IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

ROBERT BALES	)	
	)	
	)	DECLARATION OF REMINGTON L.
v.	)	NEVIN, MD, MPH, DrPH
	)	
COMMANDANT,	)	
United States Disciplinary Barracks	)	
Fort Leavenworth, Kansas	)	

DECLARATION OF DR. REMINGTON L. NEVIN

1. In 2017, Staff Sergeant Robert Bales (hereinafter SSG Bales, or Bales) first retained me as a medical expert in *U.S. v. Bales* to examine the possible role of mefloquine in the incident of March 10, 2012, the incident giving rise to this court-martial. I offer my specialized medical and public health training and experience as an occupational and preventive medicine physician, epidemiologist, and expert in the adverse effects of antimalarial drugs, particularly mefloquine (previously marketed as Lariam).

2. The following information is provided to briefly establish my credentials, qualifications, and professional experience in this area. A current curriculum vitae is attached to this declaration as Exhibit A. I served a 14-year career as a Preventive Medicine Officer in the U.S. military that included overseas service in malaria-endemic areas of Afghanistan with the 82nd Airborne Division, and in Africa with various U.S. Army Civil Affairs units.

3. I earned a BSc (Honours) in Theoretical Physiology from the University of Toronto; an MD from the Uniformed Services University of the Health Sciences, where I was awarded the Captain Richard R. Hooper Award in Preventive Medicine; and an MPH, DrPH, and certificate in Pharmacoepidemiology and Drug Safety from the Johns Hopkins Bloomberg School of Public Health, where I was elected an Alumni Inductee of the Delta Omega Honor Society, Alpha Chapter, and was later recognized with an Outstanding Recent Graduate award. I attended residency training in Preventive Medicine at the Walter Reed Army Institute of Research where I was awarded the George Miller Sternberg Award in Preventive Medicine. I also attended additional postdoctoral fellowship training in Occupational and Environmental Medicine at the Johns Hopkins Bloomberg School of Public Health.

4. I am licensed to practice medicine in the U.S. states of New York, Maryland, and Vermont, and am board certified in Occupational Medicine and Public Health and General Preventive Medicine by the American Board of Preventive Medicine. I am also Certified in Public Health by the U.S. National Board of Public Health Examiners.

5. I have authored over 80 scientific and medical publications, including over 30 letters, book chapters, and peer-reviewed articles in scientific and medical journals specifically on the topics of mefloquine or malaria. These include the first peer-reviewed article in the psychiatric literature on the forensic application of claims of adverse effects of mefloquine, which appears in the *Journal of the American Academy of Psychiatry and the Law*. I have also authored a chapter in the U.S. Army's *Textbook of Military Medicine* series titled *Mefloquine and Posttraumatic Stress Disorder*. My doctoral dissertation was titled *Pharmacovigilance of Neuropsychiatric Adverse Reactions to Mefloquine.*

6. In June 2012, I testified before the U.S. Senate Appropriations Subcommittee on Defense on issues related to mefloquine adverse effects. In January 2013, I was invited by the U.S. Food and Drug Administration to speak to their Center for Drug Evaluation and Research on the adverse effects of mefloquine. In January 2019, I was invited by the National Academies of Sciences, Engineering, and Medicine, to speak before a committee investigating the long-term adverse effects of mefloquine among veterans.

7. I am presently a consulting physician epidemiologist in private practice in White River Junction, Vermont, and serve as executive director of The Quinism Foundation, a 501(c)(3) non-profit corporation that promotes and supports education and research on quinism, the family of medical disorders caused by poisoning by mefloquine and related quinoline compounds.

REVIEW OF CASE MATERIALS

8. In preparing this declaration, I have carefully reviewed SSG Bales' available medical records, current through 2018; the medical expert reports of Drs. Golden, Pitman, Stahl, and Morgan; the complete 69-page report of the Rule for Courts-Martial (RCM) 706 sanity (competency) board (hereinafter the RCM 706 sanity (competency) board, and the 706 sanity (competency) report), dated May 3, 2013. I have also carefully reviewed the Stipulation of Facts in U.S. v. Bales, dated May 3, 2013; the government's motion to preclude references by the defense to SSG Bales' exposure to mefloquine; and the government's response to the defense request for discovery of records pertaining to SSG Bales' potential exposure to antimalarial drugs, including mefloquine.

9. I have also reviewed the declaration of Mr. Gregory Rayho, dated April 13, 2017 for the U.S. Army Court of Criminal Appeals; the decision of the U.S. Army Court of Criminal Appeals in U.S. v. Bales, dated September 27, 2017; the decision of the U.S. Court of Appeals for the Armed Forces in U.S. v. Bales, dated February 15, 2018; and the petition for a writ of certiorari filed by SSG Bales May 16, 2018 with the Supreme Court of the United States. I have also reviewed my previous declarations dated April 12, 2017; July 11, 2017; and August 13, 2017 for the U.S. Army Court of Criminal Appeals.

EXPERT MEDICAL OPINIONS REGARDING MEFLOQUINE INTOXICATION

10. As described more fully below, it is my expert medical opinion that it is very likely that SSG Bales was exposed to mefloquine during his deployment to Iraq in 2003-2004; that it is very likely that SSG Bales experienced adverse psychiatric effects as a direct result of this very likely exposure, and that these very likely constituted an involuntary intoxication, the consequences of which reasonably should have been explored and evaluated by the pretrial RCM 706 sanity (competency) board charged with determining if SSG Bales possessed mental responsibility on the night of the incidence in question.

11. As described more fully below, it is also my expert medical opinion that it is likely that at the time of the incident in question, that SSG Bales was experiencing symptoms of psychosis, including visual hallucinations of flashing lights, accompanied by paranoia and bizarre, persecutory delusions; and that these likely symptoms of psychosis, consistent with a likely severe mental disease or defect, were a direct result of the involuntary intoxication resulting from his very likely exposure to mefloquine in Iraq. These symptoms of psychosis, consistent with the lasting effects of mefloquine intoxication, bear on SSG Bales' *mens rea* on the night of the incident in question and raise substantial issues about his knowing entry into a plea of guilty without the benefit of expert medical evaluation. In my expert medical opinion, SSG Bales' mindset was compromised by the lasting effects of his involuntary mefloquine intoxication, and his ability to meaningfully enter into a guilty plea to premeditated murder charges was equally compromised.

THE ARMY'S DEVELOPMENT AND USE OF MEFLOQUINE

12. Mefloquine is a synthetic quinoline derivative antimalarial drug that is structurally related to quinine. Mefloquine was developed by the U.S. Army's Walter Reed Army Institute of Research (WRAIR) during a decades-long drug development program that began during the Vietnam War. The drug was first marketed in the U.S. in 1989. By the mid-1990s and throughout much of the early 2000s, mefloquine was the U.S. military's drug of choice for the prophylaxis (or prevention) of chloroquine-resistant malaria, owing to the drug's perceived higher efficacy and more convenient weekly dosing in comparison to alternative daily antimalarial drugs. Mefloquine has been widely prescribed, issued, or dispensed to U.S. military personnel, particularly during the early months of the war in Iraq beginning in 2003, where antimalarial prophylaxis was frequently required by policy and occasionally administered under command supervision[i].

KNOWN ADVERSE EFFECTS OF MEFLOQUINE

13. Mefloquine is strongly associated with reports of severe neuropsychiatric adverse effects, including a syndrome marked by confusion, anxiety, depression, and neurological

[i] Nevin RL. Mefloquine and Posttraumatic Stress Disorder. In: Ritchie EC, ed. *Textbook of Military Medicine. Forensic and Ethical Issues in Military Behavioral Health.* Washington, DC: Borden Institute; 2015:277-296.

disorders[ii]. Mefloquine is also associated with reports of psychosis, dissociation, and life-threatening behavior[iii].These effects are often preceded and predicted by the development of prodromal, or early warning, symptoms, including sleep disturbance. Consequently, since 1989, the U.S. mefloquine drug label has warned to discontinue the medication at the development of "unexplained anxiety, depression, restlessness or confusion", which "may be considered prodromal to a more serious event"[iv].

14. Mefloquine use is strongly associated with reports of acts of violence. In a published analysis of post-marketing drug safety data, mefloquine is listed among the top ten prescription drugs associated with these effects[v]. Mefloquine has also been implicated and the drug's role investigated by the U.S. Army in a number of homicides, including by soldiers returning home from Afghanistan and Iraq[vi].

15. In 2012, U.S. military authors writing for the U.S. Centers for Disease Control and Prevention (CDC) noted that the neuropsychiatric adverse effects of mefloquine "may confound the diagnosis and management of [PTSD] and traumatic brain injury [TBI]"[vii]. Other U.S. military authors at WRAIR have noted that "[g]iven the overlapping symptoms of [PTSD] and mefloquine toxicity, it can be challenging to distinguish between the two diagnoses"[viii]. In my book chapter in the U.S. Army's *Textbook of Military Medicine* series, I note that it is "conceivable that patients experiencing mefloquine's toxic effects may have appeared to meet formal PTSD diagnostic criteria, even if the etiology of the symptoms was distinct from the effects of traumatic stress"[ix].

16. In September 2013, the U.S. Army Special Operations Command (USASOC) issued an order directing that "commanders and medical personnel will decrease the risk of negative drug related side effects by ceasing use of mefloquine as a means of chemoprophylaxis for the prevention of malaria". The order, attached as Exhibit B, also directed that commanders and medical personnel "concurrently address and assess the possibility and impact of mefloquine toxicity in their populations".

[ii] Nevin RL, Leoutsakos JM. Identification of a Syndrome Class of Neuropsychiatric Adverse Reactions to Mefloquine from Latent Class Modeling of FDA Adverse Event Reporting System Data. *Drugs R D* 2017;17(1):199-210.

[iii] Nevin RL, Ritchie EC. The Mefloquine Intoxication Syndrome: A Significant Potential Confounder in the Diagnosis and Management of PTSD and Other Chronic Deployment-Related Neuropsychiatric Disorders. In: *Posttraumatic Stress Disorder and Related Diseases in Combat Veterans*. Cham, Switzerland: Springer International Publishing; 2015:257-278.

[iv] Nevin RL, Byrd AM. Neuropsychiatric Adverse Reactions to Mefloquine: a Systematic Comparison of Prescribing and Patient Safety Guidance in the US, UK, Ireland, Australia, New Zealand, and Canada. *Neurol Ther* 2016;5(1):69-83.

