United States District Court
District of Massachusetts

In re:	)	
	)	**MDL No.**
CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION	)	**09-02067-NMG**
PAINTERS AND ALLIED TRADES DISTRICT COUNCIL 82 HEALTH CARE FUND,	)	
Plaintiff,	)	
	)	**Civil Action No.**
v.	)	**13-13113-NMG**
FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This case arises out of the marketing and sales of the related anti-depressant drugs Celexa and Lexapro by defendants Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. ("defendants" or, collectively, "Forest"). Plaintiff Painters and Allied Trades District Council 82 Health Care Fund ("plaintiff" or "Painters") is a health and benefit fund providing benefits to covered members and their families. It acts as a third-party payor ("TPP") that reimburses the medical expenses of plan members.

Painters alleges that defendants violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), Minnesota Consumer Fraud Act ("MCFA"), Minnesota Unfair Trade Practices Act ("MUTP") and Minnesota Deceptive Trade Practices Act by misrepresenting and concealing material information about the efficacy of Celexa and Lexapro in treating major depressive disorder ("MDD") in pediatric patients.

Pending before the Court is Painters' motion to certify certain classes (Docket No. 546). For the reasons that follow, that motion will be denied.

I. Background

Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRI") anti-depressants. Forest obtained the approval of the Food and Drug Administration ("FDA") to market Celexa for adult use in 1998 and Lexapro for adult use in 2002. It later sought to market both drugs for treating MDD in children and adolescents.

A. FDA approval process

In order to obtain FDA approval to market Celexa and Lexapro as effective for pediatric use, Forest had to make a sufficient showing to the FDA that the drugs would be more effective than placebos in treating MDD in pediatric patients. The FDA typically requires the submission of at least two

"positive" placebo-controlled clinical trials supporting such use. A "positive" drug study shows statistically significant improvements for patients who are administered the drug rather than a placebo. A "negative" study is one that indicates no statistically significant difference in outcomes between patients who receive the drug and those who receive a placebo.

Drug manufacturers submit the results of such trials to the FDA as part of their "new drug applications" ("NDAs"). The manufacturer may also request FDA approval of use of the drug to treat a specific condition which is known as an "indication". A manufacturer may only market and sell the drug for approved indications.

B. Clinical studies and FDA approval

Forest conducted four double-blind, placebo-controlled studies on the efficacy of Celexa and Lexapro in treating pediatric depression. The first two studies examined the efficacy of Celexa and were completed in 2001. The Celexa Study 18 ("MD-18") produced positive results whereas Celexa Study 94404 ("Lundbeck Study") produced negative results. Forest submitted the results of the two Celexa studies to the FDA in a supplemental NDA in 2002. The FDA denied Forest's application for a pediatric indication for Celexa after finding that the Lundbeck Study was a clearly negative study.

The other two studies addressed the efficacy of Lexapro. Lexapro Study 15 produced negative results but Lexapro Study 32 arguably produced positive results.

The FDA-approved labels for both drugs prior to 2005 stated that "[s]afety and effectiveness in pediatric patients have not been established." In February, 2005, Forest revised Celexa's label to include a description of MD-18 and the Lundbeck Study and Lexapro's label to describe Lexapro's negative study.

In 2008, Forest submitted the results of the studies to the FDA in a supplemental NDA. In March, 2009, the FDA reviewed the positive results in MD-18 and Lexapro Study 32, noted the chemical similarities between Celexa and Lexapro and approved Lexapro as safe and effective in treating MDD in adolescents. Forest did not seek similar FDA approval for Celexa.

C. Procedural history

Plaintiff Painters initiated this action on behalf of two putative nationwide TPP classes in November, 2013. It filed a first amended complaint in February, 2014, asserting violations of RICO (Counts I and II) and three Minnesota consumer protection statutes (Counts III, IV and V) on behalf of the two nationwide classes of TPPs and two Minnesota classes of TPPs and consumers. This Court dismissed Count V in December, 2014.

Painters moved for class certification in February, 2016 and the Court heard oral argument in May, 2016.

II. Motion to certify class

Painters requests the certification of two nationwide classes:

1) the Celexa Class: All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit providers, in the United States of America and its territories, which paid or incurred costs for the purchase or reimbursement of the drug Celexa prescribed for use by an individual under 18 years of age, for purposes other than resale. Excluded from the Class are employees of Forest, including its officers and directors; the judge to which this case is assigned and his immediate family members; personnel of the Court to which this case is assigned; governmental entities and/or governmental healthcare payors; all claims reimbursed to health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit providers included in the settlement class certified in In re Celexa & Lexapro Mktg. & Sales Practices Litig., No. MDL 09-2067-NMG, 2014 WL 4446464 (D. Mass. Sept. 8, 2014), except for any opt outs of these entities; and, pharmacy benefit managers; and

2) the Lexapro Class: All health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit providers, in the United States of America and its territories, which paid or incurred costs for the purchase or reimbursement of the drug Lexapro prescribed for use by an individual under 18 years of age, for purposes other than resale, on or before March 19, 2009. Excluded from the Class are employees of Forest, including its officers and directors; the judge to which this case is assigned and his immediate family members; personnel of the Court to which this case is assigned;

> governmental entities and/or governmental healthcare payors; all claims reimbursed to health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third-party payors and any other health benefit providers included in the settlement class certified in In re Celexa & Lexapro Mktg. & Sales Practices Litig., No. MDL 09-2067-NMG, 2014 WL 4446464 (D. Mass. Sept. 8, 2014), except for any opt outs of these entities; and, pharmacy benefit managers.

