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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, INC.; ROCHE LABORATORIES, INC.; GENENTECH, INC.; GENENTECH USA, INC.; and DOES 1-100,

Defendants.

Case No. 4:21-cv-10074-YGR

AMENDED 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, there was vast market opportunity for the drug.

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 drugs of the the chemical family to which Mefloquine belongs was widely known by those in the pharmaceutical

industry. It was also widely known that these neurotoxic risks are typically heralded by the development of prodromal symptoms such as sleep disturbance. At that time, there were also widespread reports in the pharmaceutical industry of Mefloquine causing severe neuropsychiatric side effects, which were typically preceded by prodromal symptoms. By 1994, Defendants knew or should have known that these adverse reactions were permanent and irreversible. They also knew that a significant number of individuals would experience prodromal symptoms and that these symptoms were often followed by severe and debilitating neuropsychiatric effects. Since that time, numerous scientific studies published in peer-reviewed journals have confirmed the prevalence of lasting and disabling neuropsychiatric effects resulting from Mefloquine use.

4. Despite existing and mounting evidence of Mefloquine' devastating side effects and the prevalence thereof, Defendants concealed the scope and nature of the danger and recklessly marketed the drug to the military 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 their hold on the market and strong demand for it by the U.S. military.

5. 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 without adequately warning of the nature and prevalence of adverse neuropsychiatric symptoms. Defendants conduct also led the U.S. military to purchase and prescribe the generic-equivalents of Defendants' name-brand drug. However, shortly after the FDA put a black-box warning on the drug in 2013, the U.S. military changed its Mefloquine-prescribing policies by re-designating Mefloquine as a drug of last resort for malaria prevention.

6. Plaintiff was a U.S. military service member who was prescribed Mefloquine when deployed to Afghanistan. Upon taking the drug, Plaintiff began suffering neuropsychiatric side

effects, which continue to this day. The side effects began with prodromal symptoms, but then developed into more severe and debilitating symptoms such as paranoia and suicidal ideation. 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. He also did not know that these side effects would worsen if he continued to take the drug. Nor could Plaintiff have reasonably been able to acquire such knowledge because the drug insert did not adequately warn of the drug's toxicity, the prevalence of the prodromal symptoms he initially experienced, or the fact that prodromal symptoms often develop into severe and irreversible neuropsychiatric side effects. In fact, even the little information that did appear on the drug insert was misleading in regards to the nature and extent of the risks associated with the drug.

7. 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 medical literature supporting the causal link between Mefloquine and his symptoms. This literature is not readily available to lay people, 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.

8. 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

9. 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.

10. 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.

11. 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

12. 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.

13. 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."

14. 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.

15. 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.

16. 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.

17. 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 Safe, Well Tolerated and Practical Drug for Malaria Prevention

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

19. 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.

20. 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.

21. 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.

22. 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"). Roche sold Mefloquine to the Defense Logistics Agency (DLA), an agency within the military, under the DAPA 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 for distribution to defense forces abroad.

23. 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, a foreign affiliate to manufacture the drug. It also authorized Roche Laboratories to market and sell the drug. These entities worked in concert at all points in the manufacturing and distribution chain. Roche Inc. was also the sole owner of Roche Laboratories at all relevant times.

24. Roche marketed and sold Mefloquine to the U.S. military as a safe, well-tolerated and practical drug for the prevention of malaria in service members deployed abroad. As a result, hundreds of thousands of military service members deployed abroad took 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.

25. 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 entity in the Roche family capable of offering Mefloquine for sale to the U.S. military. Genentech also continued to market and sell the drug in other countries following the 2009 acquisition.

26. 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.

27. 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.

28. 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.

29. While generic manufacturers 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 safe and well-tolerated 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

30. 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. These studies were reported in medical journals not readily available to a lay person.

31. 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.

32. 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.

33. 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 the use of Mefloquine occurred at a rate of over 10%, which would require immediate discontinuation of the drug under the drug's current prescribing guidelines. 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 posed no risk of neurotoxicity. Nor did it require attention to prodromal symptoms, which requires immediate cessation of Mefloquine use under the drug's current prescribing guidelines. In short, the study demonstrated that Malarone was equally as effective but substantially safer.

34. Subsequent studies published in medical journals 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.

35. Prodromal symptoms typically begin after the first few doses are taken. These are an early indicator of an individual's personal susceptibility to the drug's neurotoxic and encephalopathic effects. Indeed, when neuropsychiatric symptoms occur, they frequently persist 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.

36. 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 scientific studies, they are not readily available to the public at large.

37. 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.