[v] Moore TJ, Glenmullen J, Furberg CD. Prescription drugs associated with reports of violence towards others. *PLoS One* 2010;5(12):e15337.

[vi] Nevin RL. Rational Risk-Benefit Decision-Making in the Setting of Military Mefloquine Policy. *J Parasitol Res* 2015;2015:260106.

[vii] Magill A, Cersovsky S, DeFraites R. Special Considerations for US Military Deployments. In: Brunette GW, ed. *CDC Health Information for International Travel: The Yellow Book 2012*. New York, NY: Oxford University Press; 2012:561-565.

[viii] Livezey J, Oliver T, Cantilena L. Prolonged Neuropsychiatric Symptoms in a Military Service Member Exposed to Mefloquine. *Drug Saf - Case Reports* 2016;3(1):7.

[ix] Nevin RL, 2015, *op. cit.*

SYMPTOMS EXPERIENCED BY SSG BALES PRIOR TO HIS DEPLOYMENT TO AFGHANISTAN IN LATE 2011

17. Following his deployment to Iraq in 2003-2004, Bales' complained of cognitive impairment and depression, and following subsequent combat deployments to Iraq, he complained of additional symptoms of insomnia, irritability, and anger, which the United States did not attribute to any psychiatric diagnosis. Despite his experiencing these seemingly medically unexplained symptoms, the United States deployed SSG Bales for a fourth Infantry combat tour to Afghanistan in late 2011[x]. Only following the incident in question in March 2012, at the subsequent RCM 706 sanity (competency) board, was SSG Bales diagnosed with PTSD.

THE FDA'S 2013 "BLACK BOX" WARNING REGARDING MEFLOQUINE'S LONG-LASTING ADVERSE EFFECTS

18. In July 2013, during the sentencing portion of *U.S. v. Bales*, and only two months following completion of the RCM 706 sanity (competency) board, U.S drug regulators at the U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication, attached to this declaration as Exhibit C, advising the public about "strengthened and updated warnings regarding neurologic and psychiatric side effects associated with the antimalarial drug mefloquine." In its review of reported adverse events associated with mefloquine, the FDA noted that "some of the psychiatric symptoms persisted for months or years after mefloquine was discontinued," and warned that "[t]he psychiatric side effects can include feeling anxious, mistrustful, depressed, or having hallucinations."[xi]. The lasting nature of these adverse effects were also subject of a boxed warning (or "black box") mandated by the FDA on July 29, 2013, which also directed that mefloquine be immediately discontinued at the onset of any neurologic or psychiatric symptom[xii].

SSG BALES' INCOMPLETE PRETRIAL RCM 706 SANITY (COMPETENCY) REPORT AND EXPERT MEDICAL EXAMINATIONS

19. As the evidence suggests that SSG Bales was exposed to mefloquine during his deployment to Iraq in 2003-2004, his primary RCM 706 sanity (competency) report diagnosis of PTSD would be subject to reexamination. The current Diagnostic and Statistical Manual (DSM 5), which was published in May 2013, excluded the diagnosis of PTSD if the disturbance is "attributable to the physiological effects of a substance (e.g., medication, alcohol) or another medical condition"[xiii]. The RCM 706 sanity (competency)

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[x] For a detailed review of SSG Bales' medical history prior to his deployment to Afghanistan in 2011-2012, please see the Chronology of Events attached to my declaration of April 12, 2017.

[xi] U.S. Food and Drug Administration. *FDA Drug Safety Communication: FDA approves label changes for antimalarial drug mefloquine hydrochloride due to risk of serious psychiatric and nerve side effects*. July 29, 2013. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM362232.pdf.

[xii] Nevin RL, Byrd AM, 2016, *op. cit.*

[xiii] American Psychiatric Association. *Trauma- and Stressor-Related Disorders. In: Diagnostic and Statistical Manual of Mental Disorders. 5th Edition*. American Psychiatric Association. 2013

board, in its report, did not mention the potential effects of mefloquine nor comment on SSG Bales' possible past exposure, nor acknowledge that the adverse psychiatric effects of any such possible past exposure to mefloquine may last years after use. A properly constituted and informed Rule 706 sanity (competency) board should have considered the possible lasting effects of past mefloquine exposure, in determining both SSG Bales' clinical psychiatric diagnosis, and whether SSG Bales had a severe mental disease or defect, at the time of the incident in question.

20. As the evidence suggests that SSG Bales was exposed to mefloquine during his deployment to Iraq in 2003-2004, the conclusions of his medical experts, prepared from June to August 2013, in preparation for the sentencing portion of the trial, would also be subject to reexamination. The medical experts who produced reports in support of his case do not include a discussion in their reports of the possible role of mefloquine in the incident in March 2012[xiv]. These medical experts should have considered the possible lasting effects of past mefloquine exposure, in determining both SSG Bales' clinical psychiatric diagnosis, and whether SSG Bales had a severe mental disease or defect, at the time of the incident in question.

21. Consequently, as the evidence suggests that SSG Bales had in fact been exposed to mefloquine during his deployment to Iraq in 2003-2004, during sentencing the jury was not aware of the possible effect of mefloquine on SSG Bales' *mens rea* at the time of the incident in question.

EVIDENCE SUPPORTING SSG BALES' EXPOSURE TO MEFLOQUINE DURING HIS DEPLOYMENT TO IRAQ IN 2003-2004

22. Although available medical records do not document SSG Bales being formally prescribed mefloquine during his deployment to Iraq in 2003-2004, the U.S. military has conceded that "[s]ome deploying Service members have been provided mefloquine for malaria prophylaxis without appropriate documentation in their medical records"[xv]. Mefloquine is known to have been widely used at the time, particularly during the early months of the Iraq war[xvi], and although official policies were to have discontinued the use

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[xiv] On June 25, 2013, Dr. Golden completed a comprehensive neuropsychological report on Bales based on the results of testing from June 9, 2013 through June 11, 2013. On July 1, 2013, Dr. Stahl completed a comprehensive psychopharmacology report on Bales. On July 1, 2013, Dr. Pitman also completed a forensic psychiatric report on Bales based on evaluations from June 17, 18, and 24, 2013. On August 8, 2013, Dr. Morgan completed a forensic psychiatric report on Bales. No report mentioned the potential effects of mefloquine nor commented on possible past exposure.

[xv] Assistant Secretary of Defense (Health Affairs). *Memorandum. Subject: Service Review of Mefloquine Prescribing Practices.* January 12, 2012.

[xvi] Nevin RL, 2015, *op. cit.*

of antimalarial drugs in late 2003[xvii], use of antimalarial drugs was resumed by formal policy only months later[xviii], with mefloquine later explicitly authorized by policy[xix].

23. This lack of documentation of exposure would have been contrary to DoD HA policy which required documentation of prescribing in the medical records[xx]. Additionally, there is no documentation that SSG Bales was provided a copy of the mefloquine medication guide during his deployment to Iraq in 2003-2004, as was required by federal law[xxi].

24. On March 30, 2017, I spoke with SSG Bales in a telephone call to assess the possibility of his having had symptomatic exposure to mefloquine. He denied any exposure to the drug prior to his joining the U.S. Army, but described being administered an antimalarial drug which he believes was mefloquine ("Lariam") while deployed to Iraq in 2003-2004. SSG Bales described this drug being administered to him on a recurring

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[xvii] Combined Joint Task Force Seven. *Memorandum. Subject: CJTF-7 Policy on Malaria Prevention.* December 29, 2003. This memorandum directed that "U.S. personnel in Iraq will not take malaria chemoprophylactic medication".

[xviii] Combined Joint Task Force Seven. *Memorandum. Subject: CJTF-7 Policy on Malaria Prevention.* February 12, 2004. This revised memorandum stated that "Chloroquine is considered the drug of choice because of its efficacy against the malaria strains present in the country; as well as its favorable dosing interval compared to doxycycline, its greater suitability for prolonged administration, and its lower incidence of side-effects compared to mefloquine; chloroquine is authorized for personnel on flight status. Units or personnel rotating into Iraq [see component/CJTF policies for specific risk areas] during the malaria transmission season April to November are advised to begin weekly chloroquine, one 500 mg tablet 2 weeks prior to arrival in country".

[xix] U.S. Central Command. *MOD 6 to USCENTCOM Individual Protection and Individual/Unit Deployment Policy.* May 24, 2004. This policy stated that "Chloroquine is considered the drug of choice because of its efficacy against the malaria strains present in the country; as well as its favorable dosing interval compared to doxycycline, its greater suitability for prolonged administration, and its lower incidence of side-effects compared to mefloquine; chloroquine is authorized for personnel on flight status. Units or personnel rotating into Iraq [see component/CJTF policies for specific risk areas] during the malaria transmission season April to November are advised to begin weekly chloroquine, one 500 mg tablet 2 weeks prior to arrival in country", but also stated that *"Units currently taking weekly mefloquine desiring to change to chloroquine can discontinue mefloquine and begin chloroquine the next week. Residual blood levels of mefloquine will provide protection until adequate chloroquine levels are achieved"* [emphasis and sentence case added].

[xx] Assistant Secretary of Defense (Health Affairs). *Memorandum. Subject: Policy for Use of Force Health Protection Prescription Products. HA Policy 03-007.* April 24, 2003.

[xxi] See Benjamin M, Olmsted D. Malaria drug warning follows problems. *UPI.* July 10, 2003. Available at: http://www.upi.com/Business_News/Security-Industry/2003/07/10/Malaria-drug-warning-follows-problems/UPI-84261057867715. This noted: "The [FDA] has taken the rare step of ordering that patients are warned directly of serious mental problems and reports of suicide linked to a common anti-malaria drug [mefloquine]". "The move — which the FDA has ordered only 17 times previously — follows a decade of increasingly dire warnings about the drug, and a trail of horror stories from people who said they have suffered from side effects from the drug...". "The FDA on Wednesday required by law that all doctors hand patients a 'medication guide' with the new [mefloquine] warnings. It is the 18th time the FDA has made the aggressive move". "The new warnings say the drug has been associated with 'serious psychiatric adverse events' that 'may persist even after stopping the medication'. It also notes 'rare reports have claimed that [mefloquine] users think about killing themselves' and 'rarer reports of suicides'". "The FDA says the guides are used for drugs 'that pose a serious and significant public health concern'".

basis by a member of his unit. SSG Bales does not recall being asked any questions about his mental health prior to receiving each recurring dose and does not recall receiving any printed material describing the drug's adverse effects or under what conditions he should have discontinued the drug.