Painters also requests certification of two Minnesota subclasses: 3) the Minnesota Celexa Class which includes entities who paid or incurred costs for the purchase or reimbursement of Celexa prescribed for persons under the age of 18 for purposes other than resale in Minnesota; and 4) the Minnesota Lexapro Class which includes entities who paid or incurred costs for the purchase or reimbursement of Celexa prescribed for persons under the age of 18 for purposes other than resale, on or before March 19, 2009, in Minnesota.

A. Class certification

Under Fed. R. Civ. P. 23, a court may certify a proposed class only if it satisfies all of the requirements in Rule 23(a) and one of the requirements in Rule 23(b). See Smilow v. Sw. Bell Mobile Sys., Inc., 323 F.3d 32, 38 (1st Cir. 2003). Here, Painters requests the certification of a class pursuant to Rule 23(b)(3).

Although a court must conduct a "rigorous analysis" before certifying a class, id., it should inquire into the merits of

the action only "to the extent that the merits overlap the Rule 23 criteria," In re Boston Sci. Corp. Sec. Litig., 604 F. Supp. 2d 275, 281 (D. Mass. 2009)(quoting In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 24 (1st Cir. 2008)). If there are disputed factual or legal premises, however, the court may "probe behind the pleadings to formulate some prediction as to how specific issues will play out". In re New Motor Vehicles, 522 F.3d at 20(citations omitted).

Rule 23(a) contains requirements of numerosity, commonality, typicality and adequacy:

> (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). Rule 23(b)(3) requires that 1) common questions of law or fact "predominate" over those affecting individual class members and 2) a class action be the "superior" method for fair and efficient adjudication. Fed. R. Civ. P. 23(b)(3).

B. Rule 23(a) Requirements

1. Numerosity

With respect to numerosity, it is undisputed that the proposed classes would include "hundreds of [TPPs] nationwide and many within the State of Minnesota". Those TPPs are sufficiently numerous that joinder of all members would be impractical. See In re Relafen Antitrust Litig., 218 F.R.D. 337, 342 (D. Mass. 2003)(holding that forty class members are generally sufficient to establish numerosity).

2. Commonality

In assessing commonality, the court should inquire into "the capacity of a classwide proceeding to generate common answers apt to drive the resolution of the litigation." Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 350 (2011). The plaintiff must show that there is a common contention capable of class-wide resolution such 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.

Id. There is sufficient commonality if the

> questions that go to the heart of the elements of the cause of action . . . will each be answered either "yes" or "no" for the entire class [and] the answers will not vary by individual class member.

Donovan v. Philip Morris USA, Inc., 2012 WL 957633, at *21 (D. Mass. Mar. 21, 2012).

Painters alleges that "Forest engaged in a common course of fraudulent conduct directed toward the entire class" by fraudulently promoting off-label, pediatric prescriptions of Celexa and Lexapro paid for by TPPs. Painters satisfies the commonality requirement.

3. Typicality

Under the typicality requirement, the injuries of the named plaintiff must arise from the same events or course of conduct and be based upon the same legal theory as the injuries and claims of the class. Swack v. Credit Suisse First Boston, 230 F.R.D. 250, 260 (D. Mass. 2005). The named plaintiff is not typical of the class if it may be "subject to unique defenses that would divert attention from the common claims". Id.

Painters asserts that both its claims and the class claims arise from defendants' misconduct in "deliberately provid[ing] misleading information to the class". It contends that it, like the other TPPs, "fell victim to Forest's off-label promotion scheme, and lost money as a result," see Duhaime v. John Hancock Mut. Life Ins. Co., 177 F.R.D. 54, 63 (D. Mass. 1997)("Because the named plaintiffs were subjected to the same deceptive sales techniques allegedly used by [the defendant] against other class members, their claims are typical of the class claims.").

Forest responds that Painters is atypical because 1) its claims are time-barred, 2) Forest did not cause it injury and

3) it has no viable claim and thus no standing to sue as the class representative. Forest submits that Painters did not suffer an attributable injury because Painters did not rely on, and was not exposed to, any of its representations. It suggests that Prime, Painters' pharmacy benefit manager ("PBM"), was "aware" of the negative efficacy studies and yet continued to reimburse the drugs and that such awareness is imputable to Painters. Forest also faults Painters for allegedly taking no steps to investigate the efficacy of the drugs even though it conceded at one point that it had "no idea whether these drugs work on kids or not."

