UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOHN NELSON,

Plaintiff,

v.

F. HOFFMANN-LA ROCHE, INC., et al.,

Defendants.

Case No. 21-cv-10074-TLT

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT

Re: ECF Nos. 54-56, 60-66, 71

Pending before the Court is a motion to dismiss pursuant to the Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) filed by Defendants F. Hoffman-La Roche, Inc., Roche Laboratories, Inc., Genentech, Inc. and Genentech USA, Inc. The motion came on regularly for hearing before the Court on November 15, 2022. Upon consideration of the parties' submissions and the arguments of counsel, the Court finds that Plaintiffs' claims may not be adjudicated under California law. Accordingly, defendants' motion to dismiss is GRANTED.

I. BACKGROUND

A. Plaintiff John Nelson

Plaintiff filed his first amended medical monitoring class action complaint against Defendants based on allegations that they failed to warn of the substantial and irreversible dangers of certain antimalarial drugs. ECF No. 43, First Amend. Complaint ("FAC"). The complaint further asserts that, as a result of Defendants' alleged tortious and fraudulent conduct, Plaintiff sustained, and continues to sustain, neuropsychiatric side effects. *Id*., para. 6. Plaintiff brings causes of action for (1) negligent failure to warn; (2) negligent design; (3) strict liability failure to warn; (4) strict liability design defect; (5) negligent misrepresentation; and (6) fraudulent misrepresentation.

Plaintiff entered the U.S. military in 2005, and throughout his service, he was a citizen of Kentucky, Oregon, and Tennessee. *Id*., para. 12. He is currently a citizen of Florida. *Id.* The plaintiff was deployed to Afghanistan in February 2008 and the military prescribed him Mefloquine—a generic version of Defendants' drug, Lariam. He started ingesting the generic medication two weeks before. *Id.*, paras. 17, 72. At the time of his first dose, in early February, Plaintiff was residing on a miliary base in Kentucky. Thereafter, he took Mefloquine once per week while in Afghanistan until April 2009. *Id*., paras. 69, 71-72. Plaintiff claims that he started experiencing symptoms immediately after his first dose of Mefloquine in 2008. *Id*., para. 73

Plaintiff was placed into military retirement and was honorably discharged in 2015. *Id*., para. 79. He then moved to Oregon for five years, and thereafter lived in Tennessee for one to two years. Plaintiff moved to Florida in 2019 where he is a current resident. *Id*., para. 12.

B. Lariam and Mefloquine

Researchers affiliated with the Walter Reed Army Institute of Research reported the initial synthesis of Mefloquine in the late 1960's. *Id*., para. 19. The military transferred its intellectual property rights of the drug to Defendant Roche, Ltd.[1] *Id*. In 1989, Defendant Hoffman-La Roche Inc. ("Roche, Inc.") applied for and obtained approval for Mefloquine under the brand name Lariam from the U.S. Food and Drug Administration ("FDA"). *Id*., para. 20. Roche, Inc. was the official holder of the New Drug Application for Lariam until 2002. *Id*. paras. 21, 23.

Roche, Ltd. subsequently manufactured Lariam. *Id*. para. 14. Defendant Roche Laboratories was listed on Lariam's FDA label as its distributor. *Id.* para. 14. As the distributor, Roche Laboratories marketed and sold Lariam to the Defense Logistics Agency ("DLA"), an agency within the U.S. Department of Defense. *Id*., para. 22.

In 2002, Roche, Ltd., Roche, Inc. and Roche Laboratories (collectively the "Roche entities") lost the exclusive rights to Mefloquine. During the same year, generic manufacturers began to manufacture, distribute, and sell generic Mefloquine. *Id*., paras. 23, 29. The Roche entities continued to market and manufacture Lariam until 2005. *Id*., para. 29; *see also* Motion, 3.

[1] While F. Hoffman-La Roche, Ltd. was a named defendant in Plaintiff's complaint, he was not named in the operative FAC.

The last lots of Lariam were manufactured in 2005 and expired in 2008. FAC, paras. 14–15, 24.

The Roche entities merged with Genentech, Inc. and Genentech USA, Inc. in March 2009. *Id.*, para. 15. Genetech USA, Inc. is a subsidiary of Genentech, Inc. and Genentech, Inc. is a subsidiary of the Roche entities. *Id*., paras. 15-16. Roche's U.S. marketing authorization for Lariam was officially withdrawn several months after the merger. *Id.*, paras. 14–15, 25.

In July 2013, the FDA started requiring that Mefloquine be labeled with a black-box warning, its strictest form of warning. *Id*., paras. 5, 37. The new warning advised of "the potential for development of neurologic and psychiatric adverse reactions in patients using the drug" and that Mefloquine's neurologic side effects "can last for months to years after the drug is stopped or can be permanent." *Id*., paras. 38-37. After the FDA's change to the warning label on Mefloquine, the military re-designated Mefloquine as a drug of last resort to be taken only after other malaria prevention drugs were found to be ineffective. *Id*., para. 40.

Plaintiff experienced neuropsychiatric side effects after taking Mefloquine which presently continue. He did not learn about the medical literature supporting a causal link between Mefloquine and his symptoms until February 2020. *Id*., para 7. As a consequence, Plaintiff underwent medical evaluations and test to determine the cause of his symptoms. *Id*. "It is currently believed that Plaintiff[']s symptoms are attributed to Mefloquine, however he is still undergoing further medical evaluation necessary to provide a proper diagnosis." *Id*. Plaintiff alleges that, by 1994, "Defendants knew or should have known that these adverse reactions were permanent and irreversible." *Id*., para. 3.

The generic form of Mefloquine is still on the market today and the military continues to prescribe it as a drug of last resort. *Id*., paras. 14, 40.

