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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION TWO

AMIODARONE CASES.	A161023, A161762 (Alameda County Super. Ct. No. JCCP004956)

In the coordinated cases underlying these consolidated appeals, plaintiffs allege that they suffered serious side effects as a result of taking the prescription drug amiodarone, which their physicians prescribed for them "off-label"—that is, for uses not approved by the United States Food and Drug Administration (FDA). Plaintiffs sued the companies that promoted, distributed, and sold amiodarone, alleging that the companies failed to warn them about the dangers of the drug and promoted the drug aggressively and unlawfully for unapproved uses. The trial court sustained defendants' demurrers without leave to amend. Plaintiffs appeal, making two arguments: (1) as to all defendants, that it was error to dismiss as preempted their claims that defendants failed to warn them about the dangers of amiodarone because defendants did not ensure that they received the content of the FDA-required Medication Guide for the drug; and (2) as to one defendant, Wyeth Pharmaceuticals, Inc. (Wyeth), that it was error to dismiss common law fraud claims and statutory claims arising from Wyeth's

allegedly unlawful promotion of the drug. We reject the arguments and we affirm.

FACTUAL AND PROCEDURAL BACKGROUND

The General Setting

The drug amiodarone was developed in Belgium in the 1960's for the treatment of angina, and about that time was released for marketing in most countries other than the United States. Amiodarone is associated with serious side effects, including pulmonary fibrosis, blindness, thyroid cancer, and death. In the 1970's, U.S. physicians began obtaining amiodarone from other countries for use in patients with life-threatening ventricular fibrillation or ventricular tachycardia who did not respond to other drugs. The FDA allowed this activity, but did not approve or test the drug.

In 1985, foreign manufacturers of the drug threatened to cut off the supply to U.S. patients unless the FDA allowed the drug to be sold in the United States, and that year the FDA approved Wyeth's formulation of amiodarone, called Cordarone, as a drug of last resort for patients suffering from documented recurring life-threatening ventricular fibrillation and ventricular tachycardia when those conditions would not respond to other drugs and therapies. The FDA approval of amiodarone was, and remains, a "special needs" approval, issued without randomized clinical trials of the drug.

In December 1989, the FDA sent a letter to Wyeth's chairman describing Wyeth's current promotional activities and characterizing them as "false and misleading." Among other things, the letter stated that by claiming " 'an early decision for Cordarone can improve the odds,' " Wyeth was promoting an unapproved use of the drug, failing to "recognize the drug's unique role as a drug of last resort." The letter concluded that Wyeth was

"promot[ing] Cordarone, an extraordinarily hazardous drug, in a manner we consider clearly misrepresentative of its known hazards."

In December 1990, Senator Ted Kennedy issued a press release claiming that Wyeth's promotional campaign for Cordarone was intended "to promote the drug's use for a large population of patients that could generate higher revenues, [and] to push a product beyond the limits of its scientific data, even if the company is putting patients at risk."

In February 1992, the FDA sent a letter to a Wyeth assistant vice present for regulatory affairs objecting that several promotional labeling pieces for Cordarone "present[ed] an unbalanced view of Cordarone's benefits as opposed to its risks," and explaining its concerns about specific statements in the labeling.

Various other manufacturers began developing generic amiodarone, which has been available since 1998.

Trial Court Proceedings

Several hundred individuals filed lawsuits in California superior courts alleging that they suffered unnecessary and serious side effects when they took amiodarone, as prescribed by their doctors, for off-label use to treat atrial fibrillation, a more common—and less serious—condition than ventricular fibrillation.[1] The FDA never approved amiodarone for the treatment of atrial fibrillation, even on a special-needs basis.[2]

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[1] Some plaintiffs allege that their spouses or decedents used amiodarone. Like the parties, we use the term "plaintiffs" to refer to the patients who used amiodarone.

[2] A physician may legally prescribe a drug for a purpose other than that for which it has been approved by the FDA. (*T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 158, fn. 1 (*T.H.*).)

The plaintiffs, who were prescribed amiodarone between 2005 and 2017, alleged that their physicians prescribed amiodarone for them as a result of aggressive campaigns by Wyeth and others that promoted the drug to physicians as a first-line treatment for atrial fibrillation and failed to disclose the dangers of the drug.[3] Plaintiffs alleged these promotional efforts "would have materially affected" their physicians' decisions to prescribe amiodarone for off-label use. Plaintiffs also alleged that they would not have taken amiodarone if they had received a "Medication Guide," which contains warnings about the drug and which the FDA requires be provided to pharmacies for distribution to patients.[4]

In March 2018, the cases were coordinated for pretrial proceedings in the Alameda County Superior Court, where they were assigned to the Honorable Brad Seligman. In May 2018, plaintiffs filed a Master Administrative Complaint (MAC) that combined the allegations of the underlying lawsuits.[5] The MAC asserted multiple causes of action against Wyeth, 10 manufacturers of generic amiodarone, and McKesson Corporation,

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[3] The record before us does not reveal when the underlying lawsuits were filed. Of the two individual plaintiffs named in the complaint, one allegedly started taking amiodarone in 2005 and began experiencing adverse effects from the drug in October 2015, after his doctor doubled the dose. The other plaintiff allegedly started taking amiodarone in December 2015 and began experiencing adverse effects in May 2016.

[4] We provide background on Medication Guides in the "Discussion," below.

[5] Among the original plaintiffs named in the MAC were some from states other than California. In July 2020 this court affirmed the trial court's dismissal of those plaintiffs' claims for lack of personal jurisdiction in *In re Amiodarone Cases* (July 30, 2020, A157035, A158160, A159522) (nonpub. opn.).

which was alleged to be the primary distributor of amiodarone.[6] We refer to these parties collectively as "defendants."

As relevant here, the MAC alleged claims against all defendants for fraud, violation of California's unfair competition law (Bus. & Prof. Code, § 17200 et seq., UCL), and violation of California's Consumers Legal Remedy Act (Civ. Code, § 1750 et seq. CLRA), arising from defendants' allegedly misleading promotion of off-label uses of amiodarone. Plaintiffs also alleged claims for failure to warn against all defendants under theories of strict liability and negligence arising from defendants' alleged failure to ensure that consumers were provided with FDA-required Medication Guides.

In response to defendants' demurrer to the Second Amended MAC, the trial court struck the Medication Guide claims against all defendants without leave to amend on the ground that the claims were preempted by federal law and lacked any independent basis in state law. The court gave plaintiffs leave to amend their off-label promotion claims, and plaintiffs did so in their Third Amended MAC.

