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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FOURTH APPELLATE DISTRICT

DIVISION THREE

TEVA PHARMACEUTICALS USA, INC., et al., Petitioners, v. THE SUPERIOR COURT OF ORANGE COUNTY, Respondent; OLGA PIKERIE, Real Party in Interest.	G047134 (Super. Ct. No. 30-2012-00535583) O P I N I O N

Original proceedings; petition for a writ of mandate/prohibition to challenge an order of the Superior Court of Orange County, Steven L. Perk, Judge. Petition denied.

Horvitz & Levy, Jon B. Eisenberg; Goodwin Procter, Steven A. Ellis; and Michael D. Shumsky for Petitioners Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals LLC, and Barr Laboratories, Inc.

Shook, Hardy & Bacon, Michelle M. Fujimoto and Eva M. Weiler for Petitioner Mylan Pharmaceuticals, Inc.

The Yocca Law Firm, Mark W. Yocca and Jared Glicksman for Petitioners Caraco Pharmaceutical Laboratories, Ltd., and Sun Pharmaceutical Industries, Inc.

Lewis Brisbois Bisgaard & Smith and Pamela M. Ferguson for Petitioner NorthStar Rx LLC.

No appearance for Respondent.

Robinson Calcagnie Robinson Shapiro Davis, Mark P. Robinson, Jr., Robert M. Partain, Karen B. Menzies; Skikos, Crawford, Skikos & Joseph, Steven J. Skikos and Mark G. Crawford for Real Party in Interest.

* * *

INTRODUCTION

Plaintiff suffered injuries, allegedly as a result of ingesting a brand-name drug and its generic equivalents. She sued the manufacturers of both the brand-name drug and its generic equivalents. Although plaintiff asserts 11 separate causes of action, the gist of her claims against all defendants is the same—they failed to produce a safe product, failed to adequately warn plaintiff of the safety issues regarding the products, and failed to take other available steps within their control to warn plaintiff or protect her from injury.

The generic drug manufacturers demurred to plaintiff's complaint, arguing that, under the United States Supreme Court's decision in *PLIVA, Inc. v. Mensing* (2011) 564 U.S. ___ [131 S.Ct. 2567] (*Mensing*), all of plaintiff's claims were preempted by federal law. The trial court overruled the demurrer. Defendants filed a petition for a writ of mandate and/or prohibition. We issued an order to show cause, and now deny the petition.

In *Mensing*, the United States Supreme Court held that any claims that a generic drug manufacturer should have included stronger warning labels than those approved for use on the equivalent brand-name drug are preempted by federal law. The

court explained that under federal law, the generic drug's label must be equivalent to—meaning it must *match*—the brand-name drug's label. The court also held that a state could not require a generic drug manufacturer to provide information on its label in addition to information required on the brand-name drug's label, as that would make it impossible for the generic drug manufacturer to comply with both its duty under federal law to match the brand-name label and any claimed duty under state law to do more. As a result of this impossibility, such a state requirement would be preempted by federal law.

In this case, in contrast, plaintiff alleged that the brand-name drug label was updated, but the generic drug manufacturers failed to update their products' labels accordingly. In other words, the generic drug labels did not match the brand-name drug label. Consequently, we conclude, plaintiff's claims in this regard are not preempted by federal law. Therefore, the trial court correctly overruled the demurrer.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

Alendronate sodium is a generic version of the medication Fosamax, which is manufactured and sold by Merck Sharp & Dohme Corp. and Merck & Co., Inc. Merck's patent protection for Fosamax expired in 2008, at which time Teva Pharmaceuticals USA, Inc. (Teva), Barr Pharmaceuticals LLC (Barr), Barr Laboratories, Inc. (Barr Labs), Mylan Pharmaceuticals, Inc. (Mylan), Caraco Pharmaceutical Laboratories, Ltd. (Caraco), Sun Pharmaceutical Industries, Inc. (Sun), and NorthStar Rx LLC (NorthStar) (collectively, the Teva Defendants) began manufacturing and marketing alendronate sodium.

Fosamax and alendronate sodium belong to the class of drugs known as bisphosphonates; they are indicated for the treatment and prevention of osteoporosis. Olga Pikerie was prescribed and took Fosamax and/or alendronate sodium from 2006 to 2011. Pikerie's complaint alleged prolonged use of Fosamax and/or alendronate sodium might cause fractures of the femur due to suppression of bone turnover. In April 2011,

allegedly as a result of using Fosamax and/or alendronate sodium, Pikerie suffered a left femur fracture.

In April 2011, lawsuits against the manufacturers of Fosamax and alendronate sodium were coordinated before the Orange County Superior Court. By agreement of the parties, a test case complaint was filed in January 2012, on behalf of Pikerie, to raise and resolve the issue of federal preemption. Pikerie's complaint asserted causes of action for strict liability, negligence, breach of express and implied warranties, deceit by concealment, negligent misrepresentation, fraud, violation of Business and Professions Code sections 17200 and 17500, and violation of Civil Code section 1750 et seq.

