

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING,
SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

ALL MARKETING AND SALES PRACTICES
ACTIONS

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) MDL Docket No. 1629
) Master File No. 04-10981
) Judge Patti B. Saris
) Magistrate Judge Leo T.
) Sorokin
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)

MEMORANDUM AND ORDER

May 13, 2009

Saris, U.S.D.J.

I. INTRODUCTION

In this proposed nationwide class action, plaintiffs, consumers and third-party payors ("TPPs") who paid for a prescription for the drug Neurontin, allege that defendants Warner-Lambert and Pfizer ("defendants"), the manufacturers and distributors of Neurontin, systematically and knowingly engaged in a fraudulent campaign to market and sell Neurontin for treatment of "off-label" indications -- conditions for which the Federal Drug Administration ("FDA") had not approved Neurontin -- even though defendants knew Neurontin was not effective for those conditions. Plaintiffs claim violations of the Racketeer

Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961-68 (Counts I & II); the New Jersey Consumer Fraud Act ("NJCFRA"), N.J.S.A. 56:8-1 et seq. (Count III); common law fraud (Count IV); and unjust enrichment (Count V). Plaintiffs seek economic damages only -- this is not a products liability action.

On August 29, 2007, this Court denied, without prejudice, plaintiffs' initial motion to certify a nationwide class of Consumers and TPPs that purchased Neurontin for treatment of off-label indications. See In re Neurontin Mktg. and Sale Practices Litig., 244 F.R.D. 89 (D. Mass. 2007) (hereinafter Neurontin). The Court held that plaintiffs' initial motion failed to satisfy the commonality, numerosity, typicality, and predominance requirements of Rule 23 of the Federal Rules of Civil Procedure. Id. at 105-107, 114-16.¹ The Court did, however, provide plaintiffs with an opportunity to submit a new motion for class certification that addressed the Court's concerns. Id. at 115.

Before the Court is plaintiffs' renewed motion for class certification. (Pls.' Renewed Mot. for Class Certification ("Pls.' Renewed Mot.") Docket No. 1016-18.) The parties have submitted numerous briefs and voluminous expert reports. Because the Court concludes that common questions will not predominate over issues affecting individual plaintiffs, in accordance with Rule 23(b)(3), the Court now **DENIES** plaintiffs' renewed motion

¹ The Court found that the plaintiffs had satisfied Rule 23(a)(4)'s adequacy requirement. Neurontin, 244 F.R.D. at 108.

for class certification.

II. FACTUAL BACKGROUND

The factual underpinnings of plaintiffs' complaint are discussed in great detail in Neurontin, and the Court will only repeat a brief summary here. Neurontin, 244 F.R.D. at 92-103.

In December 1993, the FDA approved Neurontin in doses ranging from 900 mg to 1800 mg per day for use as an "adjunctive therapy" for the treatment of partial seizures in adults with epilepsy. In May 2002, the FDA approved Neurontin for the management of post-herpetic neuralgia ("PHN") (pain resulting from nerve damage caused by shingles or herpes zoster) in adults. Those are the only conditions that Neurontin has ever been approved to treat. Id. at 92. Given the limited market for such a drug and Neurontin's patent life, defendants estimated that potential lifetime sales for Neurontin would likely amount to less than \$500 million. Id.

In the late 1980s and early 1990s, however, defendants explored ways to earn additional profit from Neurontin by marketing it for the treatment of at least eight off-label indications -- bipolar and other mood disorders; neuropathic pain; epilepsy monotherapy; migraine prophylaxis; anxiety disorders; Restless Leg Syndrome ("RLS")/Periodic Limb Movement Disorder ("PLMD"); nociceptive and non-neuropathic pain; and in doses exceeding 1800 mg per day. Id. at 93. Plaintiffs allege

that even though defendants were aware by 1995 that Neurontin was no better than a placebo when used to treat these off-label conditions, they aggressively marketed Neurontin to doctors in the relevant fields. Although the specific decisions made and actions taken by defendants differed by indication, the general marketing approach was similar across indications and consisted of three elements. First, plaintiffs allege that defendants skirted the FDA rules against off-label marketing by formulating a complex "peer selling strategy," whereby defendants paid both doctors and medical marketing firms to organize continuing medical education events at which doctors would speak favorably about the off-label efficacy of Neurontin. Id. at 93-94. Second, plaintiffs assert that defendants, in conjunction with medical marketing firms, willfully manipulated the publication of studies about Neurontin's off-label usefulness, delaying or withholding negative internal results, publishing negative results (if at all) in minor journals with small circulation, ghost-writing favorable studies for doctors, and pushing favorable studies toward widely read journals. Id. at 94-95. Third, plaintiffs contend that defendants used an army of "medical liaisons," non-doctor sales representatives, who withheld and/or misrepresented negative information and promoted inaccurate positive information about Neurontin's off-label efficacy when solicited by doctors for information about Neurontin's off-label uses. Id. at 95.

For example, plaintiffs allege that defendants knew as early as 1992, but certainly by November 1995, that Neurontin was connected "with increased risks of depression with and without suicidal ideation when given as adjunctive medication in refractory partial epilepsy." (Expert Report of Daniel Furberg ¶ 21a, Ex. B., Docket No. 1503; see also Pls.' Renewed Mot. at 16 n.16.) By 1995, defendants were also aware of two negative studies regarding the efficacy of Neurontin as a treatment for bipolar. Nonetheless, defendants actively marketed Neurontin as a safe and effective treatment for bipolar and other mood disorders and as a mood stabilizer and intentionally suppressed the negative studies about its efficacy. Neurontin, 244 F.R.D. at 99.

In sum, plaintiffs allege that defendants' off-label promotion scheme constituted a pervasive fraud designed to saturate the medical community with false information about Neurontin's efficacy for several highly profitable off-label indications. The strategy was designed to generate a "buzz" about Neurontin through the peer-to-peer marketing, to legitimate that "buzz" through the publications of purportedly unbiased scientific research, and to preserve the "buzz" by suppressing or misrepresenting studies that demonstrated Neurontin was not effective for the off-label uses. As a result of this fraud, consumers and TPPs purchased Neurontin for conditions for which there was no credible scientific evidence of efficacy, while

defendants reaped billions in profits. Revenue from the sale of Neurontin rose from \$97.5 million in 1995 to nearly \$2.7 billion in 2003, "making Neurontin one of the ten most popular drugs in the United States." Id. at 103. Sales grew at approximately fifty percent per year, fueled primarily by off-label sales, which by 2003 accounted for approximately 90 percent of all Neurontin prescriptions. Id. Plaintiffs allege that defendants' off-label, fraudulent marketing scheme was largely responsible for Neurontin's meteoric rise in sales.

III. DISCUSSION

The Court's denial of plaintiffs' initial motion for class certification was predicated on plaintiffs' failure to satisfy four distinct requirements of Rule 23: commonality, numerosity, typicality, and predominance. Below, the Court discusses plaintiffs' efforts to remedy the shortcomings.

A. Commonality

1. Initial Shortcomings

In Neurontin, the Court concluded that plaintiffs' proposed class failed to satisfy the commonality requirement of Rule 23(a)(2).² "Rule 23(a)'s requirement of commonality is a low bar, and courts have generally given it a 'permissive application.'" " In re New Motor Vehicles Can. Export Antitrust Litig., 522 F.3d 6, 19 (2008) (hereinafter Motor Vehicles)

² Rule 23(a)(2) requires that there be "questions of law or fact common to the class."

(quoting 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1763, at 221 (3d ed. 2005)). Commonality necessitates only the existence of a "single issue common to all members of the class." 1 Alba Conte & Herbert B. Newberg, Newberg on Class Actions § 3.10 (4th ed. 2002).