Defendants demurred to the Third Amended MAC. The court gave plaintiffs leave to amend their off-label promotion claims as to one of the defendants, Wyeth. The court dismissed the off-label promotion claims

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[6] The generic manufacturers are Sandoz, Inc.; Eon Labs, Inc.; Teva Pharmaceuticals USA, Inc.; Par Pharmaceutical, Inc. and/or Par Pharmaceutical Companies, Inc. (plaintiffs use both names, and we refer to these companies collectively as the Par defendants); Zydus Pharmaceuticals (USA), Inc.; Taro Pharmaceuticals U.S.A., Inc.; Upsher-Smith Laboratories, Inc. (Upsher-Smith); Barr Pharmaceuticals, LLC; Mayne Pharma, Inc. (Mayne); and Aurobindo Pharma USA, Inc. Plaintiffs' briefs contain no challenge to the trial court's dismissal of their claims against the Par defendants, Upsher-Smith, and Mayne. We have granted plaintiffs' unopposed request to dismiss the consolidated appeals as to the Par defendants.

against the other defendants without leave to amend. Those defendants were dismissed from the case and plaintiffs timely appealed as to them.

Plaintiffs filed a Fourth Amended MAC alleging their off-label promotion claims as to Wyeth. In response to Wyeth's demurrer, the court dismissed the off-label promotion claims against it without leave to amend. The court noted that plaintiffs' fraud claims against Wyeth arose both from Wyeth's promotional activities and from statements made by third parties. The court then concluded that Wyeth's promotional activities did not support claims for fraud because the activities had not been alleged in sufficient particularity and were too remote in time from plaintiffs' injuries, and that the third-party statements did not support claims for fraud because plaintiffs failed to allege facts allowing a reasonable inference that Wyeth had control over the statements. The court further concluded that plaintiffs' UCL and CLRA claims were derivative of the fraud claims and failed for the same reasons, even under the lower pleading requirements that apply to the statutory claims. Wyeth was dismissed as a defendant. Plaintiffs timely appealed this as well, and the two appeals were consolidated.

DISCUSSION

Standard of Review

Our standard of review is well-established. We accept as true the well-pleaded allegations in the operative complaint. (*Chiatello v. City and County of San Francisco* (2010) 189 Cal.App.4th 472, 480.) " ' " 'We treat the demurrer as admitting all material facts properly pleaded, but not contentions, deductions or conclusions of fact or law. [Citation.] We also consider matters which may be judicially noticed.' [Citations.] Further, we give the complaint a reasonable interpretation, reading it as a whole and its parts in their context. [Citation.]" ' [Citation.] We likewise accept facts that

are reasonably implied or may be inferred from the complaint's express allegations. [Citations.] ' " 'A demurrer tests the legal sufficiency of the complaint . . . .' [Citations.] On appeal from a dismissal after an order sustaining a demurrer, we review the order de novo, exercising our independent judgment about whether the complaint states a cause of action as a matter of law. [Citations.]" ' " (*Ibid.*)

Although our review is de novo, it is plaintiffs' burden to affirmatively demonstrate that the demurrer was erroneously sustained as a matter of law, which means that plaintiffs must show that they pleaded facts sufficient to establish each element of each cause of action. (*Intengan v. BAC Home Loans Servicing LP* (2013) 214 Cal.App.4th 1047, 1052.)

Plaintiffs' Appeal Against All Defendants Has No Merit

As noted, as to all defendants, plaintiffs challenge the dismissal of their failure-to-warn claims, which claims rest upon their allegations that defendants "fail[ed] to convey directly to the consumer the [FDA-required] Medication Guide or the content of the Medication Guide." We conclude that because plaintiffs seek to enforce FDA regulations, the claims are preempted as attempts to privately enforce the Federal Food, Drug, and Cosmetic Act (FDCA, 21 U.S.C. § 301 et seq.). And in doing so, we reject plaintiffs' arguments that their claims have an independent basis in state law, concluding that plaintiffs fail to state such a claim.

Preemption of Private Actions to Enforce FDA Medication Guide Regulations

Federal law preempts conflicting state law. (U.S. Const., art. VI, cl. 2.) Preemption is not limited to express conflicts between state and federal law, which occur when Congress " 'define[s] explicitly the extent to which its enactments pre-empt state law.' " (*Glennen v. Allergan, Inc.* (2016) 247 Cal.App.4th 1, 9 (*Glennen*).) Beyond that, state law is impliedly preempted

where it " ' "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." ' " (*Ibid.*) A claim is "impliedly preempted if it conflicts with the FDCA's enforcement scheme." (*Id.* at p. 10.) Federal preemption presents a question of law that we review de novo. (*Farm Raised Salmon Cases* (2008) 42 Cal.4th 1077, 1089, fn. 10 (*Salmon Cases*).)

We begin our analysis by considering the federal regulations governing Medication Guides. A "Medication Guide" is a form of FDA-approved patient labeling for drug products. (21 C.F.R. § 208.3(h).) Patient labeling is required when the FDA determines that such labeling is necessary to patients' safe and effective use of drug products because it could help prevent serious adverse side effects from the drug, or because the drug has serious risks relative to benefits of which patients should be made aware, or because the drug is important to health and adherence to directions for use is crucial to the drug's effectiveness. (21 C.F.R. § 208.1(b) & (c).) According to the FDA website, "Medication Guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to specific drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events." (FDA, *Medication Guides: Providing information on proper drug use, safety, and storage*, <www.fda.gov/drugs/drug-safety-and-availability/medication-guides> [content current as of Nov. 3, 2022].) Manufacturers are "responsible for ensuring that Medication Guides are available for distribution to patients" by providing Medication Guides, or the means to produce them, in sufficient numbers to permit "authorized dispensers," such as pharmacies, to provide a guide to each patient who receives a prescription for the drug. (21 C.F.R. § 208.24(b).) Likewise, distributors are required to provide Medication

Guides or the means to produce them to authorized dispensers.[7] (*Id.*, § 208.24(c).)