II. JURISDICTION

This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a). Plaintiff is a resident of Florida. Roche, Inc. is incorporated under the laws of New Jersey. *Id*., para. 13. Roche Laboratories, Genentech, Inc. and Genentech USA, Inc. are Delaware corporations. As of March 2009, the headquarters for Defendants are in California. *Id*., paras. 14-16.

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This Court has jurisdiction under 28 U.S.C. § 1332(d) as plaintiff alleges a class action with the matter in controversy exceeding the sum or value of $5,000,000. *Id*., para. 9.

III. REQUEST FOR JUDICIAL NOTICE

As a preliminary matter, the Court GRANTS IN PART and DENIES IN PART Defendants' request for judicial notice.[2] ECF No. 56, 64.

The Court may take judicial notice of matters that are either "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Judicial notice is appropriate for facts "not subject to reasonable dispute." *Id*.; *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001).

As a general rule, on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court may not consider matters outside the complaint. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n. 19 (9th Cir.1990). As an exception to the general rule, however, a court may consider documents referenced in the complaint that are "central" to the claims, and as to which no party questions the authenticity of the copies provided. *See Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005).

A. Exhibits 1-3

Defendants request that the Court take judicial notice of the FDA-approved labels for Lariam and generic Mefloquine from 1989, 2002, and 2013. A court may consider documents "whose contents are alleged in a complaint and whose authenticity no party questions," despite such documents not being physically attached to the pleadings. *Id*. The policy concern underlying such a rule is to "[p]revent[] plaintiffs from surviving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which their claims are based." *Abrego Abrego v. Dow Chem. Co*., 443 F.3d 676, 681 (9th Cir. 2006).

Exhibits 1 through 3 are incorporated by reference in Plaintiff's amended complaint. FAC, paras. 14, 20, 37-39, 44. Plaintiff did not oppose Defendants' request as to these exhibits so the

[2] The Court issued its ruling on Defendants' request for judicial notice at the hearing but provides its grounds here for the purpose of inclusiveness.

court GRANTS Defendants' request as to Exhibits 1 through 3.

B. Exhibit 4-5

Exhibits 4 and 5 include a copy of the Center for Disease Control and Prevention webpage titled "FDA Revises Mefloquine Labeling; Drug Still Recommended," dated October 29, 2020 and a copy of FDA's webpage titled "FDA Drug Safety Communication: FDA approves label changes for antimalarial drug mefloquine hydrochloride due to risk" dated July 29, 2013.

The Court may take judicial notice of public documents, records, and reports of government bodies. *Barron v. Reich*, 13 F.3d 1370, 1377 (9th Cir. 1994). Judicial notice may be taken of publications introduced to "indicate what was in the public realm at the time, not whether the contents of those articles were in fact true." *Heliotrope Gen. Inc. v. FordMotor Co.,* 189 F.3d 971, 981 n. 118 (9th Cir. 1999) (taking judicial notice "that the market was aware of the information contained in news articles submitted by the defendants.").

Plaintiff does not oppose Defendants request as to Exhibits 4 to 5 and, as such, the court GRANTS judicial notice of Exhibits 4 and 5—not for the truth of the matters asserted—but for the purpose of indicating "what was in the public realm at the time[.]" *Id.*; *see also* Fed. R. Evid. 802.

C. Exhibit 6

Exhibit 6 is a record published on the FDA's website titled "New Drug Application 019578, Mefloquine Hydrochloride." Plaintiff opposes Defendants' request that the court take judicial notice of Exhibit 6 on grounds that Defendant is offering the record for the truth of the matter asserted in the document. Plaintiff's Opposition to Defendants' Request for Judicial Notice of Exhibit 6, 2.

Judicial notice is not appropriate for facts "subject to reasonable dispute." Fed. R. Evid. 201(b). A document is not judicially noticeable simply because it appears on a publicly available website. *Rollins v. Dignity Health*, 338 F.Supp.3d 1025, 1032.

Given that Plaintiff disputes that the military played a role in the manufacture, sale and distribution of Lariam and Mefloquine after it transferred its intellectual property rights to Defendants in 1989, Exhibit 6 is not appropriate for judicial notice. The Court DENIES

Defendants' request as to Exhibit 6.

IV. DISCUSSION

A. Legal Standard

Under Rule 12(b)(1), a party may move to dismiss for lack of subject matter jurisdiction. "[L]ack of Article III standing requires dismissal for lack of subject matter jurisdiction under [Rule] 12(b)(1)." *Maya v. Centex Corp*., 658 F.3d 1060, 1067 (9th Cir. 2011). The "irreducible constitutional minimum" of standing requires that a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins* ("*Spokeo II*"), 136 S. Ct. 1540, 1547 (2016). These three elements are referred to as, respectively, injury-in-fact, causation, and redressability. *Planned Parenthood of Greater Was. & N. Idaho v. U.S. Dep't of Health & Human Servs*., 946 F.3d 1100, 1108 (9th Cir. 2020). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements," which at the pleadings stage means "clearly . . . alleg[ing] facts demonstrating each element." *Spokeo II*, 136 S. Ct. at 1547 (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)).

