UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:12-cv-9366-SVW-MAN	Date	June 13, 2013
Title	Jennifer L. Saavedra, et al. v. Eli Lilly and Co.		

Present: The Honorable	STEPHEN V. WILSON, U.S. DISTRICT JUDGE	
Paul M. Cruz	N/A	
Deputy Clerk	Court Reporter / Recorder	Tape No.

Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
N/A	N/A

Proceedings: IN CHAMBERS ORDER Re MOTION FOR SUMMARY JUDGMENT [54] [65]

Upon review of the parties' briefs, the Court concludes that the Motion is suitable for determination without oral argument. Fed. R. Civ. P. 78(b); Local Rule 7-15. The hearing scheduled for June 17, 2013, is VACATED.

I. INTRODUCTION AND BACKGROUND

On January 10, 2013 Plaintiffs Jennifer Saavedra, Melissa Strafford, Carol Jacquez, and David Matthews, Jr. (collectively, "Plaintiffs") filed their corrected First Amended Complaint ("FAC") against Defendant Eli Lilly and Company ("Defendant"). (Dckt. 44.) In their FAC, Plaintiffs asserted claims on behalf of themselves and all similarly situated individuals under the consumer protection laws of four different states (the "class claims"): California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ *et seq*., False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500, *et seq*, and Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq*.; Massachusetts's Consumer Protection Act ("Ch. 93A"), Mass. Gen. Laws Ch. 93A, §§ 1, *et seq*.; Missouri's Merchandising Practices Act ("MPA"), Mo. Rev. Stat. §§ 407.010, *et seq*.; and New York's Consumer Protection from Deceptive Acts and Practices Law ("NYCPA"), N.Y. Gen. Bus. Law §§ 349, *et seq*.[1] Plaintiff Saavedra also asserted five individual causes of action for breaches of express and implied warranty, unjust

[1] Plaintiffs Saavedra and Jacquez are residents of California; Plaintiff Matthews, a resident of Missouri; and Plaintiff Strafford is currently a resident of New York, but was also a resident of Massachusetts during the time period relevant to this suit.

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enrichment, strict products liability, and negligence, each arising under California law. Plaintiffs requested monetary damages and declaratory and injunctive relief.

In their FAC, Plaintiffs alleged that Defendant developed and manufactures the antidepressant Cymbalta. FAC ¶ 22. They further alleged that users who take Cymbalta are "faced severe physiological and psychological symptoms when the attempt to stop" taking it, including dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis, and vertigo (the Court refers to these symptoms as "Cymbalta withdrawal"). FAC ¶ 26. Each prescription of Cymbalta includes a label that warns about Cymbalta withdrawal. FAC ¶ 28. The label informed the reader that "[f]ollowing abrupt or tapered discontinuation in placebo-controlled clinical trial, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine [i.e. Cymbalta]-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthensia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue." FAC ¶ 28. The label further informed the reader that there have been reports of "adverse events" upon discontinuation of *other* SNRIs, including irritability, dizziness, anxiety, headache, and others. FAC ¶ 28.[2]

Plaintiffs allege that this label did not accurately inform consumers "and healthcare professionals" of the "frequency, severity, and/or duration of Cymbalta withdrawal." FAC ¶ 27. According to Plaintiffs, various studies dating back to at least 2005 have found that between 44 and 50 percent of all Cymbalta users experience Cymbalta withdrawal; and of those, approximately half experience "moderate" or "persistent" symptoms, and one in ten will experience "severe" symptoms. FAC ¶¶ 30, 33. Moreover, "nowhere on Cymbalta's label does it indicate the potential duration of withdrawal symptoms." FAC ¶ 32. Each Plaintiff alleges that, had they known the truth about the frequency, severity, and duration of Cymbalta withdrawal, they would not have started taking Cymbalta. FAC ¶¶ 8-13.

On February 26, 2013, this Court dismissed Plaintiffs' claims for injunctive and declaratory relief, but otherwise denied the Defendant's motion to dismiss. This Court subsequently instructed the parties to brief solely the legal question of whether the learned intermediary doctrine applies to the consumer protection claims at issue in this case.

[2] This warning has undergone "minor variations" since Cymbalta's approval in 2004. FAC ¶ 2.

