

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

H

United States District Court,
D. Massachusetts.
In re NEURONTIN MARKETING AND SALE
PRACTICES LITIGATION.

MDL Docket No. 1629.
Civil Action No. 04-10981.
Aug. 29, 2007.

Background: Consumer purchasers and third-party payors (TTPs) brought suit against manufacturers of epilepsy drug Neurontin, alleging that defendants engaged in a fraudulent scheme to promote and sell the drug Neurontin for “off-label” conditions in violation of the Racketeer Influenced and Corrupt Organizations Act (RICO) and the New Jersey Consumer Fraud Act (NJCFA). Plaintiffs moved for class certification.

Holdings: The District Court, [Saris, J.](#), held that: (1) commonality requirement for class certification was not satisfied by proposed classes of consumer purchasers and third-party payors (TPPs); (2) typicality requirement for class certification was satisfied only with respect to proposed consumer representatives for subclasses consisting of those who purchased drug for neuropathic pain or migraine; and (3) plaintiffs failed to satisfy predominance requirement for certification of consumer subclasses consisting of those who purchased drug for off-label conditions of neuropathic pain and migraine, absent some method other than individualized inquiry of identifying which prescribing physicians were exposed to defendants' fraudulent statements.

Motion denied.

West Headnotes

[1] Federal Civil Procedure 170A 182.5

[170A](#) Federal Civil Procedure
[170AII](#) Parties

[170AII\(D\)](#) Class Actions
[170AII\(D\)3](#) Particular Classes Represented
[170Ak182.5](#) k. Consumers, purchasers, borrowers, and debtors. [Most Cited Cases](#)

Commonality requirement for class certification was not satisfied by proposed classes of consumer purchasers and third-party payors (TPPs) in suit alleging that manufacturers of epilepsy drug Neurotin engaged in fraudulent scheme to promote the drug for “off-label” conditions; because allegations of fraud were unique for each off-label indication, proposed classes had to be further divided into subclasses by the condition for which off-label use was prescribed. [Fed.Rules Civ.Proc.Rule 23\(a\)\(2\), 28 U.S.C.A.](#)

[2] Federal Civil Procedure 170A 182.5

[170A](#) Federal Civil Procedure
[170AII](#) Parties
[170AII\(D\)](#) Class Actions
[170AII\(D\)3](#) Particular Classes Represented
[170Ak182.5](#) k. Consumers, purchasers, borrowers, and debtors. [Most Cited Cases](#)

Named plaintiffs in suit alleging that manufacturers of epilepsy drug Neurotin engaged in fraudulent scheme to promote the drug for “off-label” conditions failed to demonstrate that numerosity requirement for class certification was satisfied, as proposed consumer purchaser and third-party payor (TPP) classes had to be divided into subclasses according to the particular off-label use, and plaintiffs had not submitted proffer that the number of consumer and TPP plaintiffs in each subclass was sufficiently large that joinder of all members would be impractical. [Fed.Rules Civ.Proc.Rule 23\(a\)\(1\), 28 U.S.C.A.](#)

[3] Federal Civil Procedure 170A 182.5

[170A](#) Federal Civil Procedure
[170AII](#) Parties
[170AII\(D\)](#) Class Actions
[170AII\(D\)3](#) Particular Classes Represented
[170Ak182.5](#) k. Consumers, purchasers, borrowers, and debtors. [Most Cited Cases](#)

© 2012 Thomson Reuters. No Claim to Orig. US Gov. Works.

Reprinted from Westlaw with permission of Thomson Reuters. If you wish to check the currency of this case, you may do so using KeyCite on Westlaw by visiting <http://www.westlaw.com/>.

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Typicality requirement for class certification was satisfied in suit by consumer purchasers and third-party payors (TPPs) alleging that manufacturers of epilepsy drug Neurotin engaged in fraudulent scheme to promote the drug for “off-label” conditions only with respect to proposed consumer representatives for subclasses consisting of those who purchased drug for neuropathic pain or migraine, as named plaintiffs did not propose consumer representatives for other off-label indications and did not identify which off-label uses proposed TPP representatives paid for. [Fed.Rules Civ.Proc.Rule 23\(a\)\(3\), 28 U.S.C.A.](#)

[4] Federal Civil Procedure 170A 182.5

[170A](#) Federal Civil Procedure

[170AII](#) Parties

[170AII\(D\)](#) Class Actions

[170AII\(D\)3](#) Particular Classes Represented

[170Ak182.5](#) k. Consumers, purchasers, borrowers, and debtors. [Most Cited Cases](#)

Adequacy of representation requirement for class certification was satisfied in suit by consumer purchasers and third-party payors (TPPs) alleging that manufacturers of epilepsy drug Neurotin engaged in fraudulent scheme to promote the drug for “off-label” conditions; there were no conflicts of interest between the proposed representatives and the class, and plaintiffs’ experienced and highly-qualified counsel were adequate. [Fed.Rules Civ.Proc.Rule 23\(a\)\(4\), 28 U.S.C.A.](#)

[5] Federal Civil Procedure 170A 182.5

[170A](#) Federal Civil Procedure

[170AII](#) Parties

[170AII\(D\)](#) Class Actions

[170AII\(D\)3](#) Particular Classes Represented

[170Ak182.5](#) k. Consumers, purchasers, borrowers, and debtors. [Most Cited Cases](#)

Named plaintiffs who brought suit alleging that manufacturers of epilepsy drug Neurotin engaged in fraudulent scheme to promote the drug for “off-label” conditions failed to satisfy predominance requirement for certification of consumer subclasses consisting of those who purchased drug for off-label conditions of neuropathic pain and migraine, absent some method

other than individualized inquiry of identifying which prescribing physicians were exposed to defendants’ fraudulent statements. [Fed.Rules Civ.Proc.Rule 23\(b\)\(3\), 28 U.S.C.A.](#)

*91 [Elizabeth J. Cabraser](#), [Barry Himmelstein](#), Lieff Cabraser Heimann & Bernstein, LLP, San Francisco, CA, [Thomas Greene](#), Greene & Hoffman, Boston, MA, [Thomas M. Sobol](#), Hagens Berman Sobol Shapiro LLP, Boston, MA, [Don Barrett](#), Barrett Law Office, Lexington, MA, [Daniel Becnel, Jr.](#), Law Offices of Daniel Becnel, Jr., Reserve, LA, [James Dugan](#), Dugan & Brown, New Orleans, LA, for Class Plaintiffs.

[James P. Rouhandeh](#), [Neal A. Potischman](#), [Edmund Polubinski, III](#), [Carter H. Burwell](#), [Rajesh S. James](#), [Paul S. Mishkin](#), [Matthew B. Rowland](#), L. Reid Skibell, [Erik M. Zissu](#), Davis Polk & Wardwell, New York, NY, [David B. Chaffin](#), Hare & Chaffin, Boston, MA, [Scott W. Sayler](#), [James P. Muehlberger](#), Shook, Hardy & Bacon L.L.P., Kansas City, MO, for Defendants.

MEMORANDUM AND ORDER

[SARIS](#), District Judge.

In this proposed nationwide class action, plaintiffs allege that defendants Warner-Lambert and Pfizer engaged in a fraudulent scheme to promote and sell the drug [Neurontin](#) for “off-label” conditions. A condition is “off-label” if the Food and Drug Administration (“FDA”) has not approved [Neurontin](#) for that condition. Plaintiffs seek to certify a nationwide class of all consumers and Third Party Payors (“TPPs”) who have purchased [Neurontin](#) for “off-label” conditions. The proposed class period is from January 1, 1994 through December 31, 2004, when a generic version of the drug was introduced and Pfizer ^{FN1} abandoned its [Neurontin](#) marketing activities. Plaintiffs seek economic damages only. This is not a product liability action. ^{FN2}

^{FN1}. Pfizer acquired Warner-Lambert in 2000.

^{FN2}. Approximately 180 product liability actions have also been consolidated in this multi-district litigation by patients who claimed they were physically injured as a result of unlawful off-label marketing.

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Plaintiffs bring claims for violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), [18 U.S.C. § 1962](#) (Counts I & II); violations of the New Jersey Consumer Fraud Act (“NJCFA”), [N.J.S.A. 56:8-1 et seq.](#) (Count III); common law fraud (Count IV); and unjust enrichment (Count V). (See Docket No. 529, Third Amended Class Action Complaint (“TACAC”).)

Defendants vigorously oppose certification. Principally, they contend that plaintiffs' claims are not suitable for class treatment under [Fed.R.Civ.P. 23](#) because individual issues unique to each plaintiff predominate over common questions-including whether her doctor was exposed to any false statement regarding [Neurontin's](#) off-label uses; whether the statement caused the doctor's prescription decision; and whether the drug failed to provide any medical benefit. Defendants further contend that the proposed representatives fail to satisfy [Rule 23's](#) typicality and adequacy requirements; that the misrepresentations alleged by plaintiffs are not materially uniform; and that plaintiffs may not certify a nationwide class under New Jersey statutory and common law.

After the hearing and review of the briefs and extensive record, the motion is ***DENIED*** without prejudice.

I. THE PROPOSED CLASS

The plaintiffs propose to certify a class comprising:

All individuals and entities in the United States and its territories who, for purposes other than resale, purchased, reimbursed, and/or paid for [Neurontin](#) for indications not approved by the FDA during the period from January 1, 1994, through the present. For purposes of the Class definition, individuals and entities “purchased” [Neurontin](#) if they paid some or all of the purchase price.

(TACAC ¶ 315.) In addition, plaintiffs seek certification of two subclasses: a Third Party Payors (“TPP”) Subclass ^{FN3} and a Consumer *92 Subclass.^{FN4} The amended class period runs from January 1, 1994 through December 31, 2004.

[FN3.](#) The proposed TPP Subclass is defined as:

All private, non-governmental entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of Neurontin prescribed, provided, or administered to natural persons covered by such contract, policy, or plan for indications not approved by the FDA during the period from January 1, 1994 to the present. 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 or to administer their prescription drug benefits, private entities paid by any governmental entity (including a state Medicaid program), and other organization that for all or part of a Neurontin prescription since January 1, 1994.

(TACAC ¶ 316.)

[FN4.](#) The Consumer Subclass is defined as:

All individuals in the United States and its territories who, for purposes other than resale, purchased, reimbursed, or paid for some or all of the price of Neurontin, for indications not approved by the FDA during the period from January 1, 1994 through [December 31, 2004.].

(TACAC ¶ 317.)

II. FACTUAL BACKGROUND ^{FN5}

[FN5.](#) Except where noted, the allegations are drawn from the complaint and presumed true. Defendants contest many of the allegations.

A. AN END-RUN ON THE FDA

Defendants manufacture and distribute the prescription drug [Neurontin](#) (generic [gabapentin](#)). In December 1993, the FDA approved [Neurontin](#) for use as an “adjunctive therapy” in the treatment of partial seizures in adults with [epilepsy](#) in doses ranging from

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

900 mg to 1800 mg per day. As an adjunctive therapy, [Neurontin](#) was approved only as a “second-line” treatment for use in conjunction with another “front-line” [epilepsy](#) drug. In May 2002, the FDA approved [Neurontin](#) for the management of post-herpetic neuralgia (pain resulting from nerve damage caused by shingles or [herpes zoster](#)) in adults. (TACAC ¶ 17.)

