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Institute for Molecular Medicine
June 26, 1997

Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Reform and Oversight

We are here today as medical researchers who have been engaged in studying Gulf War Illnesses (GWI) but also as a family that has suffered from GWI. Our step-daughter returned from service in Desert Storm in 1991 as a Staff Sergeant and Crew Chief of a Blackhawk helicopter in the U.S. Army's 101st Airborne Division (Air Assault) and developed the unusual, multiple signs and symptoms of GWI that prevented her from finishing pilot training. She eventually left the Army,and we have been involved since that time in a research effort to identify some of the possible causes of GWI and develop treatments for GWI patients. Our hypothesis is that GWI is not caused by stress, it is caused by multiple exposures to chemical, environmental, radiological and/or biological agents that cause chronic multisystem signs and symptoms that for the most part can be diagnosed as existing dieeases. We have been particularly interested in veterans with GWI whose family members are now also sick with similar signs and symptoms, suggesting that many GWI patients suffer from biological, not chemical or radiological origins for their illnesses. Illnesses caused by chemical or radiological exposures should not be transmitted to family members. GWI in immediate family members is officially denied by the Departments of Defense (DoD) and Veterans Affairs (DVA). Although some family members could have developed their illnesses by contact with war souvenirs, packs or uniforms, only biological causes of GWI can account for the overwhelming fraction of family members contracting the same illness in this important subset of GWI patients. Our research into GWI and the laboratory tests for GWI-associated pathogens that we developed have been done completely without compensation or funding from the U.S. Government. Since the Institute for Molecular Medicine is a not-for-profit private research institute dedicated to discovering new diagnostic and therapeutic solutions for chronic human diseases, we do not charge veterans or their family members for our assistance and services. In fact, we are assisting without compensation Desert Storm veterans from other Coalition countries that also have GWI casualties.

In addition to an unknown number of immediate family members with GWI, over 100,000 Desert Storm veterans are experiencing a variety of chronic signs and symptoms characterized by disabling fatigue, intermittent fever, joint and muscle pain, impairments in short-term memory, headaches, skin rashes, diarrhea, vfision and gastrointestinal problems and a collection of additional signs and symptoms that has defied a clinical case definition, but has been called Mucocutaneous-Intestinal-Rheumatic Desert Syndrome by Murray-Leisure et al. of the DVA. These chronic signs and symptoms usually do not progress to cause death, but there are now thousands of U.S. Desert Storm veterans dead from a variety of illnesses. Part of the confusion in diagnosing GWI is that somewhat similar or overlapping signs and symptoms can be

caused by quite different types of exposures (chemical, radiological or biological or more likely combinations of these). The diagnosis and successful treatment of GWI are dependent on identifying the underlying exposures involved, because these illnesses are treated differently if their origins are chemical, radiological or biological. For the most part, GWI signs and symptoms began to present between 6 months to one year or more after the end of Operation Desert Storm, and when immediate family members present with the same illness, their onset usually occurred from 6 months to one year or more after the onset of the veterans' illness, and not every family member always develops GWI. Because of the apparent slow rate of transmission of GWI to immediate family members, we do not feel that the general public is at high risk for contracting GWI from casual contact with GWI patients.

The DoD has claimed from their clinical evaluation program that Gulf War veterans do not show higher rates of health problems than the U.S. population as a whole. They fail to mention, however, that all personnel that served inthe Gulf received health clearances before they were deployed, and yet many returned with illnesses or later developed illnesses that cannot be explained. National Guard and Air Force Reserve units were studied by the Center for Disease Control (CDC) in Atlanta for evidence of chronic health problems associated with deployment to the Persian Gulf, and it is clear from this CDC study that the Persian Gulf deployed soldiers have much higher frequencies (from 2.5-times to 13.5-times higher) of chronic health problems. (>6 months duration) than those who were not deployed to the Persian gulf Theater of Operations.

A major problem for Gulf War veterans with GWI is obtaining adequate care for their illnesses. Unfortunately, the signs and symptoms of GWI are not well established as creteria for particular diseases treated by the DoD or DVA. Indeed, most GWI patients do not readily fit into doD or VA diagnosis categories, resulting in many veterans receiving unknown diagnoses or psychological diagnoses, such as Post Traumatic Stress Disorder (PTSD). Although stress can exacerbate clinical conditions, we felt it unlikely that the complex signs and symptoms of GWI that veterans displayed (and especially those where immediate family members have similar signs and symptoms) were due to PTSD. When we studied 650 veterans of Operation Desert Storm and their immediate family members who suffer from GWI, we found that their multiple chronic signs and symptoms were very similar to patients with Chronic Fatigue Syndrome (CFS) (often called Chronic Fatigue-Immune Dysfunction Syndrome or CFIDS) or Fibromyalgia (FM). These chronic conditions can have stress as an exacerbating factor, but they are unlikely to be solely caused by stress or psychiatric problems. In addition, the fact that many immedaite family members have also presented with similar signs and symptoms indicates that diagnoses biased [sic] on PTSD may be a gross oversimplification of GWI. The variable incubation time of GWI, 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 are consistent with diseases caused by combinations of biological and/or chemical or radiological agent(s).

