

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN

MIDWEST HEALTH PLAN, INC.,  
A Michigan Corporation,  
Individually, and on behalf of all other  
Health plans similarly situated

Plaintiffs,

File No.

vs.

PFIZER, INC.,  
WARNER-LAMBERT, INC.,  
AND PARKE-DAVIS, A DIVISION  
OF WARNER LAMBERT, INC.,

Defendants.

---

CHARFOOS & CHRISTENSEN, P.C.  
JASON J. THOMPSON (P47184)  
Attorneys for Plaintiffs  
5510 Woodward Avenue  
Detroit, MI 48202  
Telephone: (313) 875-8080

Plaintiff Co-counsel:  
ZIMMERMAN REED, PLLP  
Ronald S. Goldser - MN #35932 (*pro hac vice* pending)  
651 Nicollet Mall, Suite 501  
Minneapolis, MN 55402  
Telephone: (612) 341-0400

DAVID ROSEN (P56408)  
Attorney at Law  
17117 W. Nine Mile Rd.  
Suite 1544  
Southfield, MI 48075  
Telephone: (248) 443-4800

---

**CLASS ACTION COMPLAINT AND JURY DEMAND**

A civil action between these parties or other parties arising out of the transaction or occurrence alleged in the Complaint has been previously filed in this Court, where it was given the docket number 01-72648 and was assigned to Judge Victoria Roberts.

---

JASON J. THOMPSON (P47184)  
Attorneys for Plaintiff

NOW COMES Plaintiff, MIDWEST HEALTH PLANS, by and through their attorneys CHARFOOS & CHRISTENSEN, P.C., and in support of their Complaint, allege as follows:

### **I. NATURE AND SUMMARY OF THE CASE**

1. This class action asserts federal claims for racketeering and illegal kickbacks, and state law claims for fraud, interference with contract, unjust enrichment and conversion, arising from Defendants' systematic illegal promotion and sale of the drug Neurontin, known generically as Gabapentin. Defendant Pfizer, Inc. ("Pfizer") currently markets and sells the drug Neurontin. Prior to its acquisition of Warner-Lambert in 2000, Neurontin was marketed and sold by Parke-Davis, a division of Warner-Lambert ("Defendants"). Hereafter, all Defendants are collectively referred to as "Defendants". Plaintiff brings this action on behalf of all health insurers and self-funded plans, as more fully described below, who paid for prescriptions for Neurontin, when Neurontin was prescribed for unapproved purposes. Hereafter all references to "Plaintiff" includes all class members, unless the context specifies otherwise.

2. Drug companies must apply to the U.S. Food and Drug Administration ("FDA") for approval to sell a new drug. In that approval process, the manufacturer often seeks FDA approval for many different purposes. Often, the FDA approves the drug for a narrower use than sought, doctors are free to prescribe a drug for a non-approved or "off-label" use. The market for off-label use often vastly exceeds the approved FDA use.

3. Drug companies spend billions of dollars each year trying to persuade doctors to prescribe their drugs. There are strict federal regulations about what form that promotion can take and, in particular, promoting "off-label" use. These regulations are meant to ensure that drug companies provide doctors with trustworthy information so that medications are prescribed appropriately.

4. The Food and Drug Administration Act of 1997 ("FDAMA"), 21 U.S.C. 360aaa et seq., specifically authorizes a manufacturer to disseminate "written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device", 21 U.S.C. 360aaa(a), if it complies with several requirements: The manufacturer must submit an application to the FDA seeking approval of the drug for the "off-label" use; the manufacturer must provide the materials to the FDA prior to dissemination; the materials themselves must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information ... necessary to provide objectivity and balance." 21 U.S.C. 360aaa(b)(1)-(6); id. at 360aaa(c); id. at 360aaa-1 (emphasis added). Importantly, FDAMA amends the Food, Drug, and Cosmetic Act to prohibit "the dissemination of information in violation" of these provisions. 21 U.S.C. 331(z); see also id. at 360aaa-4(b)(1) (emphasis added). A drug that is sold off label can be

considered misbranded. 21 U.S.C. 352; T.C. 53-1-109.

5. Thus, although FDAMA permits pharmaceutical manufacturers to disseminate to health care practitioners qualified forms of "written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug," 21 U.S.C. 360aaa(a), manufacturers are permitted to provide only "authorized information" in the form of unabridged peer-reviewed articles or qualified reference publications. *Id.* at §360aaa-1. But, the FDAMA also requires Defendants to furnish federal regulators with advance copies of the information they planned to disseminate: Sixty days prior to disseminating the information, the manufacturer must furnish the Secretary of Health and Human Services (Secretary) a copy of the information it plans to distribute, as well as clinical trial information the manufacturer has regarding the off-label use's safety and effectiveness. The manufacturer also must forward to the Secretary any reports it has concerning the safety and effectiveness of the off-label use.

6. In 1993, Defendants received FDA approval to market and sell Neurontin for the treatment of epilepsy. There are two million epileptics in the United States, a number that is not considered to be a large market to a major pharmaceutical company. Starting in 1995, Defendants' executives embarked on a scheme the purpose of which was to increase Neurontin sales for diseases with respect to which Neurontin had not received FDA approval because it had failed to demonstrate the safety or efficacy of Neurontin to treat these diseases. Defendants' sales department recognized a significant profit potential in the "off-label" promotion of Neurontin for other diseases and at higher dosages than those approved by the FDA. Executives at Defendants' company decided to completely avoid the normal regulatory process of the FDA pertaining to the marketing of a new use of a drug and

to proceed in an illegal fashion in order to capture the lucrative "off-label" market. The decision was also made to actively conceal the illegal means, which would be used to market the drug. Originally, the principal component of the scheme was the hiring and deployment in the field of approximately 60 "medical liaisons," whose real function was to actively solicit physicians to promote "off-label" uses of Neurontin, using cash payments as a reward and incentive. This "off-label" solicitation was to be done in a covert fashion, largely in private meetings with doctors.

7. In the pharmaceutical industry, medical liaisons are typically individuals with scientific training who are available at a physician's request to provide balanced scientific information about a company's products. They have no legitimate role as salespeople.

8. At Defendants' company, many of the "medical liaisons" were hired directly out of the sales department. They were all trained in sales techniques and compensated, in part, on the basis of sales. They had no discernable scientific or medical functions. They had no communication or interaction with Defendants' actual medical research divisions. The medical liaisons were assigned to act as teams with the regular sales representatives. They were given lists of doctors for "cold calls" based on the size of the doctors' practices and their ability to prescribe Neurontin. They were provided with a package of monetary incentives to offer to physicians who got involved in the Defendants program.

9. Defendants also created a complex array of monetary incentives for physicians who wrote prescriptions for Neurontin. None of these incentives have anything to do with true scientific or medical research or with the safety of patients. These incentives include cash payments to "consultants" and "preceptors", cash payments for a "speakers bureau" and for participation in teleconferences, the award of money for scientifically inadequate and

irrelevant "studies", miscellaneous cash payments for access to records of patients who are taking Neurontin, travel and Olympics tickets, and other benefits. The recipients of these awards and benefits were selected by the sales department based on their ability to prescribe Neurontin and to influence other doctors to do so.

10. The medical liaisons were trained to use knowingly false information to persuade physicians to use Neurontin for "off-label" uses. Defendants' official sales line in this regard was that because Neurontin is safe at very high doses and produced no significant side effects, there is no problem using it for "off-label" indications. Medical liaisons were trained to tell doctors that evidence exists that Neurontin, in high doses, is effective for control of bipolar mental disorder, monotherapy for seizures, for control of a variety of pain states, for attention deficit disorder, for migraines, for drug and alcohol withdrawal seizures, for restless leg syndrome, and for several other diseases. At the time these statements were made, there was no competent scientific evidence that Neurontin was safe and effective for any of these conditions or at dosages beyond the dosage approved by the FDA. The only "evidence" that existed was gossip, case reports from physicians paid by Defendants, self-referential studies and rumor. The medical liaisons were also trained to misrepresent their own credentials to the physicians in order to elevate their own credibility, by saying they were "involved in research". In fact, they were purely involved in sales.

11. Defendants' medical liaisons, using a combination of misrepresentations and cash incentives, encouraged many physicians to experiment with their own patients by prescribing very high levels of Neurontin for a variety of "off-label" indications. Defendants did this with the combined motives of increasing sales, generating a body of "medical

practice" and case reports which could later be used for further "off-label" promotion with other physicians. Defendants' sales employees expressed callous disregard for the possibility of adverse reactions occurring during these informal, non-FDA sanctioned, illegal experiments. The Defendants' scheme focused in particular on the market for bipolar disorders. It did so by a variety of methods, including sponsoring inexpensive studies later published in scientific journals, which purported to show favorable results in using Neurontin for non-approved uses. These studies were published by doctors who had received money from Defendants, either in the form of educational grants or some other form of monetary pass-through as described below.

12. An example of how the scheme works is contained in a proposal to Defendants from a Philadelphia company called Medical Education Systems ("MES"). In the proposal, which was submitted in December 1996, MES requested \$160,000 to develop a series of 12 scientific articles to "support epilepsy education". In fact, three of the articles MES proposed related to Neurontin and bipolar disorder. Defendants made sure the articles said what it wanted them to. It approved the authors and topics, it cleared the journals in which the articles were printed, and its executives edited drafts. In some cases, it approved articles that appear to have been written almost entirely by ghostwriters of the medical education company.

13. The articles on Neurontin and bipolar disorder reported that some doctors were having success with using Neurontin for their bipolar patients and that Neurontin was a "safe" drug that was easily tolerated, so doctors could quickly increase the doses they gave their patients. As part of the "off-label" marketing scheme, this message was then reinforced by Defendant's salesmen when they called on doctors to tell them about the latest

research on Neurontin and at teleconferences, lavish dinner meetings and medical seminars where Defendants paid leading doctors to speak to other doctors who were also paid a fee to listen.

14. Based on these articles, as well as other illegal promotional activity described herein, tens of thousands of bipolar disorder patients are now being treated with Neurontin. However, a scientifically valid study conducted at the Harvard Bipolar Research Program found that patients did worse on Neurontin than those who were on a sugarpill. Defendants sponsored this 1998 study, were aware of the results, but did not publish the results until two years later. By that time, Neurontin accounted for \$1.3 billion in sales, with over 80% of its use coming from non-approved uses, such as treatment of bipolar disorder.

15. Despite this lack of scientific evidence, Neurontin sales for these and other "off-label" uses have steadily increased, to the point that, according to an article published in the December 1, 2003 issue of *Medical Marketing & Media*, 90% of Neurontin sales are for "off-label" use. No other drug in the United States has such a high percentage of "off-label" use. The same article estimates that \$1.8 billion worth of Neurontin has been sold for "off-label" uses. This increase in prescription of Neurontin for "off-label" uses, without any supporting scientific studies that would be prompting such use, cannot be a random event and could not occur without continuing "off-label" promotion by Defendants' sales force. Twice in the last three years, Pfizer has been found by the Department of Health & Human Services to have engaged in illegal promotional acts with respect to the sale of Neurontin.

16. On May 13, 2004, Warner Lambert was charged with criminal violations of the Federal Food Drug and Cosmetic Act in an information brought by Department of Justice

in the United States District Court for the District of Massachusetts.

17. The information presented criminal charges against Warner Lambert for violations of 21 U.S.C. 331(a) and (d), 333(a)(2), 352(f)(1) and 355(a) based upon the misconduct set forth above.

18. The information charged that Warner Lambert violated 21 U.S.C. 331(a) and (d) by introducing and distributing Neurontin into interstate commerce for uses other than its approved uses and by introducing and delivering Neurontin into interstate commerce in violation of 21 U.S.C. 355, which required Warner Lambert to obtain FDA approval for all of the proposed intended uses of Neurontin.

19. The information further charged that Warner Lambert violated 21 U.S.C. 352(f)(1) by misbranding Neurontin without adequate directions in its label for its proper use.

20. The information further charged that Warner Lambert violated 21 U.S.C. 355(a) by introducing and delivering Neurontin into interstate commerce without applying for and obtaining FDA approval for Neurontin's proposed and intended uses.

21. Warner Lambert entered a plea of guilty to all of the above-referenced criminal charges immediately upon the filing of such charges.

## **II. FRAUDULENT CONCEALMENT**

22. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from Plaintiff. Defendants have denied and, until they recently pled guilty to fraud, continued to deny, that their representations regarding the use and efficacy of Neurontin for purposes not approved by the FDA ("off label use") were indeed fraudulent.

### **III. JURISDICTION AND PARTIES**

23. Plaintiff is a Michigan corporation and health plan organized and operating under the laws of Michigan with office at 5050 Schaefer Road, Dearborn, Michigan. Plaintiff operates as a Managed Care Organization under a contract with the State of Michigan to provide medical services to eligible individuals under the Michigan Medical Assistance Program. Plaintiff operates throughout the state of Michigan.

24. Defendant Pfizer, Inc. is a corporation duly organized and existing under the laws of the State of Delaware with its principal place of business in New York. Pfizer is the successor in interest to Warner-Lambert, Inc and Defendants.

25. This Court has jurisdiction over this action pursuant to 28 U.S.C. 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds \$75,000, exclusive of interest and costs. This Court also has jurisdiction because this Complaint presents federal questions, giving the Court jurisdiction under 28 U.S.C. 1331. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. 1367.

#### **IV. DETAILED FACTUAL ALLEGATIONS**

##### **A. Defendants' Decision to Avoid FDA Approval and the "Off-Label" Marketing Scheme**

26. Defendants were principally engaged in the manufacture and sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the FDA. Pfizer acquired Warner-Lambert in 2000.

