PANISH SHEA & BOYLE LLP
KEVIN BOYLE, State Bar No. 192718
boyle@psblaw.com
PETER L. KAUFMAN, State Bar No. 269297
kaufman@psblaw.com
JESSE MAX CREED, State Bar No. 272595
creed@psblaw.com
GREGORY M. SONSTEIN, State Bar No. 320184
sonstein@psblaw.com
11111 Santa Monica Boulevard, Suite 700
Los Angeles, California 90025
Telephone: 310.477.1700
Facsimile: 310.477.1699

SIMINOU APPEALS, INC.
BENJAMIN I. SIMINOU, State Bar No. 254815
ben@siminouappeals.com
2305 Historic Decatur Rd., Ste. 100
San Diego, CA 92106
Telephone: 858.877.4184

Attorneys for Plaintiffs, ANDREW SHEETS AND KRISTIE SHEETS

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SONOMA

ANDREW SHEETS, an individual; KRISTIE SHEETS, an individual

PLAINTIFFS,

vs.

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

DEFENDANTS.

Case No.: SCV-262710

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
6. Loss of Consortium

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiffs Andrew Sheets and Kristie Sheets (collectively, "Plaintiffs"), by and through their attorneys, bring this Complaint against Defendants F. Hoffmann-La Roche Ltd. ("Swiss Roche"), F. Hoffmann-La Roche, Inc. ("U.S. Roche," and together with Swiss Roche, "Roche"), Genentech, Inc. ("Genentech"), and Does 1-100 (together with Roche and Genentech, "Defendants") for damages. All allegations are made on information and belief, except those allegations explicitly about Plaintiff. Plaintiffs allege 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 Afghanistan for the prevention of malaria. Virtually every deployed service member took Lariam or its generic equivalent while in Afghanistan. In 2003 alone, when Roche had a monopoly on the Lariam market, nearly 50,000 prescriptions of Lariam were written by military doctors, equating to over 1 million tablets. With the War in Afghanistan dragging on for years, the market opportunity was vast and demand was strong.

3. As a result of Defendants' failure to warn and flawed drug design, Mr. Sheets has suffered lasting neurological and psychiatric injuries. He experiences severe paranoia that Al-Qaeda members seek to murder his family in the United States, repeat nightmares "reliving" a delusion of a violent helicopter crash that never actually happened, and chronic depression, anxiety, and confusion. The Sheets marriage has been profoundly impacted by Mr. Sheets' paranoia and other symptoms, leading Mrs. Sheets to suffer a deprivation of the benefits of their marriage. Mr. Sheets' Lariam-induced paranoia has led him to bug the house and surveille his wife's whereabouts. 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.

4. 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.

5. 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.

6. 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.

7. 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 and Malarone. 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.

8. 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.

9. 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 War on Terrorism, over a million U.S. forces fought abroad in Afghanistan, with virtually all being required to take the drug during months-long seasons of endemic malaria.

10. 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.

11. 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.

12. 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.

13. Mr. Sheets is a victim of Defendants' scheme to profiteer from the U.S. military. Mr. Sheets enlisted in the Navy in June 2000 without any history of neuropsychiatric symptoms. On the first day of his deployment to Afghanistan in October 2003, Mr. Sheets was given Roche-branded Lariam and immediately began experiencing severe neuropsychiatric and physical side effects. He had bad nightmares on the very first night and developed severe paranoia and psoriasis within thirty days. In the fall of 2004, Mr. Sheets started getting throbbing headaches when reading, leading him to discover that he was having vision problems and had unexplained sensitivity to sunlight. His symptoms worsened over time, with depression, boredom, insomnia, and anger degrading his quality of life in 2006. Despite his suffering, nobody had ever told him these are the classic symptoms of Lariam toxicity until May 2017.

PARTIES

14. Andrew Sheets is a Navy veteran who served honorably in the U.S. Navy from June 23, 2000, to August 31, 2006. Mr. Sheets is currently a resident of Cazadero, Sonoma County, California.

15. Plaintiff Kristie Sheets is the wife of Andrew Sheets. She is a resident of Cazadero, Sonoma County, California.

16. 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. F. Hoffmann-La Roche Ltd. is a wholly-owned subsidiary of Roche Holding AG.

17. 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.

18. 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 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.

