

**OVERSIGHT HEARING ON RESEARCH AND  
TREATMENT FOR GULF WAR ILLNESSES**

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**HEARING**  
BEFORE THE  
**COMMITTEE ON VETERANS' AFFAIRS**  
**UNITED STATES SENATE**  
ONE HUNDRED TENTH CONGRESS  
FIRST SESSION

SEPTEMBER 25, 2007

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## **OVERSIGHT HEARING ON RESEARCH AND TREATMENT FOR GULF WAR ILLNESSES**

**TUESDAY, SEPTEMBER 25**

U.S. SENATE,  
COMMITTEE ON VETERANS' AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 9:33 a.m., in room 562, Dirksen Senate Office Building, Hon. Daniel K. Akaka, Chairman of the Committee, presiding.

Present: Senators Akaka, Murray, Sanders, Craig, Burr, and Isakson.

### **OPENING STATEMENT OF HON. DANIEL K. AKAKA, CHAIRMAN, U.S. SENATOR FROM HAWAII**

Chairman AKAKA. This hearing on Research and Treatment for Gulf War Illnesses will come to order. Good morning, everyone.

Senators Sanders and Murray, asked that the Committee hold this hearing to focus on recent advances in research on the treatment of Gulf War illnesses, GWI. I want to commend them for insisting that we have this hearing. As we look into the background of this, it certainly is one that we need to hear about.

As Chairman, I must once again question whether DOD is protecting the health of troops and whether they are adequately monitoring American servicemembers' health before, during, and after deployments. This is a legitimate focus for our Committee. Today's troops are tomorrow's veterans. As servicemembers return from deployments abroad, many will separate from the military and become the newest generation of veterans. We need to ensure that VA has the capability to give these veterans the care they require.

We have this recent study on brain damage and evidence that suggests there may be an elevated rate of ALS among Gulf War veterans. Further, the National Academy of Sciences has found that service in the Gulf places veterans at increased risk for anxiety disorders, depression, and substance abuse problems.

Unfortunately, as we have heard time and again, the reasons for these illnesses may never be known because important records were not kept or were lost. In addition, DOD did not track the location of individual troops, making it difficult to identify patterns among those who have fallen ill. In short, DOD was not prepared to monitor and protect the health of troops during the Gulf War.

For whatever reasons, the health of our own troops was not safeguarded and many questions may remain forever unanswered. This raises a basic question for me, and that question is: Are troops now receiving more than pro forma pre- and post-deployment physical

examinations? The usefulness of these exams is not only critical to physical health, but for mental health, as well. A grateful Nation must never forget that the decision to send our young people into harm's way must always go hand in hand with the knowledge that it will be our responsibility to care for those who have served.

As I said, this Committee has called this hearing because of the insistence of some of our Members and we are looking forward to hearing from you. Let me now call on our Ranking Member, Senator Burr, for his statement.

**STATEMENT OF HON. RICHARD BURR,  
U.S. SENATOR FROM NORTH CAROLINA**

Senator BURR. Mr. Chairman, thank you and I thank our colleagues for joining us today.

Mr. Chairman, nearly 16 years ago, after the end of the Gulf War, questions about the health of those veterans who served in that conflict still spur passionate responses from tens of thousands of veterans across the country. This passion was ignited after many years spent fighting a government who told them it was all in their heads instead of trying to treat their illness, and that, quite frankly, was wrong.

What we now know is that as many as 175,000 veterans from the Gulf War report a whole host of illnesses and health difficulties that have affected their lives, their careers, and their families. Over the past 15 years, we have seen evidence of their suffering. Many of them suffer from fatigue, memory loss, joint pain, and skin rashes at significantly higher rates than those non-deployed Gulf War Veterans. We found evidence that suggests that ALS, a difficult and debilitating disease, seems to afflict veterans of this conflict at nearly twice the rate we would expect to see. And we have firsthand accounts of ill parents who are giving birth to ill children. They believe those illnesses were caused by their service in the Gulf War. One of those mothers is here with us this morning.

What we still don't know is why all of these people who shared the common experience of service in the Gulf War are suffering these problems. Over the past 15 years, our Nation has spent over \$300 million on research, yet we still don't have an answer. While I am frustrated by the lack of progress, I remain heartened by the fact that we know more now than we did when we started.

I am also heartened by what I see as an emerging consensus, and that is whatever the cause of the health problems experienced by Gulf War veterans, we know one thing: They are real. The best thing we can do now is to find out how to treat them.

To that end, Mr. Chairman, I would like to see our research efforts continue to focus heavily on the treatment of our veterans. If all of our scientific energy cannot provide an answer to why they are sick, I only hope that at least we can help them manage their illness.

Mr. Chairman, I look forward to hearing from the first panel about where we stand in the fight to care for those who fought, who fought for us in the Gulf War. I hope that we have done some things right instead of continuing to repeat past mistakes. And I hope to hear from our second panel, who will focus on what DOD

and VA are doing collectively to provide care and treatment to brave men and women who fought in the First Gulf War and many of whom are still fighting today.

However, Mr. Chairman, I have got to say that we are not off to a good start. Late yesterday afternoon, as I tried to prepare for today's hearing, I found that our witnesses from DOD and VA had yet to provide us their testimony. I think the Chairman has heard me raise this issue before, and I have researched the Committee rules and the Senate rules as best I can, and there is a requirement for 48 hours prior to a hearing that the testimony be in the Committee.

To those individuals who are here to testify today that testimony was not provided, this will end. I will work with the Chairman, I will work with my colleagues regardless of the administration to find a way for witnesses to meet the 48-hour rule. The issues that we take up today are way too serious for this Subcommittee not to have ample time to know what the testimonies are and, consequently, what our questions and our direction should be.

So, Mr. Chairman, I pledge to you and to my colleagues that we will find a way to resolve what I think is a continual problem of not providing testimony, regardless of how painful it is, and whether it is at OMB, whether it is at VA, or whether it is at DOD. I would suggest to the Chair that in the interim, if, in fact, we can't find a way to solve this, that we make sure, regardless of how high up the testimony comes from, that we make sure that those witnesses are, in fact, the last ones we hear from, and not the protocol being the first ones that we hear from, that we should require them to sit here for the duration of the hearing before they have an opportunity to testify.

Mr. Chairman, again, I want to thank you for holding this important hearing. I look especially forward to the testimony of the first panel and I will do my best to read the testimony of the second panel before they come up. Thank you.

Chairman AKAKA. Thank you very much, Senator Burr.

Using the early bird system here, I am going to call on Senator Isakson for your testimony, followed by Senator Murray.

**STATEMENT OF HON. JOHNNY ISAKSON,  
U.S. SENATOR FROM GEORGIA**

Senator ISAKSON. Thank you very much, Mr. Chairman. I will be brief. I want to welcome all of our panelists and thank them for being here today, particularly on our second panel. Dr. Michael Kilpatrick testified in Augusta at a field hearing I conducted at the Augusta VA in August and I appreciate his being here today. That is what I will address my few points about.

I am extremely concerned about us having the right research and the right longitudinal information to be sure we can treat our veterans of the Gulf War and of any conflict with the highest possible and best quality care, and there have been a number of problems. There are a few shining stars, though, and that Augusta VA hospital is one of them that I would like to just point out for a second as a part of the solution.

At the Augusta Hospital, DOD and Augusta have a seamless interchange where active duty troops rehabilitating from serious

injuries in the War for Iraqi Freedom actually go to VA and back again to DOD. It is a seamless handoff of treatment.

Second, the VA is critical to this entire thing because many of these afflictions, complications, or diseases take place years after service when these people are in the care of VA and they have that longitudinal information to match back with DOD.

Every city can't be like Augusta, where you have both a DOD hospital, being Eisenhower, and a VA hospital, being the Uptown VA Hospital. However, a number of our major cities in the United States have both a VA and a DOD hospital, and this is where you can truly have the coordination and that longitudinal information.

I just want to thank the Chairman for calling this most important hearing. I thank all of our witnesses for testifying today and I look forward to hearing their testimony. Thank you, Mr. Chairman.

Chairman AKAKA. Thank you very much, Senator Isakson.

I have another commitment this morning, so at this point I would like to hand the gavel to Senator Murray and will be reviewing the transcript later. Members of the Committee will regroup following the hearing and we will determine what follow-up the Committee will be taking.

Senator Murray has been a leader in this and also Senator Sanders. As a result, we have set this hearing and I would like to ask her to take the gavel at this point and for her to begin with her statement.

**STATEMENT OF HON. PATTY MURRAY,  
U.S. SENATOR FROM WASHINGTON**

Senator MURRAY [presiding]. Well, thank you very much, Mr. Chairman, and thank you for holding today's hearing on the latest research and treatment taking place for our Gulf War veterans' illness.

Let me just say, Senator Burr, I agree with you on the testimony and look forward to working with you to make sure that the agencies that we ask to come and testify before us get their material to us in a timely manner so we can be most effective. So I appreciate your comments on that.

I do want to recognize our first panel of witnesses who are here today and who have dedicated so much of their time to fighting for veterans who are afflicted with Gulf War illness, and I especially want to thank Julie Mock, who is from my home State of Washington and is president of the Veterans of Modern Warfare. Despite her very ill health and the disorders and diseases that her children struggle with, Julie flew all the way across the country here to Washington, DC, to testify about Gulf War illness and how it has affected her and her family. Julie is going to talk to us about the need for more research, better treatment, and improved access for Gulf War veterans. She is going to put a face and a story that is really important to the numbers that we are going to hear about today and speaks out for many, many others whom I have had the privilege to know and talk to and who couldn't be here today. Julie, I want to thank you for that, as well as all of our witnesses.

It has been 16 years since the Gulf War ended, and while for many Americans the conflict is nothing more than a distant mem-



ory, it remains a source of continuous anguish for thousands of veterans of that period who now suffer from chronic multi-symptom illness. This Committee held numerous hearings on Gulf War illness over the years, beginning in 1993, and those hearings explored the latest research and probed the possible causes of Gulf War illness. Since that time, our understanding of medicine has evolved, technology has improved, and more about that war has been uncovered. Yet the exact nature and cause of Gulf War illness remains disputed by many.

What is not disputed is that of the nearly 700,000 U.S. servicemembers who served in the Gulf War, about 30 percent of them suffer from chronic multi-symptom illness. Those veterans deserve to know that everything is being done to identify and connect all possible exposures to their illnesses. They need to know that their illnesses will be treated by the VA, and they need to know that every effort is being made to ensure that what happened to them will never happen to future generations of warriors.

Today's hearing is an opportunity to discuss the latest research and treatment options and to question whether current efforts are sufficient for improving the lives of veterans inflicted with Gulf War illness or if more needs to be done.

It has been said that those who ignore the past are doomed to repeat it, and I think it is with those words in mind that we are holding today's hearings. With more than 160,000 troops currently stationed in Iraq, we have to ensure that we are studying the lasting effects of the last time Americans were sent there. We must never forget the lessons of Vietnam and the horrors of Agent Orange that those exposures taught us. It is our responsibility to be proactive about the health and well-being of our men and women in uniform.

Today, we will have that opportunity to examine a disease and a group of veterans who are too often overlooked. I look forward to hearing from all of our witnesses this morning and I thank all of you for coming forward to address this problem.

We will now hear from Senator Sanders and Senator Craig and then hear from our witnesses.

**STATEMENT OF HON. BERNARD SANDERS,  
U.S. SENATOR FROM VERMONT**

Senator SANDERS. Thank you, Senator Murray, and thank you for all the work that you have done on this area, as well as Senator Akaka and many others.

Let me thank many of our panelists, I know Jim Binns and others, for their persistence on this issue. It would have been easy to sweep this issue under the rug and forget about it, but many of you and many who are not here today have continued to fight for recognition of the importance of this issue and to continue the focus on the enormous number of people who are suffering from what we call Gulf War illness.

And I think just the numbers themselves are startling. If you are talking about in a war where we suffered relatively few fatalities, to look at something like one in four people who served in the Gulf coming back with one or another symptom, that is an extraordinarily high number. It is absolutely imperative that we under-

stand what happened there, both in terms of treating as best we can those people who have been made ill, but also understanding the cause of why they have been made ill.

And one of the aspects of this whole issue that has interested me from day one is that a number of the symptoms that we see from Gulf War soldiers are symptoms that we see in civil society here in the United States of people who have never been to the Gulf War. What is the connection between the two? Whether it is fibromyalgia, whether it is multiple chemical sensitivity, whether it is short-term memory loss, whatever it may be, is there a connection between the two? So if we can get some of the answers here, not only could we ease the suffering of so many of our soldiers, we could also learn something that could be applied to the civil society, as well.

I think it is no secret, as many have already discussed, that there is a frustration, and I served on the Committee—in fact, when I was in the House, I don't think there is any issue that I spent more time on than this issue, and I spent dozens of hours with Chris Shays of Connecticut, who was then chairing the Subcommittee on the House Government Reform Committee that dealt with this issue, hearing with frustration from the Veterans' Administration, especially from the DOD, from the beginning when they would come forward and say, "No, there is no problem. Really, there is no problem." And then finally a few years later, they said, "Well, yes, there is a problem. It is a psychological problem. It is just in the heads of these people, and maybe they are malingerers. We don't know. Maybe they had other problems." And then finally more people came by and they said, "Well, you know, there really may be a problem." We see this guy who has lost 50 pounds, somebody else here died, ALS rates are very high. Maybe there is a problem. And on and on, it was like pulling teeth.

In recent years, however, I think we have been making some good results in learning a little bit more about it, and I think what our job is is to make sure that as we appropriate money, and we are working very hard to appropriate substantially more money to the research, that we target that money to those scientists who understand there is a problem and who are serious about finding an answer to this problem and not just putting it into a bureaucracy so that we keep hearing, oh, there is nothing there, we haven't found anything, and so forth and so forth.

New studies just released from a team from Boston University, VA and the Army have added to the compelling body of recent research showing that there are serious neurological conditions resulting from toxic exposures during the war. Ill veterans with five or more symptoms showed a loss of brain mass in MRI scans of areas related to memory and learning and also performed significantly worse on objective learning and memory tests. Veterans exposed to low levels of nerve gas following the destruction of a major Iraqi arms depo-in Khamisiyah, Iraq, showed a loss of brain white matter and poor performance on motor coordination tests equivalent to aging 20 years.

So we are beginning to make some progress. Madam Chair, I think we have got to continue focusing on the serious research that

is out there and I certainly look forward to working with you in that area. Thank you.

Senator MURRAY. Thank you very much.

Senator CRAIG?

**STATEMENT OF HON. LARRY E. CRAIG,  
U.S. SENATOR FROM IDAHO**

Senator CRAIG. Madam Chairman, thank you and I thank the Committee for this hearing today. I think Senator Sanders has said it as clearly as can be said. From a failure or unwillingness to recognize, I think we are now able to move beyond the idea of this being a single syndrome and recognize that there are a multitude of problems affecting our soldiers and I hope that is where ongoing research should be focused.

We have spent a lot of money on this issue and we unfortunately haven't had great results to date in helping those veterans who, in fact, suffer and have these kinds of experiences, both psychologically and physically. I would hope that a clearer direction can come from this hearing because there is no question that when well-directed, VA has done some outstanding medical research, some of the best in the country historically speaking and year after year we see that hold true. However, it is also true that in the private sector, we have the kind of research going on now that is critically important.

We have a phenomenal responsibility to our soldiers, sailors, airmen, and marines who fought to defend our national interests in the Gulf, and certainly we are grateful for their service and for their sacrifice. We must continue to treat these veterans and hopefully to bring about the kind of research and more importantly the kind of results that all of us want to see. We need some conclusiveness to this, some understanding of it beyond the hypothetical. Quality research that is ongoing can hopefully provide us that.

Again, Madam Chairman, thank you for the hearing today. I am sure it will add to the body of information that the Senate will need to be responsive to the needs of our veterans. Thank you all very much.

Senator MURRAY. Thank you, and we will now hear from our first panel. Each of you will be given a 5-minute time slot. Any testimony you don't have time to give us, we will submit for the record. But I want to again welcome all of you to this morning's panel.

We will first have James Binns. Mr. Binns is the Chairman of the Research Advisory Committee on Gulf War Veterans' Illnesses.

Next, we will have Julie Mock. As I said, she is President of Veterans of Modern Warfare and is a veteran of the Gulf War.

Next, we will hear from Dr. Meryl Nass from Mount Desert Island Hospital in Bar Harbor, Maine. She is the Director of Pulmonary Rehabilitation and is also a member of the Maine Commission to Improve the Health and Safety of Members of the National Guard.

We will then hear from Lea Steele. She is the Scientific Director of the Research Advisory Committee on Gulf War Veterans' Illnesses.

And finally, we will hear from Dr. Roberta White. She is the Chair of the Department of Environmental Health at Boston Uni-

versity's School of Public Health and recently published research on Gulf War illnesses that is of interest to our Committee today.

Again, I thank each of you for being here and your full statements will appear in the record of the Committee. Mr. Binns, we will begin with you.

Mr. BINNS. Madam Chairman, I would respectfully request if I could speak after Dr. Steele and Dr. White, as my testimony is predicated on theirs.

Senator MURRAY. I will be happy to comply with that, so Julie Mock, if you would like to begin, then.

**STATEMENT OF JULIE MOCK, GULF WAR VETERAN AND  
PRESIDENT, VETERANS OF MODERN WARFARE**

Ms. MOCK. Thank you for having me here this morning to share my life with you as a Gulf War veteran. It is an honor to be here representing my fellow veterans, those who live and those who have died early deaths as a result, presumably, of their exposures.

I served in the Persian Gulf War with the U.S. Army. I deployed with the 87th Medical Detachment Dental Services from Germany and served in theater with the 12th EVAC Hospital. Located roughly 30 kilometers from both the borders from Kuwait and Iraq, we were the first forward hospital open for patients. We also provided dental support for the 301st Military Police Camp EPWs.

During the months of January, February, and March 1991, we repeatedly experienced the loud alarms of chemical detectors. We ingested expired PB tablets. We wore masks with expired filters, inhaled dust and sand in the air that was thick with the black of burning oil smoke. I experienced respiratory difficulties, my skin grew hot with red rashes, and I began to suffer from debilitating headaches. Many of my contemporaries experienced many of the same or a combination of symptoms.

For a time, my husband, who is also a Persian Gulf War veteran, and myself were very ready to put the history of our experiences behind us and move forward with our lives and begin a family. It was after our children were born in 1995 and 1997 that we could no longer deny the possible significance of the pre-deployment vaccines we took before deployment to Saudi Arabia or the possible chemical environmental exposures we experienced while we were there.

Nor could we ignore the significant neurological challenges of our son. As our eldest son's first year passed and his second birthday approached, it was very clear that Stephen could not speak and he did not experience sensory events in a typical manner. Our hearts broke with each new diagnosis. He was severely dyspraxic. Not only would our son require aggressive speech therapy, but he was also diagnosed with a dangerous connective tissue disease, sensory integration disorder, hypotonia, sleep apnea, and learning disabilities, and eventually with bipolar disorder and Tourette's syndrome. Stephen, now 12, spent 7 weeks of his young life hospitalized in order to regulate his very irregular brain.

After a second difficult pregnancy requiring multiple hospitalizations to stop pre-term labor, we brought our youngest son home weighing just over four pounds. He, too, has struggled.

Tragically, as the needs of my children grew, my own symptoms significantly increased. I dismissed the continued physical symptoms until they began to affect my daily life and the lives and function of my family. Night sweats, fevers, tremors, joint and muscle pain, loss of muscle function, hair loss, fatigue, joint nodules, par-esthesia, and memory loss all occurred.

In 2003, I was referred to a neurologist. The lesion on my brain and the lesions in my spine were proof of my debilitating health and they provided me a diagnosis of multiple sclerosis. I could no longer take my children for walks, cook meals, or clean the house. The burden of our family situation at this time was hopeless and the stress and grief over our situation was unbearable. We were forced to move from our two-story home into a one-story rambler. I began relying on my cane more frequently and began wearing a stabilizing leg brace. My excruciating headaches necessitated trips to the emergency room.

All of my efforts and energy were focused on my children. The developmental and physical needs were significant and their demands overwhelming. Each child had weekly individual speech therapy and occupational therapy appointments. Although we have private health insurance, these rehabilitative therapies are not paid by insurance companies once a child reaches the age of 7 years. We soon found ourselves with medical expenses totaling nearly 15 percent of our annual income, after insurance payments. We are lucky we have private insurance.

We were thankful to find a private school prepared to help our son learn as only he can, never mind that I must travel 72 miles daily back and forth to get him to school and home again.

Both boys continue to receive developmental therapies. Stephen must be taught what most of us take for granted, forming sentences, self-expression, being able to realize his own hunger or tie his shoes when his fingers feel tingly. His anguish is devastating and it breaks my heart.

I have benefited from Solu-Medrol steroid infusions. Lesion activity has slowed, and my many other symptoms have become much more manageable. But I am far from a typical healthy 40-year-old woman. My headaches have forced me to the hospital three times this year alone, and any time after about 7:30 in the evening, I can be found with an approximately 60 percent deficit on the right side of my body. I have little skin bumps that grow and subside, depending on the severity of my neurological symptoms. On particularly bad days, my boys try to support me as I walk.

It is clear to my husband and myself that the exposures and vaccines that we received are more likely than not playing a large piece in the decline of my health. We have worked very hard to provide our sons with the best medical care available. More than one of their providers has taken an interest in our situation and offered to run a study on Gulf War children.

Most of the parents registered in my Gulf War veterans Yahoo! web group have stated that their children suffer from many of the same neurological symptoms as our children, or a combination thereof. At one time, the group represented nearly 100 children.

My children have the benefit of a unique bond resulting from their shared struggles. While they share the developmental strug-

gles, they encourage and help each other to a depth that is far beyond their years. Our lives differ greatly from those of our contemporaries. Before travel, we must arrange and prepare all of our medications. We must make certain that hotel rooms will accommodate their BI-PAPS, the machines that provide them nightly continued airway pressure, preventing their airway collapse.

My husband has thankfully remained healthy and he continues to serve in the U.S. Army Reserves. We have often spoken of our concern for the servicemembers who have taken pre-deployment vaccines and who are exposed daily to presumed and unknown environmental contaminants today. We believe that it is vital to the health of our most recent veterans that you continue to study the long-term health of Persian Gulf War veterans and our children. Please learn from what has happened to me, my family, and the lives, we believe, of at least 300,000 other Persian Gulf War veterans.

The Department of Defense acknowledged our exposures in letters sent to us in both 1997 and in 2001. There must be accountability for the health care of our ill veterans. A comprehensive VA registry must be funded to track Gulf War veterans and their children. This renewed family registry must be in place to record the progression of Gulf War veterans as well as the physical and neurological effects of our children.

The Veterans' Administration must also create an MS registry for Persian Gulf War veterans. We believe that many of our amalgamated symptoms are developing into diagnosable illnesses and diseases, such as brain cancer, ALS, and multiple sclerosis. We believe that a great many of our veterans who have received MRI diagnostic readings have been found to have brain and/or spinal lesions. These findings must be investigated to determine if our veterans are presenting with a typical or an atypical form of multiple sclerosis. Dedicated funding must be established to create a systematic and more standardized approach to diagnosing and treating the unique illnesses of our Gulf War veterans.

As a cohort, we are becoming increasingly debilitated. We won't let you forget. We won't let you leave us behind. Please help us and help our families.

[The prepared statement of Ms. Mock follows:]

PREPARED STATEMENT OF JULIE M. MOCK, PRESIDENT,  
VETERANS OF MODERN WARFARE, INC.

My name is Juliana M. Mock, President, Veterans of Modern Warfare, Inc., #33107 P.O. Box 96503 Washington, DC 20090-6503. It is an honor to come before you today and share with you my life as a Persian Gulf War veteran.

I served in the Persian Gulf War with the U.S. Army. I deployed with the 87th Medical Detachment (Dental Services) from Germany and served in-theater with the 12th EVAC Hospital.

Our group of 62 was dispatched into Northern Saudi Arabia in mid-December 1990 into an empty grid area that was marked by a dead camel. It is at this location that we spent our Christmas holiday wringing laundry with blistered hands just before the onset of a large sandstorm. It is also at this location that I would hear the first of a succession of chemical alarms.

At the end of December, my 12-person dental team was assigned to the 12th EVAC Hospital along Tapline Road. Located roughly 30 kilometers from both the borders of Iraq and Kuwait, we were the first forward hospital open for patients. We also provided dental support for the Iraqi EPW's at the 301st Military Police Camp.

During the months of January, February and March 1991, we repeatedly experienced the loud alarms of chemical detectors. We ingested expired pyrostigmine bromide tablets; we wore gas masks with expired filters, inhaled dust and sand in the air that was thick with the black of burning oil. I experienced respiratory difficulties, my skin grew hot with red rashes and I began to suffer from debilitating headaches. Many of my contemporaries experienced many of the same, or a combination of these symptoms.

For a time, my husband, also a Persian Gulf War veteran, and myself were very ready to put the history of our experiences and exposures in the Gulf far behind us and move forward with our lives and begin a family.

It was after our children were born in 1995 and in 1997 that we could no longer deny the possible significance of the pre-deployment vaccines we took before deployment to Saudi Arabia or the possible chemical and environmental exposures. Nor could we ignore the significant neurological challenges of our beautiful son. As our eldest son's first year passed and his second birthday approached, it was very clear that Stephen could not speak and that he did not experience sensory events in a typical manner. Our hearts broke with each new diagnosis. He was severely dyspraxic. Not only would our son require aggressive speech therapy, but he was also diagnosed with a dangerous connective-tissue disease which causes severe bruising that must constantly be monitored. He was diagnosed with an additional skin disorder, sensory-integration disorder, hypotonia, sleep apnea and learning disabilities and eventually with bipolar disorder and Tourette's Syndrome. Stephen, now 12, has spent 7 weeks of his young life hospitalized in efforts to regulate his very irregular brain.

After a second difficult pregnancy requiring multiple hospitalizations to stop preterm labor, we brought our youngest son home weighing just over four pounds. Although he was not nearly as challenged as his brother, he has struggled with auditory processing, sensory integration disorder, hypotonia and severe sleep apnea.

Tragically, as the needs of my children grew, my own symptoms significantly increased. I dismissed the continued physical symptoms until they finally began to affect my daily life and the lives and function of my family: hot red rashes, daily roving hives, night sweats, fevers, tremors, joint and muscle pain, loss of muscle function, hair loss, fatigue, joint nodules, paresthesia and memory loss.

In 2003, I was referred to a neurologist. The lesion on my brain and the lesions in my spine were found with MRI's and they provided us with proof of my debilitating health and a diagnosis of Multiple Sclerosis.

I could no longer take my children for walks, cook meals or clean the house. The burden of our family's situation at this time seemed hopeless and the stress and grief over our situation was unbearable. We were forced to move from our two-story home into a one-story rambler. I began relying on my cane more frequently and began wearing a stabilizing leg brace. My excruciating headaches necessitated trips to the emergency room.

All of my efforts and energy were focused on my children. Their developmental and physical needs were significant and their demands overwhelming. Each child had weekly individual speech therapy and occupational therapy appointments. Although we have private health insurance, these rehabilitative therapies are not paid by insurance companies once a child reaches the age of 7 years. We soon found ourselves with medical expenses totaling nearly 15 percent of our annual income—after insurance payments.

Our eldest son has seen his specialists on a regular basis: neurologist, hematologist, rheumatologist, psychiatrist, geneticist, neuropsychologist. We were thankful to find a private school prepared to help our son learn as only he can—never mind that I must travel 72 miles daily to get him to school and home again. And at 12, he is thankful to receive speech therapy at 8 a.m. on Mondays before we travel to his school. On Tuesdays he receives occupational therapy and he is learning assistive technology computer programs that will allow him to more successfully complete his school work and express his thoughts and ideas. And on Wednesday mornings, both of the boys receive sensory integration therapy before their school days begin. Stephen must be taught what most of us take for granted: forming sentences, self-expression, being able to realize his own hunger or tie his shoes when his fingers feel “tingly.” His anguish is devastating and it breaks my heart.

Some days I have help driving the boys to their schools. On the days I do not have help I return home and rest until I need to leave for the return trip to fetch them from school. Keeping our household clean is a challenge and we often must hire help.

I have benefited from Solu-Medrol steroid infusions. Lesion activity has slowed and my many other symptoms have become more manageable. But I am far from a typical, healthy 40-year old woman. My headaches have forced me to the hospital

3 times this year alone and any time after 7:30 p.m. I can be found with an approximately 60 percent deficit on the right side of my body. I have little skin bumps that grow and subside, depending on the severity of my neurological symptoms. On particularly bad days, my boys try to support me as I walk.

It is clear to my husband and myself that the exposures and vaccines that we received more likely than not have played a large piece in the decline of my own health. We have worked very hard to provide our sons with the best medical care available. More than one of their providers has taken an interest in our situation, our exposures and the neurological health of our children. More than one provider has stated that they believe it is plausible for our circumstances to have played a role in their deficits. And more than one provider has shown a strong interest in conducting a study focused on the neurological and physical health of Persian Gulf War veteran children.

We know persons who deployed with us in-theater who have not been healthy since their deployment and we know that there are many who have deteriorated slowly over the years and who are now in crisis. Most of the parents registered in my Gulf War Veterans with children yahoo! web group have stated that their children suffer from many of the same neurological challenges as our children. At one time, the group represented nearly 100 children. Parents reported a pattern of common denominators: severe speech impairments, fine and gross motor deficits requiring significant developmental intervention, learning disabilities, and blood and connective tissue disorders. Less common, although present, were the families reporting hydrocephalus and kidney disorders.

My children have the benefit of a unique bond resulting from their shared struggles. While they share their developmental struggles, they encourage and help each other to a depth that is far beyond their years. Our lives differ greatly from those of our contemporaries. Before travel, we must arrange and prepare all their medications. We must make certain that hotel rooms will accommodate their BI-PAPS the machines that provide them nightly continued airway pressure preventing airway collapse.

My husband has thankfully remained healthy and he continues to serve in the U.S. Army Reserves. We have often spoken of our concern for the servicemembers who have taken pre-deployment vaccines and who are exposed daily to presumed and unknown environmental contaminants.

We believe that it is vital to the health of our most recent veterans that you continue to study the long-term health of Persian Gulf War veterans and our children. Please, learn from what has happened to me, my family and the lives of at least 300,000 other Persian Gulf War veterans.

The Department of Defense acknowledged our exposures in letters sent in both 1997 and 2001. There must be accountability for the health care of our ill veterans. A comprehensive VA registry must be funded to track Gulf War veterans and their children. This renewed family registry must be in place to record the progression of Gulf War veterans, as well as the physical and neurological defects of our children.

The Veterans' Administration must also create an MS Registry for Persian Gulf War veterans. We believe that many of our amalgamated symptoms are developing into diagnosable illnesses and diseases, such as brain cancer, ALS and Multiple Sclerosis. We believe that a great many of our veterans who have received MRI diagnostic readings have been found to have brain and/or spinal lesions. These findings must be investigated to determine if our veterans are presenting with a typical or an atypical form of Multiple Sclerosis.

Dedicated funding must be established to create a systematic and more standardized approach to diagnosing and treating the unique illnesses of our veterans.

As a cohort, we are becoming increasingly debilitated. Please help us and help our families.

Senator MURRAY. Julie, thank you so much for coming and testifying today. I really appreciate it.

Dr. Nass?

**STATEMENT OF MERYL NASS, M.D., MOUNT DESERT ISLAND  
HOSPITAL, BAR HARBOR, MAINE**

Dr. NASS. Thank you. I practice internal medicine in Maine. I have a background in anthrax and biological warfare and have treated patients with multi-symptom illnesses, including Gulf War syndrome, for the last 8 years.



Gulf War veterans are certainly sick, and it is certain that a number of hazardous substances to which they were recklessly exposed caused their illnesses. The chronic neurological and psychological effects of sarin, pesticides, and solvents were known even before the 1999 war. We really don't need to keep studying this.

The approach of DOD and VA to these veterans has been callous. Their illnesses were denied, and when Congress insisted on researching the illnesses, DOD and VA developed a cynical research program focused on stress and psychiatric origins for the illnesses. Only a fraction of the research turned up anything of benefit to the veterans, and virtually none was geared toward curing them. Yet there has been no accountability.

DOD and VA created a mantra which they repeated over and over, "No unique Gulf War illness," which medically has no meaning, but it effectively minimized the illness and marginalized the ill.

This booklet, "A Guide to Gulf War Veterans' Health" a 3-hour training course for VA clinicians, not only repeats this mantra but also claims "VA has been able to respond to the complexity of veterans' health problems. Most are readily diagnosed and effective treatments are available." However, the treatments are primarily psychiatric drugs and cognitive behavioral therapy, despite a paucity of data to support their effectiveness.

This manual notes on page 19 that the Office of the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses operated under a three-part mission: (1) Gulf War veterans will receive appropriate medical care. (2) Two, DOD will do everything possible to understand and explain Gulf War illnesses. (3) DOD will put in place all required military doctrine, personnel, medical policies and procedures to minimize any future problems from exposure to environmental hazards and chem/bio agents. Yet the OSAGWI office and subsequent DOD efforts appear to have functioned, paradoxically, to avoid carrying out any part of this mission.

Physicians have still not been taught this is a real illness, let alone how to evaluate and care for the patients. The research portfolio continues to be, for the most part, irrelevant. Of the ten newest DOD-sponsored studies in this latest 2006 DVA Annual report to Congress on Gulf War illnesses, only two of the ten are about a medical treatment, but the treatment is for ALS, malaria, and Leishmania, which were diagnosed in only a very few veterans. Yet there remain huge gaps in the completed Gulf War research portfolio. The effects of infectious diseases acquired overseas, inhaled depleted uranium, pyridostigmine bromide, and vaccines have barely been touched.

