

**FULL COMMITTEE HEARING TO RECEIVE UPDATES ON RE-
SEARCH, INVESTIGATIONS, AND PROGRAMS INVOLVING
PERSIAN GULF WAR VETERANS' ILLNESSES**

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

—————
FEBRUARY 5, 1998
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Printed for the use of the Committee on Veterans' Affairs

Serial No. 105-30



U.S. GOVERNMENT PRINTING OFFICE

49-407CC

WASHINGTON : 1998

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-057306-8

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FULL COMMITTEE HEARING TO RECEIVE UPDATES ON RESEARCH, INVESTIGATIONS, AND PROGRAMS INVOLVING PERSIAN GULF WAR VETERANS' ILLNESSES

THURSDAY, FEBRUARY 5, 1998

**HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
*Washington, DC.***

The committee met, pursuant to call, at 1 p.m., in room 334, Cannon House Office Building, Hon. Chris Smith (vice chairman of the committee) presiding.

Present: Representatives Smith, Quinn, Stearns, Cooksey, Chenoweth, LaHood, Evans, Kennedy, Filner, Gutierrez, Doyle, Peterson, and Snyder.

OPENING STATEMENT OF HON. CHRIS SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. SMITH. Good afternoon. For more than 6 years, there have been questions about the health conditions of Persian Gulf War veterans. The Committee on Veterans' Affairs has been diligent in investigating these concerns. In fact, today marks the 15th time this Committee has heard testimony on this matter, and I expect that with the vigorous leadership of our Chairman, Bob Stump, it will not be the last.

This Committee has also been at the forefront in formulating legislation designed to assist Persian Gulf veterans. For example, through the work of this Committee, any Persian Gulf veteran, whether sick or not, can now go to a VA facility for an examination and counseling. Also, a veteran who exhibits any condition which may be associated with the veteran's service in the Gulf is now eligible for priority care through the VA.

Last year, the Veterans Benefits Act of 1997, signed into law in November, created a \$5 million competitive grant program under which up to 10 VA facilities would establish demonstration projects to test new approaches to treating and improving the satisfaction of Persian Gulf veterans suffering from undiagnosed illnesses.

As Vice Chairman of the National Security Committee, Chairman Stump—and I think everyone would take note of this, and he may be by a little later—felt an obligation to attend the DOD budget hearing at which Secretary Cohen is currently testifying. Chairman Stump had asked that I would open this hearing, and other members will be chairing it as the day goes on.

About this time last year, the Committee held a hearing to examine the progress of the Persian Gulf illness-related research. Today, we follow up on that issue by bringing in government officials, academicians, and scientists to provide an update on what we hope is significant progress over the past year.

Persian Gulf veterans' illnesses have raised difficult scientific questions. It is vital, accordingly, that we gain the benefit of the insight of the scientific and other experts who have studied these questions.

We realize that many important research studies are still underway and that our state of knowledge remains incomplete. However, real and accurate answers do not come overnight.

Residents from across my district answered the call and served in the Persian Gulf War. And let me just say how important it is that I think every member of this Committee have had people, including some members of our Committee, who served in the Persian Gulf War.

Let me finally just ask my good friend Mr. Evans if he has any opening statements.

[The prepared statement of Congressman Smith appears on p. 60.]

OPENING STATEMENT OF HON. LANE EVANS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. EVANS. Yes, I do, Mr. Chairman. I appreciate it. Thank you, Mr. Chairman. I want to commend your side for scheduling this hearing, and I look forward to the testimony.

As a result of this proceeding, our Committee should have a better understanding of the current health status of Persian Gulf veterans, the care that they are now receiving, and the care that they still need to receive. We should also better understand the research being conducted to help answer vexing questions about the cause and treatment of persistent Gulf War veterans' illnesses and VA's response to the claims for compensation filed by Persian Gulf War veterans.

Today the VA deems about 80 different hazards and 270 various disabilities, quote, "acceptable," unquote, as a basis of adjudicating Persian Gulf veterans' service-connected disability compensation claims. It could well be years and more likely decades, if then, before science can definitively link all of these exposures to illnesses.