25. As SSG Bales described to me in this telephone call, he experienced several symptoms while receiving this medication, including unexplained anxiety, depression, restlessness, and confusion, as well as vivid dreams, nightmares, disturbed sleep, anger, irritability and aggression, and problems with memory and concentration. SSG Bales also described one episode where he very clearly experienced visual hallucinations of "purple guys running down the bridge" he was surveilling.

26. In a declaration dated April 13, 2017, Mr. Gregory Rayho describes having served with SSG Bales with 2nd Battalion 3rd Infantry Regiment, 3rd Brigade 2nd Infantry Division (hereinafter the Brigade) during his deployment to Iraq from 2003-2004. In his declaration, Mr. Rayho describes being ordered to take mefloquine while in formations that included SSG Bales on at least two weekly occasions during the time period from February to June 2004. In his declaration, Mr. Rayho describes no record being made of his exposure to mefloquine in his medical records.

27. Based on my conversation with SSG Bales, my review of the Rayho declaration, my review of the available medical documentation, and my experience, education, and training, including my knowledge of U.S. military antimalarial prophylaxis policies and practices, it is my expert medical opinion that it is very likely that SSG Bales was exposed to mefloquine during his deployment to Iraq in 2003-2004. SSG Bales receiving mefloquine under command supervision during his 2003-2004 deployment to Iraq, as he describes and as described in the Rayho declaration, would be fully consistent with U.S. military antimalarial prophylaxis practices reported in effect as late as 2011[xxii].

28. Based on my review of the available documentation, my conversation with SSG Bales, and my experience, education, and training, it is also my expert medical opinion that it is very likely that SSG Bales experienced adverse psychiatric effects as a direct result of his very likely exposure to mefloquine during his deployment to Iraq in 2003-2004. It is also my opinion that the adverse psychiatric effects resulting from this very likely exposure to mefloquine very likely constitute involuntary intoxication, in that it is very likely that SSG Bales was ordered or otherwise compelled to take mefloquine despite his

[xxii] See: Solano TL. Doxy Daily Maintains APS-11 Marines' Unit Effectiveness. *United States Africa Command.* April 28, 2011. Available at: http://www.africom.mil/Newsroom/Article/8259/doxy-daily-maintains-aps-11-marines-unit-effective. This report describes a unit being administered *both* daily doxycycline and weekly mefloquine under conditions of command supervision.

developing symptoms of unexplained anxiety, depression, restlessness, and confusion that should have mandated the drug's immediate discontinuation[xxiii].

29. It is also my expert medical opinion that it is very likely that because of SSG Bales' continued use of the medication, the adverse psychiatric effects of this very likely involuntary intoxication persisted and subsequently contributed to his state of mental ill-health, including his chronic symptoms of insomnia, depression, cognitive impairment, irritability, and anger, which were present during his deployment to Afghanistan at the time of the incident of March 2012. It is also my opinion that these symptoms very likely contributed to SSG Bales seeking to self-medicate with alcohol and sleep aids during his Afghanistan deployment.

SPECIFIC RCM 706 SANITY (COMPETENCY) REPORT DEFICIENCIES

30. Based on available evidence, and my experience, education, and training, it is my expert medical opinion that it is likely that the conclusion of the RCM 706 sanity (competency) report that SSG Bales did not have a severe mental disease or defect at the time of the incident in question is erroneous, and that it is likely that certain factual statements in the RCM 706 sanity (competency) are also incorrect, as described more fully below.

31. Section 11 of the RCM 706 sanity (competency) report (titled "Mental Status Examination") states that SSG Bales "denied any past or current experience of auditory or visual hallucinations".

32. As described in paragraph 25 of this declaration, SSG Bales reported to me in a telephone call on March 30, 2017, that while deployed to Iraq in 2003-2004, during a guard shift, he perceived "purple guys running down the bridge" he was surveilling from an overwatch position. SSG Bales described to me that he shared his perceptions of the "purple guys" with other soldiers, and consequently became of the opinion that his perceptions represented visual hallucinations, rather than an accurate perception of reality.

[xxiii] See: U.S. Army Medical Command. *Memorandum. Subject: Additional Patient Information to Accompany Each Prescription of Mefloquine*. November 20, 2003. This memorandum advised: "[The revised mefloquine medication guide] provides important information that patients should know about the dug. This guide contains a wallet-sized information card that addresses the need to take the medication and provides information on side effects that may necessitate discontinued use. This card, which can be reproduced locally, *must be provided to each person who is prescribed [mefloquine] or generic forms of mefloquine*" [emphasis added]. The memorandum also stated: "*Advise persons who notice symptoms such as excessive acute anxiety, depression, restlessness or confusion while taking mefloquine to seek medical care immediately for consideration of an alternative anti-malarial medication*" [emphasis added]. The then-current mefloquine drug label, dated August 2003, warned "During prophylactic use, if *psychiatric symptoms such as* acute anxiety, depression, restlessness or confusion occur, these may be considered prodromal to a more serious event. In these cases, *the drug must be discontinued* and an alternative medication should be substituted" [emphasis added].

33. Based on available evidence, and my experience, education, and training, it is my expert medical opinion that it is very likely that, contrary to the conclusions of the RCM 706 sanity (competency) report, SSG Bales did in fact experience past visual hallucinations, namely visual hallucinations while deployed to Iraq in 2003-2004, and that these were very likely a direct result of involuntary intoxication resulting from his very likely exposure to mefloquine.

34. Additionally, based on available evidence, and my experience, education, and training, it is also my expert medical opinion that it is likely that, contrary to the conclusions of the RCM 706 sanity (competency) report, that SSG Bales also experienced visual hallucinations on the night of the incident in question, and that these were likely also a direct result of the lasting effects of this early involuntary intoxication, as described more fully below.

35. Section 18 of the RCM 706 sanity (competency) report (titled "Forensic Opinion/Mental Responsibility") states that during the time leading up to the incident in question, there "was no indication… [of] signs or symptoms indicative of impaired reality testing, such as… hallucinations, other perceptual disturbances, or bizarre delusions".

36. Similarly, section 6 of the RCM 706 sanity (competency) report (titled "Accused's Version of the Offenses") states that "SSG Bales denied any experience of perceptual disturbance (e.g., seeing persons or objects that were not seen by others…) in the past, during his guard shift or at any time during the course of events that followed". Section 14 of the RCM 706 sanity (competency) report (titled "Diagnostic Assessment"), in the first subsection (titled "Psychosis, dissociation, and associated disorders"), states that the board "found no indication that SSG Bales ever experienced psychotic symptoms", that the board "did not find that his thoughts or behaviors were influenced by delusional beliefs", and that "SSG Bales' perception that the area around VSP [Village Stability Platform] Belambay was highly dangerous" was based on "reasonably accurate, rational pieces of information".

37. However, as described in section 5 of the RCM 706 sanity (competency) report (titled "Government's Version of the Offenses"), SSG Bales "reportedly observed flashing lights at points near Alikozai and [Naja Bien]" during his guard shift the evening prior to the incident in question, and "believed those lights possibly represent[ed] signaling related to IED placement".

38. Section 6 of the RCM 706 sanity (competency) report also describes that during his guard shift, SSG Bales "believed he observed a pattern of flashing lights as he noted four flashes in the north (in the region of Alikozai) followed by what he believed to be a response of one flash from the south (in the region of [Naja Bien])". Section 6 of the RCM 706 sanity (competency) report also describes that when SSG Bales shared his perceptions with SPC Cerciello, who was on guard duty with him, that SPC Cerciello "was not certain that [he] observed a similar pattern".

39. Similarly, as described in the Stipulation of Facts, dated May 3, 2013, SSG Bales "told PFC Cerciello that he saw lights flashing in both Naja Bien and Alikozai for approximately fifteen minutes", that SSG Bales "pointed in the direction of Alikozai where he stated he saw the lights, and that SSG Bales mentioned that he thought that it might be possible that the lights represented signals between insurgents". The Stipulation of Facts also describes that "[PFC] Cerciello did not see the lights to the north". The Stipulation of Facts also describes that SSG Bales' "intention when leaving the VSP [Village Stability Platform] was to travel north to the village of Alikozai", where he had seen the flashing lights, "in an attempt to show [Special Forces] what it meant to 'take action'".

40. Based on available evidence, and my experience, education, and training, it is my opinion that it is likely that SSG Bales did in fact experience visual hallucinations of flashing lights in the region of Alikozai during his guard shift the evening prior to the incident in question. It is also my opinion that it is likely that SSG Bales' visual hallucinations of flashing lights were accompanied by paranoia and bizarre, persecutory delusions that these constituted a highly dangerous threat, and that these perceptual disturbances, which are fully consistent with the known lasting adverse effects of mefloquine intoxication, compelled SSG Bales to "take action".

41. Based on available evidence, and my experience, education, and training, it is also my opinion that SSG Bales' perceptions at the time of the incident in question were likely not based on reasonable, rational pieces of information, and that his thoughts and behaviors were instead likely influenced by delusional beliefs.

42. It is also my opinion that his likely visual hallucinations, paranoia, persecutory delusions, and subsequent unusual behavior were symptoms of psychosis consistent with a likely severe mental disease or defect at the time of the incident in question. It is also my opinion that SSG Bales' likely symptoms of psychosis were a direct result of involuntary intoxication resulting from his very likely exposure to mefloquine in Iraq in 2003-2004.

PROSECUTORIAL CONDUCT RELATED TO ITS KNOWLEDGE OF MEFLOQUINE

43. On January 17, 2012, approximately two months prior to the incident in question, the Assistant Secretary of Defense (Health Affairs), in a memorandum attached to this declaration as Exhibit D, noted problems with mefloquine prescribing documentation and directed a review of mefloquine prescribing practices be performed in deployed locations. The results of this review were due in April 2012[xxiv]. In my opinion, therefore, at the time of the incident in question, the government knew, or reasonably ought to have known based on publicly-available information, that SSG Bales may have been exposed to the drug during his deployment to Iraq in 2003-2004 without documentation of such exposure appearing in his medical records.

[xxiv] *Ibid.*

44. Furthermore, also in April 2012, the FDA received a "medically confirmed" adverse event report from Roche, the original manufacturer of mefloquine, reporting from an unnamed source that an unnamed U.S. soldier had been "treated with Mefloquine Hydrochloride ... and led to Homicide killing of 1[6]." This report is attached to this declaration as Exhibit E. The Army, as a holder of a then-current FDA marketing authorization for mefloquine[xxv], was or should have been aware of this "medically confirmed" report that clearly suggested that the United States had previously issued mefloquine to SSG Bales. In my opinion, upon receipt of this report, the government knew, or reasonably ought to have known based on this information, that SSG Bales may have been exposed to the drug, and that such exposure may have plausibly had bearing on his *mens rea* on the night of the incident in question.