The Defendants also move to dismiss under Rule 12(b)(1) for failure to establish federal subject matter jurisdiction. A Rule 12(b)(1) motion can either challenge the sufficiency of the pleadings to establish federal jurisdiction or the substance of the jurisdictional allegations despite the formal sufficiency of the complaint. *Thornhill Publ. Co. v. Gen'l Tel. & Electronics Corp.*, 594 F.2d 730, 733 (9th Cir. 1979). Where defendant challenges the actual existence of jurisdiction, as in this case, plaintiff's allegations are not presumed to be truthful, and plaintiff has the burden of proving jurisdiction exists. *Tosco Corp. v. Communities for a Better Environment*, 236 F.3d 495, 499 (9th Cir. 2001); *Thornhill Publ. Co. Inc.*, 594 F.2d at 733. Plaintiff must present admissible evidence to satisfy this burden. *Ass'n of Am. Medical Colleges, v. United States*, 217 F.3d 770, 778 (9th Cir. 2000). The Court is presumed to lack subject matter jurisdiction until plaintiff proves otherwise. *Stock West, Inc. v. Confederated Tribes*, 873 F.2d 1221, 1225 (9th Cir. 1989).

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A complaint need not contain detailed factual allegations, but facts pleaded by a plaintiff must be "enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter that, when accepted as true, states a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. While this standard is not a probability requirement, "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id*. (quoting *Bell Atl. Corp*., 550 U.S. at 556-57) (internal quotation marks omitted). In determining whether a plaintiff has met this plausibility standard, the Court must "accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable" to the plaintiff. *Knievel*, 393 F.3d at 1072.

B. Political Question Doctrine

Defendants move to dismiss plaintiff's complaint pursuant to Federal Rules of Civil Procedure 12(b)(1).[3] Defendants assert that the allegations in Plaintiff's complaint will require the Court to second-guess U.S. military decisions of a kind that are unreviewable under the political question doctrine, thereby denying the Court of subject matter jurisdiction. The Court disagrees.

"The political question doctrine serves to prevent the federal courts from intruding unduly on certain policy choices and value judgments that are constitutionally committed to Congress or the executive branch." *Koohi v. U.S.* 976 F.2d 1328, 1331 (9th Cir. 1992).

A case may be dismissed on political question grounds only if at least one of the following characteristics is present:

> [1] a textually demonstrable commitment of the issue to a coordinate political department; or [2] a lack of judicially discoverable and manageable standards for resolving it; or [3] the impossibility of deciding without an initial policy determ-

[3] At the hearing on the motion the dismiss, the Court issued a tentative order that Plaintiff's complaint did not raise issues typically excluded under the narrow exception to subject matter jurisdiction under the political question doctrine.

> ination of a kind clearly for nonjudicial discretion; or [4] the impossibility of a court's undertaking independent resolution without expressing lack of the respect due coordinate branches of government; or [5] an unusual need for unquestioning adherence to a political decision already made; or [6] the potentiality of embarrassment from multifarious pronouncements by various departments on one question.

Baker v. Carr, 369 U.S. 186, 217 (1986).

Defendants acknowledge that applying the political question doctrine to the military's decision to prescribed medication is a novel issue and that there are no cases on point that hold as such and they rely on two main theories. First, Defendants contend that equipping and controlling a military force is an issue that has a demonstrable commitment to the executive branch. *Gilligan v. Morgan*, 413 U.S. 1, 10 (1973). Case law reflects, however, that even though a case may involve military decisions, that alone does not render a case nonjusticiable under political question doctrine. See e.g., *McMahon v. Presidential Airways, Inc.*, 502 F.3d 1331, 1358 (11th Cir. 2007) ["[I]t is clear that not even military judgments are completely immune from judicial review."]; *Baker*, 369 U.S. at 211 ("[I]t is error to suppose that every case or controversy which touches foreign relations lies beyond judicial cognizance.") *Donn v. A.W. Chesterton Co., Inc*., 842 F. Supp. 2d 803 (E.D. Pa. 2012) [The political question doctrine does not preclude all claims involving military service.]

In *Gilligan*, the students injured during the Kent State massacre, sought declaratory and injunctive relief. The issue presented to the Supreme Court was whether the Ohio National Guard had a pattern of training, weaponry and orders that made the use of fatal force inevitable when called upon to retore civil order. *Id.* at 2442-2443. The students requested relief by "judicial power to assume continuing regulatory jurisdiction over the activities of the Ohio National Guard." *Id*. at 2443. Finding that the political question doctrine rendered the case nonjusticiable, the *Gilligan* court reasoned that "[t]he relief sought by respondents, requiring initial judicial review and continuing surveillance by a federal court over the training, weaponry and orders of the Guard, would therefore embrace critical areas of responsibility vested by the Constitution in the Legislative and Executive Branches of the Government." *Id.* at 2443. *Gilligan* is clearly distinguishable from the facts at hand.

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Second, Defendants identified one case involving the prevention of disease in servicemembers. In *Doe #1-#14 v. Austin*, the court stated that a "Department of Defense mandate to inoculate servicemembers plainly involves a military function." 572 F.Supp.3d 1224, 1231. However, *Austin* is distinguishable because that court's analysis and ruling did not invoke the political question doctrine. Rather, the *Doe* plaintiffs sought a permanent injunction against the Department of Defense's mandate to vaccinate its servicemembers against COVID for alleged violations under the Administrative Procedure Act.

Defendant relies on authority that is not binding and factually distinguishable. Plaintiff has carried his burden in establishing that the political question doctrine does not preclude subject matter jurisdiction.

C. Government Contractor Affirmative Defense

The Court now turns to Defendants' motion per Rule 12(b)(6) and the issue of whether Mefloquine is considered "military equipment" for purposes of establishing the government contractor affirmative defense as a total bar to Plaintiff's complaint.