I'm currently preparing legislation to provide the basis for granting claims for service-connected disability to those who served in the Persian Gulf theater as well as other Persian Gulf-era veterans who have prepared to be deployed.

While a number of details must still be finalized, I expect to introduce this measure in the very near future. Prior to its introduction, I will invite all members of our Committee to become original cosponsors of this legislation.

In general, this legislation will provide a scientific basis for Persian Gulf compensation, but it does not presume that answers exist today to all the questions veterans still have about why they are sick.

Our experiences with radiation and Agent Orange should have taught us that science does not always provide definitive, unequivocal

cal answers that conform to our timetables and deadlines. But Persian Gulf illness data available to science can make clear links to exposures in some cases. In other cases, the evidence linking specific causes to specific conditions is more controversial. And in still other cases, there is little or no available science. In addition, new information about potential exposures, like the demolition of the chemical warfare munitions site, may become available at some time in the future.

Those symptoms or medical conditions found to be prevalent in the Persian Gulf veteran population should be presumed service-connected. This does not necessitate a definitive link between a specific agent and the symptoms or the diagnosis but does provide a firm grounding in science.

No less important, it will give Persian Gulf veterans who are suffering today, years after their service to their country, the benefit of the doubt—a benefit which they all have earned.

Mr. Chairman, I'm glad that you're holding the hearing and look forward to the testimony before us today.

[The prepared statement of Congressman Evans appears on p. 52.]

Mr. SMITH. Thank you very much, Mr. Evans.

Without objection, if other members have statements, we will make them a part of the record unless—did you want to—

Mr. KENNEDY. Yes. Mr. Chairman, if you wouldn't mind, I'd like to make an opening statement. Thank you very much.

OPENING STATEMENT OF HON. JOSEPH KENNEDY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS

Mr. KENNEDY. Mr. Chairman, 7 years ago when the Persian Gulf War ended, a hearing was held here in Washington to investigate reports that the Persian Gulf veterans were suffering from a series of mysterious symptoms, but there were no veterans at the witness table in the committee room.

In 1992, Lane Evans and I held a hearing in Boston to gather testimony from sick veterans who could tell us about their health problems. At that time, sick veterans were being called malingerers or worse by the Defense Department. People didn't believe that they were really sick.

But by early 1993, it was clear that there was a problem. Literally hundreds of veterans were calling our offices to report symptoms ranging from skin rashes to respiratory problems to kidney failure and cancer that they believed were linked to their service in the Gulf conflict.

The Pentagon continued to deny any link but was forced to take a closer look at the facts once countries that were members of the Persian Gulf coalition began reporting exposures from their own troops to chemical and biological weapons.

Finally, in April of 1996, the CIA released a report showing solid evidence that thousands of chemical weapons have been stored at Khamisiyah and that our troops may have been exposed to those deadly agents after allied forces bombed storage facilities.

Now here we are 7 years after the war. We finance 103, 103, separate research projects at a cost of \$49 million. And we've had a presidential panel study the veterans' health problems.

Both DOD and the VA have not answered the veterans' questions about what caused them to get sick and when they will get effective treatment. The veterans are frustrated and rightly so. They suffer from a myriad of illnesses like stomach disorders and painful muscles and joints, just to name a few of them.

The veterans don't want to hear the argument that their illnesses are caused by stress. When I talk to veterans and they tell me what they do want to know is what caused them to get sick. And what they also want is research to be done to find effective treatment.

They are brave men and women who answered the country's service at the time of need. They deserve a full accounting of how service might be linked to these horrible illnesses that have so astated their family lives and careers.

So based on my conversations with veterans, I'd like two things. I think two things need to be done. First, I talked with the Persian Gulf veteran Brian Martin of Michigan.

