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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

JOHN NELSON, on behalf of himself and all others similarly situated

Plaintiff,

vs.

F. HOFFMANN-LA ROCHE, LTD.; F., HOFFMANN-LA ROCHE, INC.; ROCHE LABORATORIES, INC.; GENENTECH, INC.; GENENTECH USA, INC.; and DOES 1-100,

Defendants.

Case No. _____

MEDICAL MONITORING CLASS ACTION COMPLAINT

Plaintiff John Nelson ("Plaintiff") files this Medical Monitoring Class Action Complaint on behalf of himself and all others similarly situated, against the defendants named herein ("Defendants") and seeks relief to remedy the harms caused by Defendants' unlawful design, testing, manufacture, marketing, packaging, labeling, handling, distribution and/or sale of prescription mefloquine-containing medications, including those sold under the brand name Lariam and any generic equivalents. Plaintiff's allegations are based upon personal knowledge as to Plaintiff's own conduct and investigation of counsel based on publicly-available information.

INTRODUCTION

1. This action arises out of Defendants' egregious failure to warn our U.S. military and its service members of the substantial and irreversible dangers of its antimalarial drug mefloquine, which includes the brand-name Lariam and any generic equivalents of the drug (collectively, "Mefloquine"). Mefloquine is now recognized as one of the most dangerous malaria prevention drugs on the market, and Mefloquine toxicity is believed to be the modern-day version of Agent Orange in scope and scale. Mefloquine has left at least tens of thousands of our nation's veterans severely and permanently sick.

2. Defendants marketed and sold Mefloquine to the U.S. military for service members deployed to Somalia, Afghanistan and other foreign countries for the prevention of malaria. A significant proportion of service members took Mefloquine while deployed to Afghanistan and other foreign countries. With the War in Afghanistan dragging on for over a decade, the market opportunity for the drug was vast and the demand was strong.

3. At the time they sold the drug to the U.S. military, Defendants knew of the substantial danger of severe and irreversible neuropsychiatric side effects of Mefloquine. Indeed, before Defendants even began the sale of Mefloquine in 1989, the risk of brain toxicity from the chemical

family to which Mefloquine belongs had been widely known. At that time, there were already widespread reports in the pharmaceutical industry of Mefloquine causing adverse reactions, including symptoms of paranoia, hallucinations, and suicidal ideations. By 1994, Defendants knew or should have known that these adverse reactions were permanent and irreversible. Since that time, numerous scientific studies have confirmed the causal link between Mefloquine and permanent neuropsychiatric effects.

4. Despite existing and mounting evidence of Mefloquine' devastating side effects, Defendants concealed the scope and nature of the danger and recklessly sold the drug as a safe and effective first-line treatment for malaria prevention. Safer and effective drugs for malaria prevention existed on the market. But Defendants had no desire to re-brand Mefloquine as a mere secondary or alternative option for malaria prevention, as that would have extinguished its hold on the market and strong demand for it by the U.S. military.

5. Defendants also knew that Mefloquine could not be prescribed and used as directed when provided to military service members who were deployed abroad. Defendants knew that the military service members would not be capable of receiving adequate onboarding and follow-up assessments that Defendants knew were vital to the safety of individuals taking the drug. Defendants also knew that any immediately apparent side effects such as paranoia, anxiety and restlessness would be confused and/or attributed to the natural effects of war. This is further evidence of the reckless and dangerous conduct in which Defendants engaged.

6. The prospect of wartime profits led Defendants to recklessly continue to market and sell the dangerous and flawed antimalarial drug to the U.S. military. Defendants conduct also led the U.S. military to purchase and prescribe the generic-equivalents of Defendants' name-brand drug. Only after the FDA ultimately put a black-box warning on the drug in 2013 did the U.S. military change its Mefloquine-prescribing policies by re-designating Mefloquine as a drug of last resort for

malaria prevention.

7. Plaintiff was a U.S. military service member who was prescribed Mefloquine when deployed to Afghanistan. Upon taking the drug, Plaintiff immediately began suffering severe and irreversible side effects, which continue to this day. However, due to Defendants' reckless and dangerous conduct in marketing and selling Mefloquine to the U.S. military, Plaintiff had no knowledge that the neuropsychiatric side effects he was experiencing could be due in any way to Mefloquine. Nor could Plaintiff have reasonably been able to acquire such knowledge because the drug insert did not adequately warn of the drug's toxicity. Moreover, even as to the inadequate information that did appear on the drug insert, Defendants knew that U.S. military service members are not typically provided with the drug insert and therefore would be unlikely to receive any such information.

8. In February 2020, Plaintiff attended a conference in Washington D.C., where he met the leading researcher in the field of Mefloquine toxicity and learned about the extensive body of literature supporting the causal link between Mefloquine and his symptoms. This literature is not widely publicized, nor is it discussed during routine medical evaluations of military service members and veterans. Since then, Plaintiff has incurred substantial time and expense to undergo necessary medical evaluations and tests to determine the cause of his symptoms. It is currently believed that Plaintiffs' symptoms are attributed to Mefloquine, however he is still undergoing further medical evaluation necessary to provide a proper diagnosis. Plaintiff requires medical monitoring that is different from routine medical treatment to permit proper diagnosis, as well as treatments and/or medications for his symptoms.

9. Medical monitoring is a recognized form of relief that allows a plaintiff and class members to obtain diagnostic medical examinations that are funded and/or reimbursed by a defendant when the defendant's tortious conduct has exposed the plaintiff and class members to

harm that proximately causes the need for the comprehensive diagnostic examinations. As described below, Plaintiff, individually and on behalf of the Class, seeks medical monitoring as a result of their common exposure to Mefloquine.

JURISDICTION AND VENUE

10. This Court has original subject-matter jurisdiction over this action under 29 U.S.C § 1332(d)(2) because (a) there are at least 100 class members, (b) the matter in controversy exceeds $5 million, exclusive of interests and costs, and (c) Plaintiff is a citizen of a different state than Defendants. Subject matter jurisdiction also exists under 29 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

11. This Court has personal jurisdiction over Defendants because they are citizens of California. Defendants' nerve center is located in the State of California, rendering them citizens of California. At least two federal courts in this District have recently confirmed that Defendants' nerve center and principal place of business is located in California. *Pool v. F. Hoffman-La Roche, LTD.*, 386 F. Supp. 3d 1202 (N.D. Cal. 2019); *Sheets v. F. Hoffman-La Roche Ltd.*, No. 18-cv-04565 (N.D. Cal. Dec. 7, 2018). The Defendants are therefore citizens of California, thereby rendering them subject to the general jurisdiction of this Court.

12. Venue is proper in this District under 28 U.S.C §1391(b) because Defendants' principal place of business is located in this District and because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District. Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Mefloquine, and otherwise conducted extensive business, within this District.

PARTIES

13. John Nelson is an army veteran who served honorably in the U.S. Military from 2005-

2015. Mr. Nelson was a citizen of Oregon and Tennessee while he served in the U.S. Military. He is currently a citizen of Florida.

14. F. Hoffman-La Roche Ltd. ("Roche Ltd.") is a Swiss corporation with operations worldwide, with its principal place of business in the United States in San Francisco, California.

15. F. Hoffman-La Roche Inc. ("Roche Inc.") is a New Jersey Corporation with its principal place of business in San Francisco, California. Roche Ltd. is an affiliate of Roche Inc. Roche Inc. was formerly headquartered in New Jersey, but it relocated its headquarters to the Genentech headquarters in San Francisco in March 2009 following the acquisition of Genentech that same year. Genentech's website states: "Following our March 2009 merger with Roche, Genentech's South San Francisco campus because the headquarters for Roche pharmaceutical operations in the United States."

