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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ANDREA M. CASTON; RICHARD GITHENS, PATRICK EUGENE WAGHER; and KENDRICK ALLEN, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

F. HOFFMAN-LA ROCHE, INC.; ROCHE LABORATORIES, INC.; GENENTECH, INC.; GENENTECH USA, INC.; and DOES 1 – 100,

Defendants.

Case No. 3:23-cv-00928-TLT _____

AMEDED MEDICAL MONITORING CLASS ACTION COMPLAINT

Honorable Trina L. Thompson

Plaintiffs Andrea M. Caston, Richard Githens, Patrick Eugene Wagher, and Kendrick Allen ("Plaintiffs") file this Amended Medical Monitoring Class Action Complaint on behalf of themselves and all others similarly situated, against the defendants named herein ("Defendants") and seek 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 as well as any generic equivalents sold to residents of California and Massachusetts. Plaintiffs' allegations are based upon personal knowledge as to Plaintiffs' 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 sizable 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 chemical family to which Mefloquine belongs was widely known by those in the pharmaceutical industry. It was also widely known in the pharmaceutical industry 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 considerable 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 severe and permanent adverse neuropsychiatric effects resulting from Mefloquine use (herein referred to as "Mefloquine Toxicity").

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. Plaintiffs are veterans of the U.S. military who took Mefloquine while deployed abroad. After taking the drug, Plaintiffs began suffering neurological and psychiatric side effects, which have only worsened over time and persist to this day. Due to Defendants' reckless and dangerous conduct in marketing and selling Mefloquine to the U.S. military, Plaintiffs had no knowledge that the side effects they were experiencing could be due in any way to Mefloquine. They also did not know that these side effects would worsen if they continued to take the drug. Nor could they have been able to acquire such knowledge, including because the drug insert did not adequately warn of the drug's toxicity. In fact, even the little information that did appear on the drug insert was entirely misleading as to the nature and extent of the risks associated with the drug.

7. 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, Plaintiffs, individually and on behalf of the Class, seeks medical monitoring because of their common exposure to Mefloquine.

JURISDICTION AND VENUE

8. This Court has original subject-matter jurisdiction over this action under 29 U.S.C § 1332(d)(2) because (a) there are at least one hundred class members, (b) the matter in controversy exceeds $5 million, exclusive of interests and costs, and (c) at least one Plaintiff and the Defendants are citizens of different states.

9. This Court has personal jurisdiction over Defendants because they are citizens of California. Genentech Inc. and Genentech USA, Inc. (collectively, "Genentech") admittedly maintain their principal place of business in California. Accordingly, they are citizens of California.

10. Defendant Roche Laboratories, Inc. ("Roche Labs.") maintains multiple officers in California, including both of its vice presidents and its secretary. Roche Labs.' directors are also located in California. Roche Labs' directs, operates and controls its business of pharmaceutical distribution in California through the Genentech entities located in California.

11. While Defendant Hoffman La-Roche, Inc. ("Roche Inc.") conveniently removed its California officers in 2022 such that it only maintained officers in New Jersey, this was a mere formality and did not have any impact on Roche Inc.'s operations in California. Indeed, notwithstanding this formality—which was intended to avoid jurisdiction in California—Roche Inc. nevertheless continues to direct, operate and control its business of pharmaceutical development through the Genentech entities located in California.

12. Neither Roche Inc. nor Roche Labs (collectively, "Roche" or the "Roche Entities") conducts any of its pharmaceutical development and distribution business out of New Jersey. Roche's website publicly reports that its sole location in New Jersey is the headquarters only for Roche Molecular Solutions—an entity that is distinct from the Roche Entities and which is engaged an entirely different line of business than the Roche Entities.

13. Beyond this, Genentech's website currently reports that "[a]s part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. ***Genentech's South San Francisco campus serves as the headquarters for Roche pharmaceutical operations in the United States***." It further states that, when Genentech and Roche merged, Genentech became "the headquarters for Roche pharmaceutical operations in the United States." Furthermore, a Roche press release from 2009 describes Roche Inc.'s intent to transplant its manufacturing, commercial and executive functions to California and explained that Roche Inc. was relocating its commercial headquarters from Nutley, New Jersey to South San Francisco as part of the "combined organization" of Roche Inc. and Genentech. Similarly, a letter from Roche Holding

Chairman and CEO to Genentech employees described the merger as a commitment to "locating the combined company's U.S. headquarters to Genentech's current facility in South San Francisco." Press reports have stated that the "Genentech site in California…also serves as the headquarters of Roche Commercial Operations for North America." And an SEC filing made by Roche at the time of the merger reported that Roche Inc. "will base the headquarters for the combined Genentech and Roche US pharma business at the Genentech South San Francisco campus." Multiple websites currently describe Roche's US pharmaceutical research and development operations as "Roche/Genentech."

14. Mr. Sean Johnston—located in California—acted as the publicly-reported CEO of Roche Inc. until 2022 while also acting (both then and now) as the senior vice president, general counsel, chief compliance officer and corporate secretary for Genentech "Pharma North America." Although Roche, Inc., formally removed Mr. Johnston as CEO from its corporate registration status to avoid jurisdiction in California, his removal had no impact on his continuing role in directing and overseeing Roche's pharmaceutical operations carried out by Genentech in California.

15. Roche's public website also long contained a page titled "A Tale of Two Sites," which described "the Genentech site in California" as "Roche's North America hub," as its "US headquarters," and as the home to the combined entities' research and early development operations. This statement appeared as recently as 2018, although it conveniently removed the page after a district court found that Roche Inc. headquarters were located in California.

16. Accordingly, the nerve center and principal place of business for both Roche Labs and Roche Inc. is located in the State of California. As such, they are both citizens of California and subject to the general jurisdiction of this Court.

17. At least three federal courts in this District have all recently confirmed that Roche's principal place of business is in California and that it is therefore a citizen of 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); *Matsuno v. Hoffman-La Roche Inc.*, 2019 WL 5079551, at *3 (N.D. Cal. Oct. 10 2019). In so doing, the court in *Poole* pointed out that Roche had submitted a declaration regarding jurisdiction that contained inconsistent and questionable statements and omissions. *Pool*, 386 F. Supp. 3d at 1220-21. Roche has since demonstrated that it has a pattern and practice of making false and misleading statements about the location of its principal place of business to avoid liability in California.

18. In addition, specific jurisdiction also exists in California. Roche intentionally marketed, promoted and sold the dangerous Mefloquine in California. It bid for and then entered into a DAPA agreement with the military to sell Mefloquine, by virtue of which it knew Mefloquine would be distributed both in California and to California residents deployed abroad. Indeed, California is home to more than 40 military bases and the Defense Logistic Agency that purchased the drug from Roche maintains at least three locations in California. Moreover, two of the plaintiffs in this case are residents of California and have been at all relevant times. Thus, in marketing and selling the drug, Roche knew or should have known that Mefloquine would be sold in California and would cause harm to California residents.

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

PARTIES

20. Plaintiff Andrea M. Caston is a Navy veteran who served honorably in the U.S. Military from 1984-2004. Ms. Caston has been a resident of California at all relevant times,

including while she served in the U.S. Military. Ms. Caston was prescribed and ingested Mefloquine while serving in the U.S. Military, when she was a resident of California.

21. Plaintiff Richard Githens is a Military veteran who served honorably in the U.S. Military from 1987-2002. Mr. Githens was a resident of Ohio at all relevant times, including while he served in the U.S. Military. Mr. Githens was prescribed and ingested the brand name Lariam while serving in the U.S. Military.