Brian was a specialist at the Army demolition team, and he was the person who filmed the bombing of the storage facilities at Khamisiyah. He has now stomach and colon problems and has an actual scar on his brain which is called decreased uptake and diffusion of the temporal lobe. He said the VA doesn't know which chemical he was exposed to.

Brian Martin now runs the international advocacy for Gulf War syndrome, which is a coalition of 60 grass roots organizations with 18,000 veterans as members.

Brian said veterans believe the VA's main problem is that they don't have enough information from research to provide effective treatment for the symptoms that they can't diagnose. He's testified before Congress several times and told me that veterans feel like: Thanks for the research into the cause of what made us sick, but please do some research that will find effective treatment. And the veterans think that DOD's research has been DOA.

So I'm drafting a bill that I'd like to ask the members of our Committee to review and join me as original cosponsors. I don't believe that we have a focused, coherent research strategy. The bill will give priority to researching Persian Gulf veterans' exposure to biological and chemical weapons and the resulting effects on their health to find effective treatment.

In addition, the bill will call for setting up a database to monitor the health of Persian Gulf veterans who are being treated within the VA health care system and those who are being treated in private health care. I'm putting this into the bill because a veteran told me and my staff that DOD and the VA have had no follow-up system to monitor Persian Gulf veterans' clinical progress after their initial physical exam.

Second, I've asked the GAO to evaluate the research that's been started. If the evaluation shows any of these studies that won't contribute to effective health care for sick veterans, then we should pull the plug and change the direction. I'll share the results of the

GAO's evaluation with the members of the committee as soon as we get it.

Finally, Mr. Chairman, with this cat and mouse game that Saddam Hussein is playing right now with U.N.'s weapons inspectors, we may be approaching the eve of another conflict in the Persian Gulf. Just yesterday the White House press secretary said that time is running out for a diplomatic solution in Iraq.

If we need to send in ground troops, we must do all we can to make sure that they don't come back as a second wave of Persian Gulf syndrome victims. If ground troops go in, DOD must guarantee that gas masks and protective suits are not defective and that they will protect the soldiers from any exposure to hazardous substances.

In addition, before the 1991 Persian Gulf War, the soldiers were given investigational drugs, such as PB, as a pretreatment to protect them against exposure to chemical weapons. These drugs were administered without informed consent. And some of the veterans believe that those drugs might be part of their health problems.

We don't know if that's true. However, I want to try to gain assurance from the Pentagon that informed consent procedures will be carried out if our troops must go into the Gulf again, although it is my fervent hope and I'm sure all of ours that that is not the case.

Thank you very much, Mr. Chairman.

Mr. SMITH. Thank you, Mr. Kennedy. Mr. Filner.

Mr. EVANS. If I could have a unanimous consent request? Mr. Chairman, I'd like to enter into the record a letter to our colleague John Tierney of Massachusetts regarding this hearing. May I ask that this letter and its attachments be made a part of the record?

Mr. SMITH. Without objection, the letter with attachments will be made a part of the record.

[The letter to John Tierney appears on p. 55.]

Mr. EVANS. Thank you, Mr. Chairman.

Mr. SMITH. Mr. Filner.

OPENING STATEMENT OF HON. BOB FILNER, A REPRESENTATIVE FROM THE STATE OF CALIFORNIA

Mr. FILNER. Thank you, Mr. Chairman. And I thank you and Chairman Stump for holding these hearings today. Although, as you've mentioned, we've had a dozen of them or more, I don't think we have come to the bottom of the situation as yet.

Let me try to put a human face on the attitude that I will take during these hearings today. I have two constituents named Sean and Leslee Dudley. Four or five years ago, they began to experience symptoms which they could not get adequately diagnosed anywhere. And initially they were treated for chronic fatigue syndrome.

They began to read about the Persian Gulf War illnesses, and thought that they had symptoms very similar. But when they tried to make this known to both the Department of Defense and the Veterans Administration, they were told that this could not be possible, they were civilians. They had not been to the Gulf. They were not in the armed forces. They were civilians who worked near the Marine Corps Recruiting Depot in San Diego, my hometown.