As far as minimizing future problems from environmental hazards, has there been a 'lessons learned?' Were the chemical alarms explained? Were there recriminations over aerosolizing sarin on our troops? Are we now producing depleted uranium without adding in nuclear reactor waste? Have the recommendations of eight expert groups to study anthrax vaccine been carried out?

FDA has designated 670 of the 5,500 adverse event reports for anthrax vaccine filed since 1998 as serious. FDA defines serious as a death, a life-threatening event, an event requiring a hospitaliza-

tion or a permanent disability. Each of these 670 reports represents one life. Is anybody investigating them? The GAO (GAO-07-787R) told the Armed Services Committee in June that 1 to 2 percent of anthrax-vaccinated individuals “may experience severe adverse events which could result in disability or death.”

Deployed troops receive mandatory smallpox vaccine, although one in 150 recipients will develop heart muscle inflammation as a result. Some will have permanent damage. Smallpox vaccine probably contributed to mystery pneumonias and premature cardiac deaths in soldiers. Where is the risk-benefit analysis for the use of this vaccine, which was too toxic for a civilian vaccination program?

DOD has a short-term, mission-oriented view. That is its job. Congress has the responsibility to require DOD to place a much higher priority on the long-term health of its servicemembers. In my view, solving the problem will require a new Federal agency to oversee drug and vaccine safety, since FDA’s safety staff have no regulatory authority and CDC safety studies have received much criticism. DOD’s grants to these agencies may have decreased their interest in challenging and regulating DOD’s use of licensed and unlicensed drugs and vaccines.

Similarly, there is no excuse for military bases to house some of the Nation’s worst toxic waste dumps. Stronger regulation by OSHA could improve the training of soldiers in the handling and disposal of toxic substances.

A new agency to manage the three missions given OSAGWI—research, treatment, and prevention of future Gulf War-like events—is a minimum requirement if we are to finally get serious about Gulf War illnesses. It is a debt we owe our veterans now, 16 years after the end of the Gulf War. Thank you.

[The prepared statement of Dr. Nass follows:]

PREPARED STATEMENT OF MERYL NASS, M.D., MOUNT DESERT ISLAND HOSPITAL,  
BAR HARBOR, MAINE

Thank you very much for your invitation to discuss Gulf War Illnesses and ideas for improved research and treatment of affected veterans. I practice general internal medicine, have a background in bioterrorism, anthrax and vaccine injuries, and have conducted a clinic for Gulf War (GW) veterans and others with multi-symptom syndromes (fibromyalgia, chronic fatigue syndrome, multiple chemical sensitivity) since 1999.

Because so much confusion and controversy has surrounded this illness, I thought it would be helpful to discuss persisting issues using a question and answer format, while reviewing recent literature on Gulf War Illnesses. I hope to clarify what is already known, as well as what needs to be known in order to provide the best treatment to affected veterans. I will then discuss my treatment approaches. I use the terms Gulf War Illnesses (GWI) and Gulf War Syndrome (GWS) interchangeably.

#### 1. WHAT IS GULF WAR SYNDROME?

As early as 1993, Senator Donald Riegle’s staff produced a report that said, “Over 4,000 veterans of the Gulf War suffering from a myriad of illnesses collectively labeled ‘Gulf War Syndrome’ are reporting symptoms of muscle and joint pain, memory loss, intestinal and heart problems, fatigue, running noses, urinary urgency, diarrhea, twitching, rashes and sores.”<sup>1</sup> In 1998 CDC developed a case definition of the illness, which omits some common symptoms, but confirms the illness Riegle’s staff identified, and provides clinicians with a reasonable basis for diagnosing vet-

<sup>1</sup> Staff report to Senator Donald Riegle. Gulf War Syndrome: The case for multiple origin mixed chemical/biotoxin warfare related disorders. September 9, 1993.

erans and starting treatment. So there is a long, well-documented history of the reality of this illness.

Yet many physicians are unaware of the CDC case definition, and have been bamboozled by the media into thinking Gulf War Illnesses either do not exist, are psychosomatic or a result of stress. Surprisingly, this includes physicians at VA facilities who care for affected patients. This widespread ignorance is compounded by the VA treatment guidelines (posted on the VA web site for clinicians), which emphasize the use of psychotropic medications and cognitive behavioral therapy, although the science to support this is exceedingly weak.<sup>2</sup>

An estimated 200,000 1991 Gulf War veterans (25–30 percent of all deployed veterans) and some vaccinated, nondeployed Gulf “era” veterans suffer from illnesses related to their service,<sup>3</sup> and have been awarded partial or full disability benefits by the VA. Although the signs, symptoms and severity of illness vary considerably between affected veterans, the combination of symptoms known as “Gulf War Syndrome” probably affects most of the 200,000 veterans who are ill.

Their symptoms are not confined to the CDC’s defining triad of musculoskeletal pain, fatigue and cognitive and/or emotional disturbance.<sup>4</sup> Their medical conditions have been variously described in different studies. For example, one UK study found that Gulf War veterans were 20 times as likely as other veterans to complain of mood swings, 20 times as likely to complain of memory loss and/or lack of concentration, and 5 times as likely to complain of sexual dysfunction.<sup>5</sup> It is my opinion that the increased mental disorders reported in GW veterans<sup>6</sup> reflect central nervous system (brain) dysfunction, manifested in a variety of ways.

Furthermore, some affected veterans have developed anxiety and/or depression as a result of their loss of function, as well as frustration resulting from the lack of validation of their illnesses by DOD, VA and civilian health providers, and failure to receive beneficial treatment. Many veterans have endured the suspicion of military superiors and colleagues, friends and family that they are malingering, a result of the mediocre level of much popular and professional discourse about this illness.

## 2. CAN WE MAKE MEDICAL SENSE OF THE MULTIPLE SYMPTOMS THAT OCCUR IN GULF WAR VETERANS?

According to Gronseth, “Although an objective marker to GWS would be useful for studies, the absence of such a marker does not make the syndrome any less legitimate. . . . The real debate surrounding medically unexplained conditions is not whether or not they exist, but defining their cause.”<sup>7</sup>

Many patients with GWS meet criteria for other medically unexplained conditions, also known as multi-symptom syndromes, such as chronic fatigue syndrome,<sup>8</sup> fibromyalgia, and multiple chemical sensitivity.<sup>9</sup> These conditions are poorly understood, but have a very similar pattern of symptoms and findings as GWS. Some underlying mechanisms have been shown to be the same as well.<sup>10</sup>

An important VA study in which 1000 deployed 1991 Gulf War and 1,000 non-deployed Gulf era veterans were carefully examined 10 years after the Gulf War, found that deployed veterans were 2.3 times as likely to have fibromyalgia, and 40.6

<sup>2</sup>Donta ST, Clauw DJ, Engel CC Jr. et. al. Cognitive behavioral therapy and aerobic exercise for Gulf War veterans’ illnesses: a randomized controlled trial. *JAMA*. 2003 Mar 19;289(11):1396–404.

<sup>3</sup>Steele L. Prevalence and patterns of Gulf War illness in Kansas veterans: association of symptoms with characteristics of person, place, and time of military service. *Am J Epidemiol*. 2000 Nov 15;152(10):992–1002.

<sup>4</sup>Fukuda, K. et. al. Chronic Multi-symptom Illness Affecting Air Force Veterans of the Gulf War. *JAMA* 1998; 280: 981–988. “. . . a case was defined as having 1 or more chronic symptoms (more than 6 months) from 2 of the following categories: fatigue; mood and cognition; and musculoskeletal.”

<sup>5</sup>Simmons R, Maconochie N, Doyle P. Self-reported ill health in male UK Gulf War veterans: a retrospective cohort study. *BMC Public Health*. 2004 Jul 13;4:27.

<sup>6</sup>Toomey R, Kang HK, Karlinsky J et. al. Mental health of US Gulf War veterans 10 years after the war. *Br J Psychiatry* 2007; 190: 385–93.

<sup>7</sup>Gronseth GS. Gulf war syndrome: a toxic exposure? A systematic review. *Neurol Clin*. 2005 May;23(2):523–40.

<sup>8</sup>Thomas HV, Stimpson NJ, Weightman AL et. al. Systematic review of multi-symptom conditions in Gulf War veterans. *Psychol Med* 2006; 36: 735–47.

<sup>9</sup>*Ibid.*

<sup>10</sup>Baraniuk JN, Casado B, Maibach HA. Chronic Fatigue Syndrome—related proteome in human cerebrospinal fluid. *BMC Neurol*. 2005 Dec 1;5:22.

times as likely to have chronic fatigue syndrome as nondeployed era veterans,<sup>11</sup> confirming a relationship between these conditions and GWS.

### 3. DOES THE CDC CASE DEFINITION IDENTIFY ALL DEPLOYMENT-RELATED ILLNESSES IN GULF WAR VETERANS?

No. We know ALS (amyotrophic lateral sclerosis or Lou Gehrig's disease) occurs twice as often in GW vets as in the civilian population, but it also occurs 50 percent more often in soldiers in general.<sup>12</sup> The military exposures leading to these increased ALS rates are unknown.

Possible reasons ALS has been studied more carefully in GW veterans than other illnesses, are that (a) veterans develop the illness at a younger age than the civilian population,<sup>13</sup> (b) Congressional testimony by affected, now deceased Gulf War veteran Michael Donnelly in 1997 gave the illness visibility,<sup>14</sup> and (c) ALS only affects a small number of people.

Chronic diarrhea is another illness commonly seen in GW veterans, but it is not included in the CDC's case definition. GW veterans have developed a variety of other medical illnesses. What we still don't know is whether there are, for instance, more heart attacks in deployed GW veterans than there would have been, had they not deployed. The research is contradictory on whether various illnesses occur more often in Gulf War veterans, although several studies list a large number of symptoms that are seen more commonly in GW veterans.

### 4. WHY DON'T WE KNOW WHETHER DEPLOYED VETERANS HAVE MORE ILLNESSES (LIKE HEART ATTACKS) THAN THEY WOULD HAVE OTHERWISE?

The results of research depend on the methods used to investigate the research question. Epidemiological research is limited to evaluating a statistical relationship between an exposure and an illness. But statistically significant relationships occur for many reasons other than cause and effect. Thus, statistics alone cannot prove cause and effect. Only when all other factors that can bias the result have been taken into account, will the results be reliable. Here is one example of why some Gulf War research results may be contradictory:

As Steele<sup>15</sup> showed, many nondeployed Gulf "era" veterans were given vaccinations in preparation for deployment, and these vaccinated "era" veterans reported multi-symptom illness at 3 times the rate of unvaccinated, nondeployed "era" veterans.

According to the military's Defense Medical Surveillance System (DMSS) raw data, soldiers vaccinated with anthrax vaccine have heart attacks at a greater rate than prior to vaccination.<sup>16</sup> Thus, if deployed veterans are compared to a non-deployed group, of whom many received deployment vaccines, determining whether deployed veterans have more heart attacks than expected is confounded (made unreliable) by the nondeployed group's vaccinations.

Military and VA health databases have not been made available to independent researchers to study.

### 5. HAS THE HEALTH OF GULF WAR VETERANS IMPROVED OVER TIME?

Veterans who developed this syndrome have, for the most part, remained ill.<sup>17</sup> Ten years later, one study found that 29 percent of deployed veterans had chronic, multi-symptom illness.<sup>18</sup>

<sup>11</sup> Eisen SA, Kang HK, Murphy FM et. al. Gulf War veterans' health: medical evaluation of a US cohort. *Ann Intern Med* 2005; 142: 122.

<sup>12</sup> Weisskopf MG, O'Reilly EJ, McCullough ML et. al. Prospective study of military service and mortality from ALS. *Neurology* 2005;64(1):32-7.

<sup>13</sup> Haley RW. Excess incidence of ALS in young Gulf War veterans. *Neurology*. 2003 Sep 23;61(6):750-6.

<sup>14</sup> <http://members.aol.com/vetcenter1/donnelly.htm>.

<sup>15</sup> Steele L. Prevalence and patterns of Gulf War illness in Kansas veterans: association of symptoms with characteristics of person, place, and time of military service. *Am J Epidemiol*. 2000 Nov 15;152(10):992-1002.

<sup>16</sup> Data DOD shared with the Institute of Medicine in 2001: <http://merylnass.googlepages.com/AMSAtitlepage.pdf>; <http://merylnass.googlepages.com/AMSAHeartattackdata.pdf>

<sup>17</sup> Ozakincy G, Hallman WK and Kipen HM. Persistence of symptoms in veterans of the First Gulf War: 5-year follow-up. *Environ Health Perspectives* 2006; 114: 1553-7.

<sup>18</sup> Blanchard MS, Eisen SA, Alpern R et. al. Chronic multisymptom illness complex in Gulf War 1 veterans 10 years later. *Am J Epidemiol* 2006; 164: 708-9.

## 6. DO GW VETERANS DIE AT A HIGHER RATE?

Three studies have demonstrated that GW veterans had an approximately 50 percent greater risk of accidental deaths, particularly from motor vehicle accidents. Although this has been attributed to elevated risk-taking behavior in deployed GW soldiers by some, others (including myself) suspect it is at least partly related to the cognitive problems faced by GW veterans, particularly their difficulties with attention and concentration.

One study found that testicular cancer rates were increased in Persian Gulf War veterans.<sup>19</sup> This is usually a curable cancer that occurs in young males, so would not be expected to increase overall mortality rates significantly.

Other statistical studies have shown no more deaths and no more birth defects in offspring of GW soldiers than in comparable groups. However, was the control group truly comparable? Deployed troops are known to be much healthier than a group of age and sex-matched civilians, and this is commonly termed the “Healthy Warrior” effect. But they may also be healthier than the Gulf “era” troops who were not deployed, although “era” troops usually form the comparison group.

Steele showed that in Kansas veterans, the rate of multi-symptom illness varied by deployment location.<sup>20</sup> Since different units had very varied exposures during their deployments, high rates of birth defects and/or deaths in certain units are possible. Yet the types of large epidemiological studies that have been performed have usually obscured possible localized effects of service in the Gulf.

## 7. SELF REPORTS

The validity of studies of GW veterans’ health and exposures has been criticized on the basis that the exposure and illness data are reported by veterans, and not obtained from more reliable sources, such as military or VA databases. Some measures of current health could be obtained from those databases, but the data would be incomplete. Exposure data have not been a part of the available record for most veterans. Exposure data that have been supplied by DOD have been unreliable (in terms of the Khamisiyah plume modeling, according to GAO<sup>21</sup>) or the data contradicted the self-reports (as in immunization data supplied by DOD to VA, following presentation of a VA study that linked anthrax vaccinations to subsequent ill health<sup>22</sup>), or the data are missing or classified. The number, names and locations of all sites at which chemical warfare agents were exploded remain unknown to the public.

Are self-reports valid? two recent studies indicate that GW veterans give reliable answers to questions.<sup>23</sup> A study that compared GW veterans with Gulf era veterans’ performance on neuropsychological examinations found that only 1 percent of GW veterans provided “noncredible” exams versus 4 percent of era veterans.<sup>24</sup> Therefore, self-reports by GW veterans can safely be judged credible.

## 8. WHY HAS THE REALITY OF GULF WAR SYNDROME BEEN SO CONTENTIOUS?

Perhaps remarks by Alabama Congressman Glen Browder in a 1993 House Armed Services Oversight and Investigations Subcommittee meeting shed some light on this:

<sup>19</sup>Levine PH, Young HA, Simmens SJ et. al. Is testicular cancer related to Gulf War deployment? Evidence from a pilot population-based study of Gulf War veterans and cancer registries. *Mil Med* 2005; 170: 149–53.

<sup>20</sup>Steele L. *Op. cit.*

<sup>21</sup>GAO–04–821T. June 1, 2004: “The modeling assumptions . . . were inaccurate because they were uncertain, incomplete and nonvalidated.” “DOD and VA’s conclusions about no association between exposure to CW agents and rates of hospitalization and mortality . . . cannot be adequately supported because of study weaknesses.”

<sup>22</sup>Mahan CM, Kang HK, Dalager NA. Anthrax vaccination and self-reported symptoms, functional status, and medical conditions in the National Health Survey of Gulf War Era Veterans and Their Families. *Ann Epidemiol.* 2004 Feb;14(2):81–8.

<sup>23</sup>Kelsall HL, Sim MR, Forbes AB et. al. Symptoms and medical conditions in Australian veterans of the 1991 Gulf War: relation to immunisations and other Gulf War exposures. *Occup Environ Med.* 2005 Mar;62(3):142–3. “More than 10 years after the 1991 Gulf War, Australian veterans self-report all symptoms and some medical conditions more commonly than the comparison group. Further analysis of the severity of symptoms and likelihood of the diagnosis of medical conditions suggested that these findings are not due to over-reporting or to participation bias.”

<sup>24</sup>Barrash J, Denburg NL, Moser DJ et. al. Credibility of neuropsychological performances of Persian Gulf War veterans and military control subjects participating in clinical epidemiological research. *Mil Med* 2007; 172: 697–707.

“I have asked a lot of questions about why the Pentagon continues to stonewall these Gulf War veterans, or why are they so resistant to full and open examination of this problem. I don’t have any conclusive answers but I can speculate.

First, it may be pride. To acknowledge these mystery casualties may blemish our Persian Gulf victory. Or, such an acknowledgement may be a terrifying admission that the United States did not and perhaps cannot protect our military men and women against chemical and biological warfare.

But I personally suspect that dealing openly and fully with these mystery ailments, and therefore the dirty little secret, will require the Pentagon to make budgetary and programmatic adjustments that it does not want to make.”<sup>25</sup>

Military doctrine calls for continuing use of anthrax and smallpox vaccines, multiple simultaneous vaccinations, pyridostigmine bromide tablets for prophylaxis of nerve gas exposure and depleted uranium munitions and armor. Thus, military studies that concluded these exposures were safe should come as no surprise. Yet evidence of their adverse effects on health is abundant.

The American Type Culture Collection (ATCC) supplied various microbial cultures to Iraq, in shipments approved by the Department of Commerce, during a period in which the United States assisted Iraq in its war with Iran. This may have influenced why infections due to *Brucella melitensis*, one of the bacteria provided to Iraq, were not investigated. Vollum<sup>26</sup> strain anthrax (which had been weaponized by the US military before the Biological Weapons Convention came into force in 1975) was provided to Iraq by ATCC. Knowing a U.S. corporation provided Iraq virulent anthrax (not a strain used to make vaccines) may have influenced the defense department’s decision to vaccinate troops against anthrax. Similarly, the ATCC provided *Clostridium botulinum* to Iraq; some soldiers were later vaccinated for potential exposure to botulinum toxins.

Admitting that soldiers became ill as a consequence of what the US gave Iraq may be politically unacceptable, undermining the likelihood that credible scientific studies of these exposures, funded by the government, would be performed.

According to the House Committee on Government Reform and Oversight in 1997,

“VA medical policy may have been biased against findings of chemical exposure by relying on DOD assertions and unproven theories of toxic causation.

VA continues today to maintain that chronic symptoms in Gulf War veterans cannot be attributed to toxic exposures unless acute symptoms first appear at the time of exposure.”<sup>27</sup>

Yet the requirement for acute symptoms to occur in order to be harmed by chemical weapons (organophosphates) is scientifically insupportable.

Investigating certain GW exposures has been a career killer. While some researchers were amply rewarded for finding stress/psychological causes for Gulf War Illnesses, other researchers were punished for exploring politically unacceptable causes:

- Jim Moss, Ph.D. on pyridostigmine potentiation research: “Middle and upper level management at USDA promised me I would be blackballed if I did not stop the research, or if I ever disclosed my research to anybody (this was before I appeared before the Senate VA Committee). My biggest regret from my 1994 Senate VA Committee testimony has been that I did not tell the Committee about the threats.”<sup>28 29</sup>

- Charles Gutierrez, M.S., found microorganisms resembling *Brucella melitensis* in stools of dozens of Gulf War veterans in Tennessee, but had his studies halted: “In the years following the Persian Gulf War, extensive clinical studies on samples from Persian Gulf War veterans were performed at the James Quillen VA in Moun-

<sup>25</sup> Use of chemical weapons in Desert Storm. Hearing before the Oversight and Investigations subcommittee of the Committee on Armed Services, House of Representatives. 103d Congress, 1st session. November 18, 1993.

<sup>26</sup> Identified by Geoffrey Holland, who investigated the provenance of the ATCC anthrax strains supplied to Iraq. <http://www.abc.net.au/worldtoday/content/2005/s1434633.htm>.

<sup>27</sup> House Committee on Government Reform and Oversight. Gulf War Veterans’ Illnesses: VA, DOD continue to resist strong evidence linking toxic causes to chronic health effects. November 7, 1997. House Report 105–388. 105th Congress, 1st Session.

<sup>28</sup> Personal communication, September 17, 2007.

<sup>29</sup> Chaney LA, Rockhold RW, Mozingo JR, Hume AS, Moss JI. Potentiation of pyridostigmine bromide toxicity in mice by selected adrenergic agents and caffeine. *Vet Hum Toxicol*. 1997 Aug;39(4):214–9.

<sup>30</sup> Personal communication, September 17, 2007.

tain Home, Tennessee. This work was not adequately pursued by the VA, and was instead ordered stopped. The findings in these patients need to be addressed, as they may fill in gaps in the existing body of GW illness research.”<sup>30</sup>

- Garth Nicolson, Ph.D., on mycoplasma studies: “ I was told by the President of my institution (the Univ. of Texas M.D. Anderson Cancer Center) to stop my GWI research or face disciplinary action. I refused to stop my research, and my professional career, academic position (and any possible future academic position) were destroyed by character assignation and outright lies about my research activities. This occurred even though our work was published in peer-reviewed academic journals. This was described in our book Project Day Lily ([www.projectdaylily.com](http://www.projectdaylily.com)).”<sup>31 32 33</sup>.

#### 9. HOW IS IT THAT FEDERAL PUBLIC HEALTH “WATCHDOG” AGENCIES AND OVERSIGHT MECHANISMS FAILED TO PREVENT THE PUBLIC HEALTH DISASTER OF GWS?

- Federal agencies that could have weighed in on the safety of drugs and vaccines given to soldiers in the Gulf have become politicized, and their decision-making processes are opaque. The regulation of toxic substances is fragmented, overseen by a variety of agencies. Recent FDA decisions, and the agency’s structure, suggest safety has a low priority.

- FDA permitted use of unlicensed drugs and vaccines, and use of licensed products for unproven purposes, during the Gulf War and later

- FDA repeatedly approved anthrax vaccine use for bioterrorism preparedness in the absence of required human data demonstrating effectiveness, and despite ample evidence of safety concerns

- Astonishingly, FDA drug and vaccine safety experts have no regulatory authority<sup>34</sup>

- FDA “safety experts work largely in isolation, with limited resources and outdated technology.”<sup>35</sup>

- “The FDA has bungled its effort to build a new system for detecting the side effects of medicines after they go on the market, delaying its implementation by at least 4 years, according to a report commissioned by the agency itself . . . the FDA has wasted an estimated \$25 million on its efforts.”<sup>36</sup>

- CDC continues to misinform recipients of anthrax vaccine with an official Vaccine Information Statement affirming vaccine safety that is in conflict with the vaccine’s FDA-approved package insert,<sup>37</sup> and what CDC officials told GAO about adverse events following vaccination. The GAO, citing CDC and Vaccine Healthcare Center officials as sources, reported that 1–2 percent of anthrax-vaccinated individuals “may experience severe adverse events, which could result in disability or death,” in June 2007.<sup>38</sup>

- CDC conducted a trial of anthrax vaccine in 1,564 people beginning in 2002 and provided an interim report on the study to FDA. Yet CDC has released no information to the public about the trial findings, despite filing over 100 adverse event reports on trial subjects to the Vaccine Adverse Event Reporting System.

- These Federal agencies know that injured military servicemembers are prevented by the Feres Doctrine<sup>39</sup> from seeking a remedy for their injuries through the legal system.

- There are no viable legal remedies to hold military or government personnel accountable for deliberate cover-ups resulting in denial of healthcare and disability benefits mandated by Federal law.

<sup>30</sup> Personal communication, September 17, 2007.

<sup>31</sup> Personal communication, September 17, 2007.

<sup>32</sup> Nicolson GL, Nasralla MY, Haier J, Pomfret J. High frequency of systemic mycoplasmal infections in Gulf War veterans and civilians with Amyotrophic Lateral Sclerosis (ALS). *J Clin Neurosci*. 2002 Sep;9(5):525–9.

<sup>33</sup> Nicolson GL and Nicolson NL. Diagnosis and treatment of mycoplasmal infections in Persian Gulf War illness patients. *Journal of Occupational Medicine, Immunology and Toxicology* 5: 69–78, 1996.

<sup>34</sup> Smith SW. Sidelining safety—the FDA’s inadequate response to the IOM. *NEJM* September 6, 2007. 960–3.

<sup>35</sup> *Ibid*.

<sup>36</sup> Mathews AW. Report blasts FDA’s system to track drugs. Consultant says mission is hobbled by missteps; agency disputes claims. *Wall Street Journal*. March 3, 2007.

<sup>37</sup> <http://www.fda.gov/OHRMS/DOCKETS/98fr/05n-0040-bkg0001.pdf>.

<sup>38</sup> GAO–07–787R. Military Health: DOD’s Vaccine Healthcare Centers Network. June 29, 2007. Web address: <http://www.gao.gov/cgi-bin/getrpt?GAO-07-787R>.

<sup>39</sup> <http://usmilitary.about.com/library/milinfo/blferes.htm>.

9. WHAT GULF WAR EXPOSURES DID SOLDIERS FACE, AND WHAT DO WE KNOW ABOUT THE INJURIES THEY MAY CAUSE?

(a) *Depleted uranium (DU)*

DU is comprised of uranium that has had 40 percent of its radioactive isotope, uranium-235, extracted. However, the DU used by the United States military also contains “recycled” nuclear reactor waste, including small amounts of highly radioactive plutonium-239, neptunium-237, technetium-99, americium etc.<sup>40 41</sup>

Both munitions and armor may be made from DU. When a DU munition strikes an object, or when DU armor is struck, it ignites and up to 50 percent of its mass can aerosolize into minute particles that may be inhaled and will contaminate the area for the foreseeable future. Inhaled DU may have prolonged retention in the lungs, accumulates in specific brain regions (in rat experiments)<sup>42</sup> and settles in bone. Inhaled DU led to behavioral effects in animals.<sup>43</sup> It is excreted by the kidneys. Its toxicity is both chemical and radiological.

The only veterans who have been studied longitudinally for DU exposure comprise a small group with embedded DU shrapnel. They have shown limited findings of genotoxicity and are otherwise well,<sup>44</sup> but have a “relatively low uranium burden compared to historical uranium-exposed controls.”<sup>45</sup> However, other veterans with inhalation exposures are probably at greater risk of DU toxicity. One study found that reported exposure to DU doubled the risk of dying from disease.<sup>46</sup> (Reported pesticide exposure in this study doubled the likelihood of accidental death.)

Consider that the recycled nuclear materials added to DU may not be evenly dispersed. If so, there are likely some veterans with greater exposure to highly radioactive materials, who are at increased risk of cancers, immune and reproductive effects. Recent evidence also points to uranium as an endocrine disruptor.<sup>47</sup>

If we review the health of workers in uranium processing plants, we can obtain clues about what to expect in DU-exposed veterans. Uranium workers have had elevated rates of cancers, especially kidney and respiratory tract cancers. They also had elevated levels of chronic kidney disease.

The Energy Employee Occupational Illness Compensation Program Act of 2000 (P.L. 106–398) established a “special cohort” of workers employed at three Department of Energy uranium gaseous diffusion plants and Alaska’s nuclear test site: because of the absence of exposure records, and the presence of ultra hazardous workplace exposures, the burden of proof has been shifted to the government for ill workers at these facilities.<sup>48</sup> The combination of an ultra hazardous workplace and absent exposure records<sup>49</sup> mirrors the plight of Gulf War veterans, and suggests to us that burden of proof requirements could be changed for veterans who suffer from illnesses characteristic of their toxic exposures.

“Personal medical records of veterans, including sick call records, are inadequate or missing. Documents which could help verify possible exposures and military unit locations remain in DOD files. Most of the military NBC logs, which are records of toxic warfare agent detections, are missing or destroyed . . .”

(b) *Sarin*

Sarin is an organophosphate “nerve” agent or anticholinesterase, which leads to excessive accumulation of the neurotransmitter acetylcholine at nerve synapses. It

<sup>40</sup> <http://www.nato.int/du/docu/d010118b.htm>.

<sup>41</sup> Alvarez R. The legacy of depleted uranium in the United States. Institute for Policy Studies monograph. June 2003.

<sup>42</sup> Fitsanakis VA, Erickson KM, Garcia SJ et al. Brain accumulation of depleted uranium in rats following 3- or 6-month treatment with implanted depleted uranium pellets. *Biol Trace Elem Res* 2006; 111: 185–97.

<sup>43</sup> Monleau M, Bussy C, Lestaevael P et al. Bioaccumulation and behavioural effects of depleted uranium in rats exposed to repeated inhalations. *Neurosci Lett*. 2005 Dec 16;390(1):31–6.

<sup>44</sup> McDiarmid MA, Engelhardt SM, Oliver M et al. Health surveillance of Gulf War 1 veterans exposed to depleted uranium: updating the cohort. *Health Phys* 2007; 93: 60–73.

<sup>45</sup> McDiarmid MA, Engelhardt SM, Oliver M et al. Biological monitoring and surveillance results of Gulf War 1 veterans exposed to depleted uranium. *Int Arch Occup Envir Health* 2006; 79:11–21.

<sup>46</sup> MacFarlane GJ, Hotopf M, Maconochie N et al. Long-term mortality amongst Gulf War veterans: is there a relationship with experiences during deployment and subsequent morbidity? *Int J Epidemiol* 2005; 34: 1403–8.

<sup>47</sup> Raymond-Whish S, Mayer LP, O’Neal T et al. Drinking water with uranium below US EPA water standard causes estrogen receptor-dependent responses in female mice. *Envir Health Perspectives* 2007; online September 14, 2007.

<sup>48</sup> Alvarez R. *Op. cit.*

<sup>49</sup> Committee on Government Reform and Oversight. Gulf War Veterans’ Illnesses: VA, DOD continue to resist strong evidence linking toxic causes to chronic health effects. Second Report. November 7, 1997. 105th Congress, 1st session. Page 61.



is in the same family as pesticides such as parathion and malathion. A recent study found a significant association between levels of estimated sarin/cyclosarin exposure and reduced white matter in the brain.<sup>50</sup> The same researchers also found that “Sarin and cyclosarin exposure was associated with less proficient neurobehavioral functioning on tasks involving fine psychomotor dexterity and visuospatial abilities 4–5 years after exposure.”<sup>51</sup>

According to the Congressional Office of Technology Assessment (OTA) in 1990:

“Of particular concern are the delayed neurotoxic effects of some of the organophosphorous (organophosphate) insecticides. Some of these compounds cause degeneration of nerve processes in the limbs, leading to changes in sensation, muscular weakness and lack of coordination. Because of this property, the EPA requires that organophosphorous insecticides undergo special testing for delayed neurotoxicity.”<sup>52</sup>

Thus despite claims by DOD that lack of acute sarin toxicity precluded later disease, it was common knowledge at the time of the 1991 Gulf War that delayed adverse effects do occur from exposure to this class of compounds.

Furthermore, a VA study of mortality in 100,000 veterans said to be exposed to sarin at Khamisiyah found a statistically significant doubling of deaths from brain cancer in the exposed group, compared to unexposed Gulf War veterans, as well as a limited dose-response relationship.<sup>53</sup>

According to a popular toxicology textbook, anticholinesterases may cause “drowsiness, lethargy, fatigue, mental confusion, inability to concentrate, headache, pressure in head, generalized weakness.”<sup>54</sup>

*(c) Other pesticides*

Carbamate pesticides were used in the Gulf and also cause acetylcholine accumulation. They would augment the adverse effects of sarin and organophosphate insecticides. Organochlorine and pyrethrin insecticides have different mechanisms of action, but are also toxic to the peripheral and central nervous system, so their adverse effects might compound those of the acetylcholinesterases. Some pesticides have adverse immunotoxic effects as well.<sup>55</sup> A recent review by NIH’s National Institute of Environmental Health Sciences researchers discussed the state of knowledge of pesticide toxicity, and suggested that general malaise associated with mild cognitive dysfunction may be a sensitive marker for pesticide neurotoxicity.<sup>56</sup>

*(d) Organic Solvents*

These include jet and vehicle fuels, some cleaning agents and other industrial chemicals. According to the Office of Technology Assessment:

“Acute exposure to organic solvents can affect an individual’s manual dexterity, response speed, coordination and balance. Chronic exposure of workers may lead to reduced function of the peripheral nerves and such adverse neurobehavioral effects as fatigue, irritability, loss of memory, sustained changes in personality or mood, and decreased ability to learn and concentrate.”<sup>57</sup>

Therefore, sarin nerve gas, organophosphate and other pesticides, and solvents have the potential to induce the neurological and neurobehavioral effects seen in Gulf War veterans. This was known prior to the first Gulf War.

*(e) Endemic diseases and/or biological weapons exposures*

It remains unknown whether troops faced any biological attacks. Exposure to novel microorganisms has never been ruled out. The role of infections endemic to

<sup>50</sup>Heaton KJ, Palumbo CL, Proctor SP et al. Quantitative magnetic resonance brain imaging in US veterans of the 1991 Gulf War potentially exposed to sarin and cyclosarin. *Neurotoxicology* 2007 28:761–9.