22. Plaintiff Patrick Eugene Wagher is a Military veteran who served honorably in the U.S. Military from 1995-2007. Mr. Wagher was a resident of Massachusetts at all relevant times, including while he served in the U.S. Military. Mr. Wagher was prescribed and ingested the brand name Lariam while serving in the U.S. Military, when he was a resident of Massachusetts.

23. Plaintiff Kendrick Allen is a Navy veteran who served honorably in the U.S. Military from 1999-2007. Mr. Allen was a resident of California at all relevant times, including while he served in the U.S. Military. Mr. Allen was prescribed and ingested the brand name Lariam while serving in the U.S. Military, when he was a resident of California.

24. Roche Inc. is a New Jersey Corporation with its principal place of business in San Francisco, California. While formerly headquartered in New Jersey, Roche Inc. relocated its headquarters to the Genentech headquarters in San Francisco in March 2009 following the merger with Genentech that same year. Roche Inc. is the NDA holder for Mefloquine.

25. Roche Labs is a Delaware corporation with its principal place of business in San Francisco, California. Roche Labs was listed on the FDA label for the brand-name version of Mefloquine as the distributor of the drug in the United States. 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 remain available today.

26. 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.

27. The Roche and Genentech families formally merged in 2009. At that time, Roche and Genentech publicly reported that the two organizations would be combined and that there would be a single "combined company" for Roche's U.S. pharmaceutical business. Pursuant to the merger agreement, Genentech transferred all its outstanding shares to Roche such that there was a continuity of shareholders. Further "[a]s part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. ***Genentech's South San Francisco campus serves as the headquarters for Roche pharmaceutical operations in the United States***." Likewise, Genentech and Roche reported that Genentech became "the headquarters for Roche pharmaceutical operations in the United States.

28. Following the merger, Roche transferred its entire US pharmaceutical line to Genentech—including the military-Mefloquine line of business. At the same time, Roche publicly reported that it wound down its own operations and relocated its development activities to South San Francisco, where Genentech USA was already based. As a result, at least 600 employees in New Jersey—where Roche was previously based—lost their jobs. Subsequently, Roche's drug portfolio in the United States was sold under the Genentech brand.

29. As a result of the merger, Genentech became the continuation of Roche with respect to their pharmaceutical development and distribution line of businesses. Specifically, Genentech USA became the mere continuation of Roche Inc. and its pharmaceutical research and development line of business. Genentech USA also became the mere continuation of Roche Labs and its

pharmaceutical distribution line of business. As such, Genentech USA became the successor of Roche with respect to its Mefloquine line of business, thereby rendering Genentech USA liable for its predecessors' activities.

30. Genentech USA, Inc. ("Genentech USA") is a Delaware Corporation with its principal place of business in San Francisco, California. Genentech USA is a wholly owned subsidiary of Genentech Inc. The entities are collectively referred as "Genentech." Genentech. Inc. and Genentech USA Inc. commingle assets and operations and fail to observe corporate formalities. For instance, Genentech reports that it has a single board of directors and single executive committee for its entire US operations. Genentech Inc. and Genentech USA make no public distinction between the two companies and instead collectively refer to themselves as "Genentech, a Member of the Roche Group." Genentech Inc. and Genentech USA operate as a single company and they conduct business as a single entity. Accordingly, Genentech Inc. is the alter ego of Genentech USA.

31. Does 1 to 100 are the employees, servants, agents, affiliates, and/or contractors of the Defendants. Plaintiffs are 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

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

33. 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.

34. 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.

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

36. Before the merger with Genentech, Inc., Roche Labs marketed and sold Mefloquine to the Department of Defense under a Distribution and Pricing Agreement ("DAPA"). Roche Labs. sold Mefloquine to the Defense Logistics Agency (DLA), an agency within the military, under the DAPA until the Genentech merger in 2009. Such sales occurred in California, where several offices for the DLA are located and where the DLA ordered and purchased Mefloquine from Roche Labs. for distribution to defense forces abroad.

37. The Roche entities acted in concert in all marketing and sales activities targeted at the U.S. military. Roche Inc. was the official NDA holder for Mefloquine and thereby had exclusive control over the labeling for the drug. Roche Labs was responsible for marketing and selling the drug and thereby had control over marketing and sales information disseminated to the US military. These entities worked in concert at all points in the testing, approval, manufacturing and distribution stages. Roche Inc. was also the sole owner of Roche Labs. at all relevant times.

38. 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.

39. Following the merger, Genentech USA 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. Genentech USA paid Roche nothing for the military-Mefloquine line of business.

40. 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.

41. While Defendants exited the U.S. market for Mefloquine in 2009, Roche Inc.—now acting through Genentech—still maintained responsibility for the drug's labeling. Thus, from 2009-2013, when the black box warning came into effect, Genentech continued to perpetuate and failed to correct the false and misleading statements that Roche had made about Mefloquine's safety.

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

42. 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 like Mefloquine. These studies were reported in medical journals not readily available to a lay person.

43. 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.

44. 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.

45. 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 safer.

46. Subsequent studies published in medical journals have found a range of adverse neuropsychiatric effects associated with Mefloquine use. Among the many psychiatric outcomes are

mania, psychosis, hallucinations, suicidal ideation, and completed suicide. The neurological problems that Mefloquine can eventually cause include severe vestibular harm, vertigo, loss of balance, and disequilibrium. Studies have also found that Mefloquine toxicity is associated with cognitive deficits such as memory impairment and confusion. The combination of psychiatric and neurological disturbances is considered to be a hallmark of Mefloquine Toxicity.

47. Studies report that Mefloquine binds to neurotransmitter receptors in the brain and thereafter accumulates in the central nervous symptom. Because Mefloquine is neurotoxic, the inability to eliminate Mefloquine from the body will lead to permanent and irreversible neuropsychiatric symptoms in many individuals. Recent studies have found that over half of the individuals taking Mefloquine will experience adverse psychiatric effects and that over 29% of users will experience adverse neurological effects. In other words, the majority of individuals taking Mefloquine will suffer from its neurotoxic effects.

48. Prodromal symptoms such as sleep distance, abnormal dreams and anxiety may begin after the first few doses are taken. These symptoms may be an early indicator of an individual's personal susceptibility to the drug's neurotoxic and encephalopathic effects—although these symptoms do not always result in long-term Mefloquine Toxicity. Moreover, some individuals do not experience prodromal symptoms at all but go on to experience the more severe effects of Mefloquine Toxicity even after Mefloquine use has been discontinued.

49. After ingesting Mefloquine, the hallmark symptoms of Mefloquine Toxicity often do not appear until well after the drug has been ingested. For instance, latent neurological and ophthalmological symptoms may not appear until long after the drug is discontinued. Likewise, suicidal ideation and completed suicide are latent symptoms that often do not appear until years later.

50. There now exist dozens of peer-reviewed published studies describing the adverse

neuropsychiatric effects of Mefloquine Toxicity, including both retrospective and prospective observational studies. The scientific community terms the diverse neurosynaptic side effects associated with Mefloquine as manifestations of a single underlying pathophysiological process characterized as toxic limbic encephalopathy, or Mefloquine Toxicity for short. 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. Nor would military veterans have any reason to be aware of these studies or the existence of Mefloquine Toxicity.

51. 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***.

52. The revised labeling also deleted prior statements contained in the drug's labeling that no relationship had been established between suicide and suicidal ideation.

53. 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 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.