They were getting sicker and sicker. I met them when they were so sick I did not think I would see them on my next trip home because they were so ill.

They searched around for treatment and eventually came into contact with a researcher who was dealing with Persian Gulf War illness. He saw that this was the exact same situation that he had been treating in Gulf War illnesses and began to treat them with an antibiotic protocol, which he had developed. Within several months, they saw a tremendous turnaround. Now it is a year from when I first met them. They are proceeding toward some degree of normal health.

Their situation, I think, puts into human perspective some of the issues that all of us are concerned with. At first, the Dudleys were thought not to have anything that anybody could recognize. It was all in their mind. It was stress. Nobody thought it was a legitimate illness.

When they found somebody outside of the mainstream who would recognize it and begin treating them, they became activists in the attempt to help other people. And what they ran into in the Department of Defense and into in the Veterans Administration was a bureaucratic rigidity, a refusal to even hear what they had to say because it came into conflict with all of the assumptions that both departments shared.

They could not even get a hearing on the fact that here they had a treatment that seemed to work: Why weren't both the VA and DOD interested at all?

These are civilians, by the way, who believe that they caught this illness from others who had been exposed to whatever it is that caused it. Therefore, there is contagion involved. They have documented cases of other family members and pets of Gulf War veterans who have this illness.

I have never seen anywhere in the official literature that admitted any possible contagion. But the Shays Committee that has looked into this with some degree of credibility in my belief, and finds, in their words, that the programs are "irreparably flawed." And they make recommendations to improve that.

The Presidential Advisory Committee, whom we will hear from, the first witness, said that "The credibility gap between the public's views of government efforts to address these and the reality cannot be bridged without bold policy action." I quote from your report.

I have read all the testimony that I'm going to hear today. I have talked to folks in both departments. I still do not see, as Mr. Kennedy, Mr. Evans, and Mr. Smith pointed out, that the seriousness of the situation, the recognition of the fact that people are ill, and that there may be research that can lead to an improvement outside of the mainstream—I don't see any of that recognized at all in this testimony today. I do not see the bold action. I do not see a change in the policy.

As we prepare today perhaps to introduce our troops again into the same geographic area, it seems to me that the utmost of national security concerns is the truth, wherever that may lead.

If inoculations or testing of anti-chemical and biological warfare were involved and, therefore, we ourselves caused this illness, I think we have to recognize that fully because we are about to do

the same thing. We have started inoculating troops again without ever knowing what had caused the first situation, at least in public testimony. I believe that there is knowledge and testimony within the organizations that have not yet come to light.

So, Mr. Chairman, I bring to this hearing a little bit of a skepticism based on my several years of dealing with the Dudleys as we have tried to help them come to a normal life and understand their own disease and have come into roadblock after roadblock after roadblock with the existing bureaucracies. And I think we need to change that.

Mr. SMITH. Thank you, Mr. Filner.

I have been advised that Dr. Caplan is under a time constraint. So I would ask that if members do have opening statements, to perhaps reserve that for the beginning of the second panel or I'll just admit it for the record and we'll make it a part of the record.

I'd like to introduce our first panel, first of three panels. It consists of: Dr. Arthur Caplan, a member of the Presidential Advisory Committee on Gulf War Veterans' Illnesses; Dr. Donald Mattison, Chairman of the Board of Health Promotion and Disease Prevention at the Institute of Medicine, who is accompanied by Dr. Dan Blazer, Chairman of the Committee on the Comprehensive Clinical Evaluation Program at IOM.

Dr. Caplan, if you would begin?

STATEMENTS OF ARTHUR CAPLAN, Ph.D., MEMBER, PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES; DONALD MATTISON, M.D., CHAIRMAN, BOARD OF HEALTH PROMOTION AND DISEASE PREVENTION, INSTITUTE OF MEDICINE, ACCOMPANIED BY AND DAN G. BLAZER, M.D., CHAIRMAN, COMMITTEE ON THE COMPREHENSIVE CLINICAL EVALUATION PROGRAM, INSTITUTE OF MEDICINE

STATEMENT OF ARTHUR CAPLAN

Mr. CAPLAN. It is an honor to have the opportunity to offer testimony to this Committee. I'd say it's also a rare opportunity that I get to meet with a group who has probably sat through as many hearings and statements as I have on this subject.