II. DISCUSSION

A. Application of the Learned Intermediary Doctrine

The learned intermediary doctrine provides that a drug manufacturer cannot be liable for failing to warn the ultimate consumer of potential side-effects of prescription medication, so long as adequate warnings are given to the prescribing physician. See Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659, 661 (9th Cir. 2004) ("[Defendant] is obligated to warn doctors, not patients, of potential side-effects associated with its pharmaceutical products[.]"). As the Second Circuit has explained:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Plummer v. Lederle Laboratories, Div. of Am. Cyanamid Co., 819 F.2d 349, 356 (2d Cir. 1987) (internal citations and quotation marks omitted); see also Cottam v. CVS Pharmacy, 436 Mass. 316, 321 (2002) ("The rationale for the [learned intermediary] doctrine is that physicians have the duty to inform themselves about the drug and warn their patients as they deem necessary. Physicians, after considering the history and needs of their patients and the qualities of the drug, are required to inform their patients of those side effects they determine are necessary and relevant for patients to know in making an informed decision. Requiring the manufacturer to provide warnings directly to the consumer would interfere with the doctor-patient relationship.") (internal citations and quotation marks omitted); Plenger v. Alza Corp., 11 Cal. App. 4th 349, 362 n.6 (1992) ("The rationale of the [learned intermediary doctrine] is: (1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate [that physicians exercise] independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply

with the duty of direct warning, as there is no sure way to reach the patient.") (internal citations and quotation marks omitted).

Plaintiffs do not dispute that each of the relevant jurisdictions recognizes the learned intermediary doctrine applies to failure to warn claims sounding in tort.[3] Instead, they argue that the doctrine does not apply to the various consumer protection claims at issue in this suit.

The Court has not found, nor have the parties have identified, any case from the Supreme Court, or appeals courts, of the relevant jurisdictions that have specifically addressed the issue of whether the learned intermediary doctrine applies to the relevant consumer protection statutes at issue.[4] When a case raises an issue of first impression, a court sitting in diversity "must use its best judgment to predict how the [relevant state] Supreme Court would decide the issue." Burlington Ins. Co. v. Oceanic Design & Const., Inc., 383 F.3d 940, 944 (9th Cir. 2004) (internal citations, quotation marks, and alterations omitted). "In so doing, a federal court may be aided by looking to well-reasoned decisions from other jurisdictions." Id. (internal citations and quotation marks omitted).

Every case that this Court has found, and that the parties have identified, that has specifically addressed the questions has found that the learned intermediary doctrine applies to consumer protection claims predicated on a failure to warn. As one court has explained, "[i]f the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such as violation of the [state law consumer protection act] or a claim for misrepresentation, then the doctrine would be rendered meaningless." In re Norplant Contraceptive Products Liab. Litig., 955 F. Supp. 700, 709 (E.D.

[3] See Cottam, 436 Mass. at 322 ("This court has already recognized the learned intermediary doctrine in the context of prescription drug manufacturers."); Carlin v. Superior Court, 13 Cal. 4th 1104, 1116, 920 P.2d 1347, 1354 (1996) ("Moreover, in the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient."); Banker v. Hoehn, 278 A.D.2d 720, 721, 718 N.Y.S.2d 438, 440 (2000) ("Under the doctrine of 'learned intermediary', the manufacturer of the [prescription drug] satisfies its duty to warn of potential adverse effects when it adequately warns medical professionals who use the device in the treatment of patients."); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) ("Missouri courts adhere to the learned intermediary doctrine.").

[4] Defendant has identified one unpublished case from a Massachusetts trial court that appears to apply the learned intermediary doctrine to claims brought under Massachusetts' consumer protection law. See Linnen v. A.H. Robins Co., Inc., 2000 WL 89379, at *6 (Mass. Super. Dec. 14, 1999).