<sup>51</sup>Proctor SP, Heaton KJ, Heeren T et al. Effects of sarin and cyclosarin exposure during the 1991 Gulf War on neurobehavioral functioning in US army veterans. *Neurotoxicology* 2006; 27: 931–9.

<sup>52</sup>Congressional Office of Technology Assessment. *Neurotoxicity: Identifying and controlling poisons of the nervous system*. April 1990. OTA–BA–436. Page 50.

<sup>53</sup>Bullman TA, Mahan CM, Kang HK et al. Mortality in US Army Gulf War veterans exposed to 1991 Khamisiyah chemical munitions destruction. *Am J Public Health* 2005; 95:1382–8.

<sup>54</sup>Klaassen CD. *Cassarett and Doull’s Toxicology*. 5th edition, 1996. McGraw Hill, N.Y. p.657.

<sup>55</sup>Congressional Office of Technology Assessment. *Identifying and controlling immunotoxic substances. Neurotoxicity: Identifying and controlling poisons of the nervous system*. April 1990. OTA–BA–436. Government Printing Office. 1991.

<sup>56</sup>Kamel F and Hoppin JA. Association of pesticide exposure with neurologic function and disease. *Environ Health Perspect*. 2004 Jun;112(9):950–8.

<sup>57</sup>Congressional Office of Technology Assessment. 1990. *Op. cit.* page 30.

the middle east in Gulf War Illnesses is also unknown. The following three microorganisms probably infected some Gulf War veterans, but other microorganisms may also contribute to GWI.

- Leishmaniasis, due to a parasite spread by the sandfly, is endemic in Iraq, but the visceral form of the disease is difficult to diagnose. Until better diagnostics are available, it is certain that cases will be missed. It can take months or even years to develop symptoms, and leishmaniasis may develop into a chronic, debilitating illness.

- *Brucella melitensis* is both endemic to Iraq and a potential biological warfare agent. It can cause a slowly developing, fatiguing illness with a variety of possible signs and symptoms, especially joint pain and fever. It is difficult to diagnose because standard tests usually miss it, so unless it is considered in the differential diagnosis and special tests ordered, it will be overlooked.

- Mycoplasmas have been linked to chronic multi-symptom illnesses.<sup>58</sup> They are widely distributed, and the known spectrum of clinical illness they cause continues to expand.<sup>59</sup> A significant percentage of GW veterans have antibodies to mycoplasma.

(f) *Contaminated water*

Possible contaminants include endemic or deliberately added microorganisms and petroleum products. Soldiers reported that some storage tanks supplying drinking water were also used for vehicle fuels, and the water contained fuel residues.

(g) *Smoke from oil well fires*

Little reliable data on the contents and concentrations of materials comprising the oil well fire smoke is available.<sup>60</sup> Toxic inhalants could have been burned deliberately by retreating Iraqi troops.

(h) *Pyridostigmine bromide (unlicensed use) a.k.a. PB, NAPPS*

Also increases acetylcholine at nerve synapses; will augment the adverse effects of sarin, organophosphate and carbamate insecticides. Multiple studies have linked PB use to later illness in GW troops.<sup>61</sup>

(i) *Other unlicensed drugs approved for use in the Gulf theater*<sup>62</sup>

- Centoxin (J5 monoclonal antibody), purchased by the military, prior to licensure of the drug, to treat sepsis in Gulf War veterans. Found later to increase mortality rates in treated patients.<sup>63 64</sup> Never licensed.

- Ribavirin, purchased by the military for use in unspecified viral illnesses. Yet when used later as an experimental treatment for SARS, Ribavirin produced anemia, bradycardia and hypomagnesemia, increasing mortality.<sup>65</sup> Other researchers later noted, "Ribavirin should not be used empirically for the treatment of viral syndromes of unknown etiology."<sup>66</sup> Ribavirin also causes immunotoxicity.<sup>67</sup> Its adverse reactions include fatigue and depression, which may persist after the drug is stopped.

<sup>58</sup>Nasralla M, Haier J, Nicolson GL. Multiple mycoplasmal infections detected in blood of patients with chronic fatigue syndrome and/or fibromyalgia syndrome. *Eur J Clin Microbiol Infect Dis.* 1999; 18(12):859-65.

<sup>59</sup>Baseman JB, Tully JG. Mycoplasmas: sophisticated, reemerging, and burdened by their notoriety. *Emerg Infect Dis.* 1997 Jan-Mar; 3(1):21-32.

<sup>60</sup>Committee on Government Reform and Oversight. Gulf War Veterans' Illnesses: VA, DOD continue to resist strong evidence linking toxic causes to chronic health effects. Second Report. November 7, 1997. 105th Congress, 1st session. Page 67.

<sup>61</sup>Schumm, W.R., Reppert, E.J., Jurich AP et al. Pyridostigmine bromide and the long-term subjective health status of a sample of over 700 male Reserve Component Gulf War era veterans. *Psychological Reports* 2002; 90: 707-721.

<sup>62</sup>Rettig R. Military use of drugs not yet approved by the FDA for CW/BW defense. *RAND Monograph on Lessons from the Gulf War.* 1999.

<sup>63</sup>Shulman R. Current drug treatment of sepsis. *Hospital Pharmacist* 2002; 9: 97-101.

<sup>64</sup>Quezado ZM, Natanson C, Alling DW et al. A controlled trial of HA-1A in a canine model of gram-negative septic shock. *JAMA* 1993; 269: 2221-7.

<sup>65</sup>Chiou HE, Liu CL, Buttrey MJ et al. Adverse effects of ribavirin and outcome in severe acute respiratory syndrome in two medical centers. *Chest* 2005; 128:263-72.

<sup>66</sup>Muller MP, Dresser L, Raboud J et al. Adverse events associated with high-dose ribavirin: evidence from the Toronto outbreak of severe acute respiratory syndrome. *Pharmacotherapy* 2007; 27: 494-503.

<sup>67</sup>Office of Technology Assessment. Identifying and controlling immunotoxic substances. April 1991. OTA-BP-BA-75.

(j) *Electromagnetic fields*

Electromagnetic weapons, including high power microwaves,<sup>68</sup> were used to disrupt and destroy Iraqi electronic systems. Generation of electromagnetic fields may have been used for other effects, and for communication. Whether electromagnetic fields contributed to illness is unknown, as are the types and magnitudes of the exposures. However, the European Union's European Environment Agency has just called for immediate action to reduce exposure to microwaves, following an international scientific review, which concluded that safety limits set for the radiation are "thousands of times too lenient."<sup>69</sup>

(k) *Vaccines*

- Botulinum toxoid vaccine, manufactured by Michigan Department of Public Health, meant to immunize against botulinum toxins. The toxins block neurotransmission, as does the toxoid. Never licensed. Very little known about safety or efficacy.

- Anthrax vaccine, licensed with inadequate data. Concentration increased 100 times due to manufacturing changes at the time of the Gulf War. Identified as a risk factor for Gulf War illnesses by multiple studies.<sup>70 71 72 73 74</sup> The vaccine's package insert lists the CDC definition of Gulf War Syndrome as a reported adverse event following anthrax vaccine. Many of the over 5,000 reports to the Vaccine Adverse Event Reporting System of FDA-CDC for anthrax vaccine indicate chronic illnesses whose symptoms resemble GWS. I have treated many soldiers who became ill following anthrax vaccine given since the 1991 Gulf War, and the majority experience cognitive impairment, generalized pain and fatigue, among other symptoms, meeting the CDC's case definition for GWS. See my testimony to the House Veterans Affairs Health Subcommittee for additional information.<sup>75</sup>

- Multiple vaccines given together within a short time period. Are multiple simultaneous vaccinations dangerous? Although the question has been discussed by the Institute of Medicine, the Armed Forces Epidemiology Board and the British Ministry of Defense, they provide no conclusive answer. Studies of multiple vaccinations associated with Gulf War Illnesses have shown a positive, dose-response relationship, suggesting they did contribute to GWI.<sup>76 77</sup> Soldiers engaged in Operation Iraqi Freedom have also reported Gulf War Illness-like disease following multiple vaccinations, with both acute and chronic effects.<sup>78</sup>

British military policy now separates anthrax and smallpox vaccinations from other vaccinations by at least 5 days.<sup>79</sup>

## 10. WHAT CAN WE CONCLUDE ABOUT THE EXPOSURES?

(a) Several of the exposures can individually produce the symptoms GW veterans are experiencing. Injuries from these substances can affect cognition, emotion, motor and sensory function. These include sarin, pesticides, solvents, anthrax vaccine and some chronic infections, at a minimum.

<sup>68</sup><http://www.globalsecurity.org/military/systems/munitions/hpm.htm>.

<sup>69</sup>Lean G. EU calls for urgent action on wi-fi radiation. New Zealand Herald. September 16, 2007. <http://www.nzherald.co.nz/section/2/story.cfm?c-id=2&objectid=10463870>.

<sup>70</sup>Unwin C, Blatchley N, Coker W, Ferry S, Hotopf M, Hull L, et al. Health of UK servicemen who served in Persian Gulf War. *Lancet*. 1999 Jan 16; 353(9148):169-78.

<sup>71</sup>Goss-Gilroy. Study of Canadian Gulf War Veterans: NR-98.050. Study contracted by the Canadian Department of National Defense, released June 29, 1998 and published on its web site, accessed between 1999 and 2001 but no longer at the previous URL: <http://www.dnd.ca/menu/press/Reports/Health/health-study-eng-1.htm>.

<sup>72</sup>Schumm WR, Reppert EJ, Jurich AP et al. Self-reported changes in subjective health and anthrax vaccination as reported by over 900 Persian Gulf War era veterans. *Psychol Rep*. 2002 Apr;90(2):639-53.

<sup>73</sup>Boyd KC, Hallman WK, Wartenberg D, Fiedler N, Brewer NT, Kipen HM. Reported exposures, stressors, and life events among Gulf War Registry veterans. *J Occup Environ Med*. 2003 Dec;45(12):1247-56.

<sup>74</sup>Wolfe J, Proctor SP, Erickson DJ, Hu H. Risk factors for multisymptom illness in US Army veterans of the Gulf War. *J Occup Environ Med*. 2002 Mar;44(3):271-81.

<sup>75</sup><http://merylnass.googlepages.com/writtentestimony7-26-07.doc>.

<sup>76</sup>Kelsall HL, Sim MR, Forbes AB et al. Symptoms and medical conditions in Australian veterans of the 1991 Gulf War: relation to immunisations and other Gulf War exposures. *Occup Environ Med*. 2004 Dec;61(12):1006-13.

<sup>77</sup>Cherry N, Creed F, Silman A, et al. Health and exposures of United Kingdom Gulf war veterans. Part II: The relation of health to exposure. *Occup Environ Med*. 2001 May;58(5):299-306.

<sup>78</sup><http://www.bmj.com/cgi/content/full/326/7401/1234a>. Dyer O. Ministry of Defence accused of contravening inoculation guidelines. *BMJ* 2003;326:1234.

<sup>79</sup>*Ibid*.

(b) Combined exposures to certain toxic substances (and simultaneous exercise) greatly magnify the potential for adverse reactions:

- Somani et al. Exercise plus Pyridostigmine Bromide amplified oxidative injury in skeletal muscle of mice.<sup>80</sup>

- Abou-Donia et al. "These results suggest that exposure to real-life doses of malathion, DEET and permethrin, alone or in combination, produce no overt signs of toxicity but induce significant neurobehavioral deficits and neuronal degeneration in brain."<sup>81</sup>

- McCain et al. "A significant increase in lethality occurred when PB, permethrin and DEET were given concurrently, when compared to expected additive values."<sup>82</sup>

- Haley RW et al. "Some Gulf War veterans may have delayed, chronic neurotoxic syndromes from wartime exposure to combinations of chemicals that inhibit butyrylcholinesterase and neuropathy target esterase."<sup>83</sup>

(c) Multiple simultaneous vaccinations increased the risk of GWS.

(d) For some other exposures, there is very little available information on toxicity.

(e) Depleted uranium likely contributed to chronic illnesses (and deaths in soldiers tasked to clean up DU).<sup>84</sup>

(f) Illnesses resulting from infections, electromagnetic fields, smoke, drugs and possibly other exposures have not been ruled out in GW veterans.

#### 11. WHAT IS KNOWN ABOUT UNDERLYING PATHOLOGY IN GWS?

(a) Autonomic nervous system function has been shown to be altered in Gulf War veterans in multiple studies, as has hypothalamic pituitary adrenal function.<sup>85</sup>

(b) Altered immune function reflects another aspect of this disorder for many veterans.<sup>86</sup>

(c) One's genes affect the speed of processing of toxic substances and later manifestation of toxic effects.<sup>87</sup>

(d) Gulf War soldiers encountered an unprecedented mix of noxious substances, which are known to cause neurological, immunologic and other adverse effects. Gulf War Illness research even suggests a dose-response relationship between some exposures and symptoms.<sup>88</sup>

- A very reasonable hypothesis is that those who became ill reached a tipping point, where their body's ability to safely process the toxic materials they took in was exceeded. Chronic illness may have resulted from tissue damage (such as permanent loss of neurons) and/or persisting metabolic abnormalities, which have yet to be defined, but are suspected to include impaired oxidative phosphorylation<sup>89,90</sup>

<sup>80</sup>Jagannathan R, Husain K and Somani SM. Interaction of pyridostigmine and physical stress on antioxidant defense system in skeletal muscle of mice. *J App; Toxicol* 2001; 21: 341-8.

<sup>81</sup>Del-Rahman A, Dechkovskaia AM, Goldstein LB et al. Neurological deficits induced by malathion, DEET and permethrin, alone or in combination in adult rats. *J Toxicology and Environmental Health* 2004; 67: 331-356.

<sup>82</sup>McCain WC, Mark RL, Johnson JS et al. Acute oral toxicity study of pyridostigmine bromide, permethrin, and DEET in the laboratory rat. *J Toxicology and Environmental Health* 1997; 50: 113-124.

<sup>83</sup>Self-reported exposure to neurotoxic chemical combinations in the Gulf War. A cross-sectional epidemiologic study. Haley RW, Kurt TL. *JAMA*. 1997 Jan 15;277(3):231-7.

<sup>84</sup>Doug Rokke, PhD. Personal communication September 18, 2007.

<sup>85</sup>Clauw D, Groner G, Whalen K. Hypothalamic pituitary adrenal function in veterans with unexplained illness, compared to fibromyalgia subjects and controls. Presented at the Conference on Illnesses among Gulf War veterans: A decade of scientific research. January 24-26, 2001. Alexandria, VA.

<sup>86</sup>Zhang Q, Zhou XD, Denny T et al. Changes in immune parameters seen in Gulf War veterans but not in civilians with chronic fatigue syndrome. *Clin Diagn Lab Immunol*. 1999 Jan;6(1):6-13.

<sup>87</sup>Haley RW, Billecke S, La Du BN. Association of low PON1 type Q (type A) arylesterase activity with neurologic symptom complexes in Gulf War veterans. *Toxicol Appl Pharmacol*. 1999 Jun 15;157(3):227-33.

<sup>88</sup>Kelsall HL, Sim MR, Forbes AB et al. Symptoms and medical conditions in Australian veterans of the 1991 Gulf War: relation to immunisations and other Gulf War exposures. *Occup Environ Med*. 2005 Mar;62(3):142-3. "Increased symptom reporting was associated with several exposures, including having more than 10 immunisations, pyridostigmine bromide tablets, anti-biological warfare tablets, pesticides, insect repellents, reportedly being in a chemical weapons area, and stressful military service experiences in a strong dose-response relation."

<sup>89</sup>Rose MR, Sharief MK, Priddin J et al. Evaluation of neuromuscular symptoms in UK Gulf War veterans: a controlled study. *Neurology*. 2004 Nov 9;63(9):1681-7.

<sup>90</sup>Wong R, Lopaschuk G, Zhu G et al. Skeletal muscle metabolism in the chronic fatigue syndrome. In vivo assessment by <sup>31</sup>P nuclear magnetic resonance spectroscopy. *Chest*. 1992 Dec;102(6):1716-22.

and/or other fundamental changes in body chemistry that can affect multiple organ systems.

12. WHY HAVE WE NO EFFECTIVE TREATMENT STRATEGIES  
16 YEARS AFTER THE END OF THE WAR?

VA Treatment Trials<sup>91 92</sup>

The original two VA treatment trials were exorbitantly expensive, particularly given the number of subjects and cost of the interventions. Failure to conduct additional treatment studies was rationalized by these trials' high cost.

- The mycoplasma/doxycycline trial was a "failed study" in that positive results seen at 3 and 6 months did not carry over to 9 and 12-month follow-up, possibly due to a high dropout rate.<sup>93</sup> Yet it was not repeated with a larger number of veterans to reach a definitive conclusion regarding the benefit of antibiotic treatment.
- The cognitive behavioral therapy/exercise trial showed extremely modest gains and a high dropout rate; these treatments are known to be of little value in patients with chronic fatigue syndrome, and exercise can make them worse; yet cognitive behavioral therapy and exercise are primary treatments recommended for GW veterans, who have a high rate of chronic fatigue syndrome.

We do not need to continue to examine whether the noxious exposures already studied can cause GWI. They can, and they did. And we should have expected it. Some people were genetically more susceptible; some people received more or larger exposures. The result is that many veterans became chronically ill.

The manner in which DOD and VA pursued GW research was flawed for a variety of reasons.

- A significant amount of research focused on stress or psychiatric causes of illness.
- Certain exposures were studiously avoided as objects of study.
- Methodologies chosen were sometimes inadequate to answer the questions posed.
- Exposure data provided by DOD to researchers was not necessarily accurate.
- Funded studies were not selected on the basis of whether they would lead to a treatment, or to a policy change to protect future soldiers. Instead, some might suspect the research was designed to avoid uncovering negative information regarding use of DU, pyridostigmine bromide and anthrax vaccine.

This review of some GWI research shows that completed research projects have:

- confirmed the symptoms of the illnesses;
- identified specific neurological deficits in affected veterans and some of their anatomic/physiologic correlates;
- provided partial information on rates of different GW-associated illnesses; and
- furthered our knowledge of the adverse effects caused by some noxious GW exposures, alone and in combination.

13. WHERE SHOULD THE RESEARCH GO FROM HERE? HOW CAN WE MELD OUR RESEARCH GOALS WITH THE NEED TO DEVELOP EFFECTIVE TREATMENT STRATEGIES?

*Infections (where a treatment payoff could be very large)*

- Perform conclusive research to determine if GW veterans have untreated chronic infections. Utilize all modalities including microscopy, specialized cultures, serology, PCR, etc. Develop new diagnostics when needed, such as for visceral leishmaniasis.
- Also seek novel infections (biological agents), using above techniques, genetic techniques, monoclonal antibodies, etc.
- Perform empiric antibiotic trials in veterans who test positive, including a repeat trial of antibiotics for veterans with positive mycoplasma forensic PCR (the test used to screen veterans for the earlier trial).

*Value for money*

- A large number of small, inexpensive pilot studies should be funded instead of a few large, mainly epidemiologic studies; later give larger grants to those projects that show the most promise in terms of treatment strategies.

<sup>91</sup>Donta ST, Clauw DJ, Engel CC Jr et al. Cognitive behavioral therapy and aerobic exercise for Gulf War veterans' illnesses: a randomized controlled trial. JAMA. 2003 Mar 19;289(11):1396-404.

<sup>92</sup>Donta ST, Engel CC Jr, Collins JF et al. Benefits and harms of doxycycline treatment for Gulf War veterans' illnesses: a randomized, double-blind, placebo-controlled trial. Ann Intern Med. 2004 Jul 20;141(2):85-94.

<sup>93</sup>Personal communication with Sam Donta, MD, the Principal Investigator.

- Make the grant application process inclusive. Encourage clinicians who have been caring for GW veterans to participate. Reduce the complexity, time and cost needed to complete grant applications. Don't restrict VA research grants to VA employees, as has been the case: open the process to the best scientists and proposals.
- Note the low cost, excellent methodology, analysis and results of Lea Steele's Kansas veterans study,<sup>94</sup> compared to numerous federally funded studies that cost at least ten times more and yielded much less information. Use her strategies as a model for other studies: passion for the subject, careful use of funds, thoughtful design and analysis.
- The selection process for grants must be transparent, which has not previously been the case.

*Promising areas—basic research*

The underlying causes of all the multi-symptom syndromes remain unknown. It is very probable that the molecular and cellular origin of these syndromes will be the same, although they are likely triggered by a variety of noxious exposures combined with genetic susceptibility. Because together these syndromes affect an estimated 6 million Americans, research identifying their underlying causes will pay enormous dividends, and should point the way to more effective treatment and prevention strategies.

- Gene expression studies have the potential to identify fundamental physiological processes that have been altered.<sup>95,96,97</sup> Genetic and proteomic studies of both predisposing gene patterns and protein differences between affected and unaffected veterans have already shown promise in pilot studies,<sup>98,99</sup> and should be continued.
- Abnormal ion channel function may provide a conceptual and physiologic bridge between fatigue, neuropathies and motor neuron disorders like ALS, providing clues to why different disorders develop after similar exposures.<sup>100,101</sup> It may also help explain episodic alterations in mental status, arrhythmias and epileptic seizures in veterans. Maintaining ion gradients across membranes requires a lot of cellular energy. This can potentially be improved with supplements that improve intracellular adenosine triphosphate (ATP) production and oral electrolytes.

*Specific studies that could reap valuable rewards*

- Detailed study of individual families, in which family members have developed illnesses similar to the ill veteran. An exhaustive search for microorganisms should be undertaken. Search for DU that may have been present on items that returned home with the veteran. Seek other toxics in the home as appropriate to illnesses. Investigate gene expression in these families.
- Study illnesses and mortality in selected units that have reported high death rates; try to recapture their locations, job descriptions and exposures when deployed.
- Collect several hundred very ill GW veterans and perform exhaustive investigations on them, followed by treatment trials.
- Investigate those hypotheses for which researchers were threatened or forced to end their studies. Investigate the electromagnetic field strengths and frequencies of all weapons, communications devices and other equipment that may have been used in the war, and try to determine which areas or units were exposed and estimate the magnitude of exposure.

<sup>94</sup> Steele L. Prevalence and patterns of Gulf War illness in Kansas veterans: association of symptoms with characteristics of person, place, and time of military service. *Am J Epidemiol.* 2000 Nov 15;152(10):992–1002.

<sup>95</sup> Cameron B, Galbraith S, Zhang Y, Davenport T, Vollmer-Conna U, Wakefield D, Hickie I, Dunsmuir W, Whistler T, Vernon S, Reeves WC, Lloyd AR. Dubbo Infection Outcomes Study. Gene expression correlates of postinfective fatigue syndrome after infectious mononucleosis. *J Infect Dis.* 2007 Jul 1;196(1):56–66.

<sup>96</sup> Fang H, Xie Q, Boneva R, Fostel J, Perkins R, Tong W. Gene expression profile exploration of a large dataset on chronic fatigue syndrome. *Pharmacogenomics* 2006 Apr;7(3):429–40.

<sup>97</sup> Whistler T, Jones JF, Unger ER et al. Exercise responsive genes measured in peripheral blood of women with chronic fatigue syndrome and matched control subjects. *BMC Physiol.* 2005 Mar 24;5(1):5.

<sup>98</sup> Baraniuk JN, Casado B, Maibach H et al. A chronic fatigue syndrome-related proteome in human cerebrospinal fluid. *BMC Neurol* 2005; December 1: 5:22.

<sup>99</sup> Vladutiu GD and Natelson BH. Association of medically unexplained fatigue with ACE insertion/deletion polymorphisms in Gulf War veterans. *Muscle Nerve* 2004; 30: 38–43.

<sup>100</sup> Kuwabara S, Misawa S. Axonal ionic pathophysiology in human peripheral neuropathy and motor neuron disease. *Curr Neurovasc Res.* 2004 Oct;1(4):373–9.

<sup>101</sup> Chaudhuri A, Watson WS, Pearn J, Behan PO. The symptoms of chronic fatigue syndrome are related to abnormal ion channel function. *Med Hypotheses.* 2000 Jan;54(1):59–63.

- The choice of control groups in research is critical to a meaningful outcome: compare GW veterans with controls who did not receive deployment vaccines and had demonstrated equivalent health status. Review all research projects with independent experts prior to funding, to minimize confounding and bias.
- Eight expert committees have made recommendations on the research studies needed for anthrax vaccine since 1999.<sup>102</sup> Their recommendations are excellent, and should be followed.
- Eight hundred Israeli soldiers received U.S. anthrax vaccine or a similar Israeli anthrax vaccine several years ago, and dozens have reported chronic illnesses they believe are related to their vaccinations.<sup>103</sup> Information from this trial should be obtained, along with follow-up examinations to document what illnesses, if any, have developed and rates of illnesses.
- A clinical trial of various strategies to remove toxic substances would be extremely useful. Do antioxidants, vitamins, saunas, or other strategies safely remove toxins after an exposure and lead to better health?

*Obtain relevant information from existing government databases*

- The Army Medical Surveillance Activity has performed many analyses of its raw data (the Defense Medical Surveillance System) on the health status of soldiers and GW veterans. These studies were not published, nor are they easily available. A researcher<sup>104</sup> who filed Freedom of Information Act requests to learn what was studied, shared 66 pages with approximately 40 study titles listed per page with me. I have filed a Freedom of Information Act Request for the contents of 60 of these studies that pertain to the health of Gulf War veterans; my request is pending. Any serious study of Gulf War veteran health needs to make use of this material and the available military and VA databases. The Institute of Medicine noted that, "Analysis of DMSS data should be the primary approach for investigation of possible AVA (anthrax vaccine adsorbed)-related health effects of medical significance."<sup>105</sup> This should be true of other potential health impacts, in addition to anthrax vaccine.
- VA and military databases, used correctly, can tell us which other illnesses can be linked to the Gulf deployment, and the strength of the association, so that appropriate presumptions can be made about the illnesses' cause; disability decisions can then be made based on presumption.
- Independent researchers who gain access to this data to study GWI, and determine what other illnesses may be linked with the 1991 Gulf War deployment, should not be subject to the military chain of command nor be VA employees.
- We can learn more about the health risks of toxic GW exposures by gaining access to data held by Federal agencies. This includes obtaining information about anthrax vaccine adverse effects from FDA. What in-house studies or reviews have been done of anthrax vaccine? How has FDA evaluated the 5,600 adverse event reports, particularly the 670 it judged serious? What assessment was done of the 44 reported deaths associated with anthrax vaccine? How is the vaccine tested for safety? (I filed several FOIAs with FDA for this information since 2001. So far, 99 percent of what I requested was redacted, and much has never been provided in any form. Yet the material should not have been withheld according to FDA guidelines (21 CFR 20.61 and 21 CFR 601.51.)
- EPA and NIEHS have information about pesticide, heavy metal and solvent health risks. DOE has information on the makeup and production of depleted uranium. These sources of information should be explored for their potential to shed more light on the specifics of the illnesses caused by these materials.
- Anthrax vaccine trials: NIH has data on human trials of failed anthrax vaccines and CDC has data on its own clinical trial of 1,564 subjects who received anthrax vaccine since 2002. What adverse events occurred in these carefully studied groups? What is the current health of the subjects? Late follow-up could be done on these subjects to evaluate for longer-term adverse events.
- Multiple vaccines: Currently deploying soldiers are receiving multiple simultaneous vaccinations and should be studied.
- The military vaccine healthcare centers have data on over 2,000 soldiers who have become ill after anthrax vaccines. As well as documenting the illnesses in great detail, the centers have tried a variety of treatment regimens. Information on

<sup>102</sup> <http://merylnass.googlepages.com/Selectedfindings.doc>.

<sup>103</sup> <http://www.haaretz.com/hasen/spages/863699.html>.

<sup>104</sup> Michael Ravnitzky.

<sup>105</sup> IOM Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Program. An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program. 2003.

the illnesses and the effectiveness of the treatments is extremely relevant to GW veterans.

#### 14. MY MEDICAL APPROACH TO TREATMENT

GWS is one of medicine's poor stepchildren for many reasons. Patients with memory and concentration problems require a lot more time and understanding from both physicians and clinic staff, compared to other patients. They miss appointments, lose prescriptions, forget the instructions you gave them. They have an average of eight different problems to address at each visit. They often have emotional issues. They are at high risk of family breakdown and economic collapse. Standard medications don't alleviate their symptoms. Providers may not understand their illnesses nor the context in which they seek care. They may be suspected as having secondary gain (desiring a disability pension) as the driver for medical visits. Yet sometimes almost the only thing the physician can do for the GWI patient is to aid the disability process by keeping detailed notes.

This syndrome is not described in textbooks. Journal articles may list the symptoms, but fail to guide clinicians with information on effective treatments. If the clinician reads the GWI literature, she may come away confused as to whether there really is a medical illness, and whether she should transfer the patient to the psychiatric clinic.

There are no standard medical treatments for the chronic effects of exposure to pesticides, solvents, toxic materials in inhaled smoke, etc. A few doctors have experimented with various detoxification strategies,<sup>106 107</sup> and some alternative doctors use these treatments frequently, but they are not proven to be effective and are not eligible for third party reimbursement.

Medicine is a business. Third party payers use similar visit codes to reimburse physicians. Treating 4 patients in an hour pays much better than treating one. The maximal visit code pays for a 40 minute visit. Additional time spent with the patient will not be reimbursed. Extra time spent by office staff is not reimbursed. I am fortunate that as a salaried physician, my employer, Mount Desert Island Hospital, allows me to conduct a specialty clinic as a community service, even though I could bring in considerably more fees treating patients with standard illnesses during brief visits. Patients often travel long distances to see these doctors, who are few and far between. Thus they need long visits. Few GW veterans can afford to pay out of pocket for medical care, which is how most doctors who treat multi-symptom syndromes expect payment, because of the limitations placed on reimbursement by insurers. Frankly, until the financial disincentive is changed, I doubt that treatment of GW veterans will improve greatly.

What do I actually do with patients? First, patients complete detailed questionnaires prior to their visit to help me determine which aspects of the illnesses are present in their case. Because I am familiar with the features of the multisymptom syndromes, I know what to look for, ask about, and can direct treatment to these aspects of the illness. For example:

- Are they sensitive to odors (especially diesel exhaust), fluorescent lights or foods?
- What happens when exposed to these things?
- Do they have intermittent episodes of confusion?
- Do they balance their own checkbook?
- How is their driving?
- How is their GI tract function?
- How do they sleep? Has their partner noticed pauses in breathing?
- Do they have chronic pain? Where? What exacerbates or relieves it?
- What kind of activity can they perform? For how long? What makes them stop?
- Do they have rashes?
- How is their breathing?
- How is their libido and sexual function?
- Is there mold, or are there other substances at home or elsewhere that increase symptoms?

If they have developed multiple chemical sensitivity (which seems to be present in about 40 percent of GWS patients), I help them identify the odors that provoke symptoms so they can avoid them. I prescribe elimination diets to identify foods that

<sup>106</sup> Krop J. Chemical sensitivity after intoxication at work with solvents: response to sauna therapy. *J Altern Complement Med.* 1998 Spring;4(1):77-86.

<sup>107</sup> Kilburn KH, Warsaw RH, Shields MG. Neurobehavioral dysfunction in firemen exposed to polychlorinated biphenyls (PCBs): possible improvement after detoxification. *Arch Environ Health.* 1989 Nov-Dec;44(6):345-50.



trigger symptoms. I order tests to rule out other causes of symptoms, such as muscle diseases, standard autoimmune conditions, thyroid disease, anemia, etc. I may order sleep studies. Some patients may get a muscle biopsy or other specialized tests. Stools are cultured and endoscopy performed when indicated.

I then address treatment for each symptom individually, since we cannot currently address underlying causes. However, I additionally try to optimize patients' overall metabolic function with diet, vitamins and supplements designed to increase cellular energy and provide substrates for important intracellular molecules such as NADH, glutathione, ATP. Antioxidants may also be helpful. Most veterans cannot afford this treatment, however. Vitamins and supplements are not covered by insurance, although they are usually much cheaper than prescription medications.

Hopefully, clinical trials will demonstrate whether these approaches improve health, and if so, perhaps the VA will make vitamins and supplements available to GW veterans.

I treat the sleep disorder, diarrhea, pain, low hormone levels, or whatever other symptoms are present. I try one treatment after another, since there are many adverse reactions to medications, and it is often difficult to predict which medicines are likely to be effective. Usually, you can improve sleep considerably, but energy only a little. You can improve pain. The diarrhea can resolve, though it may return later. Sometimes sex hormones improve sexual function, but often they do not. Thyroid hormone may provide a modest energy boost. Autonomic dysfunction may be treated with increased salt and water intake, drugs and/or hormones to raise blood pressure, and electrolytes. If you are very lucky, cognition may improve.

The doctor-patient relationship, and lifestyle coaching, may be equally as important as medications. Patients need to know you are their partner, not a representative of a system they fear is pitted against them. I warn them that marital difficulties should be expected. I prefer their partners to attend visits, and am happy to answer partners' questions. Treating psychological problems may be helpful, but veterans are sensitive that such treatment is a denial they have physical illness. I explain that they have real medical illness, and may give them an article or book on GWS that describes the resulting psychological and physical symptoms, to help them understand their disorder. I may refer to other therapists. I suggest that people with limited mental and physical energy reserve their most challenging tasks for when they feel most rested. I may advise them not to drive alone.

With this treatment, I estimate a veterans's overall function can improve 30–40 percent and sometimes more. But it is a piecemeal, palliative, symptom-based approach that does not provide a cure. It also requires highly intensive care. A list of many of the treatments I employ was provided to the VA Research Advisory Committee and listed on my web site at: <http://www.anthraxvaccine.org/gulfwartreatment.htm>.

I greatly appreciate this opportunity to share my knowledge and opinions with the Committee.