The FDCA's enforcement scheme is set forth in the FDCA itself, which "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . : '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.' 21 U.S.C. § 337(a)." (*Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 349, fn. 4.) " 'Although citizens may petition the FDA to take administrative action, [citation], private enforcement of the statute is barred.' " (*Glennen*, *supra*, 247 Cal.App.4th at p. 11.) So, to avoid preemption, a claim alleging conduct that violates the FDCA must be a state-law claim that is not based solely on the FDCA: the claim must be premised on conduct that " ' " 'would give rise to a recovery under state law even in the absence of the FDCA.' " ' " (*Id.* at p. 12.)

Plaintiffs' claims for strict-liability and negligent failure to warn amount to attempts by them to enforce the FDA's regulatory requirements. And as such, they are preempted.

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[7] Thus, Medication Guides are directed to patients. In contrast, so-called "package inserts" are directed to physicians. (See *Hardin v. PDX, Inc.* (2014) 227 Cal.App.4th 159, 162 [contrasting "physician package inserts" with "patient medication guides"]; FDA, *The FDA Announces New Prescription Drug Information Format*, <www.fda.gov/drugs/laws-acts-and-rules/fda-announces-new-prescription-drug-information-format> (as of Nov. 3, 2022) [describing the role of the package insert as of Dec. 4, 2015].) Plaintiffs do not challenge the contents of the Medication Guide or package insert; instead, plaintiffs' failure to warn claim rests upon defendants' alleged failure to provide Medication Guides to consumers.

Failure to Provide Medication Guides as a State Law Tort Claim

Plaintiffs insist they do not seek to enforce FDA regulations. They argue that their failure to warn claims rest on state law requirements that are parallel to federal requirements (and therefore do not conflict with the FDCA) and based on established state tort law and statutory law (and therefore do not seek to enforce the FDCA). Specifically, plaintiffs argue that defendants' alleged failure to provide distributors or pharmacies with sufficient Medication Guides or the means to produce them, as required by federal law, constitutes a violation of defendants' California common law duty to provide an adequate warning. The argument fails because California has adopted the "learned intermediary doctrine," which applies where drugs are "supplied in the context of the doctor-patient relationship." (*Webb v. Special Electric Co.* (2016) 63 Cal.4th 167, 187, fn. 10.)

Manufacturers and distributors of prescription drugs have no common-law duty in California to provide warnings about those drugs directly to patients. (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1116 [stating that "the duty to warn runs *to the physician*, not to the patient," and noting that *Davis v. Wyeth Laboratories, Inc.* (9th Cir. 1968) 399 F.2d 121,131, recognizes an exception where a prescription drug is " 'not dispensed as such,' but administered in [a] mass immunization program"].) That is because for prescription drugs like amiodarone the physician "stands in the shoes of the product's ordinary user." (*Gall v. Smith & Nephew, Inc.* (2021) 71 Cal.App.5th 117, 122.) The "patient learns of the properties and proper use of the drug . . . from the physician. In these cases, the manufacturer's duty to warn runs to the physician and not to the patient." (*Ibid.*) In short, under the learned intermediary doctrine, any state law duty on the part of manufacturers and distributors to provide the information included in

Medication Guides runs to the physician, not to the patient directly, and therefore plaintiffs cannot state a claim for failure to warn based on defendants' alleged failure to provide distributors or pharmacies with sufficient FDA-required Medication Guides for distribution to plaintiffs.

Notably, when the FDA promulgated the medication guide regulation, it recognized that was creating new patient labeling requirements. (See 63 Fed. Reg. 66378 (Dec. 1, 1998) [rule "establishes a patient medication information program under which Medication Guides will be required"].) And the FDA understood that the Medication Guide requirement was a federal law requirement distinct from state law, as reflected in its rejection of the claim that the requirement would abrogate the learned intermediary doctrine—and its recognition that "the written patient medication information provided [in the Medication Guide] does not alter the duty, or set the standard of care for manufacturers, physicians, pharmacists, and other dispensers." (*Id.* at pp. 66383-66384.)

Plaintiffs make two arguments that the learned intermediary doctrine does not bar their claims. First, they argue that the doctrine is an affirmative defense that does not appear on the face of the complaint and therefore cannot be the basis for the sustaining of a demurrer. (See *Casterson v. Superior Court* (2002) 101 Cal.App.4th 177, 183 ["demurrer based on an affirmative defense [is] sustained only where the face of the complaint discloses that the action is necessarily barred by the defense"].) Second, they argue that "the Medication Guide is an exception to the learned intermediary doctrine."

Plaintiffs' first argument rests on their contention that the learned intermediary doctrine is an affirmative defense that requires defendants to plead and prove that they provided adequate warnings to plaintiffs'

prescribing physicians. In claimed support, plaintiffs rely on two unpublished orders in which federal district courts rejected defendants' claims of fraudulent joinder and remanded cases to state court: *Riemer v. Johnson & Johnson* (N.D.Cal. 2006) 2006 WL 8459718 and *W.W. v. McKesson Corp.* (C.D.Cal. 2014) 2014 WL 12577143. Claiming they are applying California law, the orders in those cases assert that the learned intermediary doctrine is an affirmative defense, but they cite nothing in support of the assertion and offer no analysis of the issue. (*Riemer*, *supra*, at pp. *2, *3; *McKesson*, *supra*, at pp. *2, *3.)

We are not aware of any California decision that characterizes the learned intermediary doctrine as an affirmative defense. To the contrary, it has long been the law in California that the learned intermediary doctrine defines the scope of a manufacturer's duty to warn in the context of prescription drugs. As our Supreme Court put it, "It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician." (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1062, fn. 9.) "While the 'ordinary consumer' may have a reasonable expectation that a product such as a machine he purchases will operate safely when used as intended, a patient's expectations regarding the effects of [a prescription] drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties." (*Id.* at pp. 1061-1062.) " 'In the case of *prescription drugs* and *implants*, the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant. Thus, the duty to warn in these cases runs to the physician, not the patient.' " (*Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 319 (*Bigler-Engler*), quoting

Valentine v. Baxter Healthcare Corp. (1999) 68 Cal.App.4th 1467, 1483, and adding italics.)

Because the duty to warn is an essential element of plaintiffs' claims, and the learned intermediary doctrine sets the scope of the duty with respect to the prescription drug amiodarone, it is plaintiffs' burden to plead and prove that defendants failed to adequately warn the prescribing physician of the potential risks. (See CACI No. 1205, "Strict Liability – Failure to Warn – Essential Factual Elements" [in the prescription drug product cases, plaintiff must prove that defendant failed to adequately warn the prescribing physician of the potential risks, citing *Bigler Engler, supra,* 7 Cal.App.5th at p. 319 in "Directions for Use"]; see also CACI No. 1222 "Negligence – Manufacturer or Supplier – Duty to Warn – Essential Factual Elements" [for prescription drug, warning must be given to prescribing physician].) Under the learned intermediary doctrine, prescription drug manufacturers satisfy their duty to warn if they provide adequate warnings to prescribing physicians. Warnings directly to patients do not enter the picture.

