilkinson's logic. Defs.' Opp., Ex. 6 (Wilkinson Dep.) at 202:17-203:8; *see Gen. Elec. Co.*, 522 U.S. at 146.

Second, the iREP data in Exhibit E to Mr. Wilkinson's report does not salvage Mr. Wilkinson's opinion. The Court acknowledges that unlike the information in Exhibit D, the iREP data tends to show that AbbVie sales representatives likely spoke to numerous TPPs and/or PBMs about the AndroGel Value Proposition Deck between July 2012 and December 2015. Indeed, the data, which AbbVie produced, states that the deck was the "[d]iscussion [t]opic" in specific calls to specific TPPs on specific dates. *See* Wilkinson Decl. ¶ 118 & Exhibit E. Nonetheless, Mr. Wilkinson fails to acknowledge that the TPPs and/or PBMs represented in the data likely comprise only a small fraction of the putative class. Mr. Wilkinson states that according to the data, "AbbVie employees made at least 741 calls to TPPs and/or their contracted PBMs to discuss" the deck. Wilkinson Decl. ¶ 118. But the data appears to double-count numerous entities (by listing more than one call to those entities) and to include calls made to prescribers and pharmacists, who are not putative class members. Based on the Court's review, if one accounts for these discrepancies, the data shows calls to approximately 164 unique entities, which likely include PBMs. Mr. Wilkinson testified during his deposition that MMO's proposed class definition likely includes between 7,000 and 10,000 self-funded employers—which are just one type of TPP in the putative class. Wilkinson Dep. at 186:19-187:12. MMO likewise states that there are thousands of putative class members, and it has not disputed defendants' argument that the class could contain 10,000 members. *See* Defs.' Opp. at 2. Accordingly, even assuming that the iREP data in Exhibit E could serve as common evidence that TPPs received direct

misrepresentations from defendants, it could do so only for approximately 1.6 percent of putative class members, and for only one document belonging to one defendant. Mr. Wilkinson does not confront any of these limitations. Mr. Wilkinson's opinion that defendants interacted with all putative class members using the same common promotional strategies, therefore, is not sufficiently connected to the data in Exhibit E. *See Gen. Elec. Co.*, 522 U.S. at 146.

c. Defendants' expert Dr. Giaquinta

MMO moves to exclude Dr. Giaquinta's opinion that MMO's formulary-related practices did not comport with industry standards for much of the class period. MMO also moves to exclude her opinions regarding the materials TPPs rely upon and the procedures they use in making formulary decisions.[6]

MMO first argues that Dr. Giaquinta used an "ad-hoc" methodology in determining that MMO is an "outlier" among TPPs. Pl.'s Reply at 21. MMO faults Dr. Giaquinta for failing to use a "statistically valid sample size" and instead "review[ing] documents from only [two] TPPs . . . other than MMO" as a basis for comparison. *Id.* at 21-22. But Dr. Giaquinta uses third-party evidence only to provide specific examples of several TPPs and PBMs that imposed prior authorization requirements on TRTs long before MMO did. She does not purport to extrapolate industry-wide conclusions from these examples, and thus she need not have a "statistically valid" sample size. *See, e.g.*, *Kumho* , 526 U.S. at 148 (stating that the *Daubert* principles are not "limited to 'scientific' knowledge"); *Lees v. Carthage Coll.*, 714 F.3d 516, 521 (7th Cir. 2013)

[6] In addition, MMO contends Dr. Giaquinta is unqualified to offer testimony on "whether TPPs increased their premiums to address Defendants' fraud." Pl.'s Reply at 20. For reasons already explained, the Court does not address this damages-related argument.

(stating "because there are 'many different kinds of experts, and many different kinds of expertise,' the reliability analysis should be geared toward the precise sort of testimony at issue and not any fixed evaluative factors" (quoting *Kumho*, 526 U.S. at 150)). MMO makes a related argument that Dr. Giaquinta impermissibly relies on data from Managed Markets and Insight Technology (MMIT) in providing still other anecdotal examples of TPPs' and PBMs' varying formulary decisions. The Court rejects this argument because MMO mischaracterizes Dr. Giaquinta's testimony about her familiarity with and use of the data, and because individuals and entities in the managed care industry use MMIT data in the ordinary course of business. *See, e.g.*, Wilkinson Decl. ¶ 28 (providing examples of the latter).

MMO also contends that Dr. Giaquinta's opinions regarding the types of materials TPPs use in making formulary decisions do not "fit" the case because "she did not look at a single document produced by Defendants to form that opinion." Pl.'s Reply at 23. According to MMO, Dr. Giaquinta also testified during her deposition that "whatever Defendants actually represented to TPPs about the TRT drugs was irrelevant." *Id.* Again, MMO misrepresents Dr. Giaquinta's testimony, which essentially boils down to a statement that the content of defendants' alleged misrepresentations is outside the scope of her opinion. Defs.' Surreply, Ex. 1, at 157:5-19.