27. In December 1993, the FDA approved Neurontin as "adjunctive therapy" for the treatment of certain types of seizures in adult patients suffering from epilepsy. "Adjunctive therapy" meant that the drug could not be prescribed by itself for the treatment of epilepsy, but as an add-on drug in the event that a primary anti-epilepsy drug was not successful. The FDA approved labeling of Neurontin stated that the drug is only effective at 900 to 1800 mg/day.

28. At the time Neurontin was approved, Parke-Davis' original patent on Neurontin was set to expire in December 1998. This left Defendants with only a small window of exclusivity for this drug; after the expiration of the Neurontin patent, Defendants would be forced to share the market for Neurontin with generic drug manufacturers, substantially reducing its profits and its ability to keep Neurontin's retail price high.

29. At the time Defendants filed its NDA (New Drug Application) with the FDA, Defendants intended Neurontin to be used for other indications besides epilepsy adjunctive therapy. In October 1990, Defendants filed a patent for Neurontin claiming it to be effective in the treatment of depression. In November 1990, it filed another patent application for

Neurontin claiming it to be effective for the treatment of neurogenerative disease. In 1995, additional patent applications were filed by Defendants for mania and bipolar disease and for anxiety and panic. Notwithstanding the claims made in its patent applications, neither Defendants nor Pfizer ever sought FDA approval for the use of Neurontin to treat the conditions described in the four patent applications referenced above.

30. The market for the only approved use for Neurontin - adjunctive therapy for epilepsy patients - is, and was, limited with a potential population of two million epilepsy patients. On the other hand, the market for the other uses of Neurontin contemplated by Defendants, such as pain management, psychiatric disorders, anxiety and depression, were huge. Defendants knew that if these markets could be tapped, Defendants could enjoy enormous profits from Neurontin.

31. Initially, Defendants intended to file supplemental NDAs in order to expand Neurontin's approved indications, including applications for monotherapy (which would permit Neurontin to be prescribed by itself for epilepsy treatment) and for various psychiatric and neurological indications. However, by 1995 Defendants recognized it would be uneconomical to assume the expense and time necessary to conduct clinical trials necessary to prove that Neurontin was safe and effective for these uses. Assuming Neurontin could be proven to be safe and effective, the near-term expiration of the patent meant that generic manufacturers of Neurontin would reap much of the reward that comes with proving Neurontin could be safely used for other indications.

32. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes

other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

33. After performing extensive economic analysis, senior officials at Defendants determined that it was not sufficiently profitable for Defendants to obtain FDA approval for Neurontin's alternative uses. Instead, Defendants officials developed a strategy that would allow Defendants to avoid the costs of proving that Neurontin was safe and effective for these other uses, while allowing Defendants to compete in the lucrative "off-label" markets. As one aspect of the scheme, Defendants decided to employ a "publication strategy" that would allow it to promote Neurontin by the massive distribution of publications supposedly written by independent researchers that purportedly described the scientific evaluation of Neurontin. Another advantage of this strategy, from Defendants' perspective, was that it could be employed immediately; there was no need to wait for the results of scientifically conducted clinical trials to determine if Neurontin was actually effective in the treatment of these conditions.

34. The Defendants scheme consisted of an elaborate and clandestine promotion of "off-label" uses of Neurontin, all in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency and, in particular, for the "off-label" uses of pain control, monotherapy for seizures using extremely high doses, control of bipolar disorder, attention deficit disorder, and other diseases and conditions.

35. Minutes of meetings held in 1995 showed that marketing and clinical employees of Defendants decided that clinical trials were too expensive and they would take

too long, so that by the time the company got the results, the patent on Neurontin would be close to running out and the market would be flooded with cheap copies of Neurontin.

36. As a result, a group of executives called the "New Products Committee" approved an alternative strategy; in other words, not the strategy that would have involved going to the FDA, but an alternative strategy to generate these additional uses of Neurontin. They decided that Defendants would pay for clinical trials in a range of uses - bipolar disorder, social phobia, migraine, and chronic pain - and then publicize the results of those trials through medical journals and medical conventions. The head of this committee was the then-president of the company, Tony Wild.

37. Although federal regulations did not permit Defendants to promote unapproved uses of Neurontin, Defendants were permitted to distribute publications created by "third parties" that described results of "off-label" uses of Neurontin if such material was distributed in response to non-solicited requests from physicians. Defendants decided to exploit this narrow exception by creating events and programs that would allow special Defendants' employees and independent contractors under Defendants' control to promote "off-label" usage under circumstances that would allow Defendants to deny, wrongfully, that it had solicited "off- label" usage.

38. Significant ingenuity and resourcefulness was necessary in order to execute this unlawful scheme without detection. Faced with the fact that its "publication strategy" required publications from independent physicians when no such publications existed, Defendants hired non-physician technical writers to create articles for medical journals and then paid actual specialists to be the articles' "authors". Faced with the fact that its normal marketing force could not deliver the "off-label" message, Defendants trained its medical

liaisons - technical employees who were supposed to provide balanced scientific information to doctors - to sell "off-label" and solicit interest in "off-label" uses. Faced with the fact that in order for a "publication strategy" to actually increase usage of a drug, Defendants required a large group of doctors interested in experimenting on patients, and an even larger group of doctors who were interested in receiving information about those experiments. Defendants generated both groups by liberally distributing payments to both groups of physicians through "consultants" meetings, speakers' bureaus, medical education seminars, grants, "studies", advisory boards and teleconferences. Further details of these programs are described below.

39. Notwithstanding their knowledge that they could not promote Neurontin lawfully for non-approved uses, marketing executives at Defendants' headquarters in Morris Plains, New Jersey, and in its five regional customer business units (CBUs), selected a marketing strategy which would deliberately lead to increased "off-label" usage of Neurontin. These executives knew what Defendants was not supposed to create or design the contents of the communications that would be distributed pursuant to the "publication strategy", or do anything to generate the practicing physicians' interest in receiving such communications. As demonstrated below, Defendants ignored these legal requirements and, instead, put into effect a pervasive pattern of illegal conduct described below, lasting from at least 1994 through 1998, and Plaintiffs believe, through 2000. The effects of this illegal activity continue today as doctors continue to prescribe Neurontin for "off-label" uses as a direct result of the wrongful activities described below.

40. The Defendants' scheme was carried out by employing these strategies, among others, as described below:

- a. Payment of illegal kickbacks to physicians who prescribed large amounts of Neurontin for "off-label" purposes to patients whose prescriptions were paid for by Medicare or Medicaid;
- b. formation of a nationwide network of employees falsely referred to as "medical liaisons" whose actual assigned duties consisted entirely of conventional direct sales activities and which did not include any legitimate scientific activity;
- c. illegal direct solicitation of physicians for "off-label" uses;
- d. making false statements to physicians and pharmacists concerning the efficacy and safety of Neurontin for "off-label" uses;
- e. making such false statements directly to the Veterans Administration concerning the safety and efficacy of Neurontin for "off-label" uses;
- f. charging full price for drugs actually being used in experimental trials and, thus, subject to federal price restriction;
- g. systematic avoidance of filing requirements with the FDA;
- h. deliberate avoidance of the FDA's classification of Neurontin as to its therapeutic equivalency and, thus, the avoidance of Medicare and Medicaid price limitations based on therapeutic equivalency;
- i. use of active concealment to avoid the FDA's enforcement mechanisms and the resultant mandatory interruption of Medicare and Medicaid payments for Neurontin prescriptions;
- j. use of active concealment to avoid the "formulary" policies of various state agencies administering Medicare and Medicaid programs which are intended to refuse payment for uses of drugs which are not medically recognized as statutorily defined;
- k. payment or offering of gratuities to Defendants' employees in order to procure their silence; and
- l. active training of Defendants' employees in methods of avoiding detection of their activities by the FDA.

Each aspect of the scheme is described below, and certain aspects of the scheme have continued in 2000, 2001 and 2002 and may be ongoing to the present time.

## **B. Defendants' Systematic Payments to Doctors for the Purpose of Increasing Neurontin Prescriptions**

41. Defendants' "publication strategy" required physicians (and its medical liaisons) to perform the work normally performed by the company's salesmen in order to promote Neurontin. Adoption of this strategy required Defendants to make tens of thousands of payments to the physicians who would act as a surrogate sales force as well as the practicing physicians who would receive the message. In other words, adoption of the "publication strategy" required Defendants to make thousands of payments to physicians for the purpose of having those doctors either recommend the prescription of Neurontin or to order Neurontin, in violation of the Medicaid anti-kickback regulations. Defendants were aware that these regulations were violated routinely. A description of the various programs Defendants used to make these payments to physicians follows.

### **1. "Consultants" Meetings**

42. A common ploy by Defendants to funnel illegal payments to physicians to encourage them to prescribe "off-label" was through "consultants" meetings. Under this guise, Defendants recruited physicians to dinners or conferences and paid them to hear presentations about "off-label" uses of Neurontin. Under the guise that these doctors were acting as "consultants", Defendants sometimes (but not always) had the doctors sign sham "consulting agreements". At these meetings, Defendants would give these doctors lengthy presentations relating to Neurontin, particularly regarding "off-label" usage. Presentations would be made by Defendants' employees or physician speakers hired by Defendants for the purpose of promoting Neurontin, and attendees' questions relating to the administration of Neurontin use would be solicited and answered. At some conferences, the sponsoring

organization or Defendants intentionally posed questions to the speakers about "off-label" use to insure that the attendees were exposed to such information.

43. At some, but not all, "consultants" meetings, a few questions would be posed to the "consultants" regarding Defendants marketing of Neurontin or how the Defendants' sales force could provide better service to the doctors. The "consultants" meetings, however, were not held (and the "consultants" were not paid) for the purpose of providing Defendants with expert, independent advice. In many cases, Defendants did not even record the "advice" provided by its "consultants," and whatever advice was collected was never acted upon or reviewed. Indeed, no legitimate business would need hundreds of "consultants" to advise it on the same topic.

44. Defendants did, however, routinely analyze whether the "consultants" meetings were successful in getting the attendees to change their prescription writing practices. At some meetings, the "consultants" were directly asked if they would write more Neurontin prescriptions as a result of the meeting. Such a question would have been irrelevant if the actual purpose of the meeting was to receive the "consultants" advice. Defendants also routinely tracked consultants' Neurontin prescription writing practices after these meetings. Using market data purchased from third parties, Defendants analyzed whether the doctors they had paid had, in fact, written more Neurontin prescriptions after the meeting. Again, such data was only relevant if the real purpose of the payments was to influence the doctors to order more Neurontin.

45. A typical "consultants" meeting was held in Jupiter Beach, Florida, for neurologists from the North East CBU during the weekend of April 19-21, 1996. The "consultants" selected for this meeting were not chosen on the basis of their consulting

acumen but, rather, because of their potential to write Neurontin prescriptions. In a memorandum announcing the event to Defendants' personnel, the Neurontin Marketing Team acknowledged that in order to target neurologists with the greatest potential for writing Neurontin prescriptions, sales personnel must select potential attendees from a list of the top prescription writers for anti-epileptic drugs in the Northeast; only persons who fell within this desirable demographic were allowed to be invited.

46. Qualifying physicians were given round-trip airfare to Florida (worth \$800.00), two nights' accommodations (worth \$340.00), free meals and entertainment, ground transportation and a "consultant's fee" of \$250.00. Ample time was provided so that the Defendants "consultants" could enjoy the beach resort. The value of the junket was approximately \$2,000.00 per physician.

47. The Jupiter Beach "consultants" meeting included two one-half days of presentations by Defendants relating to Neurontin, including extensive presentations relating to "off-label" uses. Although technically the presentations were provided by an independent company, Proworx, all aspects of the presentation were designed, monitored and approved by Defendants. It selected the speakers, picked the presentation topics and previewed the content of the presentations to make sure that they were acceptable. Defendants paid all expenses relating to the "consultants" meeting, including all payments to the attendees and the presenters, all travel accommodations, meals and entertainment expenses, all presentation expenses, all expenses and fees incurred by Proworx, and the substantial fees paid to the presenting physicians. Notwithstanding the FDA's prohibition regarding the provision of promotional materials on "off label" uses, Defendants provided written abstracts of the presentations that detailed "off-label" use of Neurontin to each of its "consultants."

48. No effort was made to obtain professional advice at Jupiter Beach from the "consultants" Defendants had wined, dined and entertained during the weekend. A follow-up memorandum to Defendants marketing officials noted that "the participants were delivered a hard hitting message about Neurontin" and emphasized that the participants were encouraged to use Neurontin at higher doses. More importantly, after the conference, Defendants generated "trending worksheets" listing the doctors who attended the "consultants" meeting. These worksheets enabled Defendants to track Neurontin prescription habits of the attendees before and after the "consultants" meetings to determine if these "high writing" prescribers wrote more Neurontin prescription after the conference. Persuading these heavy prescribers to order more Neurontin for their patients was, in fact, the sole purpose of the Jupiter Beach junket.