Plaintiffs initially proposed a single class comprised of all individuals or entities who paid all or some of the price for an off-label Neurontin prescription. Plaintiffs then divided that broad class into Consumer and TPP Subclasses. The breadth of plaintiffs' original proposed Subclasses undermined plaintiffs' claim that resolution of common questions would "affect all or a substantial number of the class members." Jenkins v. Raymark Indus., Inc., 782 F.2d 468, 472 (5th Cir. 1986). Plaintiffs' "complaint and subsequent submissions . . . ma[de] clear that their proof of fraud varies considerably by [off-label] indication." Neurontin, 244 F.R.D. at 105. As such, the Court held that in order for plaintiffs to satisfy the commonality requirement, plaintiffs must "prove up fraud use-by use," and "the proposed consumer and TPP classes must be further divided into subclasses by use." Id. (emphasis in original). The Court identified the eight off-label conditions -- (1) bipolar and other mood disorders; (2) neuropathic pain; (3) migraine and headache; (4) nociceptive and non-neuropathic pain; (5) RLS/PLMD; (6) anxiety disorders; (7) monotherapy; and (8)

doses of 1800 mg to 3600 mg per day -- for which both the Consumer and TPP classes would independently have to satisfy all of Rule 23's prerequisites for class certification. Id. "The key common question for each subclass will be whether the defendants engaged in a common course of conduct to make misrepresentations or omissions regarding Neurontin's efficacy for a particular off-label use." Id. at 105-06.

2. Plaintiffs' Response

To address the Court's concerns, plaintiffs slightly altered the parameters of the proposed TPP Subclass³ More critically,

³ In the renewed motion, plaintiffs define the TPP Subclass as:

All private, non-governmental entities in the United States and its territories that paid or reimbursed all or part of the cost of Neurontin prescribed, provided, or administered to natural person covered by any contract, policy, or plan, for any of the following indications during the following periods of time.

plaintiffs identified the indication-specific subclasses for which they sought certification within the Consumer and TPP Subclasses. Plaintiffs abandoned their claims regarding RLS/PLMD, anxiety disorders, and monotherapy. For the remaining five indications, the following chart summarizes the relevant newly proposed indication-specific subclasses and subclass periods.

Subclass	Subclass Period
Bipolar/Mood Disorders	11/95 - 12/04
Neuropathic Pain	7/95 - 12/04
Migraine/Headache	9/95 - 12/04
Nociceptive Pain	9/95 - 12/04
Doses > 1800 mg/day	3/95 - 12/04

(Pls.' Renewed Mot. at 6.)

Plaintiffs' proposed subclasses are now sufficiently narrow such that for each one "there are questions of law or fact common

Subclass	Subclass Period
Bipolar/Mood Disorders	11/95 - 12/04
Neuropathic Pain	7/95 - 12/04
Migraine/Headache	9/95 - 12/04
Nociceptive Pain	9/95 - 12/04
Doses > 1800 mg/day	3/95 - 12/04

Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-funded plans that contract with a health insurance company or other entity to serve as a third-party claims administrator to administer their prescription drug benefits, private entities paid by an governmental entity (including a state Medicaid program), and other organizations.

(Pls.' Renewed Mot. at 6.)

to the [sub]class." Fed. R. Civ. P. 23(a)(2); see also Fed. R. Civ. P. 23(c)(5) ("When appropriate, a class may be divided into subclasses that are each treated as a class under this rule."). As discussed in Neurontin, although defendants allegedly engaged in a similar pattern of conduct while fraudulently marketing Neurontin for each off-label indication, the dates of defendants' awareness of inefficacy, defendants' efforts to suppress negative studies, and defendants' affirmative marketing plans, varied considerably by indication. Now, the claims of the plaintiffs within each of the indication-specific subclasses share common issues of fact. Consequently, at least to the extent plaintiffs are alleging a fraudulent national advertising campaign which made affirmative misrepresentations and concealed known risks specific to an indication, the Court finds that the ten remaining indication-specific subclasses (five Consumer and five TPP) satisfy Rule 23's commonality requirement.

B. Numerosity

1. Initial Shortcomings

In Neurontin, the Court surmised that "[g]iven the low threshold for numerosity and the high number of off-label prescriptions," and the fact that "by 2003 Neurontin was the tenth most commonly-prescribed drug in the United States," Rule 23(a)(1)'s numerosity requirement would pose no barrier to class

certification.⁴ Neurontin, 244 F.R.D. at 106. Still, in light of the Court's holding that plaintiffs would be required to seek certification for indication-specific subclasses, the Court insisted that plaintiffs "submit a proffer that the number of consumer and TPP plaintiffs in each subclass is sufficiently large that joinder of all members would be impractical." Id.

2. Plaintiffs' Response

In their renewed motion, plaintiffs submitted a declaration from Dr. Rena Conti ("Dr. Conti"), a Ph.D. in Health Policy (Economics Track) from Harvard University and an instructor in Health Economics at the University of Chicago. (Decl. of Rena Conti ("Conti Decl."), Ex. E, Docket No. 1017.) After reviewing data from the IMS National Disease and Therapeutic Index (NDTI) and defendants' predictions of unique patient counts for Neurontin, Dr. Conti estimated that between January 1997 and December 2002, more than 350,000 individual consumers paid for at least a portion of the cost of a Neurontin prescription for each of the five indications. (Id. ¶ 53.)

⁴ Rule 23(a)(1) provides that class certification is only appropriate if "the class is so numerous that joinder of all members is impracticable."

Off-Label Condition	Estimated No. of Consumer Subclass Members from 1997 to 2002
Bipolar/Mood Disorders	1,189,189
Neuropathic Pain	2,283,907
Migraine/Headache	365,641
Nociceptive Pain	750,219
Doses > 1800 mg/day	786,236
Total	5,375,192

Because these figures do not include the entire proposed class period for any of the indications, they also necessarily underestimate the actual number of unique individuals who paid for a Neurontin prescription. (Id. ¶ 52.) Accordingly, plaintiffs' proffer regarding the number of potential plaintiffs is more than sufficient to satisfy Rule 23 for all five of the indication-specific Consumer subclasses.

Dr. Conti's analysis is equally persuasive that the number of TPPs in each indication-specific TPP subclass satisfies Rule 23(a)(1). Relying on an assumption that all TPP plans "cover[] a representative sample of the population," Dr. Conti then estimated the number of members necessary to assure with 99, 95, and 90 percent probability that a plan had at least one member who received a Neurontin prescription for a particular indication. (Id. ¶ 54.) At the 99 percent confidence interval, the migraine/headache condition required the largest minimum plan membership, 3,248 individuals; all of the other indications necessitated less than 1,600 members to ensure that at least one

individual in a plan received a Neurontin prescription for each off-label indication. (Id. ¶ 54 tbl. 2.) Dr. Conti then used publicly available data regarding the membership size of various categories of TPPs to calculate that approximately 13,070 TPPs paid for at least one Neurontin prescription to treat each of the off-label conditions.⁵ (Id. ¶ 55-58.)

Defendants take issue with Dr. Conti's assumption that the membership of each plan mirrors the composition of the general population. They argue that especially with Taft-Hartley Funds and self-insured employers, which on average are considerably smaller than commercial health plans, the demographics of a plan's membership can differ dramatically from the demographics of the entire American population. Such criticisms are certainly relevant to the class certification analysis, but speak more directly to the typicality and predominance requirements. Even if Dr. Conti's estimates are inflated by a factor of ten, plaintiffs have proffered sufficiently numerous TPP class members to justify certification. Although "numbers alone are not usually determinative" for the numerosity analysis, Andrews v. Bechtel Power Corp., 780 F.2d 124, 131 (1st Cir. 1985), the quantity and geographical diversity of the allegedly affected

⁵ As Dr. Conti notes, "[t]he actual number would be somewhat lower for migraine and higher for the more commonly used off-label indications (i.e., the pain categories as well as bipolar)" because Neurontin prescriptions for the pain categories and bipolar occurred at a greater frequency than for the other indications. (Id. ¶ 58.)