Teva, Barr, and Barr Labs demurred to the complaint. Caraco, Sun, and NorthStar joined in the demurrer.[1] Following briefing and a hearing, the trial court overruled the demurrer. The court concluded the allegations that the Teva Defendants failed to make timely labeling changes and breached a duty to communicate to the public and to health care professionals were sufficient to state causes of action, which would not be preempted by the Supreme Court's opinion in *Mensing*, *supra*, 564 U.S. ___ [131 S.Ct. 2567]. The court granted the motions by Caraco, Sun, and NorthStar to join the demurrer. The court also filed an order pursuant to Code of Civil Procedure section 166.1, in which it certified and found: "In overruling the Demurrer, the Court issued a ruling on a controlling question of law relating to federal preemption as to which there are substantial grounds for difference of opinion; and [¶] . . . Appellate resolution of the controlling question of law relating to federal preemption may materially advance the conclusion of the litigation."

[1] Mylan is not named as a defendant in Pikerie's complaint. Mylan is a manufacturer of alendronate sodium, and was one of the defendants who agreed with the plaintiffs' counsel in the coordinated litigation to test the issue of federal preemption of the plaintiffs' claims through a test case. No party disputes that Mylan is a proper petitioner in this case.

DISCUSSION

I.

STANDARD OF REVIEW

In ruling on a demurrer, the "allegations [of the complaint] must be liberally construed, with a view to substantial justice between the parties." (Code Civ. Proc., § 452; *Rickley v. Goodfriend* (2013) 212 Cal.App.4th 1136, 1141-1142 [court must liberally construe complaint, and draw all reasonable inferences in favor of its allegations].)

"'The standard of review for an order overruling a demurrer is de novo. The reviewing court accepts as true all facts properly pleaded in the complaint in order to determine whether the demurrer should be overruled. [Citation.]' [Citation.]" (*Boy Scouts of America National Foundation v. Superior Court* (2012) 206 Cal.App.4th 428, 438.)

II.

FEDERAL LAWS AND REGULATIONS REGARDING DRUG LABELING

This case involves questions arising out of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 United States Code section 301 et seq. The United States Food and Drug Administration (FDA) regulates the manufacture, sale, and labeling of prescription drug products under the FDCA. (21 U.S.C. § 355(a).) Before marketing a new drug, a drug manufacturer must obtain FDA approval, by proving the drug is safe and effective, and that the proposed label for the drug is accurate and adequate. (21 U.S.C. § 355(b)(1); see *Mensing*, *supra*, 564 U.S. at p. ___ [131 S.Ct. at p. 2574].) In order to meet this burden, the manufacturer of a new, brand-name drug must perform lengthy, expensive testing on its product. (21 U.S.C. § 355(b)(1); see *Mensing*, *supra*, at p. ___ [131 S.Ct. at p. 2574].)

Manufacturers of generic drugs, however, may avoid the clinical testing process and obtain FDA approval to market their products by filing an abbreviated new drug application (ANDA), showing the generic drug is equivalent to the brand-name drug, or reference listed drug (RLD), in active ingredients, safety, and efficacy (21 U.S.C. § 355(j)(2)(A)(ii) & (iv); 21 C.F.R. § 314.94 (2013)), and that the labeling for the generic drug is the same as the labeling for the RLD (21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8) (2013)). The 1984 legislation by which the United States Congress authorized this simplified process for approval of generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub.L. No. 98-417 (Sept. 24, 1984) 98 Stat. 1585), is commonly referred to as the "Hatch-Waxman Amendments."

The labeling on or within any prescription drug package must provide sufficient information, including, but not limited to, "any relevant hazards, contraindications, side effects, and precautions," to allow physicians and pharmacists to "use the drug safely and for the purposes for which it is intended." (21 C.F.R. § 201.100(c)(1) (2013).) Specifically, the FDA requires that drug labels "describe serious adverse reactions and potential safety hazards [and] limitations in use imposed by them." (21 C.F.R. § 201.80(e) (2013).)

Certain changes to an approved drug label require the drug manufacturer to submit a prior approval supplement to the FDA. (21 C.F.R. § 314.70(b) (2013).) Other changes may be made by the manufacturer without FDA approval, upon submission of a "Changes Being Effected" (CBE) supplement. (21 C.F.R. § 314.70(c) (2013).) A CBE supplement is permitted for "[c]hanges in the labeling to reflect newly acquired information . . . to accomplish any of the following: [¶] (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 under § 201.57(c) of this chapter." (21 C.F.R. § 314.70(c)(6)(iii)(A) (2013).)

The CBE process for changing labels is available only to manufacturers of RLD's. As explained by the United States Supreme Court: "The FDA denies that the [generic drug] Manufacturers could have used the CBE process to unilaterally strengthen their warning labels. The agency interprets the CBE regulation to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions. [Citations.] The FDA argues that CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's. [Citations.] [¶] We defer to the FDA's interpretation of its CBE and generic labeling regulations." (*Mensing, supra*, 564 U.S. at p. ___ [131 S.Ct. at p. 2575].)

