United States Court of Appeals
For the First Circuit

No. 14–1290

IN RE: CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION

RANDY and BONNIE MARCUS, on behalf of themselves and all other persons similarly situated,

Plaintiffs, Appellants,

v.

FOREST LABORATORIES, INC. and FOREST PHARMACEUTICALS, INC.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Nathaniel M. Gorton, U.S. District Judge]

Before

Lynch, Chief Judge,
Selya and Kayatta, Circuit Judges.

R. Brent Wisner, with whom Baum, Hedlund, Aristei & Goldman, P.C. and Pendley, Baudin & Coffin, LLP were on brief, for appellant.

Edwin G. Schallert, with whom Debevoise & Plimpton LLP and Sugarman, Rogers, Barshak & Cohen, P.C. were on brief, for appellee.

February 20, 2015

KAYATTA, Circuit Judge. This appeal arises out of a putative class action against Forest Pharmaceuticals, the manufacturer of Lexapro, an antidepressant medication. Plaintiffs claim that Lexapro's FDA-approved drug label misleads California consumers by omitting material efficacy information, in violation of California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 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. The district court dismissed these claims, finding them barred by California's safe harbor doctrine. See In re Celexa & Lexapro Mktg. Sales Practices Litig. (Marcus v. Forest Labs., Inc.), No. 13–11343–NMG, 2014 WL 866571 (D. Mass. March 5, 2014). See generally Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co., 20 Cal. 4th 163, 182 (1999) (outlining California's safe harbor doctrine).

Expressing no view on the California safe harbor doctrine's applicability here, we instead find that federal law impliedly preempts these claims because the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., prohibits Forest from independently changing its FDA-approved label as plaintiffs claim California law requires. See PLIVA, Inc. v. Mensing, 131 S.Ct. 2567, 2580–81 (2011). Therefore, we affirm the judgment dismissing the complaint.

I. Background

Lexapro belongs to a class of antidepressants known as selective serotonin reuptake inhibitors. Forest also manufactures Celexa, a drug with a chemical composition closely related to Lexapro. In 2002, the FDA first approved Lexapro to treat adults for depression. In 2008, Forest sought FDA approval for the use of Lexapro to treat major depressive disorder in adolescents.

A. FDA's Drug Approval Process

The FDA drug approval process is "onerous and lengthy." Mut. Pharm. Co., Inc. v. Bartlett, 133 S.Ct. 2466, 2471 (2013). The FDCA requires that drug manufacturers gain FDA approval prior to marketing or selling a drug in interstate commerce. See 21 U.S.C. § 355(a). To gain FDA approval, a drug manufacturer must submit either a new-drug application ("NDA"), for a new drug, or a supplemental new-drug application ("sNDA"), for a new treatment. See 21 C.F.R. § 314.1 et seq. NDAs and sNDAs are subject to the same approval requirements. See id. The NDA or sNDA must include "full reports of [all clinical] investigations which have been made to show whether . . . such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). The FDA may only approve the drug if the NDA or sNDA provides "substantial evidence that the drug will have the effect it . . . is represented to have." Id. § 355(d)(5). As part of its showing that it has provided such substantial evidence, a manufacturer submits the results of "adequate and well-controlled

investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." Id. § 355(d)(7).

In its evaluation of an NDA or sNDA, the FDA has discretion to determine that data from "one adequate and well-controlled clinical investigation," along with other "confirmatory evidence," are "sufficient to establish effectiveness." Id.; see 21 C.F.R. § 314.105(c) ("[The] FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards.") The FDA will not approve a drug if the NDA or sNDA lacks "substantial evidence that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d)(5).

The drug manufacturer must also submit "the labeling proposed to be used for such drug." Id. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i). The application must include the proposed label's text "with annotations to the information in the [drug application] that support the inclusion of each statement [on the label]." 21 C.F.R. § 314.50(c)(2)(i). In order to approve an NDA or sNDA, the FDA must determine, "based on a fair evaluation of all material facts," that the proposed label is not "false or misleading in any particular." 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6). After approval, the manufacturer may distribute

the drug without violating federal law as long as it uses the FDA-approved label. See 21 U.S.C. §§ 331(c), 333(a), & 352(a), (c).