Forest's arguments are unavailing. Although its statute of limitations defense involves evidence and determinations specific to Painters, that defense is not "unique" because Forest intends to launch the same kind of defense against all of the TPPs in the proposed classes. There is no danger that "absent class members will suffer if [Painters] is preoccupied with defenses unique to it." See Swack, 230 F.R.D. at 260 (quoting Gary Plastic Packaging Corp. v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 903 F.2d 176, 180 (2d Cir. 1990)).

With respect to Forest's assertions that Painters has no viable claim because Forest did not cause it injury, the Court declines, at the class certification stage, to make that determination on the merits and instead notes that Painters'

claims and injuries stem from the same factual events and legal theories that give rise to the asserted claims and injuries of the class. That is sufficient for Painters to satisfy the typicality requirement.

4. Adequacy

Adequacy requires a showing that the class representative will "fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The named plaintiff must show that 1) its interests align with those of the class and 2) its counsel is qualified, experienced and able to litigate the claims vigorously. See Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985).

Painters declares that its interests align with those of the class because it, like each class member, has a strong interest in establishing that Forest fraudulently promoted off-label use and caused it damages. It submits that its counsel is "well-versed" in litigating complex pharmaceutical cases and class actions and has represented clients in "thousands of cases relating to the use of SSRIs."

Forest reiterates that Painters has no standing and no viable claim as a result of the statute of limitations and Painters' lack of injury. Those arguments are unpersuasive for the reasons set forth above. Forest also contends that the exclusion of PBMs from the proposed classes creates a conflict

of interest between Painters, which is a TPP, and PBMs. That argument is misplaced because the adequacy requirement is concerned with whether the named plaintiff has a conflict with other class members, not individuals or entities outside of the proposed classes.

Forest cites In re Sepracor Inc., 233 F.R.D. 52, 55 (D. Mass. 2005), in support of its argument that Painters is inadequate to serve as class representative due to its minimal participation and knowledge in this action which it characterizes as "attorney-driven". Painters denies that allegation and asserts that the deposition testimony of its entity representative, Terry Nelson, shows that he 1) had a layman's understanding of the litigation and 2) reasonably relied upon fund counsel to coordinate with class counsel and to manage the responsibilities of the fund as class representative.

The Court is satisfied that Painters plays more than a "superfluous" or token role in this action. Painters is unlike the class representative in In re Sepracor who delegated case decisions and obligations to his grandson and exhibited a "serious lack of familiarity" with the basic facts of the action and a lack of interest in pursuing the suit. See id. at 55 (finding the class representative inadequate after concluding that he 1) did not know the name of the defendants, the drug at issue, the medical condition treated by the drug, the membership

of the class or the nature of his own investment in the action and 2) "len[t] his name to this suit only upon the condition that it would take a minimal amount of time"). Painters is also unlike the class representative in Abla v. Brinker Restaurant Corp., 279 F.R.D. 51 (D. Mass. 2011), who had partially settled his claims with the defendants and thus had less incentive to pursue the class action than class members who had not reached partial settlement. 279 F.R.D. at 56.

Accordingly, Painters and its counsel can adequately represent the interests of the proposed classes.

C. Rule 23(b)(3) requirements

1. Predominance

The crux of the dispute between the parties is whether Painters satisfies the predominance requirement that

> questions of law or fact common to class members predominate over any questions affecting only individual members.

Fed. R. Civ. P. 23(b)(3). The purpose of the requirement is to assess whether the proposed class is "sufficiently cohesive" to warrant class adjudication. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 623 (1997).

The predominance requirement is "far more demanding" than the commonality requirement set forth in Rule 23(a), id. at 623-24, but it does not require the plaintiff to show that each element of its claims is susceptible to class-wide proof. In re

Nexium Antitrust Litig., 777 F.3d 9, 21 (1st Cir. 2015). The plaintiff need only prove that individualized questions will not "overwhelm" the common ones so as to render class certification inappropriate. Id. Thus, the "need for some individualized determinations at the liability and damages stage" will not defeat class certification. Id.

A plaintiff with a RICO claim must establish 1) conduct 2) of an enterprise 3) through a pattern 4) of racketeering activity such as violations of the mail and wire fraud statutes located at 18 U.S.C. §§ 1341 and 1343. Giuliano v. Fulton, 399 F.3d 381, 386 (1st Cir. 2005). The parties do not dispute that, in this action, the four elements are susceptible to common proof because they "involve Forest-specific conduct".

Instead, the parties contest whether 1) Painters can establish causation, injury and damages through common proof and 2) Forest's statute of limitations defenses will require individualized determinations that overwhelm the common ones.