We suggested that GWI/CFS/FM can be explained in many patients by exposure of veterans to various bilogical agents (chronic pathogenic infections) in combination with chemical exposures and in veterans' family members to biological agents transported

back home by the veterans. to confirm or eliminate the possibility that chronic nfectins were an important factor GWI, and especaially in immediate family members with GWI, we began by examining a variety of bilgocial agents (bacteria viruses, etc,.) that can cause the chronic, overlapping, system-wide signs and symptoms seen in GWI. We could eliminate most of the acute or fast acting bacteria, because of the chronic nature of GWI and the slow appearance and nature of signs and symptoms. After examining GWI patients' blood for the presence of chronic biological agents, the most common infection found was an unusual microorganism, *Mycoplasma fermentans* (incognitus strain), a slow-growing mycoplasma located deep inside blood leukocytes (white blood cells) of slightly under one-half of GWI patients studied. This microorganism is similar to a bacterium without a cell wal, and although mycoplasmas are often found at superficial sites in humans, such as in the oral cavity, they are rearely found in the blood. When they are in the blood, similar to other bacteria, they can cause a dangerous system-wide or systemic infection. In addition, cell-penetrating mycoplasmas, such as *Mycoplasma fermentans,* may produce unusual autoimmune-like responses to host cell antigens carried on the mycoplasma surface. Our detection of mycoplasmal infections in the blookd leukocytes of ~45% of the GWI patients examined (76 out of 170 patients), including 2 out of 3 British Desert Storm veterans with GWI, indicate that systemic infections may be a major contributor to GWI.

In response to our published studies and formal lectures at the DoD (in 1994 and 1996) and DVA (in 1995), Dr. Steven Joseph, then Assistant Secretary of Defense for Health Affairs, and Dr. Kenneth Kizer, Undersecretary for Health, DVA, have stated in letters to the press and vrious members of Congress 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, the U.S. military's medical school, has been teaching its medical students for years that this type of infection, although rare in the U.S. population, is very dangerous and can progress to system-wide organ failure and death. 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 and in man. The AFIP has also suggested treating patients with this type of infection with doxycycline, which is one of the types of treatment that we have recommended. Then why has the DVA issued guidelines stating that GWI patients should not be treated with anitbiotics like doxycycline, even though in a significant number of patients it has been shown to be beneficial? In response to the comments that our tests have not been duplicated, a certified diagnostic clinical laboratory, Immunosciences Laboratories of Beverly Hills, CA, has been conducting diagnostic tests on mycoplasmal infections in blood of GWI and CFIDS patients, and they are finding essentially the same results as we have found. Thus our results have been replicated by a certified commercial laboratory. 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 Army Medical Center by Major General Leslie Burger

at the request of Congressman Norman Dicks (D-WV). 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 infectins 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 exptect them to detect the infection by these procedures.

In GWI patients that tested positive for mycoplasmal infections in their blood, we have found that this type of infection can be successfully treated with multiple courses of specific antibiotics, such as doxyxycline (200 mg/day for 6 weeks per cycle), ciprofloxacin (or Cipro, 1500 mg/day for 6 weeks per cycle), azithromycin (or Zithromax, 500 mg/day for 6 weeks per cycle), hromycin (or Biaxin, 500-1000 mg/day per 6 week cycle) or minocycline (200 mg/day for 6 weeks per cycle), along with other nutritional recommendations. Multiple treatment cycles are required, and patients relapse often after teh first few cycles, but subsequent relapses are milder adn patients eventually recover. using the techniques of Nucleoprotein Gene Tracking and foresensic Polymerase Chain Reaction, slightly under one-half (~45%) of the Desert Storm veterans and their immediate family members who had GWI/CFS/FM signs and symptoms in our studies showed evidence of mycoplasmal infections in their blook leukocytes. In contrast, in nondeployed, healthy adults the incidence of mycoplasma-positive tests were <5%. We need to stress that these 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; therefore, the percentage of mycoplasma-positive patients overall is likely to be lower than found in our studies.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 GWI patient. We found that patients on antibiotic therapy (n="73)" relapsed within weeks after the first 6-week cycle of therapy, but 58/73 recovered after up to six cycles of therapy and 14/73 are still undergoing therapy. GWI patients who recovered from their illness after several (3-7) 6-week cycles of antibiotic therapy were retested fro mycoplasmal infection and were found to have reverted to a mycoplasma-negative phenotype. We hypothesize that the therapy takes a long time because of the microorganism(s) involved (a mycoplasma) is slow-growing and is localized deep inside cells in tissues, which are more difficult locations 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/FM, 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 penicilin, 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 inendogenous

virus titers. 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 expensive, and all of our studies were conducted without any government support or help whatsoever. We have designed a double-blinded, cross-ver clinical trial that includes placebo and two antibiotics, and we would like to obtain government support for such a trial.

