UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

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DEBORAH FUST, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED; AND EDWARD PIMENTEL, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, Plaintiffs, v. GILEAD SCIENCES, INC., A DELAWARE CORPORATION REGISTERED TO DO BUSINESS AND HEADQUARTERED IN CALIFORNIA, Defendant.	No. 2:23-cv-2853 WBS DB MEMORANDUM AND ORDER

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Plaintiffs Deborah Fust and Edward Pimentel originally filed this putative class action against defendant Gilead Sciences, Inc. ("Gilead") in Shasta County Superior Court, seeking monetary and equitable relief pursuant to California's Consumers Legal Remedies Act (Claim 1); False Advertising Law (Claim 2); Unfair Competition Law (Claim 3); money had and

received (Claim 4); negligent misrepresentation (Claim 5); and unjust enrichment (Claim 6). Plaintiffs allege that defendant exaggerated the benefits and downplayed the dangers of its drug remdesivir (sold under the brand name Veklury), an antiviral medication indicated for COVID-19 treatment.

The court now considers plaintiffs' motion to remand (Docket No. 28) and defendant's motion to dismiss (Docket No. 10).

I. Motion to Remand

A. CAFA Jurisdiction

Defendant removed this action from Shasta County Superior Court pursuant to the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d). (See Removal (Docket No. 1) at 2.) CAFA gives federal district courts original jurisdiction over class actions in which the class members number at least 100, at least one plaintiff is diverse in citizenship from any defendant, and the aggregate amount in controversy exceeds $5 million, exclusive of interest and costs. 28 U.S.C. § 1332(d)(2).

Plaintiffs argue that defendant has not sufficiently demonstrated that the amount in controversy under CAFA is met. In the alternative, plaintiffs urge the court to decline jurisdiction on discretionary grounds, notwithstanding the court's diversity jurisdiction under CAFA.

1. Amount in Controversy Under CAFA

"[W]hen the defendant's assertion of the amount in controversy is challenged by plaintiffs in a motion to remand, the Supreme Court has said that both sides submit proof and the

court then decides where the preponderance lies." Ibarra v. Manheim Invs., Inc., 775 F.3d 1193, 1198 (9th Cir. 2015) (citing Dart Cherokee Basin Operating Co., LLC v. Owens, 574 U.S. 81, 88-89 (2014)). Proof "includes affidavits, declarations, or 'other summary-judgment-type evidence relevant to the amount in controversy at the time of removal.'" Sifuentes v. Roofline, Inc., No. 2:20-CV-00052 WBS KJN, 2020 WL 1303796, at *1 (E.D. Cal. Mar. 19, 2020) (citing Ibarra, 775 F.3d at 1197). See also Gonzales v. CarMax Auto Superstores, LLC, 840 F.3d 644, 648-49 (9th Cir. 2016) (amount in controversy includes "damages (compensatory, punitive, or otherwise) and the cost of complying with an injunction, as well as attorneys' fees awarded under fee shifting statutes").

Plaintiffs seek a corrective advertising campaign and recall of advertising materials; disgorgement of defendant's revenues from Veklury; and actual and punitive damages and attorney's fees. (See generally Compl., Prayer for Relief.) Defendant argues that any one of these remedies likely places the amount in controversy north of $5 million, and at any rate the remedies taken together clearly surpass the $5 million bar.

The court agrees. A corrective campaign alone, for instance, is more likely than not to cost defendant over $5 million. In support, defendant provides several cases estimating costs of a corrective campaign that range from $9.8 million to $41.8 million. See Stone Brewing Co., LLC v. MillerCoors LLC, 3:18-cv-00331-BEN-MDD, 2023 WL 6450199, at *8 (S.D. Cal. Sept. 28, 2023) ($41.8 million); U-Haul v. Jartran, Inc., 793 F.2d 1034 (9th Cir. 1986) ($13.6 million); San Diego Comic Convention v.