JURISDICTION AND VENUE

19. 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.

20. This Court has personal jurisdiction over the parties because each Defendant lives or has their principal places of business in the State of California and are fairly regarded as "at home" in the State of California.

21. Venue is proper in the Superior Court of California, Sonoma County under California Code of Civil Procedure § 395 because the injuries described herein occurred in Sonoma County.

GENERAL ALLEGATIONS

A. History of Lariam in the United States and Abroad

22. 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

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

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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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."

29. 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.

30. 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.

31. Roche marketed and sold Lariam to the U.S. military for service members deployed to Afghanistan for the prevention of malaria. During the War on Terrorism, over a million U.S. forces fought abroad in Afghanistan, 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 risk to people in Afghanistan from April to December. 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. In 2003 alone, when Roche had a patent monopoly on the Lariam market, nearly 50,000 prescriptions of Lariam were written by military doctors, equating to over 1 million tablets. With the War in Afghanistan dragging on for years, the market opportunity was vast and demand was strong.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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—

37. 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.

38. 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.

39. 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 atovaquone/proguanil (Malarone) and doxycycline. Despite these safer alternatives, Roche recklessly marketed and sold Lariam to the U.S. military for use by soldiers in Afghanistan.

40. 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 Afghanistan. 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 Taliban and enemy forces.

41. Upon information and belief, in providing Lariam to Mr. Sheets in connection with his overseas deployments, the U.S. Navy and Mr. Sheets' 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 Mr. Sheets, his physicians, and the U.S. Navy of the risks of severe and life-altering psychiatric and neurological side effects.

42. Upon information and belief, the U.S. Navy 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. Mr. Sheets' Lariam Toxicity and Ms. Sheets' Loss of Consortium as a Result of Roche's Drug

43. Mr. Sheets is a 40-year old decorated Navy Seal veteran who is permanently disabled because of Lariam toxicity. As a result, Ms. Sheets, who met Mr. Sheets Andrew and fell in love with him long before his military service, has lost the affection, companionship, and consortium of her husband and has had to give up her job, and more, to become his permanent caregiver.

44. In June 2000, Andrew entered the Navy without any history of neuropsychiatric symptoms. The Navy 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, Mr. Sheets reported no medical history of neuropsychiatric symptoms and had never once received treatment for a mental condition. He had no history of insomnia, depression, anxiety, amnesia or other memory loss, or any nervous trouble of any sort.

45. Mr. Sheets' medical examination by a Navy physician corroborated this unremarkable psychiatric medical history. The medical examination revealed not a single neuropsychiatric symptom. He was deemed qualified for service and enlisted.

46. Mr. Sheets' service to our nation before his deployment to Afghanistan in October 2003 showed no meaningful changes to his medical profile. In July 2000, Mr. Sheets signed up for Navy SEAL training and met the rigorous physical and mental standards for that elite command. He was considered to be "motivated and temperamentally suited for training in such duty." In July 2002, his reporting senior in Basic Underwater Demolition/SEAL (BUD/S) training determined that he met all the performance traits evaluated for enrollment. He had "excellent demeanor or conduct" and "always lives up to Navy Core Values: HONOR, COURAGE, COMMITMENT." The reporting senior concluded: "His professional performance was outstanding during these physically and mentally arduous courses of instruction. He is recommended for full duty at a SEAL team."

47. Mr. Sheets' consumption of Lariam after his deployment to Afghanistan in October 2013 changed his mental and psychiatric condition forever. The very first night after he took the pill he had intensely violent and tragic nightmares. The nightmares lasted about a month. The nightmares usually ended in death – his death and the death of his friends. In repeated nightmares, he was hit or run over by a train or shot or blown up. All these nightmares began prior to any kind of battle stress. He developed psoriasis within thirty days of taking the medication – another clinical sign of Lariam toxicity.

48. Mr. Sheets never recovered from the Lariam poisoning. Despite years of great pre-deployment performance reviews, in June 2006, he separated from the Navy pursuant to an administrative discharge for an "adjustment disorder with depressed mood."