TPPs leaves no question that joinder in this case would be impracticable.

Consequently, because the Court is satisfied that joinder of all parties would not be practicable within each of the indication-specific Consumer and TPP subclasses, plaintiffs have now met their burden under Rule 23(a)(1).

C. Typicality

1. Initial Shortcomings

In Neurontin, the Court also found that, in light of plaintiffs' need to certify subclasses for each condition, the proposed class representatives selected by plaintiffs were not sufficiently typical to satisfy Rule 23(a)(3). The typicality requirement "is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals." In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 531 (3d Cir. 2004) (internal quotation marks omitted).

A claim is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members and her claims are based on the same legal theory. Even though some factual variations may not defeat typicality, the requirement is meant to ensure that the named representative's claims have the same essential characteristics as the claims of the class at large.

Arreola v. Godinez, 546 F.3d 788, 798 (7th Cir. 2008) (internal quotation marks omitted). Importantly, there is some overlap between typicality and predominance, particularly in cases, such

as this, where plaintiffs intend to demonstrate causation through common proof. See Motor Vehicles, 522 F.3d at 19 (citing Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 617 (1997); 6 Conte & Newberg, supra, § 18:8).

In Neurontin, the Court held that the two Consumer Subclass representatives put forward by plaintiffs -- Gerald Smith and Loraine Kopa -- who were both prescribed Neurontin for neuropathic pain and migraine, satisfied the typicality requirement for those two indications. However, because "[p]laintiffs . . . failed to demonstrate that [Kopa and Smith's] claims are typical of the claims of the members of the [remaining six indication-specific subclasses]," the Court required that plaintiffs propose additional Consumer subclass representatives. Neurontin, 244 F.R.D. at 107. The Court also insisted that because "the Complaint does not identify which off-label uses the proposed TPP representatives have paid for," that "[p]laintiffs must make a proffer that a proposed TPP representative for each [indication-specific] subclass likely paid for the off-label indication for that subclass. For large TPPs that reimburse for numerous Neurontin prescriptions, standing and typicality could be met by a statistical likelihood of payment for a specific indication." Id.

2. Plaintiffs' Response

To satisfy the Court's directive, plaintiffs proposed Consumer subclass representatives for the nociceptive pain,

bipolar/mood disorder, and doses in excess of 1800 mg per day subclasses. For the bipolar/mood disorder subclass, plaintiffs proposed Jan Frank Wityk ("Wityk") and Gary L. Varnam ("Varnam"). (Pls.' Renewed Mot. at 7-8.) For nociceptive and non-neuropathic pain, plaintiffs proposed Carolyn Hollaway ("Hollaway"). (Id. at 8.) And for doses in excess of 1800 mg per day, plaintiffs proposed Jeanne Ramsey ("Ramsey"). (Id.)

Defendants raise objections to each of these newly proposed class representatives. (Def's.' Opp'n to Pls.' Renewed Mot. at 34-35, Docket No. 1174.) They claim that Hollaway is not typical of the class she seeks to represent because she received Neurontin for treatment of nerve related pain, not for nociceptive pain. (Id. at 34.) They suggest that Varnam and Ramsey are not typical in that each took Neurontin for almost four years "never once expressing any reservation as to its effectiveness in treating their conditions." (Id.) Similarly, they question the typicality of Wityk's claims because she "informed her psychiatrist that Neurontin had provided her with significant benefits, and admits that she 'wouldn't have gone without' Neurontin over the more than two years that [she] remained on the medication." (Id. at 35.)

On the record before the Court, none of these variations undermines the typicality of the newly proposed class representatives. The class representatives meet the definition of their indication-specific subclass, paid for at least a

portion of a Neurontin prescription, and rely on the same general legal theory: that defendants' fraudulent marketing of Neurontin for treatment of these off-label indications caused them to pay for an ineffective product. Accordingly, the claims of the proposed Consumer subclass representatives for the nociceptive pain, bipolar/mood disorder, and doses in excess of 1800 mg per day subclasses are sufficiently typical to satisfy Rule 23(a)(3).

Plaintiffs have also demonstrated that the proposed TPP class representatives are typical. Dr. Conti calculated that two of the proposed TPP class representatives, BlueCross/BlueShield of Louisiana ("BCBSLA") and ASEA/AFSCME Local 52 Health Benefits Trust ("ASEA"), both had a greater than 99 percent likelihood of having paid for at least some portion of an off-label Neurontin prescription for each of the five indications at issue; as such, they are typical for all five of the indication-specific TPP subclasses. (Conti Decl. ¶59-60 & tbl. 3.) Plaintiffs' third TPP class representative, Harden Manufacturing Corporation ("Harden"), had a greater than 99 percent probability of paying some of the cost for a Neurontin prescription to treat neuropathic pain, and is thus also typical of that indication-specific subclass. (Id. ¶ 60 tbl.3)

D. Predominance

As expressed by the Court in Neurontin, the predominance requirement -- that "questions of law or fact common to class members predominate over any questions affecting only individual

members" of the class, Fed. R. Civ. P. 23(b)(3) -- posed the most substantial obstacle to class certification. Although neither RICO nor the New Jersey Consumer Fraud Act requires proof that an individual's reliance upon a defendant's material misrepresentation or omission resulted in injury, both statutes do mandate that a plaintiff show that the defendant's conduct was the proximate cause of the alleged injury. See Neurontin, 244 F.R.D. at 103 (cases cited). The initially proposed Consumer and TPP Subclasses faced different predominance problems; however, the Court's concerns with respect to both groups emanated from their ability to demonstrate by common proof that defendants' fraudulent marketing of Neurontin caused financial injury to all plaintiffs.

1. Consumer Subclass

- a. Initial Shortcomings

The initial proposed Consumer Subclass, which included all individuals who paid for an off-label Neurontin prescription, was fatally overbroad in that plaintiffs put forward no mechanism for "determin[ing] which consumer class members' Neurontin prescriptions were caused by defendants' alleged fraud -- and who therefore have a cognizable injury -- and which would have occurred even in the absence of fraud." Id. at 111-12 (emphasis in original); see also id. at 113. The degree of difficulty in proving causation and injury was magnified by a number of factors. First, the evidence of whether the fraudulent marketing

resulted in a plaintiff's receipt of an off-label prescription for Neurontin rests primarily in the minds of the prescribing doctors, not with the plaintiffs themselves. Second, the questions that would need to be answered with respect to each doctor -- was he or she ever exposed to any fraudulent off-label marketing regarding Neurontin? did the marketing play any role in his or her decision to prescribe Neurontin to a particular plaintiff? -- seemingly defied proof by any common means.

Recognizing this difficulty, plaintiffs represented to the Court that a yet-to-be-produced econometric analysis designed by Professor Meredith Rosenthal ("Professor Rosenthal") -- incorporating voluminous data regarding defendants' off-label marketing practices, Neurontin's price and the price of its competitor drugs, and other market conditions -- would be able to identify the number of prescriptions that likely resulted from the alleged fraud. Accepting the general reliability of econometric regression analysis, the Court held that "Professor Rosenthal's proposed methodology is a plausible way of determining aggregate class-wide liability." Id. at 111 (emphasis added).

Determining the total number of prescriptions likely caused by defendants' alleged fraudulent conduct, however, would satisfy only half of plaintiffs' burden. Cf. McLaughlin v. Am. Tobacco Co., 522 F.3d 215, 223 (2d Cir. 2008) ("But proof of misrepresentation -- even widespread and uniform

misrepresentation -- only satisfies half of the equation; the other half, reliance on the misrepresentation, cannot be the subject of general proof."). The Court explained that

[w]hile Dr. Rosenthal may be able to statistically determine on a national basis that the majority of prescriptions were written as a result of fraudulent marketing activity, there is no way of identifying which doctors prescribed Neurontin based on this promotion as opposed to lawful off-label prescribing by a doctor who is exercising his own medical judgment.

