IN THE COURT OF COMMON PLEAS
OF PHILADELPHIA COUNTY

CIVIL TRIAL DIVISION

GREGORY CLARK AND LINDA MEASHEY	:	JUNE TERM, 2004
vs.	:	
PFIZER INC., ET AL.	:	NO. 1819

OPINION

Presently before the Court is defendant Pfizer, Inc. and Warner-Lambert Company, LLC Motion for Partial Summary Judgment. Defendants seek Summary Judgment as to all claims for negligence and negligent misrepresentation and intentional misrepresentation and warranty as to purchases of the drug gabapentin not manufactured by defendant. Judgment is granted as to all warranty claims, denied as to all other claims.

Plaintiffs, individually and on behalf of all similarly situated purchasers of the drug Neurontin, or its generic equivalent, gabapentin whose prescriptions were written for off-label uses not approved by the F.D.A., bring this class action lawsuit seeking a refund. The claimed loss does not exceed $75,000 per class member. Plaintiffs bring claims for Misrepresentation (Count I); Negligence (Count II); Negligence per se (Count III) and Breach of Express Warranty (Count IV).

Defendants developed the drug Neurontin. In 1993 Neurontin was approved by the FDA for use as a treatment for epilepsy. In 2002 the FDA approved Neurontin for neuralgia. Neither law nor professional standards of care prohibits off-label prescription by doctors. However, federal law prohibits a drug manufacturer from promoting off-label uses of an approved medication. At the Class Certification hearing plaintiff produced

evidence which, if believed, demonstrates that beginning in 1995, defendants' deliberately and unlawfully promoted Neurontin to physicians for "off-label use" knowing that effectiveness had not been scientifically demonstrated. Defendants did this promotion by "educating" the medical profession to effectiveness for non-FDA approved use. Defendants "educational" promotions included soliciting anecdotal articles for insertion in medical journals, paying opinion leader physicians, and sponsoring continuing medical education conferences which were actually paid promotional events.

Defendant Warner-Lambert entered into a criminal 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 355(a). As part of that plea agreement the defendant agreed to a fine of $240 Million to be paid within 14 days of sentencing. As part of that plea defendant also agreed to cease all attempts to promote the drug for off-label use.

The information to which defendant pled guilty describes defendants activities. It states in pertinent part:

WARNER-LAMBERT'S STRATEGY FOR NEUTRONTIN

"11. Warner-Lambert conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, Warner-Lambert's southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT'S annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals,

objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for those Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT'S assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a Warner-Lambert Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalent would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere.

20. In October 1995, a member of WARNER-LAMBERT'S Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of…one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

> What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin…When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for Neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETING AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between $1,500 and $2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach Conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation

abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996 WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors, and, in fact, many of them had spoken on WARNER-LAMBERTS's behalf at prior meetings.

32 Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical

Director promoted off-label uses of Neurontin to the doctors participating in the teleconference."

Evidence was introduced at the Class Certification hearing that a May 18, 1995 Parke-Davis marketing report affirmatively outlined a "publication strategy" to promote Neurontin for psychiatric uses. Defendants developed data bases of influential prescribers of Neurontin for off-label uses and affirmatively promoted their views. Defendants provided financial incentives for these influential physicians to prescribe Neurontin off-label. The publication strategy consisted of publicizing positive anecdotal and case study results of off-label uses, financially supporting articles in medical literature which affirmed Neurontin's "emerging uses," and paying for "continuing medical education programs" dinners and teleconferences featuring only presentations by physicians selected because they believed Neurontin was effective in off label uses. The evidence further demonstrated that defendant Warner-Lambert affirmatively recommended that its medical liaison sales force focus their marketing efforts on selling Neurontin for pain management generally and explained how to answer physicians' objections. One internal memo read:

> "One important point first, there have been cases of pharmacists questioning Rxs for NEUTROTIN if the patient does not have epilepsy. To avoid any problems, just tell the physician to write on the Rx pad, *For pain management,* when he/she is Rxing NEURONTIN."