45. In my opinion, in light of this FDA adverse event report, and contemporaneous expert speculation in the media regarding the possible role of mefloquine in the incident in question[xxvi], serious questions are raised by the government's decision to refer the case capital and to authorize imposition of the death penalty, without disclosing either the FDA adverse event report nor the January 2012 memorandum, acknowledging the incompleteness of mefloquine prescribing documentation, and the potentially exculpatory results of the review it directed, to SSG Bales and the defense.

46. In my opinion, upon release of the FDA warning in July 2013, the government further knew or reasonably ought to have known that SSG Bales' civilian mental health experts, in preparing or submitting their reports, would likely not have considered the possible lasting effects of any possible undocumented mefloquine exposure during SSG Bales' deployment to Iraq in 2003-2004.

47. In my opinion, upon release of the FDA warning in July 2013, the government also knew or reasonably ought to have known that the RCM 706 sanity (competency) board, having completed its RCM 706 sanity (competency) report on May 3, 2013, two months prior to the FDA's warning that psychiatric effects from mefloquine could last years after use, would likely also not have considered the possible lasting effects of such exposure.

48. In its response to the defense request for discovery of records pertaining to SSG Bales' potential exposure to antimalarial drugs, including mefloquine, the government has

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[xxv] The U.S. Army Medical Research and Development Command received independent FDA approval for mefloquine on May 2, 1989 under its New Drug Application (NDA) 19-578. This approval, and the U.S. Army's responsibility for adverse event monitoring and reporting, remained in effect until July 15, 2013, the date of publication in the Federal Register of the FDA's formal withdrawal of approval of NDA 19-578 at the request of the U.S. Army Office of the Surgeon General.

[xxvi] On March 29, 2012, a CNN report (Erin Burnett Outfront) aired featuring Dr. Ritchie, a former Army psychiatrist, speculating that SSG Bales may have been given mefloquine. The transcript of the report states: "Sometimes the medical records reveal things but sometimes they don't, especially if somebody is stationed in a remote outpost and might have gotten the medications locally [i.e. mefloquine] without being in the electronic medical records".

claimed to be "not aware of any materials or records responsive to the request"[xxvii]. If SSG Bales had in fact been exposed to mefloquine during his deployment to Iraq in 2003-2004, as in my opinion is very likely, the absence of records responsive to this request would be consistent with the U.S. military's statement that "[s]ome deploying Service members have been provided mefloquine for malaria prophylaxis without appropriate documentation in their medical records"[xxviii].

49. In its motion to preclude references pertaining to SSG Bales' exposure to mefloquine, including during his deployment to Iraq in 2003-2004, the government has claimed "none of the Accused's medical records indicate that he was given [mefloquine] at any time during his military history", and that "[n]one of the Accused's mental health experts' reports... discuss [mefloquine] as a substance relevant to this case or the Accused's mental condition in any way". In its motion, the government argued that, "[g]iven that there is no evidence that the Accused consumed [mefloquine] at any time, the defense should be precluded from referencing any of the potential effects of the drug [mefloquine] through any witness, to include their experts". In my opinion, the government's attempt to keep the court from knowing of any of the potential effects of mefloquine indicates its knowledge that SSG Bales' exposure to mefloquine may have plausibly had bearing on his *mens rea* on the night of the incident in question.

CONCLUSIONS

50. It is my expert medical opinion that it is very likely that SSG Bales experienced adverse psychiatric effects as a direct result of his very likely exposure to mefloquine during his deployment to Iraq in 2003-2004, and that as a direct result of the lasting effects of mefloquine intoxication, at the time of the incident in question, he was experiencing likely symptoms of psychosis, consistent with a likely severe mental disease or defect.

51. In my opinion, given that mefloquine has been a common exposure among U.S. military personnel, and given the association of mefloquine intoxication with acts of violence, upon learning of the FDA warning in July 2013, a properly constituted and informed Rule 706 sanity (competency) board should have considered the possible lasting effects of past mefloquine exposure, including possible undocumented exposure not reflected in the medical records, in determining both SSG Bales' clinical psychiatric diagnosis, and whether SSG Bales had a severe mental disease or defect, at the time of the incident in question.

[xxvii] In response to a request for discovery of "Unit Records Pertaining to Antimalarial Medication Dispensed to [Soldiers] Assigned to 2-3 Infantry Regiment" from November 1, 2003 through July 1, 2010, the government responded that it is "not aware of any materials or records responsive to the request". The government also files a motion "to preclude evidence pertaining to the accused's consumption of 'Lariam' or 'mefloquine'". The government noted that "none of the Accused's medical records indicate that he was given Lariam at any time during his military history", and that "[n]one of the Accused's mental health experts' reports... discuss Lariam as a substance relevant to this case or the Accused's mental condition in any way".

[xxviii] Assistant Secretary of Defense (Health Affairs). 2012, *op cit.*

52. Given my opinion that at the time of the incident in question, that SSG Bales was likely laboring under symptoms of psychosis, including visual hallucinations of flashing lights, accompanied by paranoia and bizarre, persecutory delusions, and that it was these perceptual disturbances, consistent with a likely severe mental disease or defect, that compelled SSG Bales to "take action", the jury failed to consider in its sentencing decision factors vital to establishing *mens rea*.

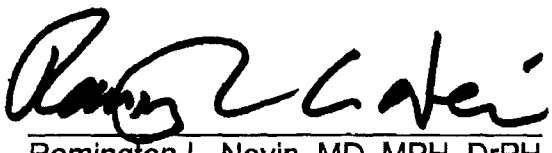
53. Given my opinion that SSG Bales was very likely involuntary intoxicated from mefloquine, substantial issues are raised about his knowing entry into a plea of guilty without the benefit of expert medical evaluation. In my expert medical opinion, SSG Bales' mindset was compromised by the lasting effects of his involuntary mefloquine intoxication, and his ability to meaningfully enter into a guilty plea to premeditated murder charges was equally compromised.

54. In January 2019, I completed a review of SSG Bales' medical records complete through late 2018[xxix]. Based on this review, I concluded that it was very likely that Mr. Bales was experiencing chronic psychiatric symptoms including insomnia, depression, anxiety, and paranoia; that have persisted from the time of his first deployment to Iraq in 2003; that these were primarily a direct causal result of his very likely exposure to mefloquine; that this very likely exposure to mefloquine provides the most parsimonious explanation for the onset, severity, and persistence of these symptoms; and that there are no more likely causes for these. I also concluded that Mr. Bales' psychiatric symptoms are likely to remain chronic and disabling and will not remit significantly with time or treatment.

55. It is my opinion that SSG Bales would benefit from continued medical care for his chronic and disabling psychiatric condition. With insight that his actions on the night of the incident in question were the likely result of a psychosis that was a direct result of involuntary intoxication resulting from his very likely exposure to mefloquine in Iraq, in my opinion, SSG Bales would be unlikely to pose a further threat to others.

Pursuant to 28 U.S.C. §1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 24th day of June, 2019.



Remington L. Nevin, MD, MPH, DrPH

[xxix] This is described in an independent medical opinion report, dated January 5, 2019.

EXHIBIT A

Remington Nevin, MD, MPH, DrPH

Consultant Physician Epidemiologist

Board Certified in Public Health & General Preventive Medicine and in Occupational Medicine by the American Board of Preventive Medicine and Certified in Public Health by the National Board of Public Health Examiners

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Curriculum Vitae

June 24, 2019

Education and Professional Training

2016-2017	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	Postdoctoral Fellowship in Occupational and Environmental Medicine
2012-2016	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	DrPH in Mental Health
2012-2014	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	Certificate in Pharmacoepidemiology and Drug Safety
2003-2005	Walter Reed Army Institute of Research, Washington, DC	Residency in Public Health and General Preventive Medicine
2003-2004	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	MPH
2002-2003	Womack Army Medical Center Ft. Bragg, NC	Internship in Family Medicine
1998-2002	Uniformed Services University of the Health Sciences Bethesda, MD	MD
1995-1998	University of Toronto University College Toronto, Ontario, Canada	BSc (Hon) with High Distinction Majors in Physics & Physiology, Minor in Mathematics

Faculty Appointments

2019	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	Faculty Associate (Part-Time) Department of Mental Health

Professional Licensure

2017-	Medicine	Vermont License 42.0013908
2012-	Medicine and Surgery	Maryland License D73583
2003-	Medicine and Surgery	New York License 229259 (Inactive)

Medical Board Certifications

2018-	Occupational Medicine	American Board of Preventive Medicine
2006-	Public Health and General Preventive Medicine	American Board of Preventive Medicine

Other Board Certifications

2015-	Certified in Public Health	National Board of Public Health Examiners

Academic Awards, Honors, and Scholarships

2014	Outstanding Recent Graduate Award Johns Hopkins University Alumni Association
	Dr. Ali Kawi Scholarship, Department of Mental Health Johns Hopkins University, Bloomberg School of Public Health
	Gordis Teaching Fellowship Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
2013	Dr. Ali Kawi Scholarship, Department of Mental Health Johns Hopkins University, Bloomberg School of Public Health
	Gordis Teaching Fellowship Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
2012	Dr. Ali Kawi Scholarship, Department of Mental Health Johns Hopkins University, Bloomberg School of Public Health
2011	Alumni Inductee, Delta Omega Honor Society, Alpha Chapter Johns Hopkins University, Bloomberg School of Public Heath
2005	George Miller Sternberg Medal in Preventive Medicine Walter Reed Army Institute of Research
2002	Captain Richard R. Hooper Award in Preventive Medicine Uniformed Services University of the Health Sciences
2000	Distinguished Academic Performance Award in Preventive Medicine Uniformed Services University of the Health Sciences
1997	R. L. Burton Scholarship in Mathematics and Physical Sciences University of Toronto, University College

Teaching

2019	Johns Hopkins University, Bloomberg School of Public Health *Current Issues in Military Mental Health.* PH.330.659 (Summer Institute).
	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences *Public Health and U.S. Military Policy.* AS.280.213 (Winter Intersession).
2018	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences *Public Health and U.S. Military Policy.* AS.280.213 (Winter Intersession).
2017	Johns Hopkins University, Bloomberg School of Public Health *Current Issues in Military Mental Health* (with Peter Zandi). PH.330.659 (Summer Institute).
	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences *Public Health and U.S. Military Policy.* AS.280.213 (Winter Intersession).
2016	Johns Hopkins University, Bloomberg School of Public Health *Current Issues in Military Mental Health* (with Peter Zandi). PH.330.659 (Summer Institute).
	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences *Public Health and U.S. Military Policy.* AS.280.213 (Winter Intersession).
2015	Johns Hopkins University, Bloomberg School of Public Health *Current Issues in Military Mental Health* (with Peter Zandi). PH.330.659 (Summer Institute).
2014	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences U.S. Military Policy and Public Health. AS.280.406 (Fall Term).
	Johns Hopkins University, Bloomberg School of Public Health *Current Issues in Military Mental Health* (with Peter Zandi). PH.330.659 (Summer Institute).
	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences *U.S. Military Policy and Public Health.* AS.280.406 (Spring Term).
2013	Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences *U.S. Military Policy and Public Health: The Consequences of Conflict.* AS.280.406 (Fall Term).