Neurontin, 244 F.R.D. at 113.

If Dr. Rosenthal's model would show that some quantity of off-label prescriptions for each indication was not caused by defendants' fraudulent marketing, the fact-finder would be required to conduct inquiries to identify which prescriptions were the result of fraud and which were not. Simply put, "[h]ere, there is no way to identify injured class members . . . [and] to establish causation and injury the plaintiffs would need to conduct inquiries into the prescribing decisions of each class member's physician." Id. at 114. Certifying the initial overbroad class would have resulted in the "torrent of individual trials," id., that Rule 23(b) (3) is designed to avoid.

Despite the seemingly insurmountable barrier these individualized inquiries posed to certification of the Consumer Subclass, the Court held that defendants "should not get off scot-free if there is a practical statistical way to address the difficult causation issues." Id. The Court concluded that if, within a given indication-specific subclass, a statistical

analysis could show that essentially all of the prescriptions written for plaintiffs were the result of the alleged fraud, then individualized inquiries would be unnecessary and the predominance requirement would be satisfied. In other words, if Dr. Rosenthal's model could demonstrate that "only a de minimis number of doctors prescribed Neurontin for an off-label condition, and then off-label prescriptions skyrocketed after a fraudulent campaign for that indication (i.e., migraines or bipolar), the Court will consider statistical proof as sufficient to demonstrate that most purchasers in that period were injured." Id.

In crafting the de minimis standard, the Court relied primarily on price inflation consumer fraud cases in which courts allowed plaintiffs to use aggregate, statistical proof to establish classwide causation. Id. 113-14 (citing In re Synthroid Mktg. Litig., 188 F.R.D. 295 (N.D. Ill. 1999); Schwab v. Phillip Morris USA, Inc., 449 F. Supp. 2d 992 (E.D.N.Y. 2006) rev'd sub nom. McLaughlin, 522 F.3d 215, 223 (2d Cir. 2008); In re Zyprexa Prods. Liability Litig., 493 F. Supp. 2d 571 (E.D.N.Y. 2007) (hereinafter Zyprexa); Aspinall v. Philip Morris Cos., 442 Mass. 381 (Mass. 2004)). The cases upon which the Court constructed the de minimis standard all had one characteristic in common; every member of the putative classes was necessarily injured because defendants' alleged fraudulent marketing caused an increase in a product's price, meaning everyone who purchased

the product paid too much.

Some of these cases also borrowed, implicitly and explicitly, from the "fraud-on-the-market" theory adopted by a plurality of the Supreme Court in Basic, Inc. v. Levinson, 485 U.S. 224 (1988). See Schwab, 449 F. Supp. 2d at 1115-17 (recognizing that Basic is "neither binding in this case, nor identical in reasoning," but holding that "[s]uch a presumption may be appropriate in the present case"); Zyprexa, 493 F. Supp. 2d at 579 (relying heavily on the portions of Schwab that spoke to Basic's fraud-on-the-market presumption). When analyzing class certification in a case of alleged fraud perpetrated on an efficient securities market, the fraud-on-the-market theory "obviates the need for a plaintiff to demonstrate individualized reliance on a defendant's misstatement by permitting a class-wide rebuttable presumption of reliance, thereby enabling a securities fraud class action to meet Rule 23(b)(3)'s commonality requirement." In re PolyMedica Corp. Secs. Litig., 432 F.3d 1, 3 (1st Cir. 2005) (hereinafter PolyMedica). The critical leap in the fraud-on-the-market theory is from market efficiency to a presumption of classwide reliance and injury. Because an asset's price in an "open and developed securities market" is

determined by the available material information regarding the company and its business[,] . . . [m]isleading statements will therefore defraud purchasers of stock even if the purchasers do not directly rely on the misstatements. . . . The causal connection between the defendants' fraud and the plaintiffs' purchase of stock in such a case is no less

significant than in a case of direct reliance on misrepresentations.

Basic, 485 U.S. at 241-42. The efficiency of the market, which internalizes the misrepresentation into the price of the asset, creates the presumption that everyone who purchased a share of stock both indirectly relied upon and was injured by the misrepresentation. PolyMedica, 432 F.3d at 7-8.

Of course, the instant suit does not involve price inflation or an efficient market. On the facts alleged by the plaintiffs, the Court could not simply presume that defendants' fraudulent conduct caused all the off-label Neurontin prescriptions. What plaintiffs requested, and what the Court permitted in Neurontin, is that plaintiffs be provided with an opportunity to show, through well-established statistical methods (i.e., Professor Rosenthal's report), that defendants' fraudulent marketing of off-label Neurontin so distorted the information in the medical marketplace that all (or nearly all) doctors who chose to prescribe Neurontin off-label were affected by defendants' fraud. In Neurontin, the Court held that if Professor Rosenthal's model could accomplish that difficult task, plaintiffs would be entitled to a presumption of causation to satisfy Rule 23's predominance requirement.

b. Developments in the Law Since August 2007

A quartet of cases decided after August 2007 has led the court to reconsider permitting the use of statistical evidence to

establish a classwide presumption of causation. First, the New Jersey Supreme Court's decision in International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc., 192 N.J. 372 (2007) (hereinafter Vioxx), forecloses the instant plaintiffs' motion to certify indication-specific Consumer subclasses under the New Jersey Consumer Fraud Act. In that case, a class of TPP plaintiffs suing under the NJCFA alleged that the defendant-pharmaceutical company's fraudulent marketing of Vioxx resulted in an increased price for the drug and its placement on TPPs' preferred status lists. Although the New Jersey Supreme Court admitted that common issues of fact permeated "defendant's marketing plan[,] withholding of adverse information, . . . the FDA warning letters [Merck received regarding Vioxx's safety, and] the drug's eventual withdrawal from the market," id. at 388, the court held that individual inquiries relating to why particular TPPs treated Vioxx in a particular manner overwhelmed questions common to the class. The court stated that

plaintiff does not suggest that each of these proposed class members, receiving the same information from defendant, reacted in a uniform or even similar manner. Rather, the record speaks loudly in its demonstration that each [proposed plaintiff] . . . made individualized decisions concerning the benefits that would be available to its members for whom Vioxx was prescribed.

Id. at 390-91. Although this holding addresses TPP plaintiffs and not consumers or doctors, its ramifications for the instant

case should be immediately apparent. Where plaintiffs (or plaintiffs' doctors) react differently to a misrepresentation, a presumption of reliance cannot be utilized to satisfy the predominance requirement under the NJCFA.

Further, even, the court squarely rebuffed plaintiffs' attempt to utilize statistical evidence to establish a presumption of causation in the consumer fraud context. The court explained that "[t]o the extent that plaintiff seeks . . . to be relieved [by the use of statistical evidence] of the usual requirement that plaintiff prove [causation], the theory must fail." Id. at 392. The Court continued stating that:

[t]o the extent that plaintiff intends to rely on a single expert to establish [causation] in place of a demonstration of an ascertainable loss or in place of proof of a causal nexus between defendant's acts and the claimed damages, . . . plaintiff's proofs would fail. That proof theory would indeed be the equivalent of fraud on the market, a theory we have not extended to CFA claims.

Vioxx, 192 N.J. at 392. Because Vioxx precludes NJCFA plaintiffs from establishing causation through a report from a single expert, and the instant plaintiffs seek to do exactly that, the Court must **DENY** plaintiffs' motion to certify all the indication-specific Consumer subclasses under the NJCFA.