At least 200,000 prescriptions were written in Pennsylvania. Defendants earned between $53,000,000.00 and $64,000,000.00 dollars on the drug per quarter in Pennsylvania alone. At the certification hearing Plaintiffs presented expert testimony that Parke-Davis' off-label marketing efforts resulted in a significant increase in the

prescription of Neurontin for off-label uses even though no scientifically reliable studies have ever demonstrated effectiveness for off-label use.

Dr. Mark Levine, a professor of pharmaceutical science at the University of British Columbia attested to the generally accepted scientific standards for demonstrating efficacy and efficiency of a new drug. He conducted a literature review of Neurontin. He concluded to a reasonable degree of scientific certainty that Neurontin has not been demonstrated to be effective for off-label non-FDA approved uses. He states: "…it is not scientifically sound to say that sufficient evidence of a drug's effectiveness exists unless there has been at least one well-structured RCT to support that conclusion. The other types of evidence are simply insufficiently robust to constitute strong evidence of efficacy/effectiveness in the absence of proper RCTs."

Defense experts conceded that there has never been a randomized controlled study which demonstrated effectiveness for off-label uses. They supported writing off-label prescriptions on the basis of uncontrolled case reviews and case reports. The testimony of Dr. B. Franklin Diamond was presented by the defense. Dr. Diamond testified that it is proper for Physicians to prescribe medications off-label. His conclusions supporting off-label use was based entirely upon his own clinical judgment, experience and reliance upon case studies published in the medical literature.[1] Upon cross-examination, Dr. Diamond admitted that he had exaggerated the truth in his report. In his report, Dr. Diamond said that the effectiveness of neurontin has been demonstrated in clinical trials in patients suffering from Reflex Sympathetic Dystrophy. He conceded in Court, however, that this suggestion that effectiveness in treating Reflex Sympathetic

[1] It is these case studies which plaintiff claims were unlawfully funded and improperly promoted by defendant.

Dystrophy had been "demonstrated in clinical trials" was inaccurate.[2] He admits that other small controlled studies on the relevant issues were inconclusive. He further conceded that case studies are not considered valid scientific proof of effectiveness.[3] He explained that such anecdotal reports in literature cannot demonstrate effectiveness because "there's no control"[4] and therefore are incapable of properly analyzing the reason for relief of symptoms. Most importantly, he testified that physician prescription decisions are based upon "less well-controlled trial, the opinions of their colleagues, the opinions of experts in the field and, most importantly, reactions of their patients."

The defendant's business plan attested to the truth of this assertion. It said "Medical education drives this market." As demonstrated prima facie at the certification hearing, their multifaceted marketing approach promoting off-label use included a $40 Million advertising and promotional budget two-thirds of which was allocated for "professional education." Physicians who frequently prescribed anticonvulsant agents were targeted. Another targeted group were physicians influential among colleagues. "Local Champions" were identified for "peer to peer" influence programs. Medical "thought leaders" "key influences" and "movers and shakers" were identified. These influential physicians were given honoraria and research grants.

Plaintiff offered into evidence a review of the defendants' promotion of Gabapentin which had been published in the Annals of Internal Medicine[5]. This article

[2] N.T. 11/21/06, pgs. 98-99. Dr. Diamond's report also contains a remarkable indictment of our entire governmental regulatory scheme for prescription drugs. He says: "If a physician were limited to using drugs that had completed clinical trials for specific indications, there would be relatively few patients treated for anything successfully."
[3] N.T. 11/21/06 pg. 78, 79.
[4] N.T. 11/21/06 pg. 80.
[5] Exhibit 213.

reviewed public documents revealed in the defendant's criminal prosecution. The conclusion of those authors was:

> "The promotion of gabapentin was a comprehensive and multifaceted process. Advisory boards, consultants meetings, and accredited continuing medical education events organized by third-party vendors were used to deliver promotional messages. These tactics were augmented by the recruitment of local champions and engagement of thought leaders, who could be used to communicate favorable messages about gabapentin to their physician colleagues. Research and scholarships were also used for marketing by encouraging "key customers" to participate in research, using a large study to advance promotional themes and build market share, paying medical communications companies to develop and publish articles about gabapentin for the medical literature, and planning to suppress unfavorably study results."

