WRITTEN TESTIMONY OF
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Special Oversight Board for Department of Defense Investigations
of Gulf War Chemical and Biological Incidents
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Dr. Garth Nicolson is currently the Chief Scientific Officer and Research Professor at the Institute for Molecular Medicine in Huntington Beach, California. He was formally the David Bruton Jr. Chair in Cancer Research and Professor at the University of Texas M. D. Anderson Cancer Center in Houston, and Professor of Internal Medicine and Professor of Pathology and Laboratory Medicine at the University of Texas Medical School at Houston. He was also Adjunct Professor of Comparative Medicine at Texas A & M University. Among the most cited scientists in the world, having published over 480 medical and scientific papers, edited 13 books, served on the Editorial Boards of 12 medical and scientific journals and currently serving as Editor of two (*Clinical & Experimental Metastasis* and the *Journal of Cellular Biochemistry*), Professor Nicolson has active peer-reviewed research grants from the U.S. Army, National Cancer Institute, National Institutes of Health, American Cancer Society and the National Foundation for Cancer Research. In 1998 he received the Stephen Paget Award from the Cancer Metastasis Research Society and the Albert Schweitzer Award in Lisbon, Portugal.

Gulf War Illnesses (GWI) have been proposed to be due to accumulated toxic insults that can result in chronic illnesses with relatively nonspecific or not unique signs and symptoms. For the most part, patients do not appear to have some new syndrome; they can be best described as patients with Chronic Fatigue Syndrome (CFS), Fibromyalgia Syndrome (FMS) or Multiple Chemical Sensitivity Syndrome (MCS) [2]. The official stance of the Department of Defense (DoD) appears to be that battlefield stress was a major factor, but most nongovernment researchers doubt that stress alone is a major cause of GWI [1, 3, 4], and it certainly does not explain how some immediate family members can present with the same signs and symptoms [2, 3, 5, 6]. GWI may be better explained as the result of multiple toxic insults to our soldiers, including those from chemical, radiological and biological sources [3, 4]. We have worked exclusively on the biological or infectious sources of patient morbidity (sickness) because whether these were obtained as primary sources or secondary opportunistic infections, they have to be identified and treated if patients are to recover from GWI [6].

Obtaining an Adequate Diagnosis and Effective Treatments for GWI

Many veterans of Operation Desert Storm face tremendous obstacles in trying to obtain an adequate diagnosis for their illnesses and then adequate care for their conditions. Up until recently, most of the emphasis in diagnosing and treating GWI within the military and VA has been on stress-related somatoform conditions, such as Post Traumatic Stress Disorder (PTSD) [7]. Since many patients do not fit this category, even with the help of military and Veterans Administration (VA) psychiatrists, and cannot be diagnosed within existing ICD-9-coded diagnosis categories, they often receive a diagnosis of unknown illness. This, unfortunately, results in their receiving reduced disability assessments, reduced benefits and essentially little or no effective treatment for GWI. It's not that they are any less sick than their compatriots who have ICD-9 diagnoses used by the DoD and DVA, they just don't fit within the military s or VA s diagnosis systems. In addition, many active-duty members of the Armed Forces are hesitant to admit that they have GWI, because they feel strongly that it will hurt their careers or result in their being medically discharged. They have good reason to fear this.

What is GWI and How is it Different from Civilian Chronic Illnesses?

GWI present as complex, multi-organ chronic signs and symptoms, including chronic fatigue, headaches, memory loss, muscle pain, nausea, gastrointestinal problems, joint pain, lymph node pain, memory loss, increased chemical sensitivities and other signs and symptoms [1-4]. Often included in this complex clinical picture are increased sensitivities to various environmental agents and enhanced allergic responses. Although CFS, FMS and now GWI have been known for years, patients have had few options for obtaining effective treatments. Unfortunately, within the DoD and VA medical systems treatments are more easily ordered on the basis of laboratory tests than on clinical observations, and the lack of clear-cut laboratory results in GWI cases tends to lend support for psychiatric diagnoses.