Drug manufacturers may also be required to mail important information about their products to physicians and other health care professionals. (21 C.F.R. § 200.5 (2013).) These mailings are commonly referred to as "Dear Doctor" letters. (See generally *Horn v. Thoratec Corp.* (3d Cir. 2004) 376 F.3d 163, 177, fn. 22.) Dear Doctor letters are a form of product labeling (21 C.F.R. § 202.1(*l*)(2) (2013)), and, therefore, subject to the same requirement that they be "consistent with and not contrary to [the] approved or permitted labeling" of the RLD (21 C.F.R. § 201.100(d)(1) (2013)). "[I]f generic drug manufacturers, but not the brand-name manufacturer, sent [Dear Doctor] letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.' [Citations.]" (*Mensing, supra*, 564 U.S. at p. ___ [131 S.Ct. at p. 2576].)

III.

PREEMPTION

The only issue raised by the parties in the demurrer to Pikerie's complaint was whether all causes of action against the Teva Defendants were barred by the

impossibility preemption doctrine. The United States Congress has the power to preempt state law concerning matters that lie within its authority. (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1087.) Preemption of state law may be express or implied. Implied preemption occurs "'(i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) *when compliance with both federal and state regulations is an impossibility* [citation]; or (iii) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."'" (*Ibid.*, italics added.) The parties agree that in this case, we are concerned only with implied preemption due to impossibility.

Not all state law claims are preempted by the FDCA. (See *Wyeth v. Levine* (2009) 555 U.S. 555, 567 [the FDCA contains a savings clause, meaning state law is only invalidated by a "'direct and positive conflict'" with the FDCA; the FDCA does not contain an express preemption provision regarding prescription drugs, although express preemption provisions exist in the FDCA for other products, such as medical devices].)

Federal preemption applies when state and federal laws "directly conflict." (*Wyeth v. Levine, supra,* 555 U.S. at p. 583 (conc. opn. of Thomas, J.).) When it is "'impossible for a private party to comply with both state and federal requirements,'" a direct conflict exists. (*Freightliner Corp. v. Myrick* (1995) 514 U.S. 280, 287.) In *Mensing, supra,* 564 U.S. at page ___ [131 S.Ct. at page 2572], the United States Supreme Court held certain state law tort claims against the manufacturers of a generic drug were preempted under the impossibility preemption doctrine. The court concluded that because the generic drug manufacturers could not comply with state law requirements without violating federal drug labeling requirements, the impossibility preemption doctrine barred the plaintiffs' state law claims. (*Id.* at p. ___ [131 S.Ct. at pp. 2577-2578].) "Taking [the plaintiffs'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic [drug]. Federal law, however,

demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. [Citation.] Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." (*Id.* at p. ___ [131 S.Ct. at p. 2578].)

IV.

ANALYSIS

In their demurrer, the Teva Defendants did not raise specific arguments regarding, or separately analyze, Pikerie's 11 causes of action. Further, the Teva Defendants did not file a motion to strike specific allegations from Pikerie's complaint. The parties agree there is a single issue before this court: Does the complaint allege sufficient facts to state a cause of action, which is not preempted by federal law? Pikerie bases all of her causes of action on the Teva Defendants' alleged failures to (1) update the alendronate sodium labels to match the updated Fosamax label; (2) communicate the updated safety information to physicians and other health care professionals; (3) stop marketing alendronate sodium after learning about safety issues regarding the drug; and (4) request the FDA to order a change to the Fosamax label, which would have enabled the Teva Defendants to then update the alendronate sodium labels to match the Fosamax label.

A.

Failure to update

The complaint alleged that on March 1, 2010, the manufacturer of Fosamax changed the postmarketing experience subsection of the adverse reactions section on the Fosamax label. The complaint further alleged that on January 25, 2011, language regarding femoral fractures was added to the precautions section of the Fosamax package insert. The complaint also alleged:

"119. Per the provisions and procedures established under Subsections (a) and (j) of FDCA §505, as amended by the Hatch-Waxman Amendments, an ANDA for a generic version of Alendronate Sodium has been required to include proposed labeling for the drug that is the same in all material respects to the labeling approved for the so-called Reference Label Drug (RLD), which was Fosamax. [¶] . . . [¶]

"121. As holders of ANDAs for generic versions of the drug, generic defendants are and have been required by federal law . . . to make timely revisions to the labeling of the labels for their Alendronate Sodium products after revisions were made to the RLD label . . . . [¶] . . . [¶]

"125. Generic defendants *failed to effectively and adequately communicate the warnings in the label* to physicians and patients, to ensure that both were aware of the risk of femoral fracture and to ensure that both were aware of the limitations regarding the duration of use of the drug. The Defendants, as manufacturers and distributors and sellers of Alendronate Sodium products, owed to Plaintiff and other patients, a duty to provide to, and effectively communicate to them and to physicians adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Alendronate Sodium products.