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Tex. 1997) aff'd sub nom. In re Norplant Contraceptive Products Litig., 165 F.3d 374 (5th Cir. 1999)[5]; see also Scelta v. Boehringer Ingelheim Pharmaceuticals, Inc., 404 F. App'x 92, 94 (8th Cir. 2010) (noting that the "parties agree" that if the plaintiff's prescribing physician knew of a prescription drug's risk, the "learned intermediary doctrine prevents [the plaintiff[from proving that the [defendant drug manufacturer's] alleged deception proximately caused his injuries" under Florida's consumer protection laws); Kee v. Zimmer, Inc., 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012) ("[A] private right of action under [Pennsylvania's consumer protection act] requires proof of justifiable reliance and causation, and such requirements cannot be present when the defendant is a pharmaceutical company that did not sell its product directly to the patient."); Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1372 (S.D. Fla. 2007) ("[F]ederal courts in jurisdictions across the country, including Florida, have held that the learned intermediary doctrine encompasses all claims based upon a pharmaceutical manufacturer's failure to warn, including claims for fraud, misrepresentation, and violation of state consumer protection laws.").[6]

Indeed, federal district courts that have considered two of the consumer protection claims at issue in this case—Missouri and New York—have concluded that the learned intermediary doctrine applies to those claims. See Carr-Davis v. Bristol-Myers Squibb Co., 2013 WL 322616, at *4-*5 (D.N.J. Jan. 28, 2013) (applying the learned intermediary doctrine to claims brought under Missouri's Merchandising Practices Act based on an interpretation of Missouri law, where the claims at issue "essentially turn[ed] on whether Defendants adequately warned that [the defendant manufacturer's drug' carried a risk of bleeding complications); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 552 (E.D. Pa. 2006) aff'd, 521 F.3d 253 (3d Cir. 2008) cert. granted, judgment vacated, 129 S. Ct. 1578 (U.S. 2009) ("[W]e agree that the learned intermediary doctrine also precludes Plaintiff's claim under [New York's] consumer protection statute.").

[5] On appeal, the Fifth Circuit specifically upheld the district court's ruling that the learned intermediary doctrine applied to the Texas Deceptive Trade Practices Act. See In re Norplant Contraceptive Products Litig., 165 F.3d 374, 378 (5th Cir. 1999)

[6] Plaintiffs cite twelve cases from the relevant jurisdictions in support of their argument that the learned intermediary doctrine does not apply to the claims at issue. See Pls. Resp. to Def.'s Mot. for Summary Judgment at 14-18. Of those twelve cases, ten do not address the question at hand; one, Plubell v. Merck & Co., expressly reserved judgment on the question at hand, see 2008 WL 4771525, at *9 (Mo. Cir. June 12, 2008); and the final one appeared to apply the learned intermediary doctrine to claims brought under Massachusetts' consumer protection law. See Linnen, 2000 WL 89379, at *6.

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Thus, the Court concurs with the great weight of authority and concludes that the learned intermediary doctrine applies to the consumer protection claims at issue.

B. Application of the Doctrine to this Case

In order to prevail to prevail on its defense, Defendant must establish that it adequately warned prescribing physicians of the effects of Cymbalta withdrawal. See, e.g. Carlin, 13 Cal. 4th at 1116 ("In the case of medical prescriptions, if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.") (internal citations and quotation marks omitted). Generally, the question of whether a warning was adequate is a question of fact. See, e.g. In re Meridia Products Liab. Litig., 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004) aff'd sub nom. Meridia Products Liab. Litig. v. Abbott Laboratories, 447 F.3d 861 (6th Cir. 2006) ("Generally, whether a particular warning is 'adequate' is a question of fact to be resolved by a jury."); see also Carlin v. Superior Court, 13 Cal. 4th 1104, 1116, 920 P.2d 1347, 1353 (1996) (noting that determining whether a warning is adequate is a question of fact, involving "inter alia, questions concerning . . . what was known or reasonably knowable by the application of scientific and medical knowledge available at the time of manufacture . . . [and] questions concerning whether the risk, in light of accepted scientific norms, was more than merely speculative or conjectural . . . ."). At a minimum, Plaintiffs are entitled to additional discovery necessary to demonstrate whether the warnings provided in this case were "adequate."

