UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ANDREA M CASTON, et al.,

Plaintiffs,

v.

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

Defendants.

Case No. 23-cv-00928-TLT

ORDER GRANTING NDA DEFENDANT'S MOTION TO DISMISS AND NON-NDA DEFENDANTS' MOTION TO DISMISS

ECF: 56, 57

STATEMENT

In this products liability class action, the first amended complaint must be dismissed. Defendants Roche, Inc. and Roche Laboratories, Inc. ("Roche Labs") are not subject to personal jurisdiction. Further, the Court does not have subject matter jurisdiction over design defect claims that effectively challenge active ingredients in pharmaceutical products as such claims implicate nonjusticiable political questions within executive jurisdiction, *i.e.*, the United States Food and Drug Administration. Last, the failure to warn and misrepresentation claims against Genentech, Inc. and Genentech USA, Inc. are preempted.

BACKGROUND

Plaintiffs are former members of the United States military. The action arises out of injuries sustained by ingesting military-prescribed mefloquine products, an anti-malarial medication. The causes of action brought against all defendants are (1) Strict Liability Failure to Warn, (2) Negligent Failure to Warn, (3) Strict Liability Design Defect, (4) Negligent Design Defect, (5) Negligent Misrepresentation, (6) Fraudulent Misrepresentation, and (7) Civil Conspiracy (Roche Labs only). Plaintiffs continue experiencing adverse neuropsychiatric side effects and request "medical monitoring," an equitable remedy.

This case follows dismissal of *Nelson v. F. Hoffman–La Roche, Ltd.*, No. 21-cv-10074 (N.D. Cal. 2022). The present action commenced on March 1, 2023. ECF 1. Plaintiffs filed an Amended Complaint on May 31, 2023. ECF 47. Defendants then filed separate motions to dismiss on July 31, 2023. ECF 56, 57. Plaintiffs timely filed responses opposing each motion to dismiss.

ECF 60, 61. Defendants replied to Plaintiff's oppositions. ECF 63, 64. A motions hearing was held on October 3, 2023, regarding both motions to dismiss. ECF 67.

Roche, Inc., is the New Drug Application ("NDA") holder for mefloquine and the brand-name mefloquine drug, Lariam. Roche Labs marketed and distributed Lariam, and the Genentech entities manufactured and sold generic mefloquine.[1]

Plaintiffs are former military service members who, at various periods before and during overseas deployment, ingested mefloquine on a weekly basis. Am. Compl. § VII–X. Plaintiff Andrea Caston took the generic form of mefloquine. Am. Compl. ¶ 97. Plaintiffs Richard Githens, Patrick Wagher, and Kendrick Allen each took Lariam. Am. Compl. §§ VIII–X. Plaintiffs describe the neuropsychiatric symptoms experienced because of mefloquine use as "severe," "debilitating," "adverse," "permanent," "only worsen[ing] over time," and "persist[ing] to this day." Am. Compl. ¶ 1, 3, 6.

Studies in the broader scientific literature on "quinoline derivatives" as "neurotoxins" span as far back as the 1940s; yet more recent studies show a concerningly high prevalence of negative side effects resulting from mefloquine use, including adverse psychiatric outcomes, such as "mania, psychosis, hallucinations, suicidal ideation, and completed suicide." Am. Compl. ¶¶ 42–50. Neurological problems include "vestibular harm, vertigo, loss of balance, and disequilibrium." Am. Compl. ¶ 46. Cognitive deficits such as "memory impairment and confusion" are also reported. *Id.* Furthermore, studies demonstrate that "prodromal" symptoms — symptoms that precede "more severe" neuropsychiatric conditions — are common. These include "sleep distance [*sic*], abnormal dreams, and anxiety," that may be an early warning sign of continued adverse reaction Am. Compl. ¶ 48.

Andrea Caston is a former Intelligence Officer with the U.S. Navy Sea, Air, and Land teams. Am. Compl. ¶ 96. Starting in September 2003, Caston took generic mefloquine on a weekly basis, as prescribed by a medical professional, during military service in Afghanistan Am. Compl. ¶ 97. With no prior history of neuropsychiatric disorders, Caston began experiencing "enhanced pain sensations, nerve pain, sleep disturbances, vivid disturbing nightmares, skin disorders, ear pain, chronic fatigue, and a constant buzzing in her body[,] including a 'zapping' sensation in her upper back," after taking mefloquine. Am. Compl. ¶ 98. She consulted a physician about the symptoms in February 2004, but was left without a medical diagnosis or a treatment

[1] Two motions to dismiss are at issue, one for the NDA-defendant, ECF 56, and another for the non-NDA defendants, ECF 57.

solution, bewildering the physician as to the symptoms' cause. Am. Compl. ¶ 99. Although she stopped taking mefloquine in February 2004, symptoms persisted and worsened over the following decade, and she has been diagnosed with a wide variety of ailments, including Post-Traumatic Stress Disorder ("PTSD"), despite never experiencing combat. Am. Compl. ¶ 100. Today, Caston continues to battle a mixture of adverse symptoms, such as "sleep disorder, chronic physical and mental fatigue, ear pain, and vision and balance issues." Am. Compl. ¶ 102.