The first set of disputes arise from the civil damages provision of the RICO statute which allows "[a]ny person injured in his business or property by reason of a [RICO violation]" to recover damages. 18 U.S.C. § 1964(c). The term "by reason of" refers to both but-for causation and proximate causation. In re Neurontin Mktg. and Sales Practices Litig., 712 F.3d 21, 34 (1st

Cir. 2013)("Neurontin I")(citing Holmes v. Sec. Investor Protection Corp., 503 U.S. 258, 268 (1992)).

a. Proximate causation

For RICO claims, proximate causation depends upon the "directness" of the causal chain and the application of three functional factors. Neurontin I, 712 F.3d at 36. Directness refers to both the foreseeability of the injury and the directness of the causal relationship between the plaintiff's injury and the defendant's misconduct. Id. at 35. The causal link between the injury and misconduct cannot be too remote or so attenuated that recovery is unwarranted. Id. at 34, 35.

The second part of the assessment involves three functional factors which implicate 1) concerns about proof, given that the less direct an injury, the more difficult it is to calculate the attributable damages, 2) concerns about administrability and avoidance of multiple recoveries and 3) the societal interest in deterring unlawful conduct and the issue of whether directly injured victims would be likely "to vindicate the law as private attorneys general". Id. at 35-36.

Here, as discussed below in the injury section, Painters asserts that it and other TPPs suffered injuries in the form of economic costs incurred when they paid for additional prescriptions for Celexa and Lexapro for pediatric use.

Painters intends to use common proof that Forest targeted physicians during its unlawful promotion with the knowledge and intent that TPPs, such as Painters and the class members, would pay for the majority of the induced prescriptions. In support, Painters submits a declaration by Dr. Peter Penna asserting that Forest "specifically marketed to health care plans to promote [the] preferential status" of Celexa and Lexapro on their official lists of prescriptions. It suggests that it and other TPPs were the intended victims of the fraudulent scheme and their injuries were the foreseeable and natural consequences of that scheme. Painters plans to use that class-wide evidence to show the directness of the causal chain between the TPPs' injuries and Forest's misconduct.

Forest responds that Painters cannot use class-wide evidence to show that TPPs relied upon, or were even exposed to, its purportedly fraudulent statements because the issue of reliance requires a predominantly individualized determination.

That argument, however, overlooks the decision of Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639 (2008), which held that first-party reliance is not an element of proximate cause for RICO claims predicated on mail fraud. Id. at 641-42. As a result, Painters need not offer member-specific proof that it and each TPP relied upon Forest's fraudulent statements. See Neurontin I, 712 F.3d at 36 (finding that the Bridge decision

precluded the defendant from arguing that the plaintiff could not show direct reliance because the defendant made his fraudulent statements only to physicians). Forest does not argue against the application of the Bridge decision to this case or submit that the wire fraud portion of the RICO claim should receive different treatment. The Court will not require Painters to present individualized proof of first-party reliance.

Forest next submits that it will present individualized evidence of certain physicians who prescribed drugs based upon patient-specific considerations, not upon Forest's statements. It argues that those physicians are intervening causes that sever the causal chain between the TPPs' asserted economic injuries and Forest's promotional statements such that Painters cannot prove proximate causation.

Forest's physician-specific evidence will not, however, trigger individualized inquiries that overwhelm the class-wide inquiries. That is because Painters has class-wide evidence that Forest fraudulently promoted its drugs with the intent to cause physicians to write more prescriptions that would be paid for by TPPs. Painters could use that common evidence to show that Forest expected and intended physicians to rely on its fraudulent statements and, therefore, the physicians were not intervening causes that severed the proximate causal chain. See

Neurontin I, 712 F.3d at 39. The causal relationship would not be severed by evidence that some physicians considered factors other than the fraudulent statements in prescribing drugs either, because that evidence concerns the number of prescriptions attributable to Forest's misconduct, i.e., damages, rather than proximate causation. Id.

Painters' evidence suggests that 1) TPPs like Painters were the foreseeable, intended and primary victims of Forest's RICO scheme, 2) TPPs suffered economic injuries as a result of that scheme because they paid for the majority of the resulting prescriptions, 3) they suffered direct injuries and are best-positioned to enforce the law and 4) allowing the case to continue as a class action will help deter unlawful conduct. Forest does not specifically allege that it will raise member-specific challenges to Painters' presentation of evidence.

The Court finds that Painters can use that evidence as class-wide proof to establish directness and a favorable balance of the three factors, just as the plaintiffs did in the three Neurontin cases that Painters cites extensively in its memoranda. See Neurontin I, 712 F.3d at 38 (concluding, on analogous facts, that plaintiff Kaiser, a TPP which paid for Neurontin prescriptions, satisfied the directness and factor-based tests for proximate causation); In re Neurontin Mktg. & Sales Practices Litig., 712 F.3d 51, 58 (1st Cir. 2013)

("Neurontin II")(reaching a similar conclusion with respect to plaintiff Aetna which, along with other TPPs, paid for "most" Neurontin prescriptions); In re Neurontin Mktg. & Sales Practices Litig., 712 F.3d 60, 67 (1st Cir. 2013)("Neurontin III")(also reaching a similar conclusion with respect to putative class representative Harden which, along with other TPPs, paid for "almost all" Neurontin prescriptions).