49. Jupiter Beach was not unique. Defendants hosted dozens of "consultants" meetings between late 1995 and 1997 in which the "consultants" received payments and gratuities as well as presentations on "off-label" Neurontin use designed to change the physicians' prescription writing habits. Comparable consultants' meetings included, but were not limited to, the following:

<u>Topic</u>	<u>Location</u>	<u>Dates</u>
Mastering Epilepsy	La Costa Resort, CA	July 20-23, 1995
Mastering Epilepsy	Santa Fe, NM	November 16-19, 1995
Neurontin Consultants Conference	Marco Island, FL	February 2-4, 1996
Pediatric Epilepsy	Hutchinson Island, FL	February 9-11, 1996
Mastering Epilepsy Science	Walt Disney World, FL	February 22-25, 1996
Pediatric Epilepsy	Hutchinson Island, FL	March 8-10, 1996

Mastering Epilepsy	Ritz Carlton, Aspen, CO	April 18-21, 1996
Affective Disorders in Psychiatry	Marco Island, FL	April 20, 1996
Affective Disorders Consultants	Southern Pines, NC	April 27, 1996
Conferences		
Neuropathic Pain Conference	Palm Beach, FL	May 11, 1996
Regional Consultants Conference	Ritz Carlton, Boston, MA	May 10-11, 1996
Epilepsy Management Advisors Meeting	Sheraton Grande Torrey Pines, La Jolla, CA	June 21-23, 1996
Epilepsy Management	Rancho Bernardo, CA	June 28-30, 1996
Use of Anti-Convulsants in Psychiatric Disorders	Short Hills, NJ	October 18-19, 1996
Psychiatric Disorders		
Non-epileptic Uses of Neurontin	Longboat Key, FL	November 6, 1996
Neurological Conditions Conference	Ritz Carlton, Atlanta, GA	September 27-28, 1997

Other "consultants" meetings took place in Charleston, SC, Coconut Grove, FL, Naples, FL, Memphis, TN, Louisville, KY, Washington, DC, Aspen, CO, and other places. Hundreds (if not thousands) of physicians received kickbacks to attend these events.

50. Not all payments to "consultants" were made at conferences as elaborate as Jupiter Beach. Many "consultants" meetings consisted of lavish dinners at local restaurants. The emphasis on these meetings was also on "off-label" uses, and \$200 "honorariums" were paid to the physicians who did nothing for the payment except show up. At none of the events did the "consultants" provide legitimate consultation to Defendants, but at all of the events the "consultants" were encouraged to increase their Neurontin prescription writing.

## **2. Medical Education Seminars**

51. Another format where Defendants paid kickbacks to physicians to hear "off-label" promotion of Neurontin were programs billed as Continuing Medical Education seminars ("CME"). These conferences and seminars were set up to appear to qualify for an exception to the FDA's "off-label" marketing restrictions which permits physicians to learn about "off-label" uses of pharmaceuticals at independent seminars. Such seminars, however, must be truly independent of the drug companies. The drug companies may make "unrestricted grants" for the purpose of a seminar, but may not be involved in formulating the content of the presentations, picking the speakers or selecting the attendees. None of these requirements were observed with regard to the CME seminars sponsored by Defendants for the promotion of "off-label" uses of Neurontin. While Defendants retained third-party organizations, such as Proworx and MES, to present the event seminars, it had control of virtually every aspect of these events, and the seminar companies obtained Defendants' approval for all content presented at the seminars. Defendants also paid all expenses, including all the seminar companies' fees.

52. Although the seminar companies acted as the conduit for the payments and gratuities given to the physician attendees, like the Jupiter Beach consultants' meetings, Defendants controlled every aspect of the CME programs. Defendants designed and approved the programs; hand-picked the speakers for the seminars; approved the seminar presentations of the seminars; previewed, in most cases, the contents of the seminars prior to delivery; selected the attendees based on their ability and willingness to prescribe high quantities of Neurontin; evaluated the presentations to make sure Defendants' "message" was appropriately delivered; black-listed presenters whose presentations were not

sufficiently pro-Neurontin; and monitored the prescribing patterns of the physicians who attended these conferences to insure the purpose of the conference - increased writing of Neurontin prescriptions - was achieved. Follow-up reports to marketing executives at Defendants highlighted that the attendees received presentations regarding "off-label" marketing and recommendations for dosages larger than those labeled effective by the FDA. These memoranda also reported to senior executives the pledges made by attendees to order more Neurontin for their patients.

53. For some seminars, high prescription writing physicians were selected to receive junkets comparable to those Defendants provided to the attendees of the Jupiter Beach "consultants" meetings described above. Others were less lavish, but physicians received free tuition, free accommodations, free meals and cash. Frequently, the Defendants CME seminars were accredited by continuing medical education organizations, which meant that the physicians taking advantage of Defendants' junkets did not have to pay tuition or spend additional time to fulfill their continuing medical education licensure requirements by attending truly independent medical education programs.

54. Representative CME programs sponsored by Defendants where it paid extensive kickbacks to attending physicians included, but are not limited to, the following:

<u>Seminar</u>	<u>Location</u>	<u>Date</u>
Merritt-Putnam Epilepsy		January 19, 1996
Postgraduate Courses		
Merritt-Putnam Seminar	Chicago, IL	January 26, 1996
New Frontiers in Anti-epileptic	California	Sept-Oct 1996

## Drug Use

Merritt-Putnam Symposium      Key Biscayne, FL      September 11, 1997

Merritt-Putnam Conference on      Palm Springs, CA      September 9, 1997

## Monotherapy

Merritt-Putnam Conference      St. Louis, MO      October 3, 1997

Merritt-Putnam Symposium      Boston, MA      December 5, 1997

### **3. Grants and "Studies"**

55. Defendants also made outright payments, in the form of grants, to reward demonstrated Neurontin believers and advocates. Defendants' sales managers identified key doctors who actively prescribed Neurontin or programs which were willing to host Neurontin speakers and encouraged such persons or programs to obtain "educational grants" from Defendants. Under this program of kickbacks Defendants paid:

\* \$2,000.00 to Berge Nimpolan, MD, "a great Neurontin believer," to attend a neurology seminar in San Francisco in March 1996;

\* \$1,000.00 to the University of Texas at Houston, Department of Neurology, to host a symposium where presentations would be made regarding successful "off-label" treatment with Neurontin;

\* \$3,000.00 to the University of Texas Medical School to host a conference in August 1996 at which a well-known specialist in epilepsy, who prescribed Neurontin, would attend;

\* \$4,000.00 to pay for a neurologist from the University of Texas at San Antonio to attend the American Epilepsy Society Conference in December 1996, a conference at which Defendants was presenting extensive documentation on "off-label" uses for Neurontin;

\* \$2,500.00 to the University of Texas at Houston to bring Dr. B.J. Wilder to the campus to hold a seminar. Dr. Wilder was one of Neurontin's biggest boosters for "off-label" indications and had been paid tens of thousands of dollars to promote Neurontin's "off-label" uses for Defendants across the country;

\* \$2,500.00 in June 1996 to pay for representatives from the University of Pennsylvania Medical Center to attend a conference in Saint Petersburg, Russia, on the utilization of anti-epileptic drugs, including Neurontin;

\* \$5,000.00 to Dr. Alan B. Ettinger, of Stony Brook, NY, in December 1996, a physician who had informed Defendants that he was interested in possibly doing research in Neurontin and maintained a database of patients who were treated with Neurontin;

\* \$500.00 to Bruce Ehrenberg, of Boston, MA, a leading speaker for Defendants regarding "off-label" uses of Neurontin, to attend a conference in China;

\* \$1,000.00 to Israel Abrams, M.D., Paul C. Marshall, M.D., Beth Rosten, M.D. and Spencer G. Weig, M.D., of Worcester, MA, for educational programs in February 1996.

\* \$1,400.00 to Dr. Ahrnad Beydoun of Ann Arbor, MI, for post-graduate training in March 1996. This grant was processed on a quick turnaround, the Defendants representative noting, "I realize that this is a very short time line; however. Dr. Beydoun is a very important customer;"

\* \$1,500.00 to Jim McAuley, R.Ph, Ph.D. for educational materials relating to epilepsy.

\* A grant in an unknown amount to University Hospital in Cleveland in exchange for hosting programs regarding Neurontin's use in treating neuropathic pain at conferences specifically devoted to obtaining referrals from other doctors.

56. These grants, and others, were charged to the Neurontin marketing budget. Each of these grants was made solely because the individual who would receive the money was a large Neurontin supporter or would host a program where a well-known Neurontin supporter would recommend that other physicians increase their prescriptions of Neurontin. Each of these grant awards constituted a reward or kickback for the recipient's advocacy of Neurontin.

57. Defendants' medical liaisons informed leading Neurontin subscribers that significant advocacy for Neurontin would result in the payment of large grants. These studies did not involve significant work for the physicians. Often times they required little more than collating and writing up office notes or records. Indeed, as noted below, Defendants frequently hired technical writers to write the articles for which the "authors" had been given grants.

58. Defendants were aware that these articles and studies provided minimal scientific benefit. In a letter to the FDA written in June 1997, Defendants submitted a list of "studies relating to pain, pain syndromes, and psychiatric disorders" which failed to include any of these numerous studies, purportedly funded by Defendants. Defendants intentionally neglected to report these "studies" to the FDA because they knew the funded "research" had no scientific value and would not be deemed to be studies by the FDA. Payments Defendants made for "studies" included, but were not limited to, the following:

<u>Funded Project</u>	<u>Payee</u>	<u>Payment</u>
Statistical Analysis of Patients Treated With Neurontin For Pain	Hans Hansen, M.D.; Statesville, NC	\$7,000.00
Reduction of Sympathetically	David R. Longmire, M.D.	\$7,000.00

Medicated Pain and Sudomotor Function	Russellville, AL	
Data entry for Neurontin and Pain Analysis	Travis Jackson, M.D., David Meyer, M.D.; Winston-Salem, NC	
Trial of Neurontin for distal symmetric polyneuropathy associated with AIDS	Joseph Weissman, M.D. Atlanta, GA	\$20,000.00
Neurontin for neuropathic pain in Chronic pain syndromes	Lavern Brett, M.D. Washington, D.C.	\$25,000.00
Retrospective chart analysis of Neurontin use with bipolar disorder patients	Ralph S. Rybeck, M.D.	\$5,000.00
Retrospective Analysis of Neurontin in the treatment of pain	David R. Longmire, M.D.; Russellville, AL	\$2,000.00
Retrospective Analysis of Neurontin in the treatment of chronic pain	Don Schanz, D.O. Traverse City, MI	\$8,000.00
Case histories relating to use of Neurontin as an adjuvant analgesic	Elizabeth J. Narcessian, M.D.; W. Orange, NJ	\$4,000.00

Plaintiffs have reason to believe that other payments were made to physicians for other "studies" of questionable scientific credibility.

59. One particularly large study conducted by Defendants served as yet another engine to financially reward physicians for prescribing Neurontin. In 1995 and 1996, Defendants conducted an enormous Phase IV trial known as STEPS. Although STEPS took the form of a research clinical trial, it was, in fact, a marketing ploy designed to induce

neurologists to become comfortable prescribing Neurontin at a far higher dose than indicated in the FDA approved labeling. While most clinical studies have a limited number of investigators treating a number of patients qualified for the study, the STEPS protocol called for over 1,200 "investigators" to enroll only a few patients each. The participating physicians were instructed to titrate their patients to higher than labeled dosages of Neurontin to demonstrate that patients could tolerate high dosages of the drug. Rewarding physicians for prescribing high doses on Neurontin was another way to increase Neurontin sales because higher per patient dosages increased the amount of Neurontin sold. Additionally, the STEPS study was also designed to habituate physicians to place non-study patients on Neurontin on doses higher than found effective in the clinical trials monitored by the FDA.

60. Physicians enrolling in the STEPS study were paid for agreeing to participate in the study and for every patient enrolled. At the conclusion of the study, Defendants offered each of the 1,200 "investigators" additional cash for each patient the doctor kept on Neurontin after the study ended. These payments were unquestionably kickbacks, each participating doctor was expressly paid for writing Neurontin prescriptions for their patients. The number of "investigators" who received such payments are too many for Plaintiffs to list herein. Additionally, Defendants has exclusive control of the information regarding who received such payments at the conclusion of the STEPS trial.

#### **4. Payments to "Authors" of Ghost Written Articles**

61. Yet another method of rewarding doctors for their advocacy of Neurontin was to pay them honoraria for lending their names to scientific articles which were actually prepared and written by third parties retained by Defendants. In 1996, Defendants retained

AMM/ADELPHI, Ltd. and Medical Education Systems, Inc. to prepare no less than twenty (20) articles for publication in various neurology and psychiatry journals. Most of these articles concerned "off-label" usage of Neurontin and were generated so that Defendants would have completely controlled publications it could distribute pursuant to its "publication strategy". The content of these articles was actually written by non-physician technical writers retained by Defendants, and Defendants had the right to control the content of all the articles. Defendants paid all expenses in connection with the creation of these publications.

62. Once Defendants and the technical writers conceived the articles, Defendants and its outside firms attempted to find recognized Neurontin prescribers whose names could be used as the authors of these articles. In some cases, drafts of the articles were completed even before an "author" agreed to place his or her name on the article. This even occurred in connection with case histories that purported to describe the "author's" personal treatment of actual patients. The "authors" were each paid an honorarium of \$1,000.00 to lend their names to these articles, and also were able to claim publication credit on their curriculum vitae.

63. After the technical writers completed their work, Defendants and its outside firms found journals that would publish the articles. Defendants' role in creating, approving and sponsoring the articles was hidden from the public and from the FDA. While the articles might reference that the author received an honorarium from the outside firm, the articles failed to state that the honorarium was paid with money provided by Defendants and that Defendants had approved the content and hired the actual authors. For example, an article created by Medical Education Systems (MES), Gabapentin and Lamotrigine: Novel Treatments for Mood and Anxiety Disorders, published in CNS Spectrums noted that "an

honorarium was received from Medical Education Systems for preparation of this article," but never revealed Defendants' retention and payment of MES or the fact that MES personnel, while under contract to Defendants, wrote the article.