Richard Githens is a decorated military veteran with an extensive track-record of military service and an impressive list of accomplishments in the Army Reserve Special Forces and the Army National Guard Special Forces groups Am. Compl. ¶ 107–115. In 1997, ten years after enlisting, Githens was deployed to Eritrea, Africa and prescribed the brand-name version of mefloquine, Lariam. Am. Compl. ¶ 116. After taking Lariam, he experienced a host of severe and adverse neuropsychiatric symptoms, including "sleep disturbances and abnormal dreams" that spiraled into "uncontrollable rage, paranoia, anxiety, and depression." Am. Compl. ¶ 117. In 2001, he was diagnosed with Seasonal Affect Disorder and treated for depression; however, the symptoms and aggressions persisted. Am. Compl. ¶¶ 118–19. Githens continued seeking medical treatment, but the prescribed medications were ineffective. Ultimately, Githens resigned from the military in 2002. Am. Compl. ¶ 119. He continued to struggle in a professional environment after leaving the military, continuing to experience fear and paranoia, memory problems, and even completing "minor tasks." Am. Compl. ¶ 120. He took a leave of absence from his job as a Special Weapons and Tactics officer to seek mental health therapy and was treated for depression. However, this treatment was ineffective and Githens fell into a deep depression, pondered suicide, and was eventually fired. Am. Compl. ¶ 121–22. He held a series of unstable jobs and became homeless, continuing to seek medical answers, without avail. At one visit to a Veteran's Affairs hospital, he was prescribed antibiotics for an ear infection. Am. Compl. ¶ 123–25. Githens attempted suicide in 2020. Am. Compl. ¶ 126.

Patrick Wagher served as a dedicated member of the Army National Guard and was deployed to Afghanistan in wake of the September 11, 2001, attacks. Am. Compl. ¶ 131–38. Just prior to deployment in 2002, he started preventative malarial therapy by taking the brand-name version of mefloquine, Lariam. Am. Compl. ¶ 139. After starting Lariam, he experienced chronic sleep disturbances, night terrors, escalating into paranoia in addition to and visual and auditory hallucinations. Am. Compl. ¶ 140–41. He did experience combat in Afghanistan, including a traumatic vehicular rollover that left him physically injured; however, the symptoms experienced after starting Lariam persisted after returning to the United States. Am. Compl. ¶ 142. Wagher fell

into a deep depression, and his wife divorced him. Am. Compl. ¶ 143. He rejoined the military as an Army Recruiter in 2007, but continuing to experience adverse neuropsychiatric symptoms, was treated for severe anxiety and depression. Am. Compl. ¶ 144–45. As this treatment seemed to be ineffective, he enrolled at a treatment program, was prescribed an anti-depressant to help with insomnia, but still experienced "a high-level of anxiety, persistent insomnia, weight loss, [and depression]." Am. Compl. ¶ 146. He sought additional treatment at the VA hospital, but none of the prescribed therapy regimens appeared to slow the progression of Wagher's underlying neuropsychiatric disease. He was diagnosed with PTSD. Am. Compl. ¶ 146–48. Wagher was fired from his job as an Army Recruiter in 2017 because his symptoms negatively affected his ability to complete his duties. Am. Compl. ¶ 149.

Kendrick Allen is a member of a Navy legacy family, following the footsteps of his father, and serving in the U.S. Navy. Am. Compl. ¶ 154–56. After the September 11, 2001, attacks, Allen was deployed to Afghanistan. Am. Compl. ¶ 157. Similar to co-plaintiffs Githens and Wagher, Allen was prescribed the brand-name version of mefloquine, Lariam, on November 22, 2001. Am. Compl. ¶ 158. Soon after starting Lariam, he experienced "extremely vivid, abnormal, and horrifying night terrors . . . insomnia, memory problems, and cognitive impairment issues." Am. Compl. ¶ 159. He left the Navy in 2007 and continues seeking treatment to ameliorate adverse neuropsychiatric symptoms. Allen is being treated for PTSD. Am. Compl. ¶ 160.

The pleadings allege that NDA-Defendant Roche, Inc. failed to perform adequate studies and misled the FDA by manipulating the information it presented in its New Drug Application ("NDA") for mefloquine, which it sold under the brand name Lariam. Am. Compl. ¶ 34. That once the NDA was approved in 1989, non-NDA Defendant Roche Laboratories, Inc., a subsidiary of Hoffman–La Roche, Inc., entered into a Distribution and Pricing Agreement ("DAPA") with the Department of Defense ("DoD") to supply the U.S. military with Lariam until 2009, when Roche Holdings, Ltd., acquired Genentech, Inc. and Genentech U.S.A., Inc. Am. Compl. ¶ 36; NDA-Def.'s Mot. to Dismiss, ECF 56-2, Ex. 1, at 2. After the merger, the DAPA was transferred to Genentech, Inc. Am. Compl. ¶ 39. Around 2002, generic manufacturers of mefloquine entered the market and began selling a supply to the U.S. military, around 2002. Am. Compl. ¶ 40. Plaintiffs allege that the NDA- and non-NDA-Defendants continued to mislead consumers, physicians, and the U.S. military throughout the life of the NDA, and that the military relied on this information to continue purchasing and prescribing Lariam and mefloquine to its servicemembers. Am. Compl. ¶ 40–41.

The pleadings report numerous studies that appear to indicate the potential adverse side

effects of mefloquine products and other "synthetic quinoline derivatives" molecularly related to mefloquine, some studies as early as the 1940s. Am. Compl. § II. They also show that new studies were released, and the Defendants knew or should have known of these adverse side effects yet failed to report the scope and intensity of these side effects to the FDA, the U.S. military, its' physicians, or its servicemembers. Am. Compl. § III. They allege that Defendants misled the U.S. military by its inaccurate label and labeling and throughout the sales process with the U.S. military Am. Compl. ¶ 63–67, § IV.

In 2013, the FDA issued a "Black Box" warning label on mefloquine products, highlighting the adverse neuropsychiatric side effects experienced by consumers, including military servicemembers. Am. Compl. ¶ 51. In response, the U.S. military changed its prescribing practices and re-classified mefloquine as a "drug of last resort." Am. Compl. ¶ 55.

Defendants challenge subject matter jurisdiction, specifically standing under Article III of the U.S. Constitution, nonjusticiability for implicating a political question reserved for the DoD, and preemption of certain state causes of action.

