

United States District Court
District of Massachusetts

<hr/>)
In re:)
)
CELEXA AND LEXAPRO MARKETING AND) MDL No.
SALES PRACTICES LITIGATION) 09-02067-NMG
<hr/>)
DELANA S. KIOSSOVSKI and)
RENEE RAMIREZ,)
)
Plaintiffs,)
)
v.) Civil Action No.
) 14-13848-NMG
)
FOREST LABORATORIES, INC.,)
FOREST LABORATORIES, LLC and)
FOREST PHARMACEUTICALS, INC.,)
)
Defendants.)
<hr/>)

MEMORANDUM & ORDER

GORTON, J.

This case arises out of the marketing and sales of the anti-depressant drugs Celexa and Lexapro by defendants Forest Laboratories, Inc., Forest Laboratories, LLC and Forest Pharmaceuticals, Inc. (collectively, "defendants" or "Forest"). Plaintiffs Delana Kiossovski and Renee Ramirez (collectively, "plaintiffs") allege that defendants 1) engaged in a fraudulent marketing scheme designed to induce consumers to purchase Celexa and Lexapro for pediatric use in violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C.

§§ 1962(c) and (d), 2) were unjustly enriched and 3) violated the Washington Consumer Protection Act, RCW § 19.86.010 et seq.

Plaintiffs' motion for class certification (Docket No. 137) is currently pending before the Court. For the reasons that follow, that motion will be denied.

I. Background and procedural history

Celexa and Lexapro are closely related anti-depressants. Forest obtained approval from 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 to treat pediatric major depressive disorder ("MDD").

A. FDA Approval Process

To obtain FDA approval to market Celexa and Lexapro for pediatric use, Forest had to show that the drugs would be more effective than placebos in treating MDD in pediatric patients. The FDA typically requires at least two "positive" placebo-controlled clinical trials before approval. A "positive" drug study shows statistically significant improvements for patients who are administered the drug rather than a placebo while a "negative" study indicates no statistically significant difference. Drug manufacturers submit trial results to the FDA as part of their "new drug applications" ("NDAs").

Forest conducted four double-blind, placebo-controlled studies on the efficacy of Celexa and Lexapro in treating

pediatric depression. The first two examined the efficacy of Celexa and were completed in 2001. The Celexa Study 18 ("MD-18") produced results that the FDA determined were positive (although plaintiffs dispute that finding). On the other hand, 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 negative. The other two studies addressed the efficacy of Lexapro. Lexapro Study 15 produced negative results but Lexapro Study ("MD-32") produced statistically significant, and therefore positive, results.

Before 2005, the FDA-approved labels for both drugs 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 the negative study.

In 2008, Forest submitted study results to the FDA in a supplemental NDA. The following year, the FDA reviewed the positive results in MD-18 and MD-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.

B. Delana Kiossovski and Renee Ramirez

The proposed class representatives both purchased Celexa and/or Lexapro for their children and both assert that they were mis-led to believe that those drugs effectively treated pediatric depression. From July, 2001 to March, 2002, Kiossovski bought Celexa for her daughter, who was then 12 years old, based upon the recommendation of her daughter's psychiatrist, Dr. Stephen Barnett. In 2002, Kiossovski's daughter attempted suicide. After that, she stopped using Celexa. Kiossovski became aware that the efficacy of Celexa for children was unproven in 2014. From February, 2003 to April, 2004, the eight-year-old son of Ramirez used Celexa for his depression and from April, 2004 to January, 2007 he used Lexapro. His physician, Dr. Michael Saito, recommended both drugs.

C. Procedural history

In August, 2014, former plaintiff Marlene LoConte and Kiossovski commenced this action in the Western District of Washington by filing a complaint on behalf of themselves and putative consumer classes. They alleged that Forest fraudulently promoted the pediatric use of Celexa and Lexapro despite knowing that the drugs did not provide any clinically significant benefit over placebos in treating MDD. The case was

transferred to this Court pursuant to a multi-district litigation assignment in October, 2014.