16. Roche Laboratories (together with Roche Ltd. and Roche Inc., "Roche") is a Delaware corporation with its principal place of business in San Francisco, California. Roche Laboratories is a general manager of Roche Ltd. in California and was listed on the FDA label for the brand-name version of Mefloquine as the distributor of the drug in the United States for pills manufactured by Roche Ltd. Collectively, Roche was in the business of developing, manufacturing, selling, marketing and distributing Mefloquine throughout the United States from 1989 to 2009. However, its generic equivalents remained available today.

17. Genentech, Inc. is a Delaware corporation with its principal place of business in San Francisco, California. Genentech is an indirect wholly-owned subsidiary of Roche and a member of the Roche family of companies. According to Genentech and Roche, Genentech now serves as the "headquarters for Roche pharmaceutical operations in the United States." Roche and Genentech merged in March 2009, and Roche subsequently relocated their New Jersey headquarters to Genentech's headquarters in San Francisco.

18. Genentech USA, Inc. is a Delaware Corporation with its principal place of business in San Francisco, California. Genentech USA, Inc. is a wholly-owned subsidiary of Genentech Inc.

19. Does 1 to 100 are the employees, servants, agents, affiliates, and/or contractors of the Defendants. Plaintiff is ignorant of the true identities of Does 1 to 100.

FACTUAL ALLEGATIONS

I. Roche Developed and Marketed Mefloquine to the U.S. Military as a First-Line Drug for Malaria Prevention

20. Mefloquine belongs to a class of medications called antimalarials. The drug is intended to prevent and/or treat malaria.

21. The initial synthesis of Mefloquine was reported in the late 1960's by researchers affiliated with the Walter Reed Army Institute of Research. Intellectual property rights and research were subsequently transferred to Roche Ltd.

22. Roche pursued and obtained FDA approval to market and sell Mefloquine in 1989. It obtained FDA approval for the drug without completing double-blinded randomized controlled trials, which are the most probing of a drug's safety. While the FDA permitted Roche to rely on alternative types of trials, Roche deliberately obfuscated the true nature and results of these trials to obtain FDA approval. Following FDA approval, Roche became the primary worldwide manufacturer of Mefloquine, which it sold under the brand-name Lariam.

23. Roche Inc. was an official holder of the New Drug Application ("NDA") for Mefloquine, making it responsible for the labeling and packaging of Mefloquine in the United States.

24. Before Roche's acquisition of Genentech, Inc., Roche Laboratories marketed and sold Mefloquine to the Department of Defense under a Distribution and Pricing Agreement ("DAPA"). The DAPA obligated Roche Laboratories to offer Mefloquine for sale to the Defense Logistics Agency ("DLA") at the prices set forth in the DAPA. Roche did in fact sell Mefloquine to

the military under these agreements up until the Genentech acquisition in 2009. Such sales occurred in California, where a number of offices for the DLA are located and where the DLA ordered and purchased Mefloquine from Roche Laboratories for distribution to defense forces abroad.

25. The Roche entities acted in concert in all marketing and sales activities targeted at the U.S. military. Roche Inc. was the NDA holder for Mefloquine and had exclusive rights to commercially exploit the drug up until 2002. Thus, Roche Inc. had to authorize, and did in fact authorize, Roche Ltd. to manufacture the drug and Roche Laboratories to market and sell the drug. The three entities worked in concert at all points in the manufacturing and distribution chain. Roche Ltd. and Roche Laboratories also had common officers and directors at all relevant times such that all relevant decisions were made or overseen by the same group of individuals. Roche Inc. was the sole owner of Roche Laboratories at all relevant times.

26. Roche marketed and sold Mefloquine to the U.S. military as a first-line drug for the prevention of malaria. As a result, hundreds of thousands of military service members deployed abroad were required to take the drug on a weekly basis. For most of the time before it withdrew its brand-name drug Lariam from the U.S. market, Roche was the U.S. military's main supplier of malaria-prevention pills. The U.S. military was also the single largest customer of Mefloquine for Roche.

27. Following the Genentech acquisition in 2009, Roche Laboratories transferred the military-Mefloquine line of business to Genentech USA, Inc., and Genentech USA, Inc. became the mere continuation of Roche Laboratories with respect to that line of business. Genentech succeeded to the DAPA agreement and became the official DAPA holder of Mefloquine for the Roche family, meaning Genentech was the only entity in the Roche family capable of offering Mefloquine for sale to the U.S. military.

28. Genentech USA, Inc. paid Roche Laboratories nothing for the military-Mefloquine

line of business. It gave Roche Laboratories no consideration for this line of business. Moreover, Genentech had a common stockholder with Roche Laboratories and Roche Inc.—Roche Holdings, Inc. Genentech USA, Inc. also had common officers and directors with Roche Laboratories, Roche Inc. and Genentech Inc. at all relevant times. In sum, Genentech USA, Inc. was a mere continuation and thus the successor of Roche Laboratories with respect to the military-Mefloquine line of business.

29. Genentech, Inc. is the sole stockholder of Genentech USA, Inc. Genentech, Inc. undercapitalized Genentech USA Inc., commingled assets and operations, and/or failed to observe corporate formalities.

30. Genentech Inc. and Genentech, USA are the successors-in-interest to the military-Mefloquine line of business of all Roche entities, thereby rendering them liable for their predecessors' activities.

31. While generic manufactures of Mefloquine entered the market in or around 2002, Roche continued to market and sell the brand name version of Mefloquine to the U.S. military as a first-line drug for the prevention of malaria. Accordingly, based on Roche's knowing and deceptive conduct in marketing and selling the brand name version of the drug, the U.S. military also purchased and prescribed generic forms of Mefloquine for U.S. military service members as a first-line drug for malaria prevention.

II. The History of Mefloquine and the Evidence of its Toxicity

32. The origins of Mefloquine's central nervous system toxicity trace back to the mid-1940's when synthetic quinoline derivatives used as antimalarials and related to Mefloquine caused irreversible central nervous system toxicity. Studies had linked the use of the antimalarial quinoline derivatives to neurological degeneration in human and animal subjects, concluding the drugs induced highly localized degenerative changes associated with functional derangement. During the

ensuing decades, more studies reached similar conclusions about quinoline derivatives similar to Mefloquine.

33. By 1990, European drug safety agencies received recurring reports of severe neuropsychiatric symptoms in individuals who had been prescribed Mefloquine. In the Netherlands, Mefloquine was the cause of the highest or second-highest number of drug-related adverse reports in 1998 and 1999. A case control study of 564 Dutch travelers between 1997 to 2000 found a three-fold increase in serious psychiatric side effects compared to the control population.

34. In 1995, researchers conducted two successive double-blind trials of Mefloquine in British soldiers in Kenya. The goal was to look at the prevalence of neuropsychiatric disorders in military users of Mefloquine. The researched compared Mefloquine with the pre-existing options for malaria prevention. The results demonstrated that a third of all soldiers taking Mefloquine had severe side effects that interfered with their daily life and were intolerable. In one of the trials, there were two extreme, unpredictable events. One soldier became psychotic and had to be evacuated to the UK and another soldier committed suicide.