Plaintiffs' second argument is that even if the learned intermediary doctrine is not an affirmative defense, it does not apply to this case. Plaintiffs argue that there are no allegations in the complaint from which it can be inferred that their physicians were adequately warned; that, to the contrary, the complaint alleges that defendants misled the prescribing physicians rather than adequately warning them; and therefore that they have adequately alleged that the learned intermediary doctrine does not apply and defendants' duty is to warn the patients directly. As plaintiffs put it, "because manufacturers do not adequately warn doctors, they must warn patients."

In support of their position, plaintiffs point to language in *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51 (*Stevens*), a case in which our Supreme Court discussed the operation of the learned intermediary doctrine, saying this: "[i]n 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.' " (*Id.* at p. 65.) We do not read *Stevens* as holding that the manufacturer has a duty to warn the patient in the absence of an adequate warning to the doctor. We are not aware of any California case that so holds. And certainly plaintiffs have not cited any.

Stevens was a wrongful death case in which plaintiffs sued a drug manufacturer and the prescribing physician, alleging that a patient's death was caused by the administration of an antibiotic drug. (*Stevens*, *supra*, 9 Cal.3d at pp. 56-57.) The jury returned a verdict in favor of plaintiffs on claims that the drug company was negligent in overpromoting the drug and the physician negligent in prescribing it. (*Id.* at pp. 58-59.) In affirming the judgment against the drug company, the Supreme Court observed that an apparently adequate warning to a physician "may be eroded or even nullified by overpromotion of the drug," (*id.* at p. 65), and concluded that the record supported an inference by the jury that the drug company "negligently failed to provide an adequate warning as to the dangers of [the drug] by so 'watering down' its warnings and so overpromoting such drug that members of the medical profession, including [patient's physician], were caused to prescribe it when it was not justified."[8] (*Id.* at p. 66.) *Stevens* is not a case in

[8] The court rejected the drug company's argument that even if it had overpromoted the drug, the negligence of the prescribing physician was an

which the learned intermediary doctrine did not apply; it is a case in which non-compliance with the duty imposed by the doctrine supported a finding of liability. *Stevens* says nothing about a duty to warn the patient.

Thus, even when a plaintiff alleges that warnings to a physician were inadequate, under California law the learned intermediary doctrine applies, and a manufacturer's duty is to warn the prescribing physician about dangers associated with the drug. (See *Sanchez v. Boston Scientific Corp.* (S.D.W.V. 2014) 38 F.Supp.3d 727, 734-735 [discussing California cases].) Plaintiffs have not demonstrated that the learned intermediary doctrine somehow does not apply when plaintiffs allege that the warnings to physicians are inadequate. Nor that the absence of an adequate warning about a prescription drug to a physician somehow results in a duty to provide a warning to the patient.

In arguing that the learned intermediary doctrine does not apply, plaintiffs cite two cases in addition to *Stevens*: *Bigler-Engler*, *supra*, 7 Cal.App.5th 276 and *Coleman v. Medtronic, Inc.* (2014) 223 Cal.App.4th 413 (*Coleman*). Neither case helps them. *Bigler-Engler* recognized that the learned intermediary doctrine applied in California to prescription drugs and implantable medical devices, and declined to extend the doctrine to medical devices that patients use and apply themselves. (*Bigler-Engler*, *supra*, 7 Cal.App.5th at pp. 318-319.) *Coleman* recognized that under the learned intermediary doctrine the duty to warn can include a duty to file adverse event reports with the FDA, as required by federal law; and that to prevail in their claims, plaintiffs would have had to prove that if the defendant had made the required reports, the " 'information would have reached [their]

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intervening cause that exonerated the company from liability. (*Stevens*, *supra*, 9 Cal.3d at p. 67.)

doctors in time to prevent' " the injuries at issue. (*Coleman, supra,* 223 Cal.App.4th at pp. 429-430, italics added.) Neither case suggests that manufacturers have a common law duty in California to provide patients (as opposed to physicians) warnings about the risks of prescription drugs.

Plaintiffs' final argument is that their failure to warn claim is saved from preemption because it is based on California's Sherman Food, Drug, and Cosmetics Law (Sherman Law, Health & Saf. Code, § 109875 et seq.)

Plaintiffs contend that defendants violated the Sherman Law by "failing to take reasonable steps to ensure that [p]laintiffs received Medication Guides." Plaintiffs rely on section 111375 of the Sherman Law, which provides that "[a]ny drug or device is misbranded unless its labeling bears . . . [¶] (c) [a]dequate warning against unsafe dosage or methods or duration of administration or application" (Health & Saf. Code, § 111375, subd. (c); see *id.* § 111440 [manufacture or sale of any misbranded drug or device is unlawful]), which warning "shall be in a manner and form as are necessary for the protection of users." (*Id.*, § 111375, subd. (c).)

Plaintiffs argue that a Medication Guide is exactly the type of warning required by the Sherman Law, because when a Medication Guide is required, the FDA has determined that patient labeling is necessary for the safe use of a drug. (See 21 C.F.R. § 208.1(b) [purpose of Medication Guides is "to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products"].) This argument fails because section 111480 of the Health and Safety Code expressly exempts prescription drugs from the requirements of section 111375.[9]

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[9] Section 111480 of the Health and Safety Code provides that "[a]ny drug . . . sold by filling or refilling a written or oral prescription of a practitioner licensed to prescribe the drug . . . shall be exempt from the labeling requirements of Section[ ] 111375, . . . if the drug . . . bears a label

Plaintiffs contend that the exemption is inapplicable, arguing that the exemption applies only if the drug "bears a label displaying . . . [¶] [t]he directions for the use of the drug" (Health & Saf. Code, § 111480, subd. (b)); that the Medication Guide is part of the directions for the use of amiodarone; and that because they allege they did not receive Medication Guides, defendants cannot rely on the exemption for prescription drugs. We disagree.