In an effort to secure FDA approval to sell Lexapro for the treatment of major depressive disorder in adolescents, Forest submitted to the FDA the results of four studies: Celexa Study 94404, Celexa Study 18, Lexapro Study 15, and Lexapro Study 32. Celexa Study 94404 and Lexapro Study 15 showed no efficacy. Celexa Study 18 and Lexapro Study 32 found positive efficacy that was statistically significant, but only barely so. In March 2009, the FDA nevertheless approved the sale of Lexapro to treat major depressive disorder in adolescents based on a finding that substantial evidence supported the efficacy of that use. In making this finding, the FDA "extrapolate[d] on the basis of a previously reviewed positive study with [Celexa]," along with the positive statistical efficacy results from Lexapro Study 32. As required by the FDCA, in approving the sNDA, the FDA made a specific finding that Lexapro's label was not "false or misleading in any particular." 21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6). That approved label included the following:

> Clinical Studies, Major Depressive Disorder -- Adolescents
>
> The efficacy of Lexapro as an acute treatment for major depressive disorder in adolescent patients was established in an 8-week, flexible-dose, placebo-controlled study that compared Lexapro 10-20 mg/day to placebo in outpatients 12 to 17 years of age inclusive who met DSM-IV criteria for major depressive

> disorder. The primary outcome was change from baseline to endpoint in the Children's Depression Rating Scale -- Revised (CDRS-R). In this study, Lexapro showed statistically significant greater mean improvement compared to placebo on the CDRS-R.
>
> The efficacy of Lexapro in the acute treatment of major depressive disorder in adolescents was established, in part, on the basis of extrapolation from the 8-week, flexible-dose, placebo-controlled study with racemic citalopram [i.e., Celexa] 20-40 mg/day. In this outpatient study in children and adolescents 7 to 17 years of age who met DSM-IV criteria for major depressive disorder, citalopram treatment showed statistically significant greater mean improvement from baseline, compared to placebo, on the CDRS-R; the positive results for this trial largely came from the adolescent subgroup.
>
> Two additional flexible-dose, placebo-controlled MDD studies (one Lexapro study in patients ages 7 to 17 and one citalopram [Celexa] study in adolescents) did not demonstrate efficacy.
>
> Although maintenance efficacy in adolescent patients has not been systematically evaluated, maintenance efficacy can be extrapolated from adult data along with comparisons of escitalopram pharmacokinetic parameters in adults and adolescent patients.

B. Changing The Label

There are two ways pertinent to this lawsuit in which a manufacturer of a brand name prescription drug can change the drug's label. First, the default rule is that a manufacturer must secure FDA approval for a proposed change prior to distributing the product with the changed label. 21 C.F.R. § 314.70(b)(2)(v)(A).

Second, under what is known as the Changes Being Effected ("CBE") regulation, id. § 314.70(c)(6)(iii), a manufacturer can make certain types of changes to its label, without prior FDA approval, by sending the FDA a "supplement submission."

To make a change under the CBE regulation, the manufacturer must satisfy at least two requirements. First, the change must "reflect newly acquired information." Id.; see also id. § 314.3(b) (defining "newly acquired information"). Second, the change must be for the purpose of accomplishing at least one of the five following objectives:

> (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling . . .;
>
> (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;
>
> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
>
> (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or
>
> (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

Id. § 314.70(c)(6)(iii).

C. The Complaint

According to the complaint, in April 2009, Randy and Bonnie Marcus, the plaintiffs, purchased Lexapro to treat their adolescent son's depression. Based on their reading of Lexapro's FDA-approved label, they and their son's physician overestimated Lexapro's effectiveness. As a result, they spent money purchasing a drug that they describe as no more clinically effective than a placebo. On behalf of all other Californians who purchased Lexapro for an adolescent from March 2009 until present, they claim that Forest Pharmaceuticals omitted material efficacy information, in violation of California state consumer protection laws: the CLRA, FAL, and UCL.