54. 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.

55. 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 if other far safer malaria prevention drugs were contraindicated, including Doxycycline and P-Alaxin. After the military changed its policy, the number of service members prescribed Mefloquine dropped drastically from 23,889 in 2008 to only 263 in 2017—a 99% reduction.

56. 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

57. Roche Inc. and Roche Labs, collectively referred to as "Roche," acted in concert as the manufacturer and distributor of Mefloquine. Roche was always 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.

58. 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. In fact, serious adverse neuropsychiatric effects were among the earliest reports adverse effects associated with the drug. 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.

59. Instead, however, Roche chose to pursue study designs that they 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 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 development—well before the FDA approved the drug and its labeling.

60. 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 Inc. as the official NDA holder for the drug, 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. Indeed, the labeling did not warn that Mefloquine use actually causes any neuropsychiatric side effects.

61. 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.

62. Roche knew or should have known of the risk and prevalence of various severe and permanent neuropsychiatric effects of Mefloquine Toxicity. Yet, Roche Inc. 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, the labeling 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 the labeling adequately warn of the prevalence of the prodromal symptoms requiring cessation of the drug. In fact, at the time it marketed and sold the drug to the military, Roche knew that prodromal symptoms had been reported to occur in at least 14% of users. Thus,

Roche was aware but failed to disclose that at least 14% of users would need to cease using the drug. Had Roche disclosed that fact, it would have been self-evident that Mefloquine was not an appropriate anti-malaria drug for soldiers deployed abroad and Roche would have thereafter lost its stronghold on the anti-malaria market. Unfortunately, later studies have confirmed that Mefloquine Toxicity is far more common and may occur in over half of the users.

63. 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, the 2008 drug labeling represented that the most frequently observed adverse experience was vomiting and that there was a 3% chance of this occurring. Thus, the labeling 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.

64. Moreover, while the labeling 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 was reported in the drug labeling.

65. Furthermore, while stating that suicide had been "reported," the labeling affirmatively and unequivocally misrepresented that there was no established relationship between Mefloquine and suicide or suicidal ideation. Roche knew or should have known not only that Mefloquine use can and does lead to suicide and suicidal ideation, but that there was a significant risk of this occurring.

66. 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."

67. In addition to the false labeling, Roche Labs perpetuated these omissions and misrepresentations when it sold and marketed the drug to the military. In connection with its sales, Roche Labs never informed the military of the nature and prevalence of prodromal or long-term neuropsychiatric effects. In fact, it represented just the opposite to the military—that Mefloquine was safe, practical, and well tolerated.

68. By misrepresenting the nature and prevalence of the risks associated with Mefloquine, Roche was able to market and sell 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. To avoid that outcome, 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.

69. 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.

70. 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.

71. Even internal scientists at Roche cautioned against its use. For instance, an army veteran who was then director of clinical research for Roche and who monitored reported adverse effects associated with the drug has stated that "he wouldn't recommend it, generally speaking," especially not for use in combat. But Roche chose to disregard warnings even from its own internal scientists so it could financially benefit from its stronghold on the anti-malaria military market.

IV. Roche's Tortious Conduct in Labeling

72. 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."

73. Roche Inc. 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 Inc. 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 Inc.

74. Given that Roche Labs is wholly owned by Roche Inc. and acted in concert with Roche Inc. at all relevant times with respect to developing, testing, manufacturing, marketing and selling the drug, Roche Labs is also responsible for the drug's tortious labeling.

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

75. California and Massachusetts law impose 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.

76. This duty, known as "innovator liability," applies to Defendants in this case and renders them liable to individuals who took any of its generic Mefloquine-containing bioequivalents and can invoke California or Massachusetts law.

VI. The Need for and Utility of Medical Monitoring

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

78. As a direct and proximate result of consuming Mefloquine, Plaintiffs and the Class Members were put at a significantly increased risk of contracting the various neuropsychiatric side effects of Mefloquine use. Given that Plaintiffs and the Class Members already took the drug, they may 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, Plaintiffs and Class members have been unaware that the symptoms they are experiencing could be 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 the nature and prevalence of 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. Many class members—including Plaintiffs—have therefore been misdiagnosed with other psychiatric conditions and mistreated for those conditions.

79. Furthermore, class members are at risk of experiencing additional symptoms associated with Mefloquine use in the future. For instance, suicidal ideation and completed suicide

are often symptoms that are not seen for years and can develop long after ingesting the drug. The same may be true of the neurological symptoms associated with the drug.

80. A prudent physician would conclude that Plaintiffs' 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.

81. The available monitoring regime, discussed in greater detail below, is 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 provided by physicians at the Department of Veteran Affairs or general practitioner setting.

82. 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.

83. 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.

84. 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.

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

86. 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.

87. 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.

88. By receiving adequate diagnostic testing, Plaintiffs and Class members will avoid the significant risk of being misdiagnosed and/or mistreated for other neurological or psychiatric conditions. This is critical as misdiagnosis will result in long-term mismanagement of affected individuals, potentially exacerbating their symptoms rather than relieving them.

89. Moreover, the mere knowledge that one's symptoms are due to a drug and can be attributed to a specific cause will reduce the level of anxiety in military service members and can thereby mitigate the potential for suicide that often occurs years into Mefloquine toxicity. Military service members are otherwise left with no explanation or reason for their symptoms and suicide is seen as the only option.

90. Further, adequate diagnostic testing will allow for treatment options that would not otherwise be prescribed. For instance, once diagnosed, class members will receive appropriate individual or group therapy targeted to their Mefloquine use. Such therapy is far more effective than the therapy provided for PTSD, the misdiagnosis individuals with Mefloquine Toxicity most often receive. Indeed, the therapeutic treatment for Mefloquine Toxicity differs substantially from the therapeutic treatments provided to individuals with PTSD. Thus, treatment options for Mefloquine Toxicity include appropriate individual and group therapy that differs substantially from the type of therapy class members would otherwise receive.

91. In addition, the physical rehabilitation required to address neurological symptoms can be more specially tailored based on the fact that an individual is suffering from Mefloquine Toxicity rather than some other undetermined cause.

92. Research into other viable treatment options is also ongoing and additional treatments are likely to become available while the medical monitoring program is in effect.

93. Of note, the Australian government very recently implemented its own form of medical monitoring consisting of health assessments for veterans and a personalized plan for further investigation and treatment. The fact that medical monitoring has already been implemented in other countries demonstrates the need for and viability of a medical monitoring program for the Class in this case.

VII. Ms. Caston's Potential Mefloquine Toxicity

94. Ms. Caston is a fifty-six-year-old decorated military veteran who is permanently disabled and needs diagnostic evaluation for Mefloquine toxicity.

95. In 1984, Ms. Caston entered the U.S. military without any history of neurological or neuropsychiatric disorder. She was deemed qualified to serve in the U.S. military and to deploy to a combat zone.

96. Ms. Caston served as an Intelligence Officer for the U.S. Navy Sea, Air, and Land (SEAL) teams. As an Intelligence Officer, Ms. Caston served at the forefront of national security and was given the highest level of security clearance.

97. In September 2003, Ms. Caston was deployed by the U.S. Navy to Afghanistan where she functioned as an Intelligence Officer tracking terrorist activities. Upon deployment to Afghanistan, Ms. Caston was prescribed and ingested Mefloquine. Ms. Caston continued to ingest Mefloquine consistently once per week until February 2004 when she left Afghanistan.