35. In 2001, researchers conducted the first formal randomized double blind controlled study of Mefloquine in a representative civilian population. The study showed that prodromal symptoms associated with use of Mefloquine occurred at a rate of over 10% and that immediate cessation of the drug would therefore be required in over 10% of cases. The study also concluded that the specific neuropsychiatric symptoms associated with Mefloquine use included nightmares, anxiety and psychosis—symptoms that are commonly attributed to combat exposure and other war-time experiences. The comparator drug Malarone was found to be equally as effective at preventing Malaria and performed far better than Mefloquine in every other respect: it had fewer treatment-related neuropsychiatric events, fewer adverse events of moderate or severe intensity, and fewer patients had to discontinue the drug. In short, the study demonstrated that Malarone was equally as

effective but substantially safer.

36. Subsequent studies have found a range of adverse neuropsychiatric effects associated with Mefloquine use. Among the many adverse outcomes are vivid and terrifying auditory or visual hallucinations, verbal, motor, and processing deficits, and behavioral changes such as aggressive violence and suicidal ideations. Studies have also found that Mefloquine toxicity is often associated with severe vestibular harms such as vertigo, loss of balance, and disequilibrium. The combination of psychiatric and neurological disturbances is considered to be a hallmark of Mefloquine toxicity. Prodromal symptoms typically begin after the first few doses are taken. However, the symptoms persist for years after Mefloquine use is discontinued and are typically permanent and irreversible. These adverse outcomes interfere with an individual's daily activities and ability to work.

37. There now exist dozens of peer-reviewed published studies describing the adverse neuropsychiatric effects of Mefloquine toxicity, including both retrospective and prospective observational studies. While the pharmaceutical industry is aware of the existence and meaning of these studies, the public at large typically is not.

38. In July 2013, in response to the prevalence of neuropsychiatric side effects experienced by service members taking Mefloquine and studies confirming the causal link between the two, the FDA put a black box warning on Mefloquine—its strictest form of warning. The FDA warned of Mefloquine's severe neuropsychiatric side effects, which could "persist after mefloquine has been discontinued."

> Neurologic side effects can occur at any time during drug use, and can last for months to years after the drug is stopped or can be permanent. Patients, caregivers, and health care professionals should watch for these side effects. When using the drug to prevent malaria, if a patient develops neurologic or psychiatric symptoms, mefloquine should be stopped, and an alternate medicine should be used. If a patient develops neurologic or psychiatric symptoms while on mefloquine, the patient should contact the prescribing health care professional. The patient should not stop taking mefloquine before discussing symptoms with the health care professional. The mefloquine drug label already states that mefloquine should not be prescribedto prevent malaria in patients with major psychiatric disorders or with

a history of seizures. ***The changes to the mefloquine drug label better describe the possibility of persistent neurologic (vestibular) adverse effects after mefloquine is discontinued and the possibility of permanent vestibular damage***.

39. According to the FDA, the new warnings added to the Mefloquine drug label in 2013 "better describe the possibility of persistent neurologic (vestibular) adverse effects after mefloquine is discontinued and the possibility of permanent vestibular damage." Indeed, it was not until these changes to the drug label that patients then prescribed the drug were adequately warned that Mefloquine can cause a range of permanent and irreversible neuropsychiatric side effects that can persist long after the drug has been discontinued. Various other changes were made to the warning label at that time, including more thorough and detailed explanations of the type of neurologic symptoms that the drug could cause, the risk of adverse effects being permanent, the need for periodic evaluations for neuropsychiatric effects, and information on studies regarding central nervous system penetration of Mefloquine. Patients who had taken the drug prior to the labeling changes were not notified of any such changes and would have no reasonable basis for becoming aware of them.

40. After the FDA's black-box warning, the U.S. military changed its Mefloquine prescribing policies. It re-designated Mefloquine as a drug of last resort to be taken only after other malaria prevention drugs were found to be ineffective. The U.S. military's policy change demonstrates that adequate warnings of Mefloquine's side effects would have spared U.S. service members lifelong psychiatric and neurological disorders.

III. Roche Obfuscated the True Dangers of Mefloquine When it Obtained Approval for and Marketed Mefloquine as a Safe First-Line Drug for Malaria Prevention

41. As the manufacturer and distributor of the drug, Roche was at all times aware of the potential dangers of Mefloquine and the ever-increasing literature reporting severe and irreversible neuropsychiatric side effects of the drug.

42. Roche applied for and obtained FDA approval of the drug in 1989. Given the

existence of studies reporting encephalitic and neurotoxic adverse effects of drugs in this class, Roche knew or should have known of the significant dangers associated with Mefloquine at that time. The known dangers of Mefloquine should have readily led Roche to conduct trials capable of and intended to validly assess the true incidence of neuropsychiatric adverse outcomes.

43. Instead, however, Roche chose to pursue study designs that it knew or should have known would mask the true incidence of the drug's psychiatric side effects. For instance, Roche flooded the Thailand market with Mefloquine, knowing the adverse effects of the drugs would not be accurately identified and/or reported by individuals taking the drug in Thailand—largely refugees of war-torn countries. Roche then used the lack of reported adverse outcomes as evidence of the drug's safety in order to obtain FDA approval of the drug. Roche's knowing pursuit of a pattern of pre-licensing clinical studies that intentionally obfuscated the true nature and incidence of the drug's adverse outcomes demonstrates that Roche engaged in dangerous and reckless conduct from the outset of the drug's approval.

44. Tellingly, the trials that Roche presented to the FDA did not include any data suggesting Mefloquine use was associated with neuropsychiatric side effects. Indeed, Roche claimed that the trials showed the drug had no psychiatric side effects when used prophylactically, despite considerable evidence to the contrary. Yet, shortly after the drug received FDA approval, Roche included a statement buried on the packaging insert that Mefloquine use should be discontinued if psychiatric side effects occur. The inclusion of this statement, by itself, demonstrates that Roche was aware of the risks and dangers associated with Mefloquine use, but failed to properly disclose that to the FDA at the time it sought and obtained FDA approval.

45. Following initial approval of Mefloquine in 1989, there continued to be increasing data establishing the severe and irreversible neuropsychiatric outcomes associated with Mefloquine use. Nonetheless, Roche continued to market and sell the drug as a safe, first-line drug for malaria

prevention. Roche knew or should have known of the risk of various severe and permanent neuropsychiatric effects of Mefloquine toxicity. Yet, Roche never adequately warned on the packaging inserts or drug labeling that Mefloquine use could cause a variety of permanent and irreversible neuropsychiatric effects.

46. Roche also knew or should have known that the risk of serious side effects of Mefloquine far outweighs the benefits of malaria prevention. Safer and equally effective alternatives for malaria prevention existed. Despite knowing that these safer alternatives existed, Roche recklessly marketed and sold Mefloquine to the U.S. military as a safe, first-line drug for malaria prevention.

47. Roche also knew or should have known that Mefloquine could not be prescribed to U.S. military service members in a manner that complied with their own prescribing protocols. Roche themselves stated that the drug should not be administrated to individuals with a history of psychiatric illness. However, Roche knew that military service members had a special risk of evading a proper risk assessment for these contraindications. For instance, in 2016, a committee of the British House of Commons conducted a months-long inquiry into the safety of Mefloquine for British Armed Forces. During the course of that investigation, which concluded that Mefloquine should be considered as a "drug of last resort," it became clear that Roche knew of the distinct risk that military culture, operations and prescribing protocols would cause military agencies to breach Roche's prescribing guidance. Mike Kindell, Roche's Lead of Established Products, testified that he was aware of the risk that the typical person prescribed the drug (*i.e.*, military service members) may, for example, feel unable to disclose to their prescribing physician a history of psychiatric illness or depression for fear of damaging their career. He further testified that it was a "fair statement" that a solider would be inhibited in reporting past anxiety to a prescribing physician.