"126. Generic defendants failed to timely and properly correct misstatements and misrepresentations in the label, *failed to update the label*, failed to ensure that the true risk[s] of femoral fracture were accurately stated in the label, and failed to utilize FDA approved means to properly emphasize and reinforce the warnings about the duration of use of the products.

"127. By failing to effectively communicate to Plaintiff . . . or [her] physicians adequate clinically relevant information and data and warnings regarding the adverse health risks associated with the ordinary, expected, and/or intended use of Alendronate Sodium products, and *failing to update the labeling of the products*, each of

the Defendants breached their duty to purchasers and consumers of its products." (Italics added & some capitalization omitted.)

From these allegations, we can reasonably infer that Pikerie alleged the Teva Defendants failed to update the labels of their alendronate sodium products to match the RLD label after the manufacturer of brand-name Fosamax updated its label. These allegations are sufficient to state a cause of action based on the failure to update the warning labels, and the causes of action based on the failure to update the generic labels' warnings are not preempted. To the extent Pikerie alleged the Teva Defendants failed to update the labels on the alendronate sodium products to say something more than or different from the approved Fosamax label, Pikerie's claims would be preempted.

Fulgenzi v. PLIVA, Inc. (6th Cir. 2013) 711 F.3d 578 supports our conclusion. In that case, a brand-name drug manufacturer had updated its warning label in July 2004 to include the risks of long-term use of the drug. (*Id.* at p. 580.) The plaintiff took the generic version of the drug for extended periods on two different occasions—between September and November 2004, and then for over a year in 2006 and 2007. (*Ibid.*) The generic drug manufacturer did not update its warning label to match the label of the brand-name drug during the entire time the plaintiff was taking the drug. (*Id.* at pp. 580, 581-582.) The plaintiff developed serious complications due to her use of the drug (*id.* at p. 580), and she sued the generic drug manufacturer under Ohio tort law (*id.* at pp. 581-582), claiming the generic drug manufacturer's failure to update its warning label "'rendered its warnings inadequate under Ohio law'" (*id.* at p. 582).

The Sixth Circuit Court of Appeals concluded that the impossibility preemption doctrine did not bar the plaintiff's claim, although the defendant's failure to comply with its federal regulatory duties was the underlying cause of the plaintiff's claim for relief. As the court explained: "Courts will find impossibility preemption where it is 'impossible for a private party to comply with both state and federal requirements.' [Citation.] This analysis can become difficult when applied to the regulatory context—

overlapping federal duties, ex-post and ex-ante agency approval, and ambiguous regulations make the question of whether a party is acting in accord with federal policies uncertain. In the wake of *Wyeth* [*v. Levine, supra,* 555 U.S. 555] and *Mensing*, [*supra,* 564 U.S. ___ [131 S.Ct. 2567],] however, the application of impossibility preemption principles has become clearer. *Mensing* explains that the key question is 'whether the private party could independently' comply with its state duty—without relying on the prior exercise of federal-agency discretion. [Citation.] *Wyeth*, by contrast, holds that there is no impossibility as long as the approval comes *after* the independent action of the private party (especially where denial is speculative and unlikely). [Citation.] In our case, not only could PLIVA have independently updated its labeling to match that of the branded manufacturer through the CBE process [citation], but it had a federal duty to do so, 21 C.F.R. § 314.150(b)(10). As a result, compliance with federal and state duties was not just possible; it was required. Impossibility preemption is inappropriate in such a case. It is true that the FDA had the authority to reject PLIVA's labeling change after the fact. But this is precisely the 'possibility of impossibility' that *Wyeth* found insufficient to warrant preemption. Indeed, as PLIVA had a clear federal duty to update its label, it is even less likely here that the FDA would have rejected the change. This case, therefore, presents an even weaker case for impossibility preemption than *Wyeth*." (*Fulgenzi v. PLIVA, Inc.*, *supra,* 711 F.3d at p. 584.)

In this case, as in *Fulgenzi v. PLIVA, Inc.*, it was possible for the Teva Defendants to comply with both a federal duty to makes their labels match the Fosamax label, and a state tort law duty to prevent harm to the consumers of alendronate sodium. Therefore, the impossibility preemption doctrine does not bar Pikerie's claims.