The CLRA prohibits unfair methods of competition and unfair or deceptive acts that result in the sale of goods to any consumer. Cal. Civ. Code. § 1770(a). The complaint alleges that Forest violated four different provisions of the CLRA, specifically § 1770(a)(2) ("Misrepresenting the source, sponsorship, approval, or certification of goods or services."); § 1770(a)(5) ("Representing that goods or services have sponsorship, approval, . . ., [or] benefits, . . . which they do not have . . . ."); § 1770(a)(7) ("Representing that goods . . . are of a particular standard, quality, or grade, . . . if they are of another."); and § 1770(a)(9) ("Advertising goods . . . with intent not to sell them as advertised."). The FAL prohibits companies from disseminating

"untrue or misleading" statements. Cal. Bus. & Prof. Code. § 17500. And the UCL prohibits "unfair or fraudulent business act[s] or practice[s] and unfair, deceptive, untrue or misleading advertising." Id. § 17200.

In support of these state law claims, the complaint takes issue with "the FDA['s] accept[ance of] the questionable data from Lexapro Study 32 and the flawed data from Celexa Study 18 to conclude that Forest met its regulatory requirement of providing two well-controlled studies showing that Lexapro was effective for the treatment of adolescent [depression]." Expressing displeasure with federal law as well as the FDA, the complaint further notes that the FDA's "standards for approving antidepressants are minimal according to the law."

The complaint gives a different read to Celexa Study 18 than did the FDA's experts, who found that the study showed a statistically significant difference between Celexa and a placebo for an acute treatment of major depressive disorder in adolescents. The complaint disagrees, and asserts instead that "[a] close evaluation of the unpublished version of Celexa Study 18 reveals that data was manipulated to create the appearance of statistical significance." In sum, the complaint characterizes Celexa Study 18's results as "fraudulent and misleading."

The complaint also reads Lexapro Study 32 differently than did the FDA's experts, who found that this study also showed

a statistically significant difference between Lexapro and placebo for an acute treatment of major depressive disorder in adolescents. As with Celexa Study 18, the complaint questions the study's finding of statistical significance, and underscores the fact--known to the FDA at the time of approval--that the difference indicated "is not clinically significant."

Based on the foregoing, the complaint argues that the "drug label for Lexapro is misleading and inadequate." In its prayer for relief, plaintiffs request that the court "[p]ermanently enjoin[] Forest from continuing to sell or market Lexapro with its current drug label and direct[] Forest to seek FDA approval of a new [drug] label." Although the complaint contains general allegations of deceptive marketing, and quotes a press release from Forest,[1] plaintiffs (who seek to represent a class) hinge their claims and the relief they seek on their challenge to the adequacy of the efficacy discussion in the FDA-approved label. For example, plaintiffs allege that "Forest's misconduct was uniformly directed at all consumers and their prescribing healthcare professionals in California through the use of a misleading drug label. Thus, all

[1] Paragraph 53 of the complaint alleges that Forest issued a press release in which Forest's CEO stated, "[w]e have long believed that Lexapro would be of benefit for the treatment of depression in adolescents and that is why we undertook the several studies described in the package insert. We are enormously gratified that Lexapro will be available for depressed adolescents who so much require the benefits which Lexapro has made available for depressed adults for the past seven years."

members of the [class] have a common cause of action . . . ." Plaintiffs then allege that "the question of Forest's conduct, i.e., whether the drug label was misleading, predominates over any individual issues."

D. Procedural History

Randy and Bonnie Marcus filed the complaint in May 2013, seeking class certification, in the Central District of California. The Judicial Panel on Multidistrict Litigation subsequently transferred the case to the District of Massachusetts as part of ongoing multidistrict litigation, In re Celexa and Lexapro Marketing and Sales Practices Litigation, No. 09–MDL–2067–NMG. Forest moved to dismiss, relying on FDCA preemption and California's safe harbor doctrine. While both parties fully briefed Forest's federal preemption defense, the district court did not reach it, relying instead on its conclusion that the complaint failed under California's safe harbor doctrine.

