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GABRIEL AUBUCHON

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN MATEO

GABRIEL AUBUCHON, an individual

Plaintiff,

vs.

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

Defendants.

Case No. 19CIV02728

COMPLAINT FOR DAMAGES

1. Strict Products Liability – Failure to Warn
2. Negligence
3. Deceit by Concealment (Violation of Civil Code §§ 1709-1710)
4. Fraud
5. Negligent Misrepresentation and Concealment

DEMAND FOR JURY TRIAL

By Fax

COMPLAINT

Plaintiff Gabriel Aubuchon ("Plaintiff"), by and through his attorneys, bring this Complaint against Defendants F. Hoffmann-La Roche Ltd. ("Swiss Roche"), Roche Laboratories, Inc. ("Roche Laboratories"), Hoffmann-La Roche, Inc. ("U.S. Roche," and together with Swiss Roche and Roche Laboratories, "Roche"), Genentech, Inc. ("Genentech"), Genentech USA, Inc. ("Genentech USA"), and Does 1-100 (together with the other defendants, "Defendants") for damages. All allegations are made on information and belief, except those allegations explicitly about Plaintiff. Plaintiff alleges as follows:

INTRODUCTION

1. This action arises out of Roche's egregious failure to warn our U.S. military and service members of the substantial and irreversible dangers of its antimalarial drug Lariam ("Lariam") that have left thousands of our nation's veterans severely and permanently sick. Lariam is widely recognized as one of the most dangerous malaria prevention drugs on the market, and Lariam toxicity is believed to be the modern-day version of Agent Orange in scope, scale, and scandal.

2. Roche marketed and sold Lariam to the U.S. military for service members deployed to Somalia for the prevention of malaria. Virtually every deployed service member took Lariam or its generic equivalent while in Somalia for the U.S.-led military operation called Operation Restore Hope during the 1990s. At the height of the Somalia operation, tens of thousands of prescription of Lariam were written by military doctors, equating to over a million tablets. The market opportunity was vast and demand was strong.

3. Plaintiff was a U.S. Army infantryman from October 1, 2002 to September 13, 2015. He was deployed to the Horn of Africa from December 16, 2003 to July 20, 2004. In early to middle December 2003, he was given Lariam as part of his deployment. As a result of Defendants' failure to warn and flawed drug design, Plaintiff has suffered lasting neurological and psychiatric injuries, resulting in the loss of his good-paying factory job and his becoming one of thousands homeless veterans.

4. Despite decades of research, Defendants willfully hid the risks of Lariam from the U.S. military, U.S. service members, and the public and continued to sell the drugs knowing of flawed prescribing protocols to pad its bottom line with wartime profits.

5. No soldier is sick with malaria when Lariam is taken for prevention. But after taking the drug, a sizeable group of soldiers have severe and irreversible symptoms that mimic the symptoms of post-traumatic stress disorder, evading accurate diagnosis.

6. These symptoms are believed to have led military service members worldwide to commit well-publicized acts of unspeakable human tragedy. In 1992, two Canadian peacekeeping soldiers who took Lariam as part of a controlled drug trial beat to death a Somali teenager. Dubbed the Shame of Canada, it led a Canadian public health agency's senior physician to blame Lariam and resign in protest. In the summer of 2002, three Special Operations soldiers murdered their wives and then committed suicide at Ft. Bragg. After taking Lariam during their deployments to Afghanistan, all three showed uncharacteristic behaviors including delusions, paranoia and fits of rage. A formal Army investigation report left open the distinct possibility that Lariam was the cause of these atrocious killings. Media reports tied Lariam to an uptick in military suicides in 2003. More recently, experts believe that the murder of 16 Afghan civilians in Afghanistan by an Army staff sergeant in 2012 was linked to his use of Lariam. Not accounting for the tragic murder of these 16 Afghan civilians, a 2007 study found that Lariam has been causally linked to 19 deaths in users, including three suicides.

7. Roche well knew of the substantial danger of severe and irreversible neuropsychiatric side effects of Lariam, because that danger is well-documented. Before Roche began the sale of Lariam in 1989, the risk of brain toxicity from the chemical family to which Lariam belongs had been widely known for decades. By 1998, there were widespread reports of Lariam causing permanent bad reactions, including symptoms of paranoia, hallucinations, and suicidal thoughts, that persisted even after the patients' discontinuation of the drug.

8. As mounting evidence of Lariam's devastating side effects became more widespread, Roche concealed their scope and nature and recklessly sold the drug as a safe and effective first-line treatment for malaria prevention. Safer and more effective drugs for malaria

prevention existed on the market, including doxycycline. But re-designing Lariam to be a last-resort pill for malaria prevention is a sure-fire way to extinguish its stranglehold on the market and the strong demand for it by the U.S. military.

9. Roche's knowledge that the U.S. military could practically never follow safe prescribing protocols is a further sign of the fundamentally flawed drug design. Not only did Roche know that U.S. service members would be incapable of receiving the follow-up assessments Roche knew were vital to their safety, but it knew that any immediately apparent side effects such as paranoia, anxiety, and restlessness would be confused for the natural feelings of soldiers in war.