Recent decisions handed down by federal courts are equally problematic for plaintiffs' proposed method for establishing classwide causation for the remaining RICO claims. Most influential among these is McLaughlin v. American Tobacco Co.,

522 F.3d 215 (2d Cir. 2008), in which the Second Circuit reversed Judge Weinstein's certification of a nationwide class of individuals who smoked "Light" cigarettes in Schwab, 449 F. Supp. 2d at 992. The McLaughlin plaintiffs' claimed "that defendants' implicit representation that Lights were healthier led them to buy Lights in greater quantity than they otherwise would have and at an artificially high price, resulting in plaintiffs' overpayment for cigarettes." Id. at 220. Although the injury alleged by the plaintiffs differed from the case at bar, the McLaughlin plaintiffs' theory of causation was nearly identical to the theory put forward by the instant plaintiffs. Invoking the "fraud-on-the-market" theory, they suggested that "that defendants distorted the body of public information and that, in purchasing Lights, plaintiffs relied upon the public's general sense that Lights were healthier than full-flavored cigarettes, whether or not individual plaintiffs were actually aware of defendants' alleged misrepresentation." Id. at 223-24. As here, plaintiffs also argued that "they should be entitled to a presumption of reliance" Id. at 225. Plaintiffs even put forward statistical evidence from an expert purportedly demonstrating that "90.1% of those who smoked Lights chose to do so because of Lights' alleged health benefits." Id. at 225 n.6.

Despite the fact that the packaging of every "Light" cigarette contained, at the very least, an implicit representation that "Light" cigarettes were healthier than normal

cigarettes, the McLaughlin court rejected plaintiffs' motion for class certification. The court concluded that

[i]ndividualized proof [was] needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative -- for example, if a Lights smoker was unaware of that representation, preferred the taste Lights, or chose Lights as an expression of personal style.

Id. at 223; see also id. at 225 ("[E]ach plaintiff in this case could have elected to purchase light cigarettes for any number of reasons, including a preference for the taste and a feeling that smoking Lights was 'cool.' "). Consequently, because litigation of the class' claims would unavoidably involve an inquiry into each plaintiff's motivation for purchasing Light cigarettes, the court found that plaintiffs failed to satisfy the predominance requirement.

The Eighth Circuit reached a similar result in In re St. Jude Medical Inc. Silzone Heart Valve Products Litigation, 522 F.3d 836 (8th Cir. 2008) (hereinafter St. Jude). Faced with a motion for class certification by a group of plaintiffs who were implanted with an unsafe heart valve, the court found that individualized questions, regarding whether patients or their doctors had ever been exposed to misrepresentations about the faulty medical device, would overwhelm issues common to the class. Even assuming that under Minnesota's consumer fraud statute the plaintiffs did not need to present direct evidence of reliance upon misleading statements, the court found that it

could not

prohibit St. Jude from presenting direct evidence that an individual plaintiff (or his or her physician) did not rely on representations from St. Jude. When such evidence is available, then it is highly relevant and probative on the question whether there is a causal nexus between alleged misrepresentations and any injury.

Id. at 840 (emphasis in original). Such a conclusion was especially warranted where the defendants had discovered evidence that many of named class representatives and their doctors had never been exposed to any misrepresentations about the device.

Id. at 839. As a result, the court concluded that class certification was inappropriate.

Finally, in In re TJX Cos. Retail Security Breach Litigation, a negligent misrepresentation case brought by credit card issuers against data security companies, Judge Young of this Court held that where reliance is an element of a claim, a presumption of reliance is never appropriate because "[p]roving the element of reliance will necessarily involve individual questions of fact." 246 F.R.D. 389, 395 (D. Mass. 2008) (hereinafter TJX); see also id. (" 'A fraud class action cannot be certified when individual reliance will be an issue.' " (quoting Castano v. Am. Tobacco Co., 84 F.3d 734, 745 (5th Cir. 1996))). Of particular relevance to the case at bar, Judge Young found that, given the evidence before the court,

[e]ven if reliance could, in some situations, be demonstrated for the class as a whole via circumstantial evidence, doing so would not be

appropriate here. . . . [Defendants] would have the right to introduce . . . evidence [that plaintiffs had not relied on misrepresentations] at trial in order to rebut the [plaintiffs'] assertion of reliance, creating precisely the type of "individualized evidentiary issue [that is] a persuasive reason for denying certification."

Id. at 396 (quoting Mowbray v. Waste Mgmt. Holdings, Inc., 189 F.R.D. 194, 198 (D. Mass. 1999)).⁶

These cases collectively stand for at least two propositions critical to the instant plaintiffs' motion. First, they reinforce the Court's conclusion in Neurontin that, if plaintiffs cannot prove classwide causation through Professor Rosenthal's report, all of the indication-specific Consumer subclasses will be unable to satisfy the predominance requirement. The McLaughlin, St. Jude, and TJX courts were unwilling to deny defendants an opportunity to present evidence that their alleged fraud did not cause a particular plaintiff's injury. As such, in all three cases, individual questions relating to exposure and causation predominated over questions common to the class as a whole. And as a result, Rule 23(b)(3) certification was not appropriate. McLaughlin is particularly compelling on this

⁶ Common law misrepresentation claims, like those at issue in TJX, require that a plaintiff prove reliance as an element of his or her prima facie case, TJX, 246 F.R.D. at 395, whereas a RICO claim requires only proof of a causal nexus between a misrepresentation and a plaintiff's injury. Judge Young's TJX opinion is useful to the case at bar, however, because it speaks to a defendant's right to present individualized evidence of the lack of reliance/causation. Further, as a practical matter, plaintiffs cannot prove causation in this case without demonstrating reliance.

point. Not only did McLaughlin reverse Schwab, a case upon which this Court relied heavily in fashioning the de minimis standard, see Neurontin, 244 F.R.D. 113-14, but McLaughlin's holding underlines the potential problems of granting class certification in the instant case. In McLaughlin, even though every single plaintiff in the class of smokers was exposed to the defendant's fraudulent misrepresentations, the court still required that the plaintiffs demonstrate, on an individual basis, that the misrepresentation caused the plaintiffs' injuries. To allow the instant plaintiffs to proceed as a class without a presumption of causation, when serious questions remain regarding individual doctors' exposure to defendants' misrepresentations and the causal nexus between those misrepresentations and plaintiffs' injuries, would inevitably result in individual issues predominating over common questions.

Second, the cases discussed above highlight courts' general unwillingness to permit a presumption of reliance/causation in consumer fraud cases. McLaughlin, 522 F.3d at 225 ("We do not think that the Basic presumption, or the district court's variation of it, applies in this case; we cannot assume that, regardless of whether individual smokers were aware of defendants' misrepresentation, the market at large internalized the misrepresentation to such an extent that all plaintiffs can be said to have relied on it."); TJX, 246 F.R.D. at 395-96; Vioxx, 192 N.J. at 392 (rejecting the fraud-on-the-market theory

"as being inappropriate in any context other than federal securities fraud litigation").⁷ That courts have been uniformly hostile to attempts to extend the fraud-on-the-market theory to consumer fraud cases is not a new development in the case law. See e.g., Securities Investor Prot. Corp. v. BDO Seidman, LLP, 222 F.3d 63, 73 (2d Cir. 2000) (holding fraud-on-the-market, "[t]o the extent that the federal courts have adopted this concept . . . has applied only in the context of the federal securities law" (citing Arthur Young & Co. v. United States District Court, 549 F.2d 686, 695 (9th Cir. 1977)); Prophias v. Pfizer, Inc., 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 380 (D.N.J. 2004); Mishkin v. Peat, Marwick, Mitchell & Co., 658 F. Supp. 271, 274-75 (S.D.N.Y. 1987)). Nonetheless, the more recent cases discussed above, with highly analogous facts, collectively make the Court leery of permitting plaintiffs the benefit of a presumption of causation even with a remarkably strong statistical showing.

Further complicating plaintiffs' task, the First Circuit's 2008 decision in In re New Motor Vehicles Canadian Export

⁷ Judge Weinstein, in an opinion published after McLaughlin, permitted a presumption of exposure and reliance akin to the fraud-on-the-market theory in a pharmaceutical price inflation case. In re Zyprexa Prods. Liability Litig., 253 F.R.D. 69, 195 (E.D.N.Y. 2008). As the instant case does not involve price inflation, that opinion has no direct bearing on the Court's decision.