Over 100,000 veterans of the Persian Gulf War have been entered into the GWI registry. For the most part, this does not include immediately family members. According to one government study, GWI has spread to family members [5], and it is likely that it has also spread in the workplace. Thus diagnoses biased on PTSD appear to be a gross oversimplification of GWI [8]. Although the official position of the DoD is that family members have not contracted GWI, a U. S. Senate report [5] indicates that at least a subset of GWI patients have a transmittable illness. In support of the Senate report, we have found similar transmittable infections in Desert Storm veterans family members. In fact, clinical tests reveal that GWI family members have the same chronic infections that have been found in ~45% of the ill veterans [9-11].

Relationship of Stress to Chronic Illnesses

Patients with CFS, FMS and GWI often have cognitive problems, such as short term memory loss, problems concentrating and other psychological problems. Psychiatrists often decide in the absence of contrary laboratory findings that these conditions are caused by somatoform disorders, such as by stress, instead of organic or medical problems that can be treated with medicines or treatments that are not specific for the Central Nervous System. The evidence that physicians have offered as proof that stress or PTSD is the source of most GWI is the assumption that most veterans must have suffered from stress by virtue of the stressful environment in which they found themselves during the Gulf War [2-4]. However, most veterans do not feel that stress-related diagnoses are an accurate portrayal of their illnesses, and testimony to the House Committee on Government Reform and Oversight questions the notion that stress is the major cause of GWI [8], and the General Accounting Office (GAO) has concluded that while stress can induce some physical illness, it is not established as the major cause of GWI [12]. Stress can exacerbate chronic illnesses and suppress immune systems, but most military personnel that we interviewed indicated that the Gulf War was not a particularly stressful war, and they strongly disagreed that stress was the origin of their illnesses. However, in the absence of physical or laboratory tests that can identify possible origins of GWI or FMS and CFS, many military and VA physicians accept that stress is the cause of these chronic illnesses.

Chronic Illnesses and Chemical and/or Biological Exposures

Chemical and biological exposures occurred during the Gulf War, and many civilian patients may have been exposed to chemical and biological substances that could be the underlying initial cause of their illnesses [3]. The variable incubation times, ranging from months to years after presumed exposure, the cyclic nature of the relapsing fevers and other signs and symptoms, and the types of signs and symptoms of GWI are consistent with diseases caused by combinations of biological and/or chemical or radiological agents (Figure 1) [3]. System-wide or systemic chemical insults and/or chronic infections that can penetrate

various tissues and organs, including the Central and Peripheral Nervous Systems, may be important in GWI [9-11]. When such infections occur, they can cause the complex signs and symptoms seen in CFS, FMS and GWI, including immune dysfunction. Changes in environmental responses as well as increased titers to various endogenous viruses that are commonly expressed in these patients have been seen in CFS, FMS and GWI. If infectious agents are involved, few can produce the complex chronic signs and symptoms found in these patients. One type of airborne infection that has received renewed interest of late as an important element in these disorders is mycoplasmal infections [13]. These microorganisms are now considered important emerging pathogens in causing chronic diseases as well as being important cofactors in some illnesses, including AIDS and other immune dysfunctional conditions [13, 14].

As chronic illnesses like GWI (and in some cases CFS and FMS) progress, there are a number of accompanying clinical problems, particularly autoimmune signs/symptoms, such as those seen in Multiple Sclerosis (MS), Amyotrophic Lateral Sclerosis (ALS or Lew Gehrig s Disease), Lupus, Graves Disease, Arthritis and other complex autoimmune diseases Mycoplasmal infections can penetrate into nerve cells, synovial cells and other cell types. The autoimmune signs and symptoms can be caused when intracellular pathogens, such as mycoplasmas, escape from cellular compartments and stimulate the host s immune system. Microorganisms like mycoplasmas can incorporate into their own structures pieces of host cell membranes that contain important host membrane antigens that can trigger autoimmune responses or their surface antigens may be similar to normal cell surface antigens. Thus patients with such infections may have unusual autoimmune signs and symptoms.