The parties fervently dispute the applicability of the three Neurontin decisions to the class certification issues in this case. Painters insists that the Neurontin cases are factually similar to the instant case which involves civil RICO claims asserted by TPPs alleging that a drug manufacturer fraudulently marketed its drugs for unapproved, off-label use.

Forest correctly points out that the Neurontin decisions did not directly address the issue of RICO class certification. Neurontin I, 712 F.3d at 25 (affirming verdicts reached by the jury and district court); Neurontin II, 712 F.3d at 53 (reversing the grant of summary judgment); Neurontin III, 712 F.3d at 70, 71 (reversing the grant of summary judgment and remanding the issue of class certification because "[t]he legal requirements to establish proximate and but-for causation under RICO were key factors across both the summary judgment and class certification decisions" by the district court).

Painters, however, does not purport to cite the Neurontin decisions in its memoranda as direct precedent in favor of class certification. It cites the Neurontin decisions because it has patterned its theories of liability and damages around the Neurontin findings which it asserts can be generalized to class actions. The Court will consider Painters' Neurontin-derived arguments to the extent that they apply to the factual and legal issues in this case rather than categorically discrediting them as inapposite. The Court will do so despite Forest's objection that some courts from other jurisdictions declined to certify nationwide RICO classes based solely upon the "generalized proof found sufficient to support individual TPP claims in Neurontin".

Based upon Painters' proposed use of class-wide evidence, the Court is satisfied, for the purposes of class certification, that adjudication of the proximate causation issue on the merits will not require individualized inquiries that overwhelm the common issues.

Accordingly, Painters satisfies the predominance requirement with respect to proximate causation.

b. But-for causation

The inquiry with respect to but-for causation asks whether the plaintiff would have suffered the injury absent the alleged misconduct. Neurontin I, 712 F.3d at 34. The plaintiff must show that it "suffered the sort of injury that would be the

expected consequence of the defendant's wrongful conduct" but need not affirmatively "prove a series of negatives" or exclude every other possible cause of injury. Id. at 45. If the plaintiff succeeds, the burden shifts to the defendant to rebut the causal inference. Id.

If the plaintiff intends to present causation evidence through expert analysis, the court must also evaluate

> whether after a sneak preview of the issues, the expert approach appears fundamentally flawed — an issue usually vetted more fully at a Daubert hearing based on a more detailed record.

In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 90 (D. Mass. 2005). The purpose of that inquiry in the context of but-for causation is to determine whether the expert's methodology for assessing but-for causation is so insubstantial as to preclude class certification. See id.

Painters asserts that it can establish but-for causation with common proof that the TPPs in the class paid for "induced off-label prescriptions" as a natural consequence of Forest's fraudulent conduct. It contends that it and other TPPs would have paid for fewer off-label prescriptions for pediatric use had Forest not engaged in its unlawful scheme.

The centerpiece of Painters' argument is the report of an expert witness who performed an econometric "regression analysis" of Forest's fraudulent promotions and the allegedly

resulting fraudulent prescriptions. The First Circuit Court of Appeals ("the First Circuit") regards regression analyses as "well recognized and scientifically valid approach[es] to understanding [the] statistical data" used to establish causation. See Neurontin I, 712 F.3d at 42.

In Neurontin I, the plaintiff relied upon an expert report by Dr. Meredith Rosenthal ("Rosenthal") as its primary evidence of causation. Id. at 29. Rosenthal based her testimony upon a regression analysis that used "aggregate data and statistical approaches" to compare patterns in Forest's promotional spending to patterns in physicians' prescriptions of Celexa and Lexapro. Id. She testified that there was a "causal connection between the fraudulent marketing and the quantity of prescriptions" for off-label use. Id.

The First Circuit considered Rosenthal's regression analysis in the Neurontin cases as sufficient evidence of but-for causation and declared, in general, that plaintiffs with RICO claims of fraudulent pharmaceutical marketing could use such aggregate evidence to show causation. Id. at 40, 47. The court found that Rosenthal's testimony established causation, rather than mere correlation, in light of evidence that the defendants expected the marketing campaign to influence the prescribing decisions of physicians. Id. at 46. The fact that some physicians were unaffected by the marketing did not defeat

the causal inference that the "misinformation had a significant influence on prescribing decisions which injured [the plaintiff]." Id. at 45. See also Neurontin III, 712 F.3d at 68-69 (concluding that Rosenthal's regression analysis "clearly" implied that the misinformation significantly influenced thousands of prescribing decisions despite evidence that some physicians were purportedly unaffected by the misinformation).

Moreover, the aggregate statistical evidence in the Rosenthal report established but-for causation even without physician-specific evidence of causation. Neurontin II, 712 F.3d at 58 (finding that the plaintiff did not need to prove "which doctor's prescriptions were caused by [the] misrepresentations" because that concern related to the quantification of damages, not but-for causation); Neurontin III, 712 F.3d at 68 ("The Rosenthal report is capable of providing proof of but-for causation. The Harden plaintiffs need not prove causation through the testimony of individual doctors.").

