UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEVADA

Ravindranath V. Purohit v. Abbott Laboratories Inc.

No. 2:25-cv-01026-JAD-EJY (D. Nev. Dec. 8, 2025) · No. 2:25-cv-01026-JAD-EJY · Decided December 8, 2025

OPINION

Purohit

PER CURIAM.

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF NEVADA

3 Case No.: 2:25-cv-01026-JAD-EJY Ravindranath V. Purohit, 4 Plaintiff Order Granting Motion to Dismiss 5 v. [ECF No. 12] 6 Abbott Laboratories Inc., 7 Defendant 8 9 Claiming that his "Trifecta" replacement heart valve failed prematurely, Ravindranath 10 Purohit sues Abbott Laboratories, which purchased the device's manufacturer, asserting a single 11 claim of strict products liability under Nevada law. Abbott Labs moves to dismiss, arguing that 12 the detailed federal process governing the approval of new medical devices expressly preempts 13 state-law claims that don't allege that the manufacturer departed from a particular requirement 14 that the Food and Drug Administration imposed. In response, Purohit doesn't name a particular 15 FDA requirement that was violated, focusing instead on his valve's failure and Abbott Labs' 16 removal of it from the market. But because Purohit doesn't identify a violation of a particular 17 FDA requirement as he must to meet the narrow exception to federal preemption, I grant Abbott 18 Labs' motion and dismiss this case. 19 Background 20 The Food and Drug Administration may approve new medical devices.1 Class III devices 21 receive the highest level of scrutiny and require premarket approval from the FDA.2 The 22 1 Weber v. Allergan, Inc., 940 F.3d 1106, 1110 (9th Cir. 2019). 23 2 Id. ("The MDA established three classes of medical devices, with Class III receiving the most FDA scrutiny."). 1 Trifecta Valve is a replacement heart valve that received Class III premarket approval from the 2 FDA more than a decade ago.3 But in recent years, Abbott Labs received reports that some 3 Trifecta Valves were deteriorating faster than expected.4 So Abbott Labs voluntarily removed 4 the Trifecta Valve from the market.5 5 While it was on the market, Ravindranath Purohit received a Trifecta Valve to replace his 6 faulty aortic valve.6 Nine years later, Purohit went to an emergency room in Las Vegas, Nevada, 7 complaining of increasing shortness of breath and bilateral lower extremity swelling.7 Doctors 8 diagnosed him with several heart-related conditions,8 and Purohit received aortic-valve 9 replacement surgery to replace his Trifecta Valve.9 Based on this incident, Purohit believes that 10 he received a defective Trifecta Valve that deteriorated faster than expected.10 11 So Purohit sues, theorizing that his Trifecta Valve had a manufacturing defect and Abbott 12 Labs is strictly liable for it.11 Abbott Labs moves to dismiss for failure to state a claim, arguing 13 that federal law preempts any state-

law claim that imposes a requirement on a Class III medical 14 15 3 Abbott Labs requests that this court take judicial notice that the Trifecta Valve received Class 16 III premarket approval. Federal Rule of Evidence 201 allows a court to "judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined 17 from sources whose accuracy cannot reasonably be questioned." Given that neither side disputes the Class III classification and FDA public records support that, I take judicial notice under Rule 18 201. See ECF No. 12-1. 4 ECF No. 1-2 at 6. 19 5 Id. 20 6 Id. at 5. 21 7 Id. at 6. 8 Id. 22 9 Id. 23 10 See id. 11 See id at 7. 1 device that "is different from, or in addition to, any requirement" imposed by the FDA.12 2 According to Abbott Labs, Purohit's products-liability claim effectively seeks to impose such an 3 impermissible requirement because he doesn't allege that his Trifecta Valve deviated from any 4 specific FDA requirement.13 Purohit argues that the presence of a defect, his allegation that 5 Abbott Labs knew of the defect, and the Trifecta Valve's withdrawal from the market is 6 sufficient to show that the manufacturer failed to comply with FDA requirements.14 7 Discussion 8 Federal pleading standards require a plaintiff's complaint to include enough factual detail 9 to "state a claim to relief that is plausible on its face."15 This "demands more than an unadorned, 10 the-defendant-unlawfully-harmed-me accusation";16 a plaintiff must make direct or inferential 11 factual allegations about "all the material elements necessary to sustain recovery under some 12 viable legal theory."17 A complaint that fails to meet this standard must be dismissed.18 13 A. Federal Preemption under the Food, Drug, and Cosmetic Act and the Medical 14 Device Amendments. 15 Abbott Labs raises federal preemption as a defense.19 The Constitution's Supremacy 16 Clause provides that federal law is "the supreme Law of the Land"20 and, as a result, "state laws 17 12 ECF No. 12 at 11 (quoting 21 U.S.C. § 360k(a)). 18