In June, 2015, this Court 1) allowed defendants' motion to dismiss with respect to the RICO, Massachusetts Consumer Protection Act, M.G.L. c. 93A ("Chapter 93A") and unjust enrichment claims brought by LoConte and 2) denied the motion with respect to the RICO, Washington Consumer Protection Act and unjust enrichment claims brought by Kiossovski. Plaintiffs amended the complaint in January, 2016 by replacing LoConte with Ramirez as the second putative class representative. The amended complaint raises two RICO claims by Kiossovski and Ramirez, an unjust enrichment claim by both plaintiffs and a Washington Consumer Protection Act claim by Kiossovski.

In February, 2016, defendants moved to dismiss the amended complaint which this Court denied in June, 2016. In March, 2017, plaintiffs moved for class certification which defendants opposed. This Court convened a hearing on the motion for class certification and that motion is the subject of this memorandum and order. For the reasons that follow, it will be denied.

II. Motion to Certify Class

Plaintiffs request the certification of the following nationwide RICO classes and subclasses:

Damages Class. All persons, in the United States of America and its territories, who, for purposes other than resale, (1) paid or incurred costs for the drug Celexa

prescribed for use by an individual under 18 years of age; and/or (2) paid or incurred costs on or before March 19, 2009, for the drug Lexapro prescribed for use by an individual under 18 years of age.

Plaintiffs also propose the following sub-classes because there is no study demonstrating that Celexa and/or Lexapro are effective for children 12 or younger and MD-32 was not submitted to the FDA in a supplemental NDA until March, 2008:

Child Subclass. All persons, in the United States of America and its territories, who, for purposes other than resale, (1) paid or incurred costs for the drug Celexa prescribed for use by an individual under 13 years of age; and/or (2) paid or incurred costs on or before March 19, 2009, for the drug Lexapro prescribed for use by an individual under 13 years of age.

MD-32 Subclass. All persons, in the United States of America and its territories, who, for purposes other than resale, (1) paid or incurred costs for the drug Celexa prescribed for use by an individual under 18 years of age; and/or (2) paid or incurred costs on or before March 11, 2008, for the drug Lexapro prescribed for use by an individual under 18 years of age.

Plaintiffs alternatively seek to certify a "liability-only class" that is the same as the proposed damages class under Fed. R. Civ. P. 23(c)(4). Plaintiffs also move for the designation of Kiossovski and Ramirez as class representatives and to appoint Christopher L. Coffin of Pendley, Baudin & Coffin, L.L.P. and Michael Baum of Baum, Hedlund, Aristei & Goldman, P.C., along with their respective law firms, as class counsel.

Plaintiffs further request certification of classes of Washington residents for the unjust enrichment and Washington

Consumer Protection Act claims. Kiossovski is the putative class representative for those claims.

A. Class Certification Pursuant to Fed. R. Civ. P. 23(b)

A court may certify a proposed class only if it satisfies all of the requirements in Fed. R. Civ. P. 23(a) and one of the requirements in Fed. R. Civ. P. 23(b). See Smilow v. Sw. Bell Mobile Sys., Inc., 323 F.3d 32, 38 (1st Cir. 2003). Here, plaintiffs seek to certify a class under 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 [as individual plaintiffs] 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 be the "superior" method for fair and efficient adjudication. Fed. R. Civ. P. 23(b)(3).

B. Application of the Rule 23(a) Requirements

1. Numerosity

It is undisputed that the proposed class includes numerous consumers who purchased Celexa or Lexapro for minors, rendering joinder impractical. See In re Relafen Antitrust Litig., 218 F.R.D. 337, 342 (D. Mass. 2003).

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. Plaintiffs assert that their "claims all originate with Forest's common course of unlawful conduct", i.e. promoting off-label, pediatric prescriptions of Celexa and Lexapro.

Plaintiffs satisfy the commonality requirement.