Antitrust Litigation, 522 F.3d 6 (1st Cir. 2008), mandates that this Court closely scrutinize the methodology and conclusions of Professor Rosenthal's report. Prior to Motor Vehicles, this Court previously held that resolution of "technical disputes," like those presented by Professor Rosenthal's report, should generally be resolved at a Daubert hearing, as opposed to at the class certification stage. In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 90 (D. Mass. 2005). Thus, the Court could have certified the class after conducting a preliminary review of Professor Rosenthal's results. Under Motor Vehicles, however, when evaluating a motion to certify a class, it is incumbent on the "the district court . . . [to] engage in a searching inquiry into the viability of [a novel or complex theory as to injury] and the existence of the facts necessary for the theory to succeed." 522 F.3d at 26; see also id. ("Such reliance on a novel theory to establish a primary element of a claim necessitates a more searching inquiry into whether plaintiffs will be able to prove the pivotal elements of their theory at trial. This is especially so when a case implicates the sort of factors that we have deemed important in the Rule 23(f) calculus, namely, when the granting of class status 'raises the stakes of litigation so substantially that the defendant likely will feel irresistible pressure to settle.' ") (quoting Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 293 (1st Cir. 2000)).

Plaintiffs' theory is nothing if not novel; they ask the Court to permit a statistical analysis to function as common proof of causation for millions of disparate and varied human interactions that resulted in off-label prescriptions for Neurontin. Consequently, it is incumbent on the Court to look closely at how Professor Rosenthal arrived at her conclusions and to determine if the evidence already produced in this case supports her methodology and findings.

With these developments in the law in mind, the Court moves on to examine Professor Rosenthal's report and whether it can operate as common proof of causation for plaintiffs' RICO claims. As the following discussion indicates, the Court is not convinced that Professor Rosenthal's statistical findings are sufficient to certify any of the indication-specific Consumer subclasses.

2. Plaintiffs' Response -- The Rosenthal Report

a. Rosenthal Report Findings

Professor Rosenthal's completed report, submitted on September 9, 2008, quantifies the effect of defendants' promotion of off-label prescriptions for Neurontin for each of the five indication-specific Consumer subclasses with which plaintiffs chose to proceed. (Decl. of Meredith Rosenthal ("Rosenthal Report") at 1, Ex. A, Docket No. 1427.) In addition, because Neurontin prescriptions to treat neuropathic and nociceptive pain were written by neurologists, who prescribed Neurontin for on-label use as an anti-epileptic drug, as well as by doctors from

other specialties, Professor Rosenthal further subdivided her analysis of off-label prescriptions for those indications by type of doctor. (Id. ¶ 26.) Professor Rosenthal then compared the actual data for the number of prescriptions written for each indication to results generated in a “but-for” model, in which defendants did not engage in any off-label marketing. (Id. ¶ 47.) From this comparison, Professor Rosenthal drew conclusions about the number of off-label Neurontin prescriptions that were caused by defendants’ “unlawful marketing efforts.” (Id. ¶ 31.) The following chart summarizes the results of Professor Rosenthal’s analysis.

Indication	Class Period	Fraudulent Prescriptions	Total Prescriptions	Percent of Fraudulent to Actual Prescriptions
Bipolar	11/95-	11,710,680	11,781,368	99.40%
Migraine	9/95-12/04	679,075	2,433,961	27.90%
Neuropathic Pain	7/95-12/04	20,775,262	29,709,354	69.93%
Neurologist		2,989,865	11,911,813	25.10%
Other Specialities		6,060,055	6,072,199	99.80%
PHN Speciality		11,725,342	11,725,342	100.00%
Nociceptive Pain	9/95-12/04	8,103,213	9,557,188	84.79%
(All)				
Neurologist		710,787	2,160,447	32.90%
Other Specialities		2,153,170	2,157,485	99.80%
PHN Speciality		5,239,256	5,239,256	100.00%
Doses > 1800 mg/day	3/95-12/04	2,147,674	5,727,131	37.50%

Total		43,415,904	59,209,001	73.33%
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(Id., attach. G.)⁸

Before the Court addresses defendants' challenges to Professor Rosenthal's methodology, a few conclusions are immediately apparent. First, the percentage of fraudulent Neurontin prescriptions written for migraines (27.90 percent), for doses greater than 1800 milligrams per day (37.50 percent), and for neuropathic (25.10 percent) and nociceptive pain (32.90 percent), by neurologists, falls short of demonstrating that defendant's off-label promotion caused all but a de minimis number of off-label prescriptions. In Professor Rosenthal's model, an individual prescription for any of these indications written by the specified type of doctor has no greater than a 50 percent (and in some cases much lower) likelihood that it was caused, directly or indirectly, by defendants' fraudulent marketing. As such, individual inquiries into why a doctor prescribed Neurontin off-label would plainly be required, and common issues would not predominate under Rule 23(b)(3). For those indication-specific Consumer subclasses, the Court denies the motion for class certification.

⁸ Attachment G to the Rosenthal Report does not include the column in the above chart entitled "Total Prescriptions" or the Percent of Fraudulent Actual Prescriptions for all indications (the lower right cell of the chart). The Court extrapolated the information for the "Total Prescription" column using the following equation: [Total Prescriptions] = [Fraudulent Prescriptions] / ([Percent of Fraudulent Actual Prescriptions] / 100).

The motion for class certification with respect to all neuropathic and nociceptive pain Consumer plaintiffs is a closer question. Non-neurologist prescriptions written for those conditions satisfy the Court's de minimis standard, but only if the subclass definitions are modified to delineate by condition and the specialty of the potential class member's physician, as done in the chart above. According to Professor Rosenthal's analysis, virtually 100 percent of Neurontin prescriptions written by non-neurologists for the treatment of neuropathic pain and nociceptive pain, respectively, were caused by defendants' off-label marketing.

The bipolar and mood disorder subclass is another indication for which Professor Rosenthal's model shows the type causal nexus between defendants' off-label marketing efforts and the increase in Neurontin prescriptions that could support a conclusion that a fraud had been perpetrated on the entire prescription market. According to Professor Rosenthal's report, 99.4 percent of Neurontin prescriptions written by psychiatrists for bipolar disorder were the direct or indirect result of defendants' unlawful marketing. In other words, absent defendants' fraudulent off-label promotion, only 0.6 percent of the Neurontin prescriptions given to patients with bipolar/mood disorders would have been written.

Because essentially all of the Neurontin prescriptions for these indications were, according to Professor Rosenthal's model,

the result of fraudulent promotion, plaintiffs' claims for the indications would not require an individual inquiry into why a particular prescription was written.

b. Rosenthal Report Methodology

Class certification of these subclasses would only be appropriate if Professor Rosenthal's methodology can withstand close scrutiny. At this juncture, it is important to reiterate that Professor Rosenthal's model must show that defendants' fraudulent marketing, not simply their off-label marketing, caused the prescriptions written for the putative class members.

Professor Rosenthal's model addresses the unsurprising hypothesis that "promotional expenditures will increase prescribing of Neurontin." (Id. ¶ 35.) It takes into account four primary variables: the retail price of Neurontin, the retail price of Neurontin's competitor drugs within a given indication, the amount of spending by defendants to promote Neurontin with respect to a particular specialty, and the amount of spending by Neurontin's competitors to promote their drugs for that same specialty. (Id. ¶ 34.) Of these factors, the promotion variable is by far the most important, as it is the only factor that purports to capture the extent of defendants' fraudulent conduct. Within the model, the promotion variable is equal to the sum of the spending by defendants on (1) detailing (i.e., sending paid representatives to doctors' offices to discuss uses for a particular drug and deliver samples) and (2) professional journal

advertising, and excludes all other expenses defendants may have incurred in marketing Neurontin for off-label use. (Id. ¶ 36.) She views expenditures on detailing as the "key explanatory variable" in a doctor's decision to prescribe Neurontin. (Id. ¶¶ 24, 33.)