98. After taking Mefloquine, Ms. Caston began to exhibit physical and mental symptoms. This included enhanced pain sensations, nerve pain, sleep disturbances, vivid disturbing nightmares, skin disorders, ear pain, chronic fatigue, and a constant buzzing in her body including a "zapping" sensation in her upper back in an area located behind her heart.

99. In February 2004, Ms. Caston experienced ever increasing debilitating neurological pain in her ankle and was medically evacuated from Afghanistan to Portsmouth Naval Hospital,

where she met with her treating Navy orthopedic surgeon. He had no answer as to why the pain Ms. Caston was experiencing had become so severe and thus had no treatment protocol to provide her.

100. Ms. Caston's symptoms and condition continued to worsen over the years, including her inability to sleep, balance issues, a decline in her cognitive learning ability and chronic fatigue. Ms. Caston is also at risk of developing additional neurological and psychiatric side effects that have not yet manifested. Each time Ms. Caston consulted with the medical physicians at her local VA, she was given a different diagnosis, including chronic fatigue syndrome, fibromyalgia, abnormal nerve conduction, restless leg syndrome, and pulmonary hypertension. Despite treatment protocols, her condition did not improve. Not once during any of her appointments with her medical physicians was Ms. Caston ever informed that her symptoms could be due to Mefloquine use. Finally, unable to determine the root cause of her ailments, and despite that while deployed in a war zone she was never in combat and had no direct traumatic "war time" experiences, Ms. Caston was provided with the usual misdiagnosis of Post Traumatic Stress Disorder (PTSD).

101. In 2014, exhausted by her chronic fatigue and in ability to sleep, Ms. Caston underwent a sleep study at the VA. At that time, she learned that her brain is unable to process the proper phases of REM sleep, a condition she had never experienced prior to her deployment to Afghanistan and ingestion of Mefloquine.

102. Despite Ms. Caston's repeated attempts since 2004 to seek diagnosis and treatment for her neurological issues, her symptoms continued and worsened without any clear explanation. Following her discharge from the military, Ms. Caston continued to experience sleep disorder, chronic physical and mental fatigue, ear pain, and vision and balance issues.

103. These effects are debilitating and permanent, and Ms. Caston has never regained the quality of life and functional abilities that she had before being ordered to ingest Mefloquine (subject to current state-of-the-art standard of care or recommendations by practitioners skilled in the

diagnosis and treatment of the condition).

104. Ms. Caston was never warned that Mefloquine had the potential to cause permanent neurological and neuropsychiatric side effects. Ms. Caston is not a scientist or trained as a medical physician and has no reason or ability to know what published scientific studies revealed about Mefloquine toxicity.

105. Had Ms. Caston been adequately warned of the dangers associated with Mefloquine use, she would have requested that she be prescribed a safer alternative drug to prevent malaria. Indeed, safer alternatives existed and were available to military service members at the time she was prescribed Mefloquine. Moreover, had the military been adequately warned of the risks in the manner contained on the black box warning, the drug would have been rebranded as one of last resort—as evidenced by the fact that the military did just that following the 2013 black box warning.

106. In 2022, Ms. Caston was searching online for answers to her chronic condition. Her search took her to a page discussing the toxic effect of Mefloquine and litigation that has been recently filed against Mefloquine's manufacturer, which seeks to establish a medical monitoring program to properly diagnose veterans who ingested Mefloquine and are experiencing side effects similar to those experience by Ms. Caston. For the first time, Ms. Caston read about the scientific studies that supported the connection between Mefloquine and its debilitating side effects, many of which she continues to suffer from. Ms. Caston will be required to pay thousands of dollars of her own money to obtain the proper testing to uncover the connection of Mefloquine toxicity to her condition because the necessary testing is not covered or approved by the Department of Veterans Affairs. Based on what Ms. Caston has uncovered through her own research as a result of the recent medical monitoring case brought in California, it is highly likely that her condition is related to her ingestion to Mefloquine and its toxicity. However, proper medical diagnostic evaluation is required to confirm the diagnosis and provide Ms. Caston with a proper treatment protocol.

VIII. Mr. Githens's Potential Mefloquine Toxicity

107. Mr. Richard Githens is a 62-year-old decorated military veteran whose personal and professional life was forever altered after ingesting Mefloquine. Realizing only a short while ago that Mefloquine toxicity is real, Mr. Githens seeks effective diagnosis and treatment for himself and his fellow veterans.

108. Mr. Githens enjoyed a healthy normal life growing up with his family around the horse farms of Lexington, Kentucky. In 1987, after graduating from Ohio State University, Mr. Githens joined the Army in perfect physical and mental health.

109. Mr. Githens went to Fort Bliss, Texas for basic training in March 1987. There, he was awarded the Basic Training Honor Graduate certificate for his superior performance. He experienced no anxiety or other mental disturbances during basic training.

110. In 1988, Mr. Githens went to Fort Sam Houston, Texas for 8 weeks for military occupational specialist training as a combat medic ("MOS").

111. Following basic training, Mr. Githens enrolled in the Basic Airborne Course ("BAC") at Fort Benning, Georgia. The purpose of the BAC is to qualify a candidate in the use of the parachute as a means of combat deployment and to develop leadership, self-confidence, and an aggressive spirit thorough mental and physical conditioning. Mr. Githens completed the BAC and then enrolled in the 1st Special Forces Command (Airborne) that trains and deploys forces that conduct special operations across the broad spectrum of conflict. Again, Mr. Githens excelled in his training and experienced no physical or mental issues.

112. After achieving his MOS qualification, Mr. Githens went to Fort Bragg, North Carolina in October 1988 for the Special Forces Assessment and Selection course, one of the most grueling selection processes in the Army that evaluates a candidate's ability and qualifications for service in the Special Forces. Mr. Githens successfully completed the course.

113. In December 1988, Mr. Githens went to Fort Sam Houston, Texas to attend the Special Forces Medical Sergeants Course that involves formal classroom training and clinical practice. He completed the classroom training (Phase 1) and went back to Fort Bragg for the clinical practice. Mr. Githens completed the training in December 1989 and achieved the level of 18D (Delta) E4 Specialist/Corporal. A MOS 18D works alongside a commandeer during battle to communicate information. Essentially, an MOS 18D is responsible for being the "eyes and ears" of the Army and must be highly qualified and mentally competent and sharp.

114. After obtaining the 18D level, the Army sent Mr. Githens to the Reserve Special Forces unit in Jamestown, Ohio, where he joined the Company B, 2nd Battalion, 11th Special Forces Group (Airborne). He served until 1993, after which he joined the Army National Guard 19th Special Forces Group Airborne, one of two National Guard groups of the Army that carry out various missions, including in Southwest Asia. The Army then deployed Mr. Githens on a Foreign Internal Defense mission to Japan to train members of the Japanese military. After returning from Japan, the Army deployed Mr. Githens to Haiti in 1994 as part of Operation Uphold Democracy, a military intervention designed to oversee and monitor government elections.

115. From the time Mr. Githens joined the military to 1997, including during and after his deployments to Japan and Haiti, he remained in perfect physical and mental health, with no exposure to combat or other situations that would cause a highly trained Army soldier to experience emotional distress or mental instability.

116. In 1997, the Army deployed Mr. Githens to Eritrea, a country in East Africa (also known as the Horn of Africa) close to Somalia and bordered by Ethiopia, Sudan, and Djibouti. Like his deployment to Japan, the mission was to train soldiers. However, this deployment differed. This time, Mr. Githens was prescribed Mefloquine to prevent malaria—specifically, the brand name Lariam. He ingested it weekly for approximately three months while stationed in Eritrea.