My field is ethics, specifically ethical issues in medicine and the life sciences. That's what I teach at the University of Pennsylvania. But, more importantly for the Committee, I was a member of the Presidential Advisory Committee on Gulf War Veterans' Illnesses, which completed its work last October 31.

I want to be clear to you all today that the testimony I am presenting, while based on my service on that committee, only represents my own views and opinions. I am not going to presume to speak for my fellow committee members.

I would like to offer my opinions to you about a number of issues your Committee is trying to address and struggle with, some of which you have talked about in your opening statements: What needs to be done to find answers to questions about Gulf War illness; what needs to be done to attend to health problems in veterans from the Gulf War; and, probably most importantly today, what lessons must be learned and zealously applied to future pos-

sible deployments in the Gulf or other areas of the world where American military personnel and support personnel might go.

Mr. Chairman, I feel obligated to begin my testimony to you by reaffirming something that our committee noted in its interim report; its final report; and when our tenure got extended in January of 1997 for another 9 months, a special report. There should be no doubt that some veterans returned home from the Persian Gulf War ill. Some of these illnesses are clearly service-connected.

The questions of what exactly Gulf War illness is has proven to be a most vexing matter. No single set of symptoms, no classic presentation of complaints has emerged which encompasses all of the different health problems that veterans told us about in an extensive period of public hearings and that have been amply documented in numerous scientific studies and assessments.

There have been pronouncements over the year, including this year, to our committee and in the media that there is no entity, no disease, no Gulf War illness. But the lack of a clear-cut set of criteria that permits easy diagnosis or a single clear-cut disease shared by all who served who have complaints and ailments should not obscure or detract from the fact that some veterans became sick and some remain sick as a consequence of their service. No one on this Committee should doubt that.

The obvious question which follows is: Why? Why were people sick? The range of complaints and ailments, differences in the degree to which the military personnel were exposed to the same agents and factors, an absence of obvious patterns in the overall distribution of illness complaints makes it most unlikely that any single agent or cause was responsible.

My own opinion is that Gulf War illness may actually constitute more than one illness, which may have been brought about by more than one cause, and may also include illnesses brought on by exposure to many factors, not a single agent, in the Gulf War environment.

Our committee in its reports, including the final report we issued just a few months back, called special attention to one factor in particular, stress, as an important contributing factor to the problems that beset some of those who were in the Gulf.

When we mentioned this factor, this led some to conclude that our committee, too, felt that Gulf War illness is all in the minds of veterans, that some veterans must be making up their symptoms, or that only those too weak or frail or unfit for service would succumb to the psychological impact of deployment in an alien environment and exposure to combat fought with terrible technological weapons. I want to state to this Committee that I find these reactions to the citing of stress as a contributing factor to Gulf War illness absurd and even at some times offensive.

Stress can effect health. This is a well-documented fact. We know it from animal studies, and we know it from studies of human beings who work and live in stressful environments and situations. To pretend that stress is something that influences our health in peacetime but not in war is patently silly.

That said, it is my opinion that stress, when we talked about it on the committee, is only one of a number of factors that may have

contributed to some of the illness symptoms that some of the veterans suffered and they still suffer from.

It is not the sole cause of Gulf War illness. It is not the primary cause. It is simply one among a number of factors that we have to think about when we try and understand why so many people in so many different locations, from being deployed on the front lines all the way to the rear, suffer this vast array of symptoms that we call under the single banner Gulf War illness.

Well, the obvious question, then, is what to do about trying to find out the answers to questions of causation. And I have to tell you that many of my colleagues on the Presidential Advisory Committee on Gulf War Illnesses were and remain optimistic that focused, carefully conducted, peer-reviewed research will lead us to answers. I'm not sure. My own opinion is, that may not be true.