Military and Non-Profit Service

2018-	**Executive Director** The Quinism Foundation, White River Junction, VT.
2010-2012	**Preventive Medicine Physician** Bayne-Jones Army Community Hospital, Fort Polk, LA.
2008-2009	**Preventive Medicine Officer** 360th Civil Affairs Brigade, United States Africa Command, Combined Joint Task Force Horn of Africa (CJTF-HOA), Camp Lemonier, Djibouti.
2008	**Preventive Medicine Officer and Deputy Chief of Staff (Acting), Force Health Protection** 18th Medical Command, US Army Garrison Yongsan, Seoul, Korea.

2007-2008	**Preventive Medicine Officer and Program Manager (Acting), Defense Medical Surveillance System** Armed Forces Health Surveillance Center, Silver Spring, MD.
2007	**Preventive Medicine Officer** International Security and Assistance Force (ISAF) Regional Command East, Combined Joint Task Force 82 (CJTF-82), Bagram Airfield, Afghanistan.
2005-2006	**Preventive Medicine Officer** Army Medical Surveillance Activity, Directorate of Epidemiology and Disease Surveillance, US Army Center for Health Promotion and Preventive Medicine, Washington, DC.

Invited Public Testimony

2019	Canadian Parliament. Standing Committee on Veterans Affairs. *Effects of Mefloquine Use Among Canadian Veterans*. Wednesday, May 1, 2019. The Wellington Building Room 420, Ottawa, Canada.
2018	Australian Senate. Foreign Affairs, Defence and Trade References Committee. *Use of the Quinoline Anti-malarial Drugs Mefloquine and Tafenoquine in the Australian Defence Force*. Thursday, October 11, 2018. Committee Room 2S1, Parliament House, Canberra, Australia. (*By Video Teleconference*).
2016	Canadian Parliament. Standing Committee on Veterans Affairs. *Mental Health and Suicide Prevention Among Veterans*. Tuesday, October 25, 2016. The Valour Building Room 228, Ottawa, Canada.
2015	UK Parliament. Defence Committee. *An Acceptable Risk? The Use of Lariam for Military Personnel*. Tuesday, December 8, 2015. The Wilson Room, Portcullis House, London, UK.
2012	U.S. Senate. Appropriations Defense Subcommittee. *Outside Witnesses: Mefloquine Research*. Wednesday, June 6, 2012. Dirksen Senate Office Building Room 162, Washington, DC.

Grants and Research Funding

2019	$18K	Royal Canadian Legion, Mefloquine Long-Term Effects
2010	$264K	Department of Defense Fiscal Year 2010 Defense Medical Research Development Program, MDR1 Polymorphisms and Risk of Anxiogenic Mefloquine Adverse Events. MRMC #D61-I-10-J5-121
2006	$1.919M	Department of Defense Global Emerging Infectious Disease Surveillance and Response System (DoD-GEIS), Pandemic Influenza Surveillance Supplemental Funding.
	$20K	Department of Defense Military Vaccine Agency, Measles/Mumps/Rubella Immunity Concordance.
2005	$4.5K	Department of Defense Military Vaccine Agency, Mumps Screening Cost-Effectiveness.
	$20K	Department of Defense Military Vaccine Agency, Hepatitis A Seroprevalence.

Peer Review

2019 **Journal Reviewer**: American Journal of Public Health; Clinical Case Reports; Federal Practitioner; Military Medicine. **Abstract Reviewer**: American College of Preventive Medicine, 2019 Annual Meeting.

2018 **Journal Reviewer**: American Journal of Tropical Medicine & Hygiene; BMJ Case Reports; Clinical Case Reports; Federal Practitioner; Journal of Medical Case Reports; Journal of Travel Medicine; Military Medicine.

2017 **Journal Reviewer**: American Journal of Infection Control; American Journal of Tropical Medicine and Hygiene; American Journal of Psychiatry; Biomedicine and Pharmacotherapy; BMJ Case Reports; Federal Practitioner; Journal of Medical Case Reports; Journal of Travel Medicine; Military Medicine. **Abstract Reviewer**: American College of Preventive Medicine, 2018 Annual Meeting.

2016 **Journal Reviewer**: American Journal of Tropical Medicine and Hygiene; Australasian Medical Journal; Disaster Medicine and Public Health Preparedness; PLOS ONE; Journal of Medical Case Reports; Military Medicine. **Abstract Reviewer**: American College of Preventive Medicine, 2017 Annual Meeting.

2015 **Journal Reviewer**: American Journal of Infection Control; American Journal of Preventive Medicine; American Journal of Public Health; American Journal of Tropical Medicine and Hygiene; Clinical Case Reports; Journal of Cerebral Blood Flow & Metabolism. **Abstract Reviewer**: American College of Preventive Medicine, 2016 Annual Meeting; International Society for Pharmacoepidemiology 2016 Mid-Year Meeting.

2014 **Journal Reviewer**: American Journal of Bioethics Neuroscience; American Journal of Infection Control; American Journal of Public Health; Military Medicine. **Abstract Reviewer**: American College of Preventive Medicine, 2015 Annual Meeting.

2013 **Journal Reviewer:** American Journal of Infection Control; American Journal of Tropical Medicine and Hygiene; Military Medicine; Paediatrics and International Child Health. **Abstract Reviewer**: American College of Preventive Medicine, 2014 Annual Meeting.

2012 **Journal Reviewer**: American Journal of Infection Control; American Journal of Public Health; Journal of the Neurological Sciences; Military Medicine. **Abstract Reviewer**: American College of Preventive Medicine, 2013 Annual Meeting.

2011 **Journal Reviewer**: American Journal of Infection Control; Journal of Infection and Public Health.

2010 **Journal Reviewer**: American Journal of Infection Control; American Journal of Tropical Medicine and Hygiene; BMC Medical Research Methodology; Emerging Infectious Diseases; The Lancet; Lancet Infectious Diseases.

2009 **Journal Reviewer:** American Journal of Public Health; American Journal of Tropical Medicine and Hygiene; Clinical Nursing Research; Military Medicine.

2008 **Journal Reviewer**: American Journal of Infection Control; American Journal of Public Health; American Journal of Tropical Medicine and Hygiene; Military Medicine.

2007 **Journal Reviewer**: American Journal of Public Health; Journal of Adolescent Health.

2006 **Abstract Reviewer**: International Society of Pharmacoeconomics and Outcomes Research, 11th International Meeting.

Publications

2018 Langston ME, Pakpahan R, **Nevin RL**, De Marzo AM, Elliott, DJ, Gaydos CA, Isaacs WB, Nelson WG, Sokoll LJ, ZenilmanJM. Sustained influence of infections on prostate-specific antigen concentration: An analysis of changes over 10 years of follow-up. Prostate. 2017;78(13):1024-1034.

2017 **Nevin RL**, Bernt J, Hodgson M. Association of Poultry Processing Industry Exposures with Reports of Occupational Finger Amputations: Results of an Analysis of OSHA Severe Injury Report (SIR) Data. J Occup Environ Med. 2017;59(10):e159.

Milbrandt M, Winter AC, **Nevin RL**, Pakpahan R, Bradwin G, De Marzo AM, Elliott DJ, Gaydos CA, Isaacs WI, Nelson WG, Rifai N, Sokoll LJ, Zenilman JM, Platz EA, Sutcliffe S. Insight into infection-mediated prostate damage: contrasting patterns of C-reactive protein and prostate-specific antigen levels during infection. Prostate. 2017;77(13):1325-1334.

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2015 **Nevin RL**. Rational Risk-Benefit Decision-Making in the Setting of Military Mefloquine Policy. J Parasitol Res. 2015;2015:260106.

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2014 **Nevin RL**. A Memoir of Mefloquine Amnesia: A Review of "The Answer to the Riddle is Me" by David Stuart MacLean. AJOB Neurosci. 2014;s5(4):88-91.

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2013 Cosby MT, Pimentel G, **Nevin RL**, Ahmed SF, Klena JD, Amir E, Younan M, Browning R, Sebeny P. Outbreak of H3N2 influenza at a US military base in Djibouti during the H1N1 pandemic of 2009. PLOS One. 2013;8(12):e82089.

Ritchie EC, Block J, **Nevin RL**. Psychiatric Side Effects of Mefloquine: Applications to Forensic Psychiatry. J Am Acad Psychiatry Law. 2013:41(2):224-235.

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2010

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2008 **Nevin RL**, Carbonell I, Thurmond V. Device-specific rates of needlestick injury at a large military teaching hospital. Am J Infect Control. 2008;36(10):750-752.

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Nevin RL, Silvestri JW, Hu Z, Tobler SK, Trotta RF. Suspected pulmonary tuberculosis exposure at a remote U.S. Army camp in northeastern Afghanistan, 2007. Mil Med. 2008;173(7):684-688.

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2007 Knapik JJ, Jones SB, Darakjy S, Hauret K, **Nevin R**, Grier T, Jones B. Injuries and injury risk factors among members of the United States Army Band. Am J Ind Med. 2007;50(12):951-961.

Hsu L, **Nevin RL**, Tobler SK, Rubertone MV. Trends in overweight and obesity among 18-year-old applicants to the U.S. military, 1993-2006. J Adolesc Health. 2007;41(6):610-612.

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Nevin R, Niebuhr D, Frick K, Grabenstein J. Improving soldier care through outcomes research: The Accession Screening and Immunization Program. U.S. Army Medical Department Journal. 2006;30-38.