Many other state and federal trial courts have reached the same conclusion, based on comparable fact patterns. (See *Phelps v. Wyeth, Inc.* (D.Or., Apr. 2, 2013, Civ. No. 6:09-cv-06168 TC) 2013 U.S.Dist. Lexis 49422, p. *8 ["Unlike the failure to warn claim in *Mensing*, plaintiffs do not claim that Pliva was required to use a different or

stronger warning label; they merely claim that, under Oregon law, Pliva was negligent by failing to update its label to match the name-brand label—a requirement that is consistent with the FDCA. Thus, because plaintiffs' state-law claim does not make it impossible for Pliva to comply with federal law, no conflict exists and preemption is not warranted" (italics added)]; *Johnson v. Teva Pharmaceuticals USA, Inc.* (W.D.La., May 21, 2012, No. 2:10 CV 404) 2012 U.S.Dist. Lexis 71384, p. *10 ["impossibility preemption would not apply to any requirement . . . that the Generic Defendants update their product labels to reflect labeling changes made by the brand name manufacturer"]; *Cooper v. Wyeth, Inc.* (M.D.La., Mar. 6, 2012, No. 09-929-JJB) 2012 U.S.Dist. Lexis 29209, pp. *11-*12 ["a generic drug manufacturer's failure to adhere to the brand-name label the generic drug is tied to would plainly violate federal law and likely violate state law . . . . In the latter scenario, the requirements of state law would coextend with, but would not exceed, the requirements of federal law, rendering impossibility preemption inapplicable"]; *Couick v. Wyeth, Inc.* (W.D.N.C., Jan. 11, 2012, No. 3:09-cv-210-RJC-DSC) 2012 U.S.Dist. Lexis 3699, p. *14 ["if Defendants' [product package inserts] did not match the brand, there are at least some changes to their [product package inserts] that federal law would allow, or even require, Defendants to make. A state law claim for failure to include such warnings would not be preempted by federal law"]; *Del Valle v. PLIVA, Inc.* (S.D.Tex., Dec. 21, 2011, Civ. A. No. B: 11-113) 2011 U.S.Dist. Lexis 153473, p. *14 [generic drug manufacturers' failure to update their labels, "after the brand named manufacturers enhanced their warning labels in 2004, might preclude the application of conflict pre-emption, but only as to the labeling information added by the brand named manufacturers in 2004"]; *In re Reglan Litigation* (Super. Ct. Atlantic County, N.J., 2012, No. 289) 2012 WL 1613329 ["if labels belonging to generic manufacturers of tablets did not match the brand-name manufacturers of tablets, then there are [at] least some changes to their labels that federal law would allow, or even require, these defendants to make, and state tort law in this situation does not conflict with federal law. Consequently, this

absence of 'sameness' runs afoul of the preemption ruling in *Mensing*, and the court finds that to the extent that generic manufacturers of metoclopramide tablets failed to update the labels to be the same as the brand-name label, they are excluded from preemption"]; *Fisher v. Pelstring* (D.S.C. 2011) 817 F.Supp.2d 791, 805 [failure to update generic label claims not preempted].)[2]

The Teva Defendants cite cases for the proposition that Pikerie's failure-to-warn claims are preempted. To the extent those cases are based on facts similar to those in *Mensing*—i.e., that the generic drug manufacturer failed to update its label or otherwise provide warnings to consumers, which update would have been inconsistent with the RLD label—they are inapposite to the issues raised in the present case. (See, e.g., *Gross v. Pfizer, Inc.* (D.Md. 2011) 825 F.Supp.2d 654, 657-660; *Beck v. Teva Pharmaceutical Industries* (E.D.La., Sept. 13, 2011, Civ. A. No. 10-1901 Section I) 2011 U.S.Dist. Lexis 102951, pp. *9-*10 ["[n]or would defendants be able to satisfy their state-law duties by asking the FDA to modify the labeling requirement *for both name-brand and generic drug manufacturers*" (italics added)]; see also *Guarino v. Wyeth LLC* (M.D.Fla. 2011) 823 F.Supp.2d 1289, 1291-1292 [opinion fails to describe the facts].)

The Teva Defendants argue that the demurrer should have been sustained because, in essence, Pikerie's failure-to-warn claims are unavailing, given her additional allegations that the 2010 and 2011 updates to the Fosamax label were insufficient. California law permits Pikerie to plead inconsistent facts. (*Adams v. Paul* (1995) 11 Cal.4th 583, 593; *Mendoza v. Continental Sales Co.* (2006) 140 Cal.App.4th 1395, 1402.) Whether Pikerie may be able to establish she would have stopped using alendronate

[2] We are, of course, not bound by the decisions of federal courts other than the United States Supreme Court (*People v. Gray* (2005) 37 Cal.4th 168, 226), although their interpretation of federal law may be persuasive (*Spellman v. Securities, Annuities & Ins. Services, Inc.* (1992) 8 Cal.App.4th 452, 459). The same is true of decisions by the courts of our sister states. (*In re Walton* (2002) 99 Cal.App.4th 934, 946.)

sodium and/or Fosamax if she and her physician had been aware of the safety risks included in the 2010 and 2011 label changes is not before us. The likelihood that Pikerie can do so is not a matter we may consider at this stage. Given the differences between federal and California pleading standards, the federal cases the Teva Defendants cite for this argument are of limited use to the analysis here.[3]

The Teva Defendants' additional argument that Pikerie's claims are preempted by *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341 (*Buckman*) also fails. In *Buckman*, the plaintiffs alleged the defendant made fraudulent representations to the FDA, which led to the FDA's approval of medical devices that caused injuries to the plaintiffs. (*Id.* at p. 343.) The Supreme Court concluded, "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law." (*Id.* at p. 348, fn. omitted.)