In the late 1980's and early 1990's, Parke-Davis, a division of Warner-Lambert, filed patent applications for [Neurontin](#) as a treatment for depression, [neurodegenerative disease](#), mania, and [bipolar disorder](#). Parke-Davis did not seek FDA-approval for any of these indications. Under the Food Drug and Cosmetic Act, [21 U.S.C. §§ 331\(d\)](#), pharmaceutical manufacturers may not market or promote a drug for a use which the FDA has not approved unless certain “stringent requirements” are met and the manufacturer resubmits the drug to the FDA testing and approval process. [United States ex rel. Franklin v. Parke-Davis](#), [147 F.Supp.2d 39, 44 \(D.Mass.2001\)](#) (citing The Food and Drug Administration Modernization Act of 1997 (“FDAMA”), [21 U.S.C. § 360a, et seq.](#)); see also [Washington Legal Found. v. Henney](#), [202 F.3d 331 \(D.C.Cir.2000\)](#) (setting out the requirements of the FDAMA).

Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such “off-label” usage “is an accepted and necessary corollary of the FDA’s mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine.”

[Franklin](#), [147 F.Supp.2d at 44](#) (quoting [Buckman Co. v. Plaintiffs’ Legal Comm.](#), [531 U.S. 341, 350, 121 S.Ct. 1012, 148 L.Ed.2d 854 \(2001\)](#)).^{FN6}

^{FN6}. While off-label marketing is illegal, there is no private right of action to enforce it. See [In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.](#), [433 F.Supp.2d 172, 179 \(D.Mass.2006\)](#) (“[T]he federal law which the enterprise members shared a common intent to violate does not create a private right of action.”). To succeed on their claims, plaintiffs must prove that defendants’ representations were false, along with all other ele-

ments of their claims.

Parke-Davis estimated that potential lifetime sales for [Neurontin](#) would likely amount to less than \$500 million due to the narrow use for which it was approved and its patent life. Thus, in 1994, Parke-Davis chose to implement a “publication strategy” designed to boost [Neurontin](#) sales by disseminating information in the medical literature about [Neurontin’s](#) potential use for psychiatric disorders, including bipolar and mood and anxiety disorders. (*Id.* ¶¶ 21-31.) Parke-Davis elected this strategy as an alternative to the clinical trials required by the FDA-approval process because it was significantly less costly. (*Id.* ¶ 25.) While other anticonvulsants had received FDA-approval for similar psychiatric conditions, defendants were aware that [Neurontin](#) had a different mechanism of action. (*Id.* ¶ 22.) Defendants were also aware that they lacked sufficient scientific evidence of efficacy to obtain regulatory approval.

Later, Parke-Davis adopted a similar strategy to promote [Neurontin](#) off-label at doses exceeding 1800 mg per day (1995); and for neuropathic pain (1995); [epilepsy](#) monotherapy^{FN7} (1995); [migraine prophylaxis](#) (1996); [Restless Leg Syndrome](#) (“RLS”)/[Periodic Limb Movement Disorder](#) (“PLMD”) (1998); and nociceptive^{FN8} and non-neuropathic pain (2000). (See Exh. A, Docket No. 752-2.) Many of these conditions-including bipolar, mood and anxiety disorders, and pain-have very high placebo response rates (that is, the percentage of patients who report a significant improvement in their condition when treated with a sugar pill) and enormous market potential.^{FN9}

^{FN7}. In 1997, Parke-Davis formally applied to the FDA to change [Neurontin’s](#) labeling to include a monotherapy indication. The FDA rejected this application because Parke-Davis failed to demonstrate efficacy. (Exh. A, Docket No. 752-2.)

^{FN8}. Nociceptive pain is pain caused by an injury to bodily tissues.

^{FN9}. For example, the placebo response rate can be as high as sixty percent for major depressive (mood) disorders and sixty-seven percent for anxiety disorders. (See Rosenthal

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Decl. at 6 n. 11, Docket No. 463.)

B. OFF-LABEL PROMOTION

Defendants off-label promotion strategy had two broad components. First, through the “publication” strategy, defendants would cause to be published articles and studies in various medical journals promoting “key messages” favorable to [Neurontin's](#) use for the off-label conditions, while at the same time suppressing or misrepresenting the results of negative or unfavorable studies. Defendants failed to disclose that virtually all of articles supporting [Neurontin's](#) uses for the off-label indications were sponsored or controlled by defendants or their agents.

Second, through the “peer selling” strategy, doctors were paid to sell [Neurontin](#) for off-label uses in the guise of independent educational or professional seminars. Doctors received kickbacks, in the form of research grants as well as honoraria and other lavish treatment, in return for presenting positive scientific, clinical or anecdotal evidence to support [Neurontin's](#) off-label uses at hundreds (and possibly thousands) of medical educational events. Plaintiffs contend that there was no credible scientific evidence of efficacy for the off-label uses as touted in these articles or presentations.

1. The Peer Selling Strategy ^{FN10}

^{FN10}. The firms that the Complaint identifies as participants in the peer selling subenterprise include Cline, Davis & Mann; Physicians World; Sudler & Hennessey; MEDED; Medical Educational Services; CME, Inc.; Boron Lepore; AMM/Adelphi; CoMed; and MAC.

Defendants knew that physicians generally view promotional presentations by drug manufacturers with skepticism, and that recommendations by other physicians have a far greater impact on prescription writing behavior. Thus, defendants instructed their sales and marketing departments to target physicians at major teaching hospitals and induce them to become “[Neurontin](#) experts” who would deliver “key messages” about [Neurontin](#) to their colleagues. To accomplish this, defendants informed the physicians that they could receive substantial research grants if they were willing to speak favorably about [Neurontin's](#) potential for the off-label uses at continuing medical

educational seminars (CMEs), consultant's meetings, advisory boards, speaker's bureaus, teleconferences and informal dinner meetings.

Critical to this strategy was the creation of parallel marketing structures. Bona fide CMEs and similar educational events were exempt from FDA rules prohibiting off-label promotion because the sponsoring organization—typically a nonprofit, like a medical school—was independent and controlled the program's content. In practice, however, the defendants, through the medical marketing firms, dictated the content of these events, handling logistics and financing; selecting speakers to deliver “key messages” about [Neurontin](#) in their presentations; and attracting physicians to attend based on their ability and willingness to prescribe high *94 quantities of [Neurontin](#) off-label. In effect, defendants constructed “turnkey” educational programs, and then found institutions that would present positive information about [Neurontin](#) in a package format that appeared to be unbiased and objective. Parke-Davis would fund these programs with grants that would cover all costs, including substantial speaking fees and traveling expenses for the participating speakers, payments to the host institutions, honoraria to the attending physicians and, in some cases, their travel, lodging, food and entertainment expenses. Plaintiffs identify twenty-eight physicians who received a total of \$2,212,501. (TACAC ¶ 110.)

The information presented at these programs about [Neurontin's](#) off-label uses was not objective or balanced. Defendants took steps to ensure that unfavorable evidence about [Neurontin's](#) off-label uses was omitted or counteracted. For example, at one CME in Boston in June 1997, after learning that a speaker would describe the negative results of a [Neurontin](#) study for an off-label use, defendants planted a doctor in the audience to ask questions that would lead the presenter to make favorable statements regarding [Neurontin](#) in the question and answer period. (TACAC ¶ 64.) In a memorandum written to Parke Davis days later, the medical marketing firm responsible for organizing the event (Cline, Davis & Mann) stated that it had a “policy to complete a literature search to determine who authors favorable articles on the topics outlined” and that “guidelines have been set to ensure that this type of situation does not happen again.” (*Id.*)

Plaintiffs identify in general terms a number of

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

allegedly fraudulent sales practices that took place at these events, including:

(a) deliberately misrepresenting the safety and medical efficacy of [Neurontin](#) for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of [Neurontin](#) for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to [Neurontin's](#) off-label uses; (d) misrepresenting the credentials and qualifications of certain of Defendants' employees as specialists, medical researchers, physicians and scientific employees in order to market and sell [Neurontin](#) for various off-label uses; (e) wrongfully and illegally compensating physicians for prescribing [Neurontin](#) for various off-label uses; (f) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of [Neurontin](#) for off-label uses; (i)[sic] intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell [Neurontin](#) to off-label markets; and (j) intentionally misrepresenting and concealing the financial ties between the Defendants and other participants in the Enterprise.

(TACAC ¶ 46.)

2. The Publication Strategy

In conjunction with the peer selling strategy, defendants used the medical marketing firms to implement their publication strategy in order to produce purportedly objective scientific articles promoting the “key messages” related to [Neurontin's](#) efficacy for various off-label indications. The medical marketing firms were used, among other things, to prepare and coordinate articles ghostwritten by non-physician technical writers and to monitor the status of publications. In so doing, plaintiffs allege that defendants fraudulently failed to disclose their involvement in the research, misrepresented the results of unfavorable studies, and suppressed the publication of negative research.

Defendants and the marketing firms prepared “virtually all” of the articles promoting [Neurontin](#) for off-label uses. The physicians who purportedly au-

thored these articles were paid honoraria for use of their names. Plaintiffs allege that because the defendants failed to disclose their involvement in the preparation of these articles, physicians were led to believe that the authors were presenting their own, unbiased clinical research. In addition, defendants published only the favorable results of internal studies. For example, defendants withheld from publication *95 negative results of an early trial that failed to show [Neurontin's](#) efficacy for migraine, and delayed publication of negative results for bipolar until the drug's patent life was set to expire. (TACAC ¶ 136.)

3. Medical Liaisons

Plaintiffs also assert that defendants' sales representatives, or medical liaisons, made use of false and misleading information, virtually all of it produced in connection with the peer selling and publication enterprises, to promote [Neurontin's](#) off-label uses directly to physicians. Federal law permits manufacturer sales representatives to discuss off-label uses with physicians in response to unsolicited requests, provided that the information presented is fair and balanced and specifically responsive to the physician's questions. (*Id.* ¶¶ 37-38.) Defendants were also required by federal law and industry standards to disclose any negative information concerning a drug's efficacy when presenting positive information. (*Id.* ¶ 138.) Despite this, plaintiffs allege that defendants' medical liaisons made numerous false statements and material omissions to physicians regarding [Neurontin's](#) potential for off-label use.

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, and to legitimate that “buzz” through the publications of purportedly unbiased scientific research and the suppression or misrepresentation of studies that demonstrated [Neurontin](#) was not effective for the off-label uses. As a result of this fraud, consumers and TTPs purchased [Neurontin](#) for conditions for which there was no credible scientific evidence of efficacy, while defendants reaped billions in profits.

4. The Alleged Misrepresentations

In the medical community, the terms “effective”

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

and “efficacy” have specific and well understood meanings. Plaintiffs state:

Because the FDA will only find a drug product to be effective if the proposed use is supported by well designed, placebo-controlled clinical trials that establish a causal relationship to a statistically significant degree, a statement that a drug is “effective,” or “works,” or “has been proven to ...” is understood to mean that well controlled clinical studies support the use. To make such a statement without such clinical trial proof is misleading. Further, failure to inform physicians that no placebo-controlled clinical trials support a representation of drug efficacy is a violation of a pharmaceutical company's obligation to disclose.

(*Id.* ¶ 139.); see Anita Berenstein, [Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation](#), 15 J.L. & Pol'y 1051, 1066-67 (2007) (explaining that “[e]fficacy refers to the propensity of a drug to achieve intended, observable clinical improvement, with ‘improvement’ in turn referring to metrics rather than a feeling of good health.... Effectiveness, by contrast, refers to the fit between what happens to patients and what manufacturers promise on drug labels”).