38. The revised labeling also informed healthcare providers to "Be alert to the potential for the development of neurologic and psychiatric adverse reactions in patients using the drug" and to immediately stop using Mefloquine if these reactions occur. Providers were not previously warned to be on alert for these potential reactions. Had providers been adequately warned to do so, they would have been substantially more likely to discontinue prescribing the drug to military service members who exhibited prodromal symptoms. This would have lessened the potential for the more severe and lasting neuropsychiatric side effects of the drug.

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." It was only after these changes to the drug label that patients 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. Adequate warnings would also have led

many physicians to be on alert for prodromal symptoms and to thereby cease prescribing the drug to service members when necessary. Had that occurred, many military service members could have avoided the severe and permanent neuropsychiatric effects caused by the drug.

III. Roche Obfuscated the True Dangers of Mefloquine When it Obtained Approval for and Marketed Mefloquine as a Safe and Well-Tolerated 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. Roche was also aware of the nature and prevalence of these dangers and that they were often preceded by the onset of prodromal symptoms.

42. Roche applied for and obtained FDA approval of the drug in 1989. Given the existence of scientific studies reporting encephalopathic 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, including the prodromal symptoms that require cessation of the drug's use.

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 prevalence 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 or the prodromal symptoms that Roche later warned required immediate cessation of the drug. 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 or conduct adequate studies regarding these risks at the time it sought and obtained FDA approval.

45. Following initial approval of Mefloquine in 1989, there continued to be increasing data in the scientific community establishing the severe and irreversible neuropsychiatric outcomes associated with Mefloquine use and the prevalence thereof. 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 and prevalence of various severe and permanent neuropsychiatric effects of Mefloquine toxicity. Yet, Roche never provided adequate warnings on the packaging inserts or drug labeling about the true nature and prevalence of the permanent and irreversible neuropsychiatric effects that Mefloquine could cause. For instance, Roche did not adequately warn of the likelihood of neuropsychiatric outcomes, the types of neuropsychiatric outcomes that could occur, and the permanent and irreversible nature of these outcomes. Nor did Roche adequately warn of the prevalence of the prodromal symptoms requiring cessation of the drug. To the contrary, Roche knowingly withheld these facts from the military, its physicians and its service members.

46. Not only did Roche fail to adequately warn of the risks, Roche also affirmatively misled the military, its physicians, and its service members about the potential risks associated with the drug. For instance, in the 2008 drug labeling, Roche represented that the most frequently

observed adverse experience was vomiting and that there was a 3% chance of this occurring. Thus, Roche affirmatively misrepresented that there was a less than 3% chance of any other side effects from occurring—including any neuropsychiatric side effects. Roche knew or should have known that there was a far greater than 3% chance that various neuropsychiatric side effects would occur. Moreover, while Roche vaguely described potential side effects of "dizziness," "emotional problems," and "emotional disturbances," it represented that the risk of such side effects was less than 1% and that they "rarely" occurred. Roche knew or should have known that the risk of neuropsychiatric symptoms was far greater than what they reported in the drug labeling. In fact, Roche knew that prodromal symptoms been reported to occur in as much as 14% of users. Thus, Roche was aware but failed to disclose that 14% of users would need to cease using the drug.

47. By misrepresenting the nature and prevalence of the risks associated with Mefloquine, Roche was able to market the drug to the military both as a safe and practical first line treatment for malaria in military service members deployed abroad. Indeed, had Roche informed the military of the true prevalence of the drug's side effects, the military would have been aware that at least 14% of its service members who need to cease using the drug in order to comply with the drug's prescribing guidelines. Under these circumstances, it would have been evident that Mefloquine was a poor candidate for use in military service members deployed abroad. Instead, Roche misled the military into believing that less than 1% of service members would need to discontinue using the drug while abroad and that the drug was therefore appropriate for use in military service members who were deployed abroad.

48. Roche further misrepresented in the drug labeling that there was no confirmed relationship between drug administration and suicidal ideation. Roche knew or should have known not only that such a relationship existed, but that there was a significant risk of it occurring. Further, despite being aware that neuropsychiatric side effects were likely to be severe, permanent and

irreversible given the neurotoxicity of the drug, Roche misrepresented that the "rare" potential for "mental problems" was "mild" and "may decrease despite continued use."

49. Roche also knew that the military did not appreciate the true nature and prevalence of the drug's neurotoxic side effects. For instance, a 2002 memorandum issued by the military stated that "mefloquine may cause psychiatric symptoms at a rate of one per 2000-13,000 persons." Roche was aware that the prevalence of neuropsychiatric symptoms was far greater than that. Yet, Roche knowingly and intentionally misled the military into believing that the risks were so rare.