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Book Chapters

2019 **Nevin RL**. Neuropsychiatric Quinism: Chronic Encephalopathy Caused by Poisoning by Mefloquine and Related Quinoline Drugs. In: Ritchie EC, Llorente M, eds. *Veteran Psychiatry in the US*. Cham, Switzerland: Springer; 2019:315-331.

2018 **Nevin RL**, Ritchie EC. Ethical Dilemmas in the Forensic Psychiatric Evaluation of Guantánamo Detainees Mass-Administered Mefloquine. In: Griffith EEH, ed. *Ethics Challenges in Forensic Psychiatry and Psychology Practice*. New York, NY: Columbia University Press; 2018:223-236.

2017 **Nevin RL**. To Squander the Fighting Strength? Personal Experiences with Preventive Psychiatry and the Dilemma of Wartime Public Mental Health. In: Ritchie EC, Warner CH, McLay R, eds. *Psychiatrists in Combat*. Cham, Switzerland: Springer; 2017:145-155.

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2005 Pablo KR, Rooks PD, **Nevin RL.** Benefits of Screening for Hepatitis B Immunity in Military Recruits. J Infect Dis. 2005;192(12):2180-2181.

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2005 **Nevin RL.** The U.S. Army Accession Screening and Immunization Program. Edgewood, MD: U.S. Army Center for Health Promotion and Preventive Medicine; November 18, 2005. Technical Guide #310.

Presentation and Poster Awards

2007 Finalist, TRICARE Innovations Awards. Demonstrating the feasibility and cost-effectiveness of serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program General Leonard Wood Army Community Hospital (GLWACH) pilot implementation. 2007 TRICARE Conference; January 29, 2007; Washington, DC.

2006 Finalist, Captain Gregory Gray Award for Military Operational Research. An economic analysis of serologic screening prior to immunization of Navy enlisted accessions. 45th Navy Occupational and Preventive Medicine Workshop; March 18 to March 23, 2006; Norfolk, VA.

Posters

2018 **Nevin RL.** Historical insights into the neurotoxicity of the 8-aminoquinolines: Implications for effective post-marketing surveillance of adverse effects associated with tafenoquine. Poster presented at: Johns Hopkins 2018 World Malaria Day Conference; April 25, 2018; Baltimore, MD.

2014 **Nevin RL.** Historical insights into the neurotoxicity of the 8-aminoquinolines: Implications for the development of tafenoquine and for global malaria control efforts. Poster presented at: Johns Hopkins 2014 World Malaria Day Conference; April 25, 2014; Baltimore, MD.

2013 Maxwell NM, **Nevin RL**, Stahl T, Block J, Shugarts S, Wu A, Dominy S, Blanco M, Kappelman-Culver S, Lee-Messer, C, Maldonado J. A 16 Year old Girl with Acute and Prolonged Mental Status Changes following Chloroquine Toxicity and Polypharmacy: Utility of Personalized Pharmacogenetic Testing. Poster presented at: 2nd International Congress on Personalized Medicine; July 25 to July 28, 2013; Paris, France.

2011 **Nevin R**. Subcortical Encephalopathy and Central Vestibulopathy Associated With Prophylactic Mefloquine Use: A Case Report. Poster presented at: 60th Annual Meeting of the American Society of Tropical Medicine and Hygiene; December 4 to December 8, 2011; Philadelphia, PA.

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2009 Jordan N, **Nevin R**, Allen A, Irish V, Gaydos J. Review of sexual health visits and well-woman exams among female military members deployed to Afghanistan. Poster presented at: 18th International Society for STD Research Meeting; June 28 to July 1, 2009; London, UK.

Jacobsmuhlen T, Gaydos C, Meyers M, Gaydos J, **Nevin R**, Foster A. Surveillance for Chlamydia trachomatis among female military personnel newly assigned to U.S. Forces Korea. Poster presented at: 18th International Society for STD Research Meeting; June 28 to July 1, 2009; London, UK.

2008 Eick A, Hu Z, **Nevin R**, Tobler S. Seroprevalence of influenza H1 and H3 antibody among U.S. military accessions. [Poster 32]. Presented at: 2008 International Conference on Emerging Infectious Diseases; March 16 to March 19, 2008; Atlanta, GA.

2007 **Nevin RL**, Carbonell IS, Miller SN, Thurmond VA, Tobler S. Device-specific rates of needlestick injury at Walter Reed Army Medical Center: Establishing baseline metrics for process improvement. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Nevin RL, Means GE, Tobler S. Longer flight times as a risk factor for increased pain among deployed rotary-wing aviators. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Nevin RL, Hu Z, Tobler S. Suspected pulmonary tuberculosis exposure at a remote U.S. Army camp in northeastern Afghanistan, 2007. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Hsu LL, Martin CB, **Nevin RL**, Tobler S. Trends in overweight and obesity among 18-year-old applicants for U.S. military service, 1995-2006. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Eick AA, Wang Z, Hu Z, **Nevin R**, Tobler SK. Serosurveillance for H5N1: Large-scale serological testing for H5N1 exposure among U.S. military

service members deployed to Thailand, Indonesia, or Vietnam. Poster presented at: Options for the Control of Influenza VI Conference; June 17 to June 23, 2007; Toronto, Canada.

Knapik JJ, Jones SB, Darakjy S, **Nevin R**, Hauret KG, Canham-Chervak M, Jones BH. Musical athletes: Injuries and injury risk factors in the United States Army Band. Abstract in: Med Sci Sports Exerc. 2007;39(5 Supplement):S395. Poster presented at: 54th Annual Meeting of the American College of Sports Medicine; May 30 to June 2, 2007; New Orleans, LA.

Eick A, **Nevin RL**, Hu Z, Hughes H, Ford SM. Measles, mumps, and rubella immunity and concordance among U.S. military recruits, 2000-2004. Poster presented at: 46th Annual NEHC Occupational Health and Preventive Medicine Conference; March 17 to March 22, 2007; Norfolk, VA.

Hughes H, **Nevin RL**, Ford SM, Anderson RG. An economic analysis of the U.S. Army Accession Screening and Immunization Program (ASIP). [Poster 152]. Presented at: 41st National Immunization Conference (NIC); March 5 to March 8, 2007; Kansas City, MO.

Eick A, Wang Z, Hu Z, Tobler S, **Nevin R**, Rubertone M. Serosurveillance for avian and pandemic influenza: Utilizing the resources of the DoDSR and AMSA. Poster presented at: 2007 Seasonal and Pandemic Influenza Conference; February 1 to February 2, 2007; Crystal City, VA.

Nevin RL. First-time episodes of mental health specialty care resulting from Post-Deployment Health Reassessments (PDHRA): Analysis of health care utilization following screening and referral. Poster presented at: 2007 TRICARE Conference; January 29, 2007; Washington, DC.

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2006

Nevin RL, Hughes H, Ford SM, Anderson R, Eick A. Risk of mumps in foreign-born U.S. military recruits deferred MMR vaccination following serologic confirmation of measles and rubella immunity. [Poster 841]. Presented at: 44th International Meeting of the Infectious Diseases Society of America (IDSA); October 15, 2006; Toronto, Canada.

Nevin RL, Green DJ. Mental health specialty clinic referrals generated during the Post-Deployment Health Reassessment process: Numbers of referrals, referral completion rates, and resultant first-time use among active duty soldiers. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL, Agnew RP. Numbers of Post-Deployment Health Reassessment forms outstanding among deployed soldiers: Cost estimates and estimated credentialed health care provider time required for resolution. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL, Kong V, Taubman S, Ford SM. Rates of influenza-like illness among active duty servicemembers receiving live attenuated influenza virus vaccine-trivalent versus trivalent inactivated influenza vaccine during the 2005-2006 influenza season. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL, Gustave J, Ford SM. Mumps cases reported in the military healthcare system during the 2006 epidemic: Geospatial comparison of counts against historical baselines among active duty servicemembers and beneficiaries. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL. Economic analysis of Latent Tuberculosis (LTBI) screening in military recruits: QuantiFERON-TB Gold In-Tube (QFT-GIT) versus Tuberculin Skin Testing (TST). [Poster PIN4]. In: Contributed Poster Presentations. Value in Health. 2006;9(3):A154. Presented at: 11th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 21, 2006; Philadelphia, PA.

Rooks P, Pablo K, **Nevin R.** Demonstrating the feasibility and cost-effectiveness of serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program General Leonard Wood Army Community Hospital pilot implementation. Poster presented at: 34th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists; March 26 to March 30, 2006; Reno, NV.

Nevin RL. An economic analysis of serologic screening prior to immunization of Navy enlisted accessions. Poster presented at: 45th Annual NEHC Occupational Health and Preventive Medicine Conference; March 18 to March 23, 2006; Norfolk, VA.

Nevin RL, Rubertone MV. Enabling improved DoD pandemic influenza preparedness: Capabilities of the proposed Armed Forces Health Surveillance Center (AFHSC). Presented at the 45th Annual NEHC Occupational Health and Preventive Medicine Conference; March 18 to March 23, 2006; Norfolk, VA.

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Nevin RL, Niebuhr DW. Incremental cost-benefit of screening for Anti-HAV in mass screening and immunization programs: Results of a 2004 U.S. Army seroprevalence study. [Poster 176]. In: Abstracts. Am J Trop Med Hygiene. 2005;73(6 Supplement):59. Presented at: 54th Annual Meeting of the American Society of Tropical Medicine and Hygiene (ASTMH); December 13, 2005; Washington, DC.

Bennett JW, **Nevin RL**, Polhemus ME, Ogutu BR. Cost-effectiveness of empiric antimalarial treatment among febrile children aged 0-4 years in areas of high malaria endemicity. Poster presented at the DC Chapter of the American College of Physicians Meeting; November 4, 2005; Bethesda, MD.

Nevin RL, Niebuhr DW. Seroprevalence of hepatitis A antibodies among new enlisted accessions to the U.S. military in 2004. [Poster 1026]. Presented at: 43rd Annual Meeting of the Infectious Diseases Society of America (IDSA); October 8, 2005; San Francisco, CA.

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Nevin RL, Niebuhr DW, Frick KD. Mathematical modeling of occupational needlestick injury reduction in a U.S. Army mass immunization program through universal serologic screening for pre-existing immunity. [Poster 50443]. In: Poster Abstracts. American Journal of Infection Control. 2005;33(5):e139-140. Poster presented at: 32nd Annual Educational Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology (APIC); June 19, 2005; Baltimore, MD.