13 Id. at 18.

19 14 ECF No. 16 at 3–5. 15 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). 20 16 Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). 21 17 Twombly, 550 U.S. at 562 (quoting Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1106 (7th Cir. 1984)). 22

18 Id. at 570.

23 19 ECF No. 12 at 3. 20 U.S. Const. art. VI, cl. 2. 1 that conflict with federal law are without effect."21 In determining the preemptive scope of a 2 federal law, the "ultimate touchstone" in preemption analysis is congressional purpose.22 3 "Congress may indicate pre-emptive intent through a statute's express language or through its 4 structure and purpose."23 But preemption analysis "starts with the assumption that the historic 5 police powers of the States are not to be superseded by Federal Act unless that is the clear and 6 manifest purpose of Congress."24 7 Congress enacted the Medical Device Amendments to the Food, Drug, and Cosmetic Act 8 in response to "the inability of the common-law tort system to manage the risks associated with 9 dangerous [medical] devices."25 The Amendments thus swept "back some state obligations and 10 imposed a regime of detailed federal oversight."26 The oversight regime tasks the FDA with 11 screening new medical devices before they enter the market.27 The FDA divides medical devices

12 into classes based on their risk, with Class III devices posing the highest risk.28 The FDA 13 performs a cost-benefit analysis when deciding whether to give premarket approval to a Class III 14 device.29 But the FDA's premarket approval of a Class III device "does not guarantee that every 15 device manufactured in that process will work"30—it may approve a device that offers great 16 21 Altria Grp., Inc. v. Good, 555 U.S. 70, 76 (2008) (cleaned up). 17 22 Id. 18 23 Id. 19 24 Cipollone v. Liggett Grp., 505 U.S. 504, 516 (1992) (cleaned up). 25 Riegel v. Medtronic, Inc., 552 U.S. 312, 315–16 (2008). 20 26 Id. 21 27 Weber, 940 F.3d at 1110. 22 28 Id. 29 See Riegel, 552 U.S. at 318; Weber, 940 F.3d at 1110. 23 30 Weber, 940 F.3d at 1111 (quoting Banner v. Cyberonics, Inc., 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010)). 1 potential medical benefits knowing that it will sometimes fail.31 And "[o]nce a [Class III] device 2 has received premarket approval, the [Amendments] forbid[] the manufacturer to make, without 3 FDA permission, changes in design specifications, manufacturing processes, labeling, or any 4 other attribute that would affect safety or effectiveness."32 5 The Amendments also expressly preempt state laws that impose any requirement on a 6 Class III device that "is different from, or in addition to, any requirement" imposed by the 7 FDA.33 The United States Supreme Court has interpreted this preemption clause to mean that 8 only "parallel" claims are not preempted, which are state-law claims alleging that a Class III 9 medical device deviated from an FDA requirement for that device34 and that deviation 10 simultaneously violated state tort law.35 For example, "if the FDA's pre-market approval 11 'required 400-degree welds but the manufacturer used a 300-degree welding process,' that could 12 show violation of an FDA requirement and establish a parallel state-law claim."36 13 B. The Food, Drug, and Cosmetic Act expressly preempts Purohit's claim because he 14 doesn't allege a violation of any particular FDA requirement. 15 The Trifecta Valve is a Class III medical device.37 To avoid having his state-law 16 products-liability claim preempted, Purohit must plausibly allege that his Trifecta Valve deviated 17 18 31 Id. at 1111–12. 32 Riegel, 552 U.S. at 319 (cleaned up) (citing 21 U.S.C. § 360e(d)(6)(A)(i)). 19 33 21 U.S.C. § 360k(a); Riegel, 552 U.S. at 316. 20 34 Weber, 940 F.3d at 1111. 21 35 McClellan v. I-Flow Corp., 776 F.3d 1035, 1040 (9th Cir. 2015); Stengel v. Medtronic Inc., 704 F.3d 1224, 1228 (9th Cir. 2013) ("The rule that emerges from these cases is that the MDA 22 does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA."). 23 36 Weber, 940 F.3d at 1111 (cleaned up). 37 Supra at n.3. 1 from a particular FDA requirement.38 Purohit seems to point to allegations that could support a 2 typical products-liability claim: his heart valve needed to be replaced, and Abbott Labs 3 voluntarily withdrew this product from the market after evidence emerged that this product 4 deteriorated faster than rival devices.39 But Abbott Labs contends that such allegations are 5 insufficient to establish a non-preempted parallel claim. 6