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[3] See *Morris v. Pliva, Inc.* (5th Cir. 2013) 713 F.3d 774, ___ [2013 U.S.App. Lexis 3167, pages *7-*8] (claim that generic drug label not updated was not raised in the operative complaint; amendment would be futile because it was "logically incoherent" to also contend the brand-name label was inadequate); *Del Valle v. PLIVA, Inc.*, *supra*, 2011 U.S.Dist. Lexis 153473 at page *14 ("Even assuming that pre-emption does not apply to [the generic manufacturers'] 2004 failure to update their labels, Del Valle has pled no facts to show that this failure caused her injuries. In fact, Del Valle asserts that the labeling by all of the manufacturers, brand name and generic alike, was defective up to 2009"); *Morris v. Wyeth, Inc.* (W.D.La., Oct. 19, 2011, Civ. A. No. 3:09-CV-854) 2011 U.S.Dist. Lexis 121052, pages *7-*8 (amendment would be futile because the plaintiff alleged the RLD label was also inadequate); *Coney v. Mylan Pharmaceuticals, Inc.* (S.D.Ga., Jan. 19, 2012, No. 6:11-cv-35) 2012 U.S.Dist. Lexis 6284, pages *9-*12 (the plaintiff could not survive summary judgment on the issue of preemption where the plaintiff argued failure to update generic label warnings to match RLD label warnings, though those claims had not been raised in the complaint).

Pikerie's claims are based on her contention that the alendronate sodium labels were not complete and accurate, and did not match the warnings on the Fosamax labels, not that the Teva Defendants committed a fraud on the FDA when submitting their ANDA's. (See *Fulgenzi v. PLIVA, Inc.*, *supra*, 711 F.3d at pp. 586-587; *Fisher v. Pelstring*, *supra*, 817 F.Supp.2d at p. 834.) We see a principled difference between a federal agency acting in the face of someone trying to defraud it, on the one hand, and a claim by a consumer that a label on a generic drug did not match the FDA-approved RLD label, on the other.

Our conclusion that *Buckman* does not aid the Teva Defendants is bolstered by the way *Buckman* itself distinguished two other cases. First, *Buckman* distinguished *Silkwood v. Kerr-McGee Corp.* (1984) 464 U.S. 238, in which the Supreme Court had found the plaintiff's private damage remedies were not impliedly preempted, although they were allegedly in conflict with the federal regulatory scheme regarding the use and development of atomic energy. The *Buckman* court stated, "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." (*Buckman*, *supra*, 531 U.S. at p. 352, citing *Silkwood v. Kerr-McGee Corp.*, *supra*, at p. 241.) In the present case, Pikerie's claims are not based on a fraud-on-the-FDA theory, but on state law tort principles of a drug manufacturer's duty to the consumers of its product.

The Supreme Court in *Buckman* also distinguished *Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, in which the court concluded, "certain state-law causes of action[] that parallel federal safety requirements" were permitted. (*Buckman*, *supra*, 531 U.S. at p. 353.) The *Buckman* court distinguished *Medtronic, Inc. v. Lohr* because in the *Buckman* case, "the fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements." (*Buckman*, *supra*, at pp. 352-353.) Pikerie's tort claims under California law parallel the federal safety requirements arising under the FDCA, but do not exist

solely due to the Teva Defendants' alleged failure to comply with those requirements. Although private rights of action "for the enforcement, or to restrain violations" of the FDCA are barred (21 U.S.C. § 337(a)), Pikerie's claims are instead based on the alleged failure to properly label alendronate sodium, not to enforce the FDCA or to prevent the Teva Defendants from violating it.

The Teva Defendants rely on a recent unpublished decision by the Court of Appeals of Iowa, which concluded that a claim for failure of a generic drug manufacturer to update a warning label to include changes to the brand-name drug's label would be preempted as a private attempt to enforce the FDCA. (*Huck v. Trimark Physicians Group* (Iowa Ct.App., Apr. 24, 2013, No. 3-129/12-0596) 2013 Iowa App. Lexis 435, p. *9 (*Huck*).)[4] We respectfully decline to follow *Huck*, based on the Supreme Court's decision in *Wyeth v. Levine*. In *Wyeth v. Levine, supra*, 555 U.S. at pages 568-572, the Supreme Court concluded a claim under state tort law that a brand-name drug manufacturer failed to warn patients of the risks of certain methods of administering the drug was not preempted by the FDCA. Indeed, in *Mensing*, the court reaffirmed its holding in *Wyeth v. Levine*: "*Wyeth* is not to the contrary. In that case, as here, the plaintiff contended that a drug manufacturer had breached a state tort-law duty to provide an adequate warning label. [Citation.] The Court held that the lawsuit was not pre-empted because it was possible for Wyeth, a brand-name drug manufacturer, to comply with both state and federal law. [Citation.] Specifically, the CBE regulation, 21 CFR § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth 'to unilaterally strengthen its warning' without prior FDA approval. [Citations.] Thus, the federal regulations applicable to Wyeth allowed the company, of its own volition, to