Plaintiffs' argument on this point presents an issue of statutory interpretation, which is subject to de novo review. (*Lopez v. Ledesma* (2022) 12 Cal.5th 848, 857.) We must " 'determine the Legislature's intent so as to effectuate the law's purpose.' " (*Skidgel v. California Unemployment Ins. Appeals Bd.* (2021) 12 Cal.5th 1, 14.) " 'We begin by examining the statutory language, giving it a plain and commonsense meaning. [Citation.] We do not, however, consider the statutory language in isolation; rather we look to the entire substance of the statutes in order to determine their scope and purposes. [Citation.] That is, we construe the words in question in context, keeping in mind the statutes' nature and obvious purposes. [Citation.] We must harmonize the various parts of enactments by considering them in the context of the statutory framework as a whole. [Citation.]' " (*Ibid.*)

We conclude that the Medication Guide is not part of a drug's "directions for use" for purposes of the Sherman Law, and therefore the exemption applies. In arguing otherwise, plaintiffs fail to take into account

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displaying all the following: [¶] (a) . . . [E]ither the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer. . . . [¶] (b) The directions for the use of the drug or device. [¶] (c) The name of the patient(s). [¶] (d) The name of the prescriber. [¶] (e) The date of issue. [¶] (f) The name, address of the furnisher, and prescription number or other means of identifying the prescription. [¶] (g) The strength of the drug or drugs dispensed. [¶] (h) The quantity of the drug or drugs dispensed. [¶] (i) The expiration date of the effectiveness of the drug . . . ."

the definition of "label" and the distinction between warnings and "directions for use" in the Sherman Law. A "[l]abel" is "a display of written, printed, or graphic matter upon a . . . drug . . . or *upon its immediate container*." (Health & Saf. Code, § 109955, italics added; compare *id.*, § 109960 [defining "[l]abeling" more broadly to mean "any label or other written, printed, or graphic matter upon a . . . drug . . . or upon its container or wrapper, or that accompanies any . . . drug"].) (*Id.*, § 109960.) The "label" must include the name of the drug, the name of the manufacturer, the directions for use, the name of the patient, the name of the prescriber, the date of issue, the name and address of the pharmacy, a prescription number, the strength of the drug, the quantity dispensed, and the expiration date. (*Id.*, § 111480.) Notably, a prescription drug "label" need not include warnings for the drug to qualify for an exemption. (*Ibid.*; see *id.*, § 111375 [distinguishing "directions for use" in subdivision (a) from "adequate warning" in subdivision (c)].) In the context of a Sherman Law prescription drug label on a drug's "immediate container" (*id.*, § 109955), information about the "directions for use" must necessarily be brief. By contrast, the Medication Guide, which is more than two single-spaced pages long, includes information beyond directions for use, a fact plaintiffs effectively concede when they allege that the Medication Guide provides "warnings" and also includes "things a consumer must know in order to make an informed decision to actually take or continue taking the drug."[10]

[10] As of November 3, 2022, the Medication Guide for Cordarone (Wyeth's brand name for amiodarone), last revised 10/2018, is available at <www.accessdata.fda.gov/drugsatfda_docs/label/2018/018972s054lbl.pdf> on pages 13 through 15.

Because the requirements imposed by the Sherman Law are different from those imposed by the FDA's regulations, this is not a case like *Salmon Cases*, *supra*, 42 Cal.4th 1077, where plaintiffs' claims were saved from preemption by the existence of a California statute creating obligations identical to those imposed by the FDCA. In *Salmon Cases*, plaintiffs alleged that grocery stores violated state law by selling artificially colored farmed salmon without disclosing the use of color additives. (*Id.* at pp. 1082-1083.) The alleged conduct violated both the FDCA and the Sherman Law, which included substantially identical provisions prohibiting the sale of food containing artificial coloring unless the food's labeling stated that fact. (*Id.* at pp. 1085-1086.) Our Supreme Court rejected the argument that the plaintiffs' claims were impliedly preempted under section 337 of the FDCA as attempts to privately enforce it. (*Id.* at p. 1095.) The court explained that section 337 "by its very terms, only implicates efforts to enforce *federal* law," and therefore did not affect plaintiffs' claims, which were "predicated on violations of obligations imposed by the Sherman Law, something that state law undisputedly allows." (*Ibid.*) The fact that the obligations under the FDCA and Sherman Law were identical did not "substantively transform plaintiffs' action into one seeking to enforce federal law." (*Ibid.*) Instead, because the plaintiffs' claims were based on California law and could be "resolved with reference to state law alone" they were not preempted. (*Id.* at pp. 1097-1098.) That is simply not the situation here, where plaintiffs do not identify any state law that is parallel to the regulations concerning Medication Guides.

Plaintiffs' Appeal Against Wyeth Has No Merit

Plaintiffs argue that they have adequately alleged claims for fraud and claims under the UCL and CLRA arising from Wyeth's marketing and

promoting of amiodarone for off-label uses, which "misled [their] doctors into prescribing [a]miodarone for atrial fibrillations, which is an unreasonably dangerous use."

Fraud

To plead a cause of action for fraud, plaintiffs must allege " '(a) misrepresentation (false representation, concealment, or nondisclosure); (b) knowledge of falsity (or "scienter"); (c) intent to defraud, i.e., to induce reliance; (d) justifiable reliance; and (e) resulting damage.' " (*Lazar v. Superior Court* (1996) 12 Cal.4th 631, 638; see CACI Nos. 1900 "Intentional Misrepresentation" & 1901 "Concealment" [listing elements to be proved].) Each element "must be pled specifically; general and conclusory allegations do not suffice." (*Lazar*, *supra*, 12 Cal.4th p. 645.) Accordingly, plaintiffs must plead " '*facts* which "show how, when, where, to whom, and by what means the representations were tendered." ' " (*Ibid.*)

Plaintiffs argue they alleged two types of specific misrepresentations, that (1) Wyeth disseminated to physicians false and misleading advertisements promoting off-label use of amiodarone, and (2) Wyeth is responsible for misleading statements made by third parties that, plaintiffs claim, Wyeth had funded.

Wyeth's Promotion of Amiodarone

With respect to misleading advertisements, plaintiffs rely primarily on the December 1989 and February 1992 letters from the FDA mentioned above. The letters identify advertisements, brochures, and "promotional labeling pieces" that were directed to physicians and minimized the dangers of the drug. The 1989 letter addresses Wyeth's "Current Promotional Activities." According to the FDA, an advertisement published in a journal was misleadingly "intended to minimize the hazards of the drug and

emphasize the drug's efficacy"; a brochure with the "statement that 'an early decision for Cordarone can improve the odds,' clearly fails to recognize the drug's unique role as a drug of last resort" and minimizes hazards associated with the drug by suggesting the drug can be administered in such a way as to eliminate the need for concern over the hazards; and another brochure fails to describe the drug as one of last resort and presents a single case study "which suggests that Cordarone is readily tolerable."