We consider it quite likely that many of the Desert Storm veterans suffering from the GWI/CFS/FM signs and symptoms may have been exposed to chemical/biological cocktails (or endogenous sources of these agents) containing slowly proliferating microorganisms, including pathogenic mycoplasmas and quite possibly other bacteria and viruses, and such infections, although not usually fatal, can produce various chronic signs and symptoms long after exposure. The DoD has maintained that Iraqi offensive chemical and biological weapons were not released during or after the Gulf War, but we did not have detection equipment deployed to be able to determine whether biological weapons were present. The Iraqi armed forces were operating under Soveit War Doctrine, which stresses offensive use of cmbinations of chemical and biological weapons together with conventional weapons. Evidence presented to this subcommittee indicates that it was extremely likely that chemical weapons were released during and certainly after the conflict when bunkers containing chemical and biological weapons were destroyed. We indicate again that chemical and/or radiological exposure(s) can result in somewhat similar signs and symptoms but this does not explain the apparent contagious nature of GWI adn teh delayed appearance of similar GWI/CFS/FM signs and symptoms in immediate family members. Fortunately, the types of slow-growing, chronic infections in GWI can be diagnosed and successfully treated with multiple cycles of specific antibiotics.

There were several potential sources of chronic biological agents in the Persian Gulf Theater of Operations. First, deployed soldiers were given multiple inoculations of experimental vaccines in unproven immunization schemes, such as vaccines that were given all at once instead of using an appropriate schedule of inoculations. Multiple vaccinations given simultaneously can result in immunosuppression and leave an indivvidual susceptible to opportunistic infections. Some of these experimental vaccines could also have been contaminated with small amounts of slow-growing microorganisms. 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 biological sprayers that deliver biological weapons onto the sand to create exclusionary zones or 'biological minefields' adn at long range in modified SCUD-B (SS-1) missiles with 'skyburst' warheads. As mentinal above, many of the storage and factory facilities where chemical and biological weapons were stored were destroyed imediately up to, during and after the Desert Storm ground offensive, releasing plumes contianing 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 with little first-hand knowledge of the conditions on the ground. There are a number of possible reasons why the DoD and DVA deny that our forces were exposed to chemical and biological agents during the Gulf War, and several possibilities are listed in Figure 8.

Finally, can GWI be completely explained by chronic bacterial and/or other infections? The answer to this is no. GWI is not one disease; it appears to be a collection of various disorders and illnesses that produce complex chronic signs and symptoms. Desert Storm veterans were exposed to a variety of toxic agents in the Persian Gulf, including oil well fires, battlefield smoke, anti-nerve agents, insecticides, or multiple chemical agents, and in some cases radiological agents (DU), and many GWI patients now have multiple sensitivities to various chemicals because of these exposures. Chemical exposures can cause toxicological effects and produce many but not all of the signs and symptoms of GWI. In addition, chemical exposures can result in immunosuppression and leave an individual susceptible to infections. Future efforts should be directed at determining the types of exposures that occurred in the Persian Gulf region, including chemical, radiological and biological exposures and how combinations of these could be involved in causing chronic illnesses. In the case of biological agents or infections where treatments exists, controlled clinical trials willhave to be designed and initiated, and the necessary resources to conduct and evaluate these trials will have to be allocated. There is, however, a bonus from our efforts at understanding the role of chronic infections in GWI. We and other laboratories have now found similar chronic infections in a rather large subset of civilian cases of CFS and FM, patients with these illnesses have been diagnosed and successfully treated, and these patients are recovering after years of unexplained illness. Since there are over one million CFS/FM patients in the U.S. alone, this means that hundreds of thousands of Americans may be able to regain their health using the diagnostic tests and treatment suggestions developed for GWI.

We believe that Congress holds the key to solving the problem of GWI. This and associated disorders (CFS and FM) must be studied and solutions found using the peer-reviewed grant award system, such as that used by NIH. Efforts to direct funding away from or rebudget allocated funds for CFS and FM research, such as done over the last several years by NIH, should be stopped. GWI research and treatment cannot be left to the DoD and DVA, because they have not shown themselves to be especially effective or responsive to the health problems of afflicted Gulf War veterans and their family members. We consider it appropriate that civilian scientists and physicians collaborate closely with their counterparts in government to study this problem in as objective manner as possible. We thank you for the opportunity to address this important issue.