Finally, the authors concluded: "…the techniques used to promote gabapentin illustrate how commercial interests can intrude into the practice of medicine in both visible and hidden ways."

Whether these conclusions are warranted by the defendants' internal documents and whether plaintiffs' claims can be proven at trial remain to be seen. However if plaintiffs can demonstrate at trial a comprehensive marketing scheme to unlawfully promote the off-label use of an FDA approved medication, a class wide claim has been proven. The claims of plaintiff class, if ultimately proven at trial, consist of an unlawful manipulation of medical literature, medical opinion, and a fraud upon the medical community of the country.

As to causation, plaintiffs presented the report of Dr. Meredith Rosenthal, an Assistant Professor of Health, Economics and Policy at the Harvard School of Public Health. She states:

"In summary, I find that the unlawful conduct alleged in the Complaint would likely have resulted in impact to the Class. Specifically, a large body of economic theory and empirical evidence suggests that pharmaceutical company marketing activities increase prescribing…Moreover, if Defendant's off-label promotion of Neurontin is proven to be illegal, it is feasible to quantify the causal effect of specific promotional strategies on off-label prescribing." Dr. Rosenthal concluded that there was "marked increases in prescribing for migraine, pain and psychiatric uses….immediately after Parke-Davis documents show the launch of off-label marketing campaigns specific to each of those categories of indications."

The fact that the substance of the alleged improper marketing activity consisted of the pretense of proper scientific medical education rather than a catchy jingle does not change the common sense observation that targeted promotional marketing is effective.[8] Even the experts presented by the defense agreed that physicians obtain prescribing information in precisely the ways defendants targeted; pharmaceutical representatives, other physicians' recommendations, medical literature, case reviews, medical

[8] Indeed, ever since Coca Cola decided to create brand identification through advertising, it has been known that marketing campaigns and advertising work. $200,000,000,000.00 is spent annually upon marketing and advertising in America.

conferences and the medical community's shared information and common understanding.[9]

Plaintiff's claim that defendants invested the resources necessary, and through their resources and prestige in the medical pharmaceutical educational community intentionally manipulated the consensus of medical opinion in America so that doctors came to believe that Gabapentin was a suitable drug for uses which had never been approved by the FDA and which had never been scientifically proven effective. Plaintiff's claim defendants did this when they had a statutorily imposed monopoly on the sale of Gabapentin and that the fruits of this illegal activity resulted in a continuing loss to class members after their monopoly had ceased. The question presented by this Motion for Partial Summary Judgment is whether this loss is compensable to class members who purchased the generic equivalent of Gabapentin after the defendant's monopoly had ceased if these allegations are eventually proven at trial.

The legal question presented by this Motion for Partial Summary Judgment is whether under Pennsylvania Law, a drug company which negligently or intentionally perpetrates a fraud upon the medical community may be held responsible for sums paid to other drug manufacturers because of their misrepresentations. For purposes of this motion, the Court assumes as plaintiff alleges, that purchases of generic Gabapentin for non-approved uses "were inspired by defendants extensive, deliberate, and illegal marketing campaign, which was expressly designed to convince physicians that Neurontin could effectively treat off-label conditions – despite the fact that no adequate scientific testing has ever supported such uses." The assumption of the truth of this

[9]Defense experts Jefferson and Greist acknowledge in their reports that their opinions as to the effectiveness of Neurontin in psychiatric treatment are based exclusively on case reviews and case reports.

allegation of fact, which will be the subject of trial, is required by the standard for granting summary judgment. The non-moving party must be given the benefit of the resolution of all questions of fact for which they have presented evidence and all reasonable inferences therefrom. The evidence presented in support of this proposition was extensively provided to the Court at the Certification Hearing and in part summarized herein and in the decision granting Class Certification.