48. During the hearing, Dr. Frances Nichols, Roche's Head of Drug Safety Quality,

admitted that the military's use of a mass prescribing protocol—a protocol initiated and encouraged by Roche's actions—violated its own prescribing guidelines:

> **[Member]:** I accept that. The premise of my question is: if there is an organization that does not do individual risk assessments, is that, or is that not, clearly outside the manufacturer's guidelines?
>
> ***Dr Nichol:*** The expectation would be that an individual risk assessment is done by prescribers at the time.
>
> …
>
> **[Member]:** When you push out the drug, you have your manufacturer's guidelines and within that you say that it should be prescribed after an assessment. So if an organization goes outside that, surely they are using the drug outside the guidelines that you stated as the manufacturer of that drug.
>
> ***Dr Nichol:*** Yes, the guidelines do say an individual risk assessment should be done….

49. Roche's testimony before the British Parliament establishes that they knew that military service members had a special risk of evading the proper risk assessment necessary before administration of the drug and that their intentional marketing and sale of the drug to the U.S. military would lead to mass prescribing protocols inconsistent with Roche's own prescribing protocols.

50. Roche also knew that Mefloquine could not be used by U.S. military service members in a manner that complied with their own prescribing protocols. Roche themselves stated that the drug should be discontinued, and an alternative medication substituted, if psychiatric symptoms of anxiety, depression, restlessness or confusion occur. Yet, Roche knew that, given the circumstances under which the drug was being prescribed, military service members would not know to discontinue use of the drug if these symptoms presented. The U.S. service members taking Mefloquine were largely in remote parts of Afghanistan and other foreign countries and surrounded by threatening enemy forces. Service members and their physicians under these conditions could not be expected to make a judgment linking the source of anxiety, depression and paranoia to Mefloquine and to thereby discontinue use of the drug, rather than attributing those symptoms to

their inherently stressful surroundings. Roche therefore knew that it would be impossible for military service members using Mefloquine to comply with the drug's prescribing protocols.

51. Importantly, while Roche's prescribing protocols provided that the drug should not be administrated to individuals with a history of psychiatric illness and that it should be discontinued if psychiatric symptoms occurred, they did not adequately warn of the likelihood of neuropsychiatric outcomes from taking the drug, the types of neuropsychiatric outcomes that could occur, or the permanent and irreversible nature of these outcomes. To the contrary, Roche knowingly withheld these facts from the individuals prescribed the drug.

IV. Roche's Tortious Conduct in Labeling

52. 21 U.S.C. § 352(a)(1) provides, in pertinent part, that a drug or device is deemed to be misbranded "[i]f its labeling is false or misleading in any particular." Roche violated 28 U.S.C. §352(a)(1) because it failed to adequately and truthfully warn the U.S. military, the military service members, and their physicians of the risk of various severe, permanent and irreversible psychiatric and neurological side effects on the package inserts and drug labeling for Mefloquine. The U.S. military relied on information published in the package inserts of Physician's Desk Reference otherwise disseminated by the Referenced Listed Drug Company or the New Drug Application Holder, and the U.S. military physicians were unaware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated by Roche

53. 21 C.F.R. § 201.5 requires a manufacturer to give adequate directions for the use of a pharmaceutical drug that a "layman can use a drug safely and for the purposes for which it is intended," and conform to the requirements governing the appearance of the label. Roche previously stated on the drug label that the drug should be discontinued if psychiatric symptoms of anxiety, depression, restlessness or confusion occur. Roche also previously stated on the drug label that the

drug should not be prescribed to individuals with a current or past history of psychiatric disorders. However, Roche knew that military service members could not be prescribed the drug and could not use the drug in a manner that conformed to those requirements.

54. For instance, Roche knew that military service members had a special risk of evading a proper risk assessment for the drug's contraindications, and that the U.S. military would have a mass prescribing protocol inconsistent with Roche's own prescribing instructions. Roche also knew that, given the circumstances under which the drug was being prescribed, military service members would not be able to use the drug safely by knowing to discontinue the use of the drug if these symptoms presented themselves. Roche nevertheless marketed the drug to the U.S. military as safe for the purposes for which it was intended—malaria prevention in U.S. military service members deployed abroad.

V. Defendants' Liability to Individuals Who Took Generic Versions of Mefloquine

55. California law applies to the claims of Plaintiff and all Class Members. California choice of law analysis carries a presumption that California law applies, and the proponent of the foreign state law bears the burden of showing a compelling reason justifying displacement of California law. Here, due to the nature of the circumstances under which Plaintiff and the Class Members were prescribed and ingested Mefloquine as U.S. military service members, they necessarily took the drug in various locations—both within the United States and abroad—and rarely if ever in their place of residence. Further, Defendants maintain their principal place of business in California, and California has a significant interest in encouraging corporations to manufacture safe products, regardless of whether these products will affect California residents. Accordingly, there is no foreign state with a greater interest in the claims of Plaintiff and Class Members than California. The presumption in favor of California law applies in this case.

56. California law imposes a duty of care on the manufacturer of a brand-name drug that

flows to the consumer of the brand-name drug's generic equivalent.

57. The California Supreme Court has recognized that "a brand-name drug manufacturer has a duty under California law to warn of the risks about which it knew or reasonably should have known, regardless of whether the consumer is prescribed the brand-name drug or its generic 'bioequivalent.'" *T.H. v. Novartis Pharm Corp.*, 4 Cal.5th 145 (2017).

58. This duty, known as "innovator liability," applies to Defendants in this case and renders them liable to individuals who took both the brand-name drug Lariam and any of its generic Mefloquine-containing bioequivalents.

VI. The Need for and Utility of Medical Monitoring

59. Plaintiff and the Class members were prescribed Mefloquine for the prevention of malaria during deployment overseas. Plaintiff and the Class Members used Mefloquine designed, manufactured and/or sold by Defendants and/or manufacturers of generic equivalents.

60. As a direct and proximate result of consuming Mefloquine, Plaintiff and the Class Members were put at a significantly increased risk of contracting the various neuropsychiatric side effects of Mefloquine use. Given that Plaintiff and the Class Members already took the drug, they have already suffered injuries associated with the use of Mefloquine. However, due to the Defendants' concerted effort to conceal and withhold information related to Mefloquine use, Plaintiff and Class members were and/or are unaware that the symptoms they are experiencing are associated with their past Mefloquine use. On information and belief, the vast majority of Class members—including Plaintiff—have been misdiagnosed with other psychiatric conditions and mistreated for those conditions.

61. A reasonably prudent physician would conclude that Plaintiff's and Class Members' exposure to Mefloquine necessitates specialized testing and treatment that is not generally given to the public at large as part of routine medical care.

62. The available monitoring regime, discussed in greater detail below, is reasonably necessary and specific for individuals exposed to Mefloquine. It is different from that normally recommended in the absence of exposure to this drug and is not generally provided by physicians at the Department of Veteran Affairs or general practitioner setting.

63. The available medical monitoring regime will mitigate the health effects associated with Mefloquine toxicity, improving prognosis, outcome and quality of life, and reducing medical costs. Indeed, Mefloquine toxicity is frequently misdiagnosed and attributed to other psychiatric causes. This results not only in misdiagnosis, but a variety of inappropriate treatments—including, *inter alia*, prescription of unnecessary antipsychotics, antidepressants, and/or bipolar medications. Administration of these types of psychiatric drugs presents the possibility that treatment of affected individuals could result in exacerbation of symptoms with significant detrimental health effects. These problems may be ameliorated by appropriate diagnostic procedures, including record review of an individual's prescribing history, careful clinical history and other neuropsychiatric evaluation.