Nevin RL, Niebuhr DW, Frick KD. Cost-minimization analysis of serologic screening policy options for U.S. Army accession immunizations. [Poster PHP47]. In: Contributed Poster Presentations. Value in Health. 2005;8(3):436. Poster presented at: 10th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 16, 2005; Washington, DC.

1999 Norwich KH, **Nevin R.** The information of simple physical events. In: Proceedings of the 25th Canadian Medical and Biological Engineering Conference. London, Ontario, Canada; June 1999; p 72. Poster presented at: 25th Canadian Medical and Biological Engineering Conference; June 1999; London, Ontario, Canada.

Presentations

2018 **Nevin RL**, Ritchie EC. A Clinician's Guide to Screening for Symptomatic Mefloquine Exposure and Evaluating Claims of Chronic Neuropsychiatric Effects from Mefloquine Poisoning. Presented at: 2018 Annual Meeting of the Association of Military Surgeons of the United States; November 29, 2018; National Harbor, MD.

2017 **Nevin RL**, Ritchie EC. A Clinician's Guide to Distinguishing Chronic Neuropsychiatric Effects from Mefloquine from Symptoms of PTSD/TBI. *Presentation 9825.* Presented at: 126th Annual Meeting of the Association of Military Surgeons of the United States; November 28, 2017; National Harbor, MD.

Nevin RL. Industry Sources of Population Risk Associated with Reports of Occupational Finger Amputations: Results of an Analysis of OSHA Severe Injury Report Data. *Abstract 138.* Presented at: 2017 American Occupational Health Conference; April 24, 2017; Denver, CO.

2015 **Nevin RL**, Ritchie EC. Mefloquine Intoxication In Clinical And Forensic Psychiatry. *Workshop 1763.* Presented at: 168th Annual Meeting of the American Psychiatric Association; May 20, 2015; Toronto, Canada.

2014 **Nevin RL**, Ritchie EC. Mefloquine and the U.S. Military. Presented at: 2014 Annual Continuing Educational Meeting of the Association of Military Surgeons of the United States; December 3, 2014; Washington, DC.

Nevin RL. Controversies Abound Around PTSD. *Workshop 5576.* Presented at: 167th Annual Meeting of the American Psychiatric Association; May 6, 2014; New York, NY.

Nevin RL. Anabolic Steroid and Supplement Use in the Military. *Workshop 5054.* Presented at: 167th Annual Meeting of the American Psychiatric Association; May 4, 2014; New York, NY.

Nevin RL. The Mefloquine Toxidrome in Clinical and Forensic Psychiatry. *Workshop 5072.* Presented at: 167th Annual Meeting of the American Psychiatric Association; May 3, 2014; New York, NY.

2013 **Nevin RL.** Mefloquine Neurotoxicity Plausibly Contributes to the Burden of PTSD, TBI, Suicide, and Violence within the U.S. Military. *Workshop 57.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 20, 2013; San Francisco, CA.

Nevin RL. Steroid Use and Consequences in the Military. *Workshop 83.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 20, 2013; San Francisco, CA.

Nevin RL. Controversies Around Posttraumatic Stress Disorder. *Workshop 73.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 20, 2013; San Francisco, CA.

Nevin RL. Violence and the American Soldier. *Workshop 40.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 19, 2013; San Francisco, CA.

2009 Jacobsmuhlen T, Gaydos C, Meyers M, Gaydos J, **Nevin R**, Foster A. Surveillance of chlamydia among female soldiers assigned to U.S. Forces Korea. Presented at: 2009 Force Health Protection Conference; August 18 to August 21, 2009; Albuquerque, NM.

Sutcliffe S, **Nevin RL**, Pakpahan P, Bruzek DJ, Cole SR, DeMarzo AM, Gaydos CA, Issaacs WB, Nelson WG, Sokoll LJ, Zenilman JM, Cersovsky SB, Platz EA. Prostate involvement during sexually transmitted infections as measured by prostate specific antigen concentration. In: J.Urol 2009;181 Apr (4 Supplement 1):64. Presented at: 2009 Annual Meeting of the American Urological Association; April 25 to April 30, 2009; Chicago, IL.

2008 **Nevin RL**, Shuping EE, Frick KD, Gaydos JC, Gaydos CA. Cost-effectiveness of chlamydia screening policies among male military recruits. Presented at: 2008 International Conference on Emerging Infectious Diseases; March 16 to March 19, 2008; Atlanta, GA.

2007 Eick A, Wang Z, Hu Z, **Nevin RL**, Tobler S. Seasonal and avian influenza: Seroprevalence among deployed servicemembers and new accessions. Presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Nevin RL, Eick A, Tobler S. Biobanking and biosurveillance: The biologic foundation for the future of armed forces health surveillance. Presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Nevin RL, Tobler S, Caci J, Johnson J. Hepatitis E outbreak in eastern Afghanistan, 2007: Risk of seroconversion among U.S. personnel and implications for vaccine development. Presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Ford S, Hughes H, Nevin RL. Outcomes research for military vaccination policy: The U.S. Army Accession Screening and Immunization Program. Presented at: 12th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 21, 2007; Arlington, VA.

2006

Nevin RL, Shuping EE, Frick KD, Gaydos JC, Gaydos CA. Cost-effectiveness of chlamydia screening among male military recruits. In: Chlamydial Infections: Proceedings of the Eleventh International Symposium on Human Chlamydial Infections. International Chlamydia Symposium; San Francisco, CA; pp 477-480. Presented at: 11th International Symposium on Human Chlamydial Infections; June 18 to June 23, 2006; Niagara-on-the-Lake, Canada.

Nevin RL, Rubertone MV. Numbers and frequencies of specimens in the Department of Defense serum repository. Presented at: 2006 Annual Meeting of the International Society of Biologic and Environmental Repositories; May 1, 2006; Bethesda, MD.

Nevin RL. The U.S. Army Accession Screening and Immunization Program at Army training centers. Presented at: U.S. Army Training and Doctrine Command Initial Entry Training Soldier Care Conference; April 11, 2006; Hampton, VA.

Nevin RL. Improving the efficiency of accession medical processing: The MEPCOM role in screening. Presented at: 2nd Annual Joint Accessions Research & Best Practices Symposium; April 6, 2006; San Antonio, TX.

Nevin RL. An economic analysis of serologic screening prior to immunization of Navy enlisted accessions. Presented at: 45th Annual NEHC Occupational Health and Preventive Medicine Conference; 8th Operational Research Competition; March 18, 2006; Norfolk, VA.

2005

Bennett JW, **Nevin RL**, Polhemus ME. Cost-effectiveness of empiric antimalarial treatment among febrile children aged 0-4 years in areas of high malaria endemicity. Presented at: Army American College of Physicians Meeting; November 19, 2005; San Antonio, TX.

Nevin RL. The U.S. Army Accession Screening and Immunization Program: Implementation and directions for future research. Presented at: U.S. Army Accessions Command Accessions Research Consortium; October 20, 2005; Hampton, VA.

Nevin RL. Cost-effectiveness modeling of serologic screening policy options for U.S. Army accession immunizations: Implications for improving the efficiency of accession medical processing. Presented at: 1st Annual Accessions Training Research & Best Practices Symposium; August 25, 2005; Lincolnshire, IL.

Nevin RL, Niebuhr DW, Frick KD. Implementing cost-effective serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program (ASIP) business plan. Presented at: 8th Annual U.S. Army Center for Health Promotion and Preventive Medicine Force Health Protection Conference; August 12, 2005; Louisville, KY.

Nevin RL. Improving the efficiency of military accession immunization programs through centralized screening for pre-existing immunity among Department of Defense applicants at military entrance processing

stations: Variable cost modeling of policy options. Presented at: 8th Annual U.S. Army Center for Health Promotion and Preventive Medicine Force Health Protection Conference; August 12, 2005; Louisville, KY.

Invited Talks and Grand Rounds

2019 **Nevin RL.** Identifying and Evaluating Sources of Evidence of Quinism: A Novel Disease Affecting U.S. Veterans. Presentation to the National Academies of Sciences, Engineering, and Medicine Committee on Long-Term Health Effects of Antimalarial Drugs; January 28, 2019: Washington, DC.

2017 **Nevin RL.** The New "Great Imitator": Chronic Neuropsychiatric Adverse Effects from Mefloquine. Mental Health Grand Rounds, Washington DC VA Medical Center; October 12, 2017: Washington, DC.

Nevin RL. The New "Great Imitator": Chronic Neuropsychiatric Adverse Effects from Mefloquine. Grand Rounds Presentation to the Department of Medicine, Washington DC VA Medical Center; May 31, 2017: Washington, DC.

2014 **Nevin RL.** Central Nervous System Toxicity of Antiparasitic Quinolines. Presentation to the Johns Hopkins University School of Medicine, Department of Clinical Pharmacology; April 2, 2014: Baltimore, MD.

2013 **Nevin RL.** An Antimalarial Toxidrome? New Insights into the Psychiatric Adverse Effects of Mefloquine (Lariam®). Presentation to the Veterans Health Administration Northwest Mental Illness Research Education & Clinical Center; December 18, 2013. Online.

Nevin RL. Mefloquine and Special Forces: An Update. Presentation to the Green Beret Foundation Annual Board Meeting; November 9, 2013: Fayetteville, NC.

Nevin RL. Mefloquine limbic encephalopathy: a model of impulsive suicidality. Presentation to the James Kirk Bernard Foundation Science Planning Meeting; March 18, 2013: Denver, CO.

Nevin RL. Mefloquine neurotoxicity. Presentation to Food and Drug Administration, Office of the Commissioner/Office of Special Health Issues (OSHI); January 11, 2013: White Marsh, MD.

2011 **Nevin RL.** Neuropsychiatric adverse events associated with mefloquine. Presentation to the Special Operations Medical Association 2011 Annual Meeting; December 12, 2011; Tampa, FL.

Nevin RL. Neuropsychiatric adverse events associated with mefloquine. Presentation to the U.S. Army Special Operations Command Preventive Medicine Symposium; April 20, 2011. Fayetteville, NC.

2010 **Nevin RL.** Neuropsychiatric adverse events associated with mefloquine. Presentation to the Special Operations Medical Association 2010 Annual Meeting; December 16, 2010; Tampa, FL.

Nevin RL. The epidemiology of weaponized disease agent outbreaks. Presentation to the Uniformed Services Academy of Family Physicians 2010 Annual Meeting; February 24, 2010; New Orleans, LA.

