NOT FOR PUBLICATION

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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

RAYMOND N. RAYES, Plaintiff-Appellant, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant-Appellee, and NOVARTIS AG; NOVARTIS PHARMA AG; NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.; NOVARTIS PHARMACEUTICALS UK LIMITED; ALCON RESEARCH, LLC, Defendants.	No. 21-55723 D.C. No. 5:21-cv-00201-JGB-KK MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Jesus G. Bernal, District Judge, Presiding

Argued and Submitted March 10, 2022
San Francisco, California

Before: WALLACE, S.R. THOMAS, and McKEOWN, Circuit Judges.

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

Raymond N. Rayes alleges that he suffered eye injuries after receiving injections of Beovu, a drug manufactured by Novartis Pharmaceuticals. Rayes sued Novartis, alleging: strict liability failure to warn (Count I); negligence (Count II); fraudulent misrepresentation (Count III); and negligent misrepresentation (Count IV). The district court dismissed the complaint for failure to state a claim and for failure to plead fraud with particularity. We have jurisdiction under 28 U.S.C. § 1291. We review de novo dismissals under Rule 12(b)(6) and under Rule 9(b). *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1102 (9th Cir. 2003). We affirm in part, reverse in part, and remand in part.

The district court properly disregarded the complaint's allegations of post-marketing adverse event reports that post-dated Rayes's final injection of Beovu on January 10, 2020. California recognizes a cause of action in strict liability for the "failure to warn about the known or reasonably scientifically knowable dangerous propensities" of prescription drugs. *Carlin v. Super. Ct.*, 920 P.2d 1347, 1348 (Cal. 1996). However, California does not recognize a continuing duty to warn in such cases. *Brown v. Super. Ct.*, 751 P.2d 470, 482–83 (Cal. 1988). For his negligence claim, although Rayes argues that additional post-treatment warnings "could have served to minimize or avoid his ultimate injury," the complaint makes no such allegation and thus fails to plead causation. We leave to the district court's discretion whether to entertain a motion to amend the complaint.

We reverse dismissal of Counts I and II, and remand for further proceedings on these counts. Although the district court properly construed Count II as a negligent failure-to-warn claim (and not as a failure-to-test claim), neither claim was preempted. Rayes sufficiently pleaded the existence of "newly acquired information" in the form of several post-marketing adverse event reports of retinal vasculitis or retinal vascular occlusion that were reported to Novartis before Rayes's final dose of the drug, and multiple cases of retinal vascular occlusion or retinal vasculitis in the clinical trials. The "changes being effected" ("CBE") regulation contemplates not only new warnings, but also strengthened warnings for risks that already appear on the initial label. 21 C.F.R. § 314.70(c)(6)(iii)(A); *see Wyeth v. Levine*, 555 U.S. 555, 569 (2009). Because Rayes has met this standard, Novartis bears the burden of showing on remand that there was "clear evidence" that the FDA would reject the change. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1677 (2019); *see also id.* at 1679 (stating that only "agency actions taken pursuant to the FDA's congressionally delegated authority" and "carrying the force of law" can constitute such clear evidence for preemption purposes).

Counts I and II are not preempted because Rayes does not allege fraud on the FDA. *See Buckman Co. v. Plaintiffs' Leg. Comm.*, 531 U.S. 341, 353 (2001). His strict liability and negligence claims are based on Novartis's duty to warn consumers and physicians, not its duty to submit accurate data to the FDA. State-law negligence

and strict liability claims premised on a duty to warn consumers or their physicians are not preempted, even when that duty "parallels" federal requirements. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013) (en banc), *cert. denied*, 573 U.S. 930 (2014); *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040–41 (9th Cir. 2015).

We also reverse dismissal of Counts III and IV for failure to plead fraud with particularity—but only as to fraud claims based on the product label. Fed. R. Civ. P. 9(b). Rule 9(b) requires that a party alleging fraud "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The rule requires that "[a]verments of fraud . . . be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Vess*, 317 F.3d at 1106 (quoting *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)). Many of Rayes's allegations fall short of this standard. First, the complaint does not plead "how" Rayes was defrauded by statements that post-date his final dose on January 10, 2020. Second, while the complaint alleges that "in January 2020" certain scientists affiliated with Novartis published a report that intentionally misrepresented data from the HAWK and HARRIER Phase III trials, it does not indicate whether the report pre-dated or post-dated his final dose on January 10, 2020. Finally, Rayes alleges that Novartis "encouraged ophthalmologists to switch their patients to Beovu" from safer alternatives, but does not identify the marketing or promotional materials that he

believes were false. Rayes's claims based on these vague allegations fail under Rule 9(b).

However, Rayes's allegation that Novartis intentionally understated the risks of Beovu on the product label satisfies Rule 9(b)'s particularity requirement. Novartis stated that only 1% of patients experienced retinal vasculitis and retinal vascular occlusion in the clinical trials, but the real number was 3.3%. This misrepresentation was allegedly directed at "the medical community and the consuming public," including Rayes and his doctor. His doctor allegedly relied on this misrepresentation in deciding to prescribe Beovu, thus causing harm to Rayes. These allegations specify the fraudulent statement, explain why the statement was fraudulent, and plausibly state that Rayes's physician relied on the misreported data. These allegations should not have been dismissed.

The parties shall bear their own costs on appeal.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED IN PART.