Here, Painters retained Dr. Christopher Baum ("Baum") to construct regression models and Dr. Rosenthal to run the "same" regression analysis from the Neurontin cases to examine whether the fraudulent, off-label promotion in this case caused physicians to write additional off-label prescriptions. Rosenthal used the models to control for unrelated variables and to compare the amount of promotional spending to aggregate sales

of Celexa and Lexapro. She then ran statistical analyses on that comparison of all promotions and all sales, estimated the effect of Forest's fraudulent marketing on fraudulently induced drug sales and concluded that, but-for the fraudulent marketing, "Celexa sales would have been 4.35% lower and Lexapro sales would have been 2.44% lower". Painters proffers Rosenthal's report as class-wide evidence establishing but-for causation and, in support, cites the Neurontin decisions which "specifically endorsed [the use of] the same econometric model and the same expert" for the same purpose.

Forest responds that the Rosenthal report in this case differs from the Rosenthal report in the Neurontin cases because 1) in the Neurontin cases, Rosenthal showed a "huge increase" in Neurontin prescriptions for off-label use during the period of misconduct, 2) 90% of the Neurontin prescriptions in those cases were for off-label use while only between 4% and 6% of the Celexa and Lexapro prescriptions in this case were for off-label use and 3) the regression analysis in the Neurontin cases measured the impact of fraudulent, off-label promotion on the quantity of off-label prescriptions, while the regression analysis in this case relies on a comparison of all promotions to all sales of prescriptions. Forest also declares that the regression analysis of its own expert reveals that the relative amount of off-label prescriptions remained "flat" throughout the

class period which indicates that the "off-label promotion was not so pervasive" as to cause TPPs nationwide to pay for excess prescriptions.

The Court is concerned with Painters' ability to present sufficient class-wide evidence of but-for causation due to the apparent "fundamental flaw" in Rosenthal's but-for approach. Rosenthal assumes that the relationship between all promotions and all sales is a "reasonable proxy" for the relationship between fraudulent promotions and fraudulently induced sales. Painters claims that the scholarly articles cited in Rosenthal's expert report and rebuttal report specifically justify her assumption of the "reasonable proxy".

After careful consideration of Rosenthal's expert report, her rebuttal report and Painters' oral argument, however, the Court is not persuaded that the cited articles justify her assumption. The expert report cites 1) the Dorfman and Steiner article in paragraph 29 for the proposition that consumer receptivity to promotional marketing and product price affects the relationship between promotional spending and total sales and 2) two analyses and two articles in paragraphs 31 and 32 for the econometric theory that profit-maximizing drug manufacturers will pursue off-label promotions if the marginal revenue of product demand exceeds the marginal costs of promotion and the expected legal costs and penalties. Rosenthal does not,

however, cite any authority to support her conclusion in paragraph 37 that:

> Economic theory shows that the profit maximizing choice depends on the response to promotion and market structure. Furthermore, based on the evidence, I conclude that these effects of promotion occur regardless of whether the messages being promoted are true or false.

She then declares in paragraph 38 that the discovery materials in this action corroborate those economic theories in the context of Forest's use of marketing activities to increase sales of Celexa and Lexapro for pediatric use.

In her rebuttal report Rosenthal cites the same articles by reference in paragraph 26 and, without citing any new articles, asserts that, based upon the scholarly literature and discovery materials previously reviewed, the relationship between total promotion and total prescribing is a "reasonable proxy" for the relationship between off-label promotion and the off-label prescribing caused by that off-label promotion.

Moreover, during oral argument, Painters' counsel relied on the authorities cited in the expert report in his explanation of how Rosenthal reached her "reasonable proxy" conclusion. Painters offered no other authorities to support that conclusion.

Accordingly, the Court concludes that Rosenthal has not justified her "reasonable proxy" conclusion. The academic

literature, as summarized by Rosenthal, suggests that all promotional activities, i.e., both fraudulent and non-fraudulent, increase drug sales but it does not specifically suggest that such a correlation is a "reasonable proxy" for the relationship between fraudulent promotions and fraudulently induced sales. Rosenthal does not therefore adequately explain the basis for her "reasonable proxy" assumption and that flaw precludes Painters from using her report as sufficient evidence of but-for causation.

Painters' reliance on Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036 (2016), is misplaced. That class action involved allegations by meat processing employees that their employer violated the Fair Labor Standards Act ("FLSA") when it withheld overtime wages for the time employees spent "donning and doffing protective equipment." Id. at 1041. To establish the requisite injury, each employee had to show that

> the amount of time spent donning and doffing, when added to his or her regular hours, amounted to more than 40 hours in a given week.

Id. at 1046. The employer contended that, to establish those injuries, plaintiffs were required to make individualized inquiries into employee-specific time records that would overwhelm the class-wide inquiries. Id. The employees rebutted that contention by asserting that they could prove injury on a class-wide basis by relying on a representative sample of

employees and assuming that each class member "donned and doffed for the same average time observed" in that sample. Id.