The 1992 letter quotes multiple specific statements by Wyeth that the FDA characterized as misleading, including several unsubstantiated statements: " 'Unprecedented antiarrhythmic efficacy;' 'The most effective antiarrhythmic you can prescribe;' 'Unparalleled efficacy.' " And the letter characterizes Wyeth's statement, " 'Decreased dosage may decrease the incidence of pulmonary toxicity,' " as "promotion of . . . unproven data." The FDA also provided examples of the presentation of information about risks and side effects that it considered misleading, and identified adverse reactions that should have been, but were not, included in the material.

In addition to the FDA letters, plaintiffs rely on Senator Kennedy's December 1990 press release, which mentioned the FDA warning to Wyeth about distributing "information about how well Cordarone was tolerated based on one individual case history in the company files" and "brochures advising doctors to 'make an early decision for Cordarone'—a highly unusual promotional message for a drug of last resort." Senator Kennedy also mentioned Wyeth's subsequent alleged promotion of Cordarone "to non-specialists, who would have no understanding of the appropriate treatments for the life-threatening condition for which the drug was approved."

Notably, none of the specific statements allegedly made by Wyeth and directed toward physicians state that amiodarone should be prescribed for

any condition other than ventricular arrhythmia, nothing that concerns the use of amiodarone for atrial fibrillation. Further, the most recent of Wyeth's alleged misrepresentations to physicians dates from the early 1990's.[11]

Because this case comes to us on a demurrer, we assume the truth of plaintiffs' allegations that Wyeth made the statements described by the FDA and Senator Kennedy; that the statements are false or misleading; that Wyeth was aware that the statements were misleading; and that Wyeth intended physicians to rely on the statements in prescribing amiodarone. Plaintiffs do not allege that any of their physicians saw Wyeth's advertising, but they need not "prove that [their physicians] saw or heard any specific misrepresentations of fact . . . or that [they] heard them directly from [Wyeth] or [its] agents," as long as the misrepresentations were "heard by or passed on" to them. (*Whiteley v. Philip Morris Inc.* (2004) 117 Cal.App.4th 635, 680-682 (*Whiteley*).)

Even so, plaintiffs' allegations lack the required specificity to survive demurrer. The Fourth Amended MAC includes details about the claims of two individual patients, but provides no specifics about when or how their physicians were allegedly influenced by Wyeth's advertising from the 1980's and early 1990's. One of the two individual plaintiffs for whom factual allegations are included in the complaint alleges generally that his doctor was "*apparently* a victim of . . . Wyeth's long term and successful brand

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[11] We disregard plaintiffs' allegations concerning a promotional magazine that Wyeth distributed at a meeting of pharmacists in 1998. Although plaintiffs allege that an article in the magazine addressed " 'An Aggressive Treatment Strategy for Atrial Fibrillation,' " plaintiffs do not specify any misleading statements that were made in that magazine (except to allege that several of the articles in it "*appear to* soften, downplay, or minimize" (italics added) the side effects of amiodarone). Nor do plaintiffs allege that the material was aimed at or reached physicians.

innovator promotional efforts . . . that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating congestive heart failure and irregular heart rhythm, which *would have* materially affected his decision to prescribe [a]miodarone." (Italics added.) The other plaintiff alleges the same thing, but omits the word "apparently" and refers to treatment for atrial fibrillation. In the absence of any other allegations about their physicians, these conclusory allegations do not suffice to state claims for fraud.

Further, plaintiffs must plead that their physicians justifiably relied on the alleged misrepresentations, even if those misrepresentations were heard only indirectly (*Mirkin v. Wasserman* (1993) 5 Cal.4th 1082, 1096), and that their physicians' justifiable reliance on Wyeth's advertisements caused their injuries. On the facts alleged here—where the most recent alleged misrepresentation by Wyeth appeared in advertising material more than a decade before amiodarone was prescribed for any of the plaintiffs—as a matter of law the necessary justifiable reliance and causation cannot be established.

Justifiable reliance is ordinarily a question of fact that is not properly determined on demurrer, but "whether a party's reliance was justified may be decided as a matter of law if reasonable minds can come to only one conclusion based on the facts," which facts include consideration of "the knowledge, education and experience" of the person whose reliance is at issue. (*Guido v. Koopman* (1991) 1 Cal.App.4th 837, 843-844.) No rational trier of fact could conclude that a physician would justifiably rely on promotional material that was more than 10 years old in prescribing medication for a patient, particularly here, where plaintiffs concede that there was nothing invalid or improper about the warnings that had long been

included in FDA-approved amiodarone labeling. (See *Lyman v. Pfizer, Inc.* (D.Ver. 2012) 2012 WL 2970627, *18 (*Lyman*) [concluding that "[b]etween September 2003 and January 2007, any prescriber's reliance on [promotional] statements made by Wyeth before 2002 . . . was not justifiable"; noting that review of current prescribing information would have revealed relevant warnings concerning use of the drug].)

This is not a case like *Stevens*, where the court rejected defendant's argument that as a matter of law the provision of warnings defeated the inference that a prescribing physician was influenced by overpromotion of a drug that continued through the time covered by the case. (*Stevens*, *supra*, 9 Cal.3d at pp. 58, 67.) Here, plaintiffs concede that the FDA-approved labeling of the drug is not invalid or improper, and they do not allege any current or recent overpromotion. In these circumstances, plaintiffs have not alleged facts sufficient to show that their physicians justifiably relied on Wyeth's advertising materials when they prescribed amiodarone for plaintiffs' conditions.