A defendant may move to dismiss a complaint for failure to state a claim when plaintiff has made allegations that, on their face, disclose some absolute defense or bar to recovery. Fed. R. Civ. P. 12(b)(6); *see*, *Weisbuch v. County of Los Angeles* (9th Cir. 1997) 119 F.3d 778, 783, fn. 1. On a motion to dismiss under Rule 12(b)(6), the court must "accept as true all of the factual allegations set out in plaintiff's complaint, draw inferences from those allegations in the light most favorable to plaintiff, and construe the complaint liberally." *Rescuecom Corp. v. Google Inc.*, 562 F3d 123, 127 (2nd Cir. 2009)(internal quotes omitted); *Doe v. United States* (9th Cir. 2005) 419 F3d 1058, 1062. The military contractor defense is an affirmative defense that defendant has the burden of establishing. *Snell v. Bell Helicopter Textron, Inc.*, 107 F.3d 744, 746.

Defendants concede that the Ninth Circuit limited the government contractor defense to "contractors who design and manufacture military equipment." *Snell v. Bell Helicopter Textron, Inc.*, 107 F.3d 744, 746 n.1 (9th Cir. 1997); Reply, 3. The test for determining whether to impose liability for design defects in military equipment was first discussed by the Supreme Court in *Boyle v. United Technologies Corp.* 487 U.S. 500, 512-514 (1988). Courts later adopted a

version of that three-factor test for failure to warn claims. *See Getz v. Boeing Co.*¸ 654 F.3d 852, 866 (9th Cir. 2011).

1. Causes of Action Regarding Design

The Court considers whether Defendants have met their burden of proof in establishing the government contractor defenses as to Plaintiff's causes of action relating to the design of Lariam and Mefloquine (Counts II and IV).

> Liability for design defects in military equipment cannot be imposed, pursuant to state law, when: (1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specification; and (3) the supplier warned the United States about the dangers in the use of the equipment that were known to the supplier but not to the United States.

Boyle v. United Technologies Corp., 487 U.S. 500, 514 (1988)

Under the test established in *Boyle*, the Defendants have not met their burden of proof with respect to Plaintiff's design claims. While it is feasible that the military may have initially approved the specifications of Mefloquine, the intellectual property rights and research were subsequently transferred to Roche Ltd. in 1989. FAC, para. 19. The complaint is silent as to the second factor and whether the product was in anyway modified by the Roche entities. Lastly, Plaintiff alleges that Roche failed to "adequately and truthfully warn the U.S. military…of the risk and prevalence of severe, permanent and irreversible psychiatric and neurological side effects…[and] prodromal symptoms that require immediate cessation of the drug." FAC 52, 117, 153.

Accepting the allegations in plaintiff's complaint as true, and drawing inferences from those in the light most favorable to plaintiff, Plaintiff has sufficiently alleged that Defendants did not warn the U.S. military about the dangers of mefloquine that were known to them. As a direct result, Defendants do not meet their burden of proof as to plaintiff's design allegations.

2. Causes of Action Regarding Label

Courts later adopted a version of that three-factor test for failure-to-warn claims. *See Getz v. Boeing Co.*¸ 654 F.3d 852, 866 (9th Cir. 2011). The government contractor defense bars failure-to-warn claims when: "(1) the government exercised its discretion and approved certain

warnings; (2) the contractor provided the warnings required by the government; and (3) the contractor warned the government about dangers in the equipment's use that were known to the contractor but not to the government." *Getz*, 654 F.3d at 866.

At the heart of Plaintiff's complaint is the warning label for Lariam which was the same label that subsequently accompanied Mefloquine. Defendant Roche, Inc. approved the labeling and packaging for Lariam in 1989. FAC, para. 21. Roche, Inc. was also an official holder New Drug Application for mefloquine, making it responsible for the labeling of mefloquine in the United States. *Id.*, para. 20. Defendants do not dispute that Roche, Inc. approved the labeling and packaging for Lariam without involvement from the military. Mtn. to Dismiss, 12. Clearly, Defendant Roche, Inc., and not the military, was responsible for the specifications of the label. As such, the government contractor defense does not apply to Plaintiff's causes of action for related to the warning label (Count I, III, V, and VI).

In light of the foregoing, Defendant has not met its burden of proof to establish the government contractor affirmative defense to Plaintiff's complaint.

D. California Choice-of-Law

Lastly, Defendants move to dismiss on grounds that Plaintiff fails to state a claim upon which relief can be granted as California law does not apply to this action. Fed. R. Civ. P. 12(b)(6). The Court turns to whether California's choice-of-law analysis prevents Plaintiff's action from being litigated under the state's laws.

To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter that, when accepted as true, states a claim that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In determining whether a plaintiff has met this plausibility standard, the Court must "accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable" to the plaintiff. *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). To grant a Rule 12(b)(6) motion based on an affirmative defense, the defendant must show some obvious bar to securing relief. *ASARCO, LLC v. Union Pac. R.R. Co.*, 765 F.3d 999, 1004 (9th Cir. 2014).

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"A federal court sitting in diversity must look to the forum state's choice of law rules to determine the controlling substantive law." *Zinser v. Accufix Research Institute, Inc*., 253 F3d 1180, 1187 (9th Cir. 2001). In California, questions of choice of law are determined by the "governmental interest analysis." *Offshore Rental Co. v. Continental Oil Co*., 22 Cal.3d 157, 161 (1978). The party advocating for application of foreign law bears the burden of proof. *See McGhee v. Arabian American Oil Co.* 871 F.2d 1412, 1422 (9th Cir. 1989).

Reading the pleadings in a light most favorable to Plaintiff, the potential basis for applying California law arises out of his allegations that, first, the Roche entities sold and distributed Lariam to the Defense Logistic Agency's located in California and that, second, there was a two-month period when Plaintiff's ingestion of Mefloquine overlapped with the Roche entities operating within California.