As such, expenditures on detailing are the primary drivers of the methodology. Professor Rosenthal's model relies on the amount spent on detailing to physician groups that ordinarily do not prescribe Neurontin for its approved uses to measure the impact of defendants' fraudulent off-label marketing campaigns. Professor Rosenthal has assumed on instruction of counsel that all detailing during the class period was both off-label and fraudulent. (Id. ¶¶ 46, 47, attachs. I.1, I.4.) She explains that "[b]ecause of the limits in [her] data, [she is] unable to account systematically" for the influence that the "manipulation of the published literature to which physicians look for impartial information" had on prescribing. (Id. ¶ 53.) As such, she views her numbers as "conservative." (Id.) Plaintiffs argue: "All such detailing was necessarily fraudulent, because it promoted Neurontin's use for indications for which it had either been proven ineffective or for which there was no scientific evidence of efficacy." (Pls.' Resp. to Defs.' Suppl. Opp'n at 5 n.7, Docket No. 1453.) The core assumption in the Rosenthal model is that off-label prescriptions caused by detailing expenditures were necessarily caused by a fraud, that is, that

off-label promotion was the same as fraudulent promotion. As Madison Avenue would have predicted, Professor Rosenthal finds a strong correlation between expenditures on Neurontin promotion and the number of prescriptions written for the drug.

While in the aggregate Professor Rosenthal's report has some surface appeal, the record in this case demonstrates why the use of spending on fraudulent off-label detailing as a means to ascertain the number of prescriptions subject to the fraud is flawed. Significantly, the testimony of the prescribing physicians for the bipolar/mood disorder, nociceptive pain (non-neurologist), and neuropathic pain (non-neurologist) subclass representatives indicates that only one of them, Dr. Gregory A. Rogers, was ever detailed by defendants about Neurontin. (See Dep. of Gregory A. Rogers ("Rogers Dep."), at 95, Ex. 12, Docket No. 1175 (stating Dr. Rogers, family doctor for nociceptive and non-neuropathic pain subclass representative Hollaway, was certain he had been detailed by defendants about Neurontin); Dep. of Jerrold Gray ("Gray Dep."), Ex. 14, Docket No. 1175 (containing no evidence that Dr. Gray, the primary care physician for bipolar/mood disorder class representative Wityk, was ever detailed by defendants about Neurontin); Dep. of John Arness ("Arness Dep."), at 65-66, Ex. 18, Docket No. 1175 (containing affirmative testimony from Dr. Arness, the only psychiatrist who treated bipolar/mood disorder class representative Varnam and who was deposed, that he was never detailed by defendants about

Neurontin and never requested information from defendants about Neurontin); Dep. of Thaddeus Poe ("Poe Dep."), Ex. 4, Docket No. 1175 (containing no evidence that Dr. Poe, family doctor for neuropathic pain subclass representative Smith, was ever detailed by defendants about Neurontin (or ever prescribed Neurontin for Smith).) And Dr. Rogers testified that all of the Neurontin detailing of his office was with respect to on-label uses for the drug. (Rogers Dep. at 95.) Because of the absence of evidence of detailing of the doctors at issue in this case, the requirement that plaintiffs establish a nexus between the doctor and the sales team will create individualized issues that will inevitably predominate over the common questions.

Even if this hurdle could be overcome, Professor Rosenthal's analysis does not take into account any other factors that may have led doctors' to prescribe Neurontin for off-label indications. The deposition testimony of the doctors for the bipolar/mood disorder class representatives shows that their decisions to prescribe Neurontin resulted from a wide variety of influences unrelated to the three components of defendants' alleged fraud. Dr. Gray, primary care physician for bipolar/mood disorder class representative Wityk, testified that the main reason he prescribed Neurontin for Wityk was that Wityk's prior physician had prescribed Neurontin and Wityk was unwilling to change medication. (Gray Dep. at 50; see also id. at 101-102 (explaining that Wityk ceased taking Neurontin for a four or five

month period of time because she could no longer afford it with her insurance coverage).) Dr. Arness, psychiatrist for bipolar/mood disorder class representative Varnam, testified that he prescribed Neurontin because of information he had learned about Neurontin from fellow doctors, because of his personal experience in successfully using the drug with other patients, because anticonvulsants like Neurontin were "widely known and widely accepted as a treatment for bipolar disorder," and because Neurontin had a relatively benign set of side effects. (Arness Dep. at 23-25, 62-64.)⁹

Finally, Professor Rosenthal, at the instruction of plaintiffs's counsel, assumes that all detailing to specialists other than neurologists was both off-label and fraudulent. (Rosenthal Report ¶¶ 46, 47.) To be certain, this assumption has

⁹ The evidence regarding Neurontin prescriptions written by non-neurologists for subclass representatives suffering from neuropathic and nociceptive pain also fails to comport with Professor Rosenthal's assumptions. Dr. Poe, physician for neuropathic pain subclass representative Smith, never prescribed Neurontin to Smith; rather, Smith's Neurontin prescriptions were written by Dr. Kylene Huler, a neurologist to whom Smith was referred. (See Poe Dep. at 29-36.) Although Dr. Rogers, family doctor for nociceptive pain subclass representative Holloway, was detailed regarding Neurontin (for on-label uses only), he began prescribing Neurontin to treat neuropathic pain before he was ever detailed by defendants regarding Neurontin. (Rogers Dep. at 95, 97.) Rather than being motivated by detailing, Dr. Rogers states that the primary reason he prescribed Neurontin to treat neuropathic pain in patients was his own experience witnessing the drug's efficacy. (Id. at 35.) His treatment of Holloway supports his statement; when after two prescriptions cycles, Neurontin did not appear to reduce Holloway's pain, Dr. Rogers stopped prescribing the drug for her. (Id. at 61-65.)

validity, especially as it might apply to the bipolar/mood disorder subclass. Evidence produced by plaintiffs indicates that defendants, at least by 1995, were aware that Neurontin (1) was no better than a placebo in treating bipolar/mood disorder and (2) was connected with an increased risk of depression and suicide. Plaintiffs assert that "the fraudulent marketing of Neurontin for bipolar disorder represents the most serious claim by the Plaintiffs and the most egregious breach of ethical conduct by Defendants." (Pls.' Mot. for Leave to File Suppl. Expert Reports at 6, Docket No. 1503.) It is a short leap from that evidence to a reasonable conclusion that no plausible, non-fraudulent reason existed for defendants to detail psychiatrists.¹⁰ Moreover, it is reasonable to infer that information about depression and suicidal side effects was material to a psychiatrist's decision-making about which drug to prescribe. However, many doctors were not detailed, and even if they were, the plaintiffs would have to demonstrate doctor-by-doctor that defendants' fraudulent misrepresentations or omissions during the off-label promotion caused the doctor to prescribe the medication. The model, while persuasive in the aggregate, cannot provide a shortcut for the indication-specific

¹⁰ Because non-neurologists could be detailed for a variety of off-label uses of Neurontin, such as for migraines, the assumption that all detailing of non-neurologists was fraudulent with respect to neuropathic and nociceptive pain cannot be drawn as readily.

Consumer subclasses.

Given the limitations in Professor Rosenthal's analysis, her report does not suffice to defeat the predominance challenge. As is discussed above, without this statistical proof to support a presumption of causation, plaintiffs cannot meet Rule 23(b)(3)'s predominance requirement. Consequently, the Court must also deny plaintiffs' motion to certify the bipolar/mood disorder consumer subclass, and the non-neurologist nociceptive and neuropathic pain Consumer subclasses.