STANDARDS OF REVIEW

I. STANDING

For a court to adjudicate under Article III, a plaintiff has the burden of proving standing, meaning they "(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*, 578 U.S. 330, 338 (2016) (emphasis added). In the pleadings, a plaintiff must "clearly . . . allege facts demonstrating" each element. *Id.* In a class action, class representatives must each allege and demonstrate that they individually, rather than the unnamed class members, have standing under the three-prong test. *Id.* at 338, n.6. When a standing issue is raised at the pleading stage, the court accepts material allegations in the complaint as true and construes them in favor of the plaintiff. *Levine v. Vilsack*, 587 F.3d 986, 991 (9th Cir. 2009).

II. RULE 12(b)(1) – 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'g Co. v. Gen'l Tel. & Elecs. Corp.*, 594 F.2d 730, 733 (9th Cir. 1979). Where Defendants challenge the actual existence of jurisdiction, as in this case, a 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 Env't*, 236 F.3d 495, 499 (9th Cir. 2001); *Thornhill Publ'g Co.*, 594 F.2d at 733. Plaintiff must present admissible evidence to satisfy this

burden. *Ass'n Am. Medical Colls. 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 v. Confederated Tribes*, 873 F.2d 1221, 1225 (9th Cir. 1989).

A. POLITICAL QUESTION DOCTRINE

The political question doctrine outlined in *Marbury v. Madison*, 5 U.S. 137 (1803), is primarily a function of separation of powers. *Baker v. Carr*, 369 U.S. 186 (1962). "Questions, in their nature political, or which are, by the constitution and laws, submitted to the executive, can never be made in this court." *Marbury*, 5 U.S. at 170. The doctrine safeguards the Constitution by ensuring that questions of "political" nature are appropriately within the authority of the Executive or Legislative Branches, and thus are nonjusticiable, lacking Article III jurisdiction.[2]

III. RULE 12(b)(2) – PERSONAL JURISDICTION

Under Rule 12(b)(2), a court must dismiss an action where it does not have personal jurisdiction over a defendant. Fed. R. Civ. Pro. 12(b)(2). "[T]he plaintiff bears the burden of establishing that jurisdiction is proper." *Mavrix Photo v. Brand Techs.*, 647 F.3d 1218, 1223 (9th Cir. 2011). "Uncontroverted allegations in the complaint must be taken as true, and factual disputes are construed in the plaintiff's favor." *Freestream Aircraft Ltd. v. Aero L. Grp.*, 905 F.3d 597, 602 (9th Cir. 2018).

However, when evaluating a motion to dismiss for lack of personal jurisdiction, a court may consider material outside of the pleadings, including evidence in affidavits and other written materials. *Data Disc v. Sys. Tech. Ass'n*, 557 F.2d 1280, 1285 (9th Cir. 2001). If factual allegations are controverted by affidavit, a plaintiff may not rest on the bare allegations in the complaint. *Yamashita v. LG Chem. Ltd.*, 62 F.4th 496, 502 (9th Cir. 2023).

In exercising personal jurisdiction, a district court must abide by the Fourteenth Amendment's Due Process Clause and the state long-arm statute. *Impossible Foods v. Impossible X*, 80 F.4th 1079, 1086 (9th Cir. 2023). California's long-arm statute limits jurisdictional reach to abiding by the U.S. Constitution. Cal. Code Civ. P. § 410.10. Personal jurisdiction may be either

[2] The application of the political question doctrine was dismissed in *Nelson v. Hoffman–La Roche, Ltd.* (Or. Granting Mot. to Dismiss, Case No. 4:21-cv-10074-TLT, ECF 82, at 7). In *Nelson*, the Court held that the political question doctrine did not apply because the Plaintiffs did not directly challenge the Military's decision to purchase Lariam or mefloquine from Defendants. *Id.* However, after de novo review here, the court finds that pharmaceutical design defect claims that effectively challenge the safety and efficacy of active ingredients implicate nonjusticiable political questions outside the scope of the Court's Article III jurisdiction. *See* discussion *infra*, Section II.

general or specific. *Impossible Foods*, 80 F.4th at 1086.

A. GENERAL JURISDICTION

General or "all-purpose" jurisdiction applies to "any and all claims" against a defendant regardless of where the conduct occurred. *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 592 U.S. 351, 358 (2021). General jurisdiction is appropriate where a defendant is domiciled or "at home" in the forum state. *Ford Motor*, 592 U.S. at 358. A corporation is domiciled where it is incorporated under the laws of a state or where it maintains its principal place of business. *Impossible Foods*, 80 F.4th at 1086 (citing *Daimler v. Bauman*, 571 U.S. 117, 137 (2014)). A corporation's principal place of business is where it has its' "nerve center," that is, its' officers "direct, control, and coordinate the corporation's activities." *Hertz Corp. v. Friend*, 559 U.S. 77, 92–93 (2010).

However, a court may also have general jurisdiction over a corporate defendant through business contacts that arc so "continuous and systematic" that it is effectively considered "at home." *Daimler*, 571 U.S. at 139 (articulating the rule established in *Goodyear Dunlop Tires Ops., v. Brown*, 564 U.S. 915 (2011)). The standard is met where there are substantial continuous corporate operations in the forum state that are distinct from those undergirding the causes of action asserted in the present action. *CollegeSource v. AcademyOne*, 653 F.3d 1066, 1074 (9th Cir. 2011). In evaluating corporate operations under this standard, a court considers "longevity, continuity, volume, economic impact, physical presence, and integration into the state's regulatory and economic markets." *Id.* This is an exacting standard because a finding of general jurisdiction implies that a defendant may be haled into a particular forum based on any of its' extraterritorial activities. *Id.*

B. SPECIFIC JURISDICTION

A non-resident defendant must have "sufficient minimum contacts" with the forum state such that jurisdiction is "reasonable" and "does not offend traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316–17 (1945). Specific jurisdiction is proper when (1) the defendant purposefully directed its' activities toward the forum or purposefully availed itself of the laws and privileges of the forum state, (2) the claim arises out of or relates to the defendant's activities in the forum state, and (3) exercising jurisdiction comports with fair play and substantial justice inasmuch as jurisdiction is reasonable. *Impossible Foods*, 80 F.4th 1079, 1086 (9th Cir. 2023).