As defendants were aware, placebo-controlled clinical trials for [Neurontin's](#) use for [bipolar disorder](#), unipolar disorder, essential tremor, spasticity, controlled diabetic pain, and [panic disorder](#) failed to show that the drug was effective. (*Id.* ¶ 140.) When defendants or their agents made a presentation concerning [Neurontin's](#) efficacy for any of these conditions without disclosing the negative results of clinical studies, plaintiffs allege that they made material false statements by omission. Further, when defendants made statements regarding efficacy based on anecdotal evidence, plaintiffs contend they were similarly required to disclose unfavorable clinical or anecdotal evidence of which they were aware. Plaintiffs allege that defendants routinely omitted all negative information in conjunction with their off-label pitches. ^{FN11}

^{FN11}. As evidence, plaintiffs rely in part on “Verbatim Reports,” which are filled out by physicians attending a CME or other event to record their thoughts and impressions of a drug. Many of these reports indicate that Neurontin's efficacy for the various off-label

uses was promoted at numerous events. These reports are not “verbatim” reports of statements made by conference speakers. (See Magistrate's Report and Recommendation, Docket No. 169, at 13.)

*96 a. Pain

Plaintiffs assert that “pain types are highly heterogeneous in terms of their etiology, pathophysiology, diagnosis and treatment.” (TACAC ¶ 143.) Because of this, the fact that a treatment may be effective for one type of pain does not indicate that it will be effective for another type. Neuropathic and nociceptive pain are two major different categories of pain. Plaintiffs allege that defendants “intentionally blurred the lines between different pain conditions by making representations to physicians that data relating to very narrow pain indications applied to all other pain indications.” (*Id.* ¶ 145.) In addition, defendants suppressed a number of clinical studies that showed [Neurontin](#) to be ineffective or were inconclusive. They also made affirmative representations touting the drug's efficacy for various types of pain without disclosing negative clinical and anecdotal evidence. (*Id.* ¶ 158.)

i. Neuropathic Pain

Defendants misrepresented the negative results of a 1996 placebo-controlled clinical trial conducted by Dr. Kenneth Gorson which found that [Neurontin](#) was not effective for [diabetic neuropathy](#), a variety of neuropathic pain. The study, along with an abstract, was submitted to Parke-Davis concluding that [Neurontin](#) “is probably no more effective than a placebo in the treatment of [painful diabetic neuropathy](#).” (*Id.* ¶ 133.) However, defendants revised the abstract and circulated a draft stating “[Gabapentin](#) may be effective in the treatment of [painful diabetic neuropathy](#). Our results suggest that further studies evaluating higher dosages of [gabapentin](#) are warranted.” (*Id.*) Dr. Gorson refused to accept this revision. The results were eventually published in a letter to the editor of a medical journal, concluding: “The results of this study suggest that [gabapentin](#) is probably ineffective or only minimally effective for the treatment of [painful diabetic neuropathy](#) at a dosage of 900 mg/day.” (*Id.* ¶ 134.)

Parke-Davis then submitted to the Drugdex Drug Information System, a widely-used computer database that contains drug information and article citations, a draft of the article with language consistent with

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Parke-Davis's revised abstract. The Drugdex citation to Dr. Gorson's article falsely stated that "the authors suggest that higher doses of gabapentin are needed" and failed to include the author's conclusion that [Neurontin](#) is "probably ineffective." (*Id.* ¶ 135.)

In 1998, defendants suppressed the results of the largest clinical trial related to [Neurontin](#) and [painful diabetic neuropathy](#). (*Id.* ¶ 149.) The lead investigator for the study was Dr. Reckless. The results were negative, and Parke-Davis did not forward the results of the study to Drugdex. ^{FN12} Parke-Davis informed Dr. Reckless that it didn't want the results published, but Dr. Reckless stated that he would publish the results on his own if Parke-Davis wouldn't. (*Id.*) However, despite submission to several peer-reviewed medical journals, the results were not published. (Defendants contest that the results were not published.)

[FN12.](#) As an example of its efforts to suppress the study, plaintiffs cite the following statement by one of defendants' representatives:

I think we can limit the potential downside of the [Reckless] study by delaying the publication for as long as possible and also from where it is published. More importantly it will be more important to how WE write up the study. We are using a medical agency to put the paper together which we will show to Dr Reckless. We are not allowing him to write it up himself.

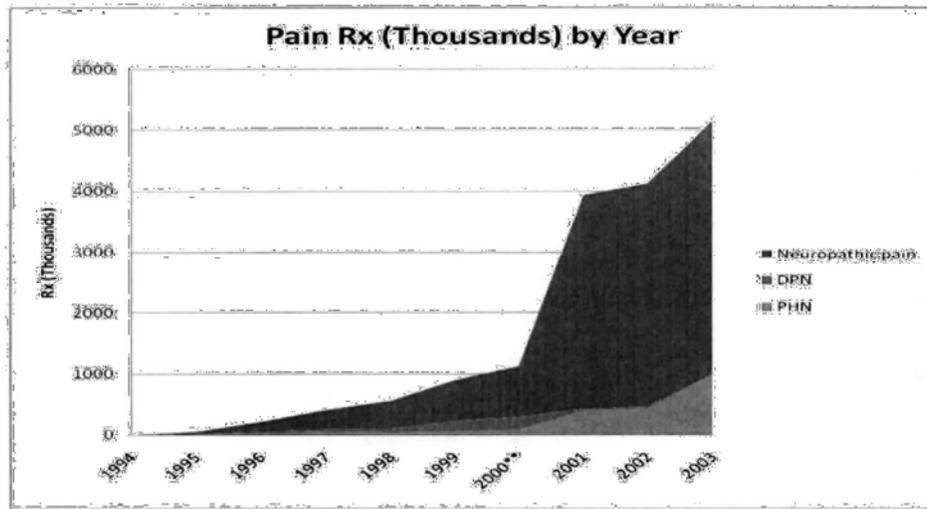
(Exh. B., Rona Decl.)

Finally, beginning in 2000, defendants were aware based on internal testing that [Neurontin's](#) efficacy with regard to various types of neuropathic pain other than [postherpetic neuralgia](#) was poor and could not be demonstrated. (*Id.* ¶ 149.) Nevertheless, by pooling the data on various [neuropathies](#), defendants created the misleading appearance that [Neurontin](#) offered significant improvement in treating neuropathic pain of *97 various types, and conveyed this message to physicians. (*Id.*) In 2001, aware of this data, defendants amended their application to the FDA to exclude all [neuropathies](#) except [postherpetic neuralgia](#) but continued to promote the drug for these uses to physicians. (*Id.* ¶ 151.)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) has proven efficacy in treating neuropathic pain, regardless of etiology; (2) [Neurontin](#) should be used as a first line therapy for all types of neuropathic pain; (3) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) to treat all types of neuropathic and/or chronic pain; and (4) [Neurontin](#) has been proven effective in treating [diabetic peripheral neuropathy](#). (Pls.' Post-Argument Submission (Docket No. 752).)

The following graph illustrates the dramatic increase in off-label prescriptions for Neuropathic pain following the launch of defendants' marketing campaign in 2000:

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
 (Cite as: 244 F.R.D. 89)



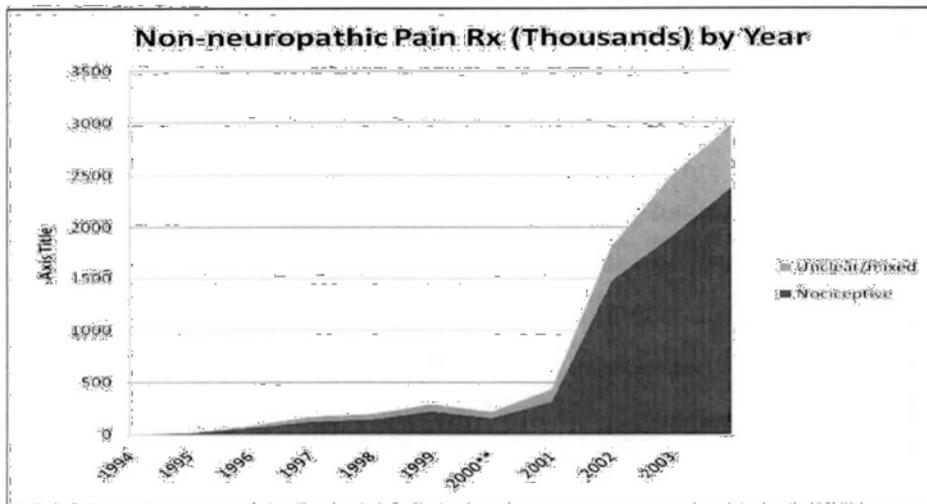
Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is an effective treatment for nociceptive and non-neuropathic pain; and (2) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) for nociceptive pain. (Pls.' Post-Argument Submission (Docket No. 752).)

ii. Nociceptive Pain (Pain caused by an injury to bodily tissues)

Defendants suppressed the results of internal testing (Protocol 1032-001) concluding that “[o]verall, the analgesic effect of [gabapentin](#) and [hydrocodone](#) treatment was similar to [hydrocodone](#) treatment alone.” (TACAC ¶ 152.) Further, Defendants suppressed the results of other internal testing (Protocol 1035-001) that did not find [Neurontin](#) to be effective in patients with postoperative pain following dental surgery. (*Id.*) Finally, defendants failed to disclose negative anecdotal evidence of [Neurontin's](#) lack of efficacy for pain.

The following graph charts the increase in off-label prescriptions for non-neuropathic pain following the start of defendants' off-label campaign in 2000:

*98



Defendants misrepresented the negative results of a 1996 study by Dr. Bruce Ehrenberg to “assess the efficacy of [Neurontin](#) ([gabapentin](#)) in the treatment of

b. RLS/PLMD

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

[RLS/PLMD].” (TACAC ¶ 164.) Parke-Davis funded the study. (*Id.*) Defendants' liaisons falsely told physicians that Dr. Ehrenberg's patients had a ninety percent response rate to the drug. (*Id.* ¶ 165.) Defendants did not publish the results, and continued to make false statements regarding [Neurontin's](#) efficacy. (*Id.* ¶ 168.) At the same time, defendants failed to acknowledge negative anecdotal evidence of which they were aware when promoting [Neurontin](#) based on positive anecdotal evidence. (*Id.* ¶ 167.)