More generally, we conclude that as a matter of law plaintiffs have not alleged facts to show that Wyeth's promotion is a proximate cause of their injuries. " 'Ordinarily, proximate cause is a question of fact which cannot be decided as a matter of law from the allegations of a complaint. . . . Nevertheless, where the facts are such that the only reasonable conclusion is an absence of causation, the question is one of law, not of fact.' " (*State Dept. of State Hospitals v. Superior Court* (2015) 61 Cal.4th 339, 353, quoting *Weissich v. County of Marin* (1990) 224 Cal.App.3d 1069, 1084 (*Weissich*); see 6 Witkin, Summary of Cal. Law (11th ed. 2017) Torts, § 1333, p. 630 [on undisputed facts courts regard proximate cause as a question of law]; see also *T.H.*, *supra*, 4 Cal.5th at p. 198, fn. 9 [citing *Lyman* and acknowledging the

possibility that the passage of time between the alleged conduct of a drug manufacturer and a plaintiff's exposure to the drug could preclude a finding of proximate cause].) Accordingly, in *State Hospitals*, our Supreme Court concluded that proximate cause was "absent as a matter of law" from the plaintiff's complaint because the facts that were pleaded were "legally insufficient to connect the breach of . . . duty with the injury." (*State Hospitals, supra,* 61 Cal.4th at pp. 355, 357.)

Among the factors to be considered in determining the existence of proximate cause is the length of time between the alleged misconduct and the harm. (*Weissich*, *supra*, 224 Cal.App.3d at p. 1084, citing Rest. 2d Torts, § 434.) In *Weissich*, Division Three of this court affirmed a judgment for defendant based on an order sustaining without leave to amend a demurrer to a claim of negligent misrepresentation where plaintiffs' allegations of misrepresentation and reasonable reliance were deficient, and therefore declined to resolve the question of proximate cause. But the court nevertheless noted that because more than 11 years had passed between the alleged negligent misrepresentation and the harm at issue, the case "may well be that exceptional case where the absence of proximate cause can be determined as a matter of law." (*Ibid.*) Here, where plaintiffs do not allege statements made by Wyeth to physicians urging the use of amiodarone for atrial fibrillation, and where the allegedly misleading promotional activity engaged in by Wyeth and directed toward physicians occurred more than a decade before amiodarone was first prescribed for any plaintiff, we conclude that a rational trier of fact cannot from the facts alleged conclude that plaintiffs' injuries were caused by Wyeth.

Statements by Third Parties

Besides alleging that Wyeth's advertising to physicians was misleading, plaintiffs allege that Wyeth misled their doctors into prescribing amiodarone for atrial fibrillation "by funding and conducting medical research into [a]miodarone that encourages this improper use [and downplays] [a]miodarone's dangerous side effects." To support this allegation, plaintiffs identify several articles that were published in medical journals from 1997 through 2007, and that allegedly "advocat[e] the use of [a]miodarone in the treatment of atrial fibrillation [by focusing] solely on the efficacy of [a]miodarone in treating [atrial fibrillation], while ignoring the safety of the drug."

Specifically, plaintiffs identify allegedly misleading statements or conclusions in a 1997 article by a doctor who was "supported in part by a grant" from Wyeth; a 1999 article by a doctor who had been hired as a speaker for Wyeth; a 2005 article "authored in part" by a doctor whose efforts were supported by unrestricted grants from Wyeth and who reported "having acted in an advisory capacity and as a speaker" for Wyeth; and a 2007 article where one of the authors was a doctor who had received research grants from Wyeth. Plaintiffs further allege that the author of the 1999 article was the "guest editor" of a 2020 article that cited the 1997 article, but do not allege that the 2020 article itself contained any misleading statements.

Plaintiffs also allege that the false statement "that Amiodarone has 'US/FDA Approved Indications: Heart Rate Control and Heart Rhythm Control for Atrial Fibrillation' " appeared as recently as 2020 on the website of the American College of Cardiology (ACC), which is allegedly "one of the leading sources of information for [p]laintiffs' physicians." Plaintiffs allege that the ACC website cited guidelines published in 2006 for the management

of patients with atrial fibrillation. Finally, plaintiffs allege that the guidelines were prepared by the ACC, the American Heart Association, and the European Society of Cardiology, and that a peer reviewer and author of the guidelines, which contain allegedly misleading information, was a doctor who "listed Wyeth as one of the companies for which he worked at the time as a 'Consultant/Advisory Member.' "

Plaintiffs argue that Wyeth is responsible for these misstatements because its agents wrote the articles. As evidence, plaintiffs cite not only the financial connections they allege between Wyeth and some of the authors, but also assert that "the articles were influenced and caused by Wyeth's earlier advertising," based on their allegations that some of the claims in the 1999, 2005, and 2007 articles "echo" statements made by Wyeth in advertisements to which the FDA had objected years before.

" ' "Agency is the relationship which results from the manifestation of consent by one person to another that the other shall act on his behalf and subject to his control, and consent by the other so to act." ' " (*Gordon v. ARC Manufacturing, Inc.* (2019) 43 Cal.App.5th 705, 718.) And plaintiffs have not alleged any facts to support a non-speculative inference that any of the authors who made the statements at issue did so as an agent of Wyeth—no facts showing that Wyeth controlled the research, conclusions, or statements of the authors here. As the trial court aptly observed, "A finder of fact might reasonably infer from [plaintiffs'] allegations that Wyeth's funding had an impact on the subjects and conclusions of the researchers, but that is not enough to make their statements attributable to Wyeth under the law of agency. . . . Such financial entanglements may require ethical disclosures or even undermine the credibility of the resulting research, but they do not mean that the researcher's statements are legally attributable to Wyeth."

Plaintiffs suggest that California law supports their view that the statements in third-party articles can be viewed as statements made by Wyeth. But the cases they cite do not help them.

This is not a case like *Eidson v. Medtronic, Inc.* (N.D. Cal. 2014) 40 F.Supp.3d 1202, where plaintiffs alleged that defendants marketed their product misleadingly "by bankrolling falsified medical studies and articles." (*Id.* at p. 1226.) Plaintiffs here do not allege that Wyeth was the sole, or even primary, source of support for any of the third-party articles here, nor that the studies on which the articles reported or articles themselves were "falsified." And the facts alleged here are nothing like those in *Whiteley*, where the tobacco industry created a supposedly "independent 'research institute' . . . to find the truth about smoking and health." The institute, however, allocated little money to research: its true purpose was public relations, and its governing committee was made up of tobacco executives. And its so-called "Scientific Advisory Board" was not independent, as the institute claimed: tobacco companies "packed the board with industry-friendly scientists, requiring that members have no 'opinion' that the studies linking smoking and lung cancer were valid." (*Whiteley*, *supra*, 117 Cal.App.4th at p. 645.) The allegations in this case, that Wyeth provided some financial support to some of the authors of scientific articles, and that some of the articles made points that Wyeth had made in its previous promotions, simply do not rise to the level that would support a reasonable inference that Wyeth controlled the articles' contents.