10. The prospect of wartime profits is what led Roche to recklessly continue to market and sell a fundamentally flawed antimalarial pill to the U.S. military. During the Somalia operation, thousands of U.S. forces fought abroad, with virtually all being required to take the drug during months-long seasons of endemic malaria.

11. The perilous design flaws of Lariam are universally recognized by regulatory agencies and the medical community. As the FDA stated in 2013 when it slapped a "black box" warning on the drug:

> 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 prescribed to 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.

12. After the FDA warning, the U.S. military immediately changed its Lariam prescribing policies. It re-designated Lariam as a drug of last resort after other malaria prevention drugs were found to be ineffective. The U.S. military's policy change demonstrates that adequate

warnings of Lariam side effects would not have just been words on a label nobody reads, but would have spared U.S. service members of lifelong psychiatric and neurological disorders.

13. The history of military use of Lariam shows that Roche's concealment was a blatant attempt to protect profits. When the U.S. military finally downgraded Lariam to a last-resort therapy after alternatives failed, the number of Lariam prescriptions dropped to 216.

14. Plaintiff is a victim of Defendants' scheme to profiteer from the U.S. military. He served his country in the U.S. Infantry on active service from October 1, 2002 to September 30, 2005, with further service in the Reserves thereafter. He took Lariam while he was deployed to the Horn of Africa in or around December 2003. He has suffered classic neuropsychiatric symptoms of mefloquine toxicity since: insomnia, abnormal dreams and nightmares, anxiety, depression, anger, irritability, aggression, paranoia, and cognitive dysfunction, which have contributed to his diagnoses of depression, major depression not otherwise specified (NOS), major depressive disorder, adjustment disorder with depressed mood and anxiety, anxiety disorder NOS, generalized anxiety disorder, insomnia, chronic neurologic symptoms of tinnitus, dizziness, headache, visual photosensitivity, paresthesias, and other vestibular disorders.

15. anxiety, depression, irritability, anger, paranoia, suicidal ideation, insomnia, restlessness, and periodic limb movements during sleep, which have contributed to his diagnoses of adjustment reaction, dysthymia, depression, mood disorder not otherwise specified (NOS), bipolar disorder, and restless leg syndrome (RLS), dizziness and disequilibrium.

16. Despite his suffering, nobody had ever told him these are the classic symptoms of Lariam toxicity until recently. His doctors at the VA had confounded his symptoms of mefloquine toxicity for post-traumatic stress disorder. He kept returning to them diligently in search of answers to his intractable medical problems, but no doctor told him about mefloquine toxicity or ever linked mefloquine to his chronic neuropsychiatric conditions. He had no knowledge, nor should he have, of Roche's failure to warn of the permanent neuropschiatric side effects of Lariam. He did not learn that the injuries he was experiencing may have been caused by Lariam until November 2017 when he read about the causal link on the VA's website. He did not learn that the injuries he was experiencing may have resulted from the wrongdoing of Roche until

no earlier than 2018, when he read about lawsuits against Roche for its wrongdoing. Because the first time Plaintiff ever had inquiry notice of mefloquine toxicity and Roche's wrongdoing was 2018, his suit is timely.

PARTIES

17. Plaintiff Gabriel Aubuchon is a resident and citizen of Missouri, MO.

18. Swiss Roche is a Swiss corporation headquartered in Basel, Switzerland, with operations worldwide, with its principal place of business in the United States in South San Francisco, California. Swiss Roche is a wholly-owned subsidiary of Roche Holding AG.

19. U.S. Roche is a New Jersey corporation with its principal place of business in South San Francisco, California. U.S. Roche is an affiliate of Swiss Roche. U.S. Roche was formerly headquartered in Nutley, New Jersey, but relocated its Nutley headquarters to the Genentech headquarters in South San Francisco in March 2009 following Roche's acquisition of Genentech that same year.[1] Genentech's website states: "Genentech's South San Francisco campus now serves as the headquarters for Roche pharmaceutical operations in the United States." *See* Exhibit A. Roche has been in the business of developing, manufacturing, selling, marketing, and distributing Lariam throughout the United States from 1989 to 2008. U.S. Roche is a general manager of Swiss Roche in California.

20. Genentech is a Delaware corporation with its principal place of business in South San Francisco, California, 94080. Genentech is an indirect wholly-owned subsidiary of Roche Holding AG and a member of the Roche Group 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 Nutley, New Jersey U.S. headquarters to Genentech's headquarters. Genentech is a general manager of Swiss Roche in California.

21. Genentech USA is a Delaware corporation with its principal place of business in South San Francisco, California. Genentech USA is a wholly-owned subsidiary of Genentech.

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[1]Genentech, *About Us*, https://www.gene.com/about-us (last accessed June 27, 2018).