I would also like to express my appreciation to Walter Schumm, Ph.D., Garth Nicolson, Ph.D., and affected Gulf War veterans Doug Rokke, Ph.D., Joyce Riley, R.N. and Kirt Love for sharing materials on GWS that were used in this presentation. My deepest thanks also to Lt. Col. John Richardson, retired Air Force GW veteran (still healthy), who has worked tirelessly to improve the condition of his fellow GW veterans and anthrax vaccine-injured soldiers.

Senator MURRAY. Thank you very much, Dr. Nass.  
Dr. Steele?

**STATEMENT OF LEA STEELE, PH.D., SCIENTIFIC DIRECTOR,  
RESEARCH ADVISORY COMMITTEE ON GULF WAR  
VETERANS' ILLNESSES, AND ASSOCIATE PROFESSOR,  
KANSAS STATE UNIVERSITY**

Dr. STEELE. Good morning. I am Dr. Lea Steele. I am an epidemiologist and have conducted research on the health of Gulf War veterans for the past 10 years. I am now privileged to serve as Scientific Director of the Research Advisory Committee on Gulf War Veterans' Illnesses. This Federal advisory body of distinguished scientists and veterans was mandated by Congress to review the scientific research on the health of Gulf War Veterans. Our members include Dr. Roberta White, who will be speaking later, other distin-

guished and leading experts, a former president of the American Association for the Advancement of Science, and the head of CDC's Neurotoxicology Laboratory. Our Committee chair, Mr. Jim Binns, will also be testifying.

Our Committee has now reviewed the extensive amount of scientific research on the health of Gulf War veterans. We will be releasing a major report on Gulf War illness in the next several months, but my purpose today is to share with you some of the highlights of what the Committee has learned in the course of our scientific work.

First, I think it is important to distinguish between Gulf War illness and other conditions connected to the Gulf War. By Gulf War illness, we mean the complex of symptoms that you have heard about that affect Gulf War veterans at high rates but are not explained by standard medical diagnoses or medical tests. Veterans with Gulf War illness typically have some combination of severe headaches, memory and cognitive problems, persistent pain throughout the body, and profound fatigue. Other difficult problems include GI symptoms. We know veterans who have had diarrhea for 16 years. Respiratory problems are also common, as well as unusual skin lesions.

This condition we refer to as Gulf War illness, then, is distinct from other diagnosed conditions that are associated with service in the Gulf War. Among these other diagnosed conditions are ALS, or Lou Gehrig's disease, which a large VA study has found affects twice as many Gulf War veterans as other veterans of that period. Brain cancer is also now a Gulf War health issue.

You may be familiar with the chemical weapons incident near Khamsiyah, Iraq in March 1991. The Pentagon has estimated that as many as 100,000 U.S. troops were potentially exposed to low-level nerve agents when a large weapons depot containing sarin and cyclosarin was destroyed. Recent studies have identified diverse neurological problems in relation to that incident, including that veterans downwind from the demolitions have died from brain cancer at twice the rate of veterans in other areas of theater.

There may also be other problems with other diagnosed diseases, but studies are lacking. Our Committee has recommended studies to assess rates of multiple sclerosis, Parkinson's disease, and other conditions in Gulf War veterans. All of these issues are important, but in truth, far fewer Gulf War veterans have ALS or brain cancer than the very large number with Gulf War illness, so I will focus now on what we have learned from the many, many scientific studies of this condition. Here are just some of the highlights.

First, I just want to underscore the point that Gulf War illness is real and it affects a large number of veterans. You may have heard in media stories or from government agencies that there is no Gulf War illness or no "unique Gulf War syndrome." That is just not true.

There is unquestionably a condition that resulted from the 1991 Gulf War, documented in study after study of Gulf War veterans very consistently from around the United States. No studies have found otherwise. The "no unique syndrome" comment means different things to different people and is more of a semantic point about what does or does not constitute a unique syndrome. Our

Committee has not considered it particularly important if this condition is called a unique syndrome. The point is that a lot of veterans are sick with a condition caused by their service in the Gulf War.

How many are sick? Well, as you have heard earlier today, studies find that between 25 and 30 percent of Gulf War veterans have this condition in relation to their service in the war. So that means that Gulf War illness affects between 175,000 and 200,000 of the 700,000 Americans who served in the Gulf War.

Next, Gulf War illness was not caused by psychological stress. The most comprehensive and well-analyzed studies have found no connection between Gulf War illness and serving in combat. In fact, psychiatric conditions like PTSD are much lower in Gulf War veterans than veterans of other wars, and this stands to reason since unlike current deployments severe trauma was relatively uncommon in the 1991 Gulf War. A decisive victory was achieved after 6 weeks of air strikes and a ground war that lasted just 4 days. Most troops did not see combat and were never in areas where battles took place.

So what did cause Gulf War illness? Many different Gulf War exposures have been suggested. These include the smoke from over 600 burning Kuwaiti oil wells, multiple vaccines, depleted uranium munitions, and chemical weapons. The most consistent evidence implicates a group of chemicals that can have toxic effects on the brain. These chemicals include the little white pills called pyridostigmine bromide that were given to troops to protect them from the effects of nerve agents. Also, excessive use of pesticides and low levels of nerve gas in theater. Some of these neurotoxic chemicals have a similar type of action. They affect a single brain chemical, the neurotransmitter acetylcholine. Studies also show that these brain toxins can act synergistically. Combined exposures are worse than any single exposure by itself.

And last but certainly not least, effective treatments for Gulf War illness are urgently needed. Studies show that few veterans—and there have now been four longitudinal studies—few veterans with Gulf War illness have recovered or even substantially improved over time. As a result, many Gulf War veterans have been sick for as long as 16 years. Effective treatments for Gulf War illness have not been found. Very few have even been studied. Our Committee continues to give highest priority to research that leads to effective treatments for Gulf War illness.

So in short, Gulf War illness is real, it is serious, and it is still widespread in veterans of the 1991 Gulf War. It is not the result of psychological stress and it is not the same thing that happens after every war. Scientific progress has certainly been made in understanding the big picture questions about Gulf War illness. The Research Advisory Committee believes that remaining questions can and must be addressed, particularly identification of treatments. Thank you.

[The prepared statement of Dr. Steele follows:]

PREPARED STATEMENT OF LEA STEELE, PH.D., SCIENTIFIC DIRECTOR, RESEARCH ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES; ASSOCIATE PROFESSOR, KANSAS STATE UNIVERSITY

Good morning and thank you for inviting me today. I'm Dr. Lea Steele, an epidemiologist and associate professor at Kansas State University. I have conducted research on the health of Gulf War veterans for the past 10 years and am privileged to serve as Scientific Director of the Research Advisory Committee on Gulf War Veterans' Illnesses. This public advisory body of distinguished scientists and veterans was mandated by Congress and charged with reviewing scientific research on the health of Gulf War Veterans. Our members include Dr. White, who will be testifying today, other leading experts, a former president of the American Academy for the Advancement of Science, and the head of CDC's Molecular Neurotoxicology Laboratory. The Committee Chair, Mr. Jim Binns, will also be testifying today.

The Committee has now reviewed and assessed the extensive amount of scientific research and government investigations on the Gulf War and the health of Gulf War veterans. We will release a major report on Gulf War illness in the next several months. My purpose today is to share with you some highlights of what the Committee has learned in the course of our scientific work.

First, I want to distinguish between the condition known as Gulf War illness and other health issues related to the 1991 Gulf War. By Gulf War illness I am referring to the multi-symptom condition that affects Gulf War veterans at high rates, but is not explained by standard diagnoses or medical tests. Veterans with Gulf War illness typically experience some combination of severe headaches, memory and concentration problems, persistent pain throughout the body, and profound fatigue. Other difficult symptoms include gastrointestinal problems—we know veterans who have had diarrhea for 16 years. Respiratory problems are also common, and unusual skin lesions and rashes. Gulf War illness is real, it was not caused by stress, it is not the same thing that happens after every war, and it is widespread among Gulf War veterans.

There are also other health issues related to Gulf War service. These include ALS, or Lou Gehrig's Disease, which a large VA study has shown affects twice as many Gulf War veterans as other veterans of that period. Brain cancer has also become a Gulf War health issue. You may be familiar with a well-known incident near Khamisiyah, Iraq, in March 1991. The Pentagon has estimated that about 100,000 U.S. military personnel were potentially exposed to low-level nerve agents with the destruction of a large weapons depot that contained sarin and cyclosarin. Recent studies have identified diverse neurological problems in relation to that incident, including findings that veterans downwind from the demolitions have died from brain cancer at twice the rate of veterans in other areas of theater.

There may also be problems with other diagnosed diseases, but studies are lacking. The Research Advisory Committee has recommended studies to assess conditions such as multiple sclerosis, Parkinson's disease, and cancer in Gulf War veterans. All of these issues are important, but far fewer Gulf War veterans have ALS or brain cancer than the very large number affected by Gulf War illness. So I will focus now on what we have learned from the many scientific studies on this condition. Here are some of the highlights:

- Gulf War illness is real and affects a large number of veterans. You might have heard in media stories or from government agencies that there is no Gulf War illness or no "unique Gulf War syndrome." There is unquestionably a condition that resulted from service in the 1991 Gulf War, documented in epidemiologic studies of Gulf War veterans from around the U.S. and some allied countries. No studies have found otherwise. The "no unique syndrome" comment refers more to a semantic point about what does or does not constitute a "unique syndrome." Our Committee has never considered it particularly important whether the condition is or is not called a unique syndrome. The point is that a lot of veterans are sick with a condition caused by their service in the Gulf War.

How many are sick? Studies consistently find that 25–30 percent of Gulf War veterans have this condition, in relation to their service in the war. This includes VA's most recent large follow-up study. That means that Gulf War illness affects between 175,000 and 200,000 of the 700,000 Americans who served in the Gulf War.

- Gulf War illness was not caused by psychological stress. The most comprehensive and well-analyzed studies have found no connection between Gulf War illness and serving in combat. In fact, rates of psychiatric conditions like PTSD are considerably lower in Gulf War veterans than veterans of other wars. This stands to reason since, unlike current deployments, severe trauma was relatively uncommon in the 1991 Gulf War. A decisive victory was achieved after 6 weeks of intensive air

strikes and a ground war that lasted just 4 days. Most troops did not see combat and were never in areas where battles took place.

- Research studies consistently identify links between Gulf War illness and neurotoxic chemicals. Many different Gulf War exposures have been suggested as causes of Gulf War illness. These include the smoke from over 600 burning Kuwaiti oil wells, multiple vaccines, depleted uranium munitions, and low-dose exposure to chemical weapons.

The most consistent and extensive evidence implicates chemicals that can have toxic effects on the brain. These chemicals include pills (pyridostigmine bromide, or PB) that were given to protect troops from effects of nerve agents, excessive use of pesticides, and low levels of nerve gas in theater. Many of these chemicals have a similar type of action; they affect levels of a particular brain chemical, the neurotransmitter acetylcholine. Studies also show that these brain toxins can act synergistically, that is, combined exposures are worse than any single exposure by itself.

A link between Gulf War illness and neurotoxic chemicals is also compatible with what we know from studies of biological abnormalities in Gulf War veterans. Diverse studies have identified abnormalities in the brain and the autonomic nervous systems of sick Gulf War veterans, using different types of sophisticated brain scans and other testing methods.

- Effective treatments for Gulf War illness are urgently needed. Studies show that few veterans with Gulf War illness have recovered or even substantially improved over time. As a result, many Gulf War veterans have been sick for as long as 16 years. Effective treatments for Gulf War illness have not been found—very few have even been studied. The Research Advisory Committee continues to give highest priority to research that leads to effective treatments for sick Gulf War veterans.

In short, Gulf War illness is real, it is serious, and it is still widespread among veterans of the 1991 Gulf War. It is not the result of psychological stress and is not the same thing that happens after every war. Progress has been made in understanding “big picture” questions about Gulf War illness. The Research Advisory Committee believes that remaining questions can and must be addressed. It is our obligation, not only to assist 1991 Gulf War veterans who are still sick as a result of their wartime service, but also to ensure that similar problems do not affect future American troops deployed to war.

Senator MURRAY. Thank you, Dr. Steele.  
Dr. White?

**STATEMENT OF ROBERTA WHITE, PH.D, PROFESSOR AND  
CHAIR, DEPARTMENT OF ENVIRONMENTAL HEALTH,  
BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH**

Dr. WHITE. Thank you, Senator Murray, and thank you for inviting me to describe research on Gulf War illnesses here this morning.

In your written testimony, you have a description of my credentials and research funding history, so I won't go over that. But briefly, I have been studying Gulf War illnesses since 1993 and was research director of one of the three initial VA-funded centers on Gulf War illness. Shortly after the Gulf War, VA's Central Office contacted the VA Boston Health Care System about the fact that Gulf War veterans were returning with unusual symptoms. They asked some of us to look into the problem.

Our approach was to examine all of the possible factors that we could think of that might explain the appearance of unexplained illnesses in Gulf War veterans. Our major study population was a group of about 3,000 veterans who had been surveyed when they returned from the war through Fort Devens, Massachusetts. We studied health symptoms, Post Traumatic Stress Disorder, milder experiences of stress related to deployment, psychiatric disorders, and hazardous exposures experienced by Gulf War veterans.

One of our findings was that veterans who reported pesticide and chemical warfare agent exposure performed worse on objective tests of intellectual skills and had higher mood complaints than veterans who did not report these exposures. This suggested that these Gulf War exposures were associated with changes in brain function. Since we had the data on Post Traumatic Stress Disorder, stress levels, psychiatric disorders, and purposeful failure of tests for our study group, we were able to rule out these factors as explaining the findings on the behavioral test measures. This led us to believe that environmental exposures in the Gulf might explain some of the problems that veterans were experiencing.

We wanted to study the question of brain changes more directly, so we began using newly available brain imaging techniques. These techniques allow quantification of the sizes of brain structures. We also wanted to utilize new data that provided estimates of actual exposures in the theater.

For two studies, we used data from DOD that modeled the amount of sarin/cyclosarin exposure experienced by troops in the Khamisiyah area described by Dr. Steele over a 4-day period. We had brain scans or data from performance on standardized behavioral tests for individuals under the plume at Khamisiyah and the same data for veterans who were in locations where nerve gas agents are thought not to have been present. We analyzed the relationship between degree or dose exposure to sarin/cyclosarin and outcomes on the brain scans and the performance tests. Our results showed that there was a dose effect relationship between degree of exposure to nerve gas agents and adverse outcomes. For example, higher exposure was associated with smaller measurements of the volume of white matter in the brain. It was also associated with poor performance on a test of hand dexterity and speed while completing a pegboard task. Senator Sanders gave you a little review of some of this.

In another study, we carried out brain imaging and a brief set of behavioral tests on Gulf War veterans who differed in the number of health symptoms they were experiencing. The object was to compare high- and low-symptom groups. We are still analyzing the outcomes from this research. However, results to date suggest that certain brain structures are smaller in Gulf War veterans with higher numbers of symptom complaints than in veterans with few complaints. For example, a portion of the cingulate gyrus was smaller in the high-symptom veterans. This brain structure is involved in memory function.

There has been widespread dismissal of Gulf War veterans' health complaints as being psychiatric or imagined. However, the data from our studies combined with increased rates of ALS and brain tumors described by Dr. Steele provide objective evidence of brain damage among Gulf War veterans. This damage appears to range from subtle effects on brain structure and function to clinical disease.

The greater definition of objective outcomes and possible outcomes of Gulf War symptoms 16 years after the war is not unexpected. It parallels the identification of critical factors in illnesses in other populations. For example, as Senator Murray mentioned,

almost 20 years passed before Agent Orange exposure was linked to certain health outcomes in Vietnam veterans.

The research described from our group in Boston and from other groups points to the nervous system as the key determinant of Gulf War-related health problems. It is essential to consider the diagnostic and treatment implications of this research. I believe that concerted planning for treatments should begin immediately.

Thank you for listening to my perspectives on this issue.

[The prepared statement of Ms. White follows:]

PREPARED STATEMENT OF ROBERTA F. WHITE, PH.D., MEMBER, RESEARCH ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES; PROFESSOR AND CHAIR, DEPARTMENT OF ENVIRONMENTAL HEALTH BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH

Good morning, and thank you for asking me to describe my research with Gulf War veterans to you. I am Roberta White, professor and chair of the Department of Environmental Health at the Boston University School of Public Health.

With a large group of colleagues from many fields, I began studying Gulf War veterans and their health problems in 1993 and was research director and principal investigator for one of the initial three centers funded by the Department of Veterans Affairs to study Gulf War-related illnesses. I have received funding as principal investigator or co-principal investigator for several successive grants to study Gulf War-related illnesses; I was fortunate to have this work supported by VA, the Department of Defense, and the Centers for Disease Control. For many years I was a member of the Federal inter-agency committee on Gulf War illnesses. I have also seen Gulf War veterans as a clinician at VA, where I was a staff neuropsychologist before taking my current job.

Over the years of my career as a scientist, I have studied how chemicals and environmental hazards affect the functioning of the human brain. In Boston, we approached the problem of symptoms and illnesses in Gulf War veterans by investigating the relationships between exposures to hazardous chemicals and conditions in the Gulf War theater and health outcomes. In this research, we have used brain imaging and behavioral tests as ways of understanding abnormalities in brain function that may be seen in Gulf War veterans. This work culminated recently in the publication of two papers focusing on Gulf War veterans who were in the vicinity of Khamisiyah at the time of the detonation of the weapons depot there and a neurology meeting abstract on brain imaging differences between Gulf War veterans with high and low symptom complaints.

The two papers that summarize our work on exposures experienced by troops during the Khamisiyah detonation used data from DOD that modeled the amount of exposure to sarin and cyclosarin nerve gas agents among troop units located around Khamisiyah over a 3-day period. We had brain scans or data from performance on standardized tests of hand dexterity and intellectual function from individuals under the plume in Khamisiyah and from some who were in locations where nerve gas agents are thought to have been absent. We analyzed the relationship between degree or "dose" exposure to sarin/cyclosarin, ranging from none to a level above the recommended minimal daily exposure level, and outcomes on the brain scans and performance tests. Our results showed that there was a dose-effect relationship between degree of exposure to nerve gas agents and adverse outcomes on the brain scans and behavioral tests. For example, higher exposure was associated with smaller measurements of the volume of white matter in the brain and with poorer performance on a test of hand dexterity and speed while completing a pegboard task.

The neurology meeting poster presentation featured initial results from a study that has just been completed and for which we are still analyzing outcomes. The results suggested that certain brain structures are smaller in Gulf War veterans with higher numbers of symptom complaints than in veterans with few symptoms. For example, an area of the cingulate gyrus, which is involved in memory function, was smaller in the high-symptom veterans.

There has been widespread dismissal of Gulf War veterans' health complaints as being "psychiatric" or imagined. However, the data from our studies, combined with the increased rates of ALS and brain tumors described by Dr. Steele, provide objective evidence of brain damage among Gulf War veterans. This damage appears to range from subtle effects on brain structure and function to clinical disease.

The greater definition of objective outcomes and possible causes of Gulf War-related symptoms 15 years after the war is not unexpected and parallels the identi-

fication of critical factors in illnesses among other veteran populations. For example, almost 20 years passed before Agent Orange exposure was linked to certain health outcomes in Vietnam veterans.

Given the role of the nervous system in their symptomatic complaints and the appearance of neurological illnesses in Gulf War veterans, it is essential to consider the diagnostic, treatment, and intervention implications of the research that I have described. I believe that concerted planning for treatment interventions should begin immediately. It should focus on neurological symptoms, including diminished energy; strategies aimed at enhancing brain function, including thinking, memory and mood; and approaches to neuro-immunological and auto-immune dysfunction.

Thank you for listening to my perspectives on the serious issue of continued ill health among our Gulf War veterans.

Senator MURRAY. Thank you, Dr. Wright.  
Mr. Binns, we will turn to you.

**STATEMENT OF JAMES BINNS, CHAIRMAN, RESEARCH  
ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES**

Mr. BINNS. Madam Chairman, Ranking Member Burr, Members of the Committee, for the past 5 years, it has been my privilege to serve as Chairman of the Research Advisory Committee on Gulf War Veterans' Illnesses. I am honored to address your Committee, which includes so many who have championed the cause of ill Gulf War veterans for so long.

Let me begin with the conclusion of the extensive 1998 report on Gulf War illnesses of the Committee on Veterans' Affairs, on which many of you served. "The most important thing that VA and DOD can now do is to provide timely, accessible, and appropriate treatment to Gulf War veterans with these illnesses and attempt to prevent such illnesses in future deployments."

It is now 9 years later, 16 years after the war. As you have heard, 175,000 veterans, one in four of those who served, remain seriously ill. There are still no effective treatments. Those who are most ill have developed neurodegenerative diseases and brain cancer. And American military personnel and civilians remain at risk of similar exposures. Reuters reported last week on the test of a sarin warhead by Syrian and Iranian engineers, and I remember the Tokyo sarin subway attacks each time I board the Washington Metro.

The Federal Government has spent over \$300 million on Gulf War illnesses research. Some of that research was productive, as you have heard. But much was spent on psychological stress, part of a deliberate effort to downplay these illnesses as the sort of thing that happens after every war rather than the result of toxic exposures. Only two treatment studies have ever been conducted, with negligible results. This is a tragic record of failure and the time lost can never be regained.

I am pleased to report, however, that new programs are finally underway to address the needs you identified in 1998. At VA, Secretary Nicholson appointed new leadership at the Office of Research and Development, and at the initiative of Senator Hutchison of this Committee, Congress added \$15 million to the VA budget for Gulf War illnesses research and VA has contracted with the University of Texas-Southwestern to launch a Manhattan-style project to discover diagnostic markers and treatments.

The Department of Defense, however, has historically funded over two-thirds of Gulf War illnesses research, in excess of \$30 mil-



lion annually. Since the start of the current war, this program has been eliminated.

In 2006, led by Senator Sanders while a Member of the House, Congress initiated an innovative new pilot program at DOD focused on studies of promising treatments already approved for other illnesses. It is open to all researchers. The success of this program, which attracted 80 proposals, demonstrates the interest of the scientific community in solving this problem, and I hope that you will ask to hear more about it from the second panel and in particular Colonel Janet Harris, who is the commander of the program and who is here today supporting it.

DOD officially, however, has again excluded this program from its 2008 budget. I urge you all to support the effort of Senator Sanders to support this proven and critical program to the \$30 million level.

Thus, while promising research programs are at last in place, they only exist because of the leadership and support of Congress. Indeed, at the same time as dedicated VA scientists and DOD scientists are working on these problems, VA and DOD public statements continue to minimize these illnesses at every opportunity, misleading Congress and the scientific community.

For example, a so-called fact sheet recently provided by VA to Senators Rockefeller, Murray, and Bond asserted that "Gulf War veterans suffer from a wide range of common illnesses which might be expected in any group of veterans their age." That, as you have heard, is garbage. You are going to hear more of the same from the DOD spokesman later this morning. It is the big lie. It just isn't true.

Thus, I enthusiastically welcome this hearing and beseech the Committee's close attention to Gulf War illnesses research as these promising but fragile new programs begin to grow and bear fruit. They depend upon your support and your oversight. Otherwise, you will find them dead on the weed pile, and the critical needs you identified in 1998, treatments for ill veterans and victims of future attacks, ever more urgent today but no closer to reality, will remain empty words.

[The prepared statement of Mr. Binns follows:]

PREPARED STATEMENT OF JAMES BINNS, CHAIRMAN,  
RESEARCH ADVISORY COMMITTEE ON GULF WAR VETERANS ILLNESSES

Mr. Chairman, Ranking Member Burr, Members of the Committee, for the past 5 years, it has been my privilege to chair the Research Advisory Committee on Gulf War Veterans Illnesses. I am honored to address your Committee, which includes so many who have championed the cause of ill Gulf War veterans for so long.

and I remember the Tokyo sarin subway attack each time I board the Washington Metro.

The Federal Government has spent over \$300 million on Gulf War illnesses research. Some of that research was productive, as you have heard from Dr. Steele and Dr. White. But much of the money was misspent on the false theory that these illnesses were caused by psychological stress, part of a deliberate effort to downplay these illnesses as the sort of thing that happens after every war, rather than the result of toxic exposures. Only two treatment studies have ever been conducted, neither with significant results.

This is a tragic record of failure, and the time lost can never be regained. I am pleased to report, however, that new programs are finally underway to address the needs you identified in 1998. At VA, former Secretary Principi determined that VA would no longer fund studies based on stress, and Secretary Nicholson appointed new leadership at the Office of Research and Development. At the initiative of Senator Hutchison of this Committee, Congress added \$15 million to the VA research budget for Gulf War illnesses research, and VA has contracted with the University of Texas, Southwestern Medical Center, a leading site of Gulf War illnesses research, to launch a Manhattan-style project to discover diagnostic markers and treatments. I am extremely pleased to see VA Gulf War illnesses research at last in the hands of scientists committed to solving the problem.

The Department of Defense, however, has historically funded over two-thirds of Gulf War illnesses research, in excess of \$30 million annually. Since the start of the current war, this program has been eliminated.

In 2006, led by Senator Sanders while a Member of the House, Congress initiated a new pilot program for Gulf War illnesses research at DOD. It was an effort to treat the needs of Gulf War veterans, and it was a significant step forward. I am pleased to see this effort continue under the leadership of Senator Sanders, and I am confident that it will continue to be a priority of the new administration.

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~~in the hands of the government, and it is a tragedy that it has been eliminated. I am pleased to see this effort continue under the leadership of Senator Sanders, and I am confident that it will continue to be a priority of the new administration.~~

Julie Mock, let me just begin by telling you thank you so much for what you have done for our country. You have done your job and served us all well and I can only imagine how difficult it has been for you since your service, for both you and your children and all of your family and the impacts that have occurred to you.

As someone who served this country and put her life on the line for all of us, do you feel that our government has met its obligations and commitments to your family?

Ms. MOCK. No. Clearly, they haven't. Gulf War veterans still are struggling as they go to the VA to be connected for their services. The VA has been dismissive historically. Gulf War veterans, for example, who are being diagnosed with multiple sclerosis are being told that they no longer have multiple sclerosis and dismissed from the MS Centers of Excellence without any appropriate protocol for follow-up. That is one good example that I can share with you.

Senator MURRAY. What kind of message do you think this sends to future generations of military?

Ms. MOCK. The government won't be there. There are a lot of hollow promises. Our soldiers enlist or commit themselves to the military and they are not going to have anything when they come back. If they are ill or they are injured, I don't think they believe they are going to be cared for when they come back.

Senator MURRAY. Thank you, and I think that is a serious concern to all of us. It should be to all of America, and I appreciate that. And one last question for you. You and I have talked many times about multiple sclerosis. You were diagnosed with MS how long after you had been back?

Ms. MOCK. I began experiencing symptoms about 3 years after I returned, but I wasn't diagnosed until 2003.

Senator MURRAY. Many of our Gulf War veterans that have been diagnosed with MS are running into an arbitrary time limit that the VA has, that you have to be diagnosed within 7 years, correct, of your service?

Ms. MOCK. You have to prove that you had symptoms within 7 years of discharge.

Senator MURRAY. I know you have a wide network of people who you have been working with on this, and for many of them, is it not true that it is very difficult for them to get that diagnosis and they miss the deadline and, therefore, are not covered?

Ms. MOCK. It is very difficult for them to prove that the symptoms began within 7 years. So by 1998, they should have been showing symptoms, and it is not that they only needed to have symptoms, but they needed to have documentation of the symptoms and that is very difficult for many people to do. Symptoms for multiple sclerosis start out very mild many times, the dizziness, the coordination, the paresthesia, and it is difficult to pinpoint.

Senator MURRAY. Which is why I share with my Committee Members why I have introduced legislation to remove that 7-year time limit, because very often, it is very difficult to diagnose, and if it is done after 7 years, then it is not VA-connected and a lot of our men and women who served in the Gulf War and in previous conflicts end up not being served well. So I appreciate all your work on that, Julie.

Ms. MOCK. I would like to interject, also, that many of the symptoms of Gulf War illness overlap with multiple sclerosis symptoms.

Senator MURRAY. Dr. Nass, you mentioned in your testimony that a number of physicians at the VA believe that Gulf War illness doesn't exist, it is psychosomatic, it is caused by stress. Do you believe that this is the result of genuine difference of opinion about the cause of the illness or simply the refusal to accept what seems to be a mounting pile of evidence that a legitimate illness exists?

Dr. NASS. I think it is a combination of things. I think, first, the clinicians at the VA have not been well trained. My ex-husband was, in fact, the Gulf War doctor at one of the VA hospitals and shared with me the training materials he was given. Again, they focused on stress and psychological issues and treatment of headache and treatment of psychological problems.

As I told the House two months ago, I was surprised to get a new patient in July who told me his VA doctor did not believe in Gulf War syndrome.

Senator MURRAY. Did not believe in Gulf War syndrome?

Dr. NASS. That is correct. I think that is a problem. The literature is so confusing. There has not been a good review article about Gulf War Syndrome and so the medical profession is confused, as well as policymakers.

Senator MURRAY. Dr. Nass, you co-authored a study that found that although PTSD and depression is associated with higher rates of reported health problems in our servicemembers, those conditions did not entirely account for the numerous symptoms that are reported by our servicemembers. Mr. Binns asserts in his testimony that a lot of the funding for research on Gulf War illness has been unwisely spent on psychological causes of Gulf War illness as opposed to exposure to environmental toxins as a cause. What do you think is the relationship between the presence of physical symptoms attributable to Gulf War illness and psychiatric illness?

Dr. WHITE. Well, I certainly don't think that psychiatric illness explains it. Many of the veterans that I have studied in the years that I have been looking at this syndrome who have symptoms do not have a psychiatric diagnosis. I have tried measuring stress or Post Traumatic Stress in lots of ways other than just diagnosis, like looking at how stressed did a person feel by their experience in the war and whether that is related to the expression of symptoms later on, and there is some relationship but it certainly doesn't explain all of it.

Senator MURRAY. Thank you. Dr. Steele, in your testimony, you mentioned that effective treatments for Gulf War illness have not been found and few have ever been studied, and you go on to say that the Research Advisory Committee places the highest priority on research that leads to effective treatments. In your opinion, are the VA and DOD placing enough emphasis on treatment in their research of Gulf War illness?

Dr. STEELE. I would say, until recently, definitely not. There have been only two studies published and neither of them provided substantial benefit to a significant number of veterans. One study showed a little bit of benefit to some veterans. But there were no other studies funded at all besides those for many years. As Mr.

Binns said, recently, DOD had a pilot program with a small amount of money to fund smaller treatment studies, and that has just begun in the last year. Those studies were only recently funded. And there are two clinical trials going on at VA, as well. But they are really not focused on the kinds of problems that we are talking about necessarily and they are not focused on the causes for—

Senator MURRAY. What are these focused on?

Dr. STEELE. There is one focused on telemedicine cognitive behavioral therapy. In other words, you can call up the VA and get psychological therapy over the phone. There is another one that I think is more on point and that is looking at sleep disorders in Gulf War veterans and using the BI-PAP machine to help Gulf War veterans with sleep disorders, and we do know that a lot of Gulf War veterans—

Senator MURRAY. So only one of them is an effective treatment study?

Dr. STEELE. They are both treatment studies. We will see if they have any effect. We know that the cognitive behavioral therapy study that was not over the phone had a negligible effect in improving veterans' health. The sleep disorders could help veterans with sleep disorders and we would welcome that. But the larger problem relating to exposures to toxic chemicals and multi-symptom illness and treating the kinds of illnesses that we also see in the civilian population, we have no studies of that right now.

Senator MURRAY. OK. And Mr. Binns, let me just ask you, you said that we are misspending a lot of money on the false theory that these illnesses were caused by psychological stress. Can you expound on why psychological stress is not a credible cause of Gulf War illness?

Mr. BINNS. Yes. First, I should mention that Secretary Principi 3 years ago did determine that VA would no longer spend money on studies based on psychological stress, so VA has reached that conclusion itself.

One study showed that—it was conducted by a British group—showed that the number of people who have been in the Gulf War who have any psychiatric diagnosis, if you look at people who are the most ill population of that group, something like on the order of 19 percent of them had a psychiatric disorder. It is similar to the number that might have been in Bosnia, who have the psychiatric disorder. That meant that over three-quarters of those who had these severe illnesses do not have any psychological disorder.

If you have a chronic illness, you are bound to get a psychological disorder. Depression is very much associated with any kind of chronic illness. So the fact that only a quarter or less than a quarter of these Gulf War veterans are depressed or have any kind of psychiatric disorder tells me how mentally healthy they are. I mean, this woman sitting next to me, I could not—I mean, I have so much admiration for Julie, and there are thousands of people out there like her.

Senator MURRAY. Thank you very much, and I will turn it over to Senator Burr for questions.

Senator BURR. I thank my colleague.

Dr. Steele, you said at the conclusion of your testimony, progress has been made in understanding the big picture questions about Gulf War illness. The Research Advisory Committee believes that remaining questions can and must be addressed. Let me ask you, did the Committee identify what those questions that could and must be addressed are?

Dr. STEELE. We are in the process of finalizing and prioritizing those questions, but there are questions such as those related to multiple sclerosis, Parkinson's disease, things like that, those studies have not been done and can be done. But there are other questions that are very important to address and that relates to the specific biological mechanisms that underlie these illnesses, and also specific treatments that can improve veterans' symptoms.

Senator BURR. Let me just encourage the Committee at the earliest possible point, as you develop those questions, even if they are not complete, share them with the Committee so that they can help to guide us in the direction that we try to go.

Dr. STEELE. And that is the focus of our upcoming report that we will be happy to share with you.