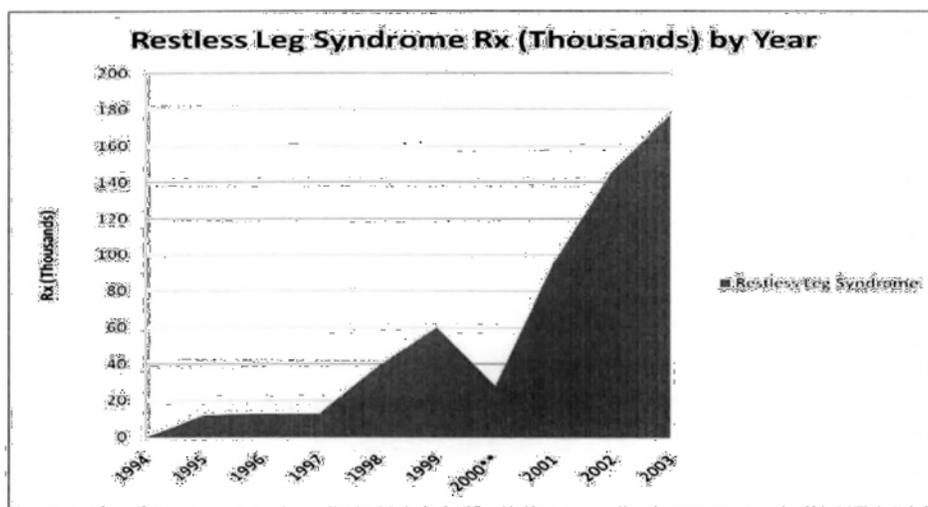
In addition, defendants misrepresented the independence of at least one study that touted [Neurontin's](#) efficacy for RLS. The article, authored by Gary A. Mellnick and Larry B. Mellnick, asserted that the authors had not and never would receive financial benefit from anyone with an interest in [Neurontin](#). (*Id.* ¶ 131.) In fact, both had received tens of thousands of dollars for speaking at defendants' events, and Gary Mellnick failed to disclose he was a consultant for

Parke-Davis and was assisting to develop the off-label market for the drug. (*Id.*)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is an effective treatment for RLS and PLMD; and (2) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) for RLS and PLMD. (Pls.' Post-Argument Submission (Docket No. 752).)

The following graph illustrates the increase in the number of off-label prescriptions for RLS following the launch of defendants' RLS marketing campaign in 1998:

*99



c. Bipolar and Mood Disorders

Defendants routinely made statements to physicians that [Neurontin](#) was an effective to treat bipolar and did not disclose the negative results of two studies, one presented at the 1997 Annual Meeting of the American Psychiatric Association in San Diego, (TACAC ¶ 172), and another internal study completed in 1997 but which defendants did not publish until 2000. (*Id.* ¶ 173.) Defendants, though they maintain that they informed Drugdex of all studies concerning [Neurontin](#) not contained in Drugdex's monograph, did not inform Drugdex of these negative results. (*Id.*) Defendants continued to make affirmative representations regarding [Neurontin's](#) efficacy for bipolar and

to sponsor events where it knew and intended such representations would be made without disclosing the negative clinical data. In addition, defendants cited anecdotal evidence of [Neurontin's](#) efficacy without disclosing that it was aware of negative anecdotal evidence. (*Id.* ¶ 175.)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is an effective treatment for bipolar and other mood disorders; (2) [Neurontin](#) is a mood stabilizer; and (3) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) for bipolar and mood disorders. (Pls.' Post-Argument Submission

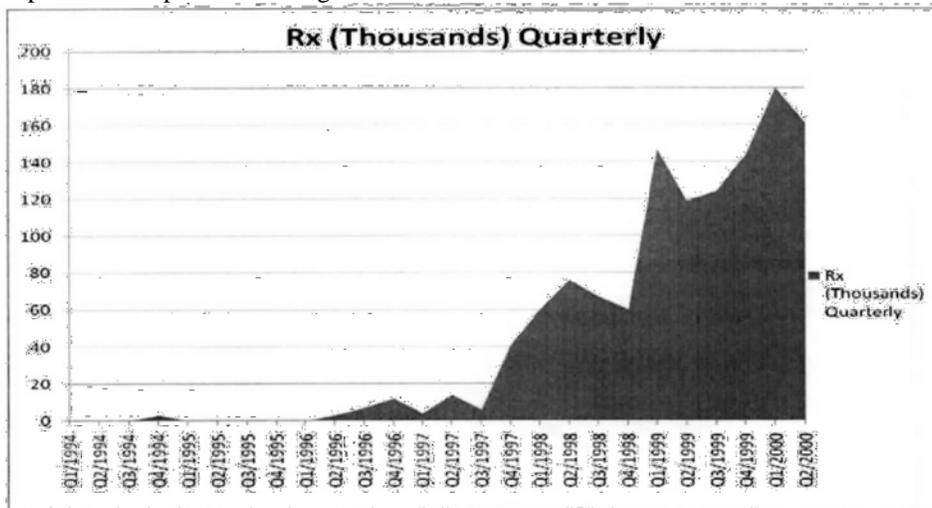
244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
 (Cite as: 244 F.R.D. 89)

(Docket No. 752).)

of defendants' off-label campaign in 1994:

The following chart reveals the increase in off-label prescriptions for bipolar following the start

*100



d. Anxiety Disorders

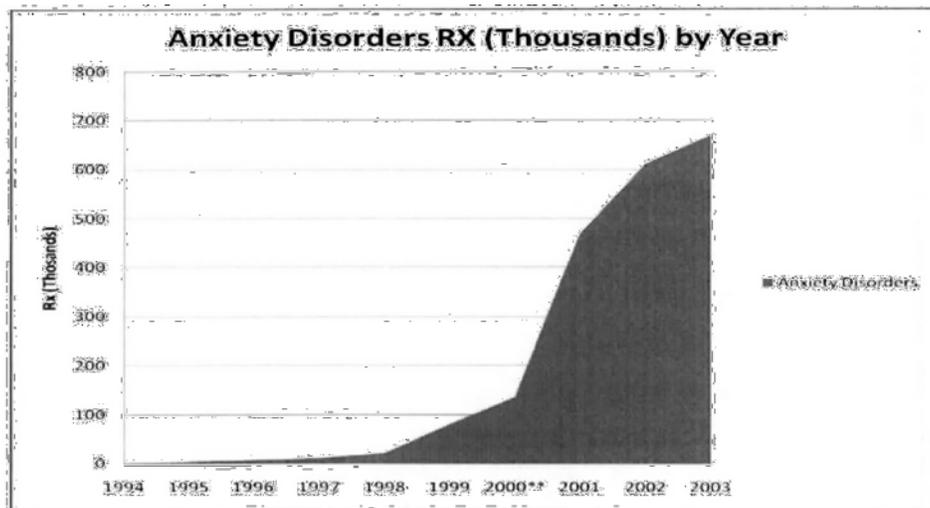
The term “anxiety disorder” refers to a general category of ailments that include [acute stress disorder](#), [agoraphobia](#), [generalized anxiety disorder](#), [obsessive compulsive disorder](#), [panic disorder](#), [post-traumatic stress disorder](#), [separation anxiety disorder](#), [social phobia](#) and specific phobia. (TACAC ¶ 177.) These disorders are difficult to distinguish from one another, and treatments frequently overlap. (*Id.* ¶ 177-80.) In October 1997, Parke-Davis received the results of an internal study finding that [Neurontin](#) was no more effective at treating [panic disorder](#) than a placebo but did not publish the results until 2000. (*Id.* ¶ 182.) In the meantime, they affirmatively represented that [Neurontin](#) was an effective treatment for various anxiety disorders. They also failed to disclose the ab-

sence of any clinical data to support the use of [Neurontin](#) for anxiety. (*Id.* ¶ 183.)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is an effective treatment for anxiety disorders; and (2) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) for anxiety disorders. (Pls.' Post-Argument Submission (Docket No. 752).)

The following graph illustrates the increase in off-label prescriptions for anxiety since the start of defendants' promotional campaign in the 1994:

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)



*101 e. Monotherapy

As early as 1995, defendants knew that evidence from clinical trials did not support the use of [Neurontin](#) for [epilepsy](#) monotherapy. The results of two monotherapy studies, Clinical Study 945-82, (TACAC ¶ 189), and an Eastern European pilot study 945-177, (*id.* ¶ 190), did not demonstrate efficacy or dose differentiation (i.e., that higher doses were more effective). Defendants did not intend to publish the results of the Eastern European study, or the combined results of the two studies together. In September 1996, the FDA rejected a supplemental new drug application (“NDA”) for [Neurontin](#) as a monotherapy for partial seizures due to the lack of evidence of efficacy. (*Id.* ¶ 191.) Defendants did not make public that its application for monotherapy had been denied. (*Id.*) Nonetheless, without disclosing the negative data, defendants promoted [Neurontin](#) as an effective treatment for monotherapy, both through its sales representatives, (*id.* ¶ 192), and at defendant-controlled “peer to peer” events. (*Id.* ¶ 191.) At one Parke-Davis marketing event in 1998, defendants went so far as to represent that [Neurontin](#) “was now approved as monotherapy for seizures.” (*Id.* ¶ 193.)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is an effective monotherapy treatment for [epilepsy](#); and (2) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) for monotherapy. (Pls.’ Post-Argument Submission (Docket No. 752).)

f. Migraine and Headache

Parke-Davis knew that there was no medical rationale that would support the use of [Neurontin](#) to prevent migraines. It conducted a twelve-week [migraine prophylaxis](#) study in Europe in the late 1980’s that revealed no statistically-significant difference in migraine attack frequency between a placebo and 900 mg of [Neurontin](#) therapy. (TACAC ¶ 195.) Parke-Davis never disclosed the results of this study to any person outside the company and never published the results. (*Id.* ¶ 197.) In addition, Parke-Davis knew of several reports of negative results from use for migraine, including reports from Dr. Seymour Solomon, Director of the Headache Unit at Montefiore Medical Center; Dr. John Rothrock, Chairman of the Department of Neurology at the University of Alabama; Dr. Kenneth Welch, Professor of Clinical Neurology at the University of Michigan; and Dr. Fred Cutrer, Department of Neurology at Massachusetts General Hospital. (*Id.* ¶ 196.) Defendants failed to disclose this negative data while making representations about the drug’s efficacy for migraine and headache, both at medical educational events they controlled and through their sales force. (*Id.* ¶¶ 198-202.)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is effective in preventing migraines (i.e., [migraine prophylaxis](#)) and other forms of headache; and (2) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) in preventing migraine and other forms of headache. (Pls.’ Post-Argument

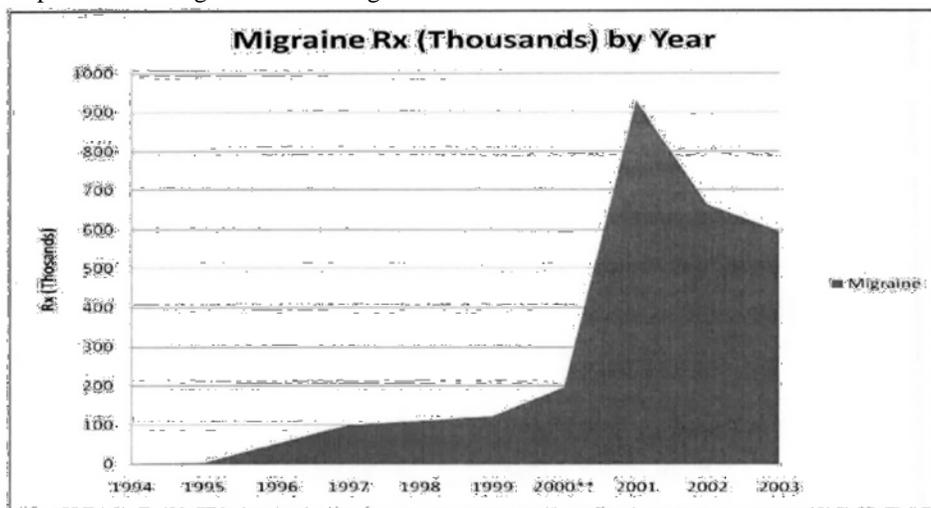
244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Submission (Docket No. 752.)

launch of defendants' campaign in 1996:

The following graph reveals the increase in off-label prescriptions for migraine following the

*102



g. Doses Above the FDA-Approved Maximum

Plaintiffs accuse defendants of misrepresenting the efficacy of [Neurontin](#) at higher doses in order to increase per patient revenues ^{FN13} and counteract the growing reputation of [Neurontin](#) as ineffective among physicians (some of whom began to refer to the drug as “gaba-water.”) (TACAC ¶¶ 204-05.) As early as 1994, defendants knew that there was a lack of proportionality between the dose of [gabapentin](#) administered to subjects and the level absorbed; that is, increasing the dose did not necessarily mean that the body absorbed higher levels of [Neurontin](#). (*Id.* ¶ 206.) By December 1996, defendants knew that clinical trial 945-82 did not show a dose related response; patients who took 600 mg daily did not show different results from those who took 1200 or 2400 mg. (*Id.* ¶ 207.) Despite these results and the decision to market the drug at higher doses, Parke-Davis chose not to initiate clinical trials to determine whether [Neurontin](#) was more effective at higher doses. (*Id.* ¶ 208.) Later, another clinical trial (945-77) found that a dose of 900 mg/day was just as effective as a dose of 1800 mg/day. (*Id.* ¶ 209.)