22. Roche Laboratories is a Delaware corporation with its principal place of business in South San Francisco, California. Roche Laboratories is a general manager of Swiss Roche in California, as Roche Laboratories was listed on the FDA label for Lariam is the distributor of Lariam in the United States for pills manufactured by Swiss Roche.

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

JURISDICTION AND VENUE

24. This Court has unlimited civil jurisdiction over this case under California Code of Civil Procedure § 88 because the amount in controversy exceeds $25,000.00.

25. This Court has personal jurisdiction over the parties because each Defendant (other than Swiss Roche) lives or has their principal places of business in the State of California and is fairly regarded as "at home" in the State of California. A federal district court has determined that U.S. Roche has its principal place of business in, and is therefore a citizen of, the State of California for diversity of citizenship purposes. *See* Exhibit B. The Supreme Court has held that a corporation is subject to general jurisdiction of the courts of a State if that corporation has its principal place of business in that State. For the same reasons identified in the federal district court order as to U.S. Roche, Roche Laboratories has its principal place of business in California. Roche Laboratories has the same officers and directors as U.S. Roche, including its principal executive officer who works out of his South San Francisco office.

26. Venue is proper in the Superior Court of California, San Mateo County under California Code of Civil Procedure § 395 because Genentech, U.S. Roche, Roche Laboratories, and Genentech USA reside in San Mateo County.

GENERAL ALLEGATIONS

A. History of Lariam in the United States and Abroad

27. Discovered by the Walter Reed Army Institute of Research after the Vietnam War, Lariam is a prescription drug indicated for the treatment and prevention of malaria. During the Vietnam War, the U.S. military conducted a malaria drug discovery program in response to outbreaks of malaria in 1% of U.S. troops in Vietnam. There is no question that the world needed

safe and effective antimalarial drugs at the time. Driven by need, Lariam was rushed through the FDA approval process, with the completion of only Phase I and Phase II clinical trials. No Phase III trial ever occurred, even though it is the most probing of drug safety and efficacy through a randomized and blind testing of a large population. Without a Phase III trial, the FDA approved the drug in 1989. Roche became the exclusive worldwide brand-name manufacturer of Lariam and is the official holder of the New Drug Application.

28. Lariam is now widely known to be a poison to the human nervous system. Within months of FDA approval, major safety concerns emerged. In the 1990s, European drug safety agencies – in the heart of Swiss-based Roche-country – received recurring reports of severe neuropsychiatric symptoms. In the Netherlands, Lariam 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.

29. In 1995, researchers conducted two successive double-blind trials of Lariam in British soldiers in Kenya. The goal was to look at the prevalence of neuro-psychiatric disorders in military users of Lariam. The researched compared Lariam with the pre-existing standard regimen of chloroquine and proguanil. The results clearly indicated that a third of all soldiers taking Lariam had very 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.

30. In the early 2000s, three randomized controlled trials confirmed that Lariam has the strong potential to cause psychological illness and an excessive number of neuropsychiatric side effects.

31. In a 2001 study, a team of researchers conducted a randomized controlled trial of Lariam in a mixed population of general travelers and compared the adverse effects of Lariam to those of another antimalarial drug sold under the brand name Malarone. The results were striking. The study found that 67.1% of study participants reported more than one adverse event, and 6% reported these events were severe. The comparator drug performed far better than Lariam

in every measure: they had fewer treatment-related neuropsychiatric events (71.4% to Lariam's 67.3%), fewer adverse events of moderate or severe intensity (10% to Lariam's 19%), and fewer patients who had to discontinue the prevention drug (1.2% to Lariam's 5%). The study decidedly concluded that Malarone was equally effective as Lariam, but substantially safer.

32. By 1996, Roche's Lariam became a focus of drug safety regulators. That year, the U.K.'s Committee on Safety of Medicines slapped Roche's Lariam drug with a warning about the dangerous incidence of neuropsychiatric side effects. In 2004, the FDA insisted that a patient medication guide be given to all Lariam patients.

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

34. Nearly three decades later, more studies reached similar conclusions about quinoline derivatives similar to Lariam. A synthetic version of the chemical then in common use as an antimalarial had been linked to neurological disorders involving the permanent degeneration of neurons. In short, initial evidence of Lariam toxicity is the central nervous system toxicity caused by its antimalarial quinoline drug cousins that are chemically related.

35. Lariam has been the cause of enormous tragedy. It has been causally linked by experts, including regulators, with the following events:

- In 1992, two Canadian soldiers who took Lariam killed a Somali civilian on a peacekeeping mission in Somalia. The incident was documented by photos. A Member of the Canadian Parliament and a senior official of Canada's equivalent of the FDA have publicly stated that the soldiers' erratic conduct may have been the result of Lariam toxicity.

- In the summer of 2002, two soldiers in the Ft. Bragg area killed their wives and then committed suicide. Two other soldiers murdered their wives in Ft. Bragg around the same time. The Army could definitively conclude that three of these soldiers took Lariam and concluded that it was possible that Lariam side effects were the cause of the murderous and suicidal behaviors.