Given the presumption that plaintiffs will be able to factually prove their allegations, the question presented becomes whether under Pennsylvania law, defendants owed any duty for which they can be held liable to purchasers of the drug because defendants had reason to anticipate those individuals would be induced to act. The sale of generic Gabapentin for non-approved uses was not only foreseeable and predictable, but in fact predicted. A heavily and successfully marketed drug will, at the time exclusive rights to the formulation have passed, be copied and sold by competitors as a generic equivalent. The medical literature which plaintiffs claim was manipulated by defendants', often referred to the generic chemical name rather than the defendants' brand name. When generic drugs become available they are often required by law or insurance companies to be prescribed as a substitute unless a physician specifically designates a brand name drug. "Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist shall substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber."[10]

Defendants themselves estimated that Neurontin would lose between 65 and 95 percent of its market once its patents had expired. Accordingly, defendant Pfizer

[10]See for example 35 P.S. Section 960.3 (a)

proposed manufacturing its own "authorized" generic, to keep a portion of that market. The significant increased sale of generic Gabapentin was a foreseeable result of defendants actions in marketing Neurontin for "off-label" use.

Under Pennsylvania law, a defendant may be liable for misrepresentation to foreseeable plaintiffs even without any direct relation between the parties. In Woodward v. Dietrich[11], the Superior Court adopted the Restatement (2nd) of Torts Section 531 as the law of Pennsylvania. Section 531 reads in pertinent part: "One who makes a fraudulent representation is subject to liability to the persons or class of persons whom he… has reason to expect to act…in reliance upon the misrepresentation, for pecuniary loss suffered by them through their justifiable reliance in the type of transaction in which he intends to has reason to expect that conduct to be influenced."

In Woodward, a builder fraudulently misrepresented that a housing development's sewer system had been designed and constructed in accordance with municipal authority requirements. Secondary purchasers of the houses which had required extensive repair for clogged drains and flooding sued the builder. The Woodward Court held that the developer who had fraudulently misrepresented compliance was found liable even though it had completed all construction long before, and the subsequent buyer plaintiff had no relationship to them whatsoever.

The Supreme Court in Bilt-Rite Contractors, Inc. Architectural Studio[12], specifically adopted Section 552 of the Restatement of Torts concerning negligent misrepresentation which states in pertinent part: "Information negligently supplied for the guidance of others" …[1] one who, in the course of his business professional

[11] 548 A.2d 301 (Pa. Super. 1988).
[12] 866 A.2d 270 (2005).

employment, or in any other transaction in which he had a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information."[13]

The Defendants rely on the District Court Opinion in Colacicco v. Apotex, Inc.[14] Pennsylvania Courts are not required to follow Federal District Court discussion which fail to accurately reflect Pennsylvania law.[15] The Colacicco decision extensively discusses preemption stating that allowing plaintiffs' case to proceed "would thwart the purpose of, and thus actually conflict with, the FDCA …." The District Court further found that deference to a recently changed policy position of the FDA required dismissal. As stated in Colacicco "the FDCA mandates that drugs are "safe and effective.[16] Therefore pharmaceutical manufacturers most obtain regulatory approval for prescription drugs prior to marketing them." The Colacicco plaintiffs sought to graft additional requirements for citizen safety onto the FDCA. The District Court found this claim preempted saying: "assigning State Tort Liability would thwart the purpose of ---and thus actually conflict with --- the Hatch-Waxman Amendments." In contrast, the case before the bar of the Court specifically seeks to enforce the exact citizen safety requirement of the FDCA and seeks recompense for the violation of that very Act.