The Tyson court agreed with the employees and found that they could use representative evidence to prove class-wide liability so long as they first demonstrated that

> each class member could have relied on that sample to establish liability if he or she had brought an individual action.

Id. The holding in Tyson does not, however, aid Painters here because Painters has not made (and cannot make) the threshold showing that each TPP in the proposed classes could have relied on the aggregate statistical evidence in the Rosenthal report to prove but-for causation in an individual action.

Because Painters relies primarily on the inapposite Rosenthal report as class-wide proof of but-for causation, it has not shown that it can establish but-for causation without individualized determinations predominating over common ones. Class certification is unwarranted for that reason.

c. Injury

Class certification is also improper because Painters has not established that individual assessments of RICO injury will not predominate over class-wide assessments.

Painters' RICO claims arise from allegations that Forest misrepresented and concealed material information about the efficacy of Celexa and Lexapro for pediatric use. The issue of

efficacy is thus at the apex of the dispute over Painters' ability to establish class-wide RICO injuries with common proof.

Painters contends that it and other TPPs suffered economic injuries in the form of payments for additional prescriptions of Celexa and Lexapro for off-label use. It claims that it has significant, class-wide evidence of inefficacy relating to

1) the four clinical studies of pediatric efficacy, three of which were statistically negative and all of which were clinically negative,

2) Forest's repeated and unsuccessful attempts to demonstrate efficacy in patients under the age of 12,

3) denial of FDA approval for a pediatric indication for Celexa and an under-12 indication for Lexapro,

4) the fact that Lexapro Study 32 reached positive results based upon fraudulent data and unblinded patients and

5) the fact that Forest fraudulently promoted Celexa and Lexapro "long before there was any evidence the drugs had efficacy."

Forest responds that 1) there is no "reliable" evidence that the drugs were ineffective for pediatric use and 2) the FDA's determination that MD-18 and Lexapro Study 32 yielded positive results for efficacy is sufficient evidence thereof. It explains that it did not seek FDA approval for Celexa for pediatric use because it ceased promoting Celexa in 2002. It further asserts that the efficacy determination turns on the utility of the drug for each individual patient.

Painters' arguments are underwhelming. In the first place, because the FDA is the "exclusive judge of safety and efficacy", In re Celexa & Lexapro Mktg. & Sales Practice Litig., 779 F.3d 34, 38 (1st Cir. 2015)("Marcus"), this Court will not question the FDA's determination that MD-18 and Lexapro Study 32 established the efficacy of Celexa and Lexapro for use by patients between the ages of 12 and 17. Painters presents no new information concerning MD-18 or Lexapro Study 32 that would warrant a judicial reconsideration of that FDA decision. See id. at 42-43 (1st Cir. 2015)("We have also examined the complaint's allegations claiming that the positive statistical efficacy results of Celexa Study 18 hinged in part on the inappropriate inclusion of some [unblinded] subjects in the data pool . . . Plaintiffs make no claim, however, that this information was unknown to the FDA prior to label approval.").

The Neurontin findings on efficacy and injury do not apply here because the Neurontin court expressly limited its findings on efficacy to cases with the same "mix" of evidence as was present in the Neurontin cases. Neurontin I, 712 F.3d at 48 ("We need not address what the standard for efficacy would be if there were no DBRCTs [double-blind randomized controlled trials] in existence, or if the results of DBRCTs were equivocal, or if there were a different mix of DBRCT and non-DBRCT evidence."). Here, the results of the clinical studies are "equivocal" in

that two studies yielded positive results for Celexa and Lexapro and two other studies yielded negative results.

Because the class-wide evidence in this action is "equivocal", adjudication of the efficacy issues will likely require individualized assessments of the utility of Celexa and/or Lexapro for each patient based upon his or her particular medical circumstances. Painters has not shown that those patient-specific determinations will not overwhelm the class-wide determinations. The Court will deny the motion for class certification on that additional ground. See In re Celexa & Lexapro Mktg. & Sales Practices Litig., 2014 WL 108197, at 9 (D. Mass. Jan. 10, 2014)("Jaeckel") ("[P]laintiffs [argue] that they purchased a product that Forest misrepresented as effective but that was not, in fact, effective. Forest correctly maintains that individualized inquiries would predominate over common issues because there would be a question of whether or not Celexa or Lexapro actually helped each class member's minor child.").

Accordingly, class certification is unwarranted due to Painters' inability to establish RICO injuries in compliance with the predominance requirement.

d. Damages

To satisfy the predominance requirement with respect to damages, plaintiffs must "present a damages model that directly

reflects and is linked to an accepted theory of liability". In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168, 183 (D. Mass. 2013).

Here, Painters estimates in its Rosenthal report that the Celexa class suffered $140.7 million in damages and the Lexapro class suffered $160.5 million in damages. Rosenthal reached those estimates by using Baum's regression models, simulating "but-for scenarios" to predict the value of prescriptions induced by Forest's misconduct and making adjustments to account for unrelated variables.

