NOT FOR PUBLICATION

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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

IGOR ROSHKOVAN, DDS, MSc; an individual, Plaintiff - Appellant, v. BRISTOL-MYERS SQUIBB COMPANY, a Delaware corporation, Defendant - Appellee.	No. 23-2912 D.C. No. 2:21-cv-08590-FWS-AGR MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Fred W. Slaughter, District Judge, Presiding

Argued and Submitted November 20, 2024
Pasadena, California

Before: RAWLINSON, CHRISTEN, and JOHNSTONE, Circuit Judges.

Igor Roshkovan (Roshkovan) appeals the district court's dismissal of his claims against Bristol-Myers Squibb Company (Bristol-Myers) for failure to state a claim. We have jurisdiction under 28 U.S.C. § 1291. Reviewing *de novo,* we affirm. *See Coalition for ICANN Transparency, Inc. v. VeriSign, Inc*., 611 F.3d

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

495, 501 (9th Cir. 2010), *as amended*.

On November 9, 2007, the United States Food and Drug Administration (FDA) approved Sprycel, a prescription medication manufactured by Bristol-Myers. The approval included approval of the accompanying warning labels. *See Wyeth v. Levine*, 555 U.S. 555, 568 (2009). The 2017/2018 update to Sprycel's warning label approved by the FDA includes warnings of bleeding related events, visual impairment, and eye hemorrhaging.

Roshkovan began taking Sprycel in July of 2019, and experienced acute onset visual loss due to retinal hemorrhaging in his right eye. Roshkovan filed a *pro se* complaint in state court alleging strict liability and negligence claims, asserting that Bristol-Myers failed to warn that Sprycel could cause vision loss due to retinal hemorrhaging. After removal to federal court, the district court granted Bristol-Myers's motion to dismiss on the bases that Roshkovan failed to adequately allege causation and that the claims were preempted by federal law.

A complaint is subject to dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure if the complaint does not allege a claim that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To successfully allege a failure-to-warn claim that is not preempted by the Food, Drug, and Cosmetic Act (FDCA), a plaintiff must plausibly plead a labeling deficiency that the defendant could have corrected under the FDA's Changes Being Effected (CBE) regulation.

See 21 C.F.R. § 314.70(c)(6)(iii); *see also Wyeth,* 555 U.S. at 568-69. The CBE regulation permits "drug manufacturers to change a label to reflect newly acquired information if the changes add or strengthen a . . . warning." *Merck Sharp & Dohme Corp. v. Albrecht,* 587 U.S. 299, 314–15 (2019) (citation and internal quotation marks omitted). The FDA defines "newly acquired information" as "data, analyses or other information not previously submitted to the Agency, which may include . . . data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses)" if the information reveals new or greater risks from taking the drug. 21 C.F.R. § 314.3(b)

Roshkovan's complaint contains allegations related to: (1) lapses in clinical trials; (2) failure to report adverse events involving Sprycel; (3) medical journal articles published between 2010 to 2018; and (4) defects in the information provided by Bristol-Myers to educate patients and their physicians. Roshkovan did not plausibly allege how the lapses in previous clinical trials resulted in "newly acquired information" that created a labeling deficiency correctable through the CBE regulation. *Id.* at 314. The adverse events alleged in Roshkovan's complaint were reported by Bristol-Myers to the FDA through a public dashboard maintained by the FDA. Thus, the district court rejected Roshkovan's allegation that the information was unknown to the FDA. Similarly, the articles cited by Roshkovan

discuss various symptoms experienced by patients taking Sprycel, including loss of vision and retinal hemorrhages. However, these articles are not "newly acquired information" because they were published either before or contemporaneously with the 2017/2018 FDA approval of Bristol-Myers' updated warning labels, the articles did not encompass new analysis of previously submitted data, and the symptoms described in the articles are listed in the 2017/2018 warning label. *Wyeth*, 555 U.S. at 569. Finally, nothing in the informational brochure developed by Bristol-Myers to educate patients and their physicians was identified as "newly acquired information." *Id.* In sum, Roshkovan failed to plausibly allege the existence of any "newly acquired information" that came to light between approval of the 2017/2018 label and 2019 when he was prescribed Sprycel. *Id.*

AFFIRMED.