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[13]While decided in favor of the defense because they had received no "pecuniary gain" the Superior Court as recently as 2007 in Excavation Techs., Inc. v. Columbia Gas Co., 936 A.2d 111 (Pa. Super. 2007), reaffirmed the application of Section 552 as Pennsylvania law.
[14]432 F. Supp. 2d 514 (E.D.P.A. 2006).
[15] Commonwealth v. Moore, 928 A.2d 1092 (Pa. Super. 2007). Cianfrani v. Johns-Manville Corp., 482 A.2d 1049 (Pa. Super. 1984).
[16] 21 U.S.C. Section 355 (a).

Giving excessive deference to the agency's reinterpretation of the Statute and the Regulations it administers as to preemption, the Colacicco Court found state claims preempted. While taking the opposite position for many years, in 2006 the FDA promulgated a "preemption preamble" which for the first time stated that FDA labeling requirements did not represent a minimal safety standard, but did in fact "establish both 'floor' and 'ceiling'." [17] Although it might be said that this preamble was a politically motivated legal opinion about statutory construction and not one of "agency expertise," in the field of Pharmaceuticals, the Colacicco Court found that the "FDA has acted within its authority and this Court must respect its expert judgment that an October 2003 warning label other than approved by the FDA would have been in direct actual conflict with Federal law." In contradiction, it is plaintiff herein who supports the FDA in the proposition that in violation of Federal law, defendants unlawfully manipulated scientific "truth" to convince by misrepresentation the entire medical community of the proposition that Gabapentin could be therapeutically used for indications never approved by the FDA.

While State Courts respect the reasoning of Federal Courts particularly when interpreting Federal law issues of nationwide import which impact upon Federal-State relations, the right of each sovereign State to protect its citizens is a matter of State law interpretation protected by the 10th Amendment to the United States Constitution. As a Pennsylvania Trial Court, this Court is obligated to enforce state law until such time as

[17] The Colacicco opinion noted that in December 22, 2000 the FDA stated "that its regulations are minimum standards, and do not preempt state tort claims" and in December 1, 1998 "Federal preemption could unduly interfere with the goals and objectives of existing State programs…This final rule is intended to complement these State efforts, not replace or hinder them." 432 F.Supp.2d at 530.
[15] "…it is the state Court that speaks with final authority on questions of state law." U.S. v. D'Amato, 436 F.2d 52, 54 (3rd Cir. 1970)(*citing* Murdock v. City of Memphis, 87 U.S. 590 (1874)).

the Supreme Court of the United States having actual authority determines that state law has been preempted.[15]

Since the state law claims in Colacicco were ruled to have been preempted, no further interpretation of state law was necessary.[16] Nonetheless, the Colacicco Court in dicta opined that a "name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug…." However, in Althaus v. Cohen[21], the Pennsylvania Supreme Court set forth a five part test for determining whether a duty exists. The factors set forth in Althaus are: 1. The relationship between the parties; 2. the social utility of the actor's conduct; 3. the nature of the risk imposed and the foreseeability of the harm incurred; 4. the consequences of imposing a duty upon the actor; and 5. the overall public interest involved.

In Colacicco, plaintiff believed that state law required an additional warning to make the product safe for its intended use. Thus, plaintiff sought to impose an affirmative obligation to do more. In this case, plaintiff seeks to impose upon the defendants an affirmative obligation only to obey Federal law, to have done less, namely, to not misrepresent medical knowledge. Applying the Althaus factors to the facts of this case, that is to the premise that significant, misrepresentations deluded the medical community into believing that there was scientific proof of Gabapentin's effectiveness then: (1) the relationship between the purchasers of generic Gabapentin and these defendant manufacturers herein is that of purchaser of drugs which never would have been purchased but for defendants' massive advertising campaign of misrepresentation. 2.

[16] Federal Courts should avoid interpreting State law unless necessary. Maryland Cas. Co. v. Knight, 96 F.3d 1284 (9th Cir. 1996).
[21] 756 A.2d 1166 (Pa. 2000).