II. Standard of Review

We give de novo review to the district court's grant of Forest's motion to dismiss for failure to state a claim. See, e.g., Cooper v. Charter Commc'ns Entm't I, LLC, 760 F.3d 103, 106 (1st Cir. 2014). We accept as true all facts in the complaint and draw all reasonable inferences in the plaintiffs' favor. Id.

III. Analysis

A.

In deciding whether the complaint states a claim upon which relief may be granted, we are urged by plaintiffs to restrict our inquiry to determining whether the safe harbor doctrine under California law defeats plaintiffs' claims. Hornbook principles of appellate procedure, however, grant us discretion to rely on any basis made apparent in the record for affirming a district court's decision. E.g., Debnam v. FedEx Home Delivery, 766 F.3d 93, 96 (1st Cir. 2014).

In moving to dismiss, Forest relied upon not just the California safe harbor doctrine, but also on principles of federal preemption. The parties briefed the federal preemption issue in the district court. On appeal, Forest repeats that argument, urging that we may affirm on that ground. Plaintiffs in response concede that "unpacking how federal law interacts with state law is key" to applying California's safe harbor doctrine. We agree. It therefore makes more sense to look first at this question of federal law rather than skipping forward to figuring out--or certifying to California's Supreme Court--the question of whether California's safe harbor doctrine would shield Forest even if

federal law did not preempt the California consumer protection claims.[2]

B.

The United States Constitution's Supremacy Clause provides that federal law "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Where state law requires a private party to violate federal law, that state law is "without effect." Bartlett, 133 S. Ct. at 2476–77 (internal quotation marks omitted). Federal law impliedly preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'" Id. (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)); see also Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995) (noting that conflict pre-emption also applies "where state law stands as an obstacle to

[2] Inexplicably, plaintiffs announced in their reply that they did not have enough pages to address the issue even though Forest properly raised it as an alternative ground for affirmance. And instead of asking for a page extension, they presumed that we would either ignore the issue, or postpone the case to solicit more briefing. We follow instead the normal course of not allowing a party to unilaterally dictate a change in customary practice. We also note that plaintiffs hedged their bet, devoting two pages of their reply brief to an express discussion of the preemption defense, and another four pages to discussing the pivotal preemption case, Wyeth v. Levine, 555 U.S. 555 (2009). Finally, we have reviewed the full brief on the preemption issue filed by plaintiffs with the district court, and we addressed the issue with counsel at oral argument.

the accomplishment and execution of the full purposes and objectives of Congress" (internal quotation marks omitted)).

Plaintiffs' complaint seeks to impose liability on Forest because of what Lexapro's FDA-approved label states or fails to state. In other words, as the complaint reads, Forest would need to change Lexapro's label in order to avoid liability under state law.

In two recent cases, the Supreme Court has addressed how principles of federal preemption apply to such claims. See PLIVA, 131 S. Ct. 2567 (2011); Wyeth v. Levine, 555 U.S. 555 (2009). We turn to these opinions to find the preemption rules that guide our decision here.

In Wyeth, a jury found a brand name drug manufacturer liable under Vermont law for what the jurors deemed to be an inadequate warning of risks in an FDA-approved label. 555 U.S. at 558. In rejecting the manufacturer's preemption defense to liability under Vermont law, the Court pointed to the CBE regulation, "which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval." Id. at 571. "Thus, when the risk . . . became apparent, Wyeth had a duty [under federal law] to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." Id. Based on these

observations, the Court found that a state law effectively penalizing the manufacturer for not having exercised its federally sanctioned ability to improve the label under the CBE regulation was not preempted. Id. at 581.