- In 2012, an Army Sargent murdered 16 Afghan civilians in Afghanistan while taking a generic version of Lariam. Experts and physicians had concluded that the murders are causally linked to the transformative side effects of Lariam.

36. Roche marketed and sold Lariam to the U.S. military for service members deployed to Somalia for the prevention of malaria. During the War on Terrorism, over a million U.S. forces fought abroad in Somalia, with virtually all being required to take the drug during months-long seasons of endemic malaria. The Centers for Disease Control and Prevention states that malaria is a high risk to people in all areas of Somalia. The U.S. military ordered all service members deployed there during those months to take malaria-prevention pills. For most of the time before its withdrawal from the U.S. market in 2008, Roche was the U.S. military's main supplier of malaria-prevention pills with assurances that Lariam was a safe and effective first-line therapy for that purpose. When Roche had a patent monopoly on the Lariam market, nearly 50,000 prescriptions of Lariam were written by military doctors annually, equating to over millions of tablets. The market opportunity was vast and demand was strong.

37. In 2009, a U.S. Army policy memorandum prioritized the use of other antimalarial medications after increased exposure to Lariam led to the recognition of the prevalence of neuropsychiatric side effects experienced by service members using the drug.

38. In July 2013, the FDA slapped a "black box" warning for Lariam – its strictest form of warning. The FDA warned of Lariam's severe neuropsychiatric side effects, which could "persist after mefloquine has been discontinued." The warning read as follows:

> 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 prescribed to prevent malaria in patients with major psychiatric disorders or with a history of

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

39. After the FDA warning, the U.S. military immediately changed its Lariam prescribing policies. It re-designated Lariam as a drug of last resort after other malaria prevention drugs were found to be ineffective. The U.S. military's policy change demonstrates that adequate warnings of Lariam side effects would not have just been words on a label nobody reads, but would have spared U.S. service members of lifelong psychiatric and neurological disorders.

40. In 2016, a committee of the British House of Commons conducted a months-long inquiry into the safety of Lariam for British Armed Forces. The investigation noted that Lariam has a high risk profile and a minority of users experience severe side-effects. The committee concluded that Lariam should be considered as a "drug of last resort" and be prescribed only to those who are unable to take any of the available alternatives. In the course of that investigation, it is clear that Roche knew of the distinct risk that military culture, operations, and prescribing protocols would cause military agencies to breach Roche's prescribing guidance. Mike Kindell, the Roche's Lead of Established Products, testified as follows :

> **Q47** **Chair:** And therefore, while reiterating that you are not responsible for the way in which the MoD and the medical staff within the MoD prescribe your product, does this not raise an obvious problem when the person who is prescribed the drug may have some history of psychiatric illness or depression, for example, but may feel unable to disclose that to the person proposing to prescribe Lariam to them for fear of damaging their career?
>
> ***Mike Kindell:*** I would think that is certainly a very much hypothetical risk, yes.
>
> **Q48** **Chair:** More than just hypothetical.
>
> ***Mike Kindell:*** It is a risk, yes.
>
> **Q49** **Chair:** So, in other words, you are a soldier and you know that you have had some episode or some anxieties in the past, but you really would feel pretty inhibited before saying to the Medical Officer in your regiment, "I really shouldn't take this stuff, because it could have a very serious effect on me."
>
> ***Mike Kindell:*** I think that is a fair statement.

41. In the hearing, Dr. Frances Nichols, Roche's Head of Drug Safety Quality, admitted that the British military's use of a mass prescribing protocol was a violation of its own prescribing guidelines:

> **Q8** **[Member]:** I accept that. The premise of my question is: if there is an organisation that does not do individual risk assessments, is that, or is that not, clearly outside the manufacturer's guidelines?
>
> ***Dr Nichol:*** The expectation would be that an individual risk assessment is done by prescribers at the time.
>
> ...
>
> **Q10** **[Member]:** When you push out the drug, you have your manufacturer's guidelines and within that you say that it should be prescribed after an assessment. So if an organisation goes outside that, surely they are using the drug outside the guidelines that you stated as the manufacturer of that drug.
>
> ***Dr Nichol:*** Yes, the guidelines do say an individual risk assessment should be done, and in the material that we have circulated there is a checklist that the physicians are supposed to go through with each individual—

42. Roche's testimony before the British Parliament establishes that they had reason to believe that British service members had a special risk of evading a proper risk assessment and the British military had a mass prescribing protocol inconsistent with Roche's own guidelines. So too for U.S. service members and the U.S. military.

43. Because of the heightened risk Lariam presents to service members, the military forces of Germany, Netherlands, Denmark, and Canada have all banned the prescription of Lariam among their personnel.

44. At least until 2009, Roche designed, made, distributed, and marketed Lariam to the U.S. military as a first-line drug for malaria prophylaxis. Roche knew or should have known that the risk of serious side effects of Lariam far outweighs the benefits of prophylaxis. Safer and equally effective alternatives for malaria prophylaxis existed, including doxycycline. Despite these safer alternatives, Roche recklessly marketed and sold Lariam to the U.S. military for use by soldiers in Somalia.