Social Utility: There is no social utility to the defendant's conduct, namely the misrepresentation of scientific knowledge broadcast through conferences, manipulation of medical data, medical literature and consulting contracts to promote junk-science. 3. The nature of the risk imposed is the use of medications for which no scientific proof of effectiveness has ever occurred; and the foreseeability of the harm, namely purchases no more productive than placebo treatment was the intention of the advertising campaign. 4. The consequences of imposing a duty upon the defendants herein is nothing greater than the requirement that pharmaceutical advertising of drugs and promotion be in accord with scientific knowledge and Federal law rather than marketing requirements and profitability concerns. And finally, 5. The overall public interest in the proposed solution that pharmaceutical companies be required to obey the FDCA and only promote drugs for approved uses or foster medical discussion for scientifically proven uses is the most salutory result possible.[17] Pennsylvania requires that to prove intentional misrepresentation, the plaintiff must show a material representation made falsely with knowledge of its falsity, or recklessness with the intent of misleading another in relying on it and justifiable reliance upon the misrepresentation resulting in causal injury, precisely the claim presented in this case.

The claims for reimbursement of sums spent on generic Gabapentin are not barred by any "economic loss" rule. In Bilt-Rite Contractors, Inc. v. Architectural Studio[22], the Pennsylvania Supreme Court said: "Pennsylvania has long recognized that purely economic losses are recoverable in a variety of tort actions including professional malpractice actions…. A plaintiff is not barred from recovering economic losses simply

[17] Interestingly the Colacicco opinion itself states that intentional misrepresentation claims would have survived if they had not been previously thrown out by preemption doctrines.
[22] 866 A.2d 270, 288 (2005).

because the action sounds in tort rather than contract law." The Economic Loss Doctrine must be read sensibly and intentionally applied to specific fact situations. The Economic Loss Doctrine prohibits recovery in Tort only when entitlement flows only from violation of contract. Where expectations have been defined by contract, those expectations and the duties defined by contract cannot be artificially augmented by titling the claim as tort. The Economic Loss Doctrine is inapplicable to this case. "This court does not believe that intentional misrepresentations and outright dishonesty, if they can indeed be proven, are properly redressed in a breach of contract or warranty action."[23]

Clearly, those purchasers of generic Gabapentin not manufactured by the defendants who suffered loss only because their physicians prescribed the medication since the medical community was deluded, have no contractual relationship with the defendants herein.

Summary Judgment is denied.

BY THE COURT

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DATE MARK I. BERNSTEIN, J.

[23] Oppenheimer v. York International, 2002 Phila. Ct. Com. Pl. LEXIS 12; *see* Zweircan v. General Motors Corp., 58 Pa. D. & C. 4th 251 (C.P. Phila. 2002) ("In declining to extend the application of the economic loss doctrine to intentional fraud claims, this court noted, there is an absence of Pennsylvania case law on the subject, but found support for the proposition that the doctrine should not bar claims where the representation is intentionally false."); *see* Worldwide Web Networks Corp. v. Entrade, Inc., 2003 Phila. Ct. Com. Pl. LEXIS 31 ("the economic loss doctrine does not apply to intentional tort claims."); *see* Teledyne Techs., Inc. v. Freedom Forge Corp., 2002 Phila. Ct. Com. Pl. LEXIS 26 ("If Pennsylvania laws were to apply the economic loss doctrine would not bar the plaintiff's intentional misrepresentation claim."); *see also* Amico v. Radius Communications, 2001 Phila. Ct. Com. Pl. LEXIS 88; First Republic Bank v. Brand, 50 Pa. D.& C 4th 329 (C.P. Phila. 2000). In Dowana v. Boykai, 2007 Phila. Ct. Com. Pl. LEXIS 248 (The economic loss doctrine does not apply to matters governed by Bilt-Rite.)