Dan Farr Prods., 14-cv-1865 AJB (JMA), 2017 WL 4869152, at *2 (S.D. Cal. Oct. 27, 2017) ($9.8 million); Cross-Fit, Inc. v. Nat'l Strength & Conditioning Ass'n, 14-cv-1191-JLS(KSC), 2018 WL 3491854, at *7 (S.D. Cal. July 18, 2018) ($15 million). Defendant also points out that in 2009, the California Attorney General announced an agreement with Bayer Corporation regarding its oral contraceptives, requiring Bayer to run a corrective advertising campaign that cost $20 million. (See Removal at 4 & n.2.)

Plaintiffs, by contrast, offer no competing facts bearing on the likely cost of a corrective campaign, or on any of the other injunctive or monetary relief that they seek. Instead, plaintiffs only assert the following: "[D]efendant's analysis purporting that the $5 million threshold is exceeded, is at best highly speculative." (Mot. to Remand (Docket No. 28) at 13.)

As the court must presently "decide[] where the preponderance lies" after weighing both sides' proof, Ibarra, 775 F.3d at 1198, the court concludes that the amount in controversy is met, and that it accordingly has jurisdiction over this suit pursuant to CAFA.

2. CAFA's Discretionary Exception

Plaintiffs also urge the court to decline jurisdiction under 28 U.S.C. § 1332(d)(3), which provides that a court may, "in the interests of justice and looking at the totality of the circumstances," decline jurisdiction if the citizenship of between one-third and two-thirds of a putative class, the citizenship of the primary defendants, and the state in which the action was originally filed are all the same state. See id. §

1332(d)(3).

Plaintiffs assert, without support, that it "seems reasonable enough" to assume that at least one-third of the putative class here are California citizens because of California's large population and its "massive healthcare infrastructure." (Mot. to Remand at 14.) This is not enough. "Once CAFA jurisdiction has been established . . . the burden falls on the party seeking remand . . . to show that an exception to CAFA jurisdiction applies. To meet this burden, the moving party must provide some facts in evidence from which the district court may make findings regarding class members' citizenship." Adams v. W. Marine Prod., Inc., 958 F.3d 1216, 1221 (9th Cir. 2020) (cleaned up). See also Brinkley v. Monterey Fin. Servs., Inc., 873 F.3d 1118, 1121 (9th Cir. 2017) ("Congress passed CAFA with the overall intent . . . to strongly favor the exercise of federal diversity jurisdiction over class actions with interstate ramifications.") (cleaned up).

Accordingly, the court will not decline CAFA jurisdiction pursuant to Section 1332(d)(3).

B. *Quackenbush, Saldana, Granato*

The remainder of plaintiffs' arguments for remand, such as they are, center on three cases that plaintiffs devote entire pages of their briefs to excerpt from. Due to the sheer weight that plaintiffs seem to put on these cases, the court addresses the relevance of each in turn.

Quackenbush. Plaintiffs appear to cite to Quackenbush v. Allstate Ins. Co., 517 U.S. 706 (1996), for the proposition that remand here would affirm and duly show "deference to the

paramount interests of another sovereign [and] principles of comity and federalism." Id. at 723. (See Mot. to Remand at 9.)

The court is unpersuaded for two reasons. First, it is unclear how the question of remand here actually implicates material federalism concerns. Plaintiffs argue that so-styled "humanitarian remedies . . . are completely unavailable to the state plaintiffs in federal court according to the defendant's own arguments in its' [sic] lengthy motion to dismiss . . . ." (Mot. to Remand at 2-3.) Not only does this confusingly veer into the merits of defendant's pending motion to dismiss; it assumes, incorrectly, that defendant's federal defense premised on the Public Readiness and Emergency Preparedness Act ("PREP Act") can be asserted in federal court, but not in state court. Contra 42 U.S.C. § 247d-6d(a)(1) (PREP Act provides immunity "from suit and liability under Federal and State law.").