45. Roche knew or should have known of the risk of severe neuropsychiatric symptoms of mefloquine toxicity and the risk that U.S. military personnel would be unable to

make an appropriate judgment to discontinue the drug if these symptoms presented. The U.S. military personnel were taking Lariam in remote parts of Somalia. They were surrounded by threatening enemy forces, making for inherently stressful environments. It was unreasonable for Roche to expect such military personnel to make a judgment linking the source of anxiety, depression, and paranoia to Lariam and discontinue the drug, rather than to the enemy forces.

46. Upon information and belief, in providing Lariam to Plaintiff in connection with his overseas deployments, the military and Plaintiff's physicians relied upon information published in the package inserts or Physician's Desk Reference (hereinafter "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter "RLD"), or the New Drug Application Holder (hereinafter "NDA holder"). Roche is responsible for the contents and dissemination of that information . Roche failed to adequately warn Plaintiff, his physicians, and the U.S. military of the risks of severe and life-altering psychiatric and neurological side effects.

47. Upon information and belief, the U.S. military and Plaintiff's physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR.

B. Defendants' Military-Lariam Business and the Role of Defendants in the Manufacture, Sale, Marketing, and Distribution of Lariam to the Military

48. At all relevant times, Swiss Roche was the manufacturer of Lariam. At all relevant times, U.S. Roche was the new drug application holder, rendering it responsible for the labeling and packaging of Lariam in the United States.

49. Before the acquisition of Genentech by the Roche Group, Roche Laboratories marketed and sold Lariam to the Department of Defense under a Distribution and Pricing Agreement ("DAPA"). A DAPA obligated Roche Laboratories to offer Lariam for sale to the Defense Logistics Agency ("DLA") at the prices set forth in the DAPA. Roche did in fact sell Lariam to the military under these agreements up until the Genentech acquisition in or around 2009. Such sales occurred in California where a number of offices for the Defense Logistics Agency are located and ordered and purchased Lariam from Roche Laboratories for distribution to defense forces abroad, including in Somalia.

50. Roche Laboratories acted in concert with U.S. Roche and Swiss Roche in all marketing and sale activities with respect to the U.S. military. U.S. Roche was the sole NDA holder for Lariam and had exclusive rights to commercially exploit the drug up until 2002 or 2003. This meant that U.S. Roche had to authorize, and did in fact authorize, Swiss Roche to manufacture the drug and Roche Laboratories to market and sell the drug. The three entities worked in concert at all points in the manufacture and distribution chain. In fact, U.S. Roche and Roche Laboratories had common officers and directors at all relevant times such that all relevant decisions were made or overseen by the same group of individuals. U.S. Roche was the sole owner of Roche Laboratories at all relevant times.

51. After the Genentech acquisition, Roche Laboratories transferred the military-Lariam business to Genentech USA and Genentech USA became the mere continuation of Roche Laboratories with respect to the military-Lariam line of business. At that time, Roche Laboratories had terminated or withdrawn from its DAPA agreement to offer Lariam for sale to the U.S. military. Concurrently therewith, Genentech USA succeeded to the DAPA agreement and became the official DAPA holder of Lariam for the Roche Group, meaning Genentech USA was the only entity in the Roche Group capable of offering Lariam for sale to the U.S. military.

52. Genentech USA paid Roche Laboratories nothing for the military-Lariam line of business. It gave Roche Laboratories no consideration for this line of business. Moreover, Genentech USA had a common stockholder with Roche Laboratories, U.S. Roche, and Genentech. All entities were owned by Roche Holdings, Inc. Genentech USA had common officers and directors with Roche Laboratories, Genentech, and U.S. Roche at all relevant times. In sum, Genentech USA was a mere continuation and thus successor of Roche Laboratories with respect to the military-Lariam line of business, and the military was the single largest customer of Lariam for the Roche Group.

53. Genentech is the alter ego of Genentech USA. Genentech is the sole stockholder of Genentech USA. Genentech undercapitalized Genentech USA, commingled assets and operations (insofar as they had common assets and operations), and/or failed to observe corporate formalities.

54. Genentech is also a successor-in-interest to Roche. After the acquisition of Genentech by Roche Holding AG, the Roche Group made a strategic decision to transfer the commercial pharmaceutical operations of U.S. Roche and Roche Labs (including manufacturing, marketing, labeling, research, design, sales, and regulatory affairs) to Genentech, rebranding all Roche drugs in the U.S. as Genentech. Genentech took over the employees, assets, brands, and other operational functions of U.S. Roche and Roche Labs. Genentech has told the public and all customers of U.S. Roche and Roche Labs of the consolidation. Genentech paid U.S. Roche and Roche Labs nothing for these assets, employees, goodwill, and operations. Genentech controls U.S. Roche and Roche Labs out of South San Francisco, where all the decisions to relocate the commercial pharmaceutical operations were made.