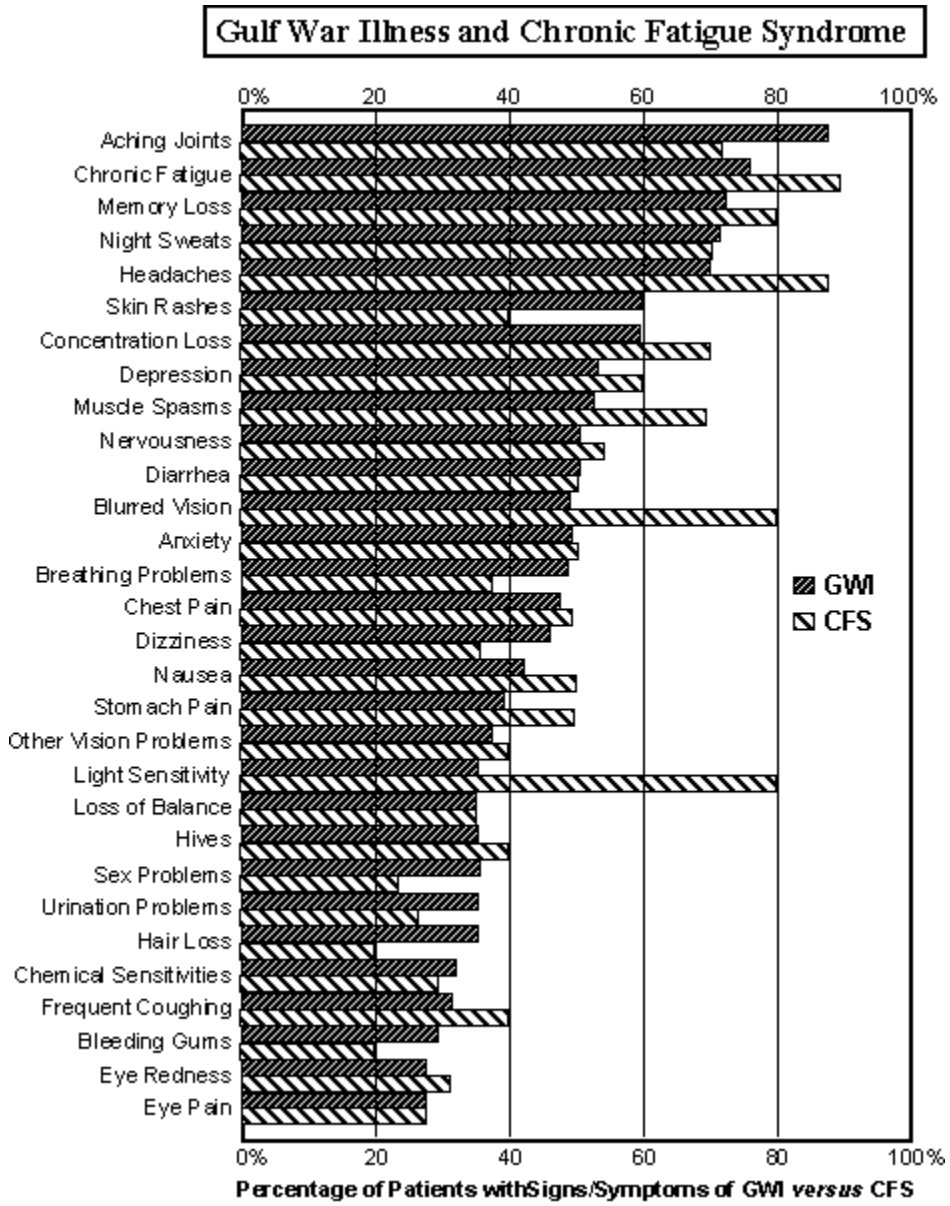

Figure 1. Multiple exposures (chemical, radiological, biological) or multifactorial causes may have resulted in GWI in susceptible individuals. Chemical exposures alone could also be responsible for Multiple Chemical Sensitivity Syndrome (MCS) or Organophosphate-Induced Delayed Neurotoxicity (OPIDN) (from Reference 3).