117. After taking Mefloquine, Mr. Githens began to experience sleep disturbances and vivid abnormal dreams. For no reason apparent to him, Mr. Githens also began to come became angry and filled with uncontrollable rage, paranoia, anxiety, and depression.

118. By 2001, the sleep disturbances Mr. Githens first experience in Eritrea had worsened and he sought a sleep assessment from a local medical center. The physician guessed that Mr. Githens may have Seasonal Affect Disorder and prescribed him the antidepressant Paroxetine to be taken once a day. The medication helped Mr. Githens to sleep better, but his mental condition worsened and he needed to take more and more of the medication to sleep.

119. By 2001, Mr. Githens would wake up each night in extreme night sweats, followed by headaches, brain fog and memory issues during his waking hours. He could not remember simple matters like the names of those he worked with every day or his work schedule. The physician Mr. Githens saw at this time had no answers for his condition and attempted to treat it with prescription drugs that did nothing to fix the problem. Finding no help in the military, and tormented by the unrelenting rage, paranoia, anxiety, and depression he was experiencing, Mr. Githens left the Army National Guard in 2002.

120. After leaving the military, Mr. Githens worked as a police officer in Ohio as a member of a SWAT team. However, his persistent abnormal and unstable mental state, which had increased and worsened over the years, caused problems in his work performance. His memory was severely impaired. He would forget to attend meetings or wear his uniform. He was always fearful and paranoid, which caused him to be suspicious of others and angry at and critical of his superiors who he suspected were plotting against him. Mr. Githens struggled to complete even minor tasks.

121. Mr. Githens's fellow police officers recognized that he needed help and took him to a hospital for mental health treatment. The physician prescribed Trazodone as a treatment for the depression. Eventually, the police force allowed Mr. Githens to return to work. However, by 2011,

Mr. Githens's condition had worsened and no medical professional could give him answers to why he was experiencing his condition or how it could be overcome.

122. When his depression and anxiety worsened, Mr. Githens lost his ability to cope with everyday life and fell into a state of social isolation and suicidal ideation. Due to his growing mental instability and inability to cope with the everyday stress that comes with being a police officer, he was fired from the police force.

123. After a series of jobs, at which he never last long for the same reason his police career ended, Mr. Githens ended up homeless, unable to obtain employment, and financially destitute.

124. Mr. Githens eventually turned to the mental health department at the VA hospital in Toledo for assistance. Once again, treatment was ineffective. The physicians Mr. Githens saw had no answers for why his neuropsychiatric health was so impaired and simply chose to treat his side effects. The treatments, however, did nothing to improve his condition.

125. In 2020, Mr. Githens received from an Army friend an article about Mefloquine toxicity. He took the article with him to his next appointment at the VA in Zanesville Ohio and showed it his treating physician. He asked if Mefloquine could be the root cause of his condition. The physician dismissed the idea and sent Mr. Githens on his way with some antibiotic drops for an ear infection. A month later, Mr. Githens went to another VA hospital in Columbus Ohio and asked the same question about a connection to taking Mefloquine with the same result—the physician dismissed any connection of his condition to Mefloquine. As such, at that time, he had no reason to believe that his symptoms could be attributable to Mefloquine.

126. By this time, Mr. Githens felt that he had no chance for recovery because no one could tell him why his brain had changed or offered him an effective treatment. In the winter of 2020, Mr. Githens unsuccessfully attempted to end his suffering with an overdose of pills and ended

up hospitalized for a week.

127. In late 2021, after his suicide attempt and feeling totally defeated by the VA medical professionals, Mr. Githens started researching online as to what could be the cause of his symptoms. He discovered social media posts by Special Forces veterans who wrote about Mefloquine toxicity causing the exact same mental health problems in them as Mr. Githens has experienced since taking Mefloquine. As he continued to research, Mr. Githens came across the lawsuit styled *Nelson v. F. Hoffman-La Roche, Ltd, et al*. The lawsuit focused Mr. Githens for the first time on the culpability of the makers of Mefloquine for Mefloquine toxicity. That case led him to articles written by medical professionals such as Dr. Remington Nevin, which contained hard scientific evidence that Mefloquine toxicity is real and is the probable cause of the debilitating and permanent neuropsychiatric side effects that Mr. Githens began experiencing while serving in Eritrea and that are with him to this day.

128. Mr. Githens was never warned that Mefloquine had the potential to cause permanent neuropsychiatric side effects, nor was he aware prior to mid-2021 that Mefloquine could be a potential cause of his ongoing neuropsychiatric conditions. Mr. Githens had no reason to be aware of scientific studies contained in peer-reviewed medical literature. Thus, he would not have had any reason to know or believe that Mefloquine could be the cause of his permanent neuropsychiatric debilitating condition.

129. Had Mr. Githens 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 to military service members 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, there was a

substantial probability that Mr. Githens would never have been offered the drug in the first place had Roche adequately warned of the dangers associated with Mefloquine use.

130. Mr. Githens is unaware of any medical professional at the VA who has the knowledge or training to perform the proper diagnostic evaluation and testing related to his Mefloquine use. Thus, Mr. Githens seeks for himself and other military veterans proper diagnostic evaluation and testing for Mefloquine toxicity and a proper treatment protocol funded by Defendants.

IX. Mr. Wagher's Potential Mefloquine Toxicity

131. Patrick Eugene Wagher is a 45-year-old decorated military veteran who earned many medals, stars, and ribbons during his years of service.

132. Mr. Wagher grew up on a family farm in Massachusetts and lived a normal healthy life free of emotional trauma or physical injuries.

133. In 1995, while attending high school, Mr. Wagher enlisted in the Army National Guard. To determine his mental and physical readiness for acceptance to serve in the U.S. Armed Forces, Mr. Wagner underwent a Form DD 2807 evaluation of his medical history. The Department of Defense physicians determined that Mr. Wagner had no disqualifying mental or physical condition, including any sort of anxiety, memory loss, sleep disturbance, depression, or other mental condition, and accepted him for service into the National Guard.

134. Mr. Wagher went to Fort McCollum, Alabama for basic training in the summer of 1995 and finished training AIT (Advanced Individual Training) in the summer of 1996. Mr. Wagher graduated with honors and an excellent physical training score. Mr. Wagher also received military training that included advanced individual training to become a member of the U.S. Army Military Police (MP) Corps, the uniformed enforcement branch of the U.S. Army.

135. Following basic training, Mr. Wagner returned to his home unit in Massachusetts to train one weekend a month and two weeks in the summer for six years until the expiration of his

term of service in January 2001. Mr. Wagher left the National Guard for a short time but stayed active in the Individual Ready Reserves.

136. On September 11, 2001, 19 militants associated with the Islamic extremist group al Qaeda hijacked four airplanes and conducted suicide attacks on U.S. soil. These attacks triggered major U.S. initiatives to combat terrorism. Mr. Wagher immediately went to the nearest Armed Forces Recruiting office to re-enlist. The Army assigned him to the Military Entrance Processing Station at Westover Air Reserve Base in Chicopee, Massachusetts for another medical history evaluation of readiness to serve. Again, Mr. Wagner was deemed fully qualified mentally and physically to serve in the military and with no mental health issues.

137. While serving in the Army National Guard from 1995 until 2003, Mr. Wagner experience no mental health issues and did not seek treatment for anxiety, depression, sleep disorders, or any form of neuropsychiatric symptoms.