55. With respect to all causes of action below, Genentech and Genentech USA is the successor-in-interest to the military-Lariam business of all Roche entities, thereby rendering it liable for its predecessors activities.

56. With respect to all causes of action below, Genentech is the alter ego of Genentech USA.

C. Plaintiff's Lariam Toxicity as a Result of Roche's Drug

57. Plaintiff is 40-year old Army veteran who is permanently disabled because of Lariam toxicity.

58. Plaintiff enlisted in the Army in 2002 without any history of neuropsychiatric symptoms. The military conducts a rigorous physical exam to see if the enlistee is in good physical and mental health and ensure he can safely make it through basic training and meet the daily demands and stress of service. During the enlistment process, Plaintiff reported no medical history of neuropsychiatric symptoms. He likewise had no history of neuropsychiatric problems.

59. Plaintiff's consumption of Lariam after his deployment to Africa in 2003 changed his life. Following his discharge from the Army, he has suffered classic symptoms of what he recently discovered were mefloquine toxicity: chronic psychiatric symptoms of insomnia, abnormal dreams and nightmares, anxiety, depression, anger, irritability, aggression, paranoia, and

cognitive dysfunction, chronic neurologic symptoms, tinnitus, dizziness, headache, visual photosensitivity, and paresthesias.

60. Defendants could have spared Plaintiff of his personal injuries had they adequately warned the U.S. military of the risks of Lariam and made a well-designed drug. In 2013, after the FDA slapped the "black box" warnings on Lariam, the U.S. military virtually ceased prescribing the drug to its soldiers in endemic malaria regions. Those warnings of risks that Roche had long knew of could have prevented Plaintiff's injuries.

61. For the reasons described in the introduction, Plaintiff did not discover or ever have any notice that Lariam caused his symptoms until November 2017 when he read about it on the VA's website. He likewise never discovered or ever had notice that Roche's wrongdoing caused his symptoms until late 2018 when he became aware that Roche had failed to warn service members of the permanent and severe nature of symptoms like his. Consequently, his statute has been tolled until 2018 at the earliest. During the period of time he suffered, he had consistent appointments and visits with his doctors seeking to understand the cause of his symptoms. His doctors did not mention Lariam as a cause of his injuries, even though the VA publishes information indicating the drug's risks and even though the military has discontinued its policy of prescribing Lariam because of such risks.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All Defendants)

62. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

63. The Roche developed, manufactured, and sold Lariam during all relevant times. As the brand-name manufacturer of Lariam, Roche is responsible under California law to warn of the risks about which it knew or reasonably should have known or were scientifically knowable.

64. Roche had actual or constructive knowledge of the substantial danger of serious and permanent neuropsychiatric side effects from the consumption of Lariam in a sizeable

minority of patients. When Plaintiff consumed Lariam, Roche knew of (1) the lasting side effects of Lariam based on the scientific and medical literature, case reports, and governmental and regulatory investigations and (2) the existence of safer, equally effective malaria prevention alternatives.

65. Roche's warnings of these substantial dangers were nonexistent or at least inadequate. Roche failed to adequately inform the U.S. military and U.S. service members of side effects that might occur upon foreseeable use of Lariam.

66. Plaintiff consumed Lariam for malaria prevention, which was an indicted use of the drug.

67. None of Plaintiff, the U.S. Military, and Plaintiff's physicians would have ordinarily discovered the substantial danger of serious and permanent neuropsychiatric side effects from consuming Lariam.

68. Had Roche adequately warned of the substantial danger of severe and permanent neuropsychiatric side effects of Lariam, the history record is clear: the U.S. military would not have purchased, and Plaintiff would not have ingested, Lariam.

69. The lack of sufficient warnings was a substantial factor in causing Plaintiff's harm.

70. As a direct and proximate result of the inadequate warnings for Lariam, Plaintiff suffered severe and permanent injuries, incurred significant expenses for medical care and treatment, suffered lost wages and earnings, was otherwise economically injured, and experienced pain and suffering.

71. Upon information and belief, Genentech and Genentech USA are the successors-in-interest to the liability of the Roche Defendants arising out of this First Cause of Action.

SECOND CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

72. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

73. Each Roche Defendant owed a duty to exercise reasonable care to Plaintiff in its manufacture, design, and labeling of Lariam so that Lariam can be safely used as intended by the consumer.

74. Each Roche Defendant breached this duty of care by negligently designing Lariam as a first-line drug for malaria prophylaxis for U.S. service members in remote and inherently stressful environments.

75. Roche knew of the substantial danger of serious neuropsychiatric side effects from Lariam and the existence of safer, equally effective alternatives. They likewise knew that it was impractical for the U.S. military to follow adequate prescribing protocols for soldiers deployed in remote parts of Somalia. The risk that those troops would not be able to accurately identify Lariam side effects in stressful combat zones surrounded by enemy threats and make a judgment to discontinue Lariam was reasonably foreseeable. Accordingly, in light of the foregoing, Roche should not have sold Lariam to the U.S. military as a first-line drug for malaria prophylaxis for our troops in Somalia without adequate warnings, distribution controls, and training for proper prescribing protocols.