Two years later, the Supreme Court distinguished Wyeth in sustaining a preemption bar to the imposition of tort liability on a generic drug manufacturer for failure to add a warning of a risk to its label. PLIVA, 131 S. Ct. at 2581. The court observed two differences in the federal "drug labeling duties" that applied to generic manufacturers as compared to brand name manufacturers. Id. at 2574. First, a generic manufacturer "is responsible for ensuring that its warning label is the same as the brand name's." Id. Second, "the CBE process was not open to [generic manufacturers]." Id. at 2575. Therefore, the generic drug manufacturer in PLIVA could not have changed its label without prior FDA approval, which it could only have obtained by proposing that the FDA require a change in the corresponding brand name label. Id. at 2576. Assuming that the manufacturer had a duty under federal law to make such a proposal, the Court nevertheless found that the possibility that the FDA would have agreed to require such a change did not preclude the court from concluding that compliance with both state and federal branding requirements was impossible. Importantly for our purposes, the Court explained that "[t]he question for 'impossibility' is whether the private

party could independently do under federal law what state law requires of it." Id. at 2579 (citing Wyeth, 555 U.S. at 573). The Court thus limited Wyeth to situations in which the drug manufacturer can, "of its own volition, . . . strengthen its label in compliance with its state tort duty." PLIVA, 131 S. Ct. at 2581.[3]

The line Wyeth and PLIVA thus draw between changes that can be independently made using the CBE regulation and changes that require prior FDA approval also makes some pragmatic sense. CBE changes rest on the existence of "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). A state law duty to initiate such a change is therefore not by its nature a second guess of an FDA judgment. Wyeth, 555 U.S. at 578–79. To the extent that the underlying policy issue is one of who decides whether and how a drug can be marketed, the line so drawn lets the FDA be the exclusive judge of safety and efficacy based on information available at the commencement of marketing, while allowing the states to reach contrary conclusions when new information not

[3] Most recently, in Bartlett, 133 S. Ct. at 2478, the Supreme Court reversed a decision of this circuit in which we rejected a preemption defense because the generic drug manufacturer could have complied with both federal and state law simply by not selling the drug for use in that state. The Supreme Court reasoned that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." Id. at 2477. "To hold otherwise would render impossibility preemption 'all but meaningless.'" Id. at 2477 n.3 (quoting PLIVA, 131 S. Ct. at 2579).

considered by the FDA develops. The CBE regulation, too, covers virtually all situations in which new information indicates new or greater risks, or misleading claims of efficacy. By hinging preemption on the availability of that procedure in a particular case, Wyeth effectively reserves the launch of new drugs to the expertise of the FDA, but then preserves a wide scope for the states in requiring manufacturers to respond to information not considered by the FDA.[4]

Our review of the Supreme Court opinions discussed above makes clear that a necessary step in defeating Forest's preemption defense is to establish that the complaint alleges a labeling deficiency that Forest could have corrected using the CBE regulation. The complaint plainly alleges that Forest is a brand name manufacturer and Lexapro is a brand name drug. So the question to which we now turn is whether the CBE regulation allows a brand name manufacturer to make the particular type of change that plaintiffs say Forest needed to have made to avoid liability under California law.

C.

The CBE procedure is only available to make changes that, among other things, are based on "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii).

[4] Of course, it would be easier for the courts if Congress would expressly indicate whether this is the line it wants drawn.

> Newly acquired information means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

Id. § 314.3(b). For example, "newly acquired information" could be an increasing body of data of an inherent risk with the drug. See Wyeth 555 U.S. at 571 ("[W]hen the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval."). Or it could be new data from a clinical study evincing Lexapro's inefficacy in treating major depressive disorder in adolescents.

We have scrutinized the complaint itself to see if it might plausibly be read as relying on "newly acquired information" in contending that Forest could have changed its label through the CBE procedures. We find only two fleeting references to academic articles published after the FDA's approval of the Lexapro label. Plaintiffs make no claim that these two academic articles are based on new data. They instead contend that these two studies are meta-analyses that were not included in Forest's submission to the FDA.