64. Defendants used these publications as part of their "publication strategy" by presenting the articles as evidence of independent research conducted by persons with no monetary interest in Neurontin. This impression, of course, was false. Defendants created the articles to promote "off-label" uses for Neurontin, purchased the names and reputations of the authors with kickbacks and controlled the content of the articles.

#### **5. Speakers' Bureau**

65. Defendants also founded the Speakers' Bureau, another method to make large and numerous payments to physicians who recommended Neurontin at teleconferences, dinner meetings, consultants meetings, educational seminars and other events. These speakers repeatedly gave short presentations relating to Neurontin which they were paid anywhere from \$250.00 to \$3,000.00 per event. Speakers such as Steven Schachter, B.J. Wilder, Gary Mellick, David Longmire, Gregory Bergey, Michael Merren, David Treiman, Michael Sperling, Martha Morrell, R. Eugene Ramsay, John Pellock, Ahmad Beydoun, Thomas Browne, John Gates, Jeffrey Gelblurn, Dennis Nitz, Robert Knobler and others received tens of thousands of dollars annually in exchange for recommending to fellow physicians that Neurontin be prescribed, particularly for "off-label" uses. The payments that these doctors received were far in excess of the fair value of the work they performed for Defendants. Speakers who most zealously advocated Neurontin were hired most frequently for speaking events, notwithstanding the fact that many of these events purported to be independent medical education seminars where independent information

was supposed to be delivered. The identity of the doctors in the Speaker's Bureau who received kickbacks through excessive compensation can only be determined after review of the records in the exclusive custody of the Defendant. Plaintiffs are aware that extensive payments through the Speaker's Bureau took place between 1995 and 1997, the last year for which Plaintiffs have access to records. Plaintiffs are aware that "off-label" promotion of Neurontin pursuant to the "publication strategy" continued after 1997 and, accordingly, believe such kickback payments continued at least through 2000.

66. Defendants' marketing personnel, including its medical liaison staff, informed physicians of the lucrative rewards of joining the Neurontin Speaker's Bureau. Physicians were informed that if they prescribed enough Neurontin, they, too, could also be eligible to receive substantial payments just for describing their clinical experience to peers at events dedicated to promoting Neurontin's "off-label" uses. Defendants' marketing personnel, however, made it clear that the only way the doctors could receive such cash payments was if they prescribed substantial amounts of Neurontin to their patients, preferably for "off-label" uses.

67. Defendants either knew that the payments described above constituted kickbacks or acted in reckless disregard of laws and regulations of which it was aware. Defendants were well aware of the Medicare and Medicaid fraud and abuse laws, which included the Medicaid anti-kickback statute. It was further aware that the safe harbors established by the Department of Health and Human Services did not cover the extensive payments it made to doctors. Defendants were aware that its payments did not comply with the guidelines of the American Medical Association for payments to physicians. It also knew that the payments had been made for the express purpose of encouraging the physicians

to order Neurontin for their patients. Defendants were also aware of the Inspector General's Special Fraud Alert, which raised particular concerns about drug marketing. Nonetheless, Defendants did nothing to curb its kickback payments to physicians and could not have marketed Neurontin's "off-label" uses without such payments.

68. In 1997, in the wake of an investigation by the FDA, Defendants conducted a review of its marketing practices in light of existing Medicaid kickback regulations. As a result of that review, Defendants determined that none of the programs described above should have been conducted in the manner previously conducted by Defendants. Defendants issued guidelines to comply with Federal Regulations, which essentially prohibited each of the programs described above. Nonetheless, the payments to physicians for the "off-label" marketing of Neurontin did not cease and the programs continued at least until 1998. Given that Defendants' records demonstrate payments of inappropriate kickbacks to doctors through 1998, Plaintiffs believe that such payments continued through the merger of Defendants' parent, Warner-Lambert, with Defendant Pfizer in 2000, or perhaps even through the calling of a grand jury regarding Defendants' marketing practices relating to Neurontin.

### **C. Defendants' Use of "Medical Liaisons" to Promote Neurontin "Off-Label"**

69. Defendants' normal sales force was not permitted to promote "off-label" uses of Neurontin to its physician customers. The FDA, however, permitted drug company representatives to provide balanced, truthful information regarding "off-label" usage, if specifically requested by a physician, and if there was no attempt to solicit such information by the drug company. Commencing in 1995, Defendants increasingly hired "medical

liaisons" and trained them to aggressively solicit requests for "off-label" information from physicians. Once this door was open, Defendants trained the "medical liaisons" to engage in full scale promotion of Neurontin's "off-label" uses, including repetitive distribution of non-scientific, anecdotal information designed to convince physicians that "off-label" usage of Neurontin was safe and effective. In effect, Defendants used the "medical liaisons" as a surrogate sales force who had liberty to solicit physicians regarding "off-label" uses. Indeed, "medical liaisons" were selected and promoted based on their ability to sell and sales training was encouraged.

70. On April 16, 1996, at a training session for medical liaisons, Defendants' in-house lawyers stopped the videotaping of a medical liaison training session to advise the liaisons that notwithstanding formal policies to the contrary, liaisons could "cold call" on physicians so long as they had executed request forms (forms that supposedly verified that the physician had initiated the meeting) at the end of the call. Moreover, the liaisons were informed that the request forms could be filled out by Defendants sales representatives instead of the doctors. Company lawyers also informed the liaisons-in-training that there was no need to present balanced information to the customers and that liaisons should always remember that sales were necessary in order to keep the company profitable. The liaisons were also informed by the lawyers, off camera, that there really was no definition of "solicitation" and that there were methods to induce the physicians to inquire about "off-label" uses. In effect, once the medical liaison got a meeting with a doctor, there were ways to get the information about "off-label" uses to the doctor even if the physician had not requested "off-label" information. The lawyers also warned the liaisons that under no circumstances should any information about "off-label" uses be put in writing.

71. Medical liaisons were instructed in the clearest possible terms that they were to market and sell Neurontin based on its "off-label" uses. During a teleconference on May 24, 1996, John Ford ("Ford"), a senior marketing executive at Defendants' Morris Plains headquarters, directly informed the medical liaisons that in order to market Neurontin effectively, Neurontin had to be marketed for monotherapy, pain, bipolar disorder and other psychiatric uses, all of which were "off-label." Ford conceded that such marketing had to be primarily performed by the medical liaisons, because they were the only ones who could discuss these matters. At another meeting with the medical liaisons, Ford was even more blunt:

"I want you out there every day selling Neurontin. Look this isn't just me, it's come down from Morris Plains that Neurontin is more profitable. . . . We all know Neurontin's not growing adjunctive therapy, beside that is not where the money is. Pain management, now that's money. Monotherapy, that's money. We don't want to share these patients with everybody, we want them on Neurontin only. We want their whole drug budget, not a quarter, not half, the whole thing . . . .We can't wait for them to ask, we need to get out there and tell them up front. . . .That's where we need to be holding their hand and whispering in their ear Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything . . . I don't want to see a single patient coming off Neurontin until they have been up to at least 4800 mg/day. I don't want to hear that safety crap either, have you tried Neurontin, every one of you should take one just to see there is nothing, it's a great drug."

72. Thus, medical liaisons were trained to cold call high decile physicians (those who saw the most patients in a given specialty), and sell them on the "off-label" benefits of Neurontin. A key aspect of this selling was misrepresentation. The first misrepresentation was usually the status of the medical liaisons. With the full approval of marketing officials at Defendant such as John Ford, Phil Magistro and John Krukar, medical liaisons were routinely introduced as specialists in the specific drug they were presenting at a particular meeting. Thus, medical liaisons could be "experts" in anti-epileptic drugs at one moment and

an hour later be an "expert" in cardiac medication. Medical liaisons were also encouraged to represent themselves as medical researchers, even though they neither conducted medical research nor analyzed medical research performed by others. It was not uncommon for medical liaisons to be introduced as physicians, even though they had no such qualifications. Sales personnel were instructed to introduce medical liaisons as scientific employees who were given momentary leave of their academic duties to make an individual presentation to the physician; the fact that the liaisons were part of Defendant standard marketing detail was intentionally hidden.

73. Defendants' employees instructed medical liaisons on the procedure that should be followed when presenting "The Neurontin Cold-Call Story" to a neurologist, general practitioner, or psychiatrist who was a target for off-label use:

- \* Mention that you are the eyes and ears of Defendants' research and that you are gathering clinical info;

- \* Then ask general questions about the nature of the practice;

- \* Mention Neurontin and its approved uses, but dismiss them as old news;

- \* Then ask leading questions about the number of pain patients that the practice sees;

- \* Then ask a series of questions that determine the practice profile for all of the potential "off-label" uses;

- \* Next reveal that Defendants' "has a great deal of information about the fantastic response rate of patients on Neurontin in all of these disease states";

- \* Move into a discussion of the clinical trials that this information is demanding;

- \* And the "90-95% response rate that we are seeing in more than 80% of patients";

- \* Present the doctor with any publications that are available and point out that many common drugs for pain treatment are in few if any publications;

- \* Ask the physician to place some patients on Neurontin and tell them that the medical liaison will stay in touch to help develop any case reports;

- \* Mention that case reports can be lucrative and can lead to clinical trials;

- \* Offer to do a presentation and luncheon for the entire practice or a group of his friends that will detail all of the "data" we have;

- \* Invite the physician to consultant meetings in the future and point out that they pay \$250 plus a nice trip or meal in the city; and

- \* If a sales representative is present they should close the sale by asking that the next patient he sees should be put on Neurontin.

74. It was during the training in Parsippany, NJ, that a whistleblower, who is now a plaintiff in a qui tam action in federal court in Boston, Dr. Paul Franklin, first witnessed the scope of the "off-label" claims that Defendants intended its medical liaisons to market. The medical liaisons were provided with new company slides that detailed the "method" to use to increase the use of Neurontin in several different "off-label" practice types. The slide show contained a slide that showed the "Anecdotal Uses of Neurontin". The list included the following:

- \* Reflex sympathetic dystrophy (RSD)

- \* Peripheral neuropathy

- \* Trigeminal neuralgia

- \* Post-Herpetic neuralgia

- \* Essential tremor

- \* Restless leg syndrome (RLS)
- \* Attention deficit disorder (ADD)
- \* Periodic limb movement disorder
- \* Migraine
- \* Bipolar disorder
- \* Amyotrophic lateral sclerosis (ALS) [Lou Gehrig's Disease]
- \* Drug or alcohol withdrawal seizures

75. Executives explained that "this list was very important to the company but that it makes Neurontin look like snake oil, so preempt the laughter by telling your physicians that 'I'm embarrassed to show you the next slide because it makes Neurontin look like snake oil, but the fact is, we are seeing extra-ordinary results, in some cases up to 90% response in all of these conditions, that will get their attention.'" This executive went on to say that, "[n]otice all the studies we talk about, nothing gets a doc more interested in a drug than a study." Richard Grady, a medical liaison, asked if "we have any money to lace studies without big docs." He was instructed to "use the potential of a study to get in the door, even get protocols, but don't waste too much time and don't say you can get them a study, we don't have much money left." He was then told that "if anyone asks for back-up data say we are putting it together, then suggest that the doc put some of his patients on Neurontin and we will help him publish case reports that could help place a study in his practice. Everybody wins."

76. None of the "off-label" claims made in the slide had been substantiated, let alone approved by the FDA. Yet, these claims were a cornerstone of the Defendants scheme to increase "off-label" sales of Neurontin.

77. Thus, extensive misrepresentations were also made regarding the scientific information concerning "off-label" usage of Neurontin. The following misrepresentations relating to "off-label" usage of Neurontin were routinely made to physicians with the knowledge and consent of marketing personnel at Defendants, and continued to be made to doctors after the 2000 merger with Pfizer:

1. **Bipolar Disorder**. Medical liaisons informed psychiatrists that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder indicated a ninety percent (90%) response rate when Neurontin was started at 900 mg/day dosage and increased to a dosage of 4800 mg/day. No such results existed. Nor was any type of clinical trial being conducted other than a pilot study. There were no clinical trials or studies indicating that Neurontin was safe or effective up to 4800 mg/day. Indeed, Defendants was in possession of clinical trial evidence which showed that there was no dose response difference between patients who received 600 mg/day, 1200 mg/day and 2400 mg/day. Any data relating to the use of Neurontin in bipolar disorder was strictly anecdotal and of nominal scientific value. Indeed, most of the published reports on this topic had been written and commercially sponsored by Defendants, although this fact was hidden. Medical liaisons were trained to inform psychiatrists that there were 110 reports of adverse effects for Neurontin when used for psychiatric purposes. In fact, such reports had been reported to Defendants' personnel, but Defendants attempted to hide such reports from physicians.

2. **Peripheral Neuropathy and Other Pain Syndromes**. Medical liaisons were trained and instructed to report that "leaks" from clinical trials demonstrated that Neurontin was highly effective in the treatment of various pain syndromes and that a ninety

percent (90%) response rate in the treatment of pain was being reported. No such body of evidence existed. Nor was there any legitimate pool of data from which a response rate, much less a ninety percent (90%) response rate, could be calculated. Medical liaisons were trained to claim support for these findings as a result of inside information about clinical trials where no such information existed. The only support for these claims was anecdotal evidence of nominal scientific value. Many of the published case reports had been created and/or sponsored by Defendants in articles which frequently hid Defendants' involvement in the creation of the article. Defendants' payment for the creation of these case reports was also hidden from physicians.