MMO's final attack on Dr. Giaquinta is that her opinion regarding the types of materials TPPs do rely upon in making formulary decisions is not derived from any "well-designed survey[]" or research, as evidenced by Dr. Giaquinta's use of the word "may" 243 times in her report. Pl.'s Reply at 24-25. Dr. Giaquinta's background and experience, however, provide a sufficient basis for her opinions. She is not required to

present an opinion grounded in science or statistics, nor does she purport to do so. *See Kumho*, 526 U.S. at 148; *Lees*, 714 F.3d at 521.

2. Class certification

a. Adequacy of representation

Federal Rule of Civil Procedure 23(a)(4) requires a showing that "the representative part[y] will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "[A]dequacy of representation is composed of two parts: the adequacy of the named plaintiff's counsel, and the adequacy of representation provided in protecting the different, separate, and distinct interest of the class members." *Retired Chicago Police Ass'n v. City of Chicago*, 7 F.3d 584, 598 (7th Cir. 1993) (internal quotation marks and citation omitted). "The presence of even an arguable defense peculiar to the named plaintiff or a small subset of the plaintiff class may destroy the required typicality of the class as well as bring into question the adequacy of the named plaintiff's representation." *CE Design Ltd. v. King Architectural Metals, Inc.*, 637 F.3d 721, 726 (7th Cir. 2011) (internal quotation marks and citation omitted); *Randall v. Rolls-Royce Corp.*, 637 F.3d 818, 824 (7th Cir. 2011) (affirming denial of class certification where named plaintiffs' claims were "significantly weaker than those of some (perhaps many) other class members").

The parties do not dispute the adequacy of MMO's counsel. Defendants, however, argue that MMO is an inadequate class representative because it is vulnerable to several individualized defenses. Defendants contend that MMO is an atypical class representative for the same reasons. Because "typicality . . . should be determined with reference to the [defendant's] actions, not with respect to particularized

defenses it might have against certain class members," the Court will "focus [its] analysis on adequacy." *CE Design*, 637 F.3d at 724-25. The Court agrees with defendants that MMO is particularly vulnerable to defenses regarding its claims of reliance and injury. For these reasons, MMO cannot adequately represent the class.

First, MMO did not implement a prior authorization requirement for topical TRTs until nearly four years after it alleges it first received notice of defendants' alleged fraud. More specifically, despite alleging that the FDA's January 2014 DSC triggered such notice; despite proffering an expert opinion stating the same; and despite filing this lawsuit in November 2014, MMO did not approve a prior authorization requirement for the TRT drugs at issue until July 2016 and did not implement the requirement until late 2017. Indeed, as evidenced in a February 2014 e-mail, MMO made a calculated decision to continue covering TRTs notwithstanding its actual knowledge of the FDA's January 2014 DSC. And although MMO contends it decided to implement a prior authorization requirement "after the FDA-mandated class label change in 2015," Pl.'s Reply at 15 n.39, its own records show the timeline was far more prolonged. In addition, it appears that fact discovery in this litigation—rather than MMO's attention to its formulary in the ordinary course of business—unearthed the delay.

Given these facts, MMO will face significant hurdles in convincing a jury that it relied on defendants' alleged misrepresentations and that the misrepresentations caused MMO's injuries. *See Teamsters Local 237 Welfare Fund v. AstraZeneca Pharm. LP*, 136 A.3d 688, 696 (Del. 2016) (affirming dismissal of false advertising lawsuit that TPPs brought against drug manufacturer because "TPPs who continue to pay or reimburse for [the defendant's drug], while claiming they were harmed by

allegedly false advertising, are neither 'victims' of the allegedly false advertising nor were they injured by reason of or as a result of it"); *MMO II*, 2016 WL 4091620, at *8 (distinguishing *Teamsters* at motion to dismiss phase because MMO's complaint did "not give the Court any information about whether [MMO] changed its coverage of TRT drugs after learning about defendants' fraud"); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 289 F. Supp. 3d 247, 255 (D. Mass. 2018) (finding that TPP had not "present[ed] affirmative evidence as to the inefficacy of the subject drugs sufficient to establish RICO injury," including because TPP had not directed its PBM "to remove the subject drugs from its approved drug formulary"); *cf*. *Oshana v. Coca-Cola Co.*, 472 F.3d 506, 514 (7th Cir. 2006) (plaintiff who claimed defendant deceptively marketed all Diet Coke products as sweetened only with aspartame was atypical where she "admitted that she continues to drink fountain Diet Coke even though she now knows it contains saccharin").