Second, Quackenbush discusses whether remand was proper pursuant to Burford abstention. See Quackenbush, 517 U.S. at 723-31 (citing Burford v. Sun Oil Co., 319 U.S. 315 (1943)). Burford abstention concerns when a federal court sitting in equity must decline to interfere with the proceedings or orders of state administrative agencies. See, e.g., New Orleans Pub. Serv., Inc. v. Council of City of New Orleans, 491 U.S. 350, 361 (1989) (summarizing Burford doctrine). It is plainly inapplicable here, and the court will not remand on this basis.

Saldana. Plaintiffs also argue that, because a Ninth Circuit panel in Saldana v. Glenhaven Healthcare LLC, 27 F.4th 679 (9th Cir. 2022) held that the PREP Act was not a "complete preemption" statute, remand is therefore proper.

The court disagrees. As already discussed, this court has jurisdiction over this case pursuant to CAFA. Whether or not plaintiffs' state law claims are completely preempted by federal law, thereby raising a federal question, is therefore irrelevant to the present motion.[1]

Granato. Plaintiffs quote extensively from Granato v. Apple Inc., No. 5:22-CV-02316-EJD, 2023 WL 4646038 (N.D. Cal. July 19, 2023), to apparently argue that the court lacks equitable jurisdiction over plaintiffs' claims. (See, e.g., Mot. to Remand at 11-13.)

Much of the decision in Granato discusses the Ninth Circuit's decision in Sonner v. Premier Nutrition Corp., 971 F.3d 834 (9th Cir. 2020), where a panel held that equitable relief is not available in federal court when there is an adequate legal remedy. See generally id. However, it is unclear to the court why Sonner would vitiate the court's already-established CAFA jurisdiction. (See supra § I.A.) First, plaintiffs in fact appear to seek damages as well as equitable relief. (See Compl., Prayer for Relief, subsection (i) (requesting "[a]n Order requiring Defendant to pay all actual and statutory damages permitted under the causes of action alleged herein . . . .").) Second, plaintiffs offer no binding authority requiring remand at the pleading stage for lack of power to grant equitable relief.

[1] See Hansen v. Group Health Coop., 902 F.3d 1051, 1057-58 (9th Cir. 2018) ("Once completely preempted, a state-law claim ceases to exist. [. . .] But that does not mean the plaintiff has no claim at all. Instead, the state-law claim is simply 'recharacterized' as the federal claim that Congress made exclusive." (citing Vaden v. Discover Bank, 556 U.S. 49, 61 (2009))) (cleaned up).

Neither can the court find any.[2]

Accordingly, the court will deny plaintiffs' motion to remand.[3]

II. Motion to Dismiss

Defendant moves to dismiss all of plaintiffs' claims on three independent grounds: (1) immunity pursuant to the PREP Act; (2) insufficient pleading under Federal Rules of Civil Procedure 8(a) and 9(b); and (3) immunity pursuant to the learned intermediary doctrine. (See generally Mot. to Dismiss (Docket No. 10).)

A. Facts

The court takes every following allegation from

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[2] Cf. Kim v. Walmart, Inc, No. 2:22-CV-08380-SB-PVC, 2023 WL 196919, at *2 (C.D. Cal. Jan. 13, 2023) ("Remand is inappropriate because diversity jurisdiction exists, and the Court's authority to hear this case does not depend on its equitable powers. [. . .] [Plaintiff] has sued not just for equitable relief -- for which equitable authority is required to award a remedy -- but also money damages, which is the archetypal form of legal relief."); Naseri v. Greenfield World Trade, Inc., No. SACV2101084CJCKESX, 2021 WL 3511040, at *1 (C.D. Cal. Aug. 10, 2021) ("But Sonner did not hold that failure to allege an inadequate legal remedy deprives a court of subject matter jurisdiction. Rather, Sonner held that failure to allege an inadequate legal remedy precludes a plaintiff from recovering at all. [. . .] [Sonner] shows that federal courts may exercise jurisdiction over equitable claims under the UCL and CLRA."); Lopez v. Cequel Commun., LLC, No. 2:20-CV-02242 TLN JDP, 2021 WL 4476831, at *2 (E.D. Cal. Sept. 30, 2021) (joining with Naseri and concluding "Sonner does not preclude courts from exercising jurisdiction over [purely equitable] claims"); Treinish v. iFit Inc., No. CV 22-4687-DMG (SKX), 2022 WL 5027083, at *4 (C.D. Cal. Oct. 3, 2022) ("[lack of equitable jurisdiction] does not justify remanding this case, because CAFA provides subject matter jurisdiction here").