Senator BURR. Thank you. Ms. Mock, I don't think any of us can thank you and your husband and your entire family enough for, one, the service that you have provided, and two, the struggles that you continue to go through as a family, as other families are. I noticed in your testimony that you stated that your husband is still serving on active duty, or is it—

Ms. MOCK. He is in the Reserves—

Senator BURR. He is in the Reserves.

Ms. MOCK.—the Army Reserves.

Senator BURR. And that he is fortunately healthy. Has he suffered from any of the conditions that have been described with the Gulf War illness?

Ms. MOCK. No, he hasn't. We were not in the same location, however. He was about 14 miles from where I was, and I can tell you that where I was at the 12th EVAC, there are three other people who were within 100 yards of me who have been diagnosed with multiple sclerosis.

Senator BURR. Mr. Binns, in your testimony, I think it is safe to say you were fairly critical of the Department of Veterans Affairs and their response to the Gulf War veterans. Last year, the Institute of Medicine conducted an exhaustive review of 850 research projects on the topic of Gulf War veterans' health and they concluded, "The investigators have attempted to define a unique health outcome of the war but none has been identified." Given that finding by what I think all of us would consider a fairly distinguished panel of scientists, what do you believe the VA should say and what they should do for the veterans?

Mr. BINNS. If I may, I will ask Dr. Steele as a scientist to comment on the finding of the Institute of Medicine Committee. The finding that there is no unique syndrome, as she mentioned, is irrelevant. The fact of the matter is that VA's most recent study shows that there are 35 percent of Gulf War veterans who have these symptoms and 10 percent of veterans of the same era who did not deploy. That is to say there are illnesses of the same na-

ture, as Senator Sanders has mentioned, in others that did not go to the Gulf. That is why they can say this is not a unique illness.

But the fact that 3.5 times as many people who went to the Gulf have this illness as compared to those who didn't—

Senator BURR. Trust me, I think we have consensus on the Committee that this is real, that the numbers are there.

I am curious from the standpoint of some of what you said suggested that maybe the interpretation of the research was flawed or that the research in total had not been evaluated.

Yet the Institute of Medicine did a fairly exhaustive review of all the research. Am I incorrect, Dr. Steele?

Dr. STEELE. I would say not at all an exhaustive review of the research.

Senator BURR. OK.

Dr. STEELE. They were charged by VA to look at a specific subset of the research. This included only human studies of occupational groups exposed to things similar to what Gulf War veterans were exposed to. Their study did not, for example, look at the large body of epidemiologic research that links symptoms in Gulf War veterans to exposures in the war. They tended not to rely on self-reported symptoms as something that might define some illness—

Senator BURR. And was this as directed by VA or was this the Institute of Medicine's choice as to how they reviewed it?

Dr. STEELE. They are commissioned by VA and their charge was given to them by VA.

Senator BURR. OK. Thank you. Dr. White, I noted in my opening statement that treatment should be the primary focus of our efforts as we try to assist those veterans who are ill from the Gulf War. Based on your research, do you believe that you can have a uniform approach to treatment, or do you believe that there has to be an individualization of that assessment and that treatment? Or is it both?

Dr. WHITE. I would say it is both. There are people who have very specific systemic syndromes involving the nervous system or the immune system. There are other people who have more generalized syndromes. And I think you have to think about both populations in thinking about research. I think the research that is out there indicates some specific kinds of physiological mechanisms that are coming to light that may be related to some of these disorders, dysfunction and degeneration in the nervous system, immune system problems, neuroendocrine problems. I think there is starting to be a body of knowledge out there that can lead us toward treatments, and I think very active, focused thinking by some neuropharmacologists, some immunopharmacologists could help us down the path toward looking at both kinds of problems.

Senator BURR. Last question. Dr. Nass, if I understand your testimony correctly, you believe that the combinations of exposures to different chemicals and substances in different people are, in fact, the cause of the illness, and my question is this. Has your research or any research that has been done that you know of uncovered any genetic indicators about those who might be at risk for exposure, illnesses, versus those who might not become ill regardless of their exposures?

Dr. NASS. In my written testimony, which you probably got late, I do cite several studies that looked into the genetics of people who became ill, and we know that people metabolize drugs and toxic substances very differently. It depends on the genes, the enzyme pool, and the substrates you have to produce the products that are necessary to detoxify. So that has been done by several people.

I am sorry, I forgot the second half of your question.

Senator BURR. Does it depend on those that might become ill, regardless of their exposure?

Dr. NASS. Certainly, there is going to be a proportion of people who will become ill without any of these military exposures. Since fibromyalgia as well as chronic fatigue are the best models for the Gulf War illness that we have discussed today. What we can say is that fibromyalgia affects about 2 percent of the U.S. population, 90 percent of whom are women. Chronic fatigue syndrome, we thought affected perhaps one-half percent or less of Americans, but CDC just did a telephone survey and decided that it affected several percent. That came out a couple of months ago. I don't think it is going to hold water.

So, yes, I think if you subtract those percentages from the 25 to 30 percent, you still have a lot of people who are sick beyond the baseline expected rates of illness.

Senator BURR. I thank you. I share your belief that a telephone survey may not be the most accurate thing for us to drive policy off of, but—

Dr. NASS. If I might, I know that Walter Reed has actually been looking at the genomes of people who have become ill after anthrax vaccine to see if there is a difference in the way they process the vaccine. That has not been published.

Senator BURR. Clearly, we have known for some time that people process vaccines differently based upon their genetic make-up. I thank the Chair.

Senator MURRAY. Thank you. Senator Sanders?

Senator SANDERS. Thank you. Well, there is one study that has not yet been funded and that is the study as to why the DOD and the VA for so many years, throughout so many wars, have attempted to deny the health problems that our soldiers have suffered. Back to World War II, where we had radiation illness, soldiers who were exposed to nuclear radiation had to fight hard to get our government to recognize their problems. And as we have heard today, in Vietnam, can you imagine that soldiers themselves had to struggle with their own government, not with Vietnam but with their own government for the recognition of what Agent Orange has done, something which is now accepted. And we are still here making that fight today.

I would just concur with what the other Senators have said to Julie Mock and thank you so much for being here and what you have done. I am sure that you performed with courage in the Gulf War and I would just say that you are performing now with at least as much courage in what you are doing here today, and what you are doing in general is so important, so thank you very much.

If I can begin by asking Mr. Binns, we are fighting, and I think we have had some success in the DOD appropriations bill, working with Senator Byrd and other Senators, in getting additional fund-



ing for the Congressionally Directed Medical Research Program. In your view, why does putting funding into that type of program make sense, if it does to you?

Mr. BINNS. As you know, Senator Sanders, this grew out of the small pilot program, \$5 million worth, that you and, as you mentioned, Congressman Shays inserted into the DOD budget in 2006. The commanding general at Fort Detrick, I believe, was the one who assigned it to the Congressionally Directed Medical Research Program. Dr. Steele and I met with Colonel Harris and her colleagues to describe what we had found and we were extremely pleasantly surprised to find that, at last, we had found a group of research managers within the Department of Defense who were truly dedicated to patients. They had extensive experience with patients with breast cancer, prostate cancer, other types of problems that they research, and they set up a very logical research program without any political overview.

So it includes a number of factors that were missing in the past. One is, as I say, really a dedication to solving the problem. Second is a group of merit reviewers who are reviewing what programs to study who actually are knowledgeable about Gulf War illness and actually include some of those who suffer from Gulf War illness, veterans who are on their panels. I should let Colonel Harris describe her program in more detail.

And most importantly, they have funded now a number of projects which are treatment oriented. They have proven by what they have funded—these programs have just been announced—

Senator SANDERS. And they are soliciting projects and ideas from a wide range of researchers all over the country, is that correct?

Mr. BINNS. I believe even researchers in foreign countries would be eligible to apply. There is no limitation on where this can come from, and what is most significant to me, so many researchers have responded to this program, even though it was a small pilot program. I think that with a more substantial amount of time and money, even greater response will be received.

Senator SANDERS. So, in other words, we are attracting some devoted researchers, people who are focusing on this issue all over the country from different perspectives and so forth?

Mr. BINNS. Exactly, and I believe some of these researchers are from VA. Some are from the Department of Defense. I do not for the minute impugn the dedication of scientists and doctors within the Department of Defense. There are many who stand ready to try to work on this.

Senator SANDERS. Let me ask anybody else on the panel, Dr. Nass, Dr. Steele, Dr. White, what is your gut feeling as to where we should be focusing new research? For example, it has only been, as I understand, within the last number of years that we have begun to see objectively demonstrated brain damage, in Gulf War returns. Is that a subject of more future research, do you think?

Dr. WHITE. Well, I think that especially as we progress with planned and existing research on high-and low-symptom complainers, people with chronic multi-symptom illness and subtle changes in brain function, that the structural changes in the brain that have been noted in white matter, the possibility of white matter degeneration leads to one set of possible treatments. The acetyl

cholinesterase inhibition hypothesis related to a number of the Gulf War chemicals that Dr. Steele talked about could lead to some other avenues of treatment.

I think that the clues are there in the literature. There is some new stuff on hypothalamic abscess, pituitary abscess, differences between people with PTSD and chronic multi-system illness in veterans. I think all of this, when you put the proper group of people together or go out with the proper RFAs for treatment protocols, I think they will lead to something.

Senator SANDERS. Dr. Steele, did you want to add?

Dr. STEELE. Yes. I agree with Dr. White. Our Committee has really strongly recommended that two paths be pursued. One is the path where you tease out the specific biology of what has gone on in the brain. What has happened as a result of these chemical exposures? What does that do to the brain, to the circuits, to the inflammatory processes, to the different parts? How do you identify that, and then how do you identify drugs and treatments that help that?

The other major path is to look at treatments that are used for things that look like Gulf War illness or that have things in common with Gulf War illness. So there are a lot of treatments right now for fibromyalgia, for example.

Other people use different things for multiple chemical sensitivity. Other people use things for the kinds of neurological damage that Dr. White is talking about.

So, one, we want to get down to the details by taking one path and looking at the specific biology of the problem, and then finding pharmacological treatments for those problems. On the other path, we want to do as has been suggested by the new DOD program, and that is look at things that are already on the shelf, take them off the shelf and see if they are helpful to Gulf War veterans.

Senator SANDERS. Now, obviously, our major focus is doing everything that we can to understand why our soldiers have been made ill and how we can treat them. Would I be correct, though, in understanding that the more knowledge that we ascertain from these studies, that it will benefit the civilian population of people who are suffering from similar-type illnesses? Would that be a fair statement, Dr. Steele?

Dr. STEELE. I think it is a very fair statement. We know that there are parallels between things like chronic fatigue syndrome, multiple chemical sensitivity, and Gulf War illness. They don't look exactly the same in all studies, but there are parallels and we think that some of the biology that underlies them may be similar. So we do think that things that we find out about Gulf War illness could help other people with similar conditions.

Senator SANDERS. Thank you Madam Chair.

Senator MURRAY. Thank you. Senator Isakson?

Senator ISAKSON. Thank you, Madam Chairman, and thanks to all the Members for testifying today.

Mr. Binns, under whose auspices is the Research Advisory Committee on Gulf War Veterans' Illnesses?

Mr. BINNS. The Committee was established by Congress under a public law in 1998 and it is appointed by the Secretary of Veterans Affairs.

Senator ISAKSON. And you also serve, Dr. Steele, on that Committee?

Dr. STEELE. Yes. I am the Scientific Director.

Senator ISAKSON. You can both answer this, if you like. In your testimony, in particular, Mr. Binns, and yours, too, Dr. Steele, it doesn't appear that a lot of the advice the Committee is giving is being taken. Is that right or wrong?

Mr. BINNS. Within the last year, there has been a definite change in the attitude of the VA Office of Research and Development. As I said, Secretary Nicholson appointed new leadership here. Dr. Kupersmith will speak later. And I think we are seeing a change in the direction of VA research, but not a complete one yet, a change.

Unfortunately, as I mentioned, VA's other official pronouncements, which come from different departments of VA, continue to minimize these problems.

Senator ISAKSON. I noticed in your testimony on one hand you were complimentary of the \$15 million designated to the University of Texas that Senator Hutchison put in for the Manhattan-type project, and on the next page the fact that the original Shay-Sanders money that had been put in had not been requested by the Department, is that correct?

Mr. BINNS. That money was at DOD.

Senator ISAKSON. That was at DOD?

Mr. BINNS. Yes. Essentially, you have had VA providing about one-third of the research, DOD providing about two-thirds. The two-thirds has gone away completely but for what Congress has inserted up to the present minute.

There is no money at DOD other than what Congress mandates.

Senator ISAKSON. So the \$15 million is at VA, though?

Mr. BINNS. That is correct.

Senator ISAKSON. Julie, I want to add what everybody has said in thanking you for your service and your coming here today, with all you have got to deal with. You are a real inspiration to all of us.

I have a question with regard to the vaccines. You referred a couple of times in your testimony to the vaccines that you were given before you deployed, and then, Dr. Nass, you made specific references to the smallpox vaccine and others. I will ask you first, Julie, and then you can comment, Dr. Nass. Were any of the difficulties that your sons have encountered in any way tied or symptomatic of those vaccines?

Ms. MOCK. Honestly, I am not sure. I think we—regarding the vaccines that we received, we don't have a good list of what we actually did receive. Depending on where you were preparing for deployment, you got a certain cocktail of vaccines, and when you were preparing to deploy from another area, you received perhaps another cocktail. So I have no idea exactly what we received.

Senator ISAKSON. Dr. Nass?

Dr. NASS. It is a very tough, politically charged question. The one study of women who got anthrax vaccine inadvertently during their first trimester of pregnancy showed that they had a 39 percent greater risk of having a child with a birth defect. That study has

never been published, even though it was reported on as early as late 2001.

This study compared women who got anthrax vaccine during the first trimester of pregnancy to women who got anthrax vaccine at any other time, so that if you compared them to women who had never gotten anthrax vaccine, the birth defect rates might be higher. And that research project looked at every woman in the military who had received anthrax vaccine and had had a pregnancy. And the paper records were obtained, not just the computer records, because the study was criticized by the Army initially. However, there are no good studies and nobody wants to touch this issue, because the military wants the ability to use these vaccines, and doesn't want to uncover any evidence that they are even worse than we already know they are.

Senator ISAKSON. Thank you for your answers. Thank you, Madam Chairman.

Senator MURRAY. Thank you. I just have a couple of questions.

Dr. Steele, can you comment on that, too, on the risks of birth defects in Gulf War veterans?

Dr. STEELE. There have been quite a number of studies of rates of birth defects in Gulf War veterans. The early studies were smaller studies and only looked at military hospitalizations and didn't find any increase. Since then, though, there have been larger studies and more comprehensive studies and they have found increased rates of birth defects, but still not high rates of birth defects. So slight increases in certain types of birth defects, but overall, the rate is still low. We don't have definitive information about which specific birth defects are increased and how much because the studies just haven't been big enough.

What we don't have are studies of children the ages of Julie's, when they got sick. The birth defects studies look at either things that you can find at birth or within the first year, and some children don't develop their problems until later. There has been one VA study that has looked at the family members of Gulf War veterans, both spouses and children, and older children, but we haven't seen published results from the children's study yet and we are not even sure if they looked at these kinds of conditions. We are thinking they only looked at psychiatric conditions. We just don't know.

So we don't have data to know if there are higher rates of problems such as Julie described in Gulf War veterans overall.

Senator MURRAY. So we may well have a number of children out there that have birth defects that could be possibly related back to the Gulf War that the parents don't even have a clue of knowing that?

Dr. STEELE. That is possible, and we are thinking that what would be classified as a birth defect could be elevated in some cases but still we don't think there are large numbers. We are also, though, concerned about these things that wouldn't be called birth defects, things that don't happen until—

Dr. NASS. Neurobehavioral effects.

Dr. STEELE.—children are older. Yes.

Senator MURRAY. Dr. Nass, I am sorry—

Dr. NASS. I am sorry. I said neurobehavioral effects that do not turn up in the first year, but when the child is talking and walking, going to school, then they get diagnosed at a later age.

Senator MURRAY. I found it very troubling, what you said to Senator Isakson that studies aren't being done because people don't want to maybe find out what the results are. Julie, how does that make you feel?

Ms. MOCK. I can't tell you how it makes me feel. It makes me feel enraged, I guess. I see my children suffer.

We are very fortunate. We can provide what our kids need, but hearing from other parents who don't have the resources that we have or the wherewithal to find the help that their children need, it is frustrating and it is a tragedy.

Senator MURRAY. And a tragedy to hear, as well.

Dr. White, let me ask you one final question, and that is that you have been a co-author on two studies. One of them indicated that there were subtle changes in the brains of deployed Gulf War veterans as compared to non-deployed veterans, and the other one was demonstrating worsening neurobehavioral functioning dependent on the amount of sarin and cyclosarin exposure. As you mentioned, I sent a letter along with Senators Bond and Rockefeller to Secretary Nicholson and to Secretary Gates asking that they move forward with more research to find better and effective treatment for thousands of our Gulf War veterans, and when they responded to us, both the VA and the DOD criticized your studies and said that they were critical of the mathematical model used to calculate the exposure data in the neurobehavioral study and they cited limitations in the MRI study suggesting that the number of veterans studied was too small to draw any conclusions. Could you respond to that criticism?

Dr. WHITE. Well, first of all, the exposure modeling that we used was from DOD and my understanding is that if it is inaccurate, it may have underestimated exposure in the Gulf, in which case it would have made it less possible for us to find results. So if the data from—if the sarin modeling data are wrong and there is no association, they had to have been systematically wrong in a way for us to see a dose effect relationship, the relationship between the dose and the effect that made me believe the results.

The other thing that made me believe the results was that I have worked with Japanese scientists around people in the train incidents in Japan and the behavioral findings and the MRI findings were very similar in those two cases.

Finally, let me say the problem with all imaging studies is that they tend to be small because they are expensive, it is hard to get people in, it is a very complicated process to do a neuroimaging study and 26 subjects is actually on the large side for an imaging study.

The one that I talked to you about with the high-and low-symptom complainers that we just finished actually has 59 veterans in it. So we are hoping that will be a little more definitive than 26, but 26 is the size these studies are.

Senator MURRAY. OK. Senator Burr? All right.

Well, I would like to thank all of our panelists. We may have some questions from the Committee that we will submit to you in

writing and ask for you to submit answers. But again, thank you to all of you for being here and I would ask our second panel to come forward at this time.

I want to thank all of our second panel for being here, as well, and I will begin by introducing Dr. Michael Kilpatrick. He is the Deputy Director for Force Health Protection and Readiness Programs in the Office of the Assistant Secretary of Defense for Health Affairs. He is accompanied by Colonel Janet Harris. She is the Director of Congressionally Directed Medical Research Programs in the Department of Army.

We also have Dr. Joel Kupersmith. He is the Chief Research and Development Officer in the VA, and he is accompanied by Dr. Timothy O'Leary, the Director of Biomedical Laboratory and Clinical Science Research and Development Services.

Thank you all for joining with us today. Again, your full statements will appear in the record and I ask you to keep your remarks to 5 minutes. We will begin with Dr. Kilpatrick.

**STATEMENT OF MICHAEL E. KILPATRICK, M.D., DEPUTY DIRECTOR FOR FORCE HEALTH PROTECTION AND READINESS PROGRAMS, OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE; ACCOMPANIED BY COLONEL JANET HARRIS, PH.D., R.M., DIRECTOR, CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS, DEPARTMENT OF THE ARMY, DEPARTMENT OF DEFENSE**

Dr. KILPATRICK. Madam Chairman and distinguished Members of the Committee, thank you for the opportunity to discuss the Department of Defense's Force Health Protection and Readiness Program with a focus on veterans of the 1990–1991 Gulf War. With me is Colonel Janet Harris, Director of Congressionally Directed Medical Research Programs.

Two primary objectives of the military health system are to ensure a medically ready force and to provide world class care to those who become ill or injured. We have a multitude of proactive programs to educate our servicemembers, their families, and our military leadership. We also have robust surveillance and research programs to monitor the health of our force. The medical lessons learned from the Gulf War led to the implementation of this Force Health Protection concept, policies, and programs.

The combined analysis of DOD and VA Gulf War veteran clinical evaluations of approximately 100,000 veterans showed that more than 80 percent had recognized health problems and received conventional treatment. Treatment programs are also available for veterans with chronic unexplained symptoms, and again, it is important to understand that once you have a diagnosis, that may not explain all the symptoms that an individual veteran has.

In 1991, DOD established the Deployment Health Research Center, the Deployment Health Clinical Center, and the Deployment Health Surveillance Center to work closely with VA's War Related Illness and Injury Study Centers. The Deployment Health Research Center, in collaboration with the VA, designed the Millennium Cohort Study to evaluate the long-term health effects of military service, specifically deployments.

Since 1992, the Departments of Defense, Veterans Affairs, and Health and Human Services have funded over 300 distinct projects related to health problems affecting Gulf War veterans, as Senator Burr mentioned. In September 2006, the Institute of Medicine did publish a review of the medical literature on illnesses of Gulf War veterans and their conclusion, “no unique syndrome, no unique illness or unique pattern of symptoms,” in Gulf War veterans was the finalization of that evaluation. The final statement of that IOM report was, “Our Committee does not recommend that more such studies be undertaken for the Gulf War veterans, but there would be value in continuing to monitor the veterans for some health endpoints, specifically cancer, especially brain and testicular cancers, neurological diseases, including ALS, and causes of death.”

The DOD Gulf War Illness Research Program was initially established in 1994 and it was renamed the Force Health Protection Research Program in 2002. While it continued to support diagnostic and treatment research for Gulf War veterans, the focus was expanded to include current and future military deployments. This includes studies on the mechanisms of illness, chronic effects of neurological substances, identifying neurological and immunological abnormalities, and the identification of promising treatments.

Pre- and post-deployment health assessments were begun in 1998. The post-deployment health assessment was augmented in 2003 and the post-deployment health reassessment was begun in June of 2005 to reevaluate servicemembers some 3 to 6 months after they return home. The two post-deployment health assessments include a one-on-one interaction of the servicemembers with a health care provider to determine need for further evaluation and diagnostic work-up. The assessments are not medical diagnostic instruments, but are screening tools to identify the need for medical evaluation.

Medical referral rates on return home are 20 percent for active duty and 24 percent for the Reserve component. Referral rates 3 to 6 months later are 19 percent for the active duty and 51 percent for the Reserve component.

Deployment-related research maintains quality care and an environment of expanding knowledge. Today, 358 deployment health research-related projects are being conducted. Examples are 50 projects on traumatic musculoskeletal injuries, 96 projects on Traumatic Brain Injury and spinal cord injury, 67 projects on mental disorders, including PTSD, and 29 projects on infectious diseases.

The Department of Defense is very concerned about the short-term and long-term health effects of deployments and military service for all its servicemembers. Our ability to analyze medical data related to deployments in a proactive way is enabling us to develop and modify programs to better prepare our servicemembers and their families for the stressors of military service, to educate them and our leadership on recognizing when to seek medical evaluation for concerns, and to make changes when medically indicated. We will continue to analyze the information to assure we are doing everything possible to protect their health and to provide the care and treatment they need and deserve while they are deployed and when they come home.

Thank you for the opportunity to present this information to you and I look forward to your questions.

[The prepared statement of Dr. Kilpatrick follows:]

PREPARED STATEMENT OF MICHAEL E KILPATRICK, M.D., DEPUTY DIRECTOR,  
FORCE HEALTH PROTECTION AND READINESS PROGRAMS, DEPARTMENT OF DEFENSE

Mr. Chairman and distinguished Members of the Committee, thank you for the opportunity to discuss the Department of Defense's (DOD's) Force Health Protection and Readiness Program and the programs within the Military Health System, with a focus on the aspects of those programs related to research on veterans of the 1991 Gulf War.

Two primary objectives of the Military Health System are to ensure a medically ready force and to provide world class care for those who become ill or injured. The importance of these objectives is recognized throughout the DOD, and we have a multitude of proactive programs in place to educate our Servicemembers and their families and our military leadership. We also have robust surveillance and research programs in place to monitor the health of our force.

The medical lessons learned from the 1991 Gulf War led to the implementation of the Force Health Protection concept, policies, and programs. Shortly after the 1991 Gulf War, some of the 700,000 Servicemembers deployed during that conflict began to present for care with symptoms they believed were related to their deployment. The unclear cause of symptoms, in some cases, presented a challenge for both military and Veterans Affairs (VA) providers.

As a result, the VA established the VA Gulf War Health Examination Registry to identify possible endemic diseases or hazardous exposures resulting from U.S. military personnel service in Southwest Asia. Subsequently, the Assistant Secretary of Defense for Health Affairs initiated the Comprehensive Clinical Evaluation Program to offer examinations to Gulf War veterans.

A combined analysis of the VA and DOD Gulf War clinical evaluation programs' study of over 100,000 participants showed that more than 80 percent of veterans evaluated had well-known health problems and received conventional diagnoses and treatment. Moreover, 6 to 9 percent of evaluated veterans reported that they did not have a clinically significant new illness. The findings from over 100,000 clinical examinations have substantially aided health care efforts. Veterans of the 1991 Gulf War who report health problems are definitely ill. However, they do not have a single type of health problem. Consequently, these veterans have to be evaluated and treated as individuals. Assumptions based on participation in the 1991 Gulf War cannot be made about the health of a veteran who presents for clinical evaluation. Each veteran requires a medical history and screening examination, with treatment tailored to the specific needs of the patient. For 1991 Gulf War veterans who have well-known health problems, effective therapy is available. Treatment also is available for veterans with chronic, unexplained symptoms.

In 1991, the DOD established the Deployment Health Research Center, the Deployment Health Clinical Center (DHCC), and the Deployment Health Surveillance Center to work closely with the VA's War Related Illness and Injury Study Centers. The DHCC's mission began with a focus on illnesses associated with the 1991 Gulf War and was expanded to include not only clinical care of deployment veterans, but also deployment-related health research and training, education, and communication responsibilities. The DHCC added risk communication, clinical and health services research, and epidemiological expertise to its staff, and now has a research portfolio comprising a dozen demographic and epidemiology projects, nine health services research projects, and clinical trials.

Major focus areas for DHCC research include post-war syndromes, especially illness related to the 1991 Gulf War, medically unexplained physical symptoms, and Post Traumatic Stress Disorder (PTSD) that occurs subsequent to combat, sexual assault, or terrorist attack. The DHCC was involved in the creation of the DOD/VA Post-Deployment Health Evaluation and Management Clinical Practice Guideline. The guideline was completed in 2001, following Institute of Medicine recommendations to incorporate deployment healthcare into primary care and to regularly screen all military beneficiaries. The DHCC also supports the DOD/VA guidelines for primary-care based detection and treatment of depression, PTSD, and medically unexplained symptoms through staff assistance, training programs, and research projects.

The Deployment Health Research Center, in collaboration with the VA, designed the Millennium Cohort Study, to evaluate the long-term health effects of military service, specifically deployments. The study was initiated in 2001. Funded by the



DOD, and supported by military, VA, and civilian researchers, almost 140,000 Servicemembers will eventually participate in this groundbreaking study. As force health protection continues to be a priority for the future of the United States military, the Millennium Cohort Study will be providing a crucial step toward enhancing the long-term health of military Servicemembers.

Since 1992, the DOD, VA, and Health and Human Services (HHS) have funded over 300 distinct projects related to health problems affecting Gulf War veterans. The DOD Gulf War Illness research program was established in 1994 and was renamed the Force Health Protection Research Program in 2002. While it continued to support diagnostic and treatment capabilities for 1991 Gulf War veterans, the focus was expanded to include current and future military deployments and how to respond better to the health care needs of those who deploy. Research pertaining to illnesses of Gulf War veterans has also been funded through the Military-Relevant Disease Management topic area of the Congressionally Directed Medical Research Program. DOD support for a coherent research program for illnesses of the veterans of the 1991 Gulf War has four focus areas:

1. Identification of mechanisms underlying the illnesses;
2. Chronic effects of neurotoxic substances to which veterans were exposed during deployment;
3. Studies that expand on earlier research identifying neurological and immunological abnormalities in ill veterans; and
4. Identification of promising treatments.

DOD has made significant improvements and advances in deployment health-related processes, based on research results and healthcare outcomes since the 1990–1991 Gulf War. Pre-Deployment and Post-Deployment Health Assessments (PDHAs) were begun in 1998. The PDHA was augmented in 2003 to collect a standardized set of information about medical symptoms or concerns, again because of medical lessons learned from those returning home from deployments. The Post-Deployment Health Reassessment (PDHRA) was begun in June 2005 to reevaluate the health of those who returned from deployments some three to six months after their return. This reassessment was initiated because of military medical research data showing increased physical and mental health symptoms and concerns in Servicemembers after they were home and reintegrating with their families and their work.

The PDHA and the PDHRA are both designed to include a one-on-one interaction of each Servicemember with a healthcare provider to review the concerns identified by the member on the assessment and to make a determination of the medical indications for referral for further evaluation and diagnostic workup. The assessments are not medical diagnostic instruments, but are screening tools to identify the need for medical evaluation.

The PDHA enables the medical provider to determine if any further medical evaluations are needed before making a medical recommendation on the individual's deployability. We are consistently finding that about 4 percent of those evaluated at the pre-deployment processing centers have medical problems identified that preclude them from deploying at that time.

The PDHAs from the worldwide deployments of Servicemembers from January 1, 2003, to February 12, 2007, show that 93 percent of Active Duty Servicemembers indicate their general health as "good," "very good," or "excellent," 22 percent indicate they have medical concerns, and 5 percent indicate they have mental health concerns. Referral rates after discussion with a medical provider show that 18 percent are referred for further medical evaluation. The referrals are fairly equally divided among "medical" only, "mental health" only, and both "medical and mental health." For the Reserve component, 90 percent rate their health as good, very good, or excellent; 41 percent indicate they have medical problems; 6 percent indicate they have mental health concerns; and 24 percent are referred.

The PDHRAs from the worldwide deployments of Servicemembers from June 2005 to March 2007, show that 85 percent of Active Duty Servicemembers indicate their general health as "good," "very good," or "excellent"; 33 percent indicate they have medical concerns; and 27 percent indicate they have mental health concerns. Referral rates after discussion with a medical provider show that 16 percent are referred for further medical evaluation. The referrals are fairly equally divided among "medical" only, "mental health" only, and both "medical and mental health." For the Reserve component, 82 percent indicate their health is good, very good, or excellent; 56 percent indicate medical concerns, 42 percent indicate mental health concerns; and 51 percent are referred. An important element of the PDHA and the PDHRA is education of the Servicemembers about medical conditions, both physical and mental, and the signs and symptoms that indicate the need for further evaluation.

To better understand the mental health needs of the deployed forces, the Army sent a Mental Health Advisory Team (MHAT) to theater in September and October 2003. This was the first time that such an assessment was conducted during a war-time deployment. The Army has sent MHATs to theater three subsequent times, September to October 2004, October to November 2005, and August to October 2006, to continue to evaluate adequacy of mental health support in theater and preparation of medical and support staff for mental health care.

Deployment-related research is performed at local, Service, and interagency collaborative levels to maintain quality care in an environment of expanding knowledge. At the present time, 358 deployment health-related research projects are being conducted across various organizations of the DOD, VA, and HHS, as well as other Federal and academic organizations. These focus on a wide variety of physical health and mental health topics. For example, there are 50 projects on traumatic musculoskeletal injuries; 97 projects on Traumatic Brain and Spinal Cord Injuries; 67 projects on mental disorders, including PTSD; and 29 projects on infectious diseases. From 1992 to 2006, more than 250 deployment health-related research projects were initiated and completed. During the past 14 years, more than 850 articles were published in peer-reviewed medical and scientific journals on deployment-related medical research.

The DOD is very concerned about the short-term and long-term health effects of deployments and military service for all of its Servicemembers. Our ability to analyze medical data related to deployments in a proactive way is enabling us to develop and modify programs to better prepare our Servicemembers and their families for the stressors of military service, to educate them and our leadership on recognizing when to seek medical evaluation for concerns and to make changes when medically indicated. Since we repeatedly assess both physical and mental health of our force, we will continue to analyze the information to assure we are doing everything possible to protect their health and to provide the care and treatment they need and deserve while they are deployed and when they come home.

Mr. Chairman, I thank you for the opportunity to provide you and the Members of the Committee with an overview of the Military Health System's Force Health Protection research program. I am ready to answer your questions.

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RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY DANIEL K. AKAKA, TO DR. MICHAEL E. KILPATRICK, M.D., U.S. DEPARTMENT OF DEFENSE

**Question.** As early as 1998, the Senate Committee on Veterans' Affairs formally recommended complete base-line and post-deployment health screens for servicemembers, but a final system has not been instituted. Why has this screening system taken so long to implement, and when can we expect full implementation?

**Answer.** The pre-deployment health assessment and post-deployment health assessment (PDHA) have been implemented since 1998.

The 1998 law required the Secretary of Defense to "establish a system to assess the medical condition of members of the armed forces (including members of the reserve components) who are deployed outside the United States." The law required the use of pre- and post-deployment examinations; this was codified as 10 U.S.C. Section 1074f.

In 2003, The Department of Defense (DOD) enhanced the PDHA. In 2005, DOD added the post-deployment health reassessment (PDHRA) to screen for health concerns at 90 to 180 days after return from deployment. In 2006, DOD implemented an annual periodic health assessment for each servicemember, in addition to the PDHA and PDHRA.