49. Over the next twelve years to the present day, Mr. Sheets has cycled through a number of psychiatric treatments and confounding diagnoses. Even though many mimic the symptoms of post-traumatic stress disorder, all of his symptoms are signs of Lariam toxicity: poor sleep patterns with frequent waking and insomnia, regular nightmares, depression, anxiety, paranoia, hallucinations, disassociation, anxiety, and anger. He exhibited suicidal ideations. In one very illuminating sign of Lariam toxicity, Mr. Sheets believed in late 2011 that a sniper was somewhere in his vicinity, prompting him to drop to the ground and crawl for cover.

50. In February 2017, Mr. Sheets was finally described as permanently disabled by his treating physician because of his debilitating Lariam-related mental disorders.

51. Defendants could have spared the Sheets of their 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 the Sheets' injuries.

52. The Sheets had no reason to suspect that his neuropsychiatric injuries resulted from Lariam until January 2017 when the Sheets learned of the possible causal link between Lariam and the elusive neuropsychiatric symptoms Mr. Sheets was then experiencing. The Sheets had no specific prior awareness of the link.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against All Defendants)

53. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

54. 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.

55. 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 Mr. Sheets 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.

56. 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.

57. Mr. Sheets consumed Lariam for malaria prevention, which was an indicted use of the drug.

58. None of Mr. Sheets, the U.S. Navy, and Mr. Sheets' physicians would have ordinarily discovered the substantial danger of serious and permanent neuropsychiatric side effects from consuming Lariam.

59. 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 Mr. Sheets would not have ingested, Lariam.

60. The lack of sufficient warnings was a substantial factor in causing Mr. Sheets' harm.

61. As a direct and proximate result of the inadequate warnings for Lariam, Mr. Sheets 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.

62. Upon information and belief, Genentech is the successor-in-interest to the liability of Roche arising out of this First Cause of Action.

SECOND CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

63. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

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

65. 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.

66. 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 Afghanistan. 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 Afghanistan without adequate warnings, distribution controls, and training for proper prescribing protocols.

67. 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.

68. Mr. Sheet'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. Navy 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.

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

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

71. 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, Plaintiffs 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.

72. Upon information and belief, Genentech is the successor-in-interest to the liability of Roche 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)

73. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

74. 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.

75. 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 Mr. Sheets' healthcare providers and the United States military would not have exposed Mr. Sheets to Lariam, had Mr. Sheets' healthcare providers known or otherwise been aware of the true facts concerning Lariam's administration.

76. Mr. Sheets and Mr. Sheets' 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.

77. 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.

78. 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, Plaintiffs 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.

79. Upon information and belief, Genentech is the successor-in-interest to the liability of Roche arising out of this Third Cause of Action.

///

///

///

FOURTH CAUSE OF ACTION

FRAUD

(Against All Defendants)

80. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

81. 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.

82. The facts concealed and not disclosed include, but are not limited to, those set forth in this Complaint.

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

84. Defendants concealed and continue to fail to disclose material facts to the consuming public with the intent that the consuming public, like Mr. Sheets, 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.

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

86. The reliance of Mr. Sheets was justified.

87. As a result of Mr. Sheets' 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, Mr. Sheets suffered the injuries and damages alleged in this Complaint.

88. As a direct and proximate result of Defendants, Mr. Sheet suffered serious physical injury, harm, damages and economic loss.

89. As a result of the foregoing by the Defendants, and each of them, Mr. Sheet suffered injuries and damage as alleged herein.

90. Upon information and belief, Genentech is the successor-in-interest to the liability of Roche arising out of this Fourth Cause of Action.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION AND CONCEALMENT

(Against All Defendants)

91. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

92. The Roche Defendants labeled, promoted, and advertised Lariam as safe, fit and effective for use in humans.

93. 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.

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

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

96. Mr. Sheets and Mr. Sheets' 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.

97. Mr. Sheets and Mr. Sheets' 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 .

98. 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, Mr. Sheets suffered severe and permanent injuries and incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise economically injured.

99. Upon information and belief, Genentech is the successor-in-interest to the liability of Roche arising out of this Fifth Cause of Action.

SIXTH CAUSE OF ACTION

LOSS OF CONSORTIUM

(Against All Defendants)

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

101. At all relevant times, Plaintiffs Andrew and Kristie Sheets were, and are, legally married as husband and wife.

102. 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 the duties required of them under California state law, Ms. Sheets, Mr. Sheets' spouse, has been, and will continue to be, deprived of the consortium, society, comfort, protection, and service of Mr. Sheets, thereby causing and continuing to cause Kristie Sheets economic damages, lost wages, grief, sorrow, mental anguish, emotional distress, and pain and suffering.

103. Upon information and belief, Genentech is the successor-in-interest to the liability of Roche arising out of this Sixth Cause of Action.

PUNITIVE DAMAGES ALLEGATIONS

104. Plaintiffs hereby incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

105. 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 Mr. Sheets.

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

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

108. 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 Mr. Sheets. Notwithstanding the foregoing, Roche continued to aggressively market Lariam to the U.S. military and consumers, including Mr. Sheets 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 Mr. Sheets.

109. 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 Mr. Sheets, in conscious and/or negligent disregard of the foreseeable risks of injury.

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray 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

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

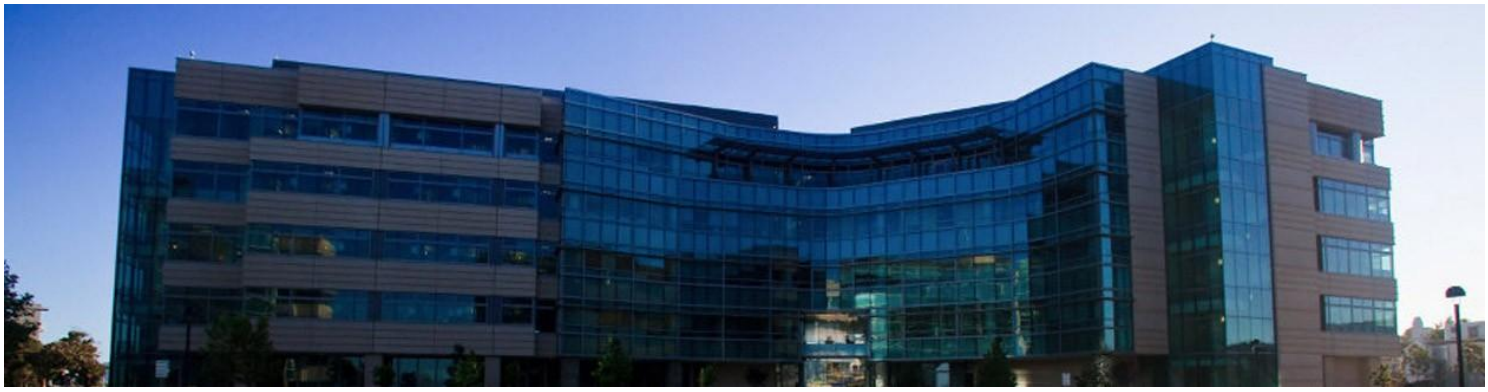
Dated: June 27, 2018

PANISH SHEA & BOYLE LLP

By _____

JESSE MAX CREED
Attorneys for Plaintiff

Exhibit A



ABOUT US

Considered the founder of the industry, Genentech, now a member of the Roche Group, has been delivering on the promise of biotechnology for over 40 years.

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. We are among the world's leading biotech companies, with multiple products on the market and a promising development pipeline.

Our Purpose: Doing now what patients need next

We believe it's urgent to deliver medical solutions right now – even as we develop innovations for the future. We are passionate about transforming patients' lives. We are courageous in both decision and action. And we believe that good business means a better world.

That is why we come to work each day. We commit ourselves to scientific rigor, unassailable ethics, and access to medical innovations for all. We do this today to build a better tomorrow.

We are proud of who we are, what we do, and how we do it. We are many, working as one across functions, across companies, and across the world.

We are Roche.

Our Values

The three Roche values—Integrity, Courage, and Passion—are core to how we want to behave, as individuals and collectively as an organization.

- **Passion** means we use our drive and commitment to energize, engage and inspire others.
- **Courage** means we are entrepreneurial and thus take risks, reach beyond boundaries and experiment.
- **Integrity** means we are consistently open, honest, ethical and genuine.

These values define fundamental attributes for guiding decisions and actions leading to increased innovation and business performance.

A Member of the Roche Group

Genentech became a member of the Roche Group in March of 2009. As part of their merger agreement, Roche and Genentech combined their pharmaceutical operations in the United States. Genentech's South San Francisco campus now serves as the headquarters for Roche pharmaceutical operations in the United States. Genentech Research and Early Development operates as an independent center within Roche.