1. Purohit cannot rely on the defect or the Trifecta Valve's withdrawal from the

7 market alone to suggest that the manufacturer deviated from FDA requirements. 8 In his complaint, Purohit alleges that his Trifecta Valve deviated from FDA requirements 9 because it

had “potential early structural valve deterioration.”40 But the Ninth Circuit’s decision 10 in Weber v. Allergan, Inc. stands for the proposition that a defect alone does not establish that a 11 manufacturer deviated from FDA requirements.41 In that case, Nicole Weber sued the 12 manufacturer of her Class III premarket-approved breast implants after the implants began to 13 leak silicone gel.42 When the manufacturer moved for summary judgment based on federal 14 preemption, Weber countered with expert testimony that a leak amount “exceeding the amount 15 specified by its product labeling” was sufficient to show “a ‘departure from the manufacturer’s 16 specifications’ and a ‘defect.’”43 But the Ninth Circuit rejected that argument because the 17 38 See, e.g., Vieira v. Mentor Worldwide, LLC, 845 F. App’x 503, 506 (9th Cir. 2021) (affirming 18 dismissal because “[f]or their manufacturing defect claims to survive express preemption under the MDA, [p]laintiffs must allege that [d]efendants ‘deviated from a particular pre-market 19 approval or other FDA requirement applicable to the Class III medical device.’”); see also Weber, 940 F.3d at 1111. 20 39 See ECF No. 16 at 3–4. 21 40 ECF No. 1-2 at 7. 22 41 Weber, 940 F.3d at 1112 (“[T]o survive MDA preemption, a plaintiff cannot simply demonstrate a defect or a malfunction.”). 23 42 Id. at 1109.

43 Id. at 112–13.

1 testimony didn’t establish that the defect happened because the defendant violated a specific 2 FDA manufacturing requirement.44 As the Weber court explained, “to survive [federal] 3 preemption, a plaintiff cannot simply demonstrate a defect or a malfunction and rely on res ipsa 4 loquitur to suggest only . . . that the thing speaks for itself.”45 “Instead, for a state law claim to 5 survive express preemption,” “a plaintiff must show that the defendant deviated from a 6 particular pre-market approval or other FDA requirement applicable to the Class III 7 medical device.”46 And because Weber failed to name a particular FDA requirement that the 8 manufacturer violated, the Ninth Circuit affirmed the dismissal of her claim.47 9 Purohit contends in his response brief that he alleges a parallel claim because his claim is 10 based on the same defect that led Abbott Labs to withdraw the Trifecta Valve from the market.48 11 But a recall or withdrawal from the market doesn’t alone show noncompliance with a particular 12 FDA requirement. Courts have widely recognized that “product recalls do not create a 13 presumption that FDA requirements have been violated.”49 The FDA approves products 14 15 44 See id. 16 45 Id. at 1112 (cleaned up). 46 Id. (emphasis added). While Weber dealt with summary judgment, other circuits and 17 unpublished decisions of the Ninth Circuit have extended this rule to the motion-to-dismiss stage. See, e.g., Vieira, 845 F. App’x at 506. As the Eleventh Circuit held in Wolicki-Gables v. 18 Arrow International, Inc., “parallel claims must be specifically stated in the initial pleadings” and a “plaintiff must allege that the defendant violated a particular federal specification referring 19 to the device at issue.” Wolicki-Gables v. Arrow Int’l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011) (cleaned up); see also Weber, 940 F.3d at 1112 (citing Wolicki-Gables with approval). 20 47 Weber, 940 F.3d at 1113–14. 21 48 ECF No. 16 at 3 (“Plaintiff provides parallel reasons for the defects for which the FDA published notice to physicians on February 27,