The government interest analysis weighs the competing interests of California and the foreign jurisdiction to determine the most appropriate law to apply. *Id.*

> First, the court must determine whether the substantive laws of California and the foreign jurisdiction differ on the issue before it. Second, if the laws do differ, then the court must determine what interest, if any, the competing jurisdictions have in the application of their respective laws. If only one jurisdiction has a legitimate interest in the application of its rule of decision, there is a 'false conflict' and the law of the interested jurisdiction is applied. But if more than one jurisdiction has a legitimate interest, the court must move to the third stage of the analysis, which focuses on the 'comparative impairment' of the interested jurisdictions. This third step requires the court to identify and apply the law of the state whose interest would be the more impaired if its law were not applied.

Id.; *see also Cooper v. Tokyo Elec. Power Co. Holdings*, 960 F.3d 549, 559 (9th Cir. 2020).

The facts of this case span three decades, involve the conduct of four business entities with different states of incorporation, principal places of businesses, and periods of operation, and—at the center—a plaintiff that sustained harm in one state and a foreign country, and continued to experience symptoms while living in three different states.

In early February 2008, Plaintiff was stationed in Kentucky where he was prescribed, and did ingest, Mefloquine, the generic version of Defendants' drug Lariam. Within 24 to 48 hours of his initial ingestion, Plaintiff started experiencing prodromal symptoms including vivid dreams

and sleep disturbances. FAC, para. 73. In late February 2008, Plaintiff deployed to Afghanistan where he continued to take Mefloquine once a week and where he took his last dose in April 2009. While in Afghanistan, Plaintiff began experiencing severe emotional instability, which led to suicidal ideations. *Id*., para. 74. For Plaintiff, some of the most significant events of this case take place during this period of one year and approximate three months.

Roche, Inc. was responsible for Lariam's labeling from 1989 to 2002. *Id*. at ⁋ 21, 23. During that time, New Jersey was its principal place of business. *Id*. at ¶ 13, 20. Roche, Inc. is a New Jersey corporation. Am. Compl. ¶ 13. Roche Laboratories was listed on the FDA label for Lariam as its distributor. *Id.* at ⁋ 14. Roche Laboratories is a Delaware corporation that was solely owned by Roche, Inc. *Id*. at ⁋ 23.

Since 2009, the principal place of business for the Roche entities has been in California. *Id.* at ⁋ 14.

Plaintiff was placed into military retirement and was honorably discharged in 2015. He then moved to Oregon for five years, and thereafter lived in Tennessee for one to two years. Plaintiff moved to Florida in 2019 where he is a current resident.

For purposes of the government interest analysis, the potential applicable foreign jurisdictions include California, New Jersey, Kentucky, Oregon, Tennessee, Delaware, and Afghanistan. None of the parties suggest that the choice of law should be that of Afghanistan.

Furthermore, Roche Laboratories, the distributor of Lariam, was a Delaware corporation. *Id.* at para. 14, 23. Neither Defendants nor Plaintiff argue that Delaware should be the choice of law.

1. Differing Substantive Laws

There is no dispute that the laws of California, New Jersey, Kentucky, Oregon, Tennessee and Florida differ with regards to liability allegations against brand name manufacturers for the labeling on generic drugs. Motion, 16; Opposition, 16 .

Under California law, a brand-name manufacturer of a drug has the duty to warn of the risks about which it knew or reasonably should have known, regardless of whether the consumer was prescribed the brand name drug or its generic bioequivalent. *T.H. v. Novartis*

Pharmaceuticals Corp., 4 Cal.5th 145 (2017). In making its holding, the *Novartis* court reasoned that "[a]lthough federal regulations impose a continuing duty on the brand-name manufacturer to update and maintain an adequate warning label (see 21 C.F.R. 201.80(e)), a brand-name manufacturer's incentive to comply with that duty declines once the patent expires and generic manufacturers enter the market, since the market share for the brand-name drug at that point may drop substantially." *Id*. at 169. California is one of a few states that apply liability against brand-name manufacturers for failure to warn about the safety risks of their drugs, even if the claimant took a generic drug. *See*, e.g., *In re Zantac (Ranitidine Products Liability Litigation)*, 510 F.Supp.3d 1175 (S.D. Fla. 2020).

If California law is applied to the present case, Plaintiff has sufficiently pled causes of action for negligent failure to warn, strict liability failure to warn, negligent misrepresentation, and fraudulent misrepresent. The balance of Plaintiff's causes of action must fail as the holding in *Novartis* did not find that consumers of a generic drug were owed a duty of care from brand name manufacturer for design defects. *Novartis*, 4 Cal.5th at 172. *Novartis* was limited to torts concerning warning labels on pharmaceutical drugs based on the court's reasoning that only brand name manufacturers can revise the warning label. *See* 21 C.F.R. 201.80(e). Since Plaintiff alleges that he ingested Mefloquine that was manufactured by a generic manufacturer, and not Lariam which was manufactured by the Roche entities, Plaintiff does not sufficiently plead causation. Therefore, he fails to state a claim upon which relief may be granted as to the causes of action for negligent design and strict liability design defect. FAC, paras. 56, 72.

On the other hand, New Jersey, on the other hand, enacted the Product Liability Act in 1987. The Act subsumes common law products liability claims into one statutory cause of action for strict liability and it is the "sole basis of relief under New Jersey law available to consumers injured by a defective product." *See Repola v. Morbanks Indus., Inc.*, 934 F.2d 483, 492 (3d Cir.1991); NJ Stat. Ann. § 2A:58C-1 (West 2022). Defendants cite to the relevant, but unpublished opinion from the New Jersey Supreme Court, *Rossi v. Hoffmann-LaRoche*, and its holding that the court "cannot create a duty on the part of the name brand manufacturer to the consumers of a generic drug." 2007 WL 7632318 at 12 (N.J. Super. Jan. 3, 2007). While *Rossi* is

not binding authority on this Court as an unpublished opinion, it is informative as to how the New Jersey Supreme Court would view Plaintiff's allegations against the present Defendants for side effects that may have been caused by Mefloquine. See *Grimm v. City of Portland*, 971 F.3d 1060, 1067 (2020).