^{FN13} At 1995 prices, a 900 mg dose cost \$2.25 a day (\$821.25 a year) while a 3600 mg dose cost \$8.10 a day (\$2956.50 a year). (TACAC ¶ 204.)

Parke-Davis filed an application with the FDA to increase the effective dose range to 3600 mg daily and to increase the maximum recommended dose to 4800 mg. In 1997, the FDA rejected the application citing the lack of evidence of efficacy. (*Id.* ¶ 216.) Further, the FDA informed Parke-Davis that if it did not provide safety data, it could only obtain the labeling change if it further disclosed that “evidence from controlled trials fails to disclose that higher dose [sic] of [Neurontin](#) are more effective than those recommended.” (*Id.* ¶ 217.) Parke-Davis never disclosed that the FDA denied its requests, that there was insufficient evidence of effectiveness at higher doses, or that there was no clinical trial evidence supporting the higher doses. (*Id.* ¶ 218.) Nonetheless, at events sponsored by defendants and through their representatives, defendants routinely made representations that [Neurontin](#) was safe and effective at these higher doses. (*Id.* ¶¶ 210-215; 219.) In fact, defendants continually represented that the failure of [Neurontin](#) to effectively treat patients suffering from the off-label conditions could be remedied by increasing the dosage.

Defendants also knew that there was a dose relationship between [Neurontin](#) and side effects and that patients taking 1800 mg/day were three times more likely to have side effects than those taking 900 mg/day. (*Id.* ¶ 220.) These effects included behavioral problems in children, weight gain, and symptoms of withdrawal. (*Id.* ¶¶ 221-23.) *103 Defendants were also aware of anecdotal evidence of side effects.

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Nonetheless, defendants represented that high doses of [Neurontin](#) did not cause side effects and failed to disclose evidence of potential adverse reactions. (*Id.* ¶ 224-25.)

By the mid-1990's, Parke-Davis had increased the average daily dose prescribed by all physicians from 1200 mg to approximately 1800 mg. (Pls.' Post-Argument Submission (Docket No. 752).) By 2003, the average daily dose prescribed by all physicians was well over 1800 mg. (*Id.*)

Plaintiffs have alleged dissemination of the following standard false messages: (1) [Neurontin](#) is more effective at doses ranging from 1800-3600 mg/day than at 1800 mg/day; (2) inefficacy cannot be determined until patients take at least 3600 mg/day; and (3) existing medical evidence (which defendants would purport to summarize in their presentation, articles, or letters) supports the use of [Neurontin](#) at doses above 1800 mg/day. (*Id.*)

5. *The Success of the Enterprise*

As a result of this scheme, from 1995 to 2003 defendants' revenues from sales of [Neurontin](#) rose from \$97.5 million to nearly \$2.7 billion, making [Neurontin](#) one of the ten most popular drugs in the United States. (TACAC ¶ 47.) By 2003, an estimated ninety percent of all [Neurontin](#) prescriptions were for off-label uses. (*Id.*) Sales grew at an approximate rate of fifty percent per year, fueled primarily by off-label sales. (*Id.*) Plaintiffs' attribute the lion's share of these increased sales to defendants' fraudulent scheme.

III. DISCUSSION

A. OVERVIEW OF THE ELEMENTS OF PLAINTIFFS' CLAIMS

1. RICO

To succeed on a claim under the civil RICO statute, a plaintiff must prove: (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity. [Sedima, S.P.R.L. v. Imrex Co., Inc.](#), 473 U.S. 479, 496, 105 S.Ct. 3275, 87 L.Ed.2d 346 (1985). Additionally, in order for a civil RICO claimant to establish standing to sue, the Supreme Court requires that she demonstrate an injury proximately caused by the defendant's conduct. [Anza v. Ideal Steel Supply Corp.](#), 547 U.S. 451, ---, 126 S.Ct. 1991, 1998, 164 L.Ed.2d 720 (2006) (RICO proximate cause inquiry

focuses on “whether the alleged violation led directly to the plaintiff's injuries”); see [Chisolm v. TranSouth Fin. Corp.](#), 95 F.3d 331, 336 (4th Cir.1996) (explaining that “[t]he pertinent inquiry in determining the existence of proximate, or ‘legal’ cause [under RICO statute], is ‘whether the conduct has been so significant and important a cause that the defendant should be held responsible’ ”).

2. *The New Jersey Consumer Fraud Act*

The NJCFA “imposes liability upon any person who uses any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission.” [Int'l Union of Operating Eng's Local # 68 Welfare Fund v. Merck & Co., Inc.](#), 384 N.J.Super. 275, 894 A.2d 1136, 1142 (App.Div.2006) (citation, quotation marks, and alteration omitted).

As a prerequisite to the right to bring a private action, under the Act, a plaintiff must be able to demonstrate that he or she suffered an ascertainable loss as a result of the unlawful conduct....

[C]onsumer fraud requires only proof of a causal nexus between the misrepresentation or concealment of the material fact by a defendant and the loss, suffered by any person. It is not necessary to prove that each class member specifically relied upon [a defendant's omissions or misrepresentations. Plaintiff must prove only that its ascertainable loss was attributable to conduct made unlawful by the Act. It is not necessary that the wrongful conduct be the sole cause of the loss, but merely that it be a cause.

Id. (citations, quotations, and alterations omitted).

*104 3. *Common Law Fraud/Unjust Enrichment*

Plaintiffs have asserted common law fraud. In New Jersey,

proof of common law fraud requires the satisfaction of five elements: a material misrepresentation by the defendant of a presently existing fact or past fact; knowledge or belief by the defendant of its falsity; an intent that the plaintiff rely on the statement; reasonable reliance by the plaintiff; and resulting damages to the plaintiff.

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

Liberty Mut. Ins. Co. v. Land, 186 N.J. 163, 175, 892 A.2d 1240 (N.J.2006); see also *Varacallo v. Mass. Mut. Life Ins. Co.*, 332 N.J.Super. 31, 752 A.2d 807 (App.Div.2000) (explaining that reliance and causation may be presumed “where omissions of material fact are common to [a] class”). Additionally, plaintiffs bring a claim for unjust enrichment. “To establish a claim for unjust enrichment, ‘a plaintiff must show both that defendant received a benefit and that retention of that benefit without payment would be unjust.’ ” *Iliadis v. Wal-Mart Stores, Inc.*, 191 N.J. 88, 110, 922 A.2d 710 (N.J.2007).

For all of their claims, plaintiffs will be required to prove that defendants' fraudulent promotion caused physicians to prescribe *Neurontin* to the plaintiffs for an off-label condition and that they were injured (i.e., suffered economic loss) by virtue of the *Neurontin's* inefficacy for that condition.

B. RULE 23 STANDARD

Under Rule 23(a), a class may be certified only if:

- (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representatives will fairly and adequately protect the interests of the class.

Plaintiffs further seek damages under Rule 23(b)(3), which provides that an action may be maintained only if, additionally,

the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action.

Fed.R.Civ.P. 23(b)(3).

A district court must determine whether a proposed class meets the exacting prerequisites established by Rule 23. *Smilow v. Sw. Bell Mobile Sys., Inc.*, 323 F.3d 32, 38 (1st Cir.2003). In “determining the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met.” *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 298 (1st Cir.2000) (quoting *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178, 94 S.Ct. 2140, 40 L.Ed.2d 732 (1974) (internal citation omitted)). However, “a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case.” *Mowbray*, 208 F.3d at 298; see also *Tardiff v. Knox County*, 365 F.3d 1, 4-5 (1st Cir.2004) (“It is sometimes taken for granted that the complaint's allegations are necessarily controlling; but class action machinery is expensive and in our view a court has the power to test disputed premises early on if and when the class action would be proper on one premise but not another.”). Plaintiffs bear the burden of demonstrating that the Rule's prerequisites have been satisfied. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613-15, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997); *Smilow*, 323 F.3d at 32.

*105 1. *Commonality*

[1] “A class has sufficient commonality ‘if there are questions of fact and law which are common to the class.’ ” *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1019 (9th Cir.1998) (quoting Rule 23(a)(2)). “The threshold of ‘commonality’ is not high. Aimed in part at ‘determining whether there is a need for combined treatment and a benefit to be derived therefrom,’ the rule requires only that resolution of the common questions affect all or a substantial number of the class members.” *Jenkins v. Raymark Indus., Inc.*, 782 F.2d 468, 472 (5th Cir.1986) (citation omitted).

All questions of fact and law need not be common to satisfy the rule. The existence of shared legal issues with divergent factual predicates is sufficient, as is a common core of salient facts coupled with disparate legal remedies within the class.

Hanlon, 150 F.3d at 1019. “The test or standard for meeting the Rule 23(a)(2) prerequisite is qualita-

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

tive rather than quantitative; that is, there need be only a single issue common to all members of the class. Therefore, this requirement is easily met in most cases.” 1 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 3.10 (4th ed.2002).

Defendants contend that the proposed class, defined to include every off-label purchaser of [Neurontin](#) for every off-label use, should not be certified because plaintiffs' allegations of fraud are unique for each off-label indication. They argue that plaintiffs may not rely on common proof to establish liability for all of the off-label conditions but must instead prove that defendants made fraudulent misrepresentations or omissions for each indication in order to succeed on any of their claims. For example, in order to establish liability for defendants' alleged misrepresentations about the efficacy of [Neurontin](#) for neuropathic pain, plaintiffs may not rely on proof that defendants misrepresented its efficacy for bipolar, and vice versa.

[FN14](#)

[FN14](#). Defendants also point out that the class period for each indication is different. While defendants' marketing activities with respect to migraine began as early as 1996, they did not begin to promote Neurontin for RLS until 1998, and nociceptive and non-neuropathic pain until 2000. (See Exh. A, Pls.' Post-Argument Submission (Docket No. 752-2).)

Plaintiffs respond that defendants' marketing efforts comprise one overarching scheme, and that the various off-label conditions are branches of that scheme. They assert that the evidence for each off-label use is largely the same because the fraud was centrally-devised and orchestrated. (*But see* Tr. 25:16-17 (“[W]e intend to prove for each indication that we go to trial on that the fraud was a substantial contributing factor for ... the lion's share of all the prescriptions.”) (statement of plaintiffs' counsel) (emphasis added).) Nonetheless, in the Complaint and subsequent submissions, plaintiffs make clear that their proof of fraud varies considerably by indication. Though defendants employed the same marketing strategy for all the off-label uses, plaintiffs will need to prove up *fraud* use-by-use.