The first is a 2010 article evaluating prior efficacy data on antidepressant medications generally as compared with a

placebo. As plaintiffs' complaint acknowledges, it contains no discussion of efficacy for the acute treatment of major depressive disorders in adolescents, focusing instead on the lack of apparent efficacy for patients generally when symptoms of depression are not severe. In short, even assuming it qualifies as "newly acquired information," it does not contain the information that plaintiffs say needs to be added to the label in order to correct the label's discussion of efficacy for treatment of major depressive disorder in adolescents.

The second is a 2011 article criticizing the FDA's approval of Lexapro. This study is an opinion piece in which the author looks at the same information that the FDA had in approving Lexapro. It simply argues that the FDA should not have approved Lexapro on the basis of that information. As described by the complaint, the only piece of relevant information in the article is an assertion that a medical communication company acting on behalf of Forest was a contributor to the published article discussing Lexapro Study 32. Plaintiffs do not argue, however, that the FDA was unaware of this fact, or that Forest is liable for failing to seek a change adding this fact to the label. Rather, plaintiffs argue that this fact means that FDA approval of Lexapro was premature.[5]

[5] We note also that neither article discloses "risks of a different type or greater severity or frequency than previously included in submissions to [the] FDA." 21 C.F.R. § 314.3; see also

We have also examined the complaint's allegations claiming that the positive statistical efficacy results of Celexa Study 18 hinged in part on the inappropriate inclusion of some subjects in the data pool.[6] This is the basis of plaintiffs' allegation that Celexa Study 18 was "manipulated." Plaintiffs make no claim, however, that this information was unknown to the FDA prior to label approval.

Finally, oral argument confirmed that the change plaintiffs seek in the label is indeed based on information concerning the marginal extent of Lexapro's effectiveness that was plainly known to the FDA prior to approving the label:

> **Court**: What specific statement do you say that Forest should have added to its description of the drug?

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id. § 314.70(c)(6)(iii).

[6] According to the complaint:

> During the study, the first nine (9) participants were given '1 week of medication with potentially unblinding information (tablets had an incorrect color coating).' When the data for Celexa Study 18 was first analyzed, the researchers correctly excluded the data from the unblinded participants, realizing it was unreliable. The results of the initial statistical analysis showed . . . [that] Celexa Study 18 was negative for efficacy. However, faced with having a clinical trial show that Celexa failed to significantly outperform placebo for treating pediatric depression, the researchers decided to include the data from the unblinded participants. By adding the unblinded patients' data, Celexa Study 18 was able to find statistical significance between the treatment and placebo-control group--even if only marginal.

> **Plaintiffs' counsel**: I believe the drug label . . . should have disclosed how Lexapro performed compared to placebo.
>
> . . . .
>
> **Plaintiffs' counsel**: . . . We are not trying to contradict the information on the label. . . . We are simply having them say . . . [Lexapro] has been shown to be effective in a clinical trial by one point. The difference between [Lexapro] and a placebo is clinically insignificant. Meaning a patient, a doctor, wouldn't be able to tell the difference.
>
> **Court**: But that "by one point"--that was known to the FDA at the time of the approval?
>
> **Plaintiffs' counsel**: Absolutely.

We can find no precedent--and plaintiffs point to none--that would have allowed Forest to use the CBE procedure to alter the FDA label in the manner that plaintiffs allege is necessary so as to render it not "misleading." Indeed, plaintiffs seem to concede this in their prayer for relief, as they ask the Court to "direct[] Forest to seek FDA approval of a new [drug] label."

Plaintiffs are thus stymied: Forest could not independently change its label to read as plaintiffs say it should have read in order to comply with California law. That construction of California law upon which plaintiffs rely--even assuming it is correct notwithstanding the safe harbor doctrine--is therefore preempted by federal law. PLIVA, 131 S. Ct. at 2581.

IV. Conclusion

Finding plaintiffs' claims preempted by the FDCA, we affirm the district court's grant of Forest's motion to dismiss. So ordered.