III. CLASS CERTIFICATION

However, even if this Court, or a fact-finder, concludes that the warnings give were inadequate, Plaintiffs would still be required to prove that "the inadequacy or absence of the warning caused the plaintiff's injury." Motus, 196 F. Supp. 2d at 991.[7] In order to determine whether or not the warnings at

[7] Indeed, Plaintiffs would be required to prove causation as to each cause of action asserted, regardless of whether the learned intermediary doctrine applied. See Bower v. AT & T Mobility, LLC, 196 Cal. App. 4th 1545, 1556 (2011) ("Relief under the CLRA is specifically limited to those who suffer damage, making causation a necessary element of proof."); Kwikset Corp. v. Superior Court, 51 Cal. 4th 310, 326 (2011) ("[California law] requires that a plaintiff's economic injury come 'as a result of' the unfair competition [UCL] or a violation of the false advertising law [Section 17500]."); Tyler v. Michaels Stores, Inc., 464 Mass. 492, 503 (2013) (noting that in order to recover under Massachusetts' Chapter 93A, it is an "established principle" that "a plaintiff must prove causation"); Stutman v. Chem. Bank, 95 N.Y.2d 24, 29, 731 N.E.2d 608, 612 (2000) (noting that, in order to recover under New York's consumer protection laws, a plaintiff "must show that the defendant's 'material deceptive act' caused the

issue caused the Plaintiffs' injuries, this Court, or a fact-finder, would be required to engage in a series of individualized assessments. Among other things, this Court would need to determine whether: 1) if the individual plaintiff had known about the severity, duration, and extent of Cymbalta withdrawal, would she or he still have taken the medication?; 2) if the individual plaintiff's physician had known about the relevant side-effects, would the physician still have recommended and prescribed Cymbalta?; 3) did the individual plaintiff's physician know of the side effects from a source other than the warning label, and prescribe Cymbalta even with this knowledge? In the context of prescription drugs, each of these determinations will necessarily be different. See, e.g. Plummer, 819 F.2d at 356 ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.") (internal citations and quotation marks omitted).

Class certification may not be granted unless "questions of law or fact common to class members predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). Although the question of whether or not the warnings given to doctors, and consumers, were inadequate or misleading may be capable of resolution on a class-wide basis, the question of whether or not, had the warnings been adequate, each plaintiff would not have taken Cymbalta are not. See Mazza v. Am. Honda Motor Co., Inc., 666 F.3d 581, 595 (9th Cir. 2012) (vacating the district court's certification of a class because the class included "many class members were never exposed to the allegedly misleading advertisements"). Indeed, after conducting an extensive review, one district court concluded that "[t]o date, no Court of Appeals decision has approved class certification of an action involving prescription drugs." In re Baycol Products Litig., 218 F.R.D. 197, 203-04 (D. Minn. 2003); see also Sweet v. Pfizer, 232 F.R.D. 360, 365 (C.D. Cal. 2005) (denying class certification based on allegations that the drug manufacturer inadequately warned consumers about the side-effects based on lack of typicality and the presence of too many individualized issues); In re Paxil Litig., 212 F.R.D. 539, 551 (C.D. Cal. 2003) (denying class certification because "individual questions of fact regarding causation nevertheless subvert any benefits to be gained through a class action proceeding. Whether, and to what extent, Paxil causes discontinuation symptoms varies from patient to patient. Not only do individual physiologies

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injury"); Owen v. Gen. Motors Corp., 533 F.3d 913, 922 (8th Cir. 2008) ("[T]he plain language of the [Missouri Merchandising Practices Act] demands a causal connection between the ascertainable loss and the unfair or deceptive merchandising practice.").

affect the causation issues, but so too do the underlying illnesses and medical history of each individual plaintiff. In the face of such facts, denial of class certification for failing to meet the 'predominance' requirement is appropriate").

While this Court is not bound by these district court decisions, it finds that, in the interests of judicial economy, the appropriate next step is for the parties to brief the issue of class certification. Accordingly, the Court establishes the following briefing schedule:

Plaintiffs' motion for class certification . ……. August 19, 2013

Defendant's opposition ……. August 26, 2013

Plaintiffs' reply …….. September 3, 2013

Hearing …… September 17, 2013 at 1:30 p.m.

For purposes of the class certification motion, the parties should assume that Plaintiffs will be able to prevail on their contention that the warnings given to physicians were inadequate as alleged in the FAC.

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