United States District Court
District of Massachusetts

In re:	)	
CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION	)	**MDL No. 09-2067-NMG**
RANDY MARCUS and BONNIE MARCUS, on behalf of themselves and all persons similarly situated,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 13-11343-NMG**
FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This case arises out of the marketing and sales of the anti-depressant drug Lexapro by defendants Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. ("defendants" or, collectively, "Forest"). Plaintiffs Bonnie and Randy Marcus ("plaintiffs") allege that defendants violated California's Consumer Legal Remedies Act, Unfair Competition Law, and False Advertising Law by misrepresenting and concealing material information about the efficacy of Lexapro in treating major depressive disorder in pediatric patients.

Pending before the Court is defendants' motion to dismiss or in the alternative to stay the case under the primary jurisdiction doctrine. For the reasons that follow, the motion will be allowed and the case will be dismissed.

I. Background

Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRI") antidepressants. Forest obtained the approval of the Food and Drug Administration ("FDA") to market Celexa (citalopram) for adult use in 1998 and to market Lexapro for adult use in 2002. It later sought to market both drugs for use in treating major depressive disorder ("MDD") in children and adolescents.

A. FDA approval process

In order to obtain FDA approval to market Celexa and Lexapro as effective for pediatric and adolescent use, Forest was required to make a sufficient showing to the FDA that the drugs would be more effective than placebos in treating MDD in pediatric or adolescent patients. The FDA typically requires parties to submit at least two "positive" placebo-controlled clinical trials supporting such use.

Drug studies are deemed "positive" if they show statistically significant improvements for patients who are administered a drug rather than a placebo. In contrast, a "negative" study is one that indicates no statistically

significant difference in outcomes between patients who are administered the drug and those who receive a placebo.

Plaintiffs assert that the FDA sets a low bar for approving drugs for a particular use because it does not require a showing of clinically significant improvement over placebo. To determine clinical significance, one must examine whether the observed benefit of a drug outweighs the risks associated with the drug when compared to alternative, less risky treatments. Thus, a drug with dangerous side effects could, in theory, be proven to be statistically superior to a placebo but not clinically superior.

Drug manufacturers submit the results of such trials to the FDA as part of "new drug applications" ("NDAs"). Through an NDA, a manufacturer may also request FDA approval of use of the drug to treat a specific condition which is known as an "indication". A manufacturer may only market and sell the drug for an approved indication. If it wishes to obtain FDA approval for a new use, it must submit a separate NDA for that indication.

B. Clinical studies and FDA approval of an adolescent indication for Lexapro

Forest arranged for researchers to conduct four double-blind, placebo-controlled studies on the efficacy of Celexa and Lexapro in treating pediatric and adolescent depression. The

first two studies, which examined the efficacy of Celexa, were completed in 2001. Of those studies, "Celexa Study 18" produced "positive" results whereas "Celexa Study 94404" produced "negative" results. Plaintiffs claim that Forest fraudulently "doctored" the data of Celexa Study 18 to make the results appear positive and also suggest that flaws in the study design may have made patients aware of whether they were receiving treatment or a placebo.

Forest submitted the results of the two Celexa studies to the FDA in a supplemental NDA in 2002. The FDA denied Forest's application for a "pediatric indication" for Celexa after finding that Celexa Study 94404 was a clearly negative study.

Two studies of Lexapro's efficacy produced similar results to the earlier Celexa studies. Lexapro Study 15, which was completed in 2004, produced negative results, whereas Lexapro Study 32 was positive. Plaintiffs contend that there are several problems with the design of Lexapro Study 32 that cast doubts upon its positive results.

In 2008, Forest submitted the results of those studies and the earlier Celexa studies to the FDA in a supplemental NDA. Based on 1) the fact that Celexa Study 18 and Lexapro Study 32 were both positive for efficacy in adolescents and 2) the chemical similarities between Celexa and Lexapro, the FDA in 2009 permitted Forest to market Lexapro as safe and effective in

treating MDD in adolescents. Forest never obtained FDA approval to market Celexa for such use.