In Kentucky and Tennessee, a name brand manufacturer's statements regarding its drug cannot "serve as the basis for liability for injuries caused by another manufacturer's drug." *In re Darvocet, Darvon, and Propoxyphene Product Liability Litigation*, 756 F.3d 917, 938 (6th Cir. 2014). Applying Tennessee law, the *Darvocet* court relied on *Barnes v. Kerr Corp*. which held that "[a]lthough a product manufacturer generally has a duty to warn of the dangers of its own products, it does not have a duty to warn of the dangers of another manufacturer's products." 418 F.3d 583, 590 (6th Cir. 2005)

Oregon falls within the Ninth Circuit like California, but the court has not addressed the holding in *Novartis*. The Oregon District Court, however, declined to "to stretch the duty of care for name-brand defendants to cover injuries caused by generic manufacturers' products" stating that to do so would "directly contradict Oregon law." *Phelps v. Wyeth, Inc*., 857 F.Supp.2d 1114, 1120 (2012) citing *McEwen v. Ortho Pharma. Corp.,* 270 Or. 375, 407 (1974) ["(W)e must determine whether each defendant's negligence could be found to be a substantial cause of plaintiff's ingestion of the (drug) *manufactured by that defendant.*"] (original emphasis).

Florida does not recognize a cause of action against a brand manufacturer by a consumer of a generic product. *Guarino v. Wyeth,* LLC, 719 F.3d 1245, 1251 citing *Metz v. Wyeth LLC,* 830 F.Supp.2d 1291, 1293 (M.D.Fla.2011) ("The vast majority of courts, in Florida and elsewhere, that have addressed the issue now before the Court have consistently held that consumers may not bring claims for negligence, fraud, strict liability, misrepresentation, or breach of warranty against a brand name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties.") As one court explained, "[i]t is well-settled under Florida law that a plaintiff may only recover from the defendant who manufactured or sold the product that caused the injuries in question." *Sharp v. Leichus*, No. 2004–CA–0643, 2006 WL 515532, at *2 (Fla.Cir.Ct. Feb. 17, 2006), *aff'd,* 952 So.2d 555 (Fla.Dist.Ct.App.2007) (per curiam) (affirming

without written opinion).

Since California is one of the only states to apply liability to manufactures of brand name drugs for harm caused by the warning labels on generic drugs, Plaintiff's complaint would not be actionable in Kentucky, Oregon, Tennessee and Florida. Clearly, the laws differ here.

2. Competing jurisdictions' interests in the application of their laws.

The next step of the government interest analysis requires the Court to consider that "if the laws differ, what interest, if any, the competing jurisdictions have in the application of their respective laws." *Offshore Rental Co. v. Continental Oil Co*., 22 Cal.3d 157, 161 (1978).

The basis of Plaintiff's claim arises out of events that occurred in Kentucky and New Jersey. Plaintiff ingested Mefloquine in Kentucky in early February 2008. FAC, para. 71. At the time of Plaintiff's ingestion, Defendants Roche, Inc. and Roche Laboratories, were responsible for the labeling and distribution of Lariam. FAC, paras. 20-23. The Roche entities were operating out of their principal place of business in New Jersey. *Id*. Any alleged wrongful conduct on the part of the Roche entities concerning the warning label that accompanied Lariam would have taken place prior to February 2008.

Specifically, Plaintiff alleges that by 1994, Defendants knew or should have known that Lariam's adverse reactions were permanent and irreversible. FAC, para. 3. Additionally, in or around 2002, the Roche entities exclusive rights to Lariam expired and knew or should have known that manufacturers of the generic Mefloquine would have relied on the Lariam warning label in preparing to release generic Mefloquine into the market. FAC, para. 29.

While Oregon and Tennessee may have an interest in protecting their citizens from harm, Plaintiff did not ingest Mefloquine in Oregon or Tennessee, though he may have experienced long term side effects while residing within those states. Since Plaintiff no longer resides in Oregon or Tennessee, and only resided in those states briefly, the interest of in having their laws applied to the instant matter is not as significant as other jurisdictions, especially when there are no allegations that Defendants have any connection to those states.

Florida has an interest in protecting its current citizen. If Plaintiff was to become incapacitated from the alleged long term or permanent side effects of Mefloquine, such economic

burden would be borne by the state of Florida. Like, Oregon and Tennessee, though, Plaintiff did not ingest Mefloquine while residing in Florida and Defendants have no alleged connection to Florida.

The states with more compelling interests in having their laws applied to the instant action include Kentucky, California, and New Jersey.

a. Kentucky

Kentucky's product liability laws "are designed primarily to protect its own citizens or those injured within its boundaries." *Rutherford v. Good Year Tire and Rubber Co.*, 943 F.Supp. 789, 792 (1996 W.D. KY). Kentucky enacted the Products Liability Act which governs "all damage claims arising from the use of products regardless of the legal theory advanced." *Smith v. Wyth, Inc*. 657 F.3d 420, 423 (6th Cir. 2011) quoting *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky 1997); KY. Rev. Stat. Ann. §§ 411.300-411.350 (West 2010). The Act includes claims brought for personal injury incurred as an alleged result of the "warning, instructing, marketing, advertising, packaging or labeling of any product." KY. Rev. Stat. Ann. § 411.300 (West 2022). Under the Act, there is a rebuttable presumption that "the subject product was not defective if the injury, death or property damage occurred either more than five (5) years after the date of sale to the first consumer or more than eight (8) years after the date of manufacture." KY. Rev. Stat. Ann. §§ 411.310(1) (West 2022). The "intent of the legislature in passing the Product Liability Act was to restrict liability." *Anderson v. Black & Decker* (U.S.), Inc., 597 F.Supp. 1298, 1302 (E.D. KY 1984).