[4] The *Huck* opinion does not rely on *Buckman* to reach this holding. Indeed, it does not rely on any state or federal authority, other than 21 United States Code section 337(a), which provides, "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."

strengthen its label in compliance with its state tort duty." (*Mensing, supra,* 564 U.S. at p. ___ [131 S.Ct. at p. 2581], fn. omitted.) The court in *Huck* failed to address the important point that *Wyeth v. Levine* finds no implied preemption for claims in which both state and federal law can be satisfied.

B.

Failure to communicate with health care professionals

The same preemption analysis applies to Pikerie's claims that the Teva Defendants failed to adequately communicate safety information about alendronate sodium to health care professionals through Dear Doctor letters. In addition to the portions of the complaint quoted *ante*, the complaint alleged in this regard, as follows:

"123. The generic defendants breached their duty to effectively communicate warnings to the medical community generally, Plaintiff'[s] physicians, Plaintiff, . . . and/or other foreseeable users of their products similarly situated, in that they failed to: [¶] . . . [¶] i. Ensure that the actual warning language and other information was effectively communicated to physicians and patients—both through proper delivery of the existing RLD label, along with other means of communication that did not require language different from the RLD label, and did not require permission or assistance from the FDA, including but not limited to issuing Dear Doctor and Dear Health Care Provider letters which do not contain additional or substantial new warning information, but which are instead consistent with and not contrary to the approved labeling, and which highlight and explain the warnings, the labeling and other information . . . ." (Some capitalization omitted.)

It would not have been impossible for the Teva Defendants to send Dear Doctor letters advising health care professionals of the risks identified in the 2010 and 2011 Fosamax label changes. Therefore, the impossibility preemption doctrine does not bar such claims, and the trial court did not err in overruling the demurrer on this

ground. As with the failure-to-update claims, to the extent Pikerie's complaint alleged the Teva Defendants failed to send Dear Doctor letters that were not the same as the approved Fosamax label, the claims would be preempted.

The Teva Defendants cite numerous state and federal cases to support their contention that "no state-law claim for failing to communicate product warnings survives *Mensing*." We respectfully disagree with the Teva Defendants' exaggerated statement. *Smith v. Wyeth, Inc.* (6th Cir. 2011) 657 F.3d 420, *Gaeta v. Perrigo Pharmaceuticals Co.* (9th Cir. 2012) 469 Fed.Appx. 556, affirming (N.D.Cal. 2009) 672 F.Supp.2d 1017, and *Johnson v. Teva Pharmaceuticals USA, Inc., supra*, 2012 U.S.Dist. Lexis 71384 at pages *7-*8, are factually indistinguishable from *Mensing*, and therefore distinguishable from the present case: they involved a generic drug manufacturer which could not send out a Dear Doctor letter that would have been inconsistent with the approved RLD label.

Other cases cited by the Teva Defendants follow this same pattern, or did not reach the issue before us at all. (See *Bowman v. Wyeth, LLC* (D.Minn., Mar. 2, 2012, Civ. No. 10-1946 (JNE/SER)) 2012 U.S.Dist. Lexis 27795, p. *19 ["The Court need not address whether this type of claim [that the generic manufacturer failed to update its label after the RLD label was updated] is preempted under *Mensing* because Bowman does not assert this claim in his Complaint"]; *Moretti v. PLIVA, Inc.* (D.Nev., Feb. 27, 2012, No. 2:08-CV-00396-JCM(CWH)) 2012 U.S.Dist. Lexis 24113 [no claim that generic drug label was not updated to be equivalent to RLD label]; *Kellogg v. Wyeth* (D.Vt., Feb. 3, 2012, No. 2:07-cv-82) 2012 U.S.Dist. Lexis 13182, p. *4 [the plaintiff alleged she stopped taking the generic drug before the RLD label was strengthened]; *Moore v. Mylan Inc.* (N.D.Ga. 2012) 840 F.Supp.2d 1337, 1348-1349; *Waguespack v. Pliva USA, Inc.* (E.D.La., Nov. 3, 2011, Civ. A. No. 10-692 Section "S" (3)) 2011 U.S.Dist. Lexis 135710, p. *8 ["Plaintiff does not allege that defendants failed to provide warnings to the physicians that were identical to the brand name product's warnings. Instead, plaintiff alleges that defendants did provide warnings to physicians, and that those warning[s]

were inadequate because they should have provided stronger warnings than those provided on the brand name product's label"]; *Morris v. Wyeth, Inc., supra*, 2011 U.S.Dist. Lexis 121052 at pp. *7-*8 [claim that failure to send Dear Doctor letter preempted; no allegation that RLD label provided stronger warnings]; *Fullington v. PLIVA, Inc.* (E.D.Ark., Dec. 12, 2011, No. 4:10CV00236 JLH) 2011 U.S.Dist. Lexis 142931, pp. *16-*17 [the plaintiff did not allege generic drug manufacturer's failure to send information to doctors after RLD label changed and before generic label changed, nor that she ingested the generic drug during that time period].)