C. Lexapro's labeling

Plaintiffs allege that the drug label for Lexapro, which was approved by the FDA in March, 2009, is misleading and inadequate. A section of the label titled "Pediatric Use" states that

> Safety and effectiveness of Lexapro has not been established in pediatric patients (less than 12 years of age) with Major Depressive Disorder. Safety and effectiveness of Lexapro has been established in adolescents (12 to 17 years of age) for the treatment of major depressive disorder....

The label goes on to describe the two positive clinical studies that formed the basis of FDA approval for the adolescent indication and describes both studies as showing "statistically significant greater mean improvement". The label also states that two studies did not demonstrate efficacy.

D. Plaintiffs' purchase of Lexapro

In April, 2009, plaintiffs' son, who was 17 years old at the time, was prescribed Lexapro by his physician to treat his ongoing depression about one month after Lexapro was approved for treating MDD in adolescents. Plaintiffs and their physician were both allegedly misled into believing that Lexapro was more effective at treating adolescent MDD than it actually was. Plaintiffs allege that they read the drug label before

purchasing Lexapro for their son and relied on the representations therein. They claim to have spent approximately $495 on purchases of Lexapro between April, 2009 and April, 2011.

E. Procedural history

Plaintiffs filed their Complaint in the Central District of California in May, 2013, and the case was transferred to this Court by the Judicial Panel on Multidistrict Litigation in June, 2013. Defendants moved to dismiss in July, 2013. The Court heard oral argument on that motion in September, 2013, and took the matter under advisement.

II. Defendants' motion to dismiss

Plaintiffs allege that defendants have misrepresented and concealed material information about the efficacy of Lexapro in treating major depressive disorder in pediatric patients. Their Complaint asserts claims under several California consumer protection statutes including the Consumer Legal Remedies Act ("CLRA"), Cal. Bus. & Prof. Code §§ 1770(a), 1780; the Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200; and the False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500-17509. Forest has moved to dismiss on the grounds that plaintiffs' claims are barred by 1) the federal preemption doctrine and 2) California's safe harbor rule. In the

alternative, defendant urges the Court to remand the case to the FDA under the primary jurisdiction doctrine.

A. Legal standard

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). The Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. Langadinos v. Am. Airlines, Inc., 199 F.3d 68, 69 (1st Cir. 2000). The Court, however, need not accept legal conclusions as true. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009).

B. Application

The Court finds that, as a matter of law, plaintiffs' claims are barred by the California safe harbor provision. As a result, it need not consider defendants' preemption or primary jurisdiction arguments.

1. California's safe harbor rule

The California safe harbor doctrine bars certain claims brought under California's unfair competition laws. For the doctrine to apply,

> another provision must actually "bar" the action or clearly permit the conduct.... In other words, courts may not use the unfair competition law to condemn actions the legislature permits.

Cel-Tech Comm'c'ns, Inc. v. L.A. Cellular Tel. Co., 973 P.2d 527, 541-42 (Cal. 1999). Courts have subsequently applied the safe harbor doctrine to bar claims brought under the CLRA, FAL and UCL based upon federal statutes and regulations. See, e.g., Davis v. HSBC Bank Nev., 691 F.3d 1152, 1165-66 (9th Cir. 2012) (affirming dismissal of UCL claim based on federal regulations); Pom Wonderful LLC v. Coca-Cola Co., No. 08-06237, 2013 WL 543361, at *5 (C.D. Cal. Feb. 13, 2013) (finding that compliance with FDA labeling regulations insulated juice manufacturer from liability under the UCL and FAL).

2. Analysis

Forest argues that the safe harbor bars plaintiffs' claims because the FDA is required by statute to decline to approve a new drug application if

> there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof [or] based on a fair evaluation of all material facts, such labeling is false or misleading in any particular....