3. Typicality

To meet the typicality prerequisite, 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 his or her claim may be "subject to unique defenses that would divert attention from the common claims". Id.

Plaintiffs contend that their injuries and the injuries of the other members of the putative class arise from the same conduct: purchasing Celexa and/or Lexapro for a child based upon the belief that the drugs would treat pediatric depression. Defendants counter that the named plaintiffs will be subject to individualized defenses based upon the unique medical histories of their children. Specifically, defendants highlight that Kiossovski's daughter twice attempted suicide, but was the victim of sexual assault before the second attempt, and that Ramirez's son had multiple symptoms and is autistic.

Defendants' assertion that the named plaintiffs are not typical is unavailing. Plaintiffs have the "essential characteristics" of the class: they purchased the drugs for their minor children. Therefore, the focus of the litigation will be the alleged injury from that purchase, not the unique medical situations of their children. See Barry v. Moran, No. CIV. A. 05-10528-RCL, 2008 WL 7526753, at *11 (D. Mass. May 7, 2008) (internal quotation and citation omitted). Plaintiffs meet the typicality requirement.

4. Adequacy

Adequacy requires 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 the class interests and 2) its counsel is qualified to litigate the claims vigorously. See Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985).

Plaintiffs claim that their interests align with those of the proposed class because, along with the members of the class, they have a strong interest in establishing that defendants fraudulently promoted the use of Celexa and/or Lexapro for minors and caused damages. They also submit that this Court has already determined that their counsel is qualified to represent classes in this MDL. Defendants respond that the unique medical situations of the children of plaintiffs prevent them from

meeting the adequacy requirement. This Court agrees with plaintiffs that they share common interests with the putative class members and their counsel can adequately represent the proposed class. Thus, the adequacy requirement is met.

C. Application of the Rule 23(b)(3) requirements

1. Predominance

The crux of the dispute between the parties is whether plaintiffs satisfy 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 in Rule 23(a), id. at 623-24, but it does not require that each element of the 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. Id. Thus, the "need for some individualized determinations" 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 case, the four elements are susceptible to common proof. Instead, the parties contest whether 1) plaintiffs can establish causation, injury and damages through common proof and 2) defendants' 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 proximate and but-for causation. In re Neurontin Mktg. and Sales Practices Litig., 712 F.3d 21, 34 (1st Cir. 2013) ("Neurontin I") (citation omitted).

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 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 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.

Plaintiffs contend that proximate cause can be demonstrated through common evidence showing that there was a fraudulent scheme and that they were the intended and foreseeable victims. Defendants state that they will not argue about proximate causation "[g]iven the Court's ruling in Painters II".

This Court agrees with plaintiffs that class-wide proof of a fraudulent scheme through which defendants intended to obtain payments from consumers can be used to establish directness and a favorable balance of the three factors, just as the plaintiffs did in the Neurontin cases. See Neurontin I, 712 F.3d at 37-40. Therefore, plaintiffs satisfy 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.

Plaintiffs contend that they can show but-for causation by having the jury resolve the factual question of whether a reasonable parent would give a child a drug "that is not better than a sugar pill but has significant side effects". Defendants reply that but-for causation must be resolved on an individual basis by examining whether physicians and consumers were exposed to the off-label promotions.

This Court agrees that whether physicians were exposed to off-label promotions must be examined on an individual basis. The individualized nature of the inquiry is highlighted by the fact that, at the class certification hearing, plaintiffs stated that that Dr. Saito felt misled by "studies that were not brought to [his] attention during the marketing blitz". Conversely, plaintiffs admitted that Dr. Barnett "didn't recall ever being exposed to . . . a sales representative", let alone an off-label promotion.

Plaintiffs' contention that the reaction of a "reasonable consumer" can be used to show but-for causation is also unavailing. They cite no cases in support of such an approach and conceded at oral argument that they "do not know of a

specific case that talks about the reasonable-consumer standard”.