The plaintiff bears the burden of establishing the first two prongs, and if done so, then defendant must present a "compelling case" that specific jurisdiction would be reasonable.

Impossible Foods, 80 F.4th at 1087.

DISCUSSION

I. PLAINTIFFS HAVE STANDING

A. INJURY-IN-FACT

Accepting the claims as true and construing them in a light most favorable to the Plaintiff, each class representative has asserted claims of experiencing severe, adverse neuropsychiatric symptoms. These symptoms manifested after ingesting Lariam or generic mefloquine and are "concrete and particularized" to each individual class member. The harms endured sufficiently demonstrate suffering an injury-in-fact. *Spokeo*, 578 U.S. at 339 (defining concrete injury as one that "must actually exist" and particularized as affecting plaintiff "in a personal and individual way."). Neither party disputes that the Plaintiffs suffered an injury-in-fact, consequently the court finds that the first element is satisfied.

B. INJURIES TRACED TO DEFENDANTS' CONDUCT

The pleadings sufficiently allege that Plaintiffs' injuries are "fairly traceable to the challenged conduct of the defendant." An injury is "fairly traceable" where causation links a injuries to the challenged conduct of a defendant. *Wit v. United Behav. Health*, 79 F.4th 1068, 1083 (9th Cir. 2023). General factual allegations of causation, rather than the specific facts necessary to support a claim at the pleading stage are sufficient. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (comparing review standards at the pleadings phase with those at the summary judgment stage that require "specific facts").

Here, the Amended Complaint alleges that Defendants withheld vital information about the potential harms of mefloquine while marketing to the U.S. military, its' physicians, and servicemembers. These alleged misrepresentations resulted in the sale of mefloquine to the military over potentially safer anti-malarial medications, which induced medical officers to prescribe mefloquine to servicemembers. As a result, Plaintiffs sustained injuries from ingesting mefloquine, which allegedly had a defective design.

The Court finds that the allegations set forth in the complaint are sufficient to find that the challenged conduct directly and proximately caused the Plaintiffs' injuries. As a result, the Court finds that the second prong is satisfied.

C. MEDICAL MONITORING SUFFICIENTLY REDRESSES THE INJURY

The Court finds that the remedy sought, *i.e.*, medical monitoring, sufficiently redresses the injuries alleged.

1. No Heightened Pleading Standard

The parties dispute the standard of review at the pleading stage. Specifically, whether there is a heightened pleading standard for the "redressability" element, established in *Levine*. 587 F.3d 986, where the Ninth Circuit held that redressability was "conclusory and speculative." The Defendants cite *Levine*'s dicta alluding that the standard of review at the pleading stage is *primarily* meant for the first two prongs of the standing analysis, and, thus, there is a heightened pleading standard for the third prong. Mot. Dismiss, ECF 56, at 7. However, the Court finds this argument unavailing.

In *Levine*, plaintiffs sought a court order designating "poultry" as "other livestock" under the Humane Methods of Slaughter Act of 1958 ("HMSA '58") for the ultimate purpose of compelling food processing companies to "humanely" slaughter poultry to decrease plaintiff's risk of food-borne illness. 587 F.3d at 987–88. However, the enforcement provision in the HMSA '58 was repealed, and thus redressability hinged on (1) the Secretary of the Department of Agriculture to independently designate "poultry" as "amenable species" *pursuant to an entirely different statute*, notwithstanding a court order regarding HMSA '58, and then promulgate regulations under that statute; *and* (2) whether food processing companies would comply with said regulations. *Id.* at 993–94. The Ninth Circuit held that, without any factual allegations that the Secretary would be compelled to designate "poultry as "amenable species" under the Federal Meat Inspection Act, the plaintiff's allegations were "conclusory and speculative" and, thus, failed the redressability standard. *Id.* at 997. Contrary to the tenuous remedy alleged in *Levine*, where there was only a semblance of chance at recovery, the remedy for medical monitoring can be directly addressed with a court order in the present case. Therefore, the Court does not apply a heightened pleading standard for "redressability" here.

2. Redressability

To have Article III standing, a plaintiff must have an injury-in-fact "that is likely to be redressed by a favorable judicial decision." *Spokeo*, 578 U.S. at 338. Here, the remedy sought is medical monitoring. Am. Compl. § VI. Medical monitoring is an equitable remedy that may be used to recover expected reasonable medical expenses in tort cases where a plaintiff, who has been exposed to a harmful substance, has developed symptoms because of that exposure and is expected to seek ongoing medical care related to those symptoms. *See Metro-N. Commuter R.R. Co. v. Buckley*, 521 U.S. 424 (1997) (seeking lump-sum of medical monitoring damages after asbestos exposure). The Ninth Circuit has also addressed the validity of medical monitoring in toxic exposure cases, applying a four-part test that applies to a medical scenario of carcinogenic-agent exposure that has yet to fully manifest into a diagnosable form of cancer. *See In re Marine*

Asbestos Cases, 265 F.3d 861 (9th Cir. 2001) (asbestos); *Abuan v. Gen. Elec. Co.*, 3 F.3d 329 (9th Circ. 1993) (poly-chlorinated biphenyls).[3]

The test applied in the carcinogenic-agent exposure cases, however, is not directly applicable here because the Plaintiffs are not alleging exposure to a well-established carcinogen, such as asbestos, where there is necessarily a latency period of perhaps several years before cancer develops.[4] On the contrary, Plaintiffs' symptoms were allegedly more acute to ingesting Lariam or generic mefloquine, manifesting after short-term repetitive use, as prescribed. Although the neurological damage from "mefloquine toxicity" is described as "permanent" in the complaint, the alleged underlying symptoms (i.e., anxiety, depression, psychosis, tinnitus, insomnia, dizziness, suicidal ideation, etc.) vary by degree and severity over time, the psychiatric symptoms a plaintiff experiences at a certain point in time may be different at a future time, as is described by the Plaintiffs' experiences laid out in the complaint. As such, there is not necessarily a prolonged latency period for the onset of the Plaintiffs' alleged condition, dubbed "mefloquine toxicity." Thus, applying a test for the adequacy of a medical monitoring remedy that requires a disease with a latency period is inapplicable to the facts alleged here.