Further, without dividing the class by indication, plaintiffs would not be able to demonstrate that the

proposed class representatives were typical. See, e.g., [Van West v. Midland Nat'l Life Ins. Co.](#), 199 F.R.D. 448, 453 (D.R.I.2001) (typicality not satisfied where evidence required to prove representative's claim differs substantially from evidence required to prove claims of other class members). In addition, class certification requires that the representations be materially uniform. See, e.g., [Moore v. PaineWebber, Inc.](#), 306 F.3d 1247, 1253-56 (2d Cir.2002). As a result, the proposed consumer and TPP classes must be further divided into subclasses by use. See [Fed.R.Civ.P. 23\(c\)\(4\)\(B\)](#) (“When appropriate ... a class may be divided into subclasses and each subclass treated as a class, and the provisions of this rule shall then be construed and applied accordingly.”).

Plaintiffs will need to satisfy the prerequisites of [Rule 23](#), both for consumers and the TPPs, for (1) bipolar and other mood disorders; (2) neuropathic pain; (3) migraine and headache; (4) nociceptive and non-neuropathic pain; (5) [restless leg syndrome](#) (“RLS”)/[periodic limb movement disorder](#) (“PLMD”); (6) anxiety disorders; (7) monotherapy; and (8) doses of 1800 mg to 3600 *106 mg per day. 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.

2. Numerosity

[\[2\]](#) Plaintiffs have asserted that by 2003 Neurontin was the tenth most commonly-prescribed drug in the United States, and that an estimated ninety percent of all prescriptions were for off-label indications. Thus, thousands of consumers and TPPs in the United States and its territories have purchased Neurontin prescriptions for the various off-label uses. Defendants have not challenged numerosity. However, given my determination that subclasses are required, plaintiffs must allege numerosity for the consumer and TPP off-label purchasers *by indication* for each subclass under [Fed. R. Civ. Pro. 23\(c\)\(4\)](#). Given the low threshold for numerosity and the high number of off-label prescriptions, this prong of [Rule 23](#) is unlikely to preclude certification. See, e.g., [Holton v. Rothschild](#), 118 F.R.D. 280, 282 (D.Mass.1987) (explaining, with respect to numerosity, that “[w]hether the number be 50 or 60, it is sufficiently large” (citation omitted)). Nevertheless, to meet their burden, plaintiffs must submit a proffer that the number of

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

consumer and TPP plaintiffs in each subclass is sufficiently large that joinder of all members would be impractical.

3. Typicality

[3] Rule 23(a)(3) provides that a class action may be maintained only if the claims of the representative parties are typical of the claims of the class.

Typicality determines whether a sufficient relationship exists between the injury to the named plaintiff and the conduct affecting the class, so that the court may properly attribute a collective nature to the challenged conduct. In other words, when such a relationship is shown, a plaintiff's injury arises from or is directly related to a wrong to a class, and that wrong includes the wrong to the plaintiff. Thus, a plaintiff's 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 if his or her claims are based on the same legal theory.

In re Am. Med. Sys., Inc., 75 F.3d 1069, 1082 (6th Cir.1996) (emphasis added) (quoting 1 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 3.13 (3d ed.1992)). “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) (citation omitted). “Typicality, as with commonality, does not require ‘that all putative class members share identical claims.’” Id. at 531-32 (citation omitted).

Moreover, typicality “should be determined with reference to the [defendant's] actions, not with respect to particularized defenses it might have against certain class members.” Wagner v. NutraSweet Co., 95 F.3d 527, 534 (7th Cir.1996). Courts have held that

to defeat class certification, a defendant must show some degree of likelihood that a unique defense will play a significant role at trial. Therefore, typicality is defeated when the proposed class representative is subject to a unique defense that has the likelihood of becoming the main focus of the litigation thereby distracting attention from the issues common to the class.

Bayshore Ford Truck Sales, Inc. v. Ford Motor Co., 2006 WL 3371690, at *12, 2006 U.S. Dist. LEXIS 64264, at *39 (D.N.J.2006) (internal quotation marks and alterations omitted) (citing Beck v. Maximus, 457 F.3d 291 (3d Cir.2006)).

Plaintiffs have proposed Gerald Smith ^{FN15} and Loraine Kopa ^{FN16} as consumer representatives*107 for neuropathic pain and migraine. They have not proposed consumer representatives for the other off-label indications. Plaintiffs have failed to demonstrate that these proposed consumer plaintiffs' claims are typical of the claims of the members of the subclasses for bipolar and other mood disorders; nociceptive and non-neuropathic pain; RLS/PLMD; anxiety disorders; epilepsy monotherapy; and doses in excess of 1800 mg per day. See, e.g., Van West, 199 F.R.D. at 453 (typicality not met where “the evidence required to prove [a proposed representative's] claim would differ considerably from the evidence required to prove the claims of other class members”).

^{FN15}. Smith is an Indiana resident who was prescribed and purchased Neurontin from approximately October 1999 through February of 2001 for the treatment of headaches and neuropathic pain, off-label uses for which Neurontin has not been approved.

^{FN16}. Kopa is a Pennsylvania resident who was prescribed and purchased Neurontin from approximately November 2003 through April 2004 for neuropathic pain, an off-label use for which Neurontin has not received FDA-approval.

Defendants argue that Smith and Kopa's claims are atypical of the members of the neuropathic pain and migraine subclasses due to individualized defenses potentially applicable to both.^{FN17} They argue that Smith has no damages because he released any claim for his Neurontin purchases pursuant to a settlement of a personal injury lawsuit in 2002. Plaintiffs answer that Smith, who released claims only against the tortfeasors in that lawsuit, did not release Pfizer or Warner-Lambert, or “any and all claims” for medical expenses.^{FN18} (See Exh. C to Liptak Aff.) Under Indiana law, which governs the agreement, “a valid release of one tortfeasor from liability for harm, given by the injured person, does not discharge others liable for the same harm, unless it is agreed that it will dis-

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

charge them.” [Huffman v. Monroe County Cmty. Sch. Corp.](#), 588 N.E.2d 1264, 1267 (Ind.1992) (quoting [Restatement \(Second\) of Torts, § 885\(1\) \(1979\)](#)).

FN17. Defendants argue that the proposed representative's claims are atypical because they arise from different factual circumstances than other class members and implicate highly individualized questions relating to causation and reliance. This argument will be reserved for the Court's discussion of predominance.

FN18. Plaintiffs also point out that in the Settlement Distribution Sheet prepared by Smith's counsel, payments for Neurontin were not listed among the medical expenses which he sought to recover.

Defendants also emphasize that Kopa continued to take [Neurontin](#) despite claimed side effects only after her physician “intimidated” her. (Kopa Dep. at 84-92, 96.) Thus, defendants contend, her physician's conduct constitutes an intervening event in the causal chain. However, plaintiffs argue that the circumstances surrounding Kopa's decision to continue to take [Neurontin](#) were not atypical because patients frequently accede to their physicians' superior knowledge and judgment regarding treatment options.

Defendants have failed to show that the existence of these potential defenses is likely to play a significant role at trial or distract from issues common to the class. Accordingly, because the proposed class representatives' claims arise from the same course of conduct and are based on the same legal theory as the consumer subclasses for neuropathic pain and migraine, their claims are typical. *See, e.g., In re Am. Med. Sys., Inc.*, 75 F.3d at 1082.

Finally, the Complaint does not identify which off-label uses the proposed TPP representatives have paid for. Both parties seem to agree that the class representative TPPs do not always know which [Neurontin](#) prescriptions they reimbursed for relate to off-label uses. It is unclear as to whether records are kept by any TPP to reflect the indication for which [Neurontin](#) is prescribed. Plaintiffs must make a proffer that a proposed TPP representative for each 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.

4. Adequacy

[4] “The adequacy inquiry under [Rule 23\(a\)\(4\)](#) serves to uncover conflicts of interest between named parties and the class they seek to represent.” [Amchem](#), 521 U.S. at 625, 117 S.Ct. 2231.

The [adequacy] rule has two parts. The moving party must show first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel *108 chosen by the representative party is qualified, experienced, and able to vigorously conduct the proposed litigation.

[Andrews v. Bechtel Power Corp.](#), 780 F.2d 124, 130 (1st Cir.1985). “The conflict that will prevent a plaintiff from meeting the [Rule 23\(a\)\(4\)](#) prerequisite must be fundamental, and speculative conflict should be disregarded at the class certification stage.” [In re Visa Check/MasterMoney Antitrust Litig.](#), 280 F.3d 124, 145 (2d Cir.2001). Defendants do not identify any conflicts of interest between the proposed representatives and the class, nor do they contest that plaintiffs' experienced and highly-qualified counsel are adequate. I find that [Rule 23](#)'s adequacy requirement has been met.

5. Predominance

[5] “The [Rule 23\(b\)\(3\)](#) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” [Amchem](#), 521 U.S. at 623, 117 S.Ct. 2231. “Predominance is a test readily met in certain cases alleging consumer or securities fraud...” *Id.* at 625, 117 S.Ct. 2231. Where “common questions predominate regarding liability, then courts generally find the predominance requirement to be satisfied even if individual damages issues remain,” for “[t]he individuation of damages in consumer class actions is rarely determinative under [Rule 23\(b\)\(3\)](#).” [Smilow](#), 323 F.3d at 40; *see also Tardiff*, 365 F.3d at 6-7 (noting that individuals subject to allegedly illegal strip search may have individual damages from emotional distress, lost wages, and medical treatment, but that these damages issues do not defeat initial certification); [Carnegie v. Household Int'l, Inc.](#), 376 F.3d 656, 661 (7th Cir.2004) (affirming RICO class certification and

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

suggesting procedural mechanisms available at later stage to cope with issues of whether particular members were defrauded and extent of individual damages).

Similarly, “where common issues otherwise predominated, courts have usually certified [Rule 23\(b\)\(3\)](#) classes even though individual issues were present in one or more affirmative defenses,” for if “evidence later shows that an affirmative defense is likely to bar claims against at least some class members, then a court has available adequate procedural mechanisms.” [Smilow](#), 323 F.3d at 39-40.

Finally, “[i]n cases involving fraudulent statements or misrepresentations, courts generally favor certification where the misrepresentations were materially uniform, but deny certification where they varied from transaction to transaction.” [In re Pharm. Indus. Average Wholesale Price Litig.](#), 230 F.R.D. 61, 82 (D.Mass.2005) (“*AWP*”) (Saris, J.) (citing [Moore v. PaineWebber, Inc.](#), 306 F.3d 1247, 1253-56 (2d Cir.2002) (explaining that the Third, Fourth, Fifth, Sixth and Seventh Circuits “have held that oral misrepresentations are presumptively individualized”)).

Where there are material variations in the nature of the misrepresentations made to each member of the proposed class, ... class certification is improper because plaintiffs will need to submit proof of the statements made to each plaintiff, the nature of the varying material misrepresentations, and the reliance of each plaintiff upon those misrepresentations in order to sustain the claim.

[Moore](#), 306 F.3d at 1253; see also [Grainger v. State Sec. Life Ins. Co.](#), 547 F.2d 303, 307 (5th Cir.1977) (“The key concept in determining the propriety of class action treatment is the existence or nonexistence of material variations in the alleged misrepresentations.”).