Metz v. Wyeth, LLC (M.D.Fla. 2012) 872 F.Supp.2d 1335, 1340, on which the Teva Defendants also rely, actually supports our conclusion on this point; there, the court determined the claim against the generic drug manufacturer for failing to provide doctors and consumers with safety information included in or recently added to the label was not necessarily preempted: "In short, it would not be impossible for Actavis to comply with its obligations under federal and state law to the extent state law is determined to require Actavis to more effectively communicate the FDA approved label to medical providers and/or consumers." (Fn. omitted.)[5]

In one per curium opinion cited by the Teva Defendants, *Morris v. Pliva, Inc., supra*, 713 F.3d at page ___ [2013 U.S.App. Lexis 3167 at pages *6-*7], the Fifth Circuit Court of Appeals reached a contrary conclusion: "Appellants first contend that *Mensing* did not dispense with claims concerning a failure to communicate *approved* warnings. They allege the generic defendants are liable for failing to convey FDA-approved information; information communicated by generic manufacturers that is

[5] Although the plaintiffs' claim that the generic drug manufacturer failed "to more effectively communicate the warnings contained in the FDA approved label" survived a motion to dismiss based on the impossibility preemption doctrine, the district court determined it could not survive a motion for summary judgment based on Florida's learned intermediary doctrine. (*Metz v. Wyeth, LLC, supra*, 872 F.Supp.2d at pp. 1343-1344.)

consistent with the brand-name labeling does not violate the duty of sameness. [¶] On the contrary, *Mensing* forecloses such claims because failure to 'communicate' extends beyond just a label change. To avoid liability, the manufacturer must take affirmative steps to alert consumers, doctors, or pharmacists of changes in the drug label. Because the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead. [Citation.] Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so. As *Mensing* concluded, preemption is thus triggered since it would be impossible for PLIVA to comply with both the state law duty to warn and the federal law duty of sameness." (Fn. omitted.)

We respectfully believe *Morris v. Pliva, Inc.* was incorrectly decided. The Supreme Court in *Mensing*, *supra*, 564 U.S. at page ___ [131 S.Ct. at page 2576], held that a generic drug manufacturer's Dear Doctor letter "contain[ing] substantial new warning information would not be consistent with the drug's approved labeling," and would therefore violate the duty of sameness. *Mensing* does not preempt a claim that a generic drug manufacturer failed to send a Dear Doctor letter containing the same information that is on the RLD's approved label. The contrary conclusion of *Morris v. Pliva, Inc.* is supported by neither the language nor the rationale of *Mensing.*

C.

Conclusion

We have analyzed and followed the United States Supreme Court's opinions in *Mensing*, *Wyeth v. Levine*, and *Buckman*. We have surveyed and analyzed the decisions of both state and federal courts applying the preemption analyses of those

Supreme Court cases. As we have discussed, many of the cases relied on by the Teva Defendants did not address, much less resolve, the issue before us in this case, namely, whether a state law tort claim can survive demurrer when it is based on an allegation that a generic drug's label did not match the RLD label approved by the FDA.

Of the opinions that actually reached the issue before us, we believe the 2013 opinion of the Sixth Circuit Court of Appeals in *Fulgenzi v. PLIVA, Inc.*, *supra*, 711 F.3d 578, is the best reasoned and most soundly based on the law. As we have explained in detail *ante*, the analysis of the *Fulgenzi* opinion comports with our analysis of the relevant authorities. Many other opinions, cited *ante*, also agree with the analysis we employ here. We acknowledge a disagreement with our analysis in the opinions of two other courts, one from the Fifth Circuit Court of Appeals and one from an intermediate Iowa court of appeals. We respectfully disagree with those opinions for the reasons we have explained.

D.

Additional arguments

The trial court also overruled the Teva Defendants' demurrer on the grounds the complaint alleged sufficient facts to state a cause of action based on the Teva Defendants' alleged failure to stop marketing alendronate sodium after learning about safety issues regarding the drug, and their alleged failure to request the FDA to order a change in the Fosamax label. Because we have concluded the trial court correctly overruled the demurrer based on the allegations that the Teva Defendants failed to update the alendronate sodium labels and failed to send Dear Doctor letters as described, we need not reach these additional issues.

DISPOSITION

The petition is denied. Real party in interest shall recover costs in this writ proceeding.

FYBEL, J.

WE CONCUR:

RYLAARSDAM, ACTING P. J.

IKOLA, J.