[3] Defendant's request for judicial notice relating to the motion to remand (Docket No. 31-1) is denied as moot.

plaintiffs' complaint as true and draws every reasonable inference in favor of plaintiffs.

Defendant Gilead Sciences, Inc. is a Delaware pharmaceutical company with its principal place of business in Foster City, California. (Compl. (Docket No. 1 Ex. 1) ¶ 7.) Defendant manufactures, advertises, and promotes remdesivir, also known under the brand name Veklury, which is an antiviral drug used to treat severe COVID-19 symptoms. (Id. ¶¶ 5, 18-19.)

On March 17, 2020, the Department of Health and Human Services ("HHS") Secretary designated COVID-19 as a "public health emergency . . . under the PREP Act [42 U.S.C. § 247d-6d]." 85 Fed. Reg. 15198-01 (Mar. 17, 2020).[4] The Secretary declared the end of the COVID-19 public health emergency on May 11, 2023. HHS SECRETARY XAVIER BECERRA STATEMENT ON END OF THE COVID-19 PUBLIC HEALTH EMERGENCY, Dep't of Health & Human Servs. (May 11, 2023), https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html. However, the Secretary also extended PREP Act protections for "covered persons" and "covered countermeasures" with respect to COVID-19 until December 31, 2024. 88 Fed. Reg. 30769 (May 12, 2023).

On March 20, 2020, the Food and Drug Administration ("FDA") gave emergency use authorization for Veklury to be used for hospitalized patients with severe COVID-19. (Compl. ¶ 19.)

[4] The court will grant defendant's request for judicial notice relating to the motion to dismiss as to Exhibit 1, which supplies the HHS Secretary's March 17, 2020 declaration of COVID-19 as a public health emergency. (Docket No. 10-1.) The court will deny defendant's request as to all other exhibits as moot.

On April 25, 2022, the HHS Secretary revoked Veklury's emergency use authorization because the FDA approved defendant's supplemental new drug application for Veklury. 87 Fed. Reg. 44407 (July 26, 2022).

A number of scientific studies warn about the dangerous side effects of Veklury, including damage to the kidneys, liver, the heart, and the vascular system. (Compl. ¶¶ 28-42.) Other studies point out Veklury's lack of efficacy in reducing mortality or the time that COVID-19 patients take to recover. (Id. ¶¶ 25-27.) Despite this, defendant continued to market and promote Veklury as safe and effective. (Id. ¶¶ 43-44.)

Plaintiffs are patients who were prescribed, purchased, and ingested Veklury while hospitalized for COVID-19. (Id. ¶ 5.) Named plaintiff Debora Fust sues on behalf of her deceased husband, Michael Fust, who died after receiving Veklury. (Id. ¶ 6.) Named plaintiff Edward Pimentel was injured after receiving Veklury. (Id.) The putative class comprises "(1) [a]ll individuals who were given Remdesivir (Veklury) while hospitalized for Covid-19 and who, as a result of its administration, survived and suffered serious physical injury, and (2) [a]ll individuals who were given Remdesivir (Veklury) while hospitalized for Covid-19 and who, as a result of its administration, died and are survived by their aggrieved family members who now represent them in their capacities as personal representatives." (Id. ¶ 9.)

B. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) allows for dismissal when the plaintiff's complaint fails to state a claim

upon which relief can be granted. See Fed. R. Civ. P. 12(b)(6). The inquiry before the court is whether, accepting the allegations in the complaint as true and drawing all reasonable inferences in the plaintiff's favor, the complaint has alleged "sufficient facts . . . to support a cognizable legal theory," Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001), and thereby stated "a claim to relief that is plausible on its face," Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In deciding such a motion, all material allegations of the complaint are accepted as true, as well as all reasonable inferences to be drawn from them. Id.

The court "need not accept as true legal conclusions or '[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.'" Whitaker v. Tesla Motors, Inc., 985 F.3d 1173, 1176 (9th Cir. 2021) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009)).

"Ordinarily affirmative defenses may not be raised by motion to dismiss . . . ." Scott v. Kuhlmann, 746 F.2d 1377, 1378 (9th Cir. 1984) (per curiam). However, "a complaint may be dismissed when the allegations of the complaint give rise to an affirmative defense that clearly appears on the face of the pleading." Boquist v. Courtney, 32 F.4th 764, 774 (9th Cir. 2022) (cleaned up). An affirmative defense is grounds for dismissal at the pleading stage only if "the plaintiff pleads itself out of court -- that is, admits all the ingredients of an impenetrable defense . . . ." Durnford v. MusclePharm Corp., 907 F.3d 595, 603 n.8 (9th Cir. 2018) (quoting Xechem, Inc. v. Bristol-Myers Squibb Co., 372 F.3d 899, 901 (7th Cir. 2004)).

C. Discussion

The bulk of defendant's motion centers on PREP Act immunity. The PREP Act protects "covered persons" using a "covered countermeasure" during a declared public health emergency from suit and liability under federal and state law based on claims of loss related to that use. See generally 42 U.S.C. § 247d-6b(b).

1. Covered Persons and Countermeasures

The PREP Act defines "covered countermeasure," in relevant part, as a drug either authorized for emergency use or approved and cleared by the FDA. Id. § 247d-6b(i)(7)(B)(i), (iii). At all relevant times, Veklury was either authorized for emergency use or approved for use by the FDA. Veklury is therefore a covered countermeasure for purposes of the PREP Act.

"[M]anufacturer[s] of such countermeasure[s]" are "covered persons" under the Act. 42 U.S.C. § 247b-6d(i)(2)(B)(i). Defendant, as the manufacturer of Veklury, therefore counts as a covered person pursuant to the Act's provisions. (See Compl. ¶ 5.)

2. Claims of Loss and Scope of Immunity

Defendant, as a covered person manufacturing a covered countermeasure, is "immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure [i.e., Veklury] . . . ." 42 U.S.C. § 247b-6d(a)(1).

The court now examines whether plaintiffs' claims allege the kinds of loss against defendant that are barred by the

PREP Act. The Act defines "loss" in sweeping terms: "'loss' means any type of loss, including (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss." Id. § 247b-6d(a)(2)(A).

The category of acts covered by immunity is similarly expansive: it "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." Id. § 247b-6d(a)(2)(B).

Such capacious language makes it difficult to see how PREP Act immunity would not apply against plaintiffs' claims. Plaintiffs allege that "Despite . . . serious adverse events including numerous fatalities, and so many others documents in 'real life', Defendant Gilead continued to market Remdesivir as safe and effective;" and "Defendant Gilead failed to disclose these crucial details regarding the dangers of Remdesivir in its marketing and advertising campaign to patients who agreed to use of Remdesivir without knowledge of this crucial information; thus Gilead falsely advertising [sic] Remdesivir and nullifying their informed consent." (Compl. ¶¶ 43, 49 (emphasis added); see generally id. ¶¶ 43-71.) Plaintiffs also allege that "Plaintiffs

and others in the Class were aware of representations by Gilead as to the 'safety and efficacy' of Remdesivir. To the extent they even had a say in the matter, Plaintiffs and the Class agreed, albeit without informed consent, to taking the drug." (Id. ¶ 72.) Finally, plaintiffs' class definition explicitly include persons who were injured or died "as a result of [Veklury's] administration . . . ." (Id. ¶ 9 (emphasis added).) Put another way, plaintiffs allege (1) acts by defendant, (2) injuries to plaintiffs, and (3) a causal relationship between the two. Every major noun and verb comprising plaintiffs' allegations regarding act, injury, and causation manifestly implicate the broad protections provided by Section 247b-6d(a)(2).