3. Third Party Payors

a. Initial Shortcomings

In Neurontin, the Court indicated that "[a] different problem in manageability exists for TPPs which reimburse for Neurontin" 244 F.R.D. at 114. Because many of the TPPs are quite large, covering more than one million individuals, the Court held, as a hypothetical matter, that "[i]f Dr. Rosenthal has an accurate methodology for calculating that, say, 85% of all Neurontin prescriptions for migraines resulted from a fraudulent marketing campaign, it seems reasonable for a TPP to allege that 85% of its reimbursements for that indication were a result of the fraud." Id. Such would not be the case, however, "if TPPs are unable to distinguish between payments for on- and off-label prescriptions, or among the indications." Id. Due to insufficiencies in the record, it was "unclear" if causation and injury with respect to the TPPs could be "resolved

statistically.” Id.

b. Plaintiffs’ Response

As is addressed in the Court’s discussion of numerosity, the plaintiffs have put forward sufficient evidence to support a conclusion that all or nearly all of the members of the proposed indication-specific TPP subclasses paid for at least one off-label Neurontin prescription. But as with the indication-specific Consumer subclasses, such a showing does not, by itself, demonstrate that common issues predominate with respect to the claims of the TPPs. To prevail on the merits, the TPPs must prove that defendants’ fraud caused the off-label Neurontin prescriptions for which the TPPs paid. If, in the process of establishing causation, individualized issues would overwhelm common questions, certification under Rule 23(b)(3) would be inappropriate.

To begin with, certification of the TPPs’ claims under the NJCFA is prohibited by Vioxx. As in Vioxx, plaintiffs here seek to use a single causation expert in the place of presenting individualized proof of causation. Vioxx, 192 N.J. at 392. The New Jersey Supreme Court held unequivocally that such a showing cannot satisfy the New Jersey predominance requirement, which parallels the federal rule.

Further, though Professor Rosenthal’s report provides reliable proof that a certain percentage off-label prescriptions for Neurontin reimbursed by the TPPs was caused by defendants’

promotion for certain indications, differences among TPPs would still necessitate individualized inquiries into whether defendants' alleged fraudulent marketing caused each TPP any economic damages. See generally Decl. of Gregory K. Bell ("Bell Decl."), Ex. 35, Docket No. 1175; see also Vioxx, 192 N.J. at 378-381 (discussing the complexities inherent in how different TPPs approve the use and reimbursement for a particular pharmaceutical).

As documented in the Declaration of Dr. Gregory Bell, TPPs exhibit a great degree of heterogeneity. Most critical to the instant analysis are differences between TPPs with respect to how they approved and reimbursed off-label Neurontin prescriptions for their members. Most TPPs, 89 percent according to a 2000 study, use complex schedules, called formularies, to define "(1) which drugs are covered; (2) guidelines and restrictions on prescribing and use; (3) the number of tiers in the formulary; (4) the placement of particular drugs in preferred or nonpreferred positions on the formulary; and (5) patient cost-sharing provisions [i.e., copays]." (Bell Decl. ¶ 53.) Some formularies require prior authorization before a particular drug can be prescribed; others require that a drug can only be dispensed for a particular indication ("use limits"), by a particular type of doctor ("specialty limits"), in a limited amount ("quantity limits"), or after other drugs have been tried and found unsatisfactory ("step therapy"). (Id. ¶ 54.) Some

TPPs produce their own formularies, while others, typically smaller TPPs, purchase formularies from other TPPs or from independent companies known as pharmaceutical benefit managers ("PBMs"). Alterations to any of the formulary's characteristics can dramatically change the amount that a TPP and its members pay for drugs and influence the prescribing decisions of the members' doctors.

The formularies themselves are typically generated by Pharmaceutical and Therapeutics ("P & T") Committees, small working groups housed within a TPP or PBM. P & T Committees are usually comprised of independent physicians from various medical specialities, clinical pharmacists, a medical director, and a representative of the quality assurance department of the entity creating the formulary. (Id. ¶ 49.) According to Dr. Bell, before deciding how to treat a pharmaceutical in a formulary, "[t]hese committees review a variety of types of information in evaluating a drug, including the FDA-approved label, clinical trials, randomized control studies, uncontrolled studies, other clinical literature, and the TPP's own experience with how patients respond to a drug in the real world" (Id.)

Within this context, formularies classified the off-label use of Neurontin for the indications at issue in this case in many different ways. According to Dr. Bell, by 2000, "approximately 30 percent of covered lives were under plans that excluded coverage for off-label prescriptions." (Id. ¶ 57.)

Those TPPs and PBMs that agreed to reimburse for off-label Neurontin prescriptions chose to include Neurontin in their formularies with varying prior authorization, use, specialty, and quantity limitations. (See id. ¶ 59 (describing how 16 different TPPs included off-label Neurontin prescriptions in 16 different ways).) Indeed, Dr. Bell asserts that many TPPs recommend or require and continue to require the use of Neurontin to treat off-label conditions. (Id. ¶ 59.)

Given this background information, formularies, and hence the decision-making of the P & T Committees that created the formularies, become central to plaintiffs' claims. To prevail, plaintiffs must prove that defendants' fraudulent omissions or representations caused these committees to approve the use and reimbursement of Neurontin for off-label indications in a manner that was different from what would have occurred absent the alleged fraudulent marketing. In attempting to satisfy that burden, the TPP plaintiffs have fewer difficulties regarding causation than their Consumer plaintiff counterparts. The burden is less onerous because a TPP plaintiff would not have to prove that the misrepresentations caused a specific doctor to prescribe Neurontin to an individual patient. An aggregate model makes particular sense for the larger TPPs, or clusters of TPPs that rely on the same formulary, because a TPP plaintiff would only have to prove that the P & T Committee was fraudulently induced to approve Neurontin for a specific indication. If 99 percent of

all bipolar prescriptions, say, were caused by a fraudulent campaign, in some circumstances, it would be reasonable to conclude that 99 percent of the TPP's reimbursements for that indication were fraudulently caused. Still, though there were far fewer P & T Committees that approved Neurontin's use for off-label indications than there were doctors who prescribed Neurontin off-label, in order to establish the requisite causation for the TPPs, plaintiffs would have to present individualized evidence about what information a P & T Committee was exposed to regarding Neurontin and how the absence of fraudulent information would have altered Neurontin's placement within its formulary and how that alternative classification of Neurontin would have saved the TPP money.

In response to these contentions by defendants' expert, plaintiffs rely exclusively on their experts' submissions that defendants had perpetrated a fraud on the entire pharmaceutical market. They claim that the all P & T Committees "were undoubtedly influenced by the same pervasive disinformation campaign as were the physicians writing the prescriptions." (Pls.' Resp. to Defs.' Supplemental Mem. at 17.) However, because of the limitations in Professor Rosenthal's report and the heterogeneity of the TPPs' formularies, plaintiffs simply have not presented the court with an acceptable form of common proof that would justify class certification of the TPP subclasses. The Court finds that class certification of the TPP

subclasses would inevitably result in a tsunami of individual, complex trials. Neurontin, 244 F.R.D. at 114. Accordingly, the Court denies plaintiffs' renewed motion for class certification with respect to all five indication-specific TPP subclasses on the grounds that common questions will not predominate.

The Court is still quite troubled by defendants' blatantly illegal off-label promotion activities for which they have been criminally sanctioned. Defendants have fought this suit tooth-and-nail, and a small TPP would be wary of taking on the drug Goliath. Still, much of the work has been done. This denial of class certification does not preclude individual TPPs from bringing suit on their own behalf, as many well-heeled TPPs have already done. In addition, hundreds of individual consumers press products liability and fraud claims as part of this multi-district litigation. Any liability findings in favor of these plaintiffs (i.e., whether there was a fraud), will have issue preclusion effects for smaller TPPs and other consumers with fewer resources. Accordingly, given the complexity of each TPP's method of reimbursement, the class action mechanism is not superior to other methods of affording relief to other TPPs.

ORDER

Plaintiffs' renewed motion for class certification is
DENIED.

S/PATTI B. SARIS _____

United States District Judge

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