138. In January 2002, the Army placed Mr. Wagher's MP unit on alert for deployment to Afghanistan with an Army battalion unit that coming March. At that time, Mr. Wagher and his unit were sent to Fort Drum in New York for combat mobilization training prior to departure to Afghanistan. During his tenure at Fort Drum, Mr. Wagher was confident, calm, and mentally and physically prepared and well-trained for his deployment to Afghanistan as an MP.

139. Prior to deployment, Mr. Wagner was prescribed Mefloquine—specifically the brand name Lariam. A day prior to his deployment, Mr. Wagner ingested his first dose of Mefloquine. The drug came in a box printed with the brand name Lariam.

140. After ingesting Mefloquine, Mr. Wagher experienced sleep problems including terrifying nightmares followed by the inability to fall back to sleep. The sleep issues intensified while in Afghanistan. Mr. Wagher could not sleep more than 3 hours a night, and when awake, he felt unusually amped up with anxiety causing him to feel suspicious and in danger of those around

him, including those he served with on the U.S. military base.

141. Mr. Wagner's mental state further deteriorated. He could no longer could sleep and started to hallucinate, seeing people around him that nobody else saw and hearing voices and talking nonsense to his fellow soldiers while on guard. His physical condition worsened and his heart rate increased to above normal levels. A military doctor prescribed Mr. Wagher a medication to slow his heart rate down but otherwise provided no other treatment for the issues he was experiencing.

142. Mr. Wagher subsequently injured his back and hip in a Humvee rollover but continued to serve in Afghanistan for another three months before returning to the U.S. Unfortunately, the mental health and emotional issues Mr. Wagher experienced after taking Mefloquine continued after his return to the U.S and he began to experience additional symptoms. For example, Mr. Wagher's thinking was clouded, strange dreams continued to haunt him, he continued to feel suspicious of those around him, and he felt an overwhelming depression. At that time, Mr. Wagher did not associate his problems with Mefloquine and simply believed his condition resulted from an inability to adjust to civilian life after years of serving in the military. He believed the mental and emotional problems he was experiencing would pass. Unfortunately, he was wrong.

143. Mr. Wagher's mental stability continued to decline and he realized that he was not the same man he was prior to deployment to Afghanistan. He had difficulty managing stress in his work environment, felt a deep depression and isolation, and lost his ability to form relationships. Mr. Wagher's mental condition caused problems in his marriage and eventually his wife divorced him.

144. At some point in 2007, Mr. Wagher reflected on how well he felt and acted when he was part of the Army National Guard. He believed that if his problem resulted from difficulty adjusting to civilian life, re-joining the military in some capacity would enable him to regain his mental and physical wellbeing. Thus, in 2007, he applied for and the Army hired him as a military

recruiter. Unfortunately, wherever Mr. Wagher went, his depression and anxiety followed. His mental health issues continued to worsen over the years as did his work performance as a recruiter. He exhibited a variety of psychosocial behaviors that hurt his ability to recruit people into the military and repelled his fellow workers.

145. By 2015, Mr. Wagher became even more irritable, frustrated by life, lethargic, unable to sleep and unable to focus and concentrate. At the suggestion of his recruitment supervisor, Mr. Wagher sought treatment from a physician at nearby Hanscom Air Force Base in Massachusetts. The physician diagnosed Mr. Wagher with severe depression and anxiety, believing his condition may be related to the stress and pressures of work. After two years of unsuccessful medical treatment, the physician recommended that Mr. Wagher see a psychotherapist to address his condition.

146. Mr. Wagner voluntarily enrolled in a mental health treatment program at the prestigious McLean Hospital in Massachusetts. There he was prescribed the antidepressant Sertraline to help him overcome his insomnia problem. However, the medication did little to help him and Mr. Wagher's condition did not improve while at McLean. He continued to feel a high-level of anxiety, persistent insomnia, weight loss, a feeling of hopelessness and the inability to feel pleasure, also known medically as anhedonia. Mr. Wagner left McLean and at the end of August 2017 and sought further mental health treatment through the mental health program at the VA Hospital located in Worchester Massachusetts.

147. Physicians and other healthcare professionals at the VA who interviewed and treated Mr. Wagher confirmed he suffered from deep depression and anxiety among other mental health disturbances, and they started him on a treatment program with various pharmaceuticals designed to address his symptoms. The professionals attributed the cause of Mr. Wagher's condition to either work stress, post-traumatic stress disorder, or lack of life coping skills. Although Mr. Wagher gave

the VA medical professionals a detailed history of his military career, including his deployment to Afghanistan in 2003 and ingestion of Mefloquine, not once did any VA healthcare professional ask Mr. Wagner questions about his experience with Mefloquine or make a connection between his symptoms and Mefloquine use.

148. During this time, Mr. Wagher saw an article about Mefloquine toxicity and wondered whether it could be responsible for his symptoms. He mentioned this to his doctors and asked if this could be the root cause of his condition. His question was quickly dismissed by the VA healthcare professionals, who had either never heard of problems associated with Mefloquine or were unwilling to consider the connection. Mr. Wagner concluded from what the medical professionals told him that his mental health problems were not related to Mefloquine. As such, at that time he had no reason to believe his symptoms were due to Mefloquine.

149. By 2017, Mr. Wagher's mental health condition had not improved with the treatment recommended by the VA medical professionals. In fact, his condition continued to deteriorate. Mr. Wagher was devastated when his recruitment supervisor at the recruiting office informed him that his deteriorating mental and emotional state, memory issues, and odd behavior affected his wellbeing and job performance and therefore he was no longer qualified to work for the Army National Guard as a recruiter, and he was relieved of duty.

150. In early 2022, after years of failed drug and therapy treatments and upon reflection about when his anxiety and depression started, Mr. Wagher began intensely researching possible causes of his symptoms. Upon doing so, Mr. Wagher learned for the first time that Mefloquine could be the root cause of his condition. With the aid of a legal professional, on August 17, 2022, Mr. Wagher filed a disability claim with the Army for Combat-Related Special Compensation based on Mefloquine toxicity. The Human Resources Command of the U.S. Army granted Mr. Wagher's claim, noting Mefloquine toxicity as the cause as his combat related injury. This was the first time

Mr. Wagher had experienced anyone associated with the military, including the VA physicians and other healthcare professionals, recognizing that Mefloquine is toxic and is responsible for long-term mental health problems experienced by those who ingested the drug while serving in the military.

151. Mr. Wagher was never warned that Mefloquine had the potential to cause neuropsychiatric side effects, nor did he conclude prior to 2022 that Mefloquine was the most likely the root cause of his ongoing condition.

152. Had Mr. Wagher 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 to military service members 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, 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.

153. Mr. Wagher has not had proper diagnostic evaluation and testing related to his Mefloquine use and needs a proper diagnostic and treatment protocol for his condition.

X. Mr. Allen's Potential Mefloquine Toxicity

154. Kendrick Allen is a 46-year-old decorated Navy veteran.

155. Mr. Allen is the son of a career military officer and lived many years overseas on military bases, including in Japan. Mr. Allen's childhood was happy and secure, and his mental state was stable and devoid of any trauma or emotional distress.

156. Mr. Allen followed in his father's footsteps and joined the Navy in 1999. He was cleared to serve after a medical evaluation determined he had no physical or mental conditions that would prevent him from qualifying for military service. Mr. Allen immediately went into training

at Naval Station Great Lakes in Great Lakes, Illinois, and eventually became qualified as a Fleet Marine Force Medic. Upon completion of Fleet Marine Force training, the Navy ordered Mr. Allen to be stationed at Camp LeJeune with the 3rd Battalion 6th Marines in the 2nd Marine Division.