2023."). Abbott Labs also points out that it 22 withdrew the Trifecta Valve from the market based on reports that it was failing after only five years, not nine years like Purohit's. ECF No. 17 at 6–7. 23 49 Erickson v. Bos. Sci. Corp., 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011); see also Weber, 940 F.3d at 1114 (citing that language in Erickson with approval). 1 knowing that there is a possibility that a fully compliant product can fail.50 So the withdrawal of 2 a product from the market does not automatically mean the product didn't meet FDA 3 requirements.51 4 Purohit's complaint thus lacks the necessary allegations for his claim to be considered a 5 parallel one. The only relevant allegation in his complaint is that "[t]he subject device implanted 6 in [Purohit] was not manufactured in conformity with the FDA's [premarket approval] 7 specifications and requirements for such devices" because it "was found to have potential early 8 structural valve deterioration in patients who received these valves."52 The complaint also notes 9 that Abbott Labs withdrew the Trifecta Valve from the market.53 10 But stripped of Purohit's bald, conclusory statements that his Trifecta Valve didn't follow 11 FDA requirements, his complaint simply doesn't support a parallel claim. Purohit doesn't 12 identify which FDA requirement was violated or how his Trifecta Valve specifically deviated 13 from those requirements. Without linking these allegations to a violation of a particular FDA 14 requirement, Purohit has failed to allege facts sufficient to avoid federal preemption. 15 16 17 18 50 Weber, 940 F.3d at 1111 ("[T]he FDA's pre-market approval of the process by which a Class III device is manufactured 'does not guarantee that every device manufactured in that process 19 will work.'"). 20 51 See, e.g., Laucella v. Medtronic, Inc., 2025 WL 1018414, at *7 (C.D. Cal. Apr. 4, 2025) ("The fact that a challenged device was included in a product recall does not create a presumption that 21 the device was not manufactured in compliance with the PMA requirements."); see also Walker v. Medtronic, Inc., 670 F.3d 569, 580 (4th Cir. 2012) ("[A Class III] device's safety and 22 reliability cannot be guaranteed indefinitely in the 'extremely hostile environment of the human body,' where myriad other factors external to the device are brought to bear."). 23 52 ECF No. 1-2 at 7.

53 Id. at 6.

1 2. Purohit's remaining argument doesn't suggest a deviation. 2 Purohit's remaining argument does not counsel a different result. Purohit confusingly 3 argues that Abbott Labs deviated from FDA requirements because it "did not timely advise the 4 public of . . . problems with the device" and, because it allegedly "knew of this problem," it 5 should have pulled the product and notified the public earlier.54 But Purohit doesn't point to any 6 FDA requirement or any relevant statute or regulation that imposes such a requirement.55 Even 7 if he had, such an allegation is irrelevant for a products-liability claim in which Purohit must 8 allege that the manufacturing of the product deviated from a particular FDA requirement. So I 9 dismiss his claim because it is preempted by the Food, Drug, and Cosmetic Act.56 10 C. Amending Purohit's complaint would be futile. 11 In his response, Purohit requests leave to amend his complaint to add "more detail" to his 12 claim.57 Abbott Labs opposes that request because Purohit has not identified what details he 13 14 54 ECF No. 16 at 3 15 55 See generally ECF Nos. 1-2, 16. While such allegations may have