The Government Accountability Office (GAO) has evaluated these health assessment programs multiple times. In June 2007, GAO published a report entitled "Defense Health Care: Comprehensive Oversight Framework Needed to Help Ensure Effective Implementation of a Deployment Health Quality Assurance Program (GAO-07-831)." One of the specific issues that GAO was requested to address was "whether DOD has established a medical tracking system to comply with the requirements of 10 U.S.C. section 1074f pertaining to pre- and post-deployment medical examinations." In the results of its study, the GAO stated, "DOD has established a medical tracking system to comply with the requirements of 10 U.S.C., section 1074f, to perform pre-deployment and post-deployment medical examinations through a variety of deployment health activities." The GAO further stated, "DOD's use of a variety of deployment health activities, including the use of pre- and post-deployment health assessment questionnaires along with reviews of servicemembers' medical records is a reasonable interpretation of section 1074f."

Question. The active monitoring of servicemember and the operational environment in which they serve is critical. In light of the lessons of the Gulf War, what steps has DOD taken to ensure there is adequate monitoring of servicemember health during deployment, and how does DOD screen for low level exposures to chemical agents in operational areas?

Answer. DOD is firmly committed to protecting the health of our Active and Reserve Component members before deployment, while they are deployed, and after they return. Occupational and environmental health surveillance is a key component of the preventive medicine activities that take place during deployments, including Operation Iraqi Freedom and Operation Enduring Freedom. DOD recognizes the need to monitor the deployed environment for potentially hazardous materials and to document and archive the results so that they can be used as an aid in the diagnosis and medical care of exposed personnel. After the 1990–91 Gulf War, DOD implemented a number of directives, instructions, and policies to improve occupational and environmental health (OEH) surveillance during deployments. As a result, the Services, the Joint Staff, and the Combatant Commands have made substantial progress to better address the immediate and long-term health issues associated with deployment occupational and environmental exposures.

DOD's deployment OEH program includes a number of key preventive measures that help to ensure Service members are protected from potentially hazardous exposures. Several of these preventive measures include:

- Comprehensive pre-deployment health threats and countermeasures briefings.
- Completion of a pre-deployment health assessment, including providing a serum sample before deployment.
- Completion of all necessary immunizations and the dispensing of preventive medications and personal protective equipment before deployment.
- Performance of baseline, routine, and incident-related occupational and environmental monitoring, with documentation in the medical records of any hazardous exposures encountered during the deployment.
- Completion of a post-deployment health assessment, including questions about health concerns and OEH exposures, and providing a serum sample within 30 days of returning home.
- Completion of a post-deployment health reassessment three to 6 months after returning from deployment, including questions about health concerns and OEH concerns.
- Referral to a health care provider, as appropriate, for follow-up and evaluation of health concerns reported on the post-deployment health assessment or reassessment.

Well-trained and equipped Army, Navy, and Air Force medical personnel conduct on-going, in-theater OEH surveillance, and closely monitor air, water, soil, food, and disease vectors for health threats. Three types of OEH data are collected and reported:

- "Baseline data," which are collected on air, water, and soil samples at the time base camps are established;
- "Routine (or periodic) data," such as follow-up air, soil, and water monitoring data used to detect any changes in concentrations of potential contaminants over time; and
- "Incident-related data," which includes data acquired during investigations of chemical spills, industrial accidents, food or waterborne illness outbreaks, and chemical/biological agent exposures or attacks.

All OEH monitoring data is documented, and archived in a systematic manner, as follows:

- All environmental samples are identified with a date, time, and location that can be potentially linked with individuals who were at a particular location at a specified date and time.
- Possible hazardous exposure incidents are thoroughly investigated, extensive environmental monitoring accomplished, appropriate medical tests ordered, and rosters of exposed personnel assembled.
- Area and date-specific environmental monitoring summaries are developed by the Services to document environmental conditions potentially affecting health and to serve as means to inform health care providers of those environmental conditions and possible health risks associated with the conditions.

When requested, the Services' Health Surveillance Centers (the US Army Center for Health Promotion and Preventive Medicine (USACHPPM)), the Navy Environmental Health Center, and the Air Force Institute for Operational Health) provide additional technical and consultative assistance to deployed medical teams, labora-

tory analysis and interpretation of samples, pre-deployment OEH hazard assessments, and OEH risk characterization reports for deployed forces. All deployment OEH data and reports are archived centrally at the USACHPPM. The Army is the lead Service for joint occupational and environmental health surveillance data archiving.

Monitoring for chemical warfare agents is a special concern in operational areas. Experts evaluate the threat of the potential use of a chemical agent based on intelligence and past experience in that country. A number of field chemical detectors are currently in use in operational areas, such as the Improved Chemical Agent Monitor (ICAM) and the M22 Automatic Chemical Agent Detector Alarm (ACADA). The ICAM is a hand-held instrument that provides indication of G-type and V-type nerve agents, as well as H-type blister agent (mustard agent) concentrations. The ICAM may be used for a variety of missions, including area reconnaissance and area surveillance, monitoring of decontamination operations, and medical triage operations. The ACADA is a portable point sampling system, which detects and identifies GA, GB, GD and VX nerve agents, and detects mustard and Lewisite blister agents. Improvements to the ACADA allow it to detect some toxic industrial chemicals.

**Question.** There is great concern over the safety of vaccinations currently and previously provided to servicemembers, specifically smallpox and anthrax. At least two witnesses of the first panel of today's hearing expressed concern that DOD is being less than forthcoming with research on the safety of vaccines. In the late 1990's, DOD contracted with the RAND Corporation for the production of an eight volume set on Gulf War exposures. At this time, the section on immunizations and Gulf War illnesses, which was completed in 1999 and revised in 2004, has not yet been released. Can you explain why this information has not been made available to ill veterans and other medical researchers?

**Answer.** We regret the delays incurred on this publication and we look forward to its final production and dissemination as soon as possible.

This remaining volume of RAND's work related to illnesses of 1990-91 Gulf War veterans, has been in various phases of completion and production for the past several years. This volume focuses on the issues pertaining to the use of vaccines (specifically the botulinum toxin and anthrax vaccinations) among 1990-91 Gulf War servicemembers. The report reviews the scientific literature as it pertains to the health effects of these two vaccines and in light of this evidence aims to reach a conclusion about whether these vaccines may have affected the health outcomes of the veterans of this war. In late 2002, with the support of the Assistant Secretary of Defense for Health Affairs, the report was pulled from production to be updated to include relevant literature based on the use of the vaccine following 2001 anthrax attacks and to undergo a technical review.

veterical res-hrax

cines (specifically the botulinum toxin and anthrax vaccinations) among 1990–91 Gulf War servicemembers. The report reviews the scientific literature as it pertains to the health effects of these two vaccines and in light of this evidence aims to reach a conclusion about whether these vaccines may have affected the health outcomes of the veterans of this war. In late 2002, with the support of the Assistant Secretary of Defense for Health Affairs, the report was pulled from production to be updated to include relevant literature based on the use of the vaccine following 2001 anthrax attacks and to undergo a technical peer review.

The RAND production process includes a rigorous and sequential technical peer review process—a process that takes time. This process is an essential element of RAND's commitment to objectivity and quality. This peer review process includes critical review from external technical experts, the RAND quality assurance management team, RAND program leaders, and the sponsor. The time required for each reviewer to provide a critical assessment of the manuscript and for Dr. Golomb to respond with revisions is commensurate with the length, scope, and significance of the manuscript itself. This particular draft has now been reviewed by five technical peer reviewers. Once the current revisions are completed, it will also be reviewed again by the RAND quality assurance management team and program directors before submission to DOD.

The author is currently making final revisions to the manuscript in response to comments received during the external technical review that occurred in late summer 2006. Once the author completes these revisions, DOD will have an opportunity for review and comment. Once DOD provides sign off and publication clearance, the report will be printed and disseminated, at which time DOD will post the document on the Force Health Protection web site to make it available to veterans, researchers, and any one else with interest.

We regret the delays incurred on this publication and we look forward to its final production and dissemination as soon as possible.

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RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. BERNARD SANDERS TO DR.  
MICHAEL E. KILPATRICK, M.D., U.S. DEPARTMENT OF DEFENSE

Question. On page three of your testimony you state: “Veterans of the 1991 Gulf War who report health problems are definitely ill. However, they do not have a single type of health problem.” How do you reconcile this statement with the latest VA Longitudinal Health Study of Gulf War Era Veterans and other epidemiological studies mentioned by Dr. Steele that consistently have shown that 25–30 percent of Gulf War veterans have multisymptom illness over and above the rate in non-deployed peer?

Answer. This question confuses two separate concepts: (1) “a single type of health problem” and (2) “one group of veterans has a higher rate of symptoms than a different group of veterans.”

The scientific consensus is that veterans of the 1991 Gulf War have a large number of diverse health problems. For example, the Institute of Medicine (IOM) reviewed more than 850 medical studies in its 2006 report, entitled *Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War*. The IOM concluded that there is “no uni0.2-dem.”.oiyHav0, robe is “nove mulhe autxof Sportunity

pertension or diabetes; therefore, CMI does not have an ICD-9 code. CDC used this empirically derived definition to compare the rates of CMI in Gulf War veterans and controls (45 percent vs. 15 percent). CDC concluded: "Our finding that 15 percent of non-deployed also met illness criteria was equally important and suggests that the multisymptom illness we observed in this population is not unique to Gulf War service." They also concluded: "Poorly characterized illness, including fatigue, neurocognitive, and musculoskeletal complaints, has affected veterans of many other wars."

The VA Longitudinal Health Study of Gulf War Era Veterans (Blanchard, et al., 2006; Eisen, et al., 2005; Kang, et al., 2000) began in 1995 and has resulted in many publications. The first phase was a survey of 11,441 Gulf War veterans and 9,476 non-deployed veterans, who were asked about 48 symptoms. Gulf War veterans reported higher rates of all 48 symptoms than did the controls. The second phase of this national VA study involved comprehensive medical examinations of a subgroup that included 1,061 Gulf War veterans and 1,128 non-deployed veterans. The authors used the CDC definition of "chronic multisymptom illness"; that is, one or more symptoms from two or more of the categories of fatigue, musculoskeletal pain, and/or mood and cognitive abnormalities, for at least 6 months. Veterans of the 1991 Gulf War reported significantly higher rates of CMI than non-deployed veterans did (28.9 percent vs. 15.8 percent). The overall conclusion was: "Ten years after the 1991 Gulf War, CMI is twice as prevalent in deployed veterans but still affects 15 percent of non-deployed veterans."

The authors of this national VA study did not conclude that the 1991 Gulf War veterans had "a single type of health problem." (Blanchard, et al., 2006; Eisen, et al., 2005; Kang, et al., 2000) In fact, the rates of many different illnesses were evaluated in the two groups of veterans. These illnesses included peripheral neuropathy, skin conditions, hypertension, hepatitis, obstructive lung disease, diabetes, thyroid disease, anemia, and renal disease. The rates of some illnesses were higher in the non-deployed veterans (controls) than in the 1991 Gulf War veterans, including hypertension (12.6 percent in non-deployed veterans vs. 9.1 percent in Gulf War veterans), peripheral neuropathy (5.9 percent vs. 4.8 percent), and obstructive lung disease (5.9 percent vs. 4.5 percent).

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Question. Do you think it is appropriate for the DOD to continue to research into treatments of Gulf War Illnesses?

Answer. DOD agrees with the conclusions of the Institute of Medicine (IOM) regarding research priorities on illnesses in veterans of the 1991 Gulf War.

The IOM reviewed more than 850 medical studies in its 2006 report, entitled *Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War*. IOM concluded: "Our committee does not recommend that more such studies be undertaken for the Gulf War veterans, but, there would be value in continuing to monitor the veterans for some health end points, specifically, cancer, especially brain and testicular cancers, neurological diseases including amyotrophic lateral sclerosis (ALS), and causes of death."

DOD and the Department of Veterans Affairs (VA) have funded multiple projects related to these health end points, as follows:

- Cancer: VA has funded studies to evaluate the rates and types of cancer in Gulf War veterans over time.

- Neurological diseases, including ALS: DOD and VA have funded multiple studies of neurological diseases in Gulf War veterans, including ALS. VA started a National ALS Registry in 2003 to identify and evaluate ALS diagnosed in all veterans nationwide.

- Causes of death: VA has monitored the causes of death in Gulf War veterans, since the end of the conflict in 1991. This mortality study will continue indefinitely.

Question. Some have said that now that veterans that served in the Gulf War are no longer active duty “soldiers” that they are not the concern of the DOD and they are VA’s problem. Do you agree with such statements?

Answer. The Department of Defense (DOD) cares about the health of servicemembers from the time of accession to the time of separation and beyond. Although DOD can only provide medical care to active-duty members and military retirees, DOD works with the Department of Veterans Affairs (VA) to understand the health of veterans, so that improvements can be made to protect the health of servicemembers in the future. The Millennium Cohort Study is an example of a major collaborative effort between DOD and VA. This 21-year study of 140,000 servicemembers will evaluate the long-term effects of military service and combat deployments.

Question. Why didn’t the DOD request money specifically for Gulf War Illnesses research in fiscal year 2008?

Answer. Research projects on illnesses in 1991 Gulf War veterans are included within the Force Health Protection research program. The DOD research program on illnesses in 1991 Gulf War veterans was established in 1994. This program was renamed the Force Health Protection program in 2002. While the program continued to support research on illnesses in 1991 Gulf War veterans, the focus was expanded to include current and future military deployments and to include methods to respond better to the health care needs of deployed servicemembers. DOD is concerned about the short-term and long-term health effects of deployments and military service for all of its servicemembers. Therefore, the expanded research program will improve the health of servicemembers of all eras.

Deployment health-related research is performed at local, Service, and inter-agency collaborative levels to maintain and improve quality care in an environment of expanding knowledge. At the present time, DOD is funding 183 deployment health-related research projects. These focus on a wide variety of physical health and mental health topics. For example, there are 18 projects on traumatic musculoskeletal injuries; 40 projects on traumatic brain and spinal cord injuries; 27 projects on mental disorders, including Post Traumatic Stress Disorder; 23 projects on infectious diseases; and 21 projects on environmental and occupational exposures.

Question. Will the DOD request research Dollars specifically for Gulf War Illnesses in fiscal year 2009?

Answer. The Department of Defense (DOD) believes research should identify causes of health concerns among servicemembers who deploy, but does not believe it is necessary to restrict research to a subset of deploying members. Therefore, DOD will request research funding in fiscal year 2009 for the Force Health Protection research program, but not specifically for illnesses in 1991 Gulf War veterans.

The DOD research program on illnesses in 1991 Gulf War veterans was established in 1994. This program was renamed the Force Health Protection program in 2002. While the program continued to support research on illnesses in 1991 Gulf War veterans, the focus was expanded to include current and future military deployments and to include methods to respond better to the health care needs of deployed servicemembers. DOD is very concerned about the short-term and long-term health effects of deployments and military service for all of its servicemembers. Therefore, the expanded research program is designed to improve the health of servicemembers of all eras. At the present time, DOD is funding 183 deployment health-related research projects.

Question. Do you think that researching Gulf War Illnesses and treatments for these illnesses can have a positive impact on care for and protection of current and future U.S. servicemembers given the prevalence of toxic exposures and other chemical threats on the modern battlefield?

Answer. The research projects in the Force Health Protection research program will benefit veterans of all eras. Research projects on illnesses in 1991 Gulf War veterans are included within the Force Health Protection program. The Department of Defense (DOD) is concerned about the short-term and long-term health effects of deployments and military service for all of its servicemembers. Therefore, DOD is funding 183 deployment health-related research projects. In particular, 21 projects specifically focus on the effects of toxic exposures and other chemical threats on the modern battlefield.

Question. A recent news story in the New York Sun (Veterans' Rare Cancers Raise Fears of Toxic Battlefields, August 6, 2007, attached below) reported that some soldiers returning from the war in Iraq are beginning to experience a strange set of illnesses including cancer. Has DOD taken any action on this issue?

Answer. The Department of Defense (DOD) is fully committed to maintaining the health of all its servicemembers, especially those who have deployed to a combat zone; and DOD is monitoring the health of servicemembers who have returned from Iraq and Afghanistan. The Army Medical Surveillance Activity (AMSA) published a report on the health of servicemembers who had deployed to Operation Iraqi Freedom (OIF) or Operation Enduring Freedom (OEF) and had returned to the US during the period of January 1, 2002 to September 30, 2006. (MSMR, 2007) This study evaluated the rates and types of hospitalizations during the first 12 months after the return home. The hospitalization rate for all types of cancer was 0.1 percent.

In a 2006 report, AMSA compared the rates of medical diagnoses of individuals who had deployed to OIF or OEF during their first year back in the US, with the diagnoses of other active-duty members. (MSMR, 2006) Records of hospitalizations and clinic visits were evaluated for the period of December 2001 to December 2005. The overall rate of new diagnoses was approximately one-third lower in the deployed group than in the controls. The overall rate of all types of cancer in the deployed group was 0.5 percent, which was similar to the rate in the control group. The rate of cancer diagnosis was higher than the rate of cancer in the 2007 study (above), because the 2007 study included hospitalization data only. The 2006 data included diagnostic data from outpatient clinic visits, which would include less serious cancers, such as skin cancer.

Diagnosis of cancer is tragic, especially if it is a cancer that is difficult to treat. The Institute of Medicine has stated that health outcomes of veterans should be followed over time and that cancers are an important group of diseases to evaluate. DOD agrees and plans to follow the health of these veterans over time.

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Question. The benefits of research on Gulf War Illnesses will help current and future soldiers, not to mention the public at large. As we all know, there have been numerous instances in Iraq where insurgents there have exploded chlorine bombs in attacks against our troops and Iraqi civilians and soldiers. As the Washington Post explained in a March 8th, 2007 article “[t]hree trucks rigged with chlorine and explosives blew up in the Sunni insurgent center of Anbar province Friday, killing at least eight people and sickening hundreds. . . Chlorine causes wheezing, coughing and skin irritation and can be fatal in heavy concentrations.” We all know that the signature wound of the Iraq war is the Traumatic Brain Injury. But we all also understand that our soldiers are not just exposed to these types of blasts but also other toxins and chemical agents. We have learned in this war and in past wars that those that battle against our troops will do anything they can do to harm them including exposing them to harmful toxins. Do you agree that this research on Gulf War Illnesses has the ability to help us develop diagnostic tools and treatments for such exposure?

Answer. The Department of Defense (DOD) research program on this issue encompasses much more than just Gulf War Illness. DOD has been concerned about the potential health effects of toxic chemicals since the first use of chemical warfare agents in World War I, including the use of chlorine gas. For that reason, for many decades DOD has supported extensive research on the potential health effects of toxic chemicals, including chlorine gas and other chemical agents. DOD has supported comprehensive research on methods of detection and analysis of chemicals, countermeasures to prevent adverse effects, diagnostic tools, including biomonitoring, and treatments.

DOD has long recognized the adverse effects of moderate to high concentrations of toxic chemicals. In the 1990's, in response to the need for a more targeted research plan on the potential health effects of low-level chemical exposure, DOD developed a comprehensive approach to respond to Defense Technology Objective CB.51, which is Low-Level Operational Toxicology of Chemical Warfare Agents. DOD continues to support robust research programs related to toxic chemicals, in-



cluding the research programs of the US Army Medical Research Institute of Chemical Defense and the Edgewood Chemical Biological Center.

DOD has funded many research projects related to diagnostic tools and treatments for chemical exposure at universities and independent research institutes. These projects have included investigations of sarin and other chemical warfare agents, pesticides, and other chemicals, and studies of diagnostic tools such as acetylcholinesterase, butyrylcholinesterase, neuropathy target esterase, and paraoxonase. DOD has funded projects at the following universities and institutes: University of North Carolina, University of Nebraska, University of Texas, University of Montana, University of California at Davis, Purdue University, University of Florida, Duke University, Southern Illinois University, Oklahoma State University, University of California at Los Angeles, Midwest Research Institute, and Lovelace Research Institute.

Dr. Kupersmith?

**STATEMENT OF JOEL KUPERSMITH, M.D., CHIEF RESEARCH AND DEVELOPMENT OFFICER, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY TIMOTHY O'LEARY, M.D., PH.D., DIRECTOR OF BIOMEDICAL LABORATORY AND CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICES, DEPARTMENT OF VETERANS AFFAIRS**

Dr. KUPERSMITH. Madam Chairman and Members of the Committee, thank you for the opportunity to appear before you today to discuss the Department of Veterans Affairs Persian Gulf research programs. With me is Dr. Timothy O'Leary, Director of Biomedical Laboratory and Clinical Science Research.

For more than 80 years, VA research has responded to veterans' needs with landmark contributions to medicine. VA investigators led the way in developing the cardiac pacemaker, pioneered concepts that led to the development of the CAT scan, and improved artificial limbs. VA investigators are among the best in their field, with three Nobel Laureates and six Lasker Award winners. While the focus of VA research has been on benefiting current and future veterans, ultimately, VA research impacts the entire Nation.

During and after their return from the Kuwaiti theater of operations, a proportion of Gulf War veterans reported a range of chronic symptoms and health problems at rates that exceeded non-deployed veterans. These symptoms include persistent headaches, joint and muscle pain, extreme fatigue, cognitive problems, gastrointestinal difficulties, sleep disturbances, and skin abnormalities. Although the precise causes for these symptoms remains elusive, the fact that these veterans are ill and suffer adverse effects on their daily lives remains unquestioned.

Accordingly, VA continues to support a broad research portfolio dedicated to understanding chronic multi-system illness, long-term health effects of potentially hazardous exposures, and conditions that may be occurring with higher prevalence in Gulf War veterans. Here are the results of a few past projects.

In 1995, the National Health Survey of Gulf War veterans and their families used mail surveys to demonstrate that Gulf War veterans were nearly twice as likely to report symptoms that included joint, muscle, respiratory, gastrointestinal, and skin problems. Complaints of emotional and cognitive difficulties were also common. Dr. Seth Eisen, who is now part of the VA Office of Research and Development's Senior Leadership Team, conducted a 10-year

follow-up to the 1995 National Health Survey. The study concluded that although the physical health of deployed and non-deployed veterans was generally similar, fibromyalgia, chronic fatigue syndrome, skin conditions, and gastrointestinal problems remained more prevalent among the deployed than the non-deployed veterans.

A VA clinical trial on the use of the antibiotic doxycycline by patients with chronic symptoms who were infected with a microorganism microplasma found improvement at 3 months. However, this improvement did not last for the remainder of the trial. This may be related to the higher incidence of nausea and light sensitivity reported by patients taking the drug. This highlights that we must be very careful when testing new therapies to do no harm.

Another VA clinical trial compared cognitive behavioral therapy, aerobic exercise, and a combination of the two therapies and demonstrated that cognitive behavioral therapy, with or without exercise, produced modest but significant improvement in physical functioning, fatigue, mental health functioning, cognitive symptoms, and stress.

VA remains committed to pursuing new treatments for ill Gulf War veterans. Clinical trials are currently underway to examine new therapies for sleep disturbances and gastrointestinal problems and to test the feasibility of behavioral therapy via telephone.

Another major focus of VA's current Gulf War research is to identify biomarkers or biologic indicators that can distinguish ill Gulf War veterans from their healthy counterparts. Biomarkers may provide clues to understanding why these veterans are ill and may provide a means of testing the effectiveness of new therapies. VA projects in this area range from genetic markers, to advanced neuroimaging procedures, to altered protein profiles in blood or cerebrospinal fluid.

You have already heard from Dr. White this morning about one of these neuroimaging projects. Additional neuroimaging projects will be performed as part of our contract with the University of Texas-Southwestern Medical Center.

While the bulk of VA's current research is aimed at understanding chronic multi-symptom illness, we have not neglected the importance of other diagnosable conditions, such as brain cancer, amyotrophic lateral sclerosis, and multiple sclerosis. VA maintains additional research portfolios in each of these areas, since they impact veterans of all deployments.

Because of concerns about the risk of MS and brain cancer in Gulf War veterans, VA is funding studies to examine the prevalence and risk for developing these conditions. In addition, VA has established a Gulf War Brain Bank to collect and store post-mortem specimens for future investigators.

It is important to note that VA research continues to have a constructive relationship with the Research Advisory Committee on Gulf War Veterans' Illnesses. This dedicated service by these Committee Members in support of veterans who served in the Gulf War is greatly appreciated.

In conclusion, VA remains committed to funding scientifically meritorious research projects that improve our understanding of Gulf War veterans' illness and enhance our ability to diagnose and

treat ill Gulf War veterans. Moreover, the knowledge we gain from these efforts may improve our ability to prevent and treat illnesses affecting participants of current and future deployments.

Madam Chairman, that concludes my statement. I am pleased to respond to any questions that you or the Committee Members may have. Thank you.

[The prepared statement of Dr. Kupersmith follows:]

PREPARED STATEMENT OF JOEL KUPERSMITH, M.D., CHIEF RESEARCH  
AND DEVELOPMENT OFFICER, DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairman and Members of the Committee, thank you for the invitation to appear before you today to discuss the Department of Veterans Affairs (VA) Persian Gulf War research programs. I appreciate this opportunity to discuss the vital role VA research has in ensuring the health and well-being of our Nation's veterans. With me is Dr. Timothy O'Leary, Director of Biomedical Laboratory and Clinical Science Research and Development. I would like first to give a brief overview of the VA research program.

OVERVIEW OF THE VA RESEARCH PROGRAM

Dating back more than 80 years, VA research has responded to veterans' needs with landmark contributions to medicine. VA investigators have led the way in developing the cardiac pacemaker, pioneered concepts that led to the development of the CAT scan and improved artificial limbs. VA investigators are distinguished as among the best in their field with three Nobel Laureates and six Lasker Award winners. VA research is a valuable investment with remarkable and lasting returns.

Because more than 70 percent of VA researchers are also clinicians who take care of patients, VA is uniquely positioned to move scientific discovery from investigators' laboratories to patient care. In turn, VA clinician-investigators identify new research questions for the laboratory at the patient's bedside, making the research program one of VA's most effective tools to improve the care of veterans. The fundamental goal is to address the needs of the entire veteran population from the young recruit who returns with injuries from recent conflicts to the aging veteran, and to use research findings proactively to benefit the future veteran.

It is important to note that VA has implemented a substantial and comprehensive research agenda to develop new treatments and tools for clinicians to ease physical and psychological pain, improve access to VA healthcare services and address the full range of health issues of Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF) veterans.

VA research is an intramural program that is also fully integrated with the larger biomedical research community through VA's academic affiliations and collaborations with other organizations. VA scientists partner with colleagues from other Federal agencies, academic medical centers, nonprofit organizations and commercial entities nationwide, further expanding the reach and scope of VA research.

While the focus of VA research is on benefiting current and future veterans, it also impacts veteran families and caregivers, VA healthcare providers, Veterans Service Organizations, other components of the Federal research establishment, academic health centers and practitioners of healthcare across the country. Ultimately, VA research impacts the entire Nation.

Let me now discuss VA's Persian Gulf War research programs.

BACKGROUND

In response to Iraq's occupation of Kuwait in August 1990, the United States deployed military personnel to Southwest Asian in support of Operations Desert Shield and Desert Storm. At the conclusion of the first year of operations on July 31, 1991, the United States had deployed 696,841 military personnel from all five services to the Kuwaiti Theater of Operations (KTO).

During and after their return from the KTO, a proportion of Gulf War veterans reported a range of chronic symptoms and health problems at rates that exceeded non-deployed era veterans. These symptoms include: persistent headaches, joint pain, extreme fatigue, muscle pain, cognitive problems, gastrointestinal difficulties, sleep disturbances and skin abnormalities.

As of November 2004, more than 30 percent of veterans who served in the 1990-1991 Gulf War had been service-connected for conditions associated with their military service, although fewer than 3,300 had been service-connected for the special "undiagnosed illness" category established for Gulf War veterans. It is recognized

that there exists a much larger number of Gulf War veterans with multiple, chronic symptoms who have not sought or received service-connected status.

#### OVERVIEW OF THE FEDERAL RESEARCH PORTFOLIO ON GWVI

In an effort to better understand the health conditions and health problems experienced by Gulf War veterans, VA, the Department of Defense (DOD) and the Department of Health and Human Services (HHS) have supported numerous research projects related to Gulf War veterans' illnesses (GWVI). As of September 30, 2006, the three Departments have funded a total of 330 distinct projects pertaining to the health consequences of military service in the Gulf War, as described in Annual Reports to Congress on federally Sponsored Research on Gulf War Veterans' Illnesses, totaling \$314 million. VA has funded 153 of these projects—eight in conjunction with DOD—totaling \$84.8 million. As of the close of FY 2006, 223 projects (68 percent of the 330 projects) were completed and 107 projects (34 percent) were new or ongoing.

The Federal research portfolio on GWVI can be generally divided into five research focus areas:

- Brain and Nervous System Function (e.g., studies on neurological or psychological deficits and/or alterations);
- Environmental Toxicology (e.g., studies focused on specific environmental exposures such as pesticides, oil well fires, jet fuel, vaccines and medical prophylactic agents);
- Immune Function and Infectious Diseases (e.g., studies on alterations in immune function, host defenses or detection and treatment of infectious diseases);
- Reproductive Health (e.g., studies on sexual or reproductive dysfunction); and
- Symptoms and General Health (e.g., studies on pulmonary disease, cancer, chronic multisymptom illnesses and mortality).

While each Department funds its GWVI research independently, each closely coordinates its efforts with the others to avoid duplication of effort and to foster the highest standards of competition and scientific merit review for all research on GWVI. The Research Subcommittee of the interagency Deployment Health Working Group currently conducts this coordination and compilation of the Annual Reports to Congress on federally Sponsored Research on Gulf War Veterans' Illnesses.

#### STATUS OF THE VA RESEARCH PORTFOLIO ON GWVI

In FY 2006, VA supported 67 GWVI research projects for a total of \$12.9 million. Nineteen of these were new projects examining brain and nervous system function, environmental toxicology, immune function and infectious diseases and symptoms and general health. VA is projecting a direct expenditure of \$6.8 million for new and ongoing research projects in FY 2007. The expenditures in FY 2006 and FY 2007 are in addition to the allocation of \$15 million per year to support a contractual agreement with the University of Texas Southwestern Medical Center for research related to illnesses affecting Gulf War veterans.

The VA Gulf War research program has been at the forefront of the field from the outset. In 1995, VA initiated The National Health Survey of Gulf War Veterans and Their Families. The first two phases of this study used surveys of self-reported symptoms mailed to 15,000 Gulf War veterans and 15,000 non-deployed veterans to demonstrate that Gulf War veterans were nearly twice as likely to report diverse symptoms, including joint, muscle, respiratory, gastrointestinal and skin problems. This population also reported higher rates of chronic fatigue (5.6 percent for Gulf War veterans vs. 1.2 percent for non-deployed veterans) and symptoms of Post Traumatic Stress Disorder (PTSD) (12.1 percent for Gulf War veterans vs. 4.3 percent for non-deployed veterans). The final phase of the study, which completed recruitment in 2001, relied on complete physical examinations (including a neurological exam) of 1,061 Gulf War veterans and 1,128 non-deployed veterans and found that Gulf War deployment was associated with a significantly increased risk of chronic fatigue syndrome (5.6 percent for Gulf War veterans vs. 1.2 percent for non-deployed veterans) 10 years after redeployment. In addition, Gulf War deployment was associated with increased prevalence of PTSD, other psychological disorders and poorer self-reported quality of life. The study findings did not indicate increased prevalence for objectively measured cognitive impairment. Researchers found no significant physical health outcomes of clinical concern among spouses of deployed or non-deployed veterans. In addition, the investigators found that Gulf War deployment of a parent was not associated with any significant differences in the frequency of birth defects compared to children of non-deployed veterans.

In 1998, VA began planning for two treatment trials referred to as the "EBT" (exercise-behavioral therapy) and "ABT" (antibiotic treatment) trials. Both addressed

similar patient characteristics and were open to all veterans who served in the Gulf War between August 1990 and July 1991. To be eligible for inclusion in the trials, a veteran must have had at least two of three symptoms (fatigue, musculoskeletal pain and cognitive dysfunction) that began after August 1990, the symptoms must have persisted for more than 6 months and they must have been symptomatic when the study began.

VA conducted the \$9.6 million EBT study between 1999 and late 2001, and 1,092 veterans participated at 18 VA and 2 DOD medical centers. All groups continued their usual healthcare. In addition, three groups received cognitive behavior therapy (CBT), aerobic exercise or a combination of the two therapies. The results, reported in the March 19, 2003, issue of the *Journal of the American Medical Association*, showed that CBT, with or without exercise, provides modest but significant improvement in physical functioning, mental health functioning, cognitive symptoms, fatigue and distress.

Enrollment for the ABT trial began in May 1999 and eventually included 491 Gulf War veterans at 26 VA and 2 DOD sites. The study's primary hypothesis was that antibiotic treatment, with doxycycline for 12 months, would improve the health status of patients with chronic symptoms who tested positive for *Mycoplasma* infection at baseline. Secondary hypotheses included that the doxycycline treatment would reduce symptoms of fatigue, pain and memory problems; and that doxycycline treatment would convert patients who were *Mycoplasma* positive to *Mycoplasma* negative. The trial was completed in December 2001, when patient follow-up was finished. Although the \$10 million trial did not result in a new treatment modality for Gulf War veterans, the failure to substantiate any of the hypotheses has enabled investigators to focus their time and resources to other lines of inquiry.

VA also supported a recent study led by Dr. Seth Eisen, now Director of VA's Health Services Research and Development Service, to assess and compare the prevalence of fibromyalgia, chronic fatigue syndrome, skin conditions, dyspepsia, physical health-related quality of life, hypertension, obstructive lung disease, arthralgias and peripheral neuropathy in a group of deployed and non-deployed Gulf War veterans. The study concluded that 10 years after the Gulf War, the physical health of deployed and non-deployed veterans is generally similar, with four of the conditions studied found to be more prevalent among deployed than non-deployed veterans: fibromyalgia, chronic fatigue syndrome, skin conditions and dyspepsia. There were no significant differences between deployed and non-deployed veterans related to the other studied conditions.