By contrast, Dr. Giaquinta has presented evidence tending to suggest that at least some TPPs and PBMs monitored their formularies and prior authorization policies during the class period more vigilantly than MMO did. For example, at least three national TPPs or PBMs, and at least five regional TPPs, implemented prior authorization policies for some or all TRTs between during the class period. Giaquinta Decl. ¶¶ 209-11. In addition, some of these entities changed the tier status of certain TRTs more than once during the class period. *Id.* MMO's representation of these and similar class members could "suffer" if MMO "devote[s] too much attention to rebutting" the defenses to which MMO's prior authorization record could give rise. *CE Design*, 637 F.3d at 726 (internal quotation marks and citation omitted). MMO's efforts to represent

these class members could similarly fall short if a jury concludes that MMO has "credibility problems" based on its continuation of coverage of TRTs for years after January 2014, whether that was accidental or deliberate. *Id.* A TPP that monitored its prior authorization procedures and its formulary in a disciplined manner would be in a better position than MMO to represent itself and the putative class.

Second, the Court doubts MMO's adequacy as a class representative in light of Dr. Giaquinta's opinions and the testimony of MMO's Vice President of Pharmacy, Dr. Canaday, that MMO's formulary and utilization management practices did not comport with industry standards. Dr. Canaday, for example, testified during her deposition that for part of the class period, MMO—unlike "all the health plans that [she] worked with" between March 2005 and 2014—did not review clinical information on an annual basis to determine whether it should change its policies for any given drug. Canaday Dep. at 86:7-87:24. Dr. Canaday testified during her deposition that conducting annual clinical literature reviews "was the norm" with all other health plans she had worked with, and that MMO now conducts such reviews. *Id.* 86:14-88:9; *see also* Giaquinta Decl. ¶ 160 (citing same in discussing disparities between MMO and other managed care organizations of the same size and geographic coverage). In addition, a non-pharmacist with no medical degree ran MMO's pharmacy for much of the class period, and MMO's PQM committee did not include "a member pharmacist employed by MMO." Giaquinta Decl. ¶¶ 5(d), 159, 221-22. According to Dr. Giaquinta, the latter is "not typical for a health plan of MMO's size," and overall, the composition of MMO's pharmacy department and PQM committee left MMO without the ability to "rigorous[ly]" manage the pharmacy benefits it provided. *Id.* ¶¶ 5(d), 159, 221-22.

MMO contends these issues are "immaterial" but does not explain why, other than by generally pointing the Court to arguments that common questions in this case are numerous. Pl.'s Opp. at 15 n.39. This argument does not quell the Court's concerns about the adequacy of MMO's representation. Nor does MMO's citation to an undated website that lists MMO's awards and accreditations. The Court concludes that the evidence of MMO's unconventional pharmacy management practices could hinder its ability to prove crucial elements of its case such as receipt of and reliance on defendants' alleged misrepresentations.

For all of these reasons, the Court concludes that MMO is an inadequate class representative and on that basis denies MMO's motion for class certification.[7]

b. Predominance

The Court denies MMO's motion for class certification for the independent reason that "questions of law or fact common to class members" will not "predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3).

Rule 23(b)(3)'s predominance requirement "calls upon courts to give careful scrutiny to the relation between common and individual questions in a case." *Tyson Foods*, 136 S. Ct. at 1045. It "asks whether the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues." *Id.* (quoting 2 W. Rubenstein, Newberg on Class Actions § 4:49 (5th ed. 2012)). The predominance requirement is met "when 'common questions

[7] Defendants also contend that MMO is an inadequate class representative because, according to defendants, MMO is at risk for spoliation sanctions. Defs.' Opp. at 41-42. Because the Court has concluded for other reasons that MMO cannot adequately represent the class, it need not address this argument.

represent a significant aspect of [a] case and . . . can be resolved for all members of [a] class in a single adjudication.'" *Messner v. Northshore Univ. HealthSystem*, 669 F.3d 802, 815 (7th Cir. 2012) (quoting 7AA Wright & Miller, Federal Practice & Procedure § 1778 (3d ed. 2011)). As the court explained in *Messner*,

> If, to make a prima facie showing on a given question, the members of a proposed class will need to present evidence that varies from member to member, then it is an individual question. If the same evidence will suffice for each member to make a prima facie showing, then it becomes a common question.

Id. (quoting *Blades v. Monsanto Co.*, 400 F.3d 562, 566 (8th Cir. 2005)); *see also Tyson Foods*, 136 S. Ct. at 1045.