Statutory Claims

Plaintiffs' claims under the UCL and the CLRA are subject to a more lenient standard for pleading than their fraud claims. (*Gutierrez v. Carmax Auto Superstores California* (2018) 19 Cal.App.5th 1234, 1261 [statutory

claims "must be stated with reasonable particularity," rather than the specificity required for claims of fraud].) Even so, we conclude that plaintiffs' allegations here concerning Wyeth's off-label promotion of amiodarone not only lack the specificity required to plead claims for fraud, they also lack the reasonable particularity required to plead claims under the UCL and CLRA.

Unfair Competition Law

The UCL defines unfair competition to include "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." (Bus. & Prof Code., § 17200.) In general, the UCL requires plaintiffs to show that the advertising or promotional practices at issue are likely to deceive a " 'reasonable consumer,'—that is, the 'ordinary consumer acting reasonably under the circumstances' " is likely to be deceived by the advertising or promotional practices at issue. (*Shaeffer v. Califia Farms, LLC* (2020) 44 Cal.App.5th 1125, 1135 (*Shaeffer*).) But where, as here, " 'the advertising or practice is targeted to a particular group or type of consumers, . . . the question whether it is misleading to the public will be viewed from the vantage point of the members of the targeted group, not others to whom it is not primarily directed.' " (*In re Vioxx Class Cases* (2009) 180 Cal.App.4th 116, 130.)

Plaintiffs allege that Wyeth's off-label promotional activities constituted unlawful business practices because they were likely to mislead plaintiffs, their physicians, and the general public. With respect to the likelihood of misleading plaintiffs and the general public, plaintiffs' claims do not survive demurrer because plaintiffs have not alleged promotional activities aimed at, or likely to mislead, plaintiffs themselves or the general public. The only promotional activities that plaintiffs allege with any particularity concern Wyeth's advertising, which plaintiffs allege was

intended for physicians, and Wyeth's support of research that was ultimately published in professional journals.

As we have explained, plaintiffs have not alleged facts supporting a reasonable inference that Wyeth is responsible for the statements in third-party publications. Therefore, plaintiffs' UCL claims rest on their allegations concerning Wyeth's own advertising. To allege claims under the UCL, plaintiffs must allege they have "suffered injury in fact and [have] lost money or property as a result of the unfair competition." (Bus. & Prof. Code, § 17204.) This is a causation requirement, and plaintiffs' allegations fall short in this respect for two reasons. First, even if Wyeth's promotion was likely to mislead a reasonable physician, plaintiffs do not allege with any particularity that Wyeth's advertising influenced their physician's decisions to prescribe amiodarone for them. Second, as explained above, Wyeth's conduct in promoting amiodarone to physicians is too remote from plaintiffs' use of amiodarone to have caused their injuries from taking a drug that was prescribed for them more than 10 years after the last of the alleged promotions.

Consumers Legal Remedy Act

The CLRA defines as unlawful certain "unfair methods of competition and unfair or deceptive acts . . . undertaken by any person in a transaction intended to result or that results in the sale . . . of goods or services to any consumer." (Civ. Code, § 1770, subd. (a).) Plaintiffs argue that their allegations of Wyeth's off-label promotion support claims that Wyeth "[m]isrepresent[ed] the source, sponsorship, approval, or certification" of amiodarone (*id.*, subd. (a)(2)) and "represent[ed] that [amiodarone has] sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that [it does] not have" (*id.*, subd. (a)(5)); "represent[ed] that

[amiodarone is] of a particular standard, quality, or grade" when it was of another (*id.*, subd. (a)(7)); "represent[ed] that a transaction . . . involves rights, remedies, or obligations . . . that are prohibited by law" (*id.*, subd. (a)(14)); and "represent[ed] that [amiodarone] has been supplied in accordance with a previous representation when it has not" (*id.*, subd. (a)(16).) The CLRA, like the URL "views representations through the eyes of 'the reasonable consumer.' " (*Shaeffer, supra*, 44 Cal.App.5th at p. 1136.)

The allegations concerning subdivisions (a)(7), (14), and (16) of Civil Code section 1770 are mere conclusions of law that do not survive demurrer: plaintiffs simply restate the statutory provisions in their complaint, and provide no supporting allegations concerning the supposed representations at issue.

With respect to subdivisions (a)(2) and (5) of Civil Code section 1770, plaintiffs rely on their allegations that Wyeth downplayed the dangers of amiodarone, falsely promoted it as a safe treatment for atrial fibrillation, and did not reveal that amiodarone had not been approved by the FDA for the treatment of atrial fibrillation. But as we have discussed, the only deceptive or misleading conduct by Wyeth alleged in the complaint is Wyeth's advertising to physicians in the 1980's and early 1990's, which does not appear to address the use of amiodarone for atrial fibrillation.[12] In any event, even if we assume that the advertising would have been misleading to a

[12] We disregard plaintiffs' argument that their allegations concerning the lack of disclosures to plaintiffs support a claim under the CLRA. In that respect, plaintiffs are apparently relying on their allegations and claims concerning the Medication Guide, which are preempted, as discussed above. We also disregard plaintiffs' allegations that a CLRA claim arises from promotional programs geared to pharmacists, because plaintiffs do not allege that their purchases of amiodarone had any connection to disclosures made or not made to their pharmacists.

reasonable physician, we conclude that it is too remote in time from the prescribing of the drug to plaintiffs and their ensuing purchase of the drug. Just as we concluded that Wyeth's conduct in promoting amiodarone to physicians is, as a matter of law, too remote from plaintiffs' use of amiodarone to have caused their injuries from taking a drug prescribed for them more than 10 years later, we conclude it is too remote from plaintiffs' purchase of the drug to have resulted in the sales of amiodarone that are at issue. (See *Massachusetts Mutual Life Ins. Co. v. Superior Court* (2002) 97 Cal.App.4th 1282, 1292 [CLRA action requires plaintiffs to "show not only that a defendant's conduct was deceptive but that the deception caused them harm"].)

DISPOSITION

The judgment is affirmed. Defendants shall recover their costs on appeal.

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Richman, Acting P.J.

WE CONCUR:

_____
Stewart, J.

_____
Van Aken, J.*

A161023, A161762, *Amiodarone Cases*

* Judge of the San Francisco Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

Court: Alameda County Superior Court

Trial Judge: Hon. Brad Seligman

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