Courts have allowed certification in cases involving uniform, scripted, and standardized misrepresentations. [In re Prudential Ins. Co. of Am. Sales Practice Litig.](#), 148 F.3d 283 (3d Cir.1998) (approving settlement class); see also [In re LifeUSA Holding](#), 242 F.3d 136, 145 (3d Cir.2001) (decertifying class because “class members’ claims arose from individual and non-standardized transactions involving non-uniform oral misrepresentations,” but explaining

that courts will grant certification for claims alleging deceptive sales practices “involv[ing] uniform, scripted, and standardized sales presentations”).

Likewise, courts have been willing to look past minor variations among a defendant’s misrepresentations, particularly with respect to a centrally-orchestrated fraudulent *109 scheme, where “[t]he center of gravity of the fraud transcends the specific details of [the] oral communications.” [In re Am. Cont’l Corp./Lincoln Sav. And Loan Sec. Litig.](#), 140 F.R.D. 425 (D.Ariz.1992) (“The exact wording of the oral misrepresentations ... is not the predominant issue. It is the underlying scheme which demands attention.”); see [Duhaime v. John Hancock Mut. Life Ins. Co.](#), 177 F.R.D. 54, 64 (D.Mass.1997) (where allegations of oral misrepresentations “describe a nationwide course of conduct, differences in oral sales presentations do not defeat predominance” in settlement class).

Certification is also appropriate where the fraudulent conduct alleged is “characterized primarily as the suppression of medical information and studies, in other words, as a scheme to conceal material information.” [In re Synthroid Marketing Litig.](#), 188 F.R.D. 295, 300 (N.D.Ill.1999) (adding that plaintiff had also alleged materially uniform affirmative misrepresentations).

C. UNIFORM MATERIAL MISREPRESENTATIONS AND OMISSIONS

Defendants first argue that plaintiffs have failed to meet their threshold burden of proving that the alleged misrepresentations were materially uniform. They point out that plaintiffs’ allegations involve potentially thousands of statements made by different speakers to different audiences at diverse venues across the country over a period of several years. They emphasize that plaintiffs have not produced evidence of written, standardized sales scripts.

Plaintiffs counter that they have alleged sufficient material uniformity among the representations by providing evidence of (1) the suppression of negative or unfavorable studies or anecdotal evidence of inefficacy; (2) the misrepresentation of negative or unfavorable studies; and (3) the dissemination of standard “key messages” related to the efficacy of [Neurontin](#) for unproven uses through the centrally-devised “peer selling” and “publication” strategies. Further, according to plaintiffs, any variation among oral state-

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

ments made to physicians was not material because the crux of both the fraud and the standard false messages is the misrepresentation concerning the evidence available to support the efficacy of each off-label use.

Plaintiffs have met their burden of demonstrating that the “key messages” of efficacy and clinical evidentiary support disseminated by plaintiffs, coupled with the suppression or misrepresentation of unfavorable data, are materially uniform per indication. See *In re Synthroid Marketing Litig.*, 188 F.R.D. at 300 (permitting class certification of consumer purchases of a drug based on an allegation of suppression of a medical examination and study showing an expensive drug was the bioequivalent of other less expensive drugs). They have alleged several instances where defendants suppressed or misrepresented the results of negative data and numerous examples of defendants' dissemination of materially uniform misrepresentations related to *Neurontin's* efficacy for each of the off-label indications. Accordingly, minor, immaterial variations among the alleged oral misrepresentations will not defeat certification.

D. CAUSATION AND INJURY

Next, defendants contend that certification is inappropriate because plaintiffs cannot prove causation or injury on a class-wide basis. Instead, defendants argue, plaintiffs must establish through individualized inquiries that each class member's prescribing physician was exposed to a statement or omission by defendants regarding *Neurontin's* efficacy for a particular off-label use; that the statement was false, or the omission material; that the false statement or omission caused the doctor to prescribe *Neurontin*; and that *Neurontin* was not effective in treating the plaintiff's condition. Thus, they argue, the individualized inquiries required to prove each of these elements predominate over questions common to the class.

Plaintiffs insist that causation and injury are susceptible to common proof. At the hearing on class certification, plaintiffs waived any reliance on an individualized theory of causation based on the exposure of a class member's prescribing physicians to defendants' allegedly fraudulent representations or omissions. (See Tr. 25:12, May 4, 2007.) Instead, plaintiffs rely on a proposed econometric analysis to distill, at the aggregate*110 level, off-label prescriptions caused by defendants' marketing activities from

those that plaintiffs concede would have been written regardless of any promotional activities on defendants' part. They rely on another expert in econometrics to monetize the damages attributable to the class. (See generally Hartman Decl.) Using these methods, plaintiffs contend that they can prove for each indication, over time, that defendants' fraud was a substantial contributing factor for substantially *all* of the prescriptions written.

1. Causation

“[A] RICO plaintiff must prove ‘some direct relation between the injury asserted and the injurious conduct alleged.’ ” *Anza*, 126 S.Ct. at 2000 (quoting *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 112 S.Ct. 1311, 117 L.Ed.2d 532 (1992)). To establish proximate cause, plaintiffs must demonstrate that their purchases occurred after the allegedly fraudulent statements were made and that the alleged fraud “directly or indirectly injured plaintiffs.” *Garner v. Healy*, 184 F.R.D. 598 (N.D.Ill.1999) (certifying class of consumers who purchased after a fraudulent marketing campaign for car wax).

Plaintiffs' principal expert, Meredith Rosenthal, an Assistant Professor of Health Economics and Policy at the Harvard School of Public Health, has submitted a declaration in which she concludes, first, that there is strong evidence of a causal link between pharmaceutical promotion and drug sales, and that the effects of promotion occur regardless of whether the messages promoted are true or false. (Rosenthal Decl. ¶ 13.) Second, she states that, using a time-series regression, plaintiffs can calculate the total number of off-label prescriptions that were caused by defendants' off-label marketing activities indication-by-indication while controlling for other factors that may have influenced off-label sales. (*Id.* ¶¶ 32-35.)

A multiple regression analysis like that proposed by Professor Rosenthal is a widely-used statistical tool employed to break apart the total effect of several explanatory variables acting simultaneously on a dependent variable into the components attributable to each explanatory variable. Professor Rosenthal proposes to use her model to isolate the effects of defendants' off-label marketing activities on off-label sales over time, and to quantify the number of off-label prescriptions, by indication and dosage, attributable to defendants' allegedly fraudulent promotional activities. In this way, she maintains that she

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

will be able to weed out the off-label prescriptions which, as plaintiffs concede, would have been written in the absence of any off-label promotion by defendants. (*Id.* ¶ 37.)

In her analysis, Professor Rosenthal will rely on extensive sales and promotional data maintained by defendants, as well as information from various other sources, including independent pharmaceutical data and consulting companies like IMS Health and Verispan, which closely track pharmaceutical sales and promotions. (*See id.* ¶ 40.) Because not all of this information has been produced or compiled, Professor Rosenthal has not yet run the data through her model. In her declaration, she identifies several potential modifications to her model that would allow her to account for various complications that may arise in the course of performing her analysis.

Defendants attack this approach on multiple fronts. First, defendants argue that Rosenthal's proposed methodology cannot accomplish what it sets out to do. They have submitted a report from Fionna Scott Morton, a Professor of Economics at the Yale School of Management, who identifies a number of perceived problems with Professor Rosenthal's econometric approach that relate to potential omitted variables that could affect the causality analysis, including insufficient or non-existent data and potential statistical errors.

On a motion for class certification, a court need not plunge into the weeds of an expert dispute about potential technical flaws in an expert methodology. *See Smilow*, 323 F.3d at 40-41 (“If later evidence disproves [the expert's proposed methods], the district court can at that stage modify or decertify the class, or use a variety of management devices.”). “The important question in a class certification context is whether after a sneak preview of the issues, the expert approach*111 appears fundamentally flawed—an issue usually vetted more fully at a Daubert hearing based on a more detailed record.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 90 (D.Mass.2005) (Saris, J.). Professor Rosenthal has taken into account the possibility that additional variables will have to be included in her analysis, and has asserted that it would be feasible to do so. In addition, Rosenthal's analysis proposes to rely on an enormous amount of data regarding off-label sales and defendants' promotional activities meticulously compiled

both by defendants and independent services.

The relator proffered dramatic statistics that even a lay judge can understand without an econometric model. One calendar quarter after the campaign to publicize [Neurontin](#) for pain started, [Neurontin](#) prescriptions for pain increased 2500%. Within three months after the migraine promotion commenced in the second quarter of 1996, usage increased 800%. After the psychiatric off-label campaign began, psychiatric use increased 1000% in only six months. (Rosenthal Report ¶ 35.) Evidence demonstrates that off-label prescriptions of [Neurontin](#) amounted to approximately 13% of total scripts prior to the off-label promotional campaign. (*Id.* at ¶ 37.) Off-label prescriptions constituted 90% of total scripts at the end of the class period.

Defendants' expert, Professor Fiona Scott Martin, complains that this surge in off-label prescriptions could be explained by advances in medical knowledge, through “postings on medical websites, advances in basic science, and informal conversations” which create a buzz about the drug. (Morton Decl. ¶ 45.) However, with such a large bump-up in off-label sales immediately following a promotional campaign, it seems more likely that the increase was not due to the diffusion of new knowledge about the “basic science” of the brain. (*Id.* ¶ 41.) It stands to reason that Pfizer believes its promotional campaign has an impact because it spends so much time and money on marketing and evaluating its effect. Plaintiffs present information, published on the IMS website, that Pfizer spends approximately \$100 million annually to obtain data for use in its own marketing analyses.

Based on this preliminary record, I conclude that Professor Rosenthal's proposed methodology is a plausible way of determining aggregate class-wide liability, and defendants have identified no fundamental flaws now appearing in her proposal to calculate aggregate damages.

Plaintiffs' main hurdle is the inability to identify which prescribing physicians were exposed to defendants' fraudulent statements; this may be fatal to their theory of liability because physicians' prescribing decisions could not have been caused by statements they never heard. In other cases involving prescription drugs, courts have refused to certify a class due to the predominance of individualized issues related to

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

causation. In one similar situation, a court rejected the argument that class-wide injury could be proven by evidence that defendants' marketing scheme increased sales of a drug by \$60 million a year, because this was insufficient to prove a direct relationship between the purchase of the drug by a consumer and the illegal media campaign. See Ruffu v. Johnson & Johnson, Inc., 181 F.R.D. 341, 343 (E.D.Tex.1998) (denying certification for RICO and consumer fraud state law claims where numerous factors unrelated to alleged fraudulent off-label marketing scheme could have influenced consumers' decision to purchase Retin-A for the treatment of wrinkles); Matjastic v. Quantum Pharmics, Ltd., 1991 WL 238304, at *5 (E.D.Pa. July 22, 1991) (denying certification for class of purchasers of generic drug where, because "not all members of the class would have relied on the alleged fraudulent misrepresentation in purchasing the product, each class member would be required to prove the issue of reliance on an individualized basis"). But cf. In re Synthroid Marketing Litigation, 188 F.R.D. at 301 (deferring issue of individual's inability to prove damages for prescription drugs until a later stage of the litigation).

Professor Rosenthal's aggregate model cannot determine *which* consumer class members' Neurontin prescriptions were caused by defendants' alleged fraud-and *112 who therefore have a cognizable injury-and which would have occurred even in the absence of the fraud.^{FN19} Defendants contend that this failure to distinguish class members who have a claim from those who do not cannot be remedied by plaintiffs' proposed utilization of a "fluid recovery" process, and that its use would violate the Rules Enabling Act, 28 U.S.C. § 2072 (procedural rules may not "abridge, enlarge, or modify any substantive right").