Microorganisms as Important Agents or Cofactors in Chronic Diseases

Some species of mycoplasmas, such as *M. fermentans, M. penetrans, M. pneumoniae, M. genitalium, M. pirum* and *M. hominis*, among others, have been closely associated with various human diseases [13, 14]. In addition, chronic infections caused by *Brucella* or *Coxiella* can also cause similar signs and symptoms. Do these agents cause or are cofactors in CFS, FMS or GWI? They can certainly be important in causing

morbidity seen in patients with chronic illnesses [14]. If so, is there any evidence for mycoplasmal infections in CFS, FMS or GWI patients? In a majority of FMS, CFS and GWI patients examined we [9-11] and others, principally Dr. Daryl See of the University of California College of Medicine, Irvine, and a commercial laboratory in Los Angeles [15] have documented mycoplasmal blood infections that can explain much of the chronic signs and symptoms seen in GWI [9-11]. In our studies on GWI, we have found mycoplasmal infections in the blood of about one-half of patients (91/200), and these patients were found to have predominantly one infectious species of mycoplasma, *M. fermentans* [9, 10], compared to ~60% of mycoplasma-positive civilians with CFS, FMS or Rheumatoid Arthritis, where several different pathogenic mycoplasma species have been found [11, 16]. The tests that we use to identify infections, Forensic Polymerase Chain Reaction [11, 16] and Nucleoprotein Gene Tracking [9-11], are very sensitive and highly specific tests compared to the relatively insensitive antibody tests that are currently used to assay for systemic mycoplasmal infections. We recently received a DoD contract to train scientists and physicians to perform these tests, including the training of staff from the Armed Forces Institute of Pathology and Walter Reed Army AMC.

Inadequate Responses of the DoD and DVA to GWI

Has the DoD responded to the published studies on microorganism infections in GWI patients? They did award us with a small training grant to teach the techniques to DoD and non-DoD scientists, but in general, the response has been inadequate and mainly denial that what we and others have found is important in GWI, even though the majority of patients diagnosed with chronic infections and treated with antibiotic protocols developed by us recover from their illness. In response to our publications and formal lectures at the DoD (in 1994 and 1996) and DVA (in 1995), the DoD stated in letters to various members of Congress and to the press that this type of infection is commonly found, not dangerous and not even a human pathogen, and our results have not been duplicated by other laboratories. These statements could not be further from the truth. The Uniformed Services University of the Health Sciences has been teaching its medical students for years that this type of infection is very dangerous and can progress to system-wide organ failure and death [17]. In addition, the Armed Forces Institute of Pathology (AFIP) has been publishing for years that this type of infection can result in death in nonhuman primates [18] and in man [17]. The AFIP has also suggested treating patients with this type of infection with doxycycline [19], which is one of the antibiotics that we have recommended [9-11, 20-22]. Then why did the DVA issue guidelines stating that GWI patients should not be treated with antibiotics like doxycycline, even though in a significant number of patients it has been shown to be beneficial [9, 10]? In response to the comments that our tests have not been duplicated, certified diagnostic clinical laboratories, Immunosciences Laboratories of CA [15] and Medical Diagnostic Laboratories of NJ have been conducting diagnostic tests on mycoplasmal infections in blood of GWI and CFS patients, and they are obtaining similar results. Thus our results have been replicated by certified commercial laboratories and published in the medical literature. The DoD and DVA have also stated that we have not cooperated with them or the CDC in studying this problem. This is not true. We have done everything possible to cooperate with the DoD, DVA and CDC on this problem, and we even published a letter in the Washington Post on 25 January 1997 indicating that we have done everything possible to cooperate with government agencies on GWI issues. We formally invited DoD and DVA scientists and physicians to the Institute for Molecular Medicine to learn our diagnostic procedures on 23 December 1996 at a meeting convened at Walter Reed AMC by MG Leslie Burger at the request of Congressman Norman Dicks (D-WA). We have been and are fully prepared to share our data and procedures with government scientists and physicians. Although government laboratories can test for mycoplasmal infections and have been conducting their own examination of mycoplasmal infections in GWI patients, they are using relatively insensitive, outdated antibody tests or conventional molecular biological tests, and we would not expect them to detect the infection by these procedures. To correct this situation we received a small training contract from the DoD to train DoD scientists in our new techniques, and the training was completed on January 30, 1998. Recently the DVA has recognized the value of our work and will initiate on 1 January 1999 VA Cooperative Clinical Trial #475, a diagnostic and treatment trial that focuses on mycoplasmal infections in GWI and their treatment with doxycycline using essentially a regimen that we published in 1995 [20].