64. A medical monitoring program in this case would typically begin with screening of all Class Members to assess for relevant exposure and symptoms. The White River Mefloquine Instrument – 2 Question (WRMI-2) has been specifically developed to screen for Mefloquine toxicity with a high-level of sensitivity. A positive exposure screen should prompt a focused Mefloquine history, inquiring about pre-exposure symptomatology, confirmed or suspected prodromal symptoms, circumstances of any continued use, evolution of symptoms, and temporal relation of symptoms to other exposures. This screening may be conducted via questionnaire, in-person before a medical practitioner, or via a telehealth appointment.

65. When the medical practitioner reviewing the questionnaire or conducting the screening appointment determines additional testing for purposes of diagnosis is required, the testing may include one or more of the tests described below, subject to the then-state-of-the art

standard of care: Careful and thorough neuropsychological testing, Vestibular Oculomotor Screening, Computerized Dynamic Posturography testing, Videonystagmography testing, Optokinetic Nystagmus testing, Maddox-Rod testing, Magnetic-Resonance Imaging, and/or Positron Emission Tomography.

66. The following are examples only, and are subject to change, based on expert testimony and/or developing standards of care.

67. The testing described above is different from that normally recommended in the absence of Mefloquine exposure. It is not conducted or analyzed by a general practitioner, including physicians employed by the Department of Veterans Affairs, nor is it recommended to the public at large as part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in their respective areas, including neurology, neuro-otology, neuro-ophthalmology, sleep medicine, and neuropsychology.

68. Mefloquine toxicity is distinguishable from other forms of psychiatric illness in that it features certain prominent and distinguishing characteristics that can be determined through careful and thorough medical evaluation. Mefloquine toxicity is typically associated with a collection of significant neurological and psychiatric symptoms affecting balance, vision, hearing, memory, mood and behavior. The presentation of permanent neurological damage, including vertigo, balance disorders and visual disturbance, in the absence of a severe initiating traumatic incident, can further aid in distinguishing Mefloquine toxicity from other psychiatric illnesses. Accordingly, appropriate and adequate diagnostic testing is capable of distinguishing Mefloquine toxicity from other forms of illness.

69. By receiving adequate diagnostic testing, the risk that Plaintiff and Class members will be misdiagnosed and/or mistreated for other mental or psychiatric conditions will be significantly reduced. Misdiagnosis could result in long-term mismanagement of affected

individuals, potentially exacerbating their symptoms rather than relieving them.

VII. Mr. Nelson's Potential Mefloquine Toxicity

70. Mr. Nelson is a 35-year-old decorated military veteran who is permanently disabled and is currently undergoing diagnostic evaluation for Mefloquine toxicity.

71. In 2005, Mr. Nelson entered the U.S. military without any history of neuropsychiatric disorder. He had no history of insomnia, depression, anxiety, amnesia, or any psychosis of any sort, and he had never once received treatment for a mental condition. Upon enlistment, Mr. Nelson was deemed qualified to serve in the U.S. military, and he did so at that time.

72. Between 2005 and February 2008, while enlisted in the U.S. military, Mr. Nelson exhibited no neuropsychiatric symptoms and never received treatment for any mental condition. From October 2005-October 2006, Mr. Nelson was sent to South Korea and stationed in an underground bunker. He never experienced any insomnia, depression, anxiety, or psychosis during his tour in South Korea or at any time prior to February 2008.

73. Mr. Nelson was deployed to Afghanistan in February 2008. As set forth above, Mr. Nelson's service in the U.S. military before his deployment to Afghanistan in February 2008 showed no meaningful changes to his medical or mental profile.

74. Prior to his deployment to Afghanistan, Mr. Nelson was provided Mefloquine to prevent Malaria. He began consuming the Mefloquine approximately two weeks prior to his deployment, and he then consumed it consistently once per week until approximately April 2009. Following Mr. Nelson's consumption of Mefloquine, his mental and psychiatric state were forever changed.

75. The first symptoms he experienced upon taking the drug were vivid stimulating dreams and other sleep disturbances. These disturbances, which began within 24-48 hours of initial Mefloquine use, caused him to repeatedly wake up during the night in an anxious and disturbed

state. While the symptoms began immediately, the impact that Mefloquine has had on Mr. Nelson's ability to sleep is permanent and irreversible under current medical standards. Mr. Nelson has rarely had a night of uninterrupted, quality sleep since he first took Mefloquine.

76. During his deployment to Afghanistan in 2008/2009, Mr. Nelson began experiencing severe emotional instability, which led to suicidal ideations and a feeling of being unable "to cope with everyday life."

77. Although surrounded by the stresses of war time, while deployed to Afghanistan, Mr. Nelson was never in direct combat and experienced no direct traumatic experiences that would typically lead to Post Traumatic Stress Disorder.

78. Mr. Nelson's symptoms continued to worsen over the years. Mr. Nelson attempted suicide in 2011 and again in 2014. He also began to engage in erratic psychosocial behaviors.

79. After Mr. Nelson's initial suicide attempt, he was evaluated by a mental health professional with the U.S. military. The evaluation was unproductive and did not result in any diagnosis or follow-up treatment. Following further progression of his symptoms, Mr. Nelson was again evaluated by a mental professional with the U.S. military in 2014. He was diagnosed with depression and prescribed an antidepressant at that time. He was also prescribed benzodiazepines and other forms of antidepressants in the ensuing months.

80. Despite these treatments, Mr. Nelson's symptoms and behaviors continued and even worsened. Thus, he was again assessed by a mental health professional with the U.S. military. At that time, he was placed in an in-patient psychiatric treatment facility. He was treated by a civilian psychiatrist, who diagnosed him with bipolar disorder and prescribed him antipsychotic medications.

81. Mr. Nelson was eventually placed into military retirement and honorably discharged from service in the military in 2015. Upon his discharge, he was subject to a thorough medical and

mental evaluation by the U.S. military and was diagnosed as having a permanent condition of bipolar disorder.

82. Following his discharge from the military, Mr. Nelson continued to experience severe and worsening neuropsychiatric effects. Despite the medications he was prescribed, he continued having suicidal ideations, severe anxiety, panic attacks, paranoia and insomnia. He also experienced severe vestibular and sensory problems, including vertigo and problems with his balance, which are a hallmark of Mefloquine toxicity. These effects are debilitating and permanent, and Mr. Nelson will never be able to regain the quality of life and functional abilities that he had before being prescribed Mefloquine (subject to current state-of-the-art standard of care or recommendations by practitioners skilled in the diagnosis and treatment of the condition).

83. In February 2020, just prior to the Covid pandemic, Mr. Nelson attended a conference in Washington D.C. regarding the long-term health effects of anti-malaria medications. At the conference, he met the leading researcher in the field on Mefloquine toxicity and discussed with him the literature and science supporting the causal link between Mefloquine and the neuropsychiatric side effects he had been experiencing. While the onset of the Covid pandemic initially prevented Mr. Nelson from pursuing diagnostic evaluation associated with what he had learned at the Washington D.C. conference, he was eventually able to begin the process of obtaining the appropriate medical evaluation and testing to determine if he is suffering from Mefloquine toxicity.