some relevance for a 16 failure-to-warn claim if Abbott Labs had failed to inform the FDA, a claim premised on failing to inform the public is likely preempted. See, e.g., Stengel, 704 F.3d at 1234 (Watford, J., 17 concurring) ("[A]ny attempt to predicate the Stengels' claim on an alleged state law duty to warn doctors directly" about an unreported defect in the product "would have been expressly 18 preempted under 21 U.S.C. § 360k."); Martin v. Medtronic, Inc., 2017 WL 825410, at *7 (E.D. Cal. Feb. 24, 2017) ("[P]laintiff seeks to impose liability on defendants for failing to provide 19 warning of medical device risks not only to the FDA, but also to "medical providers, and consumers such as Plaintiff." . . . [b]ecause plaintiff here seeks to impose a duty to warn onto 20 defendants that is broader and in addition to those required by federal law, plaintiff's failure to warn cause of action is expressly preempted."). 21 56 Abbott Labs also moves to dismiss on the separate theory that Purohit failed to state a manufacturing-defect claim under Nevada law because his "[c]omplaint is completely devoid of 22 any facts regarding what the alleged manufacturing defect with his Trifecta Valve" was. ECF No. 12 at 20–21. Because I dismiss Purohit's complaint based on preemption, I do not reach this 23 additional argument. 57 ECF No. 16 at 4. 1 would add to his complaint if given a chance to amend.58 Although the court "shall grant leave 2 to amend freely when justice so requires,"59 leave to amend should be withheld if the 3 deficiencies cannot be cured and further amendment would be futile.60 4 A more "detailed" products-liability claim would not save Purohit's complaint. Only an 5 amendment identifying a particular FDA requirement that was violated would state a parallel 6 claim here, and the exception to federal preemption in this context is "narrow."61 But in his 7 request to amend, Purohit did not identify any such requirement or explain how "more detail" 8 would allege a parallel claim.62 And given Purohit's current allegations, he likely could not 9 allege such a claim without identifying a wholly new theory of why the Trifecta Valve was 10 defective. Nothing Purohit provided indicates that he would be able to do so. So I deny Purohit 11 leave to amend because further amendment would be futile.63 12 13 14 15 58 ECF No. 17 at 9–10. 16 59 Lopez v. Smith, 203 F.3d 1122, 1130 (9th Cir. 2000) (cleaned up). 17 60 Wheeler v. City of Santa Clara, 894 F.3d 1046, 1059 (9th Cir. 2018) ("Leave to amend may be denied if the proposed amendment is futile or would be subject to dismissal."). 18 61 Weber, 940 F.3d at 1114. 19 62 See ECF No. 16 at 4. 63 Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1052 (9th Cir. 2008) ("Appellants fail to state 20 what additional facts they would plead if given leave to amend. . . . Accordingly, amendment would be futile."); Puri v. Khalsa, 674 F. App'x 679, 684 (9th Cir. 2017) ("Because the plaintiffs 21 do not identify what additional facts they would plead if they were granted leave to amend, the court did not abuse its discretion by denying leave to amend."); Gardner v. Martino, 563 F.3d 22 981, 991 (9th Cir. 2009) ("[T]he district court did not abuse its discretion when it denied Appellants' first request to amend the complaint because Appellants did not propose any new 23 facts or legal theories for an amended complaint and therefore gave the Court no basis to allow an amendment."). 1 Conclusion 2 IT IS THEREFORE ORDERED that Abbott Labs' motion to dismiss [ECF No. 12] is 3|GRANTED. Purohit's complaint is DISMISSED as preempted by the

Food, Drug, and 4! Cosmetic Act, and the Clerk of Court is directed to CLOSE THIS CASE. 5 U.S. District JudgéJennifer\A/ Dorsey

7 December 8, 2025

8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 11