VA's commitment to funding clinical trials to identify new therapies for ill Gulf War veterans continues to this day. Three pilot clinical trials are currently underway to examine two new therapies for sleep disturbances and gastrointestinal problems, and to test the feasibility of performing CBT via telephone with Gulf War veterans; CBT was found to provide modest but significant improvement in physical functioning, mental health functioning, cognitive symptoms, fatigue and distress in the earlier exercise-behavioral therapy trial done on an inpatient basis.

Another major focus of the current Gulf War research portfolio is to identify objective markers (i.e., biomarkers or tests) that can distinguish ill Gulf War veterans from their healthy counterparts. Such biomarkers serve two vital purposes. First, they may provide critical clues to understand mechanisms responsible for how and why these veterans are ill. Second, they may provide objective measures for testing the effectiveness of new therapies. VA currently funds 12 such projects, ranging from genetic markers, to advanced neuroimaging procedures, to altered protein profiles in blood or cerebrospinal fluid.

Accordingly, VA supports a broad research portfolio composed of studies dedicated to understanding chronic multi-symptom illnesses, long-term health effects of potentially hazardous substances to which Gulf War veterans may have been exposed to during deployment and conditions or symptoms that may be occurring with higher prevalence in Gulf War veterans.

Recently, the Institute of Medicine reviewed the available published literature and concluded that Gulf War and other combat veterans may be at increased risk for amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig's disease) as a result of their service. Of the studies included in this review, the largest prevalence study devoted to that devastating disease was one funded by VA in cooperation with DOD. The study, which included all 2.5 million Gulf War era veterans, identified and confirmed by medical record review ALS cases occurring over a 10-year period starting from August 1990. Investigators found that among Gulf War veterans, the rate of disease was 6.7 per million. Among other military personnel, it was 3.5 per million. Since researchers still do not know why Gulf War veterans have a higher rate of ALS, VA expanded the study to include a national registry for veterans with ALS and a genetic tissue bank (ALS-DNA) for this registry. The goals of the reg-

istry are to identify as completely as possible all veterans with ALS, not just Gulf War era veterans, and to provide a mechanism for VA to inform veterans with ALS about clinical drug trials and other studies for which they may be eligible. VA continues to fund other ALS research, including clinical trials and animal model of the disease, to study potential disease mechanisms and test new therapies.

Because of persistent concerns about the risk of multiple sclerosis (MS) and brain cancer in Gulf War veterans, in 2008 VA will begin a large study to identify the date of onset and clinical subtype of all Gulf War MS service-connected cases between 1990 and 2006. This study will also attempt to quantify the risk for developing MS in Gulf War veterans deployed to the combat theater versus those not deployed, as well as the risk for developing MS in Gulf War veterans potentially exposed to smoke from oil well fires or sarin. Another project is examining the overall and cause-specific mortality risk of ALS, MS or brain cancer in a group of more than 620,000 Gulf War veterans and assessing the in-theater exposure characteristics associated with those deaths. VA supports several additional projects examining MS, as well as basic science and rehabilitation research centers with a focus on MS. Further, VA has established a Gulf War brain bank to collect and store postmortem specimens for future investigations.

#### COLLABORATION WITH THE RESEARCH ADVISORY COMMITTEE ON GWVI

It is important to note that VA research continues to have a positive working relationship with the Research Advisory Committee on GWVI (RAC), a congressionally mandated committee that advises the Secretary of Veterans Affairs. In response to advice provided by the RAC, VA research has performed an annual portfolio review to ensure the appropriateness of all projects contained in the portfolio. The RAC's advice has also been sought when designing new Requests for Applications to solicit additional research proposals from VA investigators; the RAC was also consulted for recommendations of appropriate reviewers of these proposals.

The efforts by the RAC have improved the VA GWVI research portfolio and continue to bring us closer to finding new treatments for ill Gulf War veterans. The dedicated service by RAC members in support of veterans who served in the Gulf War is greatly appreciated.

Early on, VA recognized the need to assure training of our healthcare providers to allow them to best respond to the specific healthcare needs of Gulf War veterans. With that in mind, and in collaboration with DOD, VA clinicians developed two Clinical Practice Guidelines that give VA healthcare providers access to the best medical evidence for diagnoses and treatment. VA clinicians also developed a study guide to provide information about the problems and concerns of Gulf War veterans and information about VA programs to help these veterans. Cumulatively, from October 1990 through October 2004, VA clinicians provided high quality inpatient and outpatient care to 335,558 Gulf War veterans, or nearly half of the servicemembers deployed to that conflict.

#### CONCLUSION

In conclusion, VA remains committed to funding scientifically meritorious research projects that improve our understanding of GWVI and enhance our ability to diagnose and treat ill Gulf War veterans. Moreover, the knowledge we gain from these efforts may improve our ability to prevent and treat illnesses affecting participants of current and future deployments.

Mr. Chairman, that concludes my statement. I am pleased to respond to any questions you or the Committee Members may have.

Thank you.

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#### RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. DANIEL K. AKAKA TO THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. What steps has VA taken, or plans to take, to expand the screening of Gulf War veterans for the range of Gulf War Illnesses?

Response. Over the last 16 years since the Gulf War cease-fire, the Department of Veterans Affairs (VA) has provided high quality health care to over 335,000 Gulf War veterans, or about half of the nearly 700,000 troops deployed in that conflict.

VA has a broad array of programs to effectively respond to the range of illnesses seen among Gulf War veterans. Shortly after the 1991 Gulf War cease-fire, VA established a special Gulf War Veteran Health Examination Registry program, which has provided specialized examinations for over 100,000 Gulf War veterans as well as 7,325 veterans from Operation Iraqi Freedom.

Every VA medical center has an environmental health clinician and a coordinator assigned to assist veterans in obtaining health registry examinations. Eligible veterans receive a free specialized comprehensive health examination with blood work, urinalysis (electrocardiogram and chest x-ray where medically indicated) and answers to questions relating to any environmental exposures. Review of the diagnoses of these veterans has not revealed any unusual or unique source of the health problems they have experienced. The program remains useful for addressing the special clinical care, education and outreach needs of Gulf War veterans with deployment-related health concerns.

Gulf War veterans as well as Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans concerned about possible exposure to depleted uranium (DU) can be evaluated using a special DU exposure protocol that VA began after the 1991 Gulf War. This program offers free DU urine screening tests by referral from VA primary care physicians to veterans who have concerns about their possible exposure to this agent. Gulf War and OIF veterans are eligible to participate in the VA DU evaluation protocol/screening program for Gulf War and OIF veterans. OEF veterans are eligible to participate in the VA DU evaluation protocol/screening program for non-Gulf War veterans.

In response to health concerns about new combat veterans with retained embedded fragments from combat injuries in Afghanistan and Iraq, including blast injuries from improvised explosive devices, the Veterans Health Administration (VHA) is establishing the Toxic Embedded Fragments Surveillance Center (TEFSC) at the Baltimore VA Medical Center (VAMC). Lessons learned from the Baltimore VAMC depleted uranium program show that retained metal fragments are not inert in the body and may change over time to produce potential toxic health effects. Such effects may be minimized and managed through careful ongoing medical surveillance.

In addition, VA developed new clinical guidelines for combat veteran health care that provide VA health care providers guidelines, based on the best available medical evidence for diagnosing and treating Gulf War veteran and all combat veterans relative to (1) post-combat deployment health, and (2) unexplained pain and fatigue.

In 2001, as part of VA's overall health response for veterans returning from the 1991 Gulf War, VA established two War-Related Illness & Injury Study Centers (WRIISCs) at Washington, DC, and East Orange, NJ. Today, they are providing specialized health care for combat veterans from all deployments who experience difficult to diagnose or undiagnosed but disabling illnesses.

VA is expanding this program to better meet the health care needs of new combat veterans suffering from mild to moderate Traumatic Brain Injury. Many of the long-term chronic health effects from Traumatic Brain Injury appear similar to the difficult-to-diagnose and treat illnesses currently being treated by the WRIISC programs today. To that end, VA is establishing a third WRIISC at the Palo Alto VA Health Care System, in Palo Alto, CA. The new Palo Alto WRIISC will take advantage of the unique assets available there, including a polytrauma unit; interdisciplinary program on blast injuries which integrates the medical, psychological, rehabilitation, and prosthetic needs of injured servicemembers; its programs in Traumatic Brain Injury, spinal cord injury, blind rehabilitation, and Post Traumatic Stress Disorder; and research into new and emerging areas of combat injuries and illnesses.

Question 2. Additionally, does VA have the capacity and resources to provide all veterans potentially exposed to Sarin nerve gas an assessment to determine if they have suffered any neurological damage?

Response. VA has the capacity and the resources to thoroughly evaluate any veteran with evidence of neurological disease on clinical examination. VA is particularly concerned about possible long-term health effects from exposure to trace levels of sarin nerve gas that might have been experienced by some veterans during the 1991 Gulf War.

To help anticipate what illnesses VA health care providers might expect among veterans exposed to low-levels of nerve agents, VA requested that the National Academy of Sciences (NAS) Institute of Medicine (IOM) evaluate the many hundreds of relevant published human and animal studies on this issue. The initial 2000 NAS committee report concluded that available scientific evidence could not show an association between trace sarin exposure and subsequent long-term adverse health effects. In response, the Secretary of Veterans Affairs determined that there was not an adequate basis to support establishing presumptive service connection for any long-term health problems resulting from low-level sarin exposure.

The August 2004 NAS sarin update came to the same conclusions as the earlier 2000 report. In other words, and consistent with their earlier findings, the NAS committee was not able to find a scientific basis to associate any disease with exposure to low levels of sarin.

Question 3. The research presented on the web site of VA's Office of Public Health and Environmental Hazards is over 5 years old. Are veterans getting the most up-to-date information in a timely manner, and when can veterans expect an update to this important resource?

Response. VA places a high priority on ensuring wide-ranging outreach to all veterans, including veterans of the Gulf War. VA's Office of Public Health and Environ-

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Gulf War veteran because it is not a representative sample and only assesses veterans who come to VA for health care.

To more definitively evaluate the health of Gulf War veterans in general, VA has turned to a range of well-designed epidemiological studies, including, for example, VA's ongoing mortality study that evaluates the rates and causes of death among all Gulf War veterans in comparison to "control" groups of demographically similar but not deployed veterans and the general civilian population. That study has shown that veterans of the 1991 Gulf War have essentially identical mortality compared to their non-deployed peers, and less than one-half the mortality rates compared to similar civilian Americans.

Question 5(b). Why is a similar report not being used to track servicemembers and veterans in today's conflicts in Iraq and Afghanistan?

Response. Since 2003, VA has been producing a quarterly report on VA health care use by separated veterans who have served in OEF/OIF, titled Analysis of VA Health Care Utilization Among US Southwest Asian War Veterans. Based upon data supplied to VA by the Department of Defense (DOD), this report tracks the health care use, diagnoses and other information for all newly separated OEF/OIF veterans. The latest quarterly report, dated July 2007, records 717,196 OEF/OIF veterans who have left active duty and become eligible for VA health care since fiscal year (FY) 2002, of which 35 percent (252,095) have obtained VA health care since fiscal year 2002 (cumulative total).

Question 6. The current clinical practice guidelines for Gulf War Illness referred to by the VA as "Medically Unexplained Symptoms" has not been updated in over 5 years and seems to indicate a psychological cause of the illness, rather than environmental exposures. Given the existing research, why haven't the current practice guidelines been updated to reflect the most recent research findings?

Response. In collaboration with DOD, VA developed two clinical practice guidelines on combat veteran health issues specifically in response to health concerns of veterans of the 1991 Gulf War. These include a general guideline to post-deployment health, and a second dealing with unexplained pain and fatigue. The clinical guidelines give our health care providers diagnosis and treatment guidelines based on the best medical evidence of illnesses that are a particular concern among veterans of the 1991 Gulf War. VA recommends these for the evaluation and care of all returning combat veterans, including OEF/OIF veterans.

The subject matter experts within VA and DOD are continually assessing the need to modify their joint clinical practice guidelines as new research provides evidence-based justification for changes.

Question 7. An August 2005 study in the American Journal of Public Health by Dr. Tim Bullman and others, found that Gulf War veterans exposed to nerve agents during the March 1991 weapons demolitions in Khamisiyah, Iraq, appear to have a higher risk for brain cancer death than veterans who were not exposed. Additionally, an IOM report in September of 2006 found evidence that suggests there may be an elevated rate of Lou Gehrig's disease among Gulf War veterans.

Question 7(a). Given all this, why is there no *permanent* mechanism in place to grant presumptive disability for Gulf War veterans with amyotrophic lateral sclerosis (ALS) or brain cancer?

Response. VA is concerned with all veterans who are diagnosed with ALS. As noted, preliminary studies, discussed in a recent report from IOM, Amyotrophic Lateral Sclerosis in Veterans: Review of the Scientific Literature, show there may be some association between the onset of ALS and *all* military service—not just for veterans of the 1991 Gulf War. VA requested that IOM review the possible connection between military service and this disease following a series of scientific studies showing a possible increased risk of ALS among veterans from the 1991 Gulf War, the Korean War, the Vietnam War and World War II.

Clearly, VA must pay attention to the findings and conclusions of this recent IOM report. However, after careful review of IOM's findings, VA has concluded that the existing research is not conclusive. Therefore, VA's current position is that the question of whether ALS should have presumptive service connection requires additional study.

In regard to the need for additional research, VA funds a broad research portfolio. This includes research focused on understanding the cause(s) of ALS and on developing appropriate treatments. VA expects that more definitive answers will result from this research. As an example, several VA investigators are conducting research specifically about ALS as it relates to military service during the 1991 Gulf War. In addition, VA looks forward to research conducted in the private sector and from others in the Federal sector.

Despite the lack of conclusive research about the causes of ALS, VA offers high quality treatment and care for veterans diagnosed with this disease. ALS is a catastrophic illness, and veterans with significant disability are eligible for VA health care. VA remains committed to providing the best possible care to veterans diagnosed with this disease and in sponsoring a broad range of research on treatment, diagnoses and care for ALS patients.

Question 7(b). Dr. Kupersmith, have you informed the VA that relevant evidence exists to support a permanent presumptive disability for Gulf War veterans with ALS and brain cancer?

Response. The cited scientific study (Mortality in US Army Gulf War Veterans Exposed to 1991 Khamisiyah Chemical Munitions Destruction. TA Bullman, CM Mahan, HK Kang, WF Page. American Journal of Public Health, August 2005, 95(8), 1382–1388) reported an increased risk for brain cancer among 1991 Army Gulf War veterans possibly exposed to low-levels of chemical warfare nerve agents at Khamisiyah shortly after the 1991 Gulf War cease-fire. Concerns about health problems from possible low-level sarin exposure followed revelations that some Iraqi munitions destroyed by U.S. forces at Khamisiyah contained this agent. In 1997 and 2000, DOD sponsored modeling of potential sarin exposure and concluded no Gulf War veteran experienced large exposure, although about 100,000 veterans could have been exposed to “very low levels” (so small as to cause no immediate or obvious poisoning), consistent with DOD’s conclusions that there were no reports of any troops experiencing severe and immediate sarin exposure.

The cited study reported no difference in overall death rates or overall death rates from cancer between the exposed and non-exposed Gulf War veterans. Moreover, overall mortality and mortality for any specific cancer including brain cancer among these veterans was about half that of the comparable civilian U.S. population. However, researchers found exposed veterans were significantly more likely to have died from brain cancer compared to unexposed veterans, or about 12 excess brain cancer deaths among the 100,487 exposed veterans over a 9-year period.

There are some important issues with this study that limit its interpretation. First, Khamisiyah exposure modeling has been soundly criticized as unreliable by both the Government Accountability Office and by IOM. In their 2004 Update on sarin health effects, IOM concluded “Because of the uncertainty in the [Khamisiyah] exposure assessment models. . . studies [based on that model] do not provide strong evidence for or against the presence of neurologic effects.” Second, the study’s authors themselves point out that since sarin is not a known carcinogen, it may be that the demolitions at Khamisiyah released other hazardous agents that could have caused the apparent increased risk of brain cancer death. Sarin specifically and organophosphorus nerve agents in general, including commonly used pesticides, are not considered to be carcinogens. Further, the use of multiple statistical comparisons (apparently more than 60) used in this study could easily have lead to a spurious statistically significant association.

The study’s authors note that additional research is needed to confirm these findings. The research finding on brain cancer among Gulf War I veterans has to date been an isolated result of one research study and has not been verified by numerous other studies of Gulf War veteran populations in the U.S., UK, Canada, and Australia, which sent troops to fight in the first Gulf War.

Finally, a 2000 Congressionally mandated review and a 2004 update conducted by IOM concluded, based upon their review of a large body of scientific literature including reports using the DOD Khamisiyah modeling, that the evidence did not support any long-term health effects following sub-clinical sarin exposure such as that at least potentially experienced by some Gulf War veterans (Gulf War & Health Vol. 1: Depleted Uranium, Pyridostigmine Bromide, Sarin, Vaccines Institute of Medicine, National Academies Press, 2000, 408 pp, and Gulf War & Health: Updated Literature Review of Sarin. Institute of Medicine, National Academies Press, 2004, 120 pp, at [www.nap.edu](http://www.nap.edu)).

VA is committed to further research of Gulf War I veterans. Should future research show a connection between Gulf War I service and brain cancer, the possibility of presumptive disability will be reassessed.

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RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. BERNARD SANDERS TO THE  
SENATE COMMITTEE ON VETERANS’ AFFAIRS

Question 8. A recent news story in the *New York Sun* (Veterans’ Rare Cancers Raise Fears of Toxic Battlefields, August 6, 2007, attached) reported that some soldiers returning from the war in Iraq are beginning to experience a strange set of illnesses including cancer. Dr. Kupersmith, has the VA heard about these concerns?

Response. VA is aware of this information and continues to support a robust deployment health research portfolio that includes studies examining the wide array of health effects from military exposures—particularly new conditions or those that are occurring more frequently in veterans from the current conflict. New studies are then formulated that respond to these new issues. When making programmatic or policy decisions, VA weighs a broad spectrum of sources of information, including, but not limited to, information from VA's funded studies, other peer reviewed publications and IOM.

VA is very concerned about long-term environmental health issues surrounding any military deployment, and in particular for the current deployments in Afghanistan and Iraq. Based on our experience responding to the health concerns of veterans of the 1991 Gulf War, VA has in place today a number of strong programs that will be invaluable for addressing the environmental and other deployment-related health concerns of this new generation of combat veterans, including exposure to depleted uranium and some of the other examples in the attachment provided by Senator Sanders. Examples include:

Special DU program. Gulf War I veterans concerned about possible exposure to depleted uranium (DU) can be evaluated using a special DU exposure protocol that VA began after the 1991 Gulf War. This program offers free DU urine screening tests by referral from VA primary care physicians caring for veterans who have concerns about their possible exposure to this agent. Veterans from the current conflicts in Afghanistan and Iraq are also eligible to participate in the VA DU evaluation protocol/screening program.

New Toxic Embedded Fragments Surveillance Center. In response to health concerns about new combat veterans with retained embedded fragments from combat injuries in Afghanistan and Iraq, including blast injuries from improvised explosive devices, VHA is establishing the Toxic Embedded Fragments Surveillance Center (TEFSC) at the Baltimore VA Medical Center.

Lessons learned from the Baltimore VA DU program show that retained metal fragments are not inert in the body and may change over time to produce potential toxic health effects. Such effects may be minimized and managed through careful ongoing medical surveillance. Potential long-term toxicity is now a concern for new combat veterans suffering from injuries that produce many different types of embedded metal fragments. New studies indicate that some metals, such as certain tungsten alloy fragments, are highly carcinogenic in rats and may pose a health hazard in veterans. Some metals are also known or presumed to be human reproductive hazards, including lead, cadmium, nickel, and copper. In response, VA is expanding the Baltimore VA Depleted Uranium surveillance program into the new Toxic Embedded Fragments Surveillance Center.

VA Long-Term Health and Mortality Studies. VA has initiated mortality and morbidity studies designed to provide solid scientific answers about the risks of OEF/OIF veterans for various types of cancers and other diseases. These are similar to ongoing morbidity and mortality studies conducted by VA that follow the health of Vietnam War veterans and 1991 Gulf War veterans.

A New VA War-Related Illness & Injury Study Center (WRIISC). The new WRIISC will focus on combat veterans with mild and moderate Traumatic Brain Injury: To respond to the health care needs of new combat veterans suffering from mild to moderate Traumatic Brain Injury, VHA is establishing a third WRIISC at the Palo Alto VA Health Care System. Many of the long-term chronic health effects reported for Traumatic Brain Injury resemble the sort of difficult to diagnose and treat illnesses currently being evaluated and treated by the existing WRIISC programs.

Enhanced Outreach to New Combat Veterans on Deployment-Health Issues. VA has many new outreach and information products to offer combat veterans and their families, including:

- The Secretary of Veterans Affairs sends a letter to every newly separated OEF and OIF veteran, based on records for these veterans provided to VA by DOD. The letter thanks the veteran for their service, welcomes them home, and provides basic information about health care and other benefits provided by VA.
- In collaboration with DOD, VA published and distributed one million copies of a short brochure called A Summary of VA Benefits for National Guard and Reservists Personnel. The new brochure does a tremendous job of summarizing health care and other benefits available to this special population of combat veterans upon their return to civilian life (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).
- Health Care and Assistance for U.S. Veterans of Operation Iraqi Freedom is a brochure on basic health issues for that deployment (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).

- OEF and OIF Review is a new newsletter mailed to all separated OEF/OIF veterans (nearly 700,000 individuals as of May 2007) and their families, on VA health care and assistance programs for these newest veterans (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).

- VA Health Care and Benefits Information for Veterans is a wallet card that nicely summarizes all VA health and other benefits, along with contact information, in a single, wallet-sized card for easy reference (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).

Question 9. As you know, the VA is supposed to regularly send out the *Gulf War Review* newsletter. Its purpose is to “help veterans of the 1991 Gulf War and their families be more aware of VA’s health care and other benefits that are available for them, and of new research results on Gulf War veterans’ health. The *Gulf War Review* newsletter, is supposed to be regularly mailed out to over 400,000 veterans from that conflict.

Question 9(a). Can you tell the Committee when the last time was that the VA sent out the *Gulf War Review* newsletter?

Response. The Gulf War Review was published July 2006. The next issue of the Gulf War Review will be released after receiving the new IOM report on health effects from deployment-related stress. The IOM report is expected to be released in October 2007 with the next Gulf War Review release by the end of calendar year 2007.

Question 9(b). It is my understanding that the Newsletter is only sent out electronically, is that correct?

Response. The Gulf War Review has been published between 1 to 4 times per year since 1992. In 2004, the editors decided to test acceptability of an “on line” only version of the newsletter, and the last “hard copy” mailed version was dated October 2004. In response to prior suggestions by the VA Gulf War Advisory Committee, VA has decided to make the next issue of the “Gulf War Review” available in hard copy as well.

Question 2(c). How many veterans of the Gulf War currently have computers and can obtain this newsletter electronically?

Response. VA has not surveyed veterans of the 1991 Gulf War to determine how many veterans have computers. We appreciate that many veterans do not have access to electronic data, and consequently we are constantly attempting new forms of outreach including posters, brochures, wallet cards, etc.

Question 9(d). Do you think that this newsletter gets to all of its intended recipients?

Response. VA recognizes that any single approach to reach intended recipients would not be ideal. VA is always working to enhance communications with veterans and their families by working with new approaches and ideas to improve this process. VA is constantly attempting to improve outreach and communication to a broad range of veterans on a wide variety of health and other issues. To that end, VA publishes posters, brochures, newsletters, wallet cards, Web products including podcasts and other materials to improve this process.

Question 10. Why has VA not yet published the results of the Longitudinal Health Study of Gulf War Era Veterans that shows 25 percent of Gulf War veterans suffer from multi-symptom illness over the rate in non-deployed counterparts, when the preliminary results of the study were presented to the Research Advisory Committee two years ago? Can you tell us when it will be published?

Response. The overall study results, including the prevalence of “multi-symptom illness,” have been analyzed by VA researchers who conducted this study. This is an enormous amount of data which requires careful analysis, and then the report has to go through submittal to a journal, peer review, correction and then acceptance and publication. A manuscript is currently being prepared.

Question 11. The American Legion has recently presented to Congress its Views and Estimates on Congressional Action needed for veterans’ care. In that document they state:

“38 U.S.C. 1118 mandates how the Secretary should respond to the recommendations made in the IOM reports. The Secretary is required to make a determination of whether or not a presumption for service connection is warranted for each illness covered in the report no later than 60 days after the date the report is received. If the Secretary determines that presumption is not warranted for any of the illnesses or conditions considered in the report, a notice explaining scientific basis for the determination has to be published in the **Federal Register** within 60 days after the determination has been made. Gulf War and Health, Volume 2 was released in 2003, 4

years ago. Since then, IOM has released several other reports and V A has yet to publish its determination on those reports as well.”

Can you tell the Committee when VA will publish its determination on these reports?

Response. The notice concerning the congressionally mandated report from National Academy of Sciences Institute of Medicine committee on Gulf War veteran's health, Volume 2 (Insecticides and Solvents), was published in the Federal Register on August 24, 2007 at 72 Fed. Reg. 48734 (2007). VA has not yet published Federal Register notices for the remaining IOM committee reports. However, the Secretary has previously notified Congress of his determination that no presumptions are presently warranted based on the IOM committee reports Volumes 3 (Combustion Products, etc.) and 4 (Health Effects of Serving in the Gulf War), in letters dated February 24, 2006 (for Volume 3) and May 7, 2007 (for Volume 4). VA is currently reviewing the most recent IOM committee “Gulf War and Health” report (Volume 5), which covers infectious diseases of Southwest Asia.

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#### ATTACHMENT

At the [www.va.gov/GulfWar](http://www.va.gov/GulfWar) Web site, Gulf War veterans and their families have access to:

- VA's Gulf War Veterans Information Helpline (1-800-PGW-VETS)
- The most recent VA Gulf War Newsletter (July 2006)
- VA's Gulf War (and OIF) Registry Program Handbook (June 2007)
- The Annual Report to Congress on Gulf War Veterans' Illnesses from the VA/DOD Research Working Group
  - VA's Veterans Health Initiative (VHI) Independent Study Guide for Providers on Gulf War Health Issues
  - VA's Depleted Uranium Handbook for Gulf War Veterans (February 2004)
  - VA's Evaluation Protocol for Gulf War and Iraqi Freedom Veterans with Potential Exposure to Depleted Uranium (DU) Handbook
  - VA's Southwest Asia Poster (May 2004) (also distributed to all VA Medical Centers, Regional Offices and Vet Centers)

#### BROCHURES AND INFORMATION BULLETINS

- Health Care and Assistance for U.S. Veterans of Operation Iraqi Freedom
- Q&A Brochure—Gulf War Illnesses, August 2003 (English and Spanish)
- Information Bulletin on Gulf War veteran health issues 10-41 and -42, March 2004 (in Spanish)
- Gulf War Fact Sheet April 2000
- Depleted Uranium Frequently Asked Questions (FAQs)
- VA Gulf War Registry Examination Handbook 2005

#### RESEARCH REPORTS AND SUMMARIES

- Combined Analysis of the VA and DOD Gulf War Clinical Evaluation Programs (A Study of the Clinical Findings from Systematic Medical Examinations of 100,339 U.S. Gulf War Veterans)—September 2002
  - Gulf War Research: A Report to Veterans, October 2003 (English and Spanish)
  - Journal Article Summaries on Gulf War veteran health issues
  - Gulf LINK Medical Information (Gulf LINK is DOD's site on Gulf War veteran health issues containing Gulf War research-related information. It is a collaborative effort of three departments-DOD, VA, and HHS.

#### GULF WAR RISK FACTOR REPORT REPRINTS (TAKEN FROM VA'S "GULF WAR REVIEW" NEWSLETTER)

- Introduction
- Deplete Uranium
- Pesticides
- Pyridostigmine Bromide
- Infectious Diseases
- Chemical & Biological Warfare Agents
- Vaccinations including Anthrax & Botulinum
- Oil Well Fire Smoke and Petroleum

At the [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents) Web site, Gulf War veterans and their families have access to a wide range of information on health and other information that may affect them, including:

## BROCHURES

- Depleted Uranium & Health Pocket Guide For Clinicians (May 2007)
- Special Health Registry Examination Programs (including the Gulf War Health Examination Registry Program) (June 2006)
- Your Story: Tell Your Military History (November 2005)

## FACT SHEETS

- Iraqi Freedom Veterans: Information For Veterans Who Served in Iraq In 2003–2004 and Beyond and Their Families (IB 10–166) December 2004
- Enduring Freedom Veterans: Information For Veterans Who Served in Afghanistan and for Their Families (IB 10–71) December 2004
- Ionizing Radiation Brief: Fact Sheets For Those Concerned About Possible Long-Term Health Consequences Of Ionizing Radiation Exposure (December 2004)

## NEWSLETTERS

- Operations Iraqi Freedom/Enduring Freedom Review: Information for Veterans Who Served in Iraq and Afghanistan and Their Families (July 2007)
- Operations Iraqi Freedom/Enduring Freedom Review: Information for Veterans Who Served In Iraq and Afghanistan and Their Families (April 2007)

## POD CASTS (DOWNLOADABLE AUDIO FILES FOR VETERANS)

- Poly trauma Centers (April 2007)
- Blast Injuries (April 2007)
- Transition Assistance Advisors (April 2007)
- New Brochure Explains Registry Programs (April 2007)
- Newsletter Editor Rosenblum Retires (April 2007)
- Readjustment After Deployment (April 2007)
- How To Apply For Disability Compensation From VA (April 2007)
- En Espanol: Como aplicar para la compensacion de incapacidad en el VA (Abril 2007)
- Special Compensation (April 2007)
- Quick Guide To Traumatic Brain Injury (April 2007)
- WRIISC: National Referral Program (April 2007)
- WRIISC: Transition and Orientation Class (April 2007)

## UNDER SECRETARY FOR HEALTH INFORMATION LETTERS

- Under Secretary for Health's Information Letter (IL 10–2006–010): Potential Health Effects Among Veterans Involved In Military Chemical Warfare Agent Experiments Conducted From 1955 to 1975 (August 14, 2006)
  - Chemical Warfare Agent Experiments among U.S. Service Members (Updated August 2006)
  - VBA Letter and DOD Fact Sheet and FAQs For Veterans Involved in Military Experiments at Edgewood/Aberdeen with Chemical Warfare Agents from 1955 to 1975 (June 30, 2006)
- Under Secretary for Health's Information Letter (IL 10–2006–004): Screening and Clinical Management of Traumatic Brain Injury (January 25, 2006)
- Under Secretary For Health's Information Letter (IL 10–2005–020): New Study Reporting Increased Risk Of Brain Cancer Deaths Among 1991 Gulf War Veterans Possibly Exposed To Sarin Chemical Warfare Agent At Khamisiyah, Iraq (September 15, 2005)
  - DOD Letter, Fact Sheet and FAQs for Gulf War Veterans Who Served Near Khamisiyah, Iraq (September 27, 2005)
- Under Secretary for Health's Information Letter (IL 10–2005–004): Health Effects among Veterans Exposed To Mustard Gas And Lewisite Chemical Warfare Agents (March 14, 2005)
  - Under Secretary for Health's Information Letter (IL 10–2004–013): Guidance For The Diagnosis And Treatment Of Leishmania Infection (October 6, 2004)

- Under Secretary for Health's Information Letter (IL 10-2004-007): Possible Long-Term Health Effects from The Malarial Prophylaxis Mefloquine (Lariam) June 23, 2004
- Under Secretary for Health's Information Letter (IL 10-2003-014): Long-Term Effects of Heat-Related Illnesses (November 20, 2003)

#### VETERANS HEALTH ADMINISTRATION DIRECTIVES

- VHA Directive (2005-020)—Determining Combat Veteran Eligibility (June 2, 2005)

#### VETERANS HEALTH ADMINISTRATION HANDBOOK—VA HEALTH CARE, BENEFITS AND ELIGIBILITY INFORMATION FOR VETERANS

- VHA Handbook 1303.2, Gulf War (Including Operation Iraqi Freedom) Registry Program (March 2005)
  - “VA Health Care and Benefits Information for Veterans” is a new wallet card that nicely summarizes all VA health and other benefits for veterans, along with contact information, in a single, wallet-sized card for easy reference (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).
  - In collaboration with DOD, VA published and distributed one million copies of a new short brochure called “A Summary of VA Benefits for National Guard and Reservists Personnel.” The new brochure does a tremendous job of summarizing health care and other benefits available to this special population of combat veterans upon their return to civilian life (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).
  - VA Health Care Benefits Eligibility (Link to VA Health Eligibility Home Page)
  - Special VA Health Care Eligibility for Veterans Who Served In Combat Theaters Fact Sheet, IB 10-162 (December 2003)

#### IMPROVEMENTS IN HEALTH CARE ELIGIBILITY

- Based on VA's experience providing health care to veterans of the 1991 Gulf War, VA supported legislation that provides enhanced enrollment (Priority Group 6) placement for veterans who served in a theater of combat operations after November 11, 1998. This authority provides a 2 year post-discharge period of cost-free care or services for conditions potentially related to this service.
  - Provides full access to VA's Medical Benefits Package for recently separated combat veterans.
  - Summarized in the brochure and poster distributed to all VA facilities called “Special VA Healthcare Eligibility for Combat Veterans,” (available online at [www.va.gov/EnvironAgents](http://www.va.gov/EnvironAgents)).

#### POSTER

Two Years Free VA Medical Care-New Combat Veterans (Sept 2006)

Special Reports on Gulf War Veteran Health Issues from the National Academy of Sciences Institute of Medicine (The full reports are available online at: [www.nas.edu](http://www.nas.edu).)