3. **Epilepsy Monotherapy**. Medical liaisons were strongly encouraged to push neurologists to prescribe Neurontin as the sole medication to treat epilepsy, even though studies only found it safe and effective as adjunctive therapy. Medical liaisons were trained to inform neurologists that substantial evidence supported Defendants' claim that Neurontin was effective as monotherapy. In fact, at this time, Defendants knew that clinical trials regarding Neurontin's efficacy as a monotherapy were inconclusive. One of Defendants' clinical trials, 945-82, demonstrated that Neurontin was not an effective monotherapy agent; the vast majority of patients in the study taking Neurontin were unable to continue with Neurontin alone. The same study showed that there was no effective difference between administration of Neurontin at 600, 1200 or 2400 mg. Notwithstanding this data, Defendants continued to claim that physicians should use Neurontin at substantially higher doses than indicated by the labeling. Indeed, although medical liaisons routinely claimed Neurontin to be effective as monotherapy, in 1997 the FDA refused to find Neurontin a safe and effective monotherapy.

4. **Reflex Sympathetic Dystrophy ("RSD")**. Medical liaisons informed physicians that extensive evidence demonstrated the efficacy of Neurontin in the treatment of RSD. The only such evidence that existed was anecdotal reports of nominal scientific value. Medical liaisons were trained to refer to case reports, most of which had been created or sponsored by Defendants, as "studies."

5. **Attention Deficit Disorder ("ADD")**. Medical liaisons were instructed to inform pediatricians that Neurontin was effective for the treatment of ADD. No data, other than occasional anecdotal evidence, supported this claim. Nonetheless, the medical liaisons were trained to report that large number of physicians had success treating ADD with Neurontin, when no such case reports existed.

6. **Restless Leg Syndrome ("RLS")**. RLS was another condition where Defendants' medical liaisons were trained to refer to a growing body of data relating to the condition, when no scientific data existed. The only reports were anecdotal, most of which had been created and/or sponsored by Defendants.

7. **Trigeminal Neuralgia**. Although medical liaisons represented that Neurontin could treat Trigeminal Neuralgia, once again no scientific data supported this claim with the exception of occasional anecdotal reports. No data demonstrated that Neurontin was as effective as currently available pain killers, most of which were inexpensive.

8. **Post-Herpetic Neuralgia ("PHN")**. Medical liaisons were trained to tell physicians that seventy-five percent (75%) to eighty percent (80%) of all PHN patients were

successfully treated with Neurontin. Once again, no clinical trial data supported such a claim.

9. **Essential Tremor Periodic Limb Movement Disorder ("ETPLMD")**.

Medical liaisons were trained to allege that Neurontin was effective in the treatment of these conditions. No scientific data supported such claims with the exception of anecdotal reports of nominal scientific value.

10. **Migraine**. Claims that Neurontin was effective in the treatment of migraine headaches were made by the medical liaisons and were supposedly based on early results from clinical trials. Although pilot studies had been suggested and undertaken, no early results of clinical trials existed to support these claims. Once again, any data relating to treatment of migraines was purely anecdotal and of nominal scientific value. Most of the case reports were either created or sponsored by Defendants.

11. **Drug and Alcohol Withdrawal Seizures**. Medical liaisons suggested that Neurontin be used in the treatment of drug and alcohol withdrawals despite the lack of any data supporting Neurontin as an effective treatment for these conditions.

78. Misrepresentations by Defendants were not limited to presentations by medical liaisons. As noted above, publications that Defendants distributed as part of its "publication strategy" intentionally misrepresented Defendants' role in the creation and sponsorship of the publications. Physicians were led to believe that the publications were the independent, unbiased research of the authors of the articles. In fact, many of the publications distributed to physicians were created by Defendants and written by third parties retained by Defendants who were under Defendants' control. The fact that these articles were authored

by ghostwriters retained by Defendants was intentionally hidden, and the fact that the authors had financial ties to Defendants was also intentionally undisclosed. For example, an article widely circulated by Defendants concerning the use of Neurontin in the treatment of Restless Leg Syndrome asserted that the authors Gary A. Mellick and Larry B. Mellick, had not and never would receive financial benefit from anyone with an interest in Neurontin, yet the Mellick brothers had received tens of thousands of dollars for acting as speakers at Defendants events. This financial connection was hidden from the persons who received copies of the Mellick brothers' articles.

79. Defendants' strategy included paying doctors to appear as authors of journal articles on "off-label" uses of Neurontin, articles that were actually written by nonphysicians working under the direction of the company's marketers. The company then paid hundreds of doctors to attend expensive dinners and weekend retreats, where they were urged to prescribe Neurontin.

80. Other doctors, often frequent prescribers of Neurontin, were paid to speak to other physicians about Neurontin's benefits. Finally, the company paid doctors to prescribe Neurontin and include those patients in clinical trials, which were designed mainly for marketing purposes.

81. The company adopted the marketing strategy, after deciding not to perform the clinical trials needed to gain approval of new uses for Neurontin because it believed that the drug would soon lose patent protection.

82. In fact, Defendants engaged in an extensive and far-reaching campaign to use false statements to promote increased prescriptions of Neurontin.

83. The scheme used a team of "medical liaisons." While medical liaisons are ordinarily connected to the research divisions of the manufacturer, Defendants' medical liaisons were exclusively employed as sales and promotion personnel.

84. Defendants' medical liaisons were instructed to make exaggerated or false claims concerning the safety and efficacy of Defendants drugs for "off-label" uses. They were also trained to convey that Neurontin could be prescribed for its various "off-label" uses in amounts of up to 4800 mg/day - far above the maximum dosage of 1800 mg per day approved by the FDA. To bolster their representations to physicians, medical liaisons were encouraged to misrepresent their scientific credentials and to pose as research personnel, rather than as sales representatives. This practice continued in the years 2000, 2001 and may still be continuing.

85. Doctors were rewarded with kickbacks for prescribing large quantities of Defendants drugs. These alleged kickbacks took various forms. For instance, some doctors were paid sums of money which were ostensibly compensation for drug studies. However, these studies were shams and had no scientific value. Other doctors were paid sums of money under the guise of being compensated for their services as "consultants" or "preceptors" or for participating in a "speaker's bureau." Doctors were also allegedly given cash payments for small record-keeping tasks, such as allowing Defendants access to information about the doctors' patients who were receiving Neurontin. Other doctors prescribing large amounts of Defendants drugs were given gifts such as travel tickets and tickets to the Olympics.

86. When questions arose concerning the availability of reimbursement for prescriptions for "off-label" uses of Defendants drugs, medical liaisons were instructed to coach doctors on how to conceal the "off-label" nature of the prescription.

87. Defendants took numerous actions to conceal its activities from the FDA, including shredding documents, falsifying documents, and encouraging medical liaisons to conduct their marketing activities without leaving a "paper trail" that might be discovered by the FDA.

88. As part of the scheme and as set forth in a qui tam action filed by Dr. Paul Franklin, a former Defendants' employee:

- \* Upon order of the company and as a result of training of medical liaisons, Dr. Franklin of Defendants "deliberately contrived reports to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of Neurontin in the treatment of bipolar disease." In fact, no data existed at all to support the use of Neurontin in bipolar disorder.

- \* Dr. Franklin was trained and instructed to actively deceive physicians with contrived data, falsified "leaks" from clinical trials, scientifically flawed reports, or "success stories" that stated that Neurontin was highly effective in the treatment of a variety of pain syndromes. No such body of evidence existed.

- \* He was instructed to advise physicians that Defendants had developed a large body of data to support the use of Neurontin as monotherapy. This was an "outright lie" and left patients unknowingly without good seizure control.

\* Medical liaisons were instructed to tell physicians that a great deal of data existed that supported the safe use of Neurontin at levels that exceed 4800 mg/day. However, clinically significant safety data existed at dosing levels at only 1800 mg/day.

\* Defendants provided medical liaisons with slides that stated that Neurontin was effective for the treatment of Attention Deficit Disorders but no data existed to support that claim.

89. The strategy was a success. In 2000, Warner-Lambert reported that more than 78% of Neurontin prescriptions had been written for indications other than epilepsy. Sales of Neurontin that year were \$1.3 billion, and they rose to \$1.7 billion, according to IMS Health (news/quote), a health care information company.

#### **D. Illegal "Off- Label" Promotion Has Continued as has the Continuing Impact of the Earlier Misconduct**

90. As a result of the activities described above, many of which continue to occur after Dr. Franklin filed his whistleblower suit, physicians were inundated with false information about Neurontin. As a result, they continue to prescribe Neurontin for "off-label" uses for which there is no reliable scientific support.

91. On information and belief, Defendants have a company-wide practice of marketing "off-label" indications regardless of FDA limitations on the designated use of the product. "Off-label" marketing plans exist for Cox 2 inhibitors and, on information and belief, also exist for Neurontin. Pursuant to this practice, Defendants' sales representatives have, while visiting with doctors, violated FDA rules and regulations by marketing Neurontin for "off-label" uses.

92. This continuing course of conduct is evidenced in part by the staggering growth of Neurontin sales for non-approved FDA use. Because there are no valid scientific studies supporting such use, a reasonable inference is that the use results from past and continuing promotional efforts by Defendants. This clear and unavoidable conclusion follows from observations regarding the ongoing extent of prescriptions written for "off-label" Neurontin use.

93. First, from the perspective of overall Neurontin sales, "off-label" usage of Neurontin has actually increased during the years since 1999; in recent years, "off-label" prescriptions for Neurontin have exceeded 90% of all sales and, in some months, it appears that approved indication usage is negligible.

94. Second, although Neurontin is prescribed for scores of "off-label" indications, since 1999 the types of "off-label" usage continue to be weighted in the precise areas where Defendants focused their unlawful marketing efforts: bipolar disorder, peripheral neuropathy, migraine, etc.

95. Third, these focus treatment areas of continuing unapproved usage are subject to very intense competition between therapeutic substitutes (other drugs or treatments). Indeed, because manufacturers' incremental cost for drugs in these areas is very small (e.g., only pennies to manufacture an additional pill), manufacturers compete aggressively for market share by spending huge amounts of money for marketing, promotional and sales activities. If any company was to simply pack its tent and discontinue programmatic promotional effort in any therapeutic arena, significant loss of overall sales within that diagnosis regime would certainly occur. For Neurontin, no such dip in overall sales, let alone any significant drop, has occurred.

96. Fourth, Pfizer, like most branded drug companies, monitors the relationship of its sales to its promotional efforts in very short timeframe; Pfizer would be concerned about a drop in sales within a certain therapeutic regime not after a year look-back, or even a quarterly look-back, but over just weeks. The persistent maintenance of high Neurontin sales within multiple, targeted areas for "off-label" promotion over a period of years defies the conclusion that any significant backing away on the marketing, sales or promotion on Neurontin to each of those unapproved therapeutic areas.

97. For example, sales of Neurontin for the treatment of bipolar disorder have steadily increased since its introduction. This increase is a direct result of Defendants' sales representatives recommending to doctors its use for this purpose and their distribution of unapproved promotional materials. These promotional efforts did not stop in 1999, but continued thereafter. There are no valid scientific studies that support Neurontin's use for bipolar disorders. Dr. C. Seth Landefeld has submitted an expert opinion in the Franklin litigation that a review of Drugdex for Neurontin, as of the end of August 2002, reveals "no published scientific studies to support Neurontin's use for . . . bipolar disorder." As a result, tens of thousands of patients who need help and could use other drugs whose effectiveness has been established, were given and are being given Neurontin. These prescriptions for this purpose are still being written and are a direct result of Defendants' pre-2000 illegal promotional activities and post-2000 illegal promotional activities.

98. Likewise, sales of Neurontin for pain, ALS, attention deficit disorder, depression and dosages in excess of 1800 mg per day, are also increasing without any scientific evidence supporting use of Neurontin for such indications. Again, as noted by Dr.

Landefeld, as of the end of the third quarter of 2002 "there were no published scientific studies to support Neurontin's use for" any of these indications or in an increased dose.

99. Overall, "off-label" sales of Neurontin have steadily increased since 1998, and from 2000 to the present have consistently remained at 93% to 94% of all sales. Actual sales for approved uses have declined. Given the absence of scientific support for such uses, the genesis for those sales can only be past and continuing efforts by Defendants to promote "off-label" use.

100. These continuing "off-label" promotional efforts are evidenced in part by a July 1, 2002 letter from Dr. Lisa Stockbridge of the Department of Health & Human Services ("HHS") to Pfizer, in which HHS notified Pfizer that certain of its marketing practices are "in violation of the Federal Food, Drug and Cosmetic Act ... because it makes representations about Neurontin which are false and misleading." In particular, HHS had the following objections about Pfizer's "off-label" promotional activities:

The presentation on the model of illustrations of cellular activity. The presentation on the model of illustrations of cellular activity resulting from the administration of Neurontin ("Mechanism of Action"), in conjunction with the presentation of the human brain, and the prominent display of the name Neurontin makes representations about how Neurontin acts in the human brain. This presentation along with the depiction of the human brain and the prominent display of the name "Neurontin" suggest that the mechanism of action of Neurontin has been established in the human brain. This suggestion of proof of the mechanism of action is false. Specifically, it is contrary to the language in the approved product labeling that states that "[t]he mechanism by which gabapentin [Neurontin] exerts its anticonvulsant action is unknown."