The allegations regarding the likelihood that Plaintiffs' injuries would be redressed with continuous medical surveillance are sufficient to pass the third prong of the standing analysis. Although the neurological damage is described as "permanent," the changing nature of the adverse *psychiatric* affects allegedly from Lariam or generic mefloquine ingestion are enough to warrant significant and continuous monitoring of the Plaintiffs' evolving psychiatric condition.[5]

As all three prongs of the standing analysis have been satisfied, the court holds that the Plaintiffs have Article III standing.

---

[3] In these cases, also cited in Defendants' briefs, the test lists four elements required to recover medical monitoring damages: (1) plaintiff significantly exposed to proven hazardous substance through negligent actions of defendant, (2) plaintiff suffers significantly increased risk of contracting serious latent disease, (3) increased risk makes periodic diagnostic medical examinations reasonably necessary, and (4) monitoring and testing procedures exist which make early detection and treatment of disease possible and beneficial. *In re Marine Asbestos Cases*, 265 F.3d 861, 866 (9th Circ. 2001).

[4] A fundamental concept in the cell and molecular biology field is that exposure to carcinogenic chemicals (i.e., cancer-causing chemicals) induce genetic mutations in "proto-oncogenes" or "tumor-suppressor genes," and that such mutations alter the genetic expression of cells, which may cause the cells to rapidly proliferate in a process known as "tumorigenesis" (tumor formation) and lead to a specific cancer diagnosis. *See generally* TALKING GLOSSARY OF GENETIC AND GENOMIC TERMS, NAT'L HUMAN GENOME RSCH. INST., https://www.genome.gov/genetics-glossary (explaining a variety of scientific and medical concepts) (last updated Dec. 15, 2023).

[5] The Court will not comment on the accuracy of allegations regarding previous medical diagnoses, nor the treatment regimens prescribed as a result of those diagnoses, as those are factual determinations within the realm of a licensed medical professional that are not at issue in the present motion.

II. THE DESIGN DEFECT CLAIMS IMPLICATE NONJUSTICIABLE POLITICAL QUESTIONS UNDER ARTICLE III OF THE U.S. CONSTITUTION

A. THE PHARMACEUTICAL DESIGN DEFECT CLAIMS EFFECTIVELY CHALLENGE THE SAFETY AND EFFICACY OF MEFLOQUINE, IMPLICATING A POLITICAL QUESTION WITHIN THE PROPRIETY OF THE U.S. FOOD AND DRUG ADMINISTRATION

The political question doctrine outlined in *Marbury v. Madison* is primarily a function of separation of powers. *Baker*, 369 U.S. 186. "Questions, in their nature political, or which are, by the constitution and laws, submitted to the executive, can never be made in this court." *Marbury*, 5 U.S. at 170. The doctrine safeguards the Constitution by ensuring that questions of "political" nature are appropriately within the authority of the Executive or Legislative Branches and, thus, are nonjusticiable, lacking Article III jurisdiction.

In *Baker*, the Supreme Court rolled out a litmus test with six independent factors indicative of whether a question is "political" and nonjusticiable. *Id.* at 217. The first three factors focus on the express or inherent Constitutional limitations on jurisdiction, and the last three are "prudential" considerations that disfavor judicial intervention. *Corrie v. Caterpillar*, 503 F.3d 974, 981 (9th Cir. 2007). In totality, however, the Baker factors function in unity as a Constitutional limitation on jurisdiction. *Id.*

The *Baker* factors are (1) the issue has been committed to a coordinate political department by Constitutional text; (2) the judiciary lacks sufficient discoverability or management standards to resolve the issue; (3) the issue is impossible to decide without an initial policy determination clearly outside judicial discretion; (4) undertaking independent resolution by the court expresses lack of respect due coordinate branches of government; (5) a political decision has already been made and there is an unusual need to adhere to that decision without question; or (6) a multitude of pronouncements from various departments on a single issue is potentially embarrassing. *Baker*, 369 U.S. at 217 (rephrased for clarity). The *Baker* test is applied on a case-by-case basis, and the factors often collapse into one another. *Republic of Marshall Islands v. United States*, 865 F .3d 1187, 1200 (9th Cir. 2017). To find a political question under *Baker*, only one of the factors must be present. *Id.*

The design defect claims here inherently touch each of the *Baker* factors. The Federal Food, Drug, and Cosmetics Act of 1936 ("FDCA") requires drug sponsors to gain FDA approval before marketing any drug in interstate commerce. 21 U.S.C. § 355(a). The FDCA is a textually

demonstrable commitment for the FDA to review the adequacy of New Drug Applications ("NDAs") autonomously. Through this review process, the FDA thoroughly examines materials submitted in an NDA, such as scientific and clinical investigations, to aid in their determination of whether to approve or deny an NDA. 21 U.S.C. § 355(d).

Pharmaceutical design defect claims challenging active ingredients necessarily implicate a nonjusticiable political question under the appropriate jurisdiction of the FDA because the FDA is a highly technical, scientific, and medical agency whose mission is to safeguard the public health by ensuring safety and efficacy of human drugs.[6]

Determining the safety and efficacy of a drug's design would include the same underlying questions that the Court would review if the claims progress to the next stage, demanding the Court replace its proverbial black robe with a white lab coat.