In fact, the only cases cited in their arguments as to but-for causation are Neurontin I and In re Neurontin Mktg. & Sales Practices Litig., 712 F.3d 60, 67 (1st Cir. 2013) (“Neurontin III”). Those decisions recognize that but-for causation may be proved through a “combination of aggregate evidence and the circumstantial evidence”. Neurontin III, 712 F.3d at 68; see also Neurontin I, 712 F.3d at 40. Neither opinion, however, refers to a “reasonable consumer” standard for but-for causation and plaintiffs do not provide any aggregate or circumstantial evidence in support of but-for causation. Thus, plaintiffs have failed to show that common issues predominate with respect to but-for causation.

c. Injury

Plaintiffs claim that their injury arises from common experience of parents purchasing Celexa and/or Lexapro for their children based upon the incorrect belief that the drugs were effective. Defendants retort that assessing the purported injuries will require individualized determinations as to 1) whether the drug was ineffective and 2) whether class members would have paid more for an alternative drug.

In support of their argument, plaintiffs “incorporate[] by reference” a 30-page memorandum filed in support of their second

motion for class certification in the related case In re Celexa & Lexapro Mktg. & Sales Practice Litig., No. 14-13848-NMG ("Painters II"). Plaintiffs specifically incorporate the argument that no clinical studies for Celexa or Lexapro were positive. The Court notes that incorporating a 30-page memorandum violates the page limits set by the Court. In the interest of efficiency, however, it will address the argument incorporated by plaintiffs and the response by defendants.

Plaintiffs contend that the two positive studies, MD-18 for Celexa and MD-32 for Lexapro, do not actually show efficacy. With respect to MD-18, plaintiffs proffer that, because pink pills labeled "FP" and "20mg" were accidentally used instead of the "blinded" white, unbranded pills for some patients, the study was "unblinded" for eight patients. Plaintiffs also suggest that, in communicating the issue to the FDA, defendants used misleading language. Finally, according to plaintiffs, defendants improperly included the participants who received the pink pills in the results reported to the FDA. That had a substantial effect: when the patients who received the pink pills were included there were statistically significant results but when they were excluded the study was negative.

Defendants vigorously refute that version of events. They state that they reported the error to the FDA in 2000 and specifically mentioned that it "had the potential to cause

patient bias" and that there were "eight potentially unblinded patients". In April, 2002, according to defendants, they submitted the MD-18 study report to the FDA. That report mentioned the error five times, disclosed that the primary efficacy analysis had possibly unblinded subjects and also provided an analysis that excluded those subjects. The FDA still determined that MD-18 was a positive study.

Plaintiffs also contest the effectiveness of MD-32 but their main objection appears to be that the study was statistically significant but not clinically meaningful.

Plaintiffs' 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), this Court will not question its determination that MD-18 and MD-32 established the efficacy of Celexa and Lexapro for use by patients between the ages of 12 and 17. Moreover, although it would, perhaps, be permissible to question the FDA's conclusion if there were evidence that it was unaware of the supposedly unblinded participants, see id. at 42-43, as defendants point out, the information was disclosed to the FDA in both a letter and the MD-18 report. The information is not new simply because its disclosure was not made in language most appealing to plaintiffs.

At oral argument, plaintiffs pointed out that Dr. Laughren, who was employed by the FDA at the time it examined MD-18 and helped review that study, stated that internal Forest conversations as to how to disclose the purported unblinding to the FDA is "probably new information". Yet plaintiffs do not explain how the fact that some participants were given pink pills during the study constitutes new information when that fact was already disclosed to the FDA at the time it found MD-18 to be a positive study. Furthermore, as defendants noted at the hearing, Dr. Laughren also testified that, even with the so-called new evidence, he would have viewed MD-18 as a positive study.

Moreover, 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 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. For instance, both of the physicians of the children of the representative plaintiffs have testified that Celexa and Lexapro were beneficial for their patients. Those patient-specific determinations will overwhelm the class-wide determinations. The Court will, therefore, 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 II") ("[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.").