50. 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.

IV. Roche's Tortious Conduct in Labeling

51. 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."

52. 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 and prevalence of various severe, permanent and irreversible psychiatric and neurological side effects on the package inserts and drug labeling for Mefloquine. Roche also failed to adequately and truthfully warn of the prevalence of prodromal symptoms that require immediate cessation of the drug. The U.S. military necessarily relied on information published in the drug labeling, 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

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

53. 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 they did so for several years prior to the publication of the black box warning. In addition, Roche sold the drug to the DLA in California throughout the class period. Accordingly, the presumption in favor of California law applies in this case.

54. 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.

55. 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).

56. 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

57. 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.

58. 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, Defendants engaged in a concerted effort to conceal and withhold information related to the dangers of Mefloquine use from the military and its service members. Moreover, the scientific literature describing the dangers of the drug are contained in medical journals, which are not readily available to a lay person. Thus, Plaintiff and Class members were and/or are unaware that the symptoms they are experiencing are associated with their past Mefloquine use. Nor could they have discovered the causal connection through reasonable diligence. Roche knowingly concealed the dangers during the class period, Plaintiffs and Class members were not provided any information about these dangers following their ingestion of the drug (including as to the change in labeling in 2013), and the dangers are not widely known or publicized to the public at large. On information and belief, the vast majority of Class members—including Plaintiff—have been misdiagnosed with other psychiatric conditions and mistreated for those conditions.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

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

65. 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.

66. 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.

67. 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

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

69. 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.

70. 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.

71. 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.

72. 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.

73. The first symptoms he experienced after 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 these prodromal 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. Mr. Nelson was never warned of the prevalence of these prodromal symptoms or that Mefloquine had the potential to permanently disrupt his sleep. Nor was he aware prior to 2020 that Mefloquine could be a potential cause of his ongoing sleep disturbances.

74. 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."

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

80. 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).

81. Mr. Nelson was never warned that Mefloquine had the potential to cause permanent neuropsychiatric side effects, nor was he aware prior to 2020 that Mefloquine could be a potential cause of his ongoing neuropsychiatric conditions. Mr. Nelson is a lay person who would have no reason to be familiar with scientific studies contained in peer-reviewed medical literature. Thus, he would not have had any reason to believe Mefloquine was the cause of his permanent neuropsychiatric conditions.

82. Had Mr. Nelson been adequately warned of the dangers associated with Mefloquine use, he would have requested that he be prescribed a safer alternative drug to prevent malaria. Indeed, safer alternatives existed and were available at the time he was prescribed Mefloquine. Moreover, had the military been adequately warned of the risks in the manner contained on the black box warning, it would have re-branded the drug as one of last resort (as evidenced by the fact that it did so following the 2013 black box warning). Thus, even putting aside Mr. Nelson's own decision-making, there was a substantial probability that he would never have been offered the drug in the first place had Roche adequately warned of the dangers associated with Mefloquine use.

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. He was then informed for the first time of the extensive literature and science supporting the causal link between

Mefloquine and the neuropsychiatric side effects he had been experiencing. Prior to this time, Mr. Nelson was unaware of these facts and, as a lay person, had no reasonable basis for investigating them. Indeed, it was not until Mr. Nelson attended the conference in Washington D.C. in February 2020 that he had sufficient reason to even suspect he may be experiencing Mefloquine toxicity and that he should pursue medical evaluation and testing to confirm the diagnosis.

84. 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.

85. 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.

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, nor did he have any reasonable basis for discovering them.

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. Indeed, the labeling that existed at the time Mr. Nelson was prescribed the drug not only failed to adequately warn about the risks of the drug, it affirmatively misled the military, its physicians, and its service members about the potential risks. For instance, Roche represented that the most frequently observed adverse experience was vomiting and that there was a 3% chance of this occurring. Thus, Roche misrepresented that there was a less than 3% chance of any other side effects from occurring—including any neuropsychiatric side effects. Moreover, while Roche vaguely described potential side effects of "dizziness," "emotional problems," and "emotional disturbances," it represented that the risk of such side effects was less than 1%. Roche knew or should have known that the risk of neuropsychiatric symptoms was far greater than what they reported in the drug labeling. In fact, Roche knew that prodromal symptoms been reported to occur in as much as 14% of users, meaning 14% of users would need to cease using the drug. Roche further misrepresented in the drug labeling that there was no confirmed relationship between drug administration and suicidal ideation. Roche knew or should have known not only that such a relationship existed, but that it posed a significant risk of occurring.