Successful Treatment of GWI Mycoplasmal Infections

We have found that mycoplasmal infections in GWI, CFS, FMS and RA can be successfully treated with multiple courses of specific antibiotics, such as doxycycline, ciprofloxacin, azithromycin, clarithromycin or minocycline [9-11, 20-22], along with other nutritional recommendations. Multiple treatment cycles are required, and patients relapse often after the first few cycles, but subsequent relapses are milder and most patients eventually recover [9, 10]. In contrast, in nondeployed, healthy adults the incidence of mycoplasma-positive tests were ~6% [11]. We found that 87 mycoplasma-positive GWI patients on antibiotic therapy relapsed within weeks after the first 6-week cycle of therapy, but 69/87 recovered after up to six cycles of therapy and 18/87 are still undergoing therapy. GWI patients who recovered from their illness after several (3-7) 6-week cycles of antibiotic therapy were retested for mycoplasmal infection and were found to have reverted to a mycoplasma-negative phenotype [9, 10]. We hypothesize that the therapy takes a long time because of the microorganisms involved are slow-growing and are localized deep inside cells in tissues, where it is more difficult to achieve proper antibiotic therapeutic concentrations. As stated above, multiple cycles of therapy result in eventual recovery in a high percentage of mycoplasma-positive GWI patients. Although anti-inflammatory drugs can alleviate some of the signs and symptoms of GWI, the signs and symptoms appear to quickly return after discontinuing drug use. If the effect was due to an anti-inflammatory action of the antibiotics, then the antibiotics would have to be continuously applied and they would be expected to eliminate only some of the signs and symptoms of GWI. In addition, not all antibiotics, even those that have anti-inflammatory effects, appear to work. Only the types of antibiotics that are known to be effective against mycoplasmas are effective; most have no effect at all on the signs and symptoms of GWI/CFS/FMS/RA, and some antibiotics make the condition worse. Thus the antibiotic therapy does not appear to be a placebo effect, because only a few types of antibiotics are effective and some, like penicillin, make the condition worse. We also believe that this type of infection is immune-suppressing and can lead to other opportunistic infections by viruses and other microorganisms or increases in endogenous virus titers. The percentage of mycoplasma-positive GWI patients overall is likely to be somewhat lower than found in our studies (~45%). This is reasonable, since GWI patients that have come to us for assistance are probably more advanced patients (with more progressed disease) than the average patient. Although we have been criticized for not conducting double-blinded, controlled clinical studies on large numbers of patients, such studies are quite labor intensive and *very* expensive, and all of our studies were conducted without any government support or help whatsoever. Although our studies do not involve controlled patient populations, such as all veterans that served in a single unit compared to similar numbers of nondeployed personnel from the same unit, such controlled populations can only be studied only with the help and financial assistance of the DoD and DVA. Recently the DVA has initiated a controlled clinical trial (CSP #475) involving 18 VA medical institutions that will test the usefulness of antibiotic treatment of mycoplasma-positive GWI patients. This clinical trial is based completely on our research and publications on the diagnosis and treatment of chronic infections in GWI patients [9, 10, 20-22].

What has the DoD Stated About Our Procedures and Results?