- Health Risk Factors by the National Academy of Sciences Institute of Medicine
- Gulf War & Health Volume 1 (2000): Depleted Uranium, Pyridostigmine Bromide, Sarin, Vaccines
- Gulf War & Health Volume 2 (2002): Insecticides and Solvents
- Gulf War & Health (2004): Updated Literature Review of Sarin
- Gulf War & Health Volume 3 (2004): Fuels, Combustion Products, and Propellants
- Gulf War & Health Volume 4 (2006): Health Effects of Serving in the Gulf War
- Gulf War & Health Volume 5 (2007): Infectious Diseases

Senator MURRAY. Thank you very much.

Let me start by asking, you both were here. You heard the last panel. Was it as disturbing to you to hear that the perception is or the reality is that we are not doing research on vaccines because we might find out something?

Dr. KUPERSMITH. Well, it is certainly disturbing for that to be said. I can't certainly say that that is, in fact, the case, but we do

have a database to look at some of this, and we are also doing some studies on cellular effects of anthrax vaccine to try to find out whether it does some direct cellular harm. So we do have various kinds of studies that are looking at this, but that is a disturbing statement, certainly.

Senator MURRAY. Do you feel that that may be true in any way?

Dr. KUPERSMITH. I can't say that.

Senator MURRAY. Do you feel like it is hard to get research on a lot of the vaccines done?

Dr. KUPERSMITH. I don't know that it is. I think we could develop some research projects on vaccines that were focused. We do look at populations in that regard, but—and as I said, we do have some vaccine studies looking at illness—at effects on the cellular level.

Senator MURRAY. Dr. Kilpatrick?

Dr. KILPATRICK. Again, from the Department of Defense standpoint, we are doing, I think, a very good job of making sure that vaccinations are being documented, that they are being recorded electronically.

Senator MURRAY. Do you think we are doing enough? Are we really looking at these vaccines?

Dr. KILPATRICK. I think we are looking at them very hard. There are some pilot programs. DOD is looking at people coming in, starting with new recruits, and not giving them vaccines they have already received while they going through school. High school now, the school systems, are demanding many vaccines for school children. Not a lot of research going on in that area, but as they are coming into the military, we are asking, "What have you had? What is documented?" and only giving the shots that you would need for military service. We are looking at studying the pilots of giving one shot, then a delay period and then a second shot rather than two at the same time. So there is research going on.

There was a huge study looking at the smallpox vaccine when it was first given. It was really done in a research mode with people reporting every day for 30 days after getting the vaccine as to what symptoms they had and that was looked at electronically by researchers.

All of the anthrax vaccine has been recorded, a lot of researchers at that. I know there was a mention about pneumonias in theater. Anthrax vaccine was one of the first things looked at and there was absolutely no relationship between the timing of the anthrax vaccines and the occurrence of pneumonia in those cases.

Senator MURRAY. Well, there is a perception out there—it could be a reality—that there is not being enough done because we don't want to find out. Does that bother you as a professional, as a doctor?

Dr. KILPATRICK. As a professional, it certainly bothers me there is such a perception. We just need to do more to help educate people. We need to be more transparent. We need to let people know what is going on.

Senator MURRAY. Are we being more transparent?

Dr. KILPATRICK. Work is being done, and I am not sure when you tell the world your results.

You usually tell them after you have completed the study rather than we have 20 studies underway.



Senator MURRAY. Well, I am sure—

Dr. KILPATRICK. We could change that—

Senator MURRAY. And I am sure you are aware that DOD has a long and sort of shameful history involving Gulf War syndrome. DOD obscured the truth about Gulf War illness. We hid information. Senator Sanders referred to much of that in his opening statement. Generally not forthcoming. We had to pull teeth to be able to get DOD to recognize that Gulf War illness was a reality, and I remember those hearings well back in 1993, where people were coming to me as a U.S. Senator and describing these horrible conditions and the DOD was saying it is all in their head. So given that history, it is understandable that people don't trust the military. How do you respond to that?

Dr. KILPATRICK. I think we have to continue to tell information and provide the facts and data in a very timely and forthcoming way. We need to make sure that the servicemembers know at the time they are getting the vaccines or they are getting treatment or they are being evaluated for illnesses. We need to do an excellent job of making sure that our medical providers understand the complexities of illness after deployments. I think that is a major focus of Force Health Protection, to get the medical providers to understand what the servicemembers have experienced and to be able to do appropriate medical diagnostic work within that realm rather than being dismissive, as happened too often with Gulf War veterans.

Senator MURRAY. Dr. Kupersmith, back in 1997, the VA's Office of Policy, Planning, and Preparedness, working with a number of organizations, created the Gulf War Veterans Information System to identify Gulf War servicemembers and monitor their VBA compensation and pension benefit. This provides the best possible available current data that identifies the 6.6 million Gulf War servicemembers, but it no longer includes data on the health care usage rates for the Persian Gulf War veterans. Can you tell us why the VA no longer tracks that?

Dr. KUPERSMITH. I would have to look into that. I can't—yes. We will take that question for the record.

Senator MURRAY. OK. I would very much like to know why we are no longer tracking that and why we are apparently not doing it for today's servicemembers in Iraq and Afghanistan.

Dr. KUPERSMITH. Yes.

Senator MURRAY. And you can't answer that question?

Dr. KUPERSMITH. We will respond to that, yes.

Senator MURRAY. Well, I would like a timely response on that because I think it is very critical. I appreciate that.

I will turn it over to Senator Burr.

Senator BURR. Dr. Kilpatrick, who wrote your testimony?

Dr. KILPATRICK. Sir, I was very involved in writing that testimony.

Senator BURR. Let me ask it again. Who wrote your testimony?

Dr. KILPATRICK. I wrote that testimony.

Senator BURR. Thank you, sir. Dr. Kupersmith, who wrote your testimony?

Dr. KUPERSMITH. We had a group of four individuals including myself who wrote the testimony.

Senator BURR. Did you write it late and is that the reason we got it late, or was it held up by VA?

Dr. KUPERSMITH. I apologize for your receiving it late. I don't know why that happened.

Senator BURR. Dr. Kilpatrick, why was yours late?

Dr. KILPATRICK. I must apologize to you for it being late. If you can do something to speed the time between the time the draft is written and the approval is given and it arrives for your use, that would be most helpful.

Senator BURR. If you would share with me where the delay came from, I will be glad to try to solve it.

Dr. KILPATRICK. As far as I understand, the delay was at OMB.

Senator BURR. I thank you for that.

Senator MURRAY. I am sorry, at OMB?

Senator BURR. OMB, which, I might say, is a cultural problem within all administrations.

What is DOD policy on disclosure of vaccinations? Are troops informed of what vaccinations they have been given?

Dr. KILPATRICK. That should be the policy now. During the Gulf War, it was a unique incidence that went on and it had to do with Vaccine A and Vaccine B. We had anthrax and botulism vaccine available for the troops during the Gulf War. The decision was made in late January to give vaccine to troops that most likely would be exposed. We did not have enough vaccine for the troops in theater, all the troops in theater, and so it was coded Vaccine A for anthrax and Vaccine B for the botulism.

Senator BURR. And were they aware that they got Vaccine A or Vaccine B?

Dr. KILPATRICK. That varied from location to location. Having talked to a lot of Gulf War veterans, some were told this is anthrax or this is botulism. Others were told it is A, it is B. Others were told it is classified—

Senator BURR. Would their medical records show what they were given?

Dr. KILPATRICK. I have talked, again, to veterans.

Some of them actually have it in their records. I would say that is a minority. Paper records were what was being used at that time. There were no electronic capabilities, and so giving shots in the field and having paper records catch up with a person's health record was almost an impossibility.

Senator BURR. Dr. Binns said in his testimony that over two-thirds of Gulf War illness research, in excess of \$30 million annually, is funded—has been funded historically by DOD. Since the start of the current war, the program has been eliminated, and I know my understanding is in this year's appropriations, DOD made no request for that \$30 million. Can you explain why?

Dr. KILPATRICK. I can give you information on that and I will ask Colonel Harris to talk about what actually is happening. As I mentioned in my oral statement and testimony, the title of Gulf War Illness Research was changed in 2002 to Force Health Protection Research and it is the same portfolio of research going on, it is just not focused only on Gulf War veterans but all deployment-related health information. Maybe Colonel Harris can amplify.

Senator BURR. Colonel, thank you for your work that has been highlighted. If you have got anything to add, I would love to hear it.

Col. HARRIS. Well, the Congressionally Directed Medical Research Programs responds to needs that are put into the budget. In Fiscal Year 2006, we received \$5 million from the Army, which was the result of an amendment that was put forth here in Congress.

Dr. KILPATRICK. And I think the Congressionally Directed Research Program is different from the core military research program that is force health protection-related because that is focused on military operational medicine issues, run by another area at Fort Dietrich.

Senator BURR. Dr. Kilpatrick, your testimony noted a number of different efforts, I think undertaken by DOD following the experience with veterans of the Gulf War. Has the Department of Defense noticed any increase in illnesses or symptoms similar to those afflicting veterans from the Gulf War?

Dr. KILPATRICK. We have a couple different projects or environmental issues going on with today's troops coming back from theater. At the end of the Gulf War, we were in the middle of a major draw-down on the military size. Many people came back from the war and went home. They had no access to health care in the VA. Today's veterans coming back have a 2-year window coming back from theater for access to the VA for any illness or disease or injury that may be related to their deployment so they feel they have access into the VA.

We are doing the post-deployment health assessment and re-assessment now and what we are finding is that people are starting to come forward as leadership is being educated to make sure treatment is being afforded to servicemembers. We are finding, looking at the illnesses or the diseases being reported in theater and coming home, we are finding that about 15 to 20 percent of people are having signs, symptoms, ill-defined illness, but that is in the medical evaluation process and they are continuing to get medical care, which is a different situation than the Gulf War veterans experienced when they came home.

Senator BURR. In your testimony, you state, "Assumptions based on participation in the 1991 Gulf War cannot be made about the health of a veteran who presents himself for clinical evaluation." I realize that individual examinations are good medicine, but why is it not relevant to consider that a veteran who served in the Gulf War, when it is reported that nearly 30 percent of them are suffering from some ill effects of health, why wouldn't you use that assumption from a standpoint of some overriding clinical approach?

Dr. KILPATRICK. Again I think we are getting into the semantic issue that the first panel highlighted. These veterans, when they do present with illness, need to be taken at face value. I for 10 years have advocated that Gulf War veterans who are ill need care. They need compassionate care from a provider who understands the issues that they have experienced. And then you need to do the individualized medical work-up. To do just a routine process on everyone that comes through the door is not going to hone down on the individual's problem. I think, as you heard from the first panel,

the symptoms are wide-ranging, from gastrointestinal problems to pulmonary problems to neurological problems—

Senator BURR. But I take for granted from the statement that you made that when a veteran of the Gulf War presents themselves, that there is no benefit to that doctor knowing that they were a participant in that theater or not from a standpoint of the battery of things that they take them through for evaluation. Is that accurate?

Dr. KILPATRICK. Well, then I misrepresented or was not accurate in what I would say. As an infectious disease doctor, you always want to know where your patient has been, what the history has been, and I think taking a military medical history, you want to know, have you been deployed, and where were you, and what did you do? That needs to be the focus.

So, I think that any veteran coming in, that should be part of the dialogue for that individual, and that is what we really do have in DOD. DOD and VA developed a clinical practice guideline that asks for every servicemember coming into clinic, “are you here for a deployment-related issue?” That is the first question they should be asked when they come in the clinic. That then triggers the questions on how—

Senator BURR. The Chair has been very kind with the time and I will wait for the second round to ask additional questions, but I hope you understand, with the wide range of illnesses yet unexplained, unidentified from a standpoint of the cause, one might present themselves not believing this is the result for 16 years of having served in 1991 in the Persian Gulf. They may not have had the luxury of going in and saying, I served at this point, and all of a sudden that triggered a whole battery of things that should be looked at versus a determination having been made before they are seen that they served at this time, therefore triggered clinicians to do certain things. I think you can have an assumption that probably overrides it, and I will give Dr. Kupersmith an opportunity to address it when we come back from the VA standpoint. I thank the Chair.

Senator MURRAY. Senator Sanders?

Senator SANDERS. Thank you, Madam Chair.

Let me pick up on a question that Senator Burr asked.

Let me ask it to Dr. Kilpatrick. You indicated that your testimony was late because it had to be cleared by the OMB.

I did not know that the OMB had specialists in Gulf War illness. Why does it go to the OMB? Does it go to the political department of the White House, as well?

Dr. KILPATRICK. Sir, I can't answer that totally. I know that the process after it left my desk was to get clearance through—

Senator SANDERS. Let me express a real concern here. We are wasting everybody's time if these are political statements that you are making. We asked you to come here because you are scientists and you are physicians and we want to hear your best evidence. Frankly, I don't want to hear what the political wing of the White House has to say on this issue. You are insulting all of us. I don't want to hear what the OMB has to say unless they have some particular expertise in Gulf War illness that I was not aware of. You

are here as a scientist. You are here as a government physician. That is what we want to hear.

Let me respectfully suggest, Madam Chair, that the next time we have people from the VA or the DOD, I don't want it to go to the OMB and I don't want it to go to the political wing.

Senator MURRAY. Can I just ask, were either of your testimonies changed as a result of going through that process?

Dr. KILPATRICK. One word, "Persian" in front of Gulf War, was taken out.

Senator MURRAY. And—

Senator BURR. If I could add, Madam Chairman, and I say this with all due respect to my colleague, I have been here 13 years. I have not had a government witness in 13 years whose testimony wasn't vetted by OMB. So this is not something that was created as the result of this administration or this incident—

Senator SANDERS. I don't want—

Senator BURR.—but I am more than willing to stand beside you and go after all of them—

Senator SANDERS. Good.

Senator BURR.—and to end this, because I believe that it is healthy to get a personal perspective from those who we have got in charge.

Senator SANDERS. These are scientists and these are experts, and I presume, Senator Burr, you will agree with me that we want to hear their knowledge, yes?

Senator BURR. I agree with you totally, but I would disagree you that there is a political point here—

Senator SANDERS. I didn't want to—I just didn't want to raise the great political issue here, but it is of concern.

You have also heard today concern that while huge amounts of money, in fact, have been going to Gulf War research, there is a general consensus, I think, within Congress that a lot of that money has not been particularly well spent. On the other hand, I have heard very positive reports regarding the Congressionally Directed Medical Research Program, and I would like to address a question, if I could, to Colonel Harris.

Colonel, I know you have been working with some \$5 million, and we hope to get you actually some more money. Could you give us just some understanding of what you have been doing with the funding for Gulf War illness that has come to your agency and what you might do if more funding came?

Col. HARRIS. OK. The focus of the call for the Fiscal Year 2006 solicitation was to focus on treatments as well as to identify the underlying pathophysiology so that you would be able to then target future treatments for the illnesses that Gulf War veterans are suffering from.

The Congressionally Directed Medical Research Programs uses a two-tier review process with the first tier being a scientific peer review, and then we have a panel of experts which we call an integration panel that help us to determine what focus the research needs to take as well as they assist in the selecting of the actual studies that get funded.

We do a very broad solicitation or call because the idea is that you want to bring in as many ideas as possible and then have the opportunity to pick the best ones that are going to make it—

Senator SANDERS. If I could, this concept of a broad solicitation makes a lot of sense to me. Is it accurate that you have received 60 responses, or 80, was it, requests came in for funding?

Col. HARRIS. That is correct. We actually, for the proposals, we actually did, because it was a small amount of money—there was \$5 million—and we didn't know how large of a response we would have in this area, we actually did a pre-proposal, so individuals submit a smaller proposal that gives the basic outline of what they want to do and then the integration panel reviewed those to narrow the list down somewhat when we received full proposals. But that was the original solicitation—

Senator SANDERS. It sounds to me like 80 proposals is quite a large number. Were you surprised at that number of proposals coming in?

Col. HARRIS. Eighty is quite a few for a \$5 million solicitation.

Senator SANDERS. Does that suggest to you that all over this country, there are different universities and foundations and physicians and scientists who are interested in this issue?

Col. HARRIS. I mean, it is hard to make a judgment, but, I mean, again, the numbers speak for themselves. When you put out a call asking for looking at new ideas, because that was the focus of one of the proposals—it was exploration hypothesis development award, which is what are innovative ideas that might be causes behind the Gulf War syndrome as well as then looking at more mature ideas, looking at potential treatments.

Senator SANDERS. Thank you very much for what you have done and we look forward to continuing working with you.

Senator MURRAY. Thank you very much.

Dr. Kupersmith, the current practice guidelines for Gulf War illness referred to by the VA as medically unexplained symptoms, it has not been updated for more than 5 years and seems to indicate a psychological cause of illness rather than from environmental exposures that we have heard so much about. Why haven't those current practice guidelines been updated to reflect the current research that we know?

Dr. KUPERSMITH. I think the practice of physicians has been updated to reflect the current research, but I can't answer why that particular guideline has not. We deal with the research specifically and we don't—we inform the practice guidelines, but we do not create them. But I do think that we have a very strong program of educating physicians about taking a military history, for example. We have a strong program for our residency training program and educating—

Senator MURRAY. I am assuming you heard Doctor, I believe it was Dr. Nass in the previous panel say that a patient had just come in a few months ago and was told it was psychological.

Dr. KUPERSMITH. Well, I think that—I can't speak for the thousands of physicians, every last of the thousands of physicians that are in the VA. Certainly, it is not our overall statement or policy at this point to say that what happened in the Gulf War is due to

psychiatric illness, and certainly our research over the past 3 years has not taken that direction at all—

Senator MURRAY. So does this—

Dr. KUPERSMITH.—and that is what I can speak about best.

Senator MURRAY. So is this going to be updated so doctors get the best information?

Dr. KUPERSMITH. I have to—I mean, again, I am not the one who does that and I will get you that information about how the updating of that is being done.

Senator MURRAY. OK. I would appreciate a timely response on that.

Dr. KUPERSMITH. Mm-hmm.

Senator MURRAY. Back in August of 2005, there was a study in the American Journal of Public Health by a Dr. Tim Bullman who found that Gulf War veterans exposed to nerve agents during the March 1991 weapons demolitions in Khamisiyah, Iraq appear to have a higher risk for brain cancer death than veterans who were not exposed. There is also an IOM report in September of 2006 that found evidence that suggests there may be an elevated rate of Lou Gehrig's disease among Gulf War veterans. So given all of this, why is there no permanent mechanism in place to grant presumptive disability for Gulf War veterans with ALS or brain cancer?

Dr. KUPERSMITH. I apologize again. You know, I deal with research, which informs these things. I cannot speak for the benefits or benefits that are given. Again, we can get you a response to that.

Senator MURRAY. OK. I would like a response to that. It seems to me that there should be some mechanism in place, knowing what we have with the research we have, that there is presumptive disability. Is there evidence there to support a presumptive disability, from your perspective?

Dr. KUPERSMITH. You know, I would have to look very carefully at what the criteria are for disability. I think the studies you cite, one of which—there is a study done by a VA investigator that found—that looked at brain cancer and found a slight increase, and I believe ALS is part of comp and ben. But again, deal with research and I—we inform both the clinical and the benefits process. What criteria the benefits process uses to make those determinations is in their hands, not in mine, and I can't speak for them.

Senator MURRAY. Colonel Harris, there is a lot of research out there on Gulf War illness. Can you tell us what you think the trends show in terms of what is the best theory or perhaps theories which account for this illness?

Col. HARRIS. Well, I am actually a relative newcomer to the field of Gulf War research and I think that the experts that you had on the previous panel, you know, have looked at more of the scientific studies. But the focus currently is trying to develop some biomarkers so that you have a mechanism to be able to detect whether or not an individual has a potential and has the exposure. Having a biomarker will also assist in targets for treatment as well as being able to track a person over time to see if they improve. Several of the studies that were funded out of the 2006 solicitation, which just have been awarded, actually are looking at different biomarkers.

Senator MURRAY. Senator Burr?

Senator BURR. Senator Sanders suggested that because you had such great response to the request of research on the \$5 million that that was indicative of how much interest there was in academia and other areas to uncover something, and I would only suggest to you that the proliferation of BSL-3 and BSL-4 laboratories on academic institutions around the country, I think now exceeding almost 400, might be indicative of the great need on the part of academic institutions to go out regardless of what the research is and bid for the dollars with very aggressive proposals.

And I do hope and I trust, Colonel Harris, that we will chase the most promising areas where you place that \$5 million and how you place it. I am sure you will, because we have some very talented academic institutions around the country that are aggressively trying to get every dollar regardless of the area of expertise. With the right amount of money, every institution can become an expert on everything, I am convinced, because they now have the infrastructure that is needed to support the research dollars.

Dr. Kupersmith, I want to give you an opportunity to take a shot at what I asked Dr. Kilpatrick about and that is his statement that assumptions about health status can be made based on the service in the Gulf War.

Dr. KUPERSMITH. I am sorry, but I—could you—I am not sure what your question is.

Senator BURR. His quote specifically was, "Assumptions based on participation in the 1991 Gulf War cannot be made about the health of a veteran who presents for clinical evaluation." Do you believe knowing they were a 1991 participant is important to a clinician that sees that veteran at the VA facility?

Dr. KUPERSMITH. Absolutely. Certainly, our research has found an increase in a number of conditions, as has been stated, and certainly that should inform how the physician diagnoses and treats the patient.

Senator BURR. Mr. Binns testified in the last panel and he referred to the VA fact sheet that was sent to a few Senators on this Committee because it notes Gulf War veterans suffer from a wide range of common illnesses which might be expected in any group of veterans their age. Would you care to respond?

Dr. KUPERSMITH. Well, it is not our opinion and research that these symptoms and signs should be dismissed at all. In fact, we have brought into our leadership one of the authors of a paper. Dr. Eisen is head of our Health Services Research Section who published the increased incidence of a number of those conditions, so we certainly don't feel that way.

Senator BURR. Well, he referred to the fact sheet as garbage.

Dr. KUPERSMITH. I do not want to characterize—I don't want to use that term.

Senator BURR. I suggested in my opening statement that I believe we should focus as much research on possible treatment options for our veterans who participated in the Gulf War who are still living with difficult illnesses so many years after the conflict. Can you provide your thoughts on my comments and give me some idea as to how the \$15 million per year program in Texas will approach the research funding as it relates to treatment versus cause?



Dr. KUPERSMITH. Yes. I think you also said that—you made a comment in another part earlier this morning about looking at the genetic issues. That is something we are very interested in. The Texas program will be looking at imaging, particularly neuroimaging. It will be looking at animal studies to involve treatments. It will be looking at genetics and genomics and it will be looking at biomarkers of illness, and that is physical or chemical markers, blood test markers, or possibly imaging markers of individuals who have these syndromes.

So I think it is a pretty broad range of treatment and it also reflects, I think, a somewhat different direction. Some of these large-scale studies that have been done may not be able to sufficiently identify under the surface individuals who have—perhaps a smaller group of individuals who may have a genetic predisposition to a particular exposure or some other situation that arose in the Gulf War theater. I think we will be looking for those things, as well.

Senator BURR. I want to take this opportunity to thank all four of you who sit at the table for the job that you do. In many ways, I can understand why it is not comfortable to be called up here to testify on any given thing, but clearly you have a talent and a willingness to commit to do it. I think it has been very helpful to hear from the first panel. I think it has been insightful to hear from those of you on the second panel.

If you walk away today with one common theme from this Subcommittee, I hope it is that it is unacceptable to continue what we have done in the past. It is absolutely vital that we chart a new course and that course has to deal in large measure with the treatment of these veterans while we continue to focus on areas of research that would provide us better avenues for treatment.

Now, I share that with you and in frustration of not getting your testimonies on time and the frustration of having to sit up here and be distracted from the verbal testimonies of the first panel. I can't let you leave without noting one thing with the answers that you have given me. Both of you submitted testimony that was nine pages long. I found a comment that related to treatment only one time and that was in DOD testimony. So if I missed it, Dr. Kupersmith, in your testimony, I apologize. If I missed multiple places in your testimony, Dr. Kilpatrick, I apologize. But I believe the answers that I have heard today give me optimism that we have transitioned to a mindset of treatment. I would only hope that the testimony would also embrace and suggest that treatment is the predominant focus of where we are at VA or where you are in your specific avenue. I didn't get that in my first read, and I will read it again in great detail to find what I missed.

I thank the Chair.

Senator MURRAY. Thank you very much, Senator Burr, and thank you to all of our witnesses, as well. I agree with the comments of Senator Burr. I hope that all of us use this to move forward to make sure that the VA and the DOD are going to continue their efforts to address the effective diagnosis and treatment of these veterans, but also to remember that how we deal with and treat the veterans of any war will determine how future generations of veterans believe they are going to be treated and it is absolutely critical that we continue to monitor this.

With that, I want all of our witnesses to know that we will submit additional questions to you today. We expect an answer promptly within a week for the Committee record.

Thank you for that.

With that, this hearing is adjourned.

[Whereupon, at 11:54 a.m., the Committee was adjourned.]

## A P P E N D I X

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PREPARED STATEMENT OF PAUL SULLIVAN, EXECUTIVE DIRECTOR,  
VETERANS FOR COMMON SENSE

Chairman Akaka and Members of the Senate Veterans' Affairs Committee, Veterans for Common Sense thanks you for holding a hearing today on "Research and Treatment for Gulf War Illnesses." Veterans for Common Sense is a nonprofit organization formed in 2002 focusing on veterans' benefits and healthcare, national security, and civil liberties.

The serious Gulf War illnesses among 175,000 veterans remain a significant problem that remains unresolved after more than 17 years. Strong action by Congress is needed now in order to counter the many years of opposition to research and treatment by both the Department of Defense (DOD) and Department of Veterans Affairs (VA).

Our written statement focuses on four key areas that require the immediate attention of Congress. Each of the four items discussed in our statement address our Nation's and our government's responsibility to care for veterans. When our veterans are sent to war, they should receive prompt medical care and disability benefits when they return home. In a lesson learned from the Vietnam War, our government should promptly study wartime toxic exposures and closely monitor healthcare and benefit use among veterans.

First, Gulf War veterans have waited 17 years for medical treatment to improve our health. VCS urges Senators to provide full funding for research into medical treatments for our Gulf War veterans. VCS urges the Committee to work with their colleagues on the Senate Armed Services Committee and in the House of Representatives to make sure that Senate Amendment 2060 to H.R. 1585 is retained in the final version of the National Defense Authorization Act that the President signs this year.

VCS wants to make sure the full \$30,000,000 is included so researchers can find treatments for the 175,000 Gulf War veterans still suffering from chronic multi-symptom illnesses since 1991, according to VA's latest longitudinal health study.

VCS supports this essential funding because the DOD Congressionally Directed Medical Research Program is an innovative, open, peer-reviewed program focused on identifying effective treatments, with a first priority for pilot studies of treatments already approved for other diseases, so they could be put to use immediately. If Congress doesn't act now, the cynicism, anger, and disbelief among our veterans will rise as they continue waiting without any effective treatments.

Second, Gulf War veterans and VA need simplified rules so disability claims can be processed faster and more accurately. VCS urges Congress to enact legislation granting a presumption of service connection for our Gulf War veterans diagnosed with brain cancer or with amyotrophic lateral sclerosis (ALS). Senators should follow-up on several recent scientific reports confirming that Gulf War veterans are more likely to suffer from brain cancer and from ALS than their non-deployed peers.

VA Secretary Anthony Principi already used his authority as Secretary to grant service connection for ALS, and this temporary authority should be made permanent. Service connection for veterans opens the door sooner for treatment and disability benefits.

Third, VCS urges Congress to continue funding scientific research into the many toxic exposures that faced our 700,000 Gulf War veterans serving in Southwest Asia during 1990 and 1991. Of greatest concern are four types of exposures: anthrax vaccines, depleted uranium, chemical warfare agents, and pesticides.

Scientific studies now show there are significant adverse health effects from the experimental anthrax vaccine, from the radioactive heavy metal depleted uranium, and from pesticides. Since the vaccines, DU, and pesticides remain in use by our military, it is reasonable to continue studying the impact of these poisons on Iraq

War and Afghanistan War veterans. Our veterans deserve to know what made us ill and to receive treatment and benefits for illnesses related to our military service.

VCS is especially concerned that VA repeatedly fails to conduct a medical study on the long-term consequences of DU, even though at least one of the Gulf War veterans with DU exposure currently monitored by VA developed cancer. Recent DOD animal studies link DU with cancer and chromosomal damage. VCS also notes that chemical warfare agents and pesticides appear linked to brain damage, which may explain some of the difficult-to-diagnose conditions suffered by so many Gulf War veterans.

Fourth, VCS urges Senators to expand the Gulf War Veterans Information System (GWVIS) reports prepared each quarter by VA. These reports define the Gulf War servicemember population and report on VA healthcare use, Vet Center counseling use, and VA disability claim activity.

The GWVIS reports should be expanded to include information about Iraq War and Afghanistan War veterans as well as VA expenditures related to all three groups of veterans. Without these reports, VA and Congress would be unaware of the behavior of these cohorts of veterans, and VA may once again find itself \$3 billion short, as it did in 2005, by failing to monitor Iraq and Afghanistan War veteran activity within VA.

VCS remains concerned about VA's commitment to producing the reports because the May 2007 GWVIS report failed to include healthcare use among Gulf War veterans, a critical component of today's hearing. Congress, veterans groups, and the public have a right to know the human and financial consequences of the Gulf War, Iraq War, and Afghanistan War. Therefore, VCS strongly supports the prompt passage of S. 117, "The Lane Evans Veterans' Healthcare and Benefits Improvement Act of 2007." VCS asks that our statement, Dan Fahey's statement to the House Veterans' Affairs Committee, dated July 26, 2007, plus a copy of the May 2007 GWVIS report be included in the official record of the hearing. VCS looks forward to working with Senators on the important issues identified here as well as on other issues impacting the health and welfare of our Gulf War, Iraq War, and Afghanistan War veterans.

PREPARED STATEMENT OF DAN FAHEY TO THE HOUSE VETERANS' AFFAIRS  
COMMITTEE, JULY 26, 2007

Dear Chairman Filner and Honorable Members of the House Veterans Affairs Committee:

I respectfully submit to you this written testimony on the occasion of your hearing on Gulf War veterans' illnesses to call your attention to serious problems with the Department of Veterans Affairs (DVA) study of Gulf War veterans exposed to depleted uranium (DU). Since 1993, I have interviewed hundreds of veterans about battlefield exposures to dust and debris from armor-piercing DU ammunition and presented my research findings to numerous Federal investigations of Gulf War veterans' illnesses. I am including with this testimony a copy of my most recent presentation at the 28 June 2007 meeting of the Institute of Medicine (IOM) committee that is reviewing scientific and medical literature on the health effects of DU exposure. My IOM presentation provides more detailed information in support of this statement.

The Department of Veterans Affairs study of DU is neither structured nor functioning to provide basic information about the possible health effects of DU exposure among Gulf War veterans. There are two major flaws with the study that undermine its integrity and value.

First, the DVA study is undersized. From its inception in 1993, the study included only a tiny fraction of the number of veterans with known or suspected exposures to DU. Consequently, we have no information about the possible health effects among the thousands of Gulf War veterans exposed to DU in friendly fire incidents; during the recovery, transport, and inspection of contaminated equipment; and as a result of the July 1991 munitions fire at Doha, Kuwait.

Second, the DVA study has become politicized. In recent years, officials from both the Department of Defense (DOD) and DVA have repeatedly presented false and incomplete information about the existence of cancers and tumors among the few dozen veterans being studied. The deceitful statements and omissions by DOD and DVA officials undermine the integrity of the study and call to question its purpose.

The DVA study of veterans exposed to DU is located at the Baltimore VA Medical Center and directed by Dr. Melissa McDiarmid. When DVA created the study in 1993, only 33 Gulf War veterans were enrolled. These individuals had been heavily exposed to DU as a result of being inside vehicles hit by DU rounds in friendly fire incidents; some had been wounded by DU fragments while others inhaled DU dust.

A 1993 DVA report on the creation of the study noted: "The small size of the population . . . [makes it] highly unlikely that definitive conclusions concerning cancer induction will be obtained from the study." By 2000, however, DOD belatedly admitted that "thousands" of Gulf War veterans may have been exposed to DU during and after the Gulf War, including approximately 900 veterans who are believed to have had heavy exposures to DU during friendly fire incidents, vehicle recovery operations, and the Doha, Kuwait, munitions fire. Despite this admission, since 2001 the DVA study has examined only 46 individual Gulf War veterans. Since numerous laboratory studies have demonstrated that DU may cause cancers, tumors, neurological problems, and other effects, it is imperative to expand and improve the DVA study in order to clarify the association between exposure to DU and cancer induction or other illnesses among Gulf War veterans.

In addition to studying only a few dozen veterans, the DVA study director has not honestly and completely presented study findings either publicly or in the medical literature. This fact first emerged in 2001, when DOD and DVA officials responded to European concerns that the use of DU munitions by U.S. jets during the Kosovo conflict had affected the health of NATO troops and civilians. At the height of the European controversy in January 2001, DVA study director Dr. Melissa McDiarmid wrote in the *British Medical Journal* that no veterans in her study had developed "leukemia, bone cancer or lung cancer," yet she inexplicably failed to mention that in 1999 one veteran in the study had Hodgkin's lymphoma and a second veteran had a bone tumor. Moreover, a 2006 journal article co-authored by Dr. McDiarmid supposedly summarized all study findings for the period 1993 to 2005, yet this article notably failed to mention the findings of the Hodgkin's lymphoma and bone tumor among the few dozen study participants. During her 28 June 2007 eight

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