90. As a result of Defendants' misrepresentations and concealment, Plaintiff and Class

Members, along with their physicians, were unaware, and could not have known or have learned through reasonable diligence, of the true facts related to the risks associated with Mefloquine or that those risks were the direct and proximate result of the wrongful acts and/or omissions of Defendants.

CLASS ALLEGATIONS

91. 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.

92. 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.

93. 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.

94. 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.

95. 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 acted to conceal the true prevalence of the prodromal symptoms requiring immediate cessation of the drug;

g. whether Defendants' warnings regarding the risks of Mefloquine were inadequate;

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

i. whether Defendants drug labeling was affirmatively misleading with respect to the prevalence of adverse neuropsychiatric effects;

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

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

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

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

96. 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.

97. 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.

98. **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

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

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

101. 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.

102. 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 and prevalence of a variety of permanent and irreversible adverse neuropsychiatric harms.

103. Furthermore, Defendants' drug labeling affirmatively misled the military, its physicians and its service members about the severity, incidence, and irreversible nature of the

drug's neurotoxic side effects and the prevalence of the prodromal symptoms requiring immediate cessation of the drug.

104. 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.

105. 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. Had Defendants adequately warned of the true risks, it is substantially probable that Plaintiffs and Class Members either would not have been prescribed Mefloquine or would have declined Mefloquine and chosen a safer anti-malaria alternative.

106. 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.

107. 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.

108. 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.

109. 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.

110. Plaintiff and the Class Members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate a proper diagnosis 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.

111. 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.

112. 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

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

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

115. 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.

116. 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.

117. 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 explain the incidence and severity of adverse events associated with Mefloquine; and

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

118. 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. Had Defendants adequately warned of the true risks, it is substantially probable that Plaintiffs and Class Members either would not have been prescribed Mefloquine or would have declined Mefloquine and chosen a safer anti-malaria alternative.

119. 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.

120. 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.

121. 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.

122. 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.

123. 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.

124. 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.

125. 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

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

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

128. 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.

129. 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

130. 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.

131. 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.

132. 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.

133. 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.

134. 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.

135. 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.

136. 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.

137. 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. Had Defendants adequately warned of the true risks, it is substantially probable that Plaintiffs and Class Members either would not have been prescribed

Mefloquine or would have declined Mefloquine and chosen a safer anti-malaria alternative.

138. 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. 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.

144. 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.

145. 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

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

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

148. 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.

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

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

151. 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.

152. 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, posing a significant risk of serious and irreversible neuropsychiatric harms to Plaintiff and the Class Members.

153. 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 have such a high likelihood of causing irreversible neuropsychiatric damage.

154. 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.

155. 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.

156. 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.

157. 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. Had Defendants adequately warned of the true risks, it is substantially probable that Plaintiffs and Class Members either would not have been prescribed Mefloquine or would have declined Mefloquine and chosen a safer anti-malaria alternative.

158. 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.

159. 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.

160. 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.

161. 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.

162. 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.

163. 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.

164. 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

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

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

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

168. Defendants knew or should have known that marketing and representing Mefloquine to the U.S. military as a safe and practical 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 treatment for malaria prevention.

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 treatment for malaria prevention, Plaintiff and Class Members ingested Mefloquine. Had Defendants adequately warned of the true risks, it is substantially probable that Plaintiffs and Class Members either would not have been prescribed Mefloquine or would have declined Mefloquine and chosen a safer anti-malaria alternative.

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, well-tolerated and practical treatment for malaria prevention.

Defendants never adequately or appropriately warned of the significant risk of severe and irreversible neuropsychiatric harms associated with Mefloquine use. To the contrary, Defendants knowingly misled the military, its physicians and its service members about the true nature, severity and incidence of irreversible neuropsychiatric harms as well as the prevalence of prodromal symptoms requiring immediate cessation of the drug.

188. By not including adequate and appropriate warnings on the drug labeling and instead including affirmatively misleading information about the drug's risks, Defendants intended to induce the U.S. military, Plaintiff, the Class Members and their physicians to use Mefloquine as a treatment for malaria prevention.

189. 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.

190. In reasonable and justified reliance upon the representations that Mefloquine is safe and well-tolerated, Plaintiff and the Class Members ingested Mefloquine. Had Defendants adequately warned of the true risks, it is substantially probable that Plaintiffs and Class Members either would not have been prescribed Mefloquine or would have declined Mefloquine and chosen a safer anti-malaria alternative.

191. 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.

192. 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.

193. 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.

194. 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.

195. 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.

196. 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.

197. 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.

198. 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.

DATED: March 24, 2022

Respectfully submitted,

/s/ Erica Rutner

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CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using the Court's CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants.

/s/ *Erica Rutner*
Erica Rutner