The "design defect" claims would implicate a decision that the Court is unfit to review because it lacks the scientific and clinical expertise of the FDA. Through Section 355(d) of the FDCA, Congress allocated approval authority of NDAs to the FDA Secretary, an individual politically appointed by the President with the relevant technical knowledge and expertise to effectuate the purpose of the FDCA, to safeguard the public health. 21 U.S.C. § 355(d) (1988). Indeed, twenty-one of twenty-five FDA commissioners have been doctors, including every commissioner since the mid-l 960s.[7] During the NDA approval process, the FDA has the relevant agency expertise to weigh the potential dangers of a well-studied molecular skeleton, such as a quinoline derivative, but also consider the demand for a particular therapy at a given point in time. These multifaceted decisions are heavily scientific, and indeed economic and political, but not judicial. If adjudicated here, the Court would need to consult the broader scientific literature, and the content submitted to the FDA, and make its own determination of whether the studies submitted in the NDA were enough to warrant approval in 1989, a question designated for the FDA. The FDA has exclusive jurisdiction over the approval of New Drugs, including the designs of those drugs, pursuant to the FDCA.

If the Court adjudicated the adequacy of the mefloquine's design, it would duplicate efforts specifically allocated to the FDA through the FDCA. Furthermore, a contrary ruling would potentially call into question the FDA's credibility. It would be inappropriate for the court to

---

[6] U.S. FOOD AND DRUG ADMIN., MISSION STATEMENT (2023), https://www.fda.gov/about-fda/what-we-do.

[7] U.S. FOOD AND DRUG ADMIN., COMMISSIONERS (2023), https://www.fda.gov/about-fda/fda-leadership-l907-today/commissioners.

obfuscate a decision made more than thirty years ago by a federal government agency. *See Gilligan v. Morgan*, 413 U.S. 1 (1973) (denying review of National Guard training procedures as it would "require judicial evaluation of a wide range of possibly dissimilar procedures and policies . . . [i]t would be inappropriate for a district judge to undertake this responsibility in the unlikely event that [s]he possessed the requisite technical competence to do so."); *United States v. Mandel*, 914 F.2d 1915 (9th Cir. 1990) (denying review of Secretary of Interior's decision to place an item on commodity control list because "although the basis in fact inquiry is the narrowest form of judicial review," it carries "the possibility that the court might reverse the Secretary's determination in a particular case.").

III. NO PERSONAL JURISDICTION OVER ROCHE, INC., OR ROCHE LABS

A. LACK OF GENERAL JURISDICTION

A court has general jurisdiction over a defendant corporation where the defendant is incorporated or has its' principal place of business. *Impossible Foods*, 80 F.4th at 1086. A corporation's principal place of business, otherwise known as its' "nerve center," is where the officers direct and control the corporation. *Hertz*, 559 U.S. at 92–93.

Roche and Roche Labs' locations of incorporation are a non-issue, being in New Jersey and Delaware. Am. Comp. ¶ 24–25. However, the parties dispute whether the Roche entities' principal places of business are in California or New Jersey.

The pleadings allege that both Roche entities have their principal place of business in California. Am. Compl. ¶ 10–12. But an affidavit declares that both principal places of business are in Little Falls, New Jersey. (Decl. Resnick, ECF 56-1, ¶ 9, 16). Factual disputes must be construed in a plaintiff's favor; however, where allegations are controverted by affidavit, a plaintiff may not rest on the pleadings. *Yamashita*, 62 F.4th at 502.

1. No Imputing of Genentechs' Contacts on the Roche Entities

The pleadings allege that the Roche defendants are in an alter ego relationship with the Genentech defendants. Am. Compl. ¶ 13–15. If corporations are in an alter ego relationship, a court may "pierce the corporate veil" for jurisdictional purposes, attributing contacts of one corporation to another. *City and Cty. of S.F v. Purdue Pharma*, 491 F.Supp.2d 610, 635 (N.D. Cal. 2020). Generally, "sister-sister" or "parent-subsidiary" relationships are insufficient to establish jurisdiction based on one entity's minimum contacts with a forum. *Nike*, 793 F.3d at 1070.

An alter ego relationship is shown where (1) two entities are so closely intertwined that

their personalities blend, *i.e.*, there is "unity of interest,"[8] and (2) regarding the entities as separate and apart would not amount to any injustice or create a fraudulent perception. *Id.* at 1073.

Some of the allegations are directed at Roche, Inc. specifically; others at "Roche" generally.[9] But a "sister-sister" relationship on its' own is insufficient to impute contacts under an alter ego theory for jurisdictional purposes. *Nike*, 793 at 1070.

The complaint refers to articles, statements, and filings released before the 2009 merger between Roche and Genentech stating Roche's intentions and plan to "combine" with Genentech and move its' headquarters to California post-merger. Am. Compl. ¶ 13–15. It also refers to a few "current" statements on Roche and Genentech's websites, alleging that Roche did indeed move its' headquarters to Genentech's campus after the merger. *Id.* One statement from Roche's website in 2018 stated that the combined headquarters houses research and development operations for both entities. *Id.* at 15. The pleadings also allege that Sean Johnston, Chief Executive Officer of Roche, Inc. until 2022, currently serves as an officer and employee of Genentech. Am. Compl. ¶ 14.

In sum, the allegations are that Roche and Genentech shared corporate offices in California circa-2009 until at least 2018, some of their research and development operations were blended, and they had at least one shared officer between both companies. Taken as true, these allegations fall short of demonstrating that a "failure to disregard [the separate identities of Roche and Genentech] would result in fraud or injustice." *Nike*, 793 F.3d at 1073 (rejecting "unity of interest" where Nike was heavily involved in "*macro*management" of subsidiary but did not control "day-to-day" operations); *see Stewart v. Screen Gems-EMI Music*, 81 F.Supp.3d 938, 954 (N.D. Cal. 2015) (rejecting alter ego theory where entities had common owners of equity, identical officers and directors, and shared offices and employees); *cf. Purdue Pharma*, 491 F.Supp.2d at 636–38 (upholding alter ego theory based on allegations of commingling funds and assets, sharing virtually identical officers and committee members, manipulating subsidiaries' assets to benefit oneself, controlling high-level and day-to-day decisions of subsidiaries, and integrating subsidiaries into a single economic unit called "One Teva").

[8] Factors that support "unity of interest" are, inadequate capitalization of one entity, commingling funds, assets, and records, moving assets to one entity and liabilities to another, eschewing corporate formalities and arm's length negotiations, having common equity owners, officers, and directors, and sharing office space and employees. *Purdue Pharma*, 491 F.Supp.2d at 635.

[9] Roche Holdings, Inc., a nonparty to this suit, is the "parent" company of Roche, Inc., the parent of Roche Labs. However, Genentech, Inc., parent of Genentech USA, Inc., is only affiliated with the Roche defendants through common ownership by Roche Holdings, Inc. (Decl. Resnick, ECF 56-1, ¶ 4–7, at 1–2; Ex. 1, ECF 56-2).

Here, the conclusory allegation that Roche and Genentech are "combined" entities, along with more specific allegations that the entities shared office and laboratory space as well as a few officers and/or employees is insufficient to find that Roche and Genentech are in, or were in, an alter ego relationship. Therefore, the Court will not impute Genentech's contacts on Roche or Roche Labs for the purposes of establishing general jurisdiction.

2. The Roche Entities are "at Home" in New Jersey

A Court has general jurisdiction over a corporation where the corporation is domiciled, or "at home." For example, the place of incorporation or where the corporation has its' "nerve center," *i.e.*, where its officers control the day-to-day operations of the business. The nerve center is sometimes, but not always, the headquarters. Holding a few board meetings in one place is itself insufficient. *Hertz*, 559 U.S. at 92–93.

The parties dispute whether Roche and Roche Labs' contacts with California are "so continuous and systematic" that they are each effectively domiciled in California. *See Daimler*, 571 U.S. at 139. Relevant to this discussion, the pleadings allege the same factual basis to support this theory as the attempt to impute contacts through an alter ego theory. Nevertheless, the Court will not impute any of Genentech's contacts on Roche or Roche Labs.[10]

The parties dispute the conclusion that Roche and Roche Labs have their principal places of business in New Jersey rather than California. At the pleadings stage, conclusory allegations are insufficient to pass muster. And where allegations are controverted by affidavit, as they are here, the plaintiff must not rest on the pleadings. *Yamashita*, 62 F.4th at 502.

a. Roche Labs

Beyond conclusory statements and mere recitation of the elements defining "nerve center," the pleadings allege that Roche Labs has officers, including two vice presidents and the corporate secretary in California. Am. Compl. ¶ 10. Resnick's declaration, however, lists the names of all five officers and both directors of Roche Labs and states they perform all their work duties from Roche headquarters in Little Falls, New Jersey. Decl. Resnick, ECF 56-1, ¶ 18–19, at 3–4.

To rebut the declarations of where Roche Labs' officers are located, plaintiffs present a New Jersey business record dated May 9, 2023. Decl. Todd, ECF 61-2, Ex. A. The report may have been accessed on May 9, 2023, however, the information contained in the report, officer names and addresses, was submitted on May 2, *2022*, not 2023. *Id.* at 3. The effect of this report is

[10] *See* discussion, *supra* Section III.A.1. (refraining from the imputation of contacts between Roche and Genentech based on an insufficient alter ego theory).

minimal.

However, other than rebutting the facts set forth in Resnick's declaration, the report is used to challenge Resnick's credibility. Plaintiffs argue that Roche and Roche Labs file paperwork in New Jersey to simply *appear* that they operate out of New Jersey, manipulating jurisdiction. But the examples of jurisdictional manipulation in *Hertz* — "the alleged 'nerve center' is nothing more than a mail drop box, a bare office with a computer, or the location of an annual executive retreat"— are not what is alleged. 559 U.S. at 97. Rather, they argue the filings are an attempt at manipulation. *Hertz* does indeed discuss the evolution of the "principal place of business" standard in the context of diversity jurisdiction, and that its' purpose was to provide a jurisdictional basis other than the place of corporate register, *i.e.*, incorporation. However, we find no factual basis for jurisdictional manipulation here.

Ultimately, the unrebutted information regarding Roche Labs' "nerve center," for example, board meetings and records stored at New Jersey headquarters and the locations of the specific officers and directors, are not overcome by plaintiffs' presentations. Decl. Resnick, ECF 56-1, ¶ 19, at 3.

Considering the lack of jurisdictional contacts attributed to Roche Labs, no imputation of contacts with Genentech, and Resnick's declaration, plaintiffs have not established that Roche Labs' contacts are "so continuous and systematic" that it is virtually "at home" in California. As a result, Roche Labs is not subject to general jurisdiction in California.

b. Roche, Inc.

The same conclusion is reached for general jurisdiction over Roche, Inc. The pleadings allege almost all the same contacts for Roche, Inc. as they do with Roche Labs, even though they are distinct business entities. Decl. Resnick, ECF 56-1, ¶ 7, at 1. Minor differences, such as the location of former Roche Chief Executive Officer, Sean Johnston, are not dispositive. Am. Compl. ¶ 10, 14–15. And the allegations that Roche's research and development is in California is inapplicable to a business whose commercial operations are primarily patent licensing. Decl. Resnick, ECF 56-1, ¶ 11–12, at 2. Even though Roche does research and development,

> It is the actual place where its business operations are coordinated, directed, and carried out, which would ordinarily be the place where its officers carry on its day-to-day business, where its accounts are kept, where its payments are made, and not necessarily a State in which it may have a plant, if it is a big corporation, or something of that sort. *Hertz*, 559 U.S. at 88 (quoting Judge John Parker on "principal place of business" as defined by the Bankruptcy Act in 1957).

The allegations fall short of demonstrating general jurisdiction over Roche, Inc.

B. LACK OF SPECIFIC JURISDICTION

1. No Purposeful Availment

A citizen must "purposefully avail" to the laws and privileges of a forum state for specific jurisdiction. *Ford Motor*, 592 U.S. at 359. The spirit of this requirement is to provide defendants fair notice of where they could be haled into court rather than a result of "random, fortuitous, or attenuated" contacts. *Impossible Foods*, 80 F.4th at 1089 (citation omitted). A defendant must *intend* to reach beyond their home. Such may be demonstrated by exploiting the market of a particular state. *Ford Motor*, 592 U.S. at 359.

The pleadings allege that Roche and Roche Labs purposefully availed through a DAPA with the U.S. Military in California. Am. Compl. ¶ 18. However, the DAPA was only between *Roche Labs* and the U.S. military and entered in Pennsylvania. Am. Compl. ¶37–38, Decl. Resnick, ECF 56-1, ¶ 17, at 4. Even though California has more than 40 military bases, Am. Compl. ¶ 18, entering a DAPA with the U.S. military writ large does not show that California was specifically targeted by Roche Labs. The eventual distribution of Lariam to military bases in California—or overseas to California servicemembers—is itself not enough to show Roche Labs "deliberately reached out" to California. *See Ford Motor Co.*, 592 U.S. at 359. Rather, distribution-related contacts with California were more likely "random" or "fortuitous." *See Keeton v. Hustler Magazine*, 465 U.S. 770, 774 (1984).

The allegations fall short of demonstrating that Roche, Inc., and Roche Labs purposefully availed to the laws and privileges of doing business in California through the DAPA agreement. Therefore, specific jurisdiction is inappropriate. Discussing whether the injuries arose out of or relate to the DAPA agreement is unnecessary because purposeful availment is required for specific jurisdiction.

There is no personal jurisdiction, general or specific, over Roche, Inc., and Roche Labs.

IV. THE FAILURE TO WARN AND MISREPRESENTATION CLAIMS AGAINST GENENTECH DEFENDANTS ARE PREEMPTED BY FEDERAL LAW

When federal law and state law conflict, state law must give way. U.S. Const. Art. VI. § 2.

Although the applicable state law over the Failure to Warn and Misrepresentation Claims has not been identified by Plaintiffs, the allegations create a direct conflict between the general state law "duty to warn" and the Genentech defendants' lack of ability to update the labeling on

their own accord.

In this case, Plaintiffs assert state law tort claims of failure to warn and misrepresentation. Each of these claims are premised on allegations that the Genentech defendants did not adequately warn the Military, its' physicians, or servicemembers of the prevalence, specificity, incidence, or permanency of the adverse side effects brought on by generic mefloquine. On the flip side of the same coin, the pleadings allege that the Genentech Defendants misrepresented the safety of generic mefloquine by failing to include an accurate description of the side effects on the drug's labeling.

A manufacturer seeking approval of a generic drug must duplicate the labeling of the parent, brand-name drug to gain approval. 21 U.S.C. § 355(j)(2)(A)(v), (4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7); *PLIVA v. Mensing*, 564 U.S. 604, 613 (2011). Here, the Plaintiffs fail to specify the statutory or regulatory mechanism for which the Genentech defendants could have updated the generic drug's labeling. However, no such showing would mask a conflict preemption issue. Any proposed modification to the labeling for a generic drug requires a "side-by-side" comparison with the labeling of the brand-name drug, and "must be the same as the labeling approved for the reference listed drug," unless there were certain FDA-approved changes, or the drug is produced, or the drug is distributed by a different manufacturer. 21 C.F.R. § 314.94(a)(8)(iv). This scenario makes it impossible for Genentech, Inc. and Genentech U.S.A., Inc. to comply with the state law "duty to warn" by updating its' labeling and the federal requirement that labeling must be the same as that of the brand-name drug.

"The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. 604, 620 (2011) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)).

Here, the Genentech defendants could not have independently updated their labeling without violating federal law. *See id.* (holding that federal law preempts state tort law imposing a duty to modify labeling upon a generic drug manufacturer); *cf. Wyeth*, 555. U.S. 555 (discounting preemption for a state law failure to warn claim where a brand-name drug manufacturer could simultaneously comply with state and federal law by "unilaterally" updating its' label without FDA approval).[11] It is simply impossible for Genentech, Inc. and Genentech U.S.A., Inc. to have complied with the state's "duty to warn" and the FDCA. Therefore, the Plaintiffs failure to warn

[11] If the Court had personal jurisdiction over NDA-Defendant Roche, Inc., the failure to warn and misrepresentation claims may have survived under *Wyeth*.

and misrepresentation claims against Genentech Inc. and Genentech U.S.A., Inc. are without effect.[12]

CONCLUSION

The Motion to Dismiss claims against Roche Inc., ECF 56, is **GRANTED** for lack of personal jurisdiction. Fed. R. Civ. P. 12(b)(2). The Motion to Dismiss claims against non-NDA defendants is also **GRANTED** for (1) lack of personal jurisdiction over Roche Labs, Fed. R. Civ. P. 12(b)(2) and (2) federal preemption of failure to warn and misrepresentation claims against Genentech, Inc. and Genentech USA, Inc. This Order also holds that pharmaceutical design defect claims challenging the safety and efficacy of an active ingredient are nonjusticiable political questions within the appropriate jurisdiction of the U.S. Food and Drug Administration. Therefore, all the claims are hereby **DISMISSED** with prejudice.

IT IS SO ORDERED.

Dated: April 5, 2024

TRINA L. THOMPSON
United States District Judge

[12] The Court need not address the arguments that, in some cases, federal law has not preempted failure to warn claims against drug distributors because we do not have personal jurisdiction over Roche Labs, the alleged distributor. Additionally, none of the pre-approval preemption arguments apply to the Genentech defendants because they manufacture generic mefloquine, which is only possible post NDA approval. Plaintiffs also failed to dispute that the failure to warn and misrepresentation claims against Genentech defendants were preempted.