Furthermore, the full presentation of the aforementioned areas of the human brain accompanied by purported "Mechanism of Action" and the prominent display of the name "Neurontin" is misleading because it suggests that Neurontin is useful for a broader range of CNS conditions than has been demonstrated by substantial evidence (i.e., it can be used for the treatment of any specific or non-specific brain disorder through to involve the GABA-ergic neurotransmitted system that can originate in these parts of the brain). Most

obviously, the solo and prominent mention of the name Neurontin suggests that Neurontin can be used as monotherapy for various CNS disorders, notwithstanding that with respect to brain disorders, Neurontin is only indicated as "adjunctive therapy in the treatment of partial seizures with or without secondary generalization in patients over 12 years of age with epilepsy" and as "adjunctive therapy in the treatment of partial seizures in pediatric patients age 3-12 years."

To address these objections, DDMAC recommends that Pfizer do the following:

1. Immediately discontinue the use of this model and any other promotional material with the same or similar issues. (Emphasis added.)

101. On information and belief, the foregoing promotional materials were used by Pfizer employees to promote "off-label" use of Neurontin.

102. These continuing efforts to illegally promote "off-label" use of Neurontin are also evidenced in part by a letter from HHS dated June 6, 2001, in which HHS found Pfizer to have again violated applicable law. This letter was sent by HHS in response to Pfizer's promotional advertising sent to doctors in 2001 claiming that a study had indicated "Quality of Life Improvements" with use of Neurontin. HHS found this promotional material to be misleading as set forth in its letter to Pfizer:

Ms. Andrea Garrity  
Director, Regulatory Affairs  
Pfizer, Inc.  
235 East 42nd Street  
New York, New York 10017-5755  
Re: NDA #s 20-235, 20-882  
Neurontin (gabapentin)  
MACMIS # 10174

Dear Ms. Garrity:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a slim jim (ID #NSJ5095A1) for Neurontin that is misleading and in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically, this slim jim misleadingly claims improvements in quality of life (QOL) parameters based on the Neurontin Evaluation of Outcomes in Neurological Practice (NEON) study. Among other QOL parameters, the misleading presentation includes improvement in social limitations, memory difficulties, energy level, and work limitations. The NEON study is not considered to be substantial evidence for claims of QOL improvements because it is not a controlled study.

To address these objections, DDMAC recommends that Pfizer do the following:

1. Immediately discontinue the use of this slim jim and any other promotional material and practices with the same or similar messages.
2. Respond to this letter within ten days. Your response should include a statement of your intent to comply with the above, a list of all promotional materials with the same or similar issues, and your methods for discontinuing these promotional materials. (Emphasis added.)

103. Pfizer employees had been using the foregoing promotional materials to promote "off-label" use of Neurontin up until this letter of June 6, 2001

104. Defendants have sent promotional material to physicians suggesting that Neurontin was "well tolerated" with "proven efficacy" at doses "up to 2400 mg/day" and that doses of 3600 mg/day were also "well tolerated." As noted herein, there was no scientific evidence that would have met with FDA criteria supporting a claim for dosages in excess of 1800 mg/day and these promotional efforts are illegal attempts to encourage "off-label" uses.

105. The promotional materials referred to above, as well as other promotional activities cited herein, were not submitted to the FDA for approval as required by FDAMA, 21 U.S.C.360aaa. Indeed, in the above-cited examples where HHS cited Pfizer for violating federal law, the violations were discovered as a result of HHS's "routine monitoring and

surveillance" activities and not because Pfizer had submitted the materials as required by law.

#### **E. "Off-Label" Promotion is Illegal**

106. The "off-label" uses of Neurontin which are actively being promoted by Defendants are uses which are not recognized as medically accepted uses by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature. Thus, these "off-label" uses are beyond the scope of uses designated by federal law and regulation, in particular 42 U.S.C. 1396r-8, as eligible coverage by the Medicare and Medicaid programs.

107. The citations in Drugdex for Neurontin, as of August 1997, indicate that the published scientific literature did not support the use of Neurontin for the following conditions: alcohol detoxification/alcohol withdrawal syndrome, ALS, antidepressant-induced bruxism, anxiety disorder, attention deficit disorder/attention deficit and hyperactivity disorder, behavior problems-dementia related, behavior dyscontrol, bipolar disorder, brachioradial pruritis, back pain, Charles Bonnet syndrome, ciguatera poisoning, cluster headache, cocaine dependency, depression, dosages in excess of 1800 mg per day, dystonia, essential tremor, failed back surgery syndrome, headache (SUNCT), headache, hemifacial spasm, hiccups, Lesch-Nyhan syndrome, mania, migraine prophylaxis, menopausal hot flashes, mood stabilization, multiple sclerosis complications, myalgias taxane induced neuropathic pain syndromes, neuropathic cancer pain, HIV-related neuropathy, nicotine withdrawal, nystagmus, obsessivecompulsive disorder, orthostatis

tremor, pain-postpoliomyelitis pain, pain-RSD, pain disorder, partial seizures-monotheapy, partial seizures-pediatric, partial seizures-refractory, phantom limb syndrome, postherpetic neuralgia, restless les syndrome, trigeminal neuralgia, seizures - acute intermittent prophyria, seizures - brain tumor-induced, seizures - clozapine- induced, seizures - generalized, seizures - status epilepticus, schizophrenia, social phobia, spasticity, or any other indication other than seizures - adjunctive therapy.

108. As set forth above, despite the lack of scientific support, Defendants engaged in promotional activities for the purpose of having doctors use Neurontin to treat these diseases.

109. Further, any representations by any agent, employee, or person hired by Defendants that as of August 1997 there was scientific evidence supporting Neurontin's use for: alcohol detoxification/alcohol withdrawal syndrome, ALS, antidepressant-induced bruxism, anxiety disorder, attention deficit disorder, attention deficit and hyperactivity disorder, behavior problems, dementia related, behavior dyscontrol, dipolar disorder, brachioradial pruritis, back pain, Charles Bonnet syndrome, ciguatera poisoning, cluster headache, cocaine dependency, depression, dosages in excess of 1800 mg per day, dystonia, essential tremor, failed back surgery syndrome, headache (SUNCT), headache, hemifacial spasm, hiccups, Lesch-Nyhan syndrome, mania, migraine prophylaxis, menopausal hot flashes, mood stabilization, multiple sclerosis complications, myalgias taxane induced neuropathic pain syndromes, neuropathic cancer pain, HIV-related neuropathy, nicotine withdrawal, nystagnus, obsessive-compulsive disorder, orthostatis tremor, pain-postpoliomyelitis pain, pain-RSD, pain disorder, partial seizuresmonotheapy, partial seizures-pediatric, partial seizures-refractory, phantom limb syndrome, postherpetic

neuralgia, restless leg syndrome, trigeminal neuralgia, seizures - acute intermittent porphyria, seizures - brain tumor-induced, seizures - clozapine-induced, seizures - generalized, seizures - status epilepticus, schizophrenia, social phobia, spasticity, or any other indication other than the partial seizures-adjunctive therapy; would have been misleading in that the published literature cited in Drugdex did not support these indications at that time. On information and belief, representations were made by Defendants' employees that Neurontin was appropriate for treatment of some of the foregoing diseases.

110. The citations in Drugdex for Neurontin as of the third quarter of 2002, indicate that there were no published scientific studies to support Neurontin's use for the following indications: alcohol detoxification / alcohol withdrawal syndrome, ALS, antidepressant-induced bruxism, anxiety disorder, attention deficit disorder/attention deficit and hyperactivity disorder, behavior problems-dementia related, behavior dyscontrol, bipolar disorder, brachioradial pruritis, back pain, Charles Bonnet syndrome, ciguatera poisoning, cluster headache, cocaine dependency, depression, dosages in excess of 1800 mg per day, dystonia, essential tremor, failed back surgery syndrome, headache (SUNCT), headache, hemifacial spasm, hiccups, Lesch-Nyhan syndrome, mania, migraine prophylaxis, menopausal hot flashes, mood stabilization, multiple sclerosis complications, myalgias taxane induced neuropathic pain syndromes, neuropathic cancer pain, HN-related neuropathy, nicotine withdrawal, nystagmus, obsessive-compulsive disorder, orthostatic tremor, pain-postpoliomyelitis pain, pain-RSD, pain disorder, partial seizures-monotherapy, partial seizures-pediatric, partial seizures-refractory, phantom limb syndrome, postherpetic neuralgia, restless leg syndrome, trigeminal neuralgia, seizures - acute intermittent porphyria, seizures - brain tumor-induced, seizures - clozapine-induced, seizures -

generalized, seizures - status epilepticus, schizophrenia, social phobia, spasticity, or any other indication other than the partial seizures-adjunctive therapy, partial seizures-pediatric, postherpetic neuralgia.

111. With the complete absence of scientific support for treatment of these diseases, sales growth which occurred for the use of Neurontin for these diseases was the result of Defendants' continuing promotional activities.

112. Any representations by any agent, employee, or person hired by defendants that as of 2003 there was scientific evidence supporting Neurontin's use for: alcohol detoxification/alcohol withdrawal syndrome, ALS, antidepressant-induced bruxism, anxiety disorder, attention deficit disorder/attention deficit and hyperactivity disorder, behavior problems-dementia related, behavior dyscontrol, bipolar disorder, brachioradial pruritis, back pain, Charles Bonnet syndrome, ciguatera poisoning, cluster headache, cocaine dependency, depression, dosages in excess of 1800 mg per day, dystonia, essential tremor, failed back surgery syndrome, headache (SUNCT), headache, hemifacial spasm, hiccups, Lesch-Nyhan syndrome, mania, migraine prophylaxis, menopausal hot flashes, mood stabilization, multiple sclerosis complications, myalgias taxane induced neuropathic pain syndromes, neuropathic cancer pain, HIV-related neuropathy, nicotine withdrawal, nystagmus, obsessive-compulsive disorder, orthostatic tremor, pain-postpoliomyelitis pain, pain-RSD, pain disorder, partial seizuresmonotherapy, partial seizures-pediatric, partial seizures-refractory, phantom limb syndrome, postherpetic neuralgia, restless leg syndrome, trigeminal neuralgia, seizures - acute intermittent porphyria, seizures - brain tumor-induced, seizures - clozapine-induced, seizures - generalized, seizures - status epilepticus, schizophrenia, social phobia, spasticity, or any other indication other than the partial

seizures-adjunctive therapy, partial seizures-pediatric, and postherpetic neuralgia would have been misleading in that the published literature cited in Drugdex did not support these indications at that time. On information and belief, Defendants made representations that there was scientific evidence supporting use for these diseases.

113. Any statement or representation made by Defendants, their employees or agents that Neurontin was safe and effective for migraine prophylaxis that provided information only on positive reports or trials while failing to disclose negative studies of similar or better methodologic quality would not be a fair and balanced presentation and would be false and misleading. On information and belief, such statements were made during the period from 1995 through 2000.

114. Any statement or representation made by Defendants, their employees, or agents that Neurontin was safe and effective for treatment of neuropathic pain that provided information on positive reports or trials, while failing to disclose negative studies of similar or better methodologic quality, would not be a fair and balanced presentation and would be false and misleading. On information and belief, such statements were made during the period from 1995 through 2002.

115. Federal laws and regulations governing the Medicare and Medicaid programs, in particular, 42 U.S.C. 1320A-7 and 42 C.F.R. 1001, prohibit kickbacks to physicians and medical care providers. "Kickbacks" have been defined as including payments, gratuities and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

116. As part of its nationwide program of "off-label" promotion of Neurontin, Defendants established a system of paying kickbacks to physicians who are prescribers of

large amounts of Neurontin. These kickbacks were administered by the Defendants' sales department, and frequently disguised as consultantships, although unrelated to any scientific or educational activity. The kickbacks took the form of cash payments, travel benefits, entertainment, Olympics tickets and other benefits. Defendants established formal internal guidelines for the award of these benefits to physicians which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Neurontin for "off-label" uses.

117. These kickbacks are strictly illegal and have had the effect of greatly increasing the amount of Neurontin prescriptions and indirectly the amount of money spent by the federal government for reimbursement of prescriptions covered by Medicare.

118. As part of its illegal "off-label" promotion of Neurontin, Defendants have instructed and caused its sales personnel and its medical liaison employees to make false statements to physicians, and to provide physicians with written materials containing false statements, concerning the safety and efficacy of Neurontin for "off-label" uses. These statements were made with the intent of, and had the effect of, inducing physicians to increase their "off-label" prescription of Neurontin.

119. The false and misleading statements made by Defendants' employees to physicians have included representations that scientific evidence exists that Neurontin is an effective remedy for pain, bipolar disorder, attention deficit disorder, reflex sympathetic dystrophy, post-herpetic neuralgia, and monotherapy for seizures. The false and misleading statements also include representations that Neurontin is known to be safe and effective in dosages of up to 4800 mg/day in all populations. The false statements include representations that clinical trials are ongoing or planned with respect to each of the above

off-label uses. Each of these statements is unsupported by any legitimate scientific evidence.

#### **V. STRUCTURE OF THE MEDICAID SYSTEM AND MANAGED CARE UNDER MICHIGAN LAW**

120. The Social Security Act created the Medical Assistance Program. Title XIX of the Social Security Act, codified at 42 USC § 1396 et seq.<sup>1</sup> within the Social Security Act are provisions for states to create Medicaid Managed Care Organizations (“MCO”) to administer Medical Assistance. 42 USC § 1396m. That Section permits a state to enter into a contract with a qualified MCO to provide medical care to patients eligible for Medical assistance. *Id.* The State then pays the MCO with federal dollars made available under the Medical Assistance Program. *Id.*

121. The Act permitted promulgation of regulations to enable the managed care portion of Medical Assistance. These regulations are found beginning at 42 CFR Part 438. The regulations provide that the contract between the state and the MCO must define the scope of services provided. 42 CFR Part 438.210. The MCO is responsible for any subcontractor with whom it contracts. 42 CFR Part 438.230. Each MCO must adopt practice guidelines which are based on “valid and reliable clinical evidence or a consensus of health care professionals in the particular field.” 42 CFR Part 438.236(b)(1).

122. In Michigan, under MCL 400.105, the state Department of Community Health has been authorized to establish a program of medical assistance for the medically indigent

---

<sup>1</sup>The Act was codified at 42 USC Sec 1396 et seq. References in the Code of Federal Regulations are to sections of the Act, not the codification thereof. Thus, Section 1901 of the Act is 42 USC Sec 1396; Section 1902 of the Act is 42 USC Sec 1396a, and so forth.

pursuant to Title XIX. In establishing this program, the term “professionally accepted standards” is defined as those standards developed by peer review advisory committees and professionals and experts with whom the director is required to consult.” Id. Under this section, “provider” means an individual, sole proprietorship, partnership, association, corporation, institution, agency, or other legal entity, who has entered into an agreement of enrollment specified by the director pursuant to section 400.111b(1)(c).” An eligible person may receive hospital services, including drugs, MCL 400.109(1)(a), and may also receive “pharmaceutical services” from an approved provider. MCL 400.109(1)(d).

123. Each provider is required to meet certain conditions to participate in the Medicaid program. MCL 400.111b. That statute provides in part:

(22) It is the obligation of a provider to assure that services, supplies, or equipment provided to, ordered, or prescribed on behalf of a medically indigent individual by that provider will meet professionally accepted standards for the medical necessity, appropriateness, and quality of health care.”

The department may contract with any private agency to act as fiscal agent in dealing with vendors providing services. MCL 400.112.

124. Pursuant to that statute, the Department of Community Health has promulgated a vendor contract for Comprehensive Health Care Program Services for Medicaid Beneficiaries (Form DMB 234 (Rev.1/96)). The stated purpose of the contract is to “obtain the services of the contractor to provide Comprehensive Health Care Program Services for Medicaid beneficiaries” in a defined geographic region. Para I-A. The contract defines what services are covered; it also explicitly excludes certain services. Among the excluded services are “experimental/investigational drugs...” Para II-H(4).

125. The State of Michigan Medicaid program does not cover off-label uses of prescription drugs. The Michigan Department of Community Health Medicaid Provider Manual, Pharmacy (“Manual”), identifies certain categories of drugs that are not covered as a benefit under the Michigan Medicaid Program. This includes drugs prescribed for off label use if there is no generally accepted medical indication in peer reviewed medical literature. See Manual at Sec 6. This is consistent with other provisions of Michigan law. See, e.g. MCL §§550.1416c, 550.3406q.

126. Plaintiff is a Managed Care Organization, many of whose beneficiaries were prescribed Neurontin for one of the above unapproved uses. Plaintiff paid for the prescriptions for such unapproved uses. Plaintiff would not have paid for such prescriptions but for the representations of Defendants that such off-label uses were safe, effective and permitted under law.

127. As a result Plaintiff suffered financial harm in that it paid for products that had been misrepresented concerning their fitness for their represented purposes and as to its efficacy for any purpose other than as a secondary drug for treatment of seizures.

## **VI. THE ROLE OF THIRD PARTIES IN DEFENDANTS’ MARKETING SCHEME**

128. The major non-physician writers, “authors”, and vendors (collectively “Third Parties”) were important parts in Defendants’ overall marketing plan. These third parties knowingly and intentionally, communicated and distributed the misrepresentations concerning off-label uses of Neurontin. For instance, the non-physician writers generated

inaccurate and unscientific articles pertaining to the safety and efficacy of Neurontin and the physicians loaned their names and thereby became “authors” to these articles.

128. The vendors, AMM and MES, published these articles in medical journals across the nation. Also, physicians participated in so-called “studies” that misrepresented facts and evidence pertaining to Neurontin.

129. These Third Parties were participants in Defendants’ marketing scheme and were conscious of, and participated in, the illegal scheme. They also operated collectively, for a common purpose, and as a continuing unit to perpetuate Defendants’ scheme.

130. The Third Parties’ knowledge, involvement, and activity is exhibited by (1) the failure to alert physicians, patient, FDA officials, or consumers about the spread of misinformation concerning off-label uses; (2) their acceptance of incentives in exchange for supporting, authoring, or publicizing the above described misrepresentations knowing physicians and consumers would rely on these misrepresentations; and (3) their agreement to permit Defendants to control the information relaying to the public in the articles.

**VII. WARNER LAMBERT’S PLEA OF GUILTY TO THE  
FEDERAL INFORMATION CHARGING CRIMINAL  
VIOLATIONS OF THE FOOD DRUG AND COSMETIC ACT**

131. On May 13, 2004, Warner Lambert was charged with criminal violations of the federal Food Drug and Cosmetic Act in an information brought by Department of Justice in the United States District Court for the District of Massachusetts.

132. The information presented criminal charges against Warner Lambert for violations of 21 U.S.C. 331(a) and (d), 333(a)(2), 352(f)(1) and 355(a) based upon the misconduct set forth above.

133. The information charged that Warner Lambert violated 21 U.S.C. 331(a) and (d) by introducing and distributing Neurontin into interstate commerce for uses other than its approved uses and by introducing and delivering Neurontin into interstate commerce in violation of 21 U.S.C. 355, which required Warner Lambert to obtain FDA approval for all of the proposed intended uses of Neurontin .

134. The information further charged that Warner Lambert violated 21 U.S.C. 352(f) (1) by misbranding Neurontin without adequate directions in its label for its proper use.

135. The information further charged that Warner Lambert violated 21 U.S.C 355(a) by introducing and delivering Neurontin into interstate commerce without applying for and obtaining FDA approval for Neurontin's proposed and intended uses.

136. Warner Lambert entered a plea of guilty to all of the above-referenced criminal charges immediately upon the filing of such charges.

### **VIII. USE OF THE MAILS AND WIRES**

137. During the Class Period, Defendants used thousands of mail and interstate wire communications to create and manage their fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed physicians and victims across the country.

138. Defendants' use of the mails and wires to perpetrate their fraud involved thousands of communications throughout the Class Period, including:

\* marketing and advertising materials about the off-label uses of Neurontin for which the drug is not safe and medically efficacious, such materials being sent to doctors across the country;

\* communications, including financial payments, with the Vendors, AMM and MES, non-physician technical writers, and physician “authors” discussing and relating to the publication of articles touting off-label uses of Neurontin for which the drug is not safe and medically efficacious; communications with the Vendors and physicians that fraudulently misrepresented that Neurontin was scientifically proven to be safe and effective for off-label uses;

\* communications with patients and consumers, including Plaintiffs and the Class, inducing payments for Neurontin to be made in reliance on misrepresentations concerning the use of Neurontin for non-medically necessary uses; and

\* receiving the proceeds of the Defendants’ improper scheme.

139. In addition, Defendants’ corporate headquarters have communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons and pharmaceutical representatives in furtherance of Defendants’ scheme.

### **IX. CLASS ALLEGATIONS**

140. Plaintiff brings this lawsuit pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of himself and a class of persons (“The Class”). The Class consists of all insurers, including but not limited to health insurance companies and self funded health plans whether or not organized under ERISA, throughout the United States who satisfy each of the following criteria:

a. At any time during the class period;

b. Paid for a prescription of Neurontin on behalf of a health plan member or beneficiary by prescription for a diagnosis of any disorder other than epilepsy;

141. Excluded from the Class are the Defendants, their directors, officers, employees, parents, affiliates and subsidiaries, their successors, agents, legal representatives, heirs and assigns, and any persons controlled by any excluded person.

142. The requirements of Rule 23 are satisfied and class certification is proper.

143. The members of the Class are so numerous that joinder of all members is impracticable. Defendants have promoted and sold Neurontin on millions of occasions during the class period.

144. There are common questions of law and fact common to the claims of all members of the Class concerning whether Defendants violated the law described within by marketing Neurontin for off label purposes.

145. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff has the same interests as all members of the Class.

146. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class and has retained competent counsel experienced in consumer class litigation and litigation involving pharmaceutical drugs. Plaintiff is a member of the Class and does not have interests antagonistic to or in conflict with members of the Class. Neither Plaintiff nor Plaintiff's counsel have any interests which might cause them not to pursue this claim vigorously. Plaintiff's claims are the same as those of the claims of the class, which all arise from the same operative facts and are based on the same legal theories.

147. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since the membership of the Class is so numerous and sufficiently geographically widespread that joinder of all members is impracticable. Furthermore, the expense and burden of any non-class litigation may well make it practically impossible for Plaintiff or other persons to vindicate their rights. There will be no difficulty in the management of this case as a class action.

148. There are questions of law and fact common to the class which predominate over questions solely affecting individual members of the class. These common questions of law and fact include, but are not limited to:

- a. Whether Defendants engaged in marketing practices designed to sell neurontin for purposes other than those for which the drug was approved by the Food and Drug Administration?
- b. Whether Defendants' actions violate relevant Consumer Protection laws?
- c. Whether Defendants' actions constitute false advertising?
- d. Whether Defendants' actions breach and interfere with the insurance contract Plaintiffs and the class have with their health insurers?
- e. Whether Defendants have usurped unto themselves property belonging to others?
- f. Whether Defendants have acquired property unjustly, which property should be disgorged?

These common questions of law and fact predominate over any issue affecting individual class members. Resolving these issues for Plaintiff or any other class member will also resolve the claims of the entire class. Certification of the class is appropriate because Defendants acted uniformly with respect to the members of the class.

149. The only individual question is the amount by which the class members were improperly charged, and which should be disgorged.

150. Certification of the class is also appropriate because a class claim is the only appropriate method for the fair and efficient adjudication of this controversy. The interest of class members in individually controlling the prosecution of separate claims against Defendants is non-existent because it is not feasible for them to bring individual claims. The nature of the practices complained of is such as to make a class claim essential.

Management of this class claim is likely to present significantly fewer difficulties than those presented in many class claims.

## **COUNT ONE**

### **VIOLATION OF 18 U.S.C. 1962(c) - MES ENTERPRISE**

151. Plaintiff incorporates the allegations contained in the preceding paragraphs.

152. Defendants are “persons” within the meaning of 18 U.S.C. 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. 1962(c).

153. The “MES Enterprise” is an association-in-fact within the meaning of 18 U.S.C. 1961(4), consisting of each Defendant, including their employees and agents, and MES. The MES Enterprise is an ongoing organization that functions as a continuing unit. The MES Enterprise was created and/or used as a tool to effectuate Defendants’ pattern of racketeering activity. The Defendant “persons” are distinct from the MES Enterprise.

154. The MES Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

155. Defendants have exerted control over the MES Enterprise, and Defendants have participated in the operation or management of the affairs of the MES Enterprise, through the following actions:

- \* Defendants have asserted direct control over the information and content disseminated to the Vendors (including MES), physicians and the public regarding the

medical safety and efficacy of Neurontin for off-label uses in articles published across the country;

- \* Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States

- \* Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Vendors and physicians through the United States; and

- \* Defendants have placed their own employees and agents in positions of authority and control in the MES Enterprise.

156. Defendants have conducted and participated in the affairs of the MES Enterprise through a pattern of racketeering activity by selling or otherwise dealing in dangerous drug in a manner punishable under the laws of the United States, as set forth in the information and guilty plea described above, as well by acts indictable under 18 U.S.C. 1341 and 1343 (mail and wire fraud), as described above.

157. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty of Defendants in representing the safety and medical efficacy of Neurontin's uses.

158. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiff and members of the Class were unaware that contrary to their plain language they were purchasing Neurontin for off-label uses; (b) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiff and members of the Class paid for this drug to treat symptoms for which it was not scientifically

proven to be safe and effective; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

159. Defendants' scheme was calculated to ensure Plaintiff and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

160. Each of Defendants' acts involved in the selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States and Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. 1961(5).

161. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff and the Class.

162. The above-described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff and the Class. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the members of the Class. Defendants' fraudulent activities

are part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

163. The pattern of racketeering activity alleged herein and the MES Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the MES Enterprise.

164. Plaintiff and members of the Class have been injured in their property because Plaintiff and members of the Class have made billions of dollars in payments of Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

165. Plaintiff and members of the Class relied to their detriment on Defendants' fraudulent misrepresentations and omissions.

166. Plaintiff and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

167. By virtue of these violations of 18 U.S.C. 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fee.

## **COUNT TWO**

### **VIOLATION OF 18 U.S.C. 1962(c) AMM ENTERPRISE**

168. Plaintiff incorporates the allegations contained in the preceding paragraphs.

169. Defendants are "persons" within the meaning of 18 U.S.C. 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. 1962(c).

170. The “AMM Enterprise” is an association-in-fact within the meaning of 18 U.S.C. 1961(4), consisting of each of Defendants, including their employees and agents, and AMM. The AMM Enterprise is an ongoing organization that functions as a continuing unit. The AMM Enterprise was created and/or used as a tool to effectuate Defendants’ pattern of racketeering activity. The Defendant “persons” are distinct from the AMM Enterprise.

171. The AMM Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

172. Defendants have exerted control over the AMM Enterprise, and Defendants have participated in the operation or management of the affairs of the AMM Enterprise, through the following actions:

- \* Defendants have asserted direct control over the information and content disseminated to the Vendors (including AMM), physicians and the public regarding the medical safety and efficacy of Neurontin for off-label uses in articles published across the country;

- \* Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;

- \* Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to Vendors and physicians through the United States; and

- \* Defendants have placed their own employees and agents in positions of authority and control in the AMM Enterprise.

173. Defendants have conducted and participated in the affairs of the AMM Enterprise through a pattern of racketeering activity by selling or otherwise dealing in dangerous drug in a manner punishable under the laws of the United States, as set forth in the information and guilty plea described above, as well by acts indictable under 18 U.S.C. 1341 and 1343 (mail and wire fraud), as described above.

174. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty of Defendants in representing the safety and medical efficacy of Neurontin's uses.

175. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiff and members of the Class were unaware that contrary to their plain language they were purchasing Neurontin for off-label uses; (b) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiff and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

176. Defendants' scheme was calculated to ensure the Plaintiff and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

177. Each of Defendants' acts involved in the selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States and Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. 1961(5).

178. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff and the Class.

179. The above-described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff and the Class. Defendants' criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the members of the Class. Defendants' fraudulent activities as part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

180. The pattern of racketeering activity alleged herein and the AMM Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the AMM Enterprise.

181. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have made billions of dollars in payments of Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

182. Plaintiff and members of the Class relied to their detriment on Defendants' fraudulent misrepresentations and omissions.

183. Plaintiffs and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

184. By virtue of these violations of 18 U.S.C. 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fee.

### **COUNT THREE**

#### **VIOLATION OF 18 U.S.C. 1962(c) GROUP ENTERPRISE**

185. Plaintiff incorporates the allegations contained in the preceding paragraphs.

186. Defendants are "persons" within the meaning of 18 U.S.C. 1961(3) who conducted the affairs of the enterprise through a pattern of racketeering activity in violation of 18 U.S.C. 1962(c).

187. The "Group Enterprise" is an association-in-fact within the meaning of 18 U.S.C. 1961(4), consisting of Pfizer and Warner-Lambert, including their employees and agents, and the non-physician writers, physician "authors" and Vendors located throughout the United States who participated in the fraudulent schemes described above. The Group Enterprise is an ongoing organization and functions as a continuing unit. The Group Enterprise was created and/or used as a tool to effectuate Defendants' pattern of racketeering activity. The Defendant "persons" are distinct from the Group Enterprise.

188. The Group Enterprise falls within the meaning of 18 U.S.C. 1961(4), and consists of a group of “persons” associated together for the common purposes of marketing and selling Neurontin to Plaintiff and the Class and earning profits therefrom.

189. The Group Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, purchased, or provided Neurontin to thousands of individuals throughout the United States.

190. Defendants have exerted control over the Group Enterprise, and Defendants have participated in the operation or management of the affairs of the Group Enterprise, through the following actions:

- \* Defendants have asserted direct control over the information and content disseminated to doctors and the public regarding the medical safety and efficacy of Neurontin for off-label uses in articles published across the country;

- \* Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;

- \* Defendants have asserted direct control over the creation and distribution of mass-marketing and sales materials sent to doctors through the United States; and

- \* Defendants have placed their own employees and agents in positions of authority and control in the Group Enterprise.

191. Defendants have conducted and participated in the affairs of the Group Enterprise through a pattern of racketeering activity by selling or otherwise dealing in dangerous drug in a manner punishable under the laws of the United States, as set forth in the information and guilty plea described above, as well by acts indictable under 18 U.S.C. 1341 and 1343 (mail and wire fraud), as described above.

192. In implementing their fraudulent scheme, Defendants were acutely aware that Plaintiff and members of the Class depend on the honesty of Defendants in representing the safety and medical efficacy of Neurontin's uses.

193. As detailed above, Defendants' fraudulent scheme consisted of, *inter alia*: (a) causing providers to misrepresent the off-label use(s) for which Neurontin was being prescribed so that Plaintiff and members of the Class were unaware that contrary to their plain language they were purchasing Neurontin for off-label uses; (b) deliberately misrepresenting the uses for which Neurontin was safe and effective so that Plaintiff and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective; (c) publishing or causing to have published materials containing false information upon which physicians, Plaintiff, and members of the Class relied upon when choosing to prescribe or pay for Neurontin to treat off-label uses for which the drug is not scientifically proven to be safe or medically efficacious; and (d) actively concealing, and causing others to conceal, information about the true safety and efficacy of Neurontin to treat conditions for which it had not been approved by the FDA.

194. Defendants' scheme was calculated to ensure the Plaintiff and the Class would pay for Neurontin to treat a wide variety of uses which Defendants knew were not necessarily treatable with Neurontin.

195. Each of Defendants' acts involved in the selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States and Defendants' fraudulent mailings and interstate wire transmissions constitute "racketeering activity" within the meaning of 18 U.S.C. 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. 1961(5). Collectively,

these violations constitute a “pattern of racketeering activity” within the meaning of 18 U.S.C. 1961(5).

196. Defendants engaged in a pattern of racketeering activity intending to defraud Plaintiff and the Class.

197. The above described racketeering activities amounted to a common course of conduct intended to deceive Plaintiff and the Class. Defendants’ criminal acts of racketeering had the same pattern and similar purpose of defrauding Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff and the members of the Class. Defendants’ fraudulent activities as part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

198. The pattern of racketeering activity alleged herein and the Group Enterprise are separate and distinct from each other. Defendants engaged in a pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the Group Enterprise.

199. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have made billions of dollars in payments of Neurontin that they would not have made had Defendants not engaged in their pattern of racketeering activity.

200. Plaintiff and members of the Class relied to their detriment on Defendants’ fraudulent misrepresentations and omissions.

201. Plaintiff’s and members of the Class’ injuries were directly and proximately caused by Defendants’ racketeering activity as described above.

202. By virtue of these violations of 18 U.S.C. 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorneys' fee.

#### **COUNT FOUR**

##### **VIOLATION OF 18 U.S.C. 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. 1962(c)**

203. Plaintiff incorporates the allegations contained in the preceding paragraphs.

204. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section".

205. Defendants have violated 1962(d) by conspiring to violate 18 U.S.C. 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the 1962(c) Enterprises described previously through a pattern of racketeering activity.

206. As demonstrated in detail above, Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class of money.

207. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. 1962(d) violation of RICO by conspiring to violate 18 U.S.C. 1962(c), but they were aware that their ongoing

fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

208. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. 1962(d) by conspiring to violate 18 U.S.C. 1962(c), Plaintiff and the Class have been and are continuing to be injured in their business or property as set forth more fully above.

209. Defendants have sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- \* Multiple instances of mail and wire fraud violations of 18 U.S.C. 1341 and 1342;
- \* Multiple instances of selling or otherwise dealing in dangerous drugs in a manner punishable under the laws of the United States;
- \* Multiple instances of mail and wire fraud violations of 18 U.S.C. 1341 and 1346; and
- \* Multiple instances of wire fraud violations of 18 U.S.C. 1343 and 1346.

210. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue unless injunctive relief prohibiting Defendants' illegal acts constituting a pattern of racketeering activity is fashioned and imposed by the Court.

## **COUNT FIVE**

### **FRAUD AND MISREPRESENTATION BY COMMISSION**

211. Defendants knew that the advertisements, promotional statements and other communications actively made to Plaintiff, physicians, and other consumers regarding Neurontin were false and misleading in one or more material ways.

212. Defendants intended that Plaintiff, physicians and other consumers, rely upon the representations.

213. Defendants knew that Plaintiff, physicians and consumers were ignorant of the falsity of their representations.

214. Defendants had a duty to correct this false and misleading information, but failed to do so.

215. Plaintiff, and all other users of Neurontin, who were not suffering from seizures, and their physicians had no reason to use and prescribe Neurontin, but for the misrepresentations regarding its efficacy in off-label uses.

216. Had Defendants not promoted these uses, no person and no physician would have considered using the drug for anything but seizures.

217. The wrongful acts alleged above were their each substantial and proximate causes that contributed to the injuries and damages Plaintiff has suffered.

## **COUNT SIX**

### **FRAUD AND MISREPRESENTATION BY OMISSION**

218. Defendants knew that it was promoting Neurontin for off label uses not approved by the Food and Drug Administration.

219. Defendants have duties, imposed by federal and state law, to promote their drugs only for the purposes for which such drugs are approved by the FDA, or otherwise in accordance with approved FDA policies and procedures.

220. Defendants further knew that physicians were intending to use, and were in fact using, Neurontin for purposes that were not approved by the FDA.

221. Defendants knew that the off label uses to which Neurontin was being put were not safe and effective.

222. Defendants failed to disclose its knowledge about the lack of safety and efficacy of Neurontin for the off label uses to which Neurontin was being put.

## **COUNT SEVEN**

### **ILLEGAL KICKBACKS**

223. Federal laws and regulations governing the Medicare and Medicaid programs prohibit kick-backs to physicians and medical care providers, in particular 42 U.S.C. 320a-7 and 42 C.F.R. 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

224. As part of its nationwide program of off-label promotion of gabapentin, Defendants has established a system of kick-backs to physicians who are prescribers of large amounts of Gabapentin. These kick-backs are administered by the Defendants sales department, and frequently disguised as consultantships although unrelated to any scientific or educational activity. The kickbacks have taken the form of cash payments, travel benefits, entertainment, Olympics tickets, and other benefits. Defendants has established formal internal guidelines for the award of these benefits to physicians which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Gabapentin for off-label uses.

225. These "kick-backs" are strictly illegal, 42 U.S.C. 1320A-7, 42 C.F.R. Part 1001, and 62 PS 1403, and have had the effect of greatly increasing the amount of

Gabapentin prescriptions, and indirectly the amount of money spent by Plaintiff for reimbursement of prescriptions covered by medical assistance.

## **COUNT EIGHT**

### **INTERFERENCE WITH CONTRACT**

226. Under the contracts between the State of Michigan and Plaintiff, payment for prescription drugs is based upon uses approved by the Food and Drug Administration.

227. Such contracts prohibit payment for off label or experimental use of such drugs, as described in this Complaint.

228. Many contracts and plans intend not to reimburse for prescription drugs for uses not set forth in the publications referred to in the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or the American Medical Association Drug Evaluations, or by any peer-reviewed medical literature, in that the plans do not intend to spend money on prescriptions not recognized as medically necessary in such sources. However, the plans lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted.

229. Defendants recognized and aggressively exploited this technical inability on the part of the plans by means of a direct, illegal, nationwide program of promotion of off-label use of Gabapentin by physicians.

230. Defendants conducted this program of promotion knowing that prescriptions for Gabapentin are generally reimbursed by the plans even though individual prescriptions

for Gabapentin fall outside of contractual formularies because they are not medically accepted.

231. Defendants' aggressive, illegal scheme of off-label promotion has induced payments through a pattern of fraudulent conduct by causing the plans to pay out sums to claimants they did not intend, to benefit.

232. Defendants' conduct constitutes interference with the contracts between Plaintiff and the State of Michigan.

### **COUNT NINE**

#### **UNJUST ENRICHMENT**

233. Defendants' conduct alleged in this complaint constitutes an unlawful, unfair or fraudulent business act or practice.

234. Defendants, by the actions above alleged, have collected money from the Plaintiff under such circumstances that in equity and good conscience it cannot retain, and which in justice and fairness belongs to Plaintiff.

235. As a result of Defendants' violations, described above, it has unjustly enriched itself at the expense of the Plaintiff. Defendants' unjust enrichment continues to accrue as it continues to engage in its unlawful business acts and practices.

236. Defendants' retention of money gained through its unlawful and deceptive practices is unjust considering the circumstances under which the funds were obtained. Defendants' acts were done knowingly.

237. As a result of the foregoing, Plaintiff has been deprived of its money and suffered loss and damages as alleged above.

238. To prevent its unjust enrichment, Defendants should be required to disgorge all of their ill-gotten gains in the form of restitution to Plaintiff.

### **COUNT TEN**

#### **CONVERSION**

239. Defendants, by the actions above alleged, have exerted unauthorized control over the property of Plaintiff.

240. Plaintiff owned, and had a right to possession of, the money which is in the unauthorized possession of Defendants.

241. Defendants have exerted unauthorized ownership of money belonging to Plaintiff to the exclusion of Plaintiff's rights.

242. Defendants, by the actions above alleged, have unlawfully converted property of Plaintiff. Defendants have made profits as a result of the unlawful conversion.

243. As a result of the foregoing, Plaintiff has suffered actual damages and injury for which it is entitled to recover.

**WHEREFORE**, Plaintiff demands judgment against Defendant:

1. Certifying a class as described herein;
2. Declaring that Defendant has violated the laws stated within;
3. Awarding Plaintiff its actual damages, along with prejudgment interest, attorneys fees, and costs; and
4. Awarding other relief and award to which Plaintiff may be entitled, or as determined to be just and appropriate by this Court.

CHARFOOS & CHRISTENSEN, P.C.

BY: \_\_\_\_\_  
JASON J. THOMPSON (P47184)  
Attorneys for Plaintiff  
5510 Woodward  
Detroit, MI 48202  
(313) 875-8080

Dated: October 29, 2004

**DEMAND FOR TRIAL BY JURY**

NOW COMES the Plaintiffs, by and through their counsel, CHARFOOS & CHRISTENSEN, P.C., and hereby respectfully demands a trial by jury of the within cause of action.

CHARFOOS & CHRISTENSEN, P.C.

BY: \_\_\_\_\_  
JASON J. THOMPSON (P47184)  
Attorney for Plaintiffs  
5510 Woodward  
Detroit, MI 48202  
(313) 875-8080