Since Plaintiff briefly resided in Kentucky while ingesting Mefloquine and is no longer a citizen, Kentucky's interest in having its laws applied is minimal.

b. California

Plaintiff first asserts that California has a strong interest in applying its laws to this case because it has an interest in regulating corporate entities that sell products and operate within the state. The Roche entities allegedly marketed and sold Mefloquine to the Defense Logistics Agency, an agency under the Department of Defense, which has a "number of offices" in California. FAC, para. 22. Plaintiff concedes that California is not the only state where the DLA

has offices.

Second, Plaintiff contends that California law should apply because Defendants were headquartered in California when he ingested Mefloquine. Opposition, 17. Reading the pleadings in a light most favorable to Plaintiff, there was a two-month period of time when Plaintiff's ingestion of Mefloquine overlapped with the Roche entities operating within California by means of their merger with the Genentech entities. Plaintiff ingested his last dose of Mefloquine while in Afghanistan in April 2009. FAC, 72. The Roche entities merged with the Genentech entities in March 2009 and operated out of their headquarters in California. *Id.*, para. 15. Plaintiff never resided in California.

The public policy behind California's imposition of strict liability is to "ensure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves" and to "provide an economic incentive for improved product safety." *Barrett v. Superior Court*, 222 Cal.App.3d 1176 (1990). California has strong regulatory interest in "the conduct of manufacturers who produce products in [the] state which causes injury to persons in other jurisdictions." *Strangvik v. Shiley, Inc.* 54 Cal.3d 744, 759 (1991). Nonetheless, California's interest in deterring wrongful conduct has been held to not be sufficient to justify the commitment of judicial time and resources that would be required. *See Id*.

Plaintiff correctly points out that the location where he sustained his injury does not automatically control which state's laws apply to his claims. Opposition, 17 citing *Boaz v. Boyle & Co.*, 40 Cal.App.4th 700, 713 (1995) ("The situs of the injury is no longer the beginning and end of the analysis, but it remains a relevant consideration."). However, when the subject matter of the litigation occurred outside of California and the only connection to California is a corporation's principal place of business, California does not have a sufficient interest in apply its law. *Howe v. Diversified Builders, Inc.*, 262 Cal. App. 2d 741. In *Howe*, a California court conducted a choice-of-law analysis in a case where a welder was injured while performing work in Nevada. *Howe*, 262 Cal. App. 2d at 745-746 (1968). The general contractors for the construction project were California corporations. The court found that Nevada law should apply on grounds

that the plaintiff was injured there, and the parties' services were being performed there. The fact that the general contractors were California corporations was not a sufficient interest to apply California law.

In the balance of equity, it would be unfair for Plaintiff to be able to bring his claims in California and, by virtue of the state's innovator liability doctrine, he would be extended greater rights than he would be granted in his own state of residence, Florida. "California has no interest in extending to out-of-state residents greater rights than are afforded them by their own state of domicile." *Id*. "The reach of California's lawmaking power in respect of its products liability policy is appropriately confined to the protection of California residents and persons injured within California's borders." *Chen v. Los Angeles Truck Centers, LLC,* 42 Cal.App.5th 488, 503 (2019).

c. New Jersey

Defendants contend that New Jersey law applies because their alleged omissions and misrepresentations emanated from New Jersey. *See* Motion, 17. "From its headquarters in New Jersey, Roche, Inc. approved the labeling and packaging for Lariam, and developed, manufactured, marketed, and distributed the medication to the military." Motion, 3; FAC, paras. 13-15, 21. For 20 years, the Roche entities headquarters were in New Jersey. FAC, para. 13.

New Jersey has an interest in regulating business that is conducted within its borders. New Jersey seeks to "compensate people injured by defective products and regulate the conduct of manufacturers and distributors (i.e., ensure production of safe products) within the state." *Torres v. Lucca's Bakery*, 487 F.Supp.2d 507, 513-514 (D. NJ 2007). That being said, New Jersey has an interest in balancing the interests between its citizens and manufacturers operating within its borders. "The New Jersey Products Liability Act was enacted to limit the expansion of products-liability law and to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality." *Montich v. Miele USA, Inc*., 849 F.Supp.2d 439 (Dist. N.J. 2012).

The limitation of liability extends to pharmaceutical drugs under the New Jersey Products Liability Act which codifies a rebuttable presumption of adequacy of warning approved by the

FDA. As the New Jersey Supreme Court has stated, "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive" of a failure-to-warn claim. *Perez v. Wyeth Labs., Inc.*, 161 *N.J.* 1, 25, 734 *A.*2d 1245 (1999).

Under its statutory framework to limit the expansion of products-liability law, the state of New Jersey accrued benefits in the form of attracting and retaining business entities to operate within their borders. New Jersey also reaped the tax benefits of that policy. In fact, for over fifteen years—and the entire duration of time that the Roche entities sold Lariam—they were operating out of New Jersey.

3. State most impaired if its laws are not applied.

The Court must now consider which state's interest would be more impaired if its laws were not applied to Plaintiff's complaint. *Offshore Rental Co. v. Cont'l Oil Co*., 22 Cal. 3d 157 (1978).