^{FN19} Defendants also object that Professor Rosenthal's model offers no way to distinguish those off-label consumers for whom Neurontin was effective. (See Decl. of Fiona Scott Morton, ¶ 34.) However, plaintiffs have alleged that Neurontin was not effective for *any* of the off-label conditions at issue.

Under the "fluid recovery" (or "cy pres distribution") process, "the jury determines the aggregate damage to the class without deciding how much each individual class member is to receive. Allocation of

the award is made later, administratively, upon the submission of claims, and often according to a formula." In re New Motor Vehicles Canadian Exp. Antitrust Litig., 235 F.R.D. 127, 143 (D.Me.2006) (citing 3 Conte & Newberg, Newberg on Class Actions, § 10:17); see also Schwab v. Philip Morris USA, Inc., 2005 U.S. Dist. LEXIS 27469, No. CV 04-1945, 2005 WL 3032556, at *5-9 (E.D.N.Y. Nov.14, 2005) (Weinstein, S.J.) (canvassing authorities on this approach in great detail) (stayed pending appeal).

Some courts have refused to certify classes where the plaintiffs' proposed fluid recovery process offered no way to identify eligible (i.e., injured) class members. See Dumas v. Albers Med., Inc., 2005 WL 2172030, at *7, 2005 U.S. Dist. LEXIS 33482, at *22 (W.D.Mo. Sept. 7, 2005) (fluid recovery "not appropriate when it is used to assess the damages of the class without proof of damages suffered by individual class members" and class action was otherwise unmanageable); In re Phenylpropanolamine Prods. Liab. Litig., 214 F.R.D. 614, 620 (D.Wash.2003) (noting that "[t]he Ninth Circuit rejected the use of fluid recovery as a means of dispensing with proof of individual injury under Rule 23") (citing In re Hotel Charges, 500 F.2d 86, 89-90 (9th Cir.1974) ("Such enlargement or modification of substantive statutory rights by procedural devices is clearly prohibited by the Enabling Act that authorizes the Supreme Court to promulgate the Federal Rules of Civil Procedure.")). Nevertheless,

Aggregate computation of class monetary relief is lawful and proper. Courts have not required absolute precision as to damages and have allowed damages to be proven by reference to the class as a whole, rather than by reference to each individual class member. Challenges that such aggregate proof affects substantive law and otherwise violates the defendant's due process or jury rights to contest each member's claim individually, will not withstand analysis.

3 Conte & Newberg, Newberg on Class Actions, § 10:5 (2002).

The Seventh Circuit has held that when determining the propriety of fluid recovery, the "general inquiry is whether the use of such a mechanism is consistent with the policy or policies reflected by the statute violated." Simer v. Rios, 661 F.2d 655, 676 (7th

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

[Cir.1981](#)) (particularizing the inquiry further “into an assessment of to what extent the statute embodies policies of deterrence, disgorgement, and compensation”). Still, the Court rejected “any approach which would automatically utilize a fluid recovery mechanism as a procedural alternative to class action disposition.” [Id. at 676](#) (declining to certify class because individual issues regarding knowledge of class members and other factors made the class unmanageable).

In this case, plaintiffs' proposed use of fluid recovery would effectuate the policies underlying the civil RICO statute, “a law which was enacted both to provide compensation to injured people and to increase enforcement of federal law through the creation of ‘private attorneys general.’ ” [Schwab v. Philip Morris USA, Inc.](#), 449 F.Supp.2d 992, 1268-69 (E.D.N.Y.2006). This result also furthers the broad remedial goals of state consumer protection laws. *See, e.g., Int'l Union of Operating Eng's Local # 68 Welfare Fund*, 894 A.2d at 1142-43 (NJCA *113 intended to be applied liberally to compensate victims of fraudulent and unconscionable practices and deter wrongdoers).

However, the cy pres doctrine does not circumvent the bedrock principle that members of a class must be identifiable. *See Crosby v. Social Sec. Admin.*, 796 F.2d 576, 580 (1st Cir.1986) (class-wide relief not available “[w]ithout an identifiable class of ... claimants”); [7A Charles Allen Wright et al., Federal Practice and Procedure](#), § 1760, at 140 (certification inappropriate “unless the class description is sufficiently definite so that it is administratively feasible to determine whether a particular individual is a member”). [Rule 23](#) does not permit “dispensing with individual proof of damages.” [Six Mexican Workers v. Arizona Citrus Growers](#), 904 F.2d 1301, 1305 (9th Cir.1990). “A plaintiff suing under civil RICO must demonstrate injury as a result of racketeering activity and a specifiable amount of damages.” [Sikes v. Teleline, Inc.](#), 281 F.3d 1350, 1365 (11th Cir.2002). “To allow recovery by persons who have not been injured or to allow recovery for an injury greater than that caused by offending conduct would run counter to the plain language of the statute.” [Id.](#) (citing [18 U.S.C. § 1964\(c\)](#)) (“Any person injured ... shall recover three fold the damages he sustains ... ‘Shortcuts’ like presumptions of injury are not permitted to lessen the burden of proof.”))

The First Circuit has not yet had occasion to address the “cy pres” or “fluid recovery” doctrine. Under this doctrine, many courts have distributed excess funds not claimed by class members to a charity. *See, e.g., Masters v. Wilhelmina Model Agency, Inc.*, 473 F.3d 423, 436 (2d Cir.2007) (explaining that “Cy Pres means ‘as near as possible,’ and ‘[c]ourts have utilized Cy Pres distributions where class members are difficult to identify, or where they change constantly, or where there are unclaimed funds.’ ” (emphasis added) (quoting [Newberg, supra, at § 10:16](#) n. 1.)); *see also In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 235 F.R.D. 127, 144 (D.Me.2006) (use of fluid recovery to calculate damages does not defeat class certification).

Here, however, plaintiffs have failed to articulate a method of identifying *any* members of the consumer class. This is a complicated task because the consumers purchased drugs based on the prescription of a doctor who is a “learned intermediary.” While 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. Plaintiffs' Donnybrook is identifying class members with respect to the consumer claims.

Though plaintiffs have pointed to cases in which courts have certified consumer classes without requiring proof of individual causation and injury, they have not identified a single case where a court certified an overbroad class with members who were not injured under such a theory. Even in [Synthroid](#), plaintiffs' flagship case, the court certified a RICO class of consumers who purchased the prescription drug Synthroid at higher prices than they would have paid had the manufacturer accurately represented the drug's bioequivalency to certain generic drugs. *See* [188 F.R.D. at 295](#). There, as here, defendants argued that the plaintiffs would need to demonstrate that the misrepresentations actually caused a class member to purchase the drug. However, the court ruled, without much analysis, that “if an individualized determination of proximate cause or damages becomes necessary, such questions can be resolved after the liability issue is decided.” [Id. at 300](#) (explaining that “a RICO

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

claim based on mail and wire fraud ‘focuses on the defendant’s conduct in devising or intending to devise a scheme to defraud, not the individual experiences of each defrauded person’). Significantly, though, every purchaser of Synthroid was allegedly injured when she paid the manufacturer’s inflated price.

In *Schwab*, Judge Weinstein struggled with similar obstacles to proof of individual injury. Though approving the use of an aggregate, cy pres approach to RICO causation,*114 the court acknowledged that plaintiffs—who sought the difference in the purchase price paid for “light” cigarettes and the price they would have paid had the cigarettes’ dangers been honestly disclosed—“may have relied differently on the ‘lights’ designation and may have acted differently and for different reasons relevant to damages.” [449 F.Supp.2d at 1022](#). Nonetheless, aggregate proof and cy pres distribution was appropriate because every class member paid more for “light” cigarettes than the product was worth and therefore had a cognizable injury under the RICO statute, even if the extent of that injury was subject to individual variation. See also *In re Zyprexa Prods. Liability Litig.*, [493 F.Supp.2d 571, 579 \(E.D.N.Y.2007\)](#) (Weinstein, S.J.) (“Statistical proof of reliance is appropriate in the RICO context where a ‘sophisticated, broad-based [scheme,] by [its] very nature ... likely to be designed to distort the entire body of public knowledge rather than to individually mislead millions of people[,]’ is alleged” and where the fraud results in inflated prices (quoting *Schwab*, [449 F.Supp.2d at 1047](#))). Moreover, in *Schwab*, the misrepresentations were prominently displayed on every pack of cigarettes purchased by every consumer.

Under similar circumstances, the Massachusetts Supreme Judicial Court certified under the Massachusetts consumer protection statute (not [Rule 23](#)) a class of smokers who purchased “light” cigarettes at inflated prices. *Aspinall v. Philip Morris Cos.*, [442 Mass. 381, 398, 813 N.E.2d 476 \(Mass.2004\)](#). The court rejected defendants’ argument that individual proof of injury and damages precluded class treatment, reasoning that “on the plaintiffs’ theory of economic damages ... the market price for Marlboro Lights was higher than it would have been had the cigarettes been honestly advertised and, therefore, all purchasers of the product paid more because of the deception.” *Id.* (emphasis in original). Moreover, the court recognized that the “purchase of an intentionally

falsely represented product” could be “by itself, an ascertainable injury under [the] consumer protection statute.” *Id.* at 394, [813 N.E.2d 476](#). Accordingly, the class did not include non-injured persons.

The plaintiffs have not identified any case in which a court has certified a class of consumers that necessarily includes a substantial number of unidentifiable non-injured persons. Under [Rule 23](#), a class action must be a superior vehicle for resolving plaintiffs’ claims. See [Fed.R.Civ.P. 23\(b\)\(3\)](#) (court should consider “the difficulties likely to be encountered in the management of a class action”). Here, there is no way to identify injured class members, and plaintiffs have not proposed a feasible cy pres distribution process. In the “light” cigarette cases, the plaintiffs themselves could testify about their purchasing decisions. Here, by contrast, to establish causation and injury the plaintiffs would need to conduct inquiries into the prescribing decisions of each class member’s physician. As a practical matter, fluid recovery would flood the Court with a torrent of individual trials.

This case is troublesome because defendants allegedly used a national marketing scheme to promote a fraud. If true, they should not get off scot-free if there is a practical statistical way to address the difficult causation issues. Plaintiffs claim that Dr. Rosenthal’s model can prove what the effect of any fraudulent promotional campaign for an off-label indication was. If 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. At present, however, the record does not contain such a proffer. As such, Plaintiffs’ motion to certify a consumer class for neuropathic pain and migraine is **DENIED** without prejudice.

A different problem in manageability exists for TPPs which reimburse for [Neurontin](#) for many plan beneficiaries. If 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. This approach is problematic,*115 however, if TPPs are unable to distinguish between payments for on- and

244 F.R.D. 89, RICO Bus.Disp.Guide 11,344
(Cite as: 244 F.R.D. 89)

off-label prescriptions, or among the indications. It is unclear if that problem can be resolved statistically. Because plaintiffs have not proposed typical TPP class representatives and there are so many open questions, I need not address the viability of plaintiffs' theory on an incomplete record.

ORDER

For the reasons stated, the Court ***DENIES*** without prejudice plaintiffs' motion for class certification. Plaintiffs shall file any new motion for class certification within 60 days.

D.Mass.,2007.
In re Neurontin Marketing and Sale Practices Litigation
244 F.R.D. 89, RICO Bus.Disp.Guide 11,344

END OF DOCUMENT