76. A reasonably careful drug maker would have warned the U.S. military and the public at large of the substantial danger of Lariam's permanent and severe neuropsychiatric side effects under the circumstances. Such a drug maker would have designed and marketed the drug as a last-resort therapy after all other equally effective alternatives (which existed) failed or presented equally severe side effects. A reasonably careful drug maker would have issued guidance and technical assistance to the U.S. military to ensure effective protocols for drug administration and follow-up were in place for soldiers in remote and threatening environments.

77. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of the Defendants as follows:

a. In their manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of the prescription drug Lariam;

b. In their failure to warn or instruct and/or adequately warn or adequately instruct, prescribing physicians, the U.S. Military and users of Lariam, including Plaintiff herein, of the dangerous and defective characteristics of Lariam;

c. In their promotion of the prescription drug Lariam in a deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury;

d. In representing that the prescription drug Lariam was safe for its intended use when, in fact, the product was unsafe for its intended use;

e. In failing to perform appropriate pre-market testing of the prescription drug Lariam;

f. In failing to perform appropriate post-market testing of Lariam; and

g. In failing to perform appropriate post-market surveillance of Lariam.

78. Roche knew or should have known that patients such as Plaintiff would foreseeably suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.

79. Roche failed to exercise reasonable and ordinary care by failing to adequately warn prescribing physicians and patients, such as Plaintiff, of the serious risk of developing neuropsychiatric injuries and mefloquine toxicity after ingesting Lariam.

80. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of Lariam, and Roche's failure to comply with the care required of a careful drug manufacturer, Plaintiff suffered severe and permanent injuries and incurred significant expenses for medical care and treatment, suffered lost wages and earnings, was otherwise economically injured, and experienced pain and suffering.

81. Upon information and belief, Genentech and Genentech USA are the successors-in-interest to the liability of the Roche Defendants arising out of this Second Cause of Action.

THIRD CAUSE OF ACTION

DECEIT BY CONCEALMENT – VIOLATION OF

CALIFORNIA CIVIL CODE §§ 1709, 1710

(Against All Defendants)

82. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

83. The Roche Defendants had actual knowledge based upon studies, published reports, and clinical experience, that the prescription drug Lariam created an unreasonable risk of serious bodily injury, such as neuropsychiatric injuries and mefloquine toxicity, or should have known such information.

84. The Roche Defendants willfully omitted, concealed and suppressed this information from the product labeling, promotions, and advertising of Lariam, and instead labeled, promoted, and advertised the prescription drug Lariam as safe in order to avoid losses and sustain profits in its sale to consumers and thereby induce consumers and their prescribing or treating physicians to use Lariam. Defendants knew that Plaintiff's healthcare providers and the United States military would not have exposed Plaintiff to Lariam, had Plaintiff's healthcare providers known or otherwise been aware of the true facts concerning Lariam's administration. Specifically, the Roche Defendants concealed that (1) neurological side effects of Lariam can be permanent, persistent, and chronic, (2) their knowledge that mefloquine should be immediately stopped if a patient develops neurologic or psychiatric symptoms, (3) the risk of permanent vestibular damage (ear and balance issues), (4) the risk these permanent neuropsychiatric symptoms would interfere with patients' daily activities and ability to work, (5) the risk that nightmares would be the first indication of severe and permanent neuropsychiatric injuries, and (6) the risk that the permanent neuropsychiatric symptoms would cause suicidal and homicidal ideations.

85. Plaintiff and Plaintiff's healthcare providers reasonably relied, to their detriment, upon Roche's fraudulent actions and omissions in their representations concerning the risks of Lariam in the labeling, advertising, and promoting of said product.

86. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the Roche Defendants' representations to them that Lariam was safe for human consumption and/or use, and that Roche's labeling, advertising, and promotions fully described all known risks of Lariam.

87. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of Lariam, and the Defendants' failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries and incurred significant expenses for medical care and treatment, suffered lost wages and earnings, was otherwise economically injured, and experienced pain and suffering.

88. Upon information and belief, Genentech and Genentech USA are the successors-in-interest to the liability of the Roche Defendants arising out of this Third Cause of Action.

FOURTH CAUSE OF ACTION

FRAUD

(Against All Defendants)

89. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

90. The Roche Defendants concealed, and continue to conceal, past and present facts from the consuming public, including Plaintiff, which they had a duty to disclose.

91. The facts concealed and not disclosed include, but are not limited to, those set forth in this Complaint, including but not limited to the following: (1) Roche told prescribers that injuries caused by Lariam would cease after the drug was discontinued, (2) Roche told prescribers that the risk that injuries caused by Lariam would be permanent was minimal, and such permanent injuries would be insubstantial, (3) Roche told prescribers that serious mental problems in some patients is "rare" when in fact it was fairly common, impacting up to 10% of the total population, (4) Roche told prescribers that suicidal ideation as a result of taking the drug was rare, when in fact it was fairly common, and (5) Roche told prescribers that Lariam was safe and

effective to use, when in fact it was so risky the U.S. military de-designated it after the FDA slapped a Black Box warning on it and Roche decided to wash its hands of the drug completely. Roche knew each of these statements was false, or concealed the truth, or had a reckless disregard for the truth of such statements.