21 U.S.C. § 355(d); see also 21 C.F.R. § 314.125(b)(6) (requiring FDA to reject application when proposed labeling is "false or misleading in any particular"). Moreover, it asserts that the FDA's "voluminous" regulations concerning prescription drug labeling provide further support for its argument that FDA approval of a drug label protects Forest from liability under

state consumer protection law for statements or omissions within that label. See 21 C.F.R. §§ 201.56, 201.57 (describing labeling requirements with respect to, inter alia, efficacy information, safety information and approved uses).

Plaintiffs respond that Forest would be entitled to safe harbor protection only if federal law

> specifically allowed Forest to conceal material information about a drug's efficacy from consumers and prescribers.

They contend that federal law in fact provides the exact opposite because it prohibits Forest from distributing drugs that are labeled in a false or misleading way. That argument misstates the relevant inquiry: the safe harbor provision, in essence, reflects a judgment by the California Supreme Court that California's unfair competition law should not be employed to second guess legislative judgments. See Cel-Tech, 973 P.2d at 541-42 (explaining that the policy underlying the safe harbor rule is that "courts may not use the unfair competition law to condemn actions the legislature permits").

Where, as here, Congress has entrusted the FDA to determine 1) whether there is a substantial evidence of efficacy for a particular indication and 2) whether a proposed label is false or misleading in any way, and the FDA approves a label for a certain indication, the safe harbor provision applies to bar a claim that the label was false or misleading. Furthermore,

neither of the two potential exceptions to the safe harbor rule applies.

First, this case is distinguishable from cases involving FDA regulation of food and homeopathic remedies in which courts have held that the safe harbor provision did not apply. See, e.g., Delarosa v. Boiron, Inc., 818 F. Supp. 2d 1177, 1189-90 & n.8 (C.D. Cal. 2011) (declining to apply safe harbor provision after reasoning that "unlike with non-homeopathic [over-the-counter] drugs, the FDA has not set up a comprehensive process to evaluate the safety or efficacy of homeopathic [over-the-counter] remedies"); Von Koenig v. Snapple Beverage Corp., 713 F. Supp. 2d 1066, 1075-76 (E.D. Cal. 2010) (holding that informal FDA policy "cannot be accorded the weight of federal law for purposes of the safe harbor rule"). In contrast to the insufficient regulatory frameworks in those cases, the prescription drug industry is subject to comprehensive regulations promulgated by the FDA. Bober v. Glaxo Wellcome PLC, 246 F.3d 934, 942 (7th Cir. 2001).

Second, this case is distinguishable from cases in which plaintiffs argued that the practice in question violated federal law. For instance, in Prohias v. Pfizer, Inc., 490 F. Supp. 2d 1228 (S.D. Fla. 2007), the court addressed whether safe harbor provisions of the consumer protection statutes of Massachusetts and Florida barred claims against the drug manufacturer Pfizer

based on advertisements that claimed that the drug Lipitor reduced the risk of coronary heart disease. Prohias, 490 F. Supp. 2d at 1232-35. The court found that the safe harbor provisions barred claims arising after the FDA approved the use of Lipitor to reduce the risk of heart disease in some patients because, at that point, the FDA specifically authorized such advertising by approving the use for which Lipitor was advertised. Id. at 1233-34. It found, however, that the safe harbor provisions did not bar claims based on advertisements that pre-dated FDA approval because such advertisements were not expressly authorized by the FDA. Id. at 1234-35. Here, where plaintiffs base their claims entirely on the marketing and sales of Lexapro after the FDA approved Forest's application for an adolescent indication and a proposed label, the safe harbor applies to bar such claims.

Finally, the Court is not persuaded that Wyeth v. Levine, 555 U.S. 555 (2009) calls into doubt the viability of safe harbor provisions in state consumer protection statutes. Wyeth held that FDA approval of a drug label does not necessarily preempt state-law failure to warn claims. Plaintiffs provide no justification to extend that holding to preclude state safe harbor defenses to claims arising under state consumer protection law and this Court has found no authority permitting it to do so.

ORDER

Accordingly, defendants' motion to dismiss (Docket No. 16/ Master Docket No. 243) is **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated March 5, 2014