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). Plaintiffs rely on expert reports from Drs. Rosenthal and Baum to estimate that the Celexa class suffered

\$140.7 million in damages and the Lexapro class \$160.5 million. Dr. Rosenthal reached those estimates by using Dr. Blum's regression models, simulating "but-for scenarios" to predict the value of prescriptions induced by Forest's misconduct.

Defendants respond that the damages calculations are flawed because they fail to consider the difference between what a consumer paid for the drug and the cost of an alternative medication and assume that 1) all physicians were subject to off-label promotion, 2) the drugs were ineffective and 3) all sales were the result of fraudulent promotions.

This Court agrees that, given the individualized questions that predominate with respect to but-for causation and injury, individualized questions also overwhelm the question of damages.

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); see also Lares Grp., II v. Tobin, 221 F.3d 41, 44 (1st Cir. 2000).

Defendants state that they plan to challenge the timeliness of each consumer's claim. For instance, defendants allege that the claims of the named plaintiffs are untimely because they filed suit more than 12 years after they first purchased the drugs, nine years after the labels were edited and five years after the qui tam suit was publicly available and other

consumers filed suit. Plaintiffs respond that common questions can predominate even if there are individualized affirmative defenses. Again incorporating arguments from the memorandum in the related case, they further proclaim that, because Forest first publicly admitted to off-label promotion in 2010, no reasonable consumer would have suspected injury before then.

Plaintiffs' bald assertion that no reasonable consumer would have suspected fraudulent promotion before 2010 is belied by the fact that other plaintiffs discovered their injuries in 2009. Although the public disclosure of the off-label promotion in 2010 makes it more likely that consumers would have discovered their injury, the fact that other consumers discovered their injuries before then supports an individualized approach to the statute of limitations defense. See Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 296 (1st Cir. 2000). Accordingly, Plaintiffs have not shown that common issues predominate with respect the statute of limitations defenses.

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, 3) the

desirability of concentrating the litigation of the claims in a one forum and 4) the difficulty in managing a class action. Id.

Plaintiffs submit that a class action would be superior because 1) the cost of litigating the action individually would "eclipse any possible recovery", 2) the Judicial Panel on Multidistrict Litigation has already determined that the litigation will be concentrated in this Court, 3) a class action would be more efficient and 4) there are no issues of manageability. Defendants respond that, because but-for causation and injury require individualized proof, resolution of the claims through a class action would result in a quagmire of unmanageable individual interests.

This Court agrees that resolution of the claims will require an individualized assessment of whether the drugs would have been prescribed but-for the off-label promotions and whether the drugs were effective. Because resolving this case as a class action would present serious issues of manageability, plaintiffs have not satisfied the superiority requirement pursuant to Fed. R. Civ. P. 23(b)(3).

The Court thus declines to certify the nationwide RICO class and subclasses because Plaintiffs have not satisfied the Fed. R. Civ. P. 23(b)(3) requirements of predominance with respect to but-for causation, injury, damages and the statute of limitations defenses or superiority.

D. Class Certification Under Fed. R. Civ. P. 23(c)(4)

An issue class may be certified if there are common issues with respect to liability. In re McKesson Governmental Entities Average Wholesale Price Litig., 767 F. Supp. 2d 263, 269 (D. Mass. 2011). Plaintiffs move to certify an "issue class" pursuant to Fed. R. Civ. P. 23(c)(4) for the following issues:

- 1) Whether Celexa or Lexapro are effective in treating pediatric depression, i.e., can they significantly or clinically outperform placebo;
- 2) Whether Forest promoted Celexa and/or Lexapro for pediatric use;
- 3) Whether Forest's promotion of Celexa and/or Lexapro was fraudulent;
- 4) Whether Forest's promotion of Celexa and/or Lexapro was part of an Enterprise;
- 5) Whether Forest's promotion of Celexa and/or Lexapro involved conduct indictable under federal wire or mail fraud statutes; and
- 6) Whether Forest's conduct violated RICO.