The recent comments of Mr. Bernard Rostker, Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses and more recently Assistant Secretary of the Army, at the 17th Town Hall meeting on Gulf War Illnesses at Camp Pendleton on 23 September 1998 indicate that the DoD is still trying to bury the issue of infectious diseases and GWI. According to the comments of Mr. Rostker as related by two participants (S. and L. Dudley of San Diego, CA) in their TV interview after the meeting, "Dr. Shyh-Ching Lo, Armed Forces pathologist, is going to publish that he was not able to reproduce Nicolson s results and that Nicolson was not cooperating in terms of not obtaining those results in the medical community and in fact was hampering it." This is not the truth. In fact, two commercial laboratories that we assisted in setting up similar clinical tests, one in California and one in New Jersey, have confirmed our mycoplasma results in Gulf War Illness patients. It seems that only the AFIP cannot apparently repeat the results, which is why we were awarded a small contract to train them in January of this year. They have never submitted their

data for peer-review, even after several years. We have published our data [9-11, 20-22], and we have also published that blood for analysis must be at refrigerator temperatures and prepared very quickly in order to prevent mycoplasma deterioration [11]. GWI patients have told me (and Dr. Lo even admitted to this to patients) that the AFIP does not store blood properly, and we claim that they do not do the tests properly, which could be why the DoD has never obtained accurate data on mycoplasmal infections in GWI patients.

The DoD pronouncements on the lack of chronic infections (*Mycoplasma, Brucella, Coxiella*, etc.) in GWI and CFS patients flies in the face of published data from university and nongovernmental laboratories. Mr. Rostker stated that "the DoD/VA had initiated a program with Dr. Nicolson to train labs on his testing techniques but were unable to get Dr. Nicolson to send blood samples as he promised to do and were unable to identify the techniques he used and were unable to find the mycoplasma in the blood." These are complete distortions and untruths. The laboratories involved in these studies are using blood from NIH not my laboratory, and these laboratories can and have been detecting mycoplasmal infections using the techniques that we taught them. Why would high officials use untruths and distortions in an effort to cast nongovernmental scientists in an unfavorable light. Was this done to cover up a completely inadequate government response to GWI? And why are they still going to such great lengths to cover this up more than 8 years after Dessert Storm? We have been able to help thousands of GWI patients after years of suffering obtain a diagnosis and treatment and recover from their illnesses, and these same patients were not even given a diagnoses or effective treatments by DoD or VA medical facilities. If we are wrong, then why are our patients doing better than the DoD/VA patients with GWI? Why then is the DVA willing to allocate more than $12,000,000 to conduct a cooperative clinical trial based entirely on our diagnosis and treatment protocol for treating mycoplasmal infections?

Potential Sources of Exposures That Could Have Caused GWI

We consider it quite likely that many of the Desert Storm veterans suffering from the GWI signs and symptoms may have been exposed to chemical/biological toxins (exogenous or endogenous sources of these agents) containing slowly proliferating microorganisms (*Mycoplasma, Brucella, Coxiella*, etc.), and such infections, although not usually fatal, can produce various chronic signs and symptoms long after exposure. This would account for the illnesses being passed to immediate family members. The DoD has maintained that Iraqi offensive Chemical and Biological Weapons (CBW) were not released during or after the Gulf War, but over 14,000 Chemical Weapons alarms sounded during but not before the conflict and we did not have detection equipment forward deployed to be able to determine whether Biological Weapons were present. The Iraqi armed forces were operating under Soviet War Doctrine, which stresses offensive use of combinations of Chemical and Biological Weapons together with conventional weapons [23]. Evidence presented to Congress [8] indicated that it was extremely likely that Chemical Weapons were released during and certainly after the conflict when bunkers containing CBW were destroyed. Although chemical and/or radiological exposure(s) can result in somewhat similar signs and symptoms to those found in GWI, this does not explain the apparent contagious nature of GWI and the delayed appearance of similar signs and symptoms in immediate family members. Fortunately, the types of slow-growing, chronic infections found in a subset of GWI patients can be diagnosed and successfully treated using our published protocols [9-11, 20-22].