84. Mr. Nelson is currently undergoing a variety of diagnostic evaluation and testing related to his Mefloquine use, all of which he has had to pay for out-of-pocket because the requisite testing is not covered and/or approved by the Department of Veteran Affairs. Mr. Nelson is currently being seen by a neuro-otologist specializing in vestibular injuries. Based on his most recent tests, his treating physician indicated that he was likely experiencing Mefloquine-induced

encephalopathy. However, further medical diagnostic evaluation is still required to confirm the diagnosis.

85. It was not until Mr. Nelson attended the conference in Washington D.C. in February 2020 that he had sufficient information to believe he may be experiencing Mefloquine toxicity and that he should pursue medical evaluation and testing to confirm the appropriate diagnosis.

VIII. Tolling/Fraudulent Concealment

86. Plaintiff brings this medical monitoring complaint within the applicable statute of limitations. Specifically, Plaintiff brings this action within the prescribed time limits following Plaintiff's awareness of the potential wrongful cause of his injuries. Prior to such time, Plaintiff did not know of the potential wrongful cause of his injuries.

87. Plaintiff asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

88. The discovery rule applies to toll the running of the statute of limitations until Plaintiff and Class Members knew, or through the exercise of reasonable care and diligence should have known, that they had been injured, the cause of the injury, and the tortious nature of the wrongdoing that led to their injury.

89. The running of the statute of limitations is also tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiff and Class Members about the severe and irreversible risks associated with Mefloquine use. As a result of Defendants' misrepresentations and concealment, Plaintiff's and Class Members' physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to Defendants' misrepresentations or omissions that they had been exposed to the risk alleged

herein or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

CLASS ALLEGATIONS

90. Plaintiff brings this action on behalf of himself and all other similarly situated class members (the "Class Members") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following class against Defendants:

> All U.S. military service members who took Mefloquine, including as to both the brand name Lariam and any generic equivalents, and who experienced prodromal neuropsychiatric symptoms during use of the drug.
>
> Excluded from the Class are individuals who have already been diagnosed with Mefloquine-toxicity. Also excluded from this Class are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

91. Alternatively, Plaintiff brings this action on behalf of the following state subclasses:

> California Subclass: All U.S. military service members currently citizens of California who took Mefloquine, including as to both the brand name Lariam and any generic equivalents, and who experienced prodromal neuropsychiatric symptoms during use of the drug.
>
> Florida Subclass: All U.S. military service members currently citizens of Florida who took Mefloquine, including as to both the brand name Lariam and any generic equivalents, and who experienced prodromal neuropsychiatric symptoms during use of the drug.

92. The members of the Class are so numerous that joinder of all Class Members is impracticable. Plaintiff is informed and believes that the proposed Class contains hundreds of thousands of military service members who require medical monitoring as a result of Defendants' actions, as alleged herein. The precise number of Class Members is unknown to Plaintiff at this

time.

93. Plaintiff's claims are typical to those of all Class Members because Class Members were all exposed to the same uniform misconduct described above and were all subject to Defendants' negligent and reckless conduct. Plaintiff is advancing the same claims and legal theories on behalf of himself and all Class Members.

94. Plaintiff's claims raise questions of law and fact common to all Class Members, and they predominate over any questions affecting only individual Class Members. These common legal and factual questions include the following:

a. whether Mefloquine is capable of causing adverse neuropsychiatric effects;

b. whether Defendants knew or should have known that Mefloquine was capable of causing adverse neuropsychiatric side effects;

c. whether Defendants acted negligently or recklessly in marketing Mefloquine as a first-line treatment for malaria to the U.S. military;

d. whether, in obtaining FDA approval for Mefloquine, Defendants conducted and relied on clinical trials intended to obfuscate the true incidence of neuropsychiatric harms associated with Mefloquine use;

e. whether Defendants acted to conceal the fact that Mefloquine poses an unacceptable risk of adverse neuropsychiatric side effects;

f. whether Defendants' warnings regarding the risks of Mefloquine were adequate;

g. whether Defendants provided inadequate information about the risks of Mefloquine toxicity in the packaging inserts and/or labeling for the drug;

h. whether Defendants knew or should have known that U.S. military service members could not be prescribed the drug in a manner that complied with Defendant's own prescribing protocols;

i. whether Defendants knew or should have known that U.S. military service members were at a special risk of evading a proper risk assessment for Mefloquine use;

j. whether Defendants knew or should have known that U.S. military service members could not use the drug in a manner that complied with Defendants' own prescribing protocols;

k. whether Defendants knew or should have known that U.S. military service members and their physicians could not be expected to know to discontinue Mefloquine use upon the onset of psychiatric symptoms;

l. whether Defendants were negligent in labeling, marketing advertising, promoting, manufacturing and/or selling Mefloquine to the U.S. military;

m. whether Defendants are liable for failing to adequately warn of the risks associated with use of Mefloquine;

n. whether Plaintiff and Class Members are entitled to medical monitoring relief as a result of their exposure to Mefloquine;

o. the type and format of medical monitoring relief that is appropriate.

95. Plaintiff and his counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff has retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases similar to that here and has the resources and abilities to fully litigate and protect the interests of the Class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses.

96. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The quintessential purpose of the class action mechanisms is to

permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiff and Class Members are relatively small when compared to the burden and expense required to individually litigate their claims against Defendants, and thus, individual litigation to redress Defendants' wrongful conduct would be impracticable. Individual litigation by each Class Member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

97. **Injunctive and Declaratory Relief**: Class certification is also appropriate under Rule 23(b)(2) because Defendants acted and refused to act on grounds generally applicable to the Class as a whole, such that final declaratory and injunctive relief is appropriate with respect to the Class as a whole. Such declaratory and/or injunctive relief includes, but is not limited to, the implementation and funding of a medical monitoring program for Plaintiff and Class Members that is sufficient to monitor their health and ensure appropriate detection and diagnosis of Mefloquine toxicity.

CAUSES OF ACTION

COUNT I
Negligent Failure to Warn
All Classes

98. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

99. Plaintiff brings this claim individually and on behalf of the Class Members.

100. Manufacturers, including Defendants, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing

scientific and medical knowledge available at the time of manufacture and distribution.

101. Defendants breached the duties imposed on them in the marketing and sale of Mefloquine. The warnings included on Mefloquine were inadequate because they did not adequately warn of the risk of a variety of permanent and irreversible adverse neuropsychiatric harms.

102. Furthermore, Defendants failed to warn of the special risk that U.S. military service members faced in being prescribed Mefloquine, including the special risk of evading a proper risk assessment and the inability to appropriately cease use of the drug upon onset of neuropsychiatric symptoms.

103. Defendants also failed to warn that the risks of Mefloquine toxicity outweighed its benefits and that there were other, safer alternatives available for malaria-prevention than Mefloquine.

104. As a direct and proximate result of Defendants' failure to provide adequate warnings of the risk of Mefloquine, Plaintiff and Class Members were commonly exposed to a significantly increased risk of Mefloquine toxicity and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring, including appropriate diagnostic testing and evaluation.

105. The injuries from which Plaintiff and Class Members suffer require specialized testing that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to Mefloquine and is different from that normally recommended in the absence of exposure to this risk of harm.

106. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of Mefloquine toxicity. The diagnostic program will counteract the likelihood of unnecessary treatments and medications

for misdiagnosed conditions and will help to mitigate the health effects associated with Mefloquine toxicity.

107. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of Mefloquine toxicity.

108. By monitoring and testing Plaintiff and the Class Members, the risk that Plaintiff and Class Members will suffer losses without adequate treatment or inappropriate treatment will be significantly reduced.

109. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate a proper diagnoses of Mefloquine toxicity. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and Class Members as frequently and appropriately as necessary.

110. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of every Class Member; and (b) notifying all the Class Members in writing that they may require medical monitoring for the purpose of diagnosis.

111. Plaintiff and the Class Members have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Mefloquine. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and Class Members will continue to face an unreasonable risk of remaining undiagnosed and/or being misdiagnosed and mistreated**.**

COUNT II
Negligent Design
All Classes

112. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

113. Plaintiff brings this claim individually and on behalf of the Class Members.

114. Manufacturers, including Defendants, have a duty of reasonable care in all aspects of the design, formulation, manufacture, testing, inspection, packaging, labeling, distribution, marketing, sale and testing to assure the safety of Mefloquine when used as intended in a way that Defendants could reasonably have anticipated, and to assure that the public, including Plaintiff and Class Members, obtained accurate information and adequate instructions for the use or non-use of Mefloquine.

115. Defendants failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Mefloquine was not properly manufactured, designed, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

116. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Negligent and careless research and testing of Mefloquine;

b. Negligent and careless design or formulation of Mefloquine;

c. Negligent and careless failure to provide instructions on ways to safely use Mefloquine to avoid injury;

d. Negligent and careless failure to explain the mechanism, mode, and types of adverse events associated with Mefloquine; and

e. Negligent and careless failure to conduct post marketing surveillance of adverse events associated with Mefloquine.

117. As a direct and proximate result of Defendants' negligence, Plaintiff and Class Members were commonly exposed to a significantly increased risk of Mefloquine toxicity and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring, including appropriate diagnostic testing and evaluation.

118. The injuries from which Plaintiff and Class Members suffer require specialized testing that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to Mefloquine and is different from that normally recommended in the absence of exposure to this risk of harm.

119. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of Mefloquine toxicity. The diagnostic program will counteract the likelihood of unnecessary treatments and medications for misdiagnosed conditions and will help to mitigate the health effects associated with Mefloquine toxicity.

120. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of Mefloquine toxicity.

121. By monitoring and testing Plaintiff and Class Members, the risk that Plaintiff and Class Members will suffer losses without adequate treatment or inappropriate treatment will be significantly reduced.

122. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Mefloquine toxicity. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and Class Members as frequently and appropriately as necessary.

123. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of every Class Member, as frequently and appropriately as necessary; and (b) notifying all Class Members in writing that they may require medical monitoring for the purpose of diagnosis.

124. Plaintiff and Class Members have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Mefloquine. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated.

COUNT III
Strict Liability-Failure to Warn
All Classes

125. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

126. Plaintiff brings this claim individually and on behalf of the Class Members.

127. Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Mefloquine and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

128. Defendants had a duty to provide adequate warnings and instructions for Mefloquine, to use reasonable care to design a product that is not unreasonably dangerous to the intended users, and to adequately understand, test, and monitor their product

129. The Mefloquine drug supplied to Plaintiff and Class Members was defective due to inadequate warnings, labeling, or instructions concerning the foreseeable risks of its use. Defendants' failure to provide these adequate warnings and/or instructions made Mefloquine unreasonably dangerous.

130. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, or otherwise, that Mefloquine creates a significant risk of serious and irreversible neuropsychiatric harms.

131. Defendants' failure to provide adequate warnings or instructions rendered

Mefloquine unreasonably dangerous in that it failed to perform as safely as an ordinary service member and prescriber would expect when used as intended and/or in a manner reasonably foreseeable by the Defendants, and in that the risk of danger outweighs the benefits.

132. The Mefloquine supplied to Plaintiff and Class Members was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold. Further, Defendants continued to acquire mounting evidence and information confirming the defective and unreasonably dangerous nature of Mefloquine. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings that Mefloquine causes serious and irreversible neuropsychiatric harms.

133. Defendants failed to provide adequate warnings to the U.S. military and its service members, and instead continued to sell Mefloquine in an unreasonably dangerous form without adequate warnings or instructions.

134. By failing to adequately test and research harms associated with Mefloquine, and by failing to provide appropriate warnings and instructions about Mefloquine use, the U.S. military, service members and their prescribing doctors were inadequately informed about the true risk-benefit profile of Mefloquine and were not sufficiently aware of the serious and irreversible neuropsychiatric harms harm associated with the use of Mefloquine.

135. The Mefloquine designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was also defective due to inadequate post marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks of severe and permanent neuropsychiatric harm from ingesting Mefloquine, they failed to provide adequate warnings to users of the drug, and continued to improperly advertise, market and/or promote Mefloquine.

136. The foreseeable risk of serious and irreversible neuropsychiatric harms caused by

Mefloquine could have been reduced or avoided had Defendants provided reasonable and appropriate instructions or warnings about these harms.

137. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class Members were commonly exposed to a significantly increased risk of Mefloquine toxicity and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring, including appropriate diagnostic testing and evaluation.

138. The injuries from which Plaintiff and the Class Members suffer require specialized testing that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to Mefloquine and is different from that normally recommended in the absence of exposure to this risk of harm.

139. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of Mefloquine toxicity. The diagnostic program will counteract the likelihood of unnecessary treatments and medications for misdiagnosed conditions and will help to mitigate the health effects associated with Mefloquine toxicity.

140. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of Mefloquine toxicity.

141. By monitoring and testing Plaintiff and Class Members, the risk that Plaintiff and Class Members will suffer losses without adequate treatment or inappropriate treatment will be significantly reduced.

142. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Mefloquine toxicity. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of

Plaintiff and Class Members as frequently and appropriately as necessary.

143. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of every Class Member, as frequently and appropriately as necessary; and (b) notifying all Class Members in writing that they may require medical monitoring for the purpose of diagnosis.

144. Plaintiff and Class Members have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Mefloquine. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated.

COUNT IV
Strict Liability-Design Defect
All Classes

145. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

146. Plaintiff brings this claim individually and on behalf of the Class Members.

147. Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Mefloquine and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

148. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use by military service members.

149. Defendants breached that duty when they created a product unreasonably dangerous for its intended and foreseeable use by military service members.

150. Defendants designed, researched, manufactured, tested, advertised, promoted,

marketed, sold and distributed a defective product to the U.S. military which created an unreasonable risk to the health of military service members, and Defendants are therefore strictly liable to Plaintiff and Class Members.

151. The Mefloquine drug supplied to Plaintiff and Class Members was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and defective condition because it failed to perform as safely as an ordinary military service member would expect when used as intended or in a manner reasonably foreseeable to Defendants, posinga risk of serious and irreversible neuropsychiatric harms to Plaintiff and the Class Members.

152. Plaintiff, the Class Members, and their prescribing physicians would not expect a drug designed, marketed, and labeled for malaria prevention in military service members to cause irreversible neuropsychiatric damage.

153. These design defects render Mefloquine more dangerous than other drugs and therapies designed to prevent Malaria and cause an unreasonable increased risk of injury, including but not limited to irreversible neuropsychiatric harms.

154. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, or otherwise, that Mefloquine created a risk of serious and irreversible neuropsychiatric harms.

155. Mefloquine is defective and unreasonably dangerous to Plaintiff and Class Members in that, despite early indications and concerns that Mefloquine use could result in neuropsychiatric harms, Defendants failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, the potential effects and risks of long-term use, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

156. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class Members were commonly exposed to a significantly increased risk of Mefloquine toxicity and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring, including appropriate diagnostic testing and evaluation.

157. The injuries from which Plaintiff and Class Members suffer require specialized testing that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to Mefloquine and is different from that normally recommended in the absence of exposure to this risk of harm.

158. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of Mefloquine toxicity. The diagnostic program will counteract the likelihood of unnecessary treatments and medications for misdiagnosed conditions and will help to mitigate the health effects associated with Mefloquine toxicity.

159. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of Mefloquine toxicity.

160. By monitoring and testing Plaintiff and Class Members, the risk that Plaintiff and Class Members will suffer losses without adequate treatment or inappropriate treatment will be significantly reduced.

161. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Mefloquine toxicity. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and Class Members as frequently and appropriately as necessary.

162. Accordingly, Defendants should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of every Class Member, as frequently and appropriately as necessary; and (b) notifying all Class Members in writing that they may require medical monitoring for the purpose of diagnosis.

163. Plaintiff and Class Members have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Mefloquine. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated

Count V
Negligent Misrepresentation
All Classes

164. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

165. Plaintiff brings this claim individually and on behalf of the Class Members.

166. Defendants misrepresented to the U.S. military, physicians and end-users, including Plaintiff and the Class Members, that Mefloquine was a safe first-line treatment for malaria prevention, when, in fact, Mefloquine was dangerous to the well-being of its users and particularly military service members.

167. Defendants knew or should have known that marketing and representing Mefloquine to the U.S. military as a safe, first-line treatment for malaria prevention in military service members was a false representation that would, and did, mislead the U.S. military, physicians and service members to believe that Mefloquine should and can be used as a first-line treatment for malaria prevention.

168. Not only did Defendants know of the falsity of the aforementioned representations, but Defendants purposefully marketed Mefloquine to the U.S. military with an intent to induce it

to prescribe Mefloquine to service members when it knew service members could not use the drug in a manner that complied with their own prescribing protocols.

169. At the time Defendants promoted Mefloquine as safe and well-tolerated, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Mefloquine was dangerous to the well-being of Plaintiff and Class Members, including because Defendants relied on intentionally misleading and inadequate studies to obtain FDA approval for the drug.

170. Defendants failed to exercise reasonable care and competence in obtaining or communicating information regarding the use of Mefloquine and otherwise failed to exercise reasonable care in transmitting information to the U.S. military, Plaintiff, the Class Members and their physicians regarding both the fact that Mefloquine not safe or well-tolerated and that other, safer treatment options for Mefloquine were available.

171. Defendants made the aforesaid representations during Defendants' business as designers, manufacturers, and distributors of Mefloquine despite having no reasonable basis for their assertion that these representations were true and without having accurate or sufficient information concerning the aforesaid representations.

172. At the time the aforesaid representations were made, Defendants intended to induce the U.S. military, Plaintiff, the Class Members and their physicians to rely upon such representations in an effort to increase their sales of Mefloquine.

173. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff and the Class Members received Mefloquine, Plaintiff and the Class Members reasonably believed them to be true. In reasonable and justified reliance upon the representations that Mefloquine was safe and well-tolerated as a first-line treatment for malaria prevention, Plaintiff and Class Members ingested Mefloquine.

174. As a direct and proximate consequence of Defendants' aforementioned conduct, Defendant obtained increased sales profits from the sale of Mefloquine.

175. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff and Class Members were commonly exposed to a significantly increased risk of Mefloquine toxicity and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring, including appropriate diagnostic testing and evaluation.

176. The injuries from which Plaintiff and Class Members suffer require specialized testing that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to Mefloquine and is different from that normally recommended in the absence of exposure to this risk of harm.

177. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosis of Mefloquine toxicity. The diagnostic program will counteract the likelihood of unnecessary treatments and medications for misdiagnosed conditions and will help to mitigate the health effects associated with Mefloquine toxicity.

178. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of Mefloquine toxicity.

179. By monitoring and testing Plaintiff and Class Members, the risk that Plaintiff and Class Members will suffer losses without adequate treatment or inappropriate treatment will be significantly reduced.

180. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Mefloquine toxicity. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of

Plaintiff and Class Members as frequently and appropriately as necessary.

181. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of every Class Member, as frequently and appropriately as necessary; and (b) notifying all Class Members in writing that they may require medical monitoring for the purpose of diagnosis.

182. Plaintiff and Class Members have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Mefloquine. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated.

COUNT VI
Fraudulent Misrepresentation
All Classes

183. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

184. Plaintiff brings this claim individually and on behalf of the Class Members.

185. At all relevant times, Defendants knew that Mefloquine is not safe and well-tolerated but that it instead causes significant and irreversible neuropsychiatric harms.

186. In 1989, prior to seeking FDA approval of Mefloquine, Defendants knew of the significant and irreparable damage that Mefloquine could cause to users, including Plaintiff and Class Members. Nevertheless, based on intentionally false and misleading clinical trials, Defendants sought and obtained FDA approval for Mefloquine as a safe and well-tolerated treatment for malaria prevention.

187. Following receipt of FDA approval, Defendants continued to represent to the public that Mefloquine was a safe and well-tolerated first-line treatment for malaria prevention.

Defendants never adequately or appropriately warned of the significant risk of severe and irreversible neuropsychiatric harms associated with Mefloquine use.

188. Defendants also knew of the significant risk that Mefloquine could not be used and prescribed to military service members in a manner that complied with their own prescribing protocols. Nevertheless, Defendants intentionally marketed the drug to the U.S. military and misrepresented to the U.S. military that Mefloquine can and should be used as a first-line treatment for malaria prevention in service members who were deployed abroad.

189. By not including adequate and appropriate warnings on the drug labeling, Defendants intended to induce the U.S. military, Plaintiff, the Class Members and their physicians to use Mefloquine as a first-line treatment for malaria prevention.

190. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff and the Class Members received Mefloquine, Plaintiff and the Class Members reasonably believed them to be true.

191. In reasonable and justified reliance upon the representations that Mefloquine is safe and well-tolerated, Plaintiff and the Class Members ingested Mefloquine.

192. As a direct and proximate result of Defendants' intentional misrepresentations, Plaintiff and the Class Members were commonly exposed to a significantly increased risk of Mefloquine toxicity and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring, including appropriate diagnostic testing and evaluation.

193. The injuries from which Plaintiff and Class Members suffer require specialized testing that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to Mefloquine and is different from that normally recommended in the absence of exposure to this risk of harm.

194. The medical monitoring regime should include, but is not limited to, baseline tests

and diagnostic examination that will assist in early detection and diagnosis of Mefloquine toxicity. The diagnostic program will counteract the likelihood of unnecessary treatments and medications for misdiagnosed conditions and will help to mitigate the health effects associated with Mefloquine toxicity.

195. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of Mefloquine toxicity.

196. By monitoring and testing Plaintiff and Class Members, the risk that Plaintiff and Class Members will suffer losses without adequate treatment or inappropriate treatment will be significantly reduced.

197. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Mefloquine toxicity. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and Class Members as frequently and appropriately as necessary.

198. Accordingly, Defendants should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of every Class Member, as frequently and appropriately as necessary; and (b) notifying all Class Members in writing that they may require medical monitoring for the purpose of diagnosis.

199. Plaintiff and Class Members have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Mefloquine. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, pray for judgment against the Defendants as to each count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiff and his counsel to represent the Class, and requiring Defendants to bear the costs of class notice;

B. A judgment against Defendants and in favor of Plaintiff and the Class Members;

C. An order granting equitable relief in the form of a medical monitoring program to be funded by Defendants;

D. An order awarding Plaintiff and the Class Members their costs of suit, including reasonable attorneys' fees, as provided by law;

E. An order awarding any other relief that is deemed just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Erica Rutner

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