157. Mr. Allen was stationed at Camp LeJenue on September 11, 2001, during the Islamic terrorist attacks on the U.S. Not long after the attacks, the Navy informed Mr. Allen's unit to ready for deployment to Afghanistan. In November 2001, Mr. Allen landed in Kandahar, Afghanistan with the Marines in support of Operation Enduring Freedom.

158. Prior to deployment to Afghanistan, on November 22, 2001, the Medical Officer at Camp LeJeune prescribed Mr. Allen Mefloquine—specifically, the brand name Lariam.

159. Mr. Allen took an initial loading dose of Mefloquine, and then continued to take the drug weekly while in Afghanistan. After taking Mefloquine, Mr. Allen experienced the first of what turned out to be many extremely vivid, abnormal, and horrifying night terrors. The nightmares were so severe they caused him to wake up screeching in terror, which alarmed his fellow soldiers causing them to run to aid him. Mr. Allen also began to have insomnia, memory problems and cognitive impairment issues. As time went on, Mr. Allen began to feel as if his brain was somehow poisoned. However, neither he nor any medical professional at the time associate his condition with taking Mefloquine.

160. The cognitive issues Mr. Allen first experienced after taking Mefloquine continued to worsen long after he left the Navy in 2007. He continues to suffer from brain fog and stupor, his memory issues persist and have worsened, he rarely has a single night of undisturbed sleep if he sleeps at all, and he has difficulty processing thoughts, multi-tasking and concentrating.

161. For many years, Mr. Allen has sought treatment from medical professionals for these cognitive issues. However, to date, none of the treatments he has received have been helpful in addressing the complications and underlying issues he continues to suffer from. He also has never

been provided with an explanation for his condition, other than attributing it to post-traumatic stress disorder. Mr. Allen believes this could be a misdiagnosis and that the symptoms and complications that he is experiencing are being overlooked and wrongly attributed to PTSD. Moreover, the medications prescribed by his treating physicians for PSTD have done nothing to cure his cognitive problems, which by now appear permanent and continue to worsen.

162. Mr. Allen was never told that Mefloquine had the potential to cause neuropsychiatric side effects. He believed Mefloquine was a simple, safe, and effective drug that would prevent him contracting malaria. However, on or about the end of January 2023, Mr. Allen stumbled upon an article written by Dr. Remington Nevin about the permanent and irreversible neuropsychiatric side effects of Mefloquine toxicity. The symptoms described exactly what Mr. Allen began experiencing shortly after ingesting Mefloquine and has been experiencing since then. Mr. Allen was previously unaware that Mefloquine can cause severe neuropsychiatric problems and he therefore had no reason to suspect that it could be the cause of his problems. In fact, when he saw Dr. Remington's article, it was the very first moment that Mr. Allen made the connection between ingesting Mefloquine and the debilitating side effects he suffers from.

163. Had Mr. Allen 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 to military service members 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, there was a substantial probability that he would never have been offered the drug in the first place had Roche adequately warned the military of the dangers associated with Mefloquine use.

164. Mr. Allen now believes that Mefloquine is the root cause of the damage to his brain,

including his memory loss, insomnia, and lack of processing power. However, he requires proper diagnostic evaluation and testing related to his Mefloquine use and a proper diagnostic and treatment protocol.

XI. Tolling/Fraudulent Concealment

165. Plaintiffs brings this medical monitoring complaint within the applicable statute of limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following their individual awareness of the potential wrongful cause of their symptoms and conditions. Prior to such time, none of the Plaintiffs knew of the potential wrongful cause of their condition, nor did they have any reasonable basis for discovering them.

166. Plaintiffs assert 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.

167. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs 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.

168. 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 Plaintiffs and Class Members about the severe and irreversible risks associated with Mefloquine use. Indeed, the labeling that existed at the time Plaintiffs each ingested Mefloquine not only failed to adequately warn about the risks of the drug, but it also affirmatively misled the military, its physicians, and its service members about the potential risks. For instance, Roche Inc. affirmatively misrepresented that the potential for mental problems was “rare” and “mild.” Roche Inc. also affirmatively

misrepresented that the symptoms requiring cessation of the drug under the drug's prescribing guidelines would only occur in a "small percentage of cases." Roche Inc. further misrepresented that there was no confirmed relationship between drug administration and suicidal ideation, even though Roche knew or should have known not only that such a relationship existed, but that it posed a significant risk of occurring. And Roche Inc. affirmatively misrepresented that other than vomiting, there was a less than 3% chance of any side effects from occurring—which necessarily included any neuropsychiatric side effects.

169. In addition, Roche Labs affirmatively misled the military, its service members and its physicians into believing that Mefloquine was a safe and practical first-line prevention for Malaria. Roche Labs never informed the military that at least 14% of users would need to cease using the drug. Roche Labs never informed the military that there was a greater than 3% risk of Mefloquine causing psychiatric effects. And Roche Labs misled the military into believing that there was no risk whatsoever for ant neurological symptoms—much less that such symptoms could be permanent and irreversible.

170. Roche's fraudulent concealment continued up until the time they existed the U.S. market for Mefloquine. As a result of these misrepresentations and concealment, Plaintiffs 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 described herein.

CLASS ALLEGATIONS

171. Plaintiffs bring this action on behalf of themselves 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 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.

172. Alternatively, Plaintiffs bring this action on behalf of the following subclasses:

> Nationwide Subclass: All U.S. military service members who took the brand name Lariam and who experienced prodromal neuropsychiatric symptoms during use of the drug.
>
> California and Massachusetts Subclass: All U.S. military service members currently citizens of California or Massachusetts 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.

173. The members of the Class are so numerous that joinder of all Class Members is impracticable. Plaintiffs are informed and believe that the proposed Class contains hundreds of thousands of military service members who require medical monitoring because of Defendants' actions, as alleged herein. The precise number of Class Members is unknown to Plaintiffs currently.

174. Plaintiffs' 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. Plaintiffs are advancing the same claims and legal theories on behalf of themselves and all Class Members.

175. Plaintiffs' 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 can cause adverse neuropsychiatric effects;

b. whether Defendants knew or should have known that Mefloquine could cause 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 Plaintiffs and Class Members are entitled to medical monitoring relief because of their exposure to Mefloquine;

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

176. Plaintiffs and their counsel will fairly and adequately protect and represent the

interests of each member of the class. Plaintiffs have retained counsel experienced in complex litigation and class actions. Plaintiffs' counsel has successfully litigated other class action cases like that here and have the resources and abilities to fully litigate and protect the interests of the Class. Plaintiffs intends to prosecute this claim vigorously. Plaintiffs has no adverse or antagonistic interests to those of the Class, nor are Plaintiffs subject to any unique defenses.

177. 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 Plaintiffs and Class Members are 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.

178. **Injunctive and Declaratory Relief**: Class certification is also appropriate under Rule 23(b)(2) because Defendants acted and refused to act on grounds 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 Plaintiffs 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

179. Plaintiffs incorporate by reference and re-allege each allegationcontained above, as though fully set forth herein.

180. Plaintiffs bring this claim individually and on behalf of the Class Members.

181. Manufacturers, including Defendants, have a duty of reasonable care to warn of risks that are known or knowable considering the recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

182. 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.

183. 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.

184. 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.