There were several potential sources of chronic biological agents in the Persian Gulf Theater [9, 23]. First, deployed soldiers were given multiple inoculations, in some cases with experimental vaccines in unproved immunization schemes, such as vaccines that were given all at once instead of using an appropriate schedule of inoculations over months or years. Multiple vaccinations given simultaneously can result in immunosuppression and leave an individual susceptible to opportunistic infections. Some of these experimental vaccines could also have been contaminated with small amounts of slow-growing microorganisms. In fact, some of the vaccine lots to be sent to the Gulf were removed because of

"microorganism contamination." Next, the Iraqis were known to have extensive stockpiles of Biological Weapons and the potential to deliver these weapons offensively, at short range in modified Italian-made biological sprayers that deliver Biological Weapons onto the sand to create exclusionary zones or 'biological minefields' and at long range in modified SCUD-B (SS-1) missiles with 'airburst' warheads or sprayers carried by aircraft. As mentioned above, many of the storage and factory facilities where CBW were stored were destroyed immediately up to, during and after the Desert Storm ground offensive, releasing plumes containing these agents high in the atmosphere where they could be carried downwind ('blow-back' exposures) to our lines. These and other possible mechanisms of potential exposure must be carefully examined, not categorically dismissed by DoD personnel in Washington DC with little first-hand knowledge of the conditions on the ground. A number of possible reasons exist that could explain why the DoD and DVA deny that our forces were exposed to CBW agents during the Gulf War, but this does not rationalize the poor responses to GWI casualties [23].

Conclusions and Suggestions

It seems counterproductive to continue the contentious battle over whether or not our forces were exposed to toxic agents in the Gulf Theater of Operations and whether or not they have chronic infections in their blood. I firmly believe that it is now time to diagnose and treat the casualties irrespective of how politically painful the truth may be. Our lack of an adequate response to GWI may dictate how our weaknesses are assessed and exploited in any future conflict [24]. Therefore, we need to act. I have the following suggestions:

1. We must stop the denial that immediate family members do not have GWI from the war. Denial that this has occurred has only angered veterans and their families and created a serious public health problem, including spread of the illness to the civilian population and contamination of our blood supply.

2. The ICD-9-coded diagnosis system used by the DoD and DVA to determine illness diagnosis must be overhauled. The categories in this system have not kept pace with new medical discoveries in the diagnosis and treatment of chronic illnesses. This has resulted in large numbers of patients from the Gulf War with undiagnosed illnesses who cannot obtain treatment or benefits for their medical conditions.

3. Denying claims and benefits by assigning partial disabilities due to PTSD should not be continued in patients that have organic (medical) causes for their illnesses. For example, patients with chronic infections that can take up to or over a year to successfully treat should be allowed benefits.

4. Research efforts must be increased in the area of chronic illnesses. Unfortunately, federal funding for such illnesses is often rebudgeted or funds removed. For example, Dr. William Reeves of the CDC in Atlanta recently sought protection under the Federal Whistle Blower s Act after he exposed such misappropriation of funds at the CDC. It is estimated that over 3% of the adult U.S. population suffers from chronic illnesses similar to GWI, yet there are few federal dollars available for research on the diagnosis and treatment of these chronic illnesses, even though each year Congress allocates such funds.

5. Senior DoD and DVA personnel must be held accountable for the utter mismanagement of the entire GWI problem. This has been especially apparent in the continuing denial that chronic infections could play a role in GWI and the denial that immediate family members could have contracted their illnesses from veterans with GWI. This has resulted in sick spouses and children being turned away from DoD and DVA

facilities without diagnoses or treatments. The responsibility for these civilians must ultimately be borne by the DoD and DVA. I believe that it is now accountability time. The files must be opened so the American public has a better idea how many veterans and civilians have died and how many have become sick because of an inadequate response to this health crisis.

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Under penalty of perjury, I swear that the statements above are true and correct to the best of my knowledge, information and belief.

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