Because "[t]he text of Rule 23(b)(3) itself contemplates that . . . individual questions will be present," the presence of individual questions will not defeat class certification. *Messner*, 669 F.3d at 815. "The rule requires only that those questions not predominate over the common questions affecting the class as a whole." *Id.* A district court "should evaluate the evidence pragmatically . . . [to] decide whether classwide resolution would substantially advance the case." *Costello v. BeavEx, Inc.*, 810 F.3d 1045, 1059 (7th Cir. 2016) (internal quotation marks and citation omitted). "Rule 23(b)(3)'s predominance criterion is . . . more demanding than Rule 23(a)." *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013); *see also McCaster*, 845 F.3d at 800.

MMO contends that common evidence can be used to prove nearly every issue in this case. Defendants argue that "[t]here are no 'common' questions 'central' to each TPP's claim as to any Defendant." Defs.' Opp. at 6. After carefully reviewing the evidence, the Court concludes that individual issues will predominate over common

ones.

i. TPPs' exposure to alleged misrepresentations

As previously discussed, MMO will have to show that each TPP actually received defendants' alleged misrepresentations. Defendants have pointed to documents and deposition testimony that underscore the individualized nature of the question whether they did. Namely, defendants highlight evidence demonstrating that whether a TPP receives sales calls and clinical information from defendants depends on the number of beneficiaries the TPP insures; whether the TPP permits or prohibits meetings with drug manufacturers as a matter of policy; whether the TPP prefers to hear only business information, only clinical information, or both; and whether the TPP adopts formularies without modification from a PBM.

In response, MMO contends that it can use common proof to show that thousands of putative class members received direct misrepresentations. More specifically, MMO argues that defendants' "internal memoranda, emails, tracking spreadsheets, and other documents identify exactly which TPPs each Defendant communicated with, and when." Pl.'s Reply at 3. MMO cites two sets of spreadsheets in support of this argument.[8] One spreadsheet, which Lilly produced, appears to list five calls that Lilly made to MMO (two of which are characterized as "planned" calls) and three calls that Lilly made to Medco. Pl.'s Reply, Ex. 121. The spreadsheet contains notes about the planned or completed calls, two of which discuss oncology drugs and

[8] MMO also cites the 280-page Wilkinson Declaration with no page number. The Court assumes MMO is referring to Mr. Wilkinson's opinion, based on Exhibits D and E to his declaration, that defendants' contacts with all TPPs were uniform. The Court has excluded this opinion.

the remainder of which do not discuss any identifiable drug or disease state. *Id.* The other spreadsheet, which Auxilium produced, appears to list health plans to which Auxilium sales representatives are assigned. Pl.'s Reply, Ex. 122. MMO does not cite anything specific in the seventy-seven-page spreadsheet, and in the Court's own review, it has not located any references to defendants' TRTs. Rather, the notes in the spreadsheet discuss TPPs' policies regarding coverage of Testopel, a subcutaneous testosterone pellet that is no longer at issue in this case. And even those notes give no indication that Auxilium provided TPPs with standardized information. The Court is not persuaded that any TPP could use these spreadsheets to prove it received direct misrepresentations from defendants.

Unlike these spreadsheets, Exhibit E to Mr. Wilkinson's report could likely serve as common proof that certain putative class members or their contracted PBMs received uniform misrepresentations regarding TRTs' safety and efficacy. As previously discussed, however, Exhibit E can serve as common proof only for a small fraction (approximately 1.6 percent) of the putative class. Defendants have similarly characterized the iREP data, *see* Defs.' Opp. at 7 (arguing the data shows that in the timeframe represented, AbbVie "employees interacted with only 163 customers concerning AndroGel for any purpose"), and MMO has not disputed that characterization. Nor has MMO argued how or whether the iREP data in Exhibit E can be extrapolated to 10,000 TPPs.

MMO also contends that common proof should not be restricted to defendants' records and suggests that putative class members can provide "sworn statements" to show they received direct misrepresentations. Pl.'s Reply at 3. But sworn statements

from class members regarding what they were told amounts to individualized, not common evidence. Similarly, MMO argues that putative class members could "point to statements made to their PBMs." Pl.'s Reply at 3. Even assuming TPPs can satisfy RICO's but-for and proximate causation requirements using evidence of misrepresentations to PBMs, MMO's argument only increases the workload of the putative class: individualized evidence would be needed to show whether and how a TPP relied on a PBM, and individualized evidence would likewise be needed to show whether that PBM received misrepresentations. Indeed, MMO cites the Lilly and Auxilium spreadsheets discussed above to argue that common evidence can show defendants made "uniform statements (or omissions) to all PBMs." Pl.'s Reply at 12. MMO also cites an exhibit that shows AbbVie provided "Pinnacle" promotional materials to several PBMs (Pl.'s Reply, Ex. 188) and another that shows one PBM agreed to review an AndroGel dossier (Pl.'s Reply, Ex. 189). Haphazard evidence relevant only to certain PBMs, however, cannot serve as class-wide proof.

MMO next argues that even if each TPP's receipt of direct misrepresentations cannot be shown through common proof, receipt can be inferred based on evidence that defendants spent millions of dollars on promotional efforts aimed at TPPs. According to MMO, these efforts included "disseminat[ion] [of] standardized promotional materials." Pl.'s Reply at 4 (citing *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 595 (9th Cir. 2012)). But in *Mazza*, the court found it was "*unreasonable* to assume that all class members" viewed the allegedly misleading advertisements and indicated that a presumption of exposure is appropriate only where a defendant's "extensive" and standardized advertising leaves "little doubt" that all class members were exposed. 666

F.3d 595-96.

Here, there is ample doubt. MMO points the Court to certain materials it argues are "standardized," such as AbbVie's "Value Proposition" slide decks for AndroGel. Pl.'s Mot. at 10-11. AbbVie's account manager for MMO, however, testified that because "[e]very payer is different," he does not always present the slide decks, or presents only portions of them, when meeting with TPPs. Defs.' Opp., Ex. 4 (Hollinden Dep) at 272:18-274:4. MMO also relies on its expert, Mr. Wilkinson, for the proposition that "drug makers use various common strategies to influence" TPPs' formulary decisions. Wilkinson Decl. ¶ 85. But as discussed above, the Court has excluded this opinion.

MMO also contends that defendants deliberately omitted safety and efficacy information from their promotional materials and product labels and asks the Court to infer that all putative class members were exposed to the alleged omissions. This argument fails as well. Although a "half-truth" or a "misleading omission" can be actionable as mail and wire fraud even in the absence of a statutory or other duty to disclose, *see, e.g.*, *Emery v. Am. Gen. Fin., Inc.*, 71 F.3d 1343, 1348 (7th Cir. 1995); *United States v. Weimart*, 819 F.3d 351, 355 (7th Cir. 2016), one would need to know what particular representations a TPP received in order to assess whether that TPP was exposed to half-truths. This inquiry would require TPP-by-TPP proof. MMO's citations to promotional materials that allegedly contain omissions do not change this conclusion.

MMO also presses its "standardized" omission theory by arguing that defendants "admit" that TPPs and PBMs consider drug labels in making formulary decisions. *Id.* at

8. MMO supports this contention, however, only by pointing the Court to defendants' interrogatory responses—which contain no such admissions. In addition, MMO cites to *Krueger v. Wyeth, Inc.*, 310 F.R.D. 468, 477 (S.D. Cal. 2015), for the proposition that "omissions in [a] drug label present[] [a] common question." Pl.'s Reply at 8 n.24. As discussed below, the Court acknowledges that whether a particular drug label omits information is indeed a common question. But whether a particular class member received the label is a different issue altogether. Finally, MMO argues that *In re Synthroid Marketing Litigation*, 188 F.R.D. 287, 292 (N.D. Ill. 1999), supports its theory. There, the court certified a TPP RICO class that "allege[d] a pattern of standardized conduct by the defendants, consisting mainly of a fraudulent scheme to conceal scientific information" about various drugs. *Id.* These allegations, the court found, "involve 'a common course of conduct that leads to injury of all the class members'" and indicate that common issues will predominate. *Id.* (citation omitted). In *Szabo*, 249 F.3d at 675, however, the Seventh Circuit criticized the district court's reliance on *Synthroid* to the extent it accepted "the substantive allegations in the complaint . . . as true for purposes of the class motion" and thus failed to "resolv[e] factual and legal disputes that strongly influence the wisdom of class treatment."

Finally, the Court notes that MMO's omission theory would likely fail as a matter of law for the Ohio subclass. Ohio appellate courts have held that a negligent misrepresentation claim requires an affirmative statement and thus cannot be based on an omission, regardless of whether a defendant owes a duty to disclose. *See, e.g.*, *Bundy v. Harrison*, 2002-Ohio-1806, 2002 WL 506423, at *5 (Ohio Ct. App. Apr. 5, 2002); *Textron Fin. Corp. v. Nationwide Mut. Ins. Co.*, 684 N.E.2d 1261, 1269 (Ohio Ct.

App. 1996); *see also Toledo Edison Co. v. ABC Supply Co.*, 46 F. App'x 757, 762 (6th Cir. 2002). MMO argues otherwise but does not cite any cases that support its position.

In sum, the Court agrees with defendants that MMO will not be able to use "the same evidence . . . for each" of the thousands of putative class members to demonstrate that each received direct misrepresentations (including omissions) from defendants. *Messner*, 669 F.3d at 815 (quoting *Blades*, 400 F.3d at 566). And the Court rejects MMO's suggestion that the Court incorporate "a TPP exposure criterion" "into the class definition." Pl.'s Reply at 4 n.10. MMO proposes this idea in a footnote in its reply, and "perfunctory and underdeveloped arguments . . . are waived." *White Eagle Coop Ass'n v. Conner*, 553 F.3d 467, 476 n.6 (7th Cir. 2009). Furthermore, to determine whether any exposure requirement is met would require TPP-specific evidence for all of the reasons just discussed.

ii. Reliance

Just as MMO must prove that each of the thousands of putative class members received misrepresentations directly, MMO must also prove that each relied on the misrepresentations. *See, e.g.*, *Sidney Hillman*, 873 F.3d at 578; *see also Abboud v. Liberty Mut. Ins. Grp., Inc.*, 711 F. App'x 773, 777 (6th Cir. 2017) (in assessing "justifiable reliance" for purposes of Ohio negligent misrepresentation, courts "must consider the nature of the transaction, the form and materiality of the representation, the relationship of the parties and their respective means and knowledge, as well as other circumstances") (quoting *Johnson v. Church of the Open Door*, 902 N.E.2d 1002, 1007 (Ohio Ct. App. 2008)).

Defendants point to evidence tending to show that TPPs' formulary and utilization

management decisions are complex and individualized. Some TPPs do not meet with drug manufacturers at all and are thus unlikely to rely on information from them. Some TPPs use PBMs but customize the PBMs' standardized formularies. Other TPPs, including MMO for much of the class period, adopt their PBMs' formularies without modification but make their own utilization management decisions. In addition, Dr. Canaday testified that she has never relied exclusively on information from drug manufacturers in making utilization management decisions; she does not know of anyone at MMO who has done so; ESI has not done so; and based on her experience, she does not believe that other TPPs have done so. Canaday Dep. at 233:1-234:4. Dr. Marko Blagojevic, MMO's Manager of Clinical Pharmacy Programs, similarly testified during his deposition that MMO "use[s] a lot of sources to make decisions." Defs. Opp., Ex. 8 at 172:16. According to Dr. Blagojevic, although MMO's sources include information from drug representatives, they also include peer-reviewed journals, professional guidelines, and advice from experts, physicians, and PBMs. *Id.* Finally, according to Dr. Canaday, TPPs (or the PBMs on which they rely) consider drug costs and rebate opportunities in determining drugs' "tier" placement within formularies, which in turn affects the drugs' affordability for and availability to plan members. Canaday Dep. at 35:19-37:12; *see also* Defs.' Opp., Ex. 22 (e-mail from Lilly sales representative discussing Axiron's tier "upgrade" on MMO's formulary and attributing the upgrade to the fact that MMO's "#1 objective for 2013 [was] rebate aggregation").

Dr. Giaquinta corroborates this information on an industry-wide scale. She opines that TPPs and PBMs do not always consider information drug manufacturers provide and that even if they do, they would not "rely solely or even principally on" such

information "in establishing a drug's place on a formulary." Giaquinta Decl. ¶¶ 71-72. She also opines that TPPs' and PBMs' review processes, including the weight they assign to the sources of information they consider, can vary based on the reviewers' professional backgrounds and the resources the TPPs or PBMs can dedicate to the review process. And she opines that rebate availability can influence formulary and utilization management decisions. Even MMO's expert, Mr. Wilkinson, testified during his deposition that context is essential to determine "whether a [TPP] would have changed its treatment of a particular drug in response to a particular piece of information." Wilkinson Dep. at 308:3-11.

In response, MMO argues that in RICO actions, first-party reliance "may be inferred on a class-wide basis when no other plausible explanations exist for why a party would pay for a product"—and that here, "[n]o evidence suggests a single TPP knew that Defendants' TRT drugs" were ineffective for treating "age-related Low T." Pl.'s Reply at 11.[9] Defendants, however, have presented evidence giving rise to an argument that some TPPs, including MMO, were on notice in the early 2000s of concerns regarding TRT drugs' safety and efficacy for treating age-related hypogonadism. *See, e.g.*, Giaquinta Decl. ¶¶ 5(c), 197-206 (describing documents regarding TRT safety and efficacy concerns that five TPPs and/or PBMs produced in third-party discovery); *id.* ¶¶ 172-86 (describing documents from MMO's files regarding TRT safety and efficacy concerns). In addition, as previously discussed, rebate opportunities could be a "plausible" explanation, or at least partial explanation, for

[9] MMO does not make this argument for purposes of its negligent misrepresentation claims.

formulary decisions. MMO's suggestion that TPPs consider "misleading drug labels" and defendant-influenced clinical information in "making formulary decisions" does not dampen the significance of this evidence. Pl.'s Reply at 11. And its authority for the proposition that reliance may be presumed in a RICO action is unpersuasive. For example, in *Torres v. S.G.E. Management LLC*, 838 F.3d 629 (5th Cir. 2016), the alleged fraud was an inherently deceptive pyramid scheme that presented a "losing proposition . . . to the vast majority of participants," and, unlike in the present case, there was no "evidence indicating that *any* putative class member knew of the fraud." *Id.* at 646; *see also Peterson v. H&R Block Tax Servs., Inc.*, 174 F.R.D. 78, 81, 85 (N.D. Ill. 1997) (reliance on defendant's standardized "fact sheet" was "apparent" because it was "inconceivable that the class members would rationally choose to pay for a fee service they knew was unavailable").

MMO next argues it can use common evidence to show that PBMs (rather than TPPs) relied on defendants' misrepresentations and omissions and that TPPs in turn relied on PBMs' formulary decisions. The Court previously rejected this proposal in discussing the issue of exposure to defendants' materials, finding that it only increases the likely need for individualized inquiries. The same is true here.

For all of these reasons, the Court is persuaded that even assuming all TPPs received the same alleged misrepresentations, the question whether all TPPs based their formulary or utilization management decisions on the misrepresentations cannot be answered with common evidence. Several courts have reached similar conclusions. *See, e.g.*, *In re Actiq Sales & Mktg. Prac. Litig.*, 307 F.R.D. 150, 171 (E.D. Pa. 2015) (crediting defendant's expert opinion that "TPPs treated claims for Actiq reimbursement

differently throughout the proposed class period" and concluding that the question "whether TPPs' payments for Actiq prescriptions resulted in [defendant's] unjust enrichment" could not be resolved with common proof); *Sergeants Benevolent Assoc. Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, No. 08-cv-0179 (SLT) (RER), 2011 WL 824607, at *16 n.27 (E.D.N.Y. Feb. 16, 2011) (stating in dicta that if "called upon" to determine whether TPP formulary placement "can be proved using common evidence," the court would recommend that it cannot because "each TPP . . . determine[s] drug placement in formularies differently"); *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 192 N.J. 372, 390-91, 929 A.2d 1076, 1087 (2007) (evidence that putative TPP class members were "a diverse group of entities" in that they "separately created formularies," had "different types of tier systems," and had "individualized requirements for approval or reimbursement," suggested that "the common fact questions surrounding" defendant's actions "would not predominate").

iii. Common issues

Against this backdrop of individualized questions are several common ones, including whether (1) defendants' promotional materials were false and misleading; (2) defendants' alleged misrepresentations were material (for RICO purposes); (3) defendants knowingly or negligently made the alleged misrepresentations; and (4) defendants "agree[d] to participate in an endeavor which, if completed, would constitute a violation of the substantive [RICO] statute." *Goren v. New Vision Int'l, Inc.*, 156 F.3d 721, 732 (7th Cir. 1998). These questions are central to each of MMO's claims. Contrary to defendants' protestations, each can be answered with defendant-specific—rather than TPP-specific—proof. *See Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338,

350 (2011) (a common question is one that "is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke").

For example, the proposed class members could use the "same evidence" to "make a prima facie showing" on the question whether defendants' promotional materials are false and misleading. *Messner*, 669 F.3d at 815. Such evidence could include a sampling of defendants' drug dossiers, slide decks prepared for sales and informational meetings with TPPs, and FDA communications with defendants.

Defendants' *scienter*, too, is a common question. Although defendants argue that "each TPP will have to prove what each [d]efendant 'knew or should have known' at the *specific time(s)* within the 14-year class period when *it* received any relevant statement(s)," Defs.' Opp. at 25, the requisite proof will nevertheless come from defendants, not from TPPs. Defendants similarly assess materiality from the wrong perspective. Though TPPs likely vary widely in making formulary decisions, materiality for RICO purposes need not be assessed on a TPP-by-TPP basis, because the inquiry is an objective one. *See, e.g.*, *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39, 44 (2011) (materiality assessed from viewpoint of "*reasonable* investor"); *Neder v. United States*, 527 U.S. 1, 16 (1999) ("[A] false statement is material if it has 'a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed.'" (quoting *United States v. Gaudin*, 515 U.S. 506, 509 (1995))); *United States v. Betts-Gaston*, 860 F.3d 525, 532 (7th Cir. 2017) ("A false statement is material if it *objectively* had a tendency to influence, or was capable of influencing, a lender to approve a loan." (quoting *United States v. Lindsey*, 850 F.3d

1009, 1015 (9th Cir. 2017)).[10]

Finally, although "MMO alleges six different conspiracies, each with different objects, involving different groupings of Defendants, employing different tactics, and operating at different times," Defs.' Opp. at 34, and although MMO cannot prevail on a RICO conspiracy claim without proving that it "suffered an injury caused by an overt act that violates the RICO statute," *see MMO II*, 2016 WL 4091620, at *5, the question whether each defendant agreed to participate in the endeavor that could give rise to conspiracy liability is defendant-specific.