2006 **Nevin RL.** Uses of the Department of Defense serum repository in support of vaccine-related studies: Case-control, cohort, and cross-sectional study designs. Presentation to the Johns Hopkins Bloomberg School of Public Health Department of International Health; October 5, 2006; Baltimore, MD.

Nevin RL. The U.S. Army Accession Screening and Immunization Program. Presentation to the Military Vaccine Agency (MILVAX) Annual Meeting; June 6, 2006; Arlington, VA.

Nevin RL. Advancing research in seroepidemiology: Visions for the future of the Department of Defense serum repository. Presentation to the National Institutes of Health Autoimmune Diseases Coordinating Committee, NIH; February 24, 2006; Rockville, MD.

2005 **Nevin RL.** The Department of Defense serum repository: Opportunities for seroepidemiolgic research utilizing the world's largest serum repository. Presentation to the Johns Hopkins Bloomberg School of Public Health Department of Epidemiology; October 31, 2005; Baltimore, MD.

Acknowledgements

2016 Avilés-Santa ML, Hsu LL, Arredondo M, Menke A, Werner E, Thyagarajan B, Heiss G, Teng Y, Schneiderman N, Giachello AL, Gallo LC, Talavera GA, Cowie CC. Differences in Hemoglobin A1c Between Hispanics/Latinos and Non-Hispanic Whites: An Analysis of the Hispanic Community Health Study/Study of Latinos and the 2007-2012 National Health and Nutrition Examination Survey. Diabetes Care. 2016;39(6):1010-1017.

2012 Wang Z, Chen F, Ward M, Bhattacharyya T. Compliance with Surgical Care Improvement Project Measures and Hospital-Associated Infections Following Hip Arthroplasty. J Bone Joint Surg Am. 2012;94(15):1359-1366.

2011 Hutfless S, Matos P, Talor MV, Caturegli P, Rose NR. Significance of Prediagnostic Thyroid Antibodies in Women with Autoimmune Disease. J Clin Endocrin Metab. 2011;96(9):e1466-71.

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EXHIBIT B

EXHIBIT C

FDA Drug Safety Communication: FDA approves label changes for antimalarial drug mefloquine hydrochloride due to risk of serious psychiatric and nerve side effects

[7-29-2013] The U.S. Food and Drug Administration (FDA) is advising the public about strengthened and updated warnings regarding neurologic and psychiatric side effects associated with the antimalarial drug mefloquine hydrochloride. A boxed warning, the most serious kind of warning about these potential problems, has been added to the drug label. FDA has revised the patient Medication Guide dispensed with each prescription and wallet card to include this information and the possibility that the neurologic side effects may persist or become permanent. The neurologic side effects can include dizziness, loss of balance, or ringing in the ears. The psychiatric side effects can include feeling anxious, mistrustful, depressed, or having hallucinations (For a more complete list of potential side effects, see Additional Information for Patients).

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.

Malaria is a serious disease caused by a parasite that commonly infects mosquitoes, which then bite humans. It is a major cause of death worldwide but is less common in the United States. The disease is a problem primarily in developing countries with warm climates. Persons who travel to these countries may be at risk of malaria infection and should take drugs to prevent or reduce that risk. People with malaria often experience fever, chills, and flu-like symptoms. Drugs must be taken to treat the disease if you have been infected, but may, themselves, have side effects.

FDA will continue to evaluate the safety of mefloquine and will communicate with the public again if additional information becomes available.

FACTS about mefloquine tablets

- Antimalarial drug indicated for the treatment of mild to moderate acute malaria caused by mefloquine-susceptible *P. falciparum* and *P. vivax*.
- Also indicated for the prevention of malaria infections by *P. falciparum* (including chloroquine-resistant *P. falciparum*) and *P. vivax*.

- Previously marketed under the brand name Lariam; however, the Lariam product is not currently marketed. Generic mefloquine products are available in the US.

Additional Information for Patients

- Mefloquine may cause dizziness, balance problems, and ringing in the ears. These symptoms can occur at any time during use and can last for months to years after the drug is stopped or can be permanent.
- Contact your health care professional right away if you take mefloquine and experience any of the following signs and symptoms; it may be necessary to stop mefloquine and take another medication to prevent malaria, but do not do so without first talking with your health care professional:
    - Dizziness
    - Balance problems such as a feeling that you or things around you are moving or spinning (vertigo)
    - Ringing in your ears (tinnitus)
    - Convulsions or seizures
    - Inability to sleep (insomnia)
- If you already have or develop any mental problems, you should contact your health care professional right away. These mental problems include:
    - Anxiety
    - Feelings of mistrust towards others (paranoia)
    - Seeing or hearing things that are not there (hallucinations)
    - Depression
    - Restlessness
    - Confusion
    - Behavior that is unusual
- Carefully read the Medication Guide and the wallet card that come with your mefloquine prescription.
- Discuss any questions or concerns about mefloquine with your health care professional.

- Report any side effects you experience to your health care professional and the FDA MedWatch program, using the information in the Contact FDA box at the bottom of the page.

Additional Information for Health Care Professionals

- Encourage your patients to contact you if they develop neurologic or psychiatric symptoms.
- Make sure your patients receive the Medication Guide with every prescription.
- Be alert to the potential for the development of neurologic and psychiatric adverse reactions in patients using the drug. If the patient develops psychiatric or neurologic symptoms during preventive use, mefloquine should be stopped and an alternate antimalarial medicine should be used.
- Neurologic and psychiatric symptoms can be difficult to identify in children.
- Report adverse reactions involving mefloquine to the FDA MedWatch program, using the information in the Contact FDA box at the bottom of the page.

Data Summary

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.

In conducting its assessment of vestibular adverse reactions associated with mefloquine use, FDA reviewed adverse event reports from the FDA Adverse Event Reporting System (FAERS) and the published literature, identifying patients that reported one or more vestibular symptoms such as dizziness, loss of balance, tinnitus, and vertigo. Patients who reported vestibular adverse reactions were healthy with no known major medical problems prior to taking mefloquine for malaria prophylaxis. Some patients did not suspect their symptoms were due to mefloquine and continued to take the drug after the symptoms started.

In many cases, these symptoms developed early in the course of treatment, sometimes after one or two doses of mefloquine. Dizziness, loss of balance, tinnitus, or vertigo persisted for months to years after mefloquine was discontinued, and permanent vestibular damage was diagnosed in some cases. These symptoms interfered with patients' daily activities and ability to work. Some cases described abnormal vestibular function tests and a diagnosis of vestibular damage. In some cases, the vestibular damage was thought to be caused by mefloquine use. Some patients reported recurrence of psychiatric and vestibular symptoms when they took mefloquine for the second time. Patients who experienced vestibular symptoms usually had concomitant psychiatric symptoms such as anxiety, confusion, paranoia, and depression. Some of the psychiatric symptoms persisted for months to years after mefloquine was discontinued.

FDA will continue to evaluate the safety of mefloquine and will communicate again if additional information becomes available.

EXHIBIT D

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

17 Jan 2012

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
COMMANDER, JOINT TASK FORCE NATIONAL CAPITAL REGION MEDICAL

SUBJECT: Service Review of Mefloquine Prescribing Practices

Some deploying Service members have been provided mefloquine for malaria prophylaxis without appropriate documentation in their medical records and without proper screening for contraindications. In addition, not all individuals have been provided the required mefloquine medication guide and wallet information card, as required by the Food and Drug Administration. Providing our Service members with the highest quality care is one of the most important things we do; thus, it is incumbent upon us to ensure our Service members are appropriately screened and informed about the medicines they are taking, and we must accurately record their prescriptions in their medical records.

The Department of Defense Instruction 6490.03, "Deployment Health," dated August 11, 2006, addresses the administration of Force Health Protection prescription products and remains in effect. It requires qualified personnel to dispense all Force Health Protection prescription products under a prescription, and that the prescription be recorded in individual medical records.

Please review your Service's quality assurance procedures for the use of mefloquine, with particular emphasis placed on screening for contraindications, documentation of patient education, and documentation of mefloquine prescriptions in medical records. The contraindications for mefloquine use are discussed in the attached Health Affairs Policy 09-017, "Policy Memorandum on the Use of Mefloquine (Lariam®) in Malaria Prophylaxis." Your review should include mefloquine dispensed at medical treatment facilities, pre-deployment processing locations, and in deployed locations. Your review also should confirm that your health care providers understand the important screening and documentation requirements associated with prescribing mefloquine.

Please provide me with the results of your review within 90 days of this memorandum, including deficiencies identified, and measures taken to correct them, along with a copy of any updated Service-wide policies addressing these issues. The point of contact for this matter is COL Scott Stanek. COL Stanek may be reached at (703) 575-2669, or Scott.Stanek@tma.osd.mil.

Jonathan Woodson, M.D.

Attachments:
As stated

Cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Medical Officer of the Marine Corps
Joint Staff Surgeon

EXHIBIT E

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8504150

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** Y **Country:** USA **Outcomes:** OT **(A)NDA/BLA:** 019591 /

FDA Rcvd Date: 11-Apr-2012 **Mfr Rcvd Date:** 29-Mar-2012 **Mfr Control #:** US-ROCHE-1054403

Patient Information:

Age: **Sex:** **Weight:**

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	LARIAM				PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	LARIAM							

Event Information:

Preferred Term (MedDRA Version #: 16.0)	Start Date	End Date	ReC
HOMICIDE			

Event/Problem Narrative:

Initial Information for this Spontaneous case, AER number 1054403, was received on 29/Mar/2012 from a Pharmacist and concerns a patient of unknown demographics who was treated with Mefloquine Hydrochloride (Lariam) for an unknown indication. Medical history included TBI (Traumatic brain injury). No concurrent illnesses were reported. No concomitant medications or past drugs were reported. On an unknown date, the patient started Mefloquine Hydrochloride (dose, form and frequency not reported). On an unknown date the patient who was a soldier in the US Army developed homicidal behavior and led to Homicide killing 17 Afghanis. It was reported that this patient was administered Mefloquine in direct contradiction to US military rules that Mefloquine should not be given to soldiers who had suffered TBI (Traumatic brain injury) due to its propensity to cross blood brain barriers inciting psychotic, homicidal or suicidal behavior. The outcome of Homicide was not Reported. There was insufficient information regarding the therapy ongoing status of Mefloquine Hydrochloride. The reporter did not provide the seriousness criteria of the event of Homicide and its causal relationship with Mefloquine Hydrochloride. The company assessed the event of Homicide as medically significant. No further information was available.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8504150

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No **Sender Organization:** ROCHE

Literature Text: