IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PHILADELPHIA
CIVIL TRIAL DIVISION

GREGORY CLARK and LINDA MEASHEY,	:	June Term 2004
Plaintiffs,	:	No. 1819
v.	:	
PFIZER INC, and WARNER-LAMBERT COMPANY, LLC,	:	Commerce Program
Defendants.	:	Control Nos. 061293/061291
	:	

ORDER

AND NOW, this 9TH day of February 2009, upon consideration of Defendants Motion for Summary Judgment and Motion for Decertification, all responses in opposition and in accord with the attached Opinion, it hereby is **ORDERED** as follows:

1. Summary Judgment is **granted** on plaintiffs' class claims for breach of warranty.
2. Summary Judgment is **granted** as to all class claim as to members of the class who actually benefited from off label use of Neurontin.
3. All other aspects of the Motion for Summary Judgment are **denied.**
4. The Motion for Class Decertification is **granted**.
5. Trial scheduled for March 9, 2009 shall proceed as individual claims unless a continuance is requested in light of these rulings.

BY THE COURT,

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MARK I. BERNSTEIN, J.

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OPINION

This class action is filed on behalf of plaintiffs Gregory Clark and Linda Meashey (hereinafter "Plaintiffs") and all other similarly situated purchasers of the drug Neurontin or its generic equivalent, gabapentin, whose prescriptions were written for off label uses not approved by the FDA. The class members bring claims for misrepresentation, negligence, negligence per se and breach of express warranty seeking a refund of all the non-insured payments actually made. Presently before the court are Defendants Pfizer, Inc. and Warner-Lambert Company, LLC's motion for summary judgment and motion for class decertification.

Defendants Pfizer, Inc. and Warner-Lambert Company, LLC developed the drug Neurontin. In 1993, the Food and Drug Administration ("FDA") approved Neurontin for epilepsy treatment. In 2002, the FDA approved Neurontin for neuralgia. Physicians are free to prescribe that medication for any condition that they believe to be appropriate even if not FDA approved. This is known as off-label prescribing and although permissible in the medical profession, federal law prohibits a drug manufacturer from promoting off-label uses of an approved medication.

Plaintiffs have produced evidence if believed, that demonstrates that beginning in 1995 defendants' deliberately and unlawfully promoted Neurontin to physicians for "off-label uses" for which effectiveness had not been scientifically demonstrated. Defendants promoted Neurontin for off label uses by convincing the medical profession of effectiveness for non FDA approved uses. They did this by soliciting anecdotal articles for insertion in medical journals, paying opinion leader physicians who prescribed off label uses and sponsoring continuing medical education conferences which were actually paid promotional events. Defendants created internal quarterly and annual goals, objectives, strategies and tactics for increasing sales of off label uses of Neurontin and had sales representatives ask doctors during details if they use other anti-epileptic drugs for painful neuropathies. The promoted off label uses include psychiatric disorders, pain syndromes, reflex sympathetic dystrophy ("RSD"), restless leg syndrome ("RLS"), fibromyalgia, anxiety disorder and migraine headaches. In addition to promoting Neurontin for off label uses, defendants also promoted uses above the maximum approved dose Neurontin.

Defendants were criminally charged and entered into a plea agreement in the Federal District Court of Massachusetts on charges of violations of Title 21 United States Code Sections 331 (a), 331(d), 352(f)(1) and 335 (a). Defendants plead guilty to two specific violations involving off-label marketing in 1995 and 1996. Defendants agreed to a fine of $240 million and agreed to cease all attempts to promote off-label use.

Dr. Richard Brown, plaintiff Linda Measheyʼs prescribing physician testified at deposition that he relied upon fellow physicians, trade journals, articles, reference books and medical databases decided to prescribe Neurontin to plaintiff Measheyand his other

patients. Dr. Brown identified Dr. Norman Sussman, a psychiatrist and Clinical Professor of Psychiatry at New York University Medical School and Dr. Susan McElroy, a psychiatrist and former classmate who practices and does research at the University of Cincinnati as recommending Neurontin for anxiety disorders, an off label use. Dr. Sussman had written an article discussing anxiety and Neurontin. Dr. McElroy had published a study on the use of gabapentin in the treatment of bipolar disorder. Dr. McElroy had received a grant and other research support from defendants.

Dr. Brown further testified that after seeing a Dateline program concerning Neurontin he took his patients off Neurontin but subsequently represcribed Neurontin for five patients because they had experienced worsening anxiety. Dr. Brown's clinical judgment was that Neurontin was effective for these patients and the improvement in their medical condition was not merely a placebo effect.

Ms. Measheys medical records demonstrate that she took Neurontin for a three year period and had been tapered off Neurontin use as a result of the Dateline program. Dr. Brown noted that she had gotten help with anxiety while on Neurontin.

Dr. Michael Okin, M.D. is plaintiff Gregory Clark's treating physician. Dr. Okin briefly prescribed Neurontin off label for plaintiff Clark however he was unable to tolerate the medication. Dr. Okin testified that he prescribes Neurontin for peripheral neuropathy, entrapment neuropathies and RSD and continues to prescribe Neurontin for these conditions because in his clinical judgment it is effective.[1] Other physicians

[1] Dr. Okin deposition p. 34, 37, 41, 42 attached to Defendants' Supplemental Brief in Support of Motion for Decertification of the Class.

testified that Neurontin is effective for the treatment of neuropathic pain, migraines headaches, RSD, back pain and RLS and continues to prescribe it today.[2]

Plaintiffs' class complaint presents a claim for breach of express warranty. Plaintiffs' class claims that defendants' publication campaign expressly warranted that Neurontin should be used in circumstances not approved by the FDA. An express warranty is statutorily defined as any affirmation of fact or promise made by the seller to the buyer which relates to the goods, any description of the goods and any sample or model which is made part of the basis of the bargain.[3] Here, there is no evidence that plaintiffs saw, heard or in any way received any warranties that Neurontin could be used in circumstances not approved by the FDA. The alleged fraud on the medical profession which is the essence of plaintiffs' claims does not create any warranty. Plaintiff's breach of express warranty claim has not been proven and defendants' motion for summary judgment is granted as to this claim.

Plaintiffs' class remaining claims are for misrepresentation, negligence and negligence per se. Plaintiffs class claim that through defendants' concerted activities they incorrectly convinced that entire medical community of the effectiveness of off label uses. The evidence reveals that some of the class members have suffered no injury. The record demonstrates that some patients prescribed Neurontin for off label received a medical benefit from Neurontin.[4] Class members who have benefited from off label use

[2] Dr. Fitzsimmons deposition p. 16, 17, 18. 20; Dr. Ahlstrom deposition p. 14, 16, 17, 18, 20; Dr. Graham deposition p. 16, 17, 20, 21, 23, 25; Dr. Hoellein deposition p. 14, 15, 16; Dr. Norelli deposition p. 17, 18, 19, 20; Dr.Esper deposition 14, 15, 16, 17 attached to Defendants' Supplemental Brief in Support of Motion for Decertification of the Class.

[3] 13 Pa. C.S. § 2313.

[4] Dr. Brown's testimony p. 122 attached to Defendants' Supplemental Brief in Support of Motion for Decertification of the Class.

of Neurontin have suffered no injury and are not entitled to receive reimbursement of their non-insured expenses. Defendants' motion for summary judgment is granted as to those class members who benefited from prescribed off label uses of Neurontin, denied as to all class members who received no benefit from off label uses of Neurontin.

Defendants have also moved for class decertification. Since some class members have benefited from the use of Neurontin and other class members have not benefited, individual questions of fact are presented making the case unsuitable for class resolution. Individual questions of fact exist as to each class member to determine whether their off-label prescription of Neurontin was beneficial. Whether an individual class member suffered a compensable loss is an inherently individualized question which predominates making class resolution impracticable and possibly impossible. The motion for decertification of the class is granted.[5]

BY THE COURT,

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MARK I. BERNSTEIN, J.

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[5] In order to demonstrate numerosity, a plaintiff must show more than just a large number of potential plaintiffs. To satisfy this criterion, the class must be both numerous and identifiable. For the court to determine if there are enough class members to warrant a class action, the class definition must be clear enough for the court to reasonably ascertain who the potential class members are. Without a clear class definition it is impossible for the court to determine numerosity because the identity of the individuals to be included in the class cannot be determined. The Pennsylvania Superior Court has held that "where the class definition is so poorly established that the court cannot even discern who the potential class members are, the numerosity criterion has not been met." Weismer v. Beech-Nut Nutrition Corp., 419 Pa. Super. 403, 408, 615 A.2d 428 (Pa. Super. Ct., 1992).