92. Each of the facts concealed and not disclosed were material.

93. Defendants concealed and continue to fail to disclose material facts to the consuming public with the intent that the consuming public, like Plaintiff, would take a course of action that it would otherwise not have taken if it had been informed of the actual facts known to the Defendants, including the totality of the risks associated with the use of Lariam.

94. Plaintiff took such action relying on the assumption that the undisclosed facts did not exist and/or were different than they actually were.

95. The reliance of Plaintiff was justified.

96. As a result of Plaintiff's reliance on the incomplete and inaccurate information communicated by the Defendants and their assumption that the non-disclosed facts about the risks associated with the use of Lariam did not exist, Plaintiff suffered the injuries and damages alleged in this Complaint.

97. As a direct and proximate result of Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss.

98. As a result of the foregoing by the Defendants, and each of them, Plaintiff suffered injuries and damage as alleged herein.

99. Upon information and belief, Genentech and Genentech USA are the successors-in-interest to the liability of the Roche Defendants arising out of this Fourth Cause of Action.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION AND CONCEALMENT

(Against All Defendants)

100. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

101. The Roche Defendants labeled, promoted, and advertised Lariam as safe, fit and effective for use in humans. They also made the statements specifically stated in the Fourth Cause of Action and concealed the facts specifically stated in the Third Cause of Action.

102. The Roche Defendants made the foregoing representations without any reasonable ground for believing them to be true. In supplying the false information, Roche failed to exercise reasonable care in labeling, promoting and advertising the prescription drug Lariam.

103. The representations made by Roche were, in fact, false, in that Lariam was not safe, fit and effective for use in humans.

104. Plaintiff's healthcare providers would not have exposed Plaintiff to Lariam had his healthcare providers known or otherwise been aware of the true facts concerning the prescription drug Lariam.

105. Plaintiff and Plaintiff's healthcare providers reasonably relied, to their detriment, upon Roche's actions, concealment and omissions in their representations concerning the risks of Lariam in the labeling, advertising, and promoting of said product.

106. Plaintiff and Plaintiff's healthcare providers reasonably relied upon Roche's representations to them that Lariam was safe for human consumption and/or use and that the Defendants' labeling, advertising, and promotions fully described all known risks of Lariam .

107. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of Lariam, and Roche's failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries and incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise economically injured.

108. Upon information and belief, Genentech and Genentech USA are the successors-in-interest to the liability of the Roche Defendants arising out of this Fifth Cause of Action.

PUNITIVE DAMAGES ALLEGATIONS

109. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

110. Roche knew or should have known that the administration of Lariam could result in the development of mefloquine toxicity and severe and lasting neuropsychiatric side effects when administered to patients in the manner as was administered to Plaintiff.

111. Roche attempted to misrepresent and did misrepresent facts concerning the safety of Lariam.

112. The Roche Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of Lariam.

113. Roche knew and recklessly disregarded the fact that Lariam could result in the development of mefloquine toxicity and severe and lasting neuropsychiatric side effects when administered to patients in the manner as was administered to Plaintiff. Notwithstanding the foregoing, Roche continued to aggressively market Lariam to the U.S. military and consumers, including Plaintiff herein, without disclosing the fact that administration of Lariam could result in the development of mefloquine toxicity when administered to patients in the manner as was administered to Plaintiff.

114. The Roche Defendants knew of the defective and unreasonably dangerous nature of the prescription drug Lariam as set forth herein, but continued to manufacture, market, distribute, and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable risks of injury.

115. The Roche Defendants intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff, the potentially life-threatening side effects of the administration of Lariam in order to ensure continued and increased sales.

116. The Roche Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff and his health care providers of necessary information to enable Plaintiff and his healthcare providers to weigh the true risks of using Lariam against the benefits.

117. As a direct and proximate result of Roche's conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, and the unreasonably dangerous and defective characteristics of Lariam, and Roche's failure to comply with federal standards and requirements, Plaintiff suffered severe and permanent injuries, including but not limited to the development of mefloquine toxicity and severe and lasting neuropsychiatric injuries. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise economically injured. Plaintiff suffered severe pecuniary loss. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

118. Roche's conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Roche and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Awarding actual damages in an amount to be determined at trial;

b. Awarding punitive damages to the Plaintiff;

c. Awarding pre-judgment and post-judgment interest to the Plaintiff;

d. Awarding the costs and expenses of this litigation to the Plaintiff;

e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

f. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Dated: May 20, 2019

PANISH SHEA & BOYLE LLP

By _____

JESSE MAX CREED
Attorneys for Plaintiff