185. As a direct and proximate result of Defendants' failure to provide adequate warnings of the risk of Mefloquine, Plaintiffs 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 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.

186. The injuries from which Plaintiffs and Class Members suffer require specialized testing that is not 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.

187. 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.

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

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

190. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

191. 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.

192. Plaintiffs 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, Plaintiffs 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

193. Plaintiffs incorporate by reference and re-allege each allegation contained above, as though fully set forth herein.

194. Plaintiffs bring this claim individually and on behalf of the Class Members.

195. Manufacturers, including Defendants, have a duty of reasonable care in all aspects of the design, formulation, manufacture, testing, evaluating, 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 Plaintiffs and Class Members, obtained accurate information and adequate instructions for the use or non-use of Mefloquine.

196. 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, evaluated, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

197. 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.

198. As a direct and proximate result of Defendants' negligence, Plaintiffs 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 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.

199. The injuries from which Plaintiffs and Class Members suffer require specialized testing that is not 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.

200. 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.

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

202. By monitoring and testing Plaintiffs and Class Members, the risk that Plaintiffs and Class Members will suffer losses without adequate treatment or inappropriate treatment will

be significantly reduced.

203. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

204. 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.

205. Plaintiffs 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, Plaintiffs 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

206. Plaintiffs incorporate by reference and re-allege each allegationcontained above, as though fully set forth herein.

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

208. 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.

209. 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, evaluate, and monitor their product.

210. 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.

211. 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.

212. 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 foreseeable by the Defendants, and in that the risk of danger outweighs the benefits.

213. 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.

214. 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.

215. By failing to adequately evaluate 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 physicians 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.

216. The Mefloquine designed, researched, manufactured, tested, evaluated, 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.

217. 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 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.

218. As a direct and proximate result of Defendants' conduct, Plaintiffs 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.

219. The injuries from which Plaintiffs and the Class Members suffer require specialized testing that is not 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.

220. 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.

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

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

223. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

224. 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.

225. Plaintiffs 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, Plaintiffs 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

226. Plaintiffs incorporate by reference and re-allege each allegationcontained above, as though fully set forth herein.

227. Plaintiffs bring this claim individually and on behalf of the Class Members.

228. Defendants engaged in the business of researching, testing, evaluating, 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.

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

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

231. Defendants designed, researched, manufactured, tested, evaluated, 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 Plaintiffs and Class Members.

232. The Mefloquine drug supplied to Plaintiffs 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 Plaintiffs and the Class Members.

233. Plaintiffs, 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.

234. 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.

235. 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.

236. Mefloquine is defective and unreasonably dangerous to Plaintiffs 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.

237. As a direct and proximate result of Defendants' conduct, Plaintiffs 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 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.

238. The injuries from which Plaintiffs and Class Members suffer require specialized testing that is not 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.

239. 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.

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

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

242. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

243. 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.

244. Plaintiffs 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, Plaintiffs 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

245. Plaintiffs incorporate by reference and re-allege each allegation contained above, as though fully set forth herein.

246. Plaintiffs bring this claim individually and on behalf of the Class Members.

247. Defendants misrepresented to the U.S. military, physicians, and end-users, including Plaintiffs 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.

248. 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.

249. 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 Plaintiffs and Class Members, including because Defendants relied on intentionally misleading and inadequate studies to obtain FDA approval for the drug.

250. 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, Plaintiffs, 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.

251. Defendants made the previously mentioned 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 previously mentioned representations.

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

253. At the time, the previously mentioned representations were made by Defendants, and at the time Plaintiffs and the Class Members received Mefloquine, Plaintiffs 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, Plaintiffs and Class Members ingested Mefloquine. Had Defendants adequately warned of the true risks, it is 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.

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

255. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs 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.

256. The injuries from which Plaintiffs and Class Members suffer require specialized testing that is not 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.

257. 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.

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

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

260. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

261. 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.

262. Plaintiffs 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, Plaintiffs 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

263. Plaintiffs incorporate by reference and re-allege each allegationcontained above, as though fully set forth herein.

264. Plaintiffs bring this claim individually and on behalf of the Class Members.

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

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

267. Following receipt of FDA approval, Roche Inc. and Roche Labs continued to represent to the public that Mefloquine was a safe, well-tolerated and practical treatment for malaria prevention. They never adequately or appropriately warned of the significant risk of severe and irreversible neuropsychiatric harms associated with Mefloquine use. To the contrary, they 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.

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

269. At the time, the previously mentioned representations were made, Plaintiffs and the Class Members reasonably believed them to be true.

270. In reasonable and justified reliance upon the representations that Mefloquine is safe

and well-tolerated, Plaintiffs and the Class Members ingested Mefloquine. Had Roche Inc. or Roche Labs 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.

271. As a direct and proximate result of these intentional misrepresentations, Plaintiffs 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.

272. The injuries from which Plaintiffs 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.

273. 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.

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

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

276. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

277. 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.

278. Plaintiffs 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, Plaintiffs and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated.

COUNT VI
Civil Conspiracy by Roche Labs
All Classes

279. Plaintiffs incorporate by reference and re-allege each allegations contained above, as though fully set forth herein.

280. Plaintiffs bring this claim individually and on behalf of the Class Members against Roche Labs.

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

282. In 1989, prior to seeking FDA approval of Mefloquine, Roche Labs knew of the significant and irreparable damage that Mefloquine could cause to users, including Plaintiffs and Class Members. Nevertheless, based on intentionally false and misleading clinical trials, Roche Labs acted in concert with Roche Inc. to seek and obtain FDA approval for Mefloquine as a safe

and well-tolerated treatment for malaria prevention.

283. Following receipt of FDA approval, as the brand-name distributor of the drug, Roche Labs continued to mislead the public and especially into believed that the military that Mefloquine was a safe, well-tolerated and practical treatment for malaria prevention. In so doing, Roche Labs acted in concert with Roche Inc. at all times. While Roche Inc. was responsible for preparing the false and misleading label, Roche Labs acted in concert with Roche Inc. by then perpetuating false and misleading statements to the military in the course of marketing and selling them the drug.

284. By affirmatively misleading the military about the drug's risks, Roche Labs intended to induce the U.S. military, Plaintiffs, the Class Members, and their physicians to use Mefloquine as a treatment for malaria prevention.

285. At the time the previously mentioned representations were made by Roche Labs, and at the time Plaintiffs and the Class Members received Mefloquine, Plaintiffs and the Class Members reasonably believed them to be true.

286. In reasonable and justified reliance upon the representations that Mefloquine is safe and well-tolerated, Plaintiffs and the Class Members ingested Mefloquine. Had Roche Lab not misled the military about the drug's 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.

287. As a direct and proximate result of Roche Lab's intentional misrepresentations to the military, in combination with the false and misleading statements contained on the drug label, Plaintiffs 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.

288. The injuries from which Plaintiffs 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.

289. 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.

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

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

292. Plaintiffs 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 Plaintiffs and Class Members as frequently and appropriately as necessary.

293. Accordingly, Roche Labs 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.

294. Plaintiffs 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, Plaintiffs and Class Members will continue to face an unreasonable risk of remaining undiagnosed and or being misdiagnosed and mistreated.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, 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 Plaintiffs andt their counsel to represent the Class, and requiring Defendants to bear the costs of class notice;

B. A judgment against Defendants and in favor of Plaintiffs 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 Plaintiffs 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

Plaintiffs demand a trial by jury on all issues so triable.

DATED May 31, 2023

Respectfully submitted,

/s/ Erica Rutner

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CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2023, 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