After considering these common questions in relation to the individual questions, the Court concludes that they do not tip the balance in favor of MMO. Indeed, even assuming that "the same evidence [could] suffice for each [class] member to make a prima facie showing" that defendants violated 18 U.S.C. § 1962(c) and (d), *Messner*, 669 F.3d at 815 (quoting *Blades*, 400 F.3d at 566), and even assuming common evidence would suffice to prove that defendants negligently supplied false information in violation of Ohio law, MMO cannot recover on those claims unless it *also* shows that defendants' alleged misconduct was both the but-for and proximate cause of all putative class members' injuries. As previously discussed, this evidence—on which MMO's case depends—will necessarily "var[y] from member to member" in a class that could include 10,000 or more TPPs. *Id*. Individualized issues are not just present in this

[10] By contrast, materiality for purposes of Ohio negligent misrepresentation appears to be a subjective question and thus would add to the pile of individualized inquiries in this case. *See Andersons, Inc. v. Consol, Inc.*, 185 F. Supp. 2d 833, 845 (N.D. Ohio 2001) (for representations to be material, they "must have operated as an inducement to the making of the contract in question, that is, must have influenced the mind of the party to whom they are made in making the contract or fixing its terms" (quoting *Mulvey v. King*, 39 Ohio St. 491, 495 (1883))).

case, but rather loom large. *See, e.g.*, *Sergeants Benevolent Assoc. Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 87 (2d Cir. 2015) (affirming denial of class certification for failure to meet predominance requirement because, although parties did not dispute that defendant "'use[d] the mail' in connection with its alleged fraud," plaintiffs "could not establish using generalized proof that each putative class member suffered an injury 'by reason of' [defendant's] alleged fraud"). The Court thus concludes that "classwide resolution" would not "substantially advance the case." *Costello*, 810 F.3d at 1059.[11]

In sum, MMO has failed to show by the preponderance of the evidence that it meets the predominance requirement under Rule 23(b)(3). The Court denies MMO's motion for class certification on this basis and thus need not address whether a class action is superior to other available methods for adjudicating the controversy fairly and efficiently. Fed. R. Civ. P. 23(b)(3).

[11] The Court's conclusion does not change even assuming that common proof could answer the question whether TPPs' reimbursement payments for TRTs can be considered injuries. *See, e.g.*, Pl.'s Mot. at 30, Defs.' Opp. at 22-24. Among other reasons, the fact that a TPP may have suffered such an injury does not detract from MMO's need for proof of what caused the injury. The conclusion that individualized issues predominate likewise does not change even if one assumes that the statute of limitations defense is a common issue. *See, e.g.*, Defs.' Opp. at 25-28; Pl.'s Reply at 14. A fact-finder might, for example, be able to decide whether the putative class members' claims are time-barred using common proof such as clinical studies and the FDA's January 2014 DSC. But again, to determine whether MMO can ultimately prevail on its claims, a fact-finder would also have to wade through proof on causation that will vary among thousands of putative class members. For MMO's Ohio negligent misrepresentation claims, a fact-finder will likely have to wade through individualized proof of materiality as well. The Court has "evaluate[d] the evidence pragmatically" and has concluded that these tasks would overwhelm the inquiries that can be resolved with common evidence. *Costello*, 810 F.3d at 1059.

Conclusion

For the foregoing reasons, the Court denies MMO's motion to exclude Dr. Giaquinta's testimony [dkt. no. 375]; grants in part and denies in part defendants' motion to exclude Mr. Wilkinson's testimony [dkt. no. 348]; terminates as moot defendants' motion to exclude Dr. Rosenthal's testimony [dkt. no. 348]; terminates as moot MMO's motion to exclude Dr. Gaier's testimony [dkt. no. 375]; and terminates as moot defendants' motion to exclude Dr. Harris's testimony [dkt. no. 348]. Finally, the Court denies MMO's motion for class certification [dkt. no. 268].

MATTHEW F. KENNELLY
United States District Judge

Date: July 26, 2018