A court in the Central District of California very recently reached the same conclusion regarding Veklury. It held, on substantially identical grounds, that the PREP Act immunized defendant Gilead against similar claims predicated on informed consent about the dangers of Veklury. See generally Baghikian v. Providence Health & Services, No. CV 23-9082-JFW(JPRX), 2024 WL 487769 (C.D. Cal. Feb. 6, 2024). Several other courts have also found that PREP Act immunity applies against similar claims regarding COVID-19 drugs. See, e.g., Bird v. State, 2023 WY 102, ¶¶ 15-17, 537 P.3d 332, 336 (Wyo. 2023) (PREP Act immunity applies to claims alleging failure to provide information reasonably necessary to make informed decision about COVID-19 vaccine); Cowen v. Walgreen Co., 2022 WL 17640208, at *3 (N.D. Okla. Dec. 13, 2022) (same re: administering COVID shot instead of flu shot without patient consent); M.T. as next friend of M.K.

v. Walmart Stores, Inc., 528 P.3d 1067, 1084 (Kan. Ct. App. 2023) ("a claim based on the administration of a covered countermeasure without parental consent is causally related to the administration of a covered countermeasure"); Gibson v. Johnson and Johnson, 2023 WL 4851413, at *3 (E.D. Pa. July 28, 2023) (PREP Act immunity applies to marketing-based claim that Johnson & Johnson "provid[ed] intentionally misleading information that it knew or should have known"); see also Kehler v. Hood, 2012 WL 1945952, at *1 (E.D. Mo. May 30, 2012) (PREP Act immunity applied to "failure to warn claims" in H1N1 context).

The court therefore concludes that the PREP Act immunizes defendant from suit and liability and will dismiss plaintiffs' claims on this basis.[5]

D. No Leave to Amend

Courts commonly consider four factors when deciding whether to grant leave to amend a complaint under Rule 15(a): bad faith, undue delay, prejudice, and futility of amendment. Roth v. Marquez, 942 F.2d 617, 628 (9th Cir. 1991). Because Rule 16(b)'s "good cause" inquiry essentially incorporates the first three factors, if a court finds that good cause exists, it should then deny leave to amend only if such amendment would be futile.

Here, the court concludes that amendment would be futile. The applicability of PREP Act immunity against these claims by these plaintiffs is plain on the face of plaintiffs' complaint, and when asked by the court at oral argument how

[5] Accordingly, the court need not consider whether plaintiffs' claims are inadequately pled or the applicability of the learned intermediary doctrine.

plaintiffs might amend their complaint if granted leave to do so, plaintiffs' counsel was unable to suggest any amendments which could overcome PREP Act immunity.

IT IS THEREFORE ORDERED that plaintiffs' motion to remand (Docket No. 28) be, and the same hereby is, DENIED.

IT IS FURTHER ORDERED that defendant's motion to dismiss (Docket No. 10) be, and the same hereby is, GRANTED, and plaintiffs' complaint is hereby DISMISSED with prejudice.[6]

Dated: February 21, 2024

WILLIAM B. SHUBB
UNITED STATES DISTRICT JUDGE

[6] The court expresses no opinion on the viability of different claims which might be brought in the appropriate court under the PREP Act's willful misconduct exception, 42 U.S.C. § 247d-6d(d)(1), or compensation sought under the PREP Act's Covered Countermeasures Process Fund, id. § 247d-6e.