The "comparative impairment" analysis portion of the government interest analysis, involves determining—"not which conflicting law manifests the better or worthier social policy on the specific issue"—but, rather, the subject states' commitment to their respective laws. *Id*. In conducting this analysis, several factors should be considered, including: (1) the history and current status of the states' laws; (2) the function and purpose of the laws; (3) the focal point of concern of the lawmaking groups; and (4) the comparative pertinence of that concern to the immediate case." *Id*., at 159, holding modified by *I. J. Weinrot & Son, Inc. v. Jackson*, 40 Cal. 3d 327 (1985).

Failure to apply California law to the present case will cause minimal impairment to California's interest. On this point of contention, the Court finds the California Supreme Court case of *McCann v. Foster Wheeler LLC* instructive. 48 Cal.4th 68 (2010). In *McCann*, a former construction worker brought a personal injury action against a boiler manufacturer for mesothelioma allegedly caused by asbestos exposure that occurred while he was working in Oklahoma. After his alleged exposure to asbestos, the worker resided in several different states but eventually took residence in California where he filed his personal injury action after

becoming ill. *Id.*

The *McCann* Court held that, under California common law, it is appropriate for a court to give limited weight to California's interests in providing a remedy for a current California citizen when the defendant's alleged wrongful conduct occurred in another state that has different laws governing defendant's potential liability. The court found that Oklahoma had an interest in having a policy of limited liability applied to businesses incorporated or headquartered within the state specifically because it adopted a statute of repose to limit liability for commercial activity conducted within the state to provide fair treatment to, and an appropriate incentive for, business enterprises. The Court held that Oklahoma's interests would be more impaired than California's interest. *Id.* at 76.

With respect to the California's interests in providing a remedy for a California citizen, the court remarked that, "California decisions have adopted a restrained view of the scope or reach of California law with regard to the imposition of liability for conduct that occurs in another jurisdiction and that would not subject the defendant to liability under the law of the other jurisdiction." Even the plaintiff's residence in California did not prevent the court from finding that "a current California resident properly must be subordinated because of this state's diminished authority over activity that occurs in another state." *Id.* at 100–01.

In the case at bar, Plaintiff is not, and has never been, a California resident. The interest in applying California law is even more diminished here than it was in *McCann*. Based on the reasoning in *McCann*, New Jersey would have the stronger interest because it specifically enacted laws to limit liability for commercial activity conducted within the state to provide fair treatment to, and appropriate incentive for, business enterprises.

In light of the relevant facts of this case, the Court finds that a failure to apply New Jersey law, would significantly impair New Jersey's interests. If Defendants were to be denied the protection afforded by the New Jersey Product Liability Act and were subjected to liability for generic drug labeling, it would rest solely upon the circumstance that after defendants engaged in the allegedly tortious conduct in New Jersey, they happened to move to California.

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New Jersey has an interest in protecting its corporate citizens from liability for harm that occurred in New Jersey. The imposition of liability by under California law, would strike at the essence of New Jersey law. *See Id.* at 92-93.

Even though the Roche entities regularly sold Lariam to the Defense Logistic Agency offices located in California, the DLA had at least one other office in a different state. Plaintiff does not allege that the Lariam sold to the DLA offices in California were distributed to military bases located in California or that they were consumed by California citizens.

Plaintiffs assert that California has a strong interest in deterring the tortious conduct of its corporate citizens for harm caused beyond its borders. While the general proposition is true, the facts as alleged do not buttress this interest in the comparative impairment analysis. Any alleged wrongful conduct would have emanated from New Jersey. Plaintiff's allegations reflect that any failure to act on the part of the Roche entities occurred before the merger with the Genentech entities and relocation to California.

Based on the government interest analysis, California does not have a sufficient interest in having its laws applied to Plaintiff's complaint over the interest of New Jersey. Given that California is one of a handful of states that applies a duty on the part of a name-brand manufacturers for the warning label on that of a generic drug ingested by a consumer, if the "innovator law" does not apply here, Plaintiffs claims against the Genentech entities must also fail based on the lack of a continuing duty.

The defendants have carried their burden in establishing that, in the present action, California's interest in having its laws applied are subordinate to the interests of New Jersey.

V. Conclusion

Plaintiff has carried his burden of proof in establishing that the political question doctrine does not preclude subject matter jurisdiction. Plaintiff's complaint sufficiently pleads facts that reflect that the Court, in extending jurisdiction, would not intrude in an area which has a demonstrable commitment to the executive branch.

Defendants have not met their burden of proof to establish the government contractor affirmative defense to Plaintiff's complaint. Plaintiff has sufficiently alleged that Defendants did

not warn the U.S. military about the dangers of mefloquine that were known to them. As a direct result, Defendants have not met their burden of proof as to Plaintiff's design claims. Additionally, Defendants did not meet their burden in establishing that the U.S. military directed what was contained on the warning label and, therefore, do not meet their burden as to Plaintiff's warning claims.

Defendants have carried their burden in establishing that, in the present action, California's interest in having its laws applied are subordinate to the interests of New Jersey. Defendants have carried their burden in establishing an affirmative defense that is an obvious bar to securing relief. Fed. R. Civ. P. 12(b)(6); *ASARCO, LLC v. Union Pac. R.R. Co.*, 765 F.3d 999, 1004 (9th Cir. 2014).

As Plaintiff cannot cure by amendment, the Court dismisses the complaint in its entirety with prejudice. *Reddy v. Litton Indus.*, 912 F.2d 291, 296 (9th Cir.1990), *cert. denied*, 502 U.S. 921, 112 S.Ct. 332, 116 L.Ed.2d 272 (1991) [A district court does not err in denying leave to amend where the amendment would be futile.]

IT IS SO ORDERED.

Dated: November 28, 2022

TRINA L. THOMPSON
United States District Judge