As discussed above, however, the unsubstantiated assumption in the expert report that the relationship between all promotions and all sales is a "reasonable proxy" for the relationship between fraudulent promotions and fraudulently induced sales creates a fundamental flaw in Rosenthal's expert analysis. Because Painters relies primarily on Rosenthal's expert report as its evidence of but-for causation and its model of damages, it lacks both an accepted theory of liability and a valid model of damages. Accordingly, Painters cannot establish damages pursuant to the predominance requirement.

e. Statute of limitations

The statute of limitations for civil RICO claims is four years after the plaintiff discovers or should have discovered the injury. See Rotella v. Wood, 528 U.S. 549, 553 (2000). The

limitations period commences when the plaintiff "knew or should have known of his injury." Lares Grp., II v. Tobin, 221 F.3d 41, 44 (1st Cir. 2000).

Forest informs the Court that it intends to challenge the timeliness of each TPP's claim through evidence specific to each TPP and PBM. Forest plans to establish that each class member knew, or reasonably should have known, before August 2, 2008 that it paid for potentially ineffective drugs. It contends that Painters is a sophisticated TPP with a fiduciary duty to monitor its prescriptions and that it had access to information available to Prime, its PBM, that should have put it on notice of its asserted injury "well before" August 2, 2008. It intends to present evidence that Prime and Painters were, or reasonably should have been, aware of the negative clinical studies and revised FDA labels before August, 2008.

Forest's limitations defense will involve TPP-specific evidence and predominating, individualized inquiries as to when each TPP knew or should have known, based upon its own access to information and/or that of its PBM, that it had paid for potentially ineffective prescriptions. Those TPP-specific assessments sever the "constellation of common issues [binding] class members together" and further support the Court's conclusion that class certification is unwarranted under the predominance requirement. See Waste Mgmt. Holdings, Inc. v.

Mowbray, 208 F.3d 288, 296 (1st Cir. 2000)("As long as a sufficient constellation of common issues binds class members together, variations in the sources and application of statutes of limitations will not automatically foreclose class certification under Rule 23(b)(3).").

Accordingly, Painters has not shown that it satisfies the predominance requirement with respect to the individualized issues raised by Forest's statute of limitations defense.

2. Superiority

The superiority criterion requires that class action be "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). In evaluating superiority, courts consider 1) the interests of class members in individually litigating separate actions, 2) the extent and nature of existing litigation that concerns the controversy and involves the class members, 3) the desirability of concentrating the litigation of the claims in a particular forum and 4) the likely difficulty in managing a class action. Id.

Painters asserts that a class action would be superior because 1) for most TPPs, the cost of litigating the action individually would "likely eclipse any possible recovery", 2) the Judicial Panel on Multidistrict Litigation has already determined that the litigation be concentrated in this Court,

3) adjudicating one class action is more judicially efficient than adjudicating "thousands of individual" actions and 4) there are no issues of manageability.

Forest responds that the "myriad individualized inquiries" indicate that class-wide adjudication would not be superior. It claims that the purpose of class adjudication does not apply here where TPPs are sophisticated entities with ample incentive and significant resources to pursue individual actions, particularly in light of their observations that 1) successful RICO plaintiffs can receive treble damages and attorney's fees and 2) "[o]ver half a dozen TPPs have filed suit in this MDL and in state court".

A class action is not the superior method of adjudicating this case. As discussed above, Painters cannot establish but-for causation or injury with common proof sufficient to satisfy the predominance requirement. Evaluation of the but-for causation and injury issues will require individualized evidence from each TPP that

1) identifies specific plan members for whom Celexa or Lexapro was ineffective,

2) presents evidence that the drugs were not effective for those particular members and

3) proves that it would not have paid for the additional prescriptions for those patients if Forest had not fraudulently marketed the drugs.

Adjudication of this case as a class action would implicate substantial individualized interests and serious issues of case manageability. Accordingly, Painters has not satisfied the superiority requirement pursuant to Fed. R. Civ. P. 23(b)(3).

The Court thus declines to certify the nationwide RICO classes because Painters cannot satisfy the Rule 23(b)(3) requirements of 1) predominance with respect to but-for causation, injury, damages and the statute of limitations defense or 2) superiority.

D. Minnesota subclasses

Painters, a Minnesota TPP, also seeks certification of two subclasses under the Minnesota Consumer Fraud Act and the Minnesota Unlawful Trade Practices Act. The MCFA prohibits:

> The act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement of deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby . . .

Minn. Stat. § 325F.69(1). The MUPTA provides:

> No person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients or origin of such merchandise.

Minn. Stat. § 325D.13. Painters brings its Minnesota claims pursuant to the "private attorney general statute" which provides a private cause of action to "any person injured by a violation" of the MCFA or MUPTA. Minn. Stat. § 8.31(3)(a).

The Minnesota subclasses do not satisfy the Rule 23(b)(3) requirements of predominance or superiority for the same reasons that the nationwide RICO classes do not meet those requirements. The subclasses will not be certified.

ORDER

For the foregoing reasons, plaintiff's motion to certify class (Docket No. 546) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated June 2, 2016