Plaintiffs contend that, if the above issues are resolved on a class-wide basis, causation and damages can be easily resolved individually, for instance with

a declaration by the consumer . . . that they would not have purchased the drugs for their child if they had known about the fraud.

Defendants maintain that the certification of an issues class is inappropriate because liability issues, such as whether the drugs were promoted for pediatric use and whether they were

effective, require individual analyses. This Court agrees. Thus, the motion to certify an issue class will be denied.

E. Proposed State Law Classes

In their reply memorandum, plaintiffs briefly argue that classes of residents of Washington State should be certified to pursue the state claims. The first state law claim is unjust enrichment. To show unjust enrichment, a plaintiff must prove that a defendant has "retain[ed] money or benefits which in justice and equity belong to another." Bailie Commc'ns, Ltd. v. Trend Bus. Sys., Inc., 810 P.2d 12, 18, amended sub nom. Bailie Commc'ns, Ltd v. Trend Bus. Sys., Inc., 814 P.2d 699 (Wash. Ct. App. 1991). This Court agrees with defendants that individualized issues as to justice and equity, such as whether off-label promotion caused the purchase of the drugs, predominate, preventing certification of a class for the unjust enrichment claim. See In re Actiq Sales & Mktg. Practices Litig., 307 F.R.D. 150, 168-69 (E.D. Pa. 2015).

Plaintiffs also contend that a class should be certified for the Washington Consumer Protection Act ("WCPA") claim. RCW § 19.86.010 et seq. With respect to a WCPA claim, a plaintiff must show:

- (1) an unfair or deceptive act or practice, (2) occurring in trade or commerce, (3) affecting the public interest, (4) injury to a person's business or property, and (5) causation.

Panag v. Farmers Ins. Co. of Washington, 204 P.3d 885, 889 (Wash. 2009). Plaintiffs assert that, similar to the Missouri class that this Court certified in Jaeckel II, 2014 WL 108197, a WCPA class is appropriate because 1) the WCPA allows claims based upon informational injuries and 2) reliance is not required. Defendants counter that the injury and causation issues that adversely affect the certification of a RICO class also apply to a WCPA class.

Plaintiffs correctly contend that the WCPA permits claims based upon informational injuries. To bring a claim under that statute, "the injury need not be great, or even quantifiable" but a plaintiff must show that their property or business was harmed. Ambach v. French, 216 P.3d 405, 407 (Wash. 2009). An "informational injury" may meet the injury requirement. Torres v. Mercer Canyons Inc., 835 F.3d 1125, 1135-36 (9th Cir. 2016).

Yet in contending that, like the Missouri statute in Jaeckel II, the WCPA does not require reliance, plaintiffs fail to account for the causation requirement of that statute. Defendants are correct that the Washington Supreme Court has "firmly rejected the principle that reliance is necessarily an element" of a WCPA claim. Schnall v. AT & T Wireless Servs., Inc., 259 P.3d 129, 137 (Wash. 2011). That Court has also recently held, however, that proximate cause is required to show causation under WCPA and determined that

[for] the causation analysis for a [WCPA] claim, a plaintiff would have to establish that but for the defendant's unfair or deceptive act or practice the plaintiff's injury would not have occurred.

Indoor Billboard/Washington, Inc. v. Integra Telecom of Washington, Inc., 170 P.3d 10, 21 (Wash. 2007).

Thus, the WCPA is distinguished from the Missouri statute which

does not require an individualized showing that Forest's alleged misrepresentations caused consumers to purchase Celexa or Lexapro.

Jaeckel II, 2014 WL 108197, at *7. Because individual issues as to but-for causation persist, the predominance requirement is not satisfied and WCPA class will not be certified.

ORDER

For the foregoing reasons, plaintiffs' motion to certify a class (Docket No. 137) is **DENIED**.

So ordered.

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

Dated August 15, 2017