The Gulf War was fought under unusual circumstances. Large numbers of reservists were called into action at a rapid pace. For the first time, many women served at or near the front lines. The war itself was prosecuted with lightning speed.

Technology was deployed during this war that, thankfully, kept American casualties to an absolute minimum while causing great devastation to our enemy but that brought in its wake certain risks. Environmental hazards were omnipresent on the battlefield.

What I'd like this Committee to understand basically is that trying to go backwards 9 years in time to figure out who was where exposed to what when combinations of factors may be responsible for many different types of illnesses may be more than science is going to be able to reckon with.

Should we then abandon the effort to find the answer to what caused Gulf War illness? Absolutely not. The reason to push on is that the single most important lesson in my view of the Gulf War is that the only way to prevent another tragedy is to redouble our efforts into research to establish what the health effects are of various agents and factors that were in play in the Gulf theater and could be again should we be back there again.

It is vital that Congress insist that the armed Services and the Department of Defense make a concerted effort, moreover, to establish a baseline of health and surveillance that would allow us not to get into this situation one week from now or one month or one year from now.

We need to have uniform standardized policies for pre-deployment in-depth health assessments as well as for demobilization. These did not exist in Desert Storm and Desert Shield. And, in my opinion, I'm here to tell you today I don't think they exist now.

Despite the injunction that health monitoring and assessment in our reports receive top priority from the military in an era of technological wars fought in alien environments at a rapid pace, this has not happened. There is still insufficient attention to issues of adequate physicals, in-depth health assessments for samples of active and reserve troops, comprehensive and usable recordkeeping, standardization of medical information across the Services, storage of tissue samples for assessment, adequate monitoring of vaccine use and other preventive measures for deployed troops. We still aren't even sure that the equipment we're putting out there to

measure chemical and biological warfare detection meets the standards that we ought to expect of it.

The problem that we face, then, is that we should have learned a lesson from the Gulf War, which is; if we don't understand the health of the people we send there in depth before they go, it's going to be difficult for us to figure out why some of them become sick when they get back.

We are not taking the steps, in my opinion, to make sure that we don't repeat this tragedy again. That is where our research should focus. In addition, we should focus our research as well on the presumption that those who were sick may not get an answer. And, therefore, what we have to do is give the veterans the benefit of the doubt and make sure that our government is spending the money that it takes to provide them with therapy, treatment, and palliation.

I'm not saying give up on trying to answer the question of what made people sick. What I do think has to happen is a bold effort to make sure that they get treatment; that they get disability; that we do right by the veterans who were there; and then we make sure that you all, if I might respectfully suggest, make sure that the infrastructure is in place to make sure that we're not in a situation where another contemporary conflict brings us back sick or ill or disabled veterans, leaving us uncertain as to why they wound up in that state in the first place.

[The prepared statement of Mr. Caplan appears on p. 75.]

Mr. SMITH. Because there's a roll call vote on the floor, the committee will stand in recess for about 5 to 10 minutes. Thank you.

[Recess.]

Mr. SMITH. The committee will continue its hearing. Dr. Mattison, I believe you would be next. Please proceed.

Dr. MATTISON. Thank you.

STATEMENT OF DONALD MATTISON

Dr. MATTISON. Mr. Chairman, members of the committee, my name is Don Mattison. I am Dean of the Graduate School of Public Health at the University of Pittsburgh and Chair of the Institute of Medicine's Board on Health Promotion and Disease Prevention.

I am accompanied today by Dr. Dan Blazer, who is Dean of Medical Education at Duke and chairs the IOM Committee on the Evaluation of the Comprehensive Clinical Evaluation Program for Persian Gulf Veterans.

We appreciate the opportunity to provide testimony to you regarding a new IOM study. This study will evaluate the available scientific evidence and medical literature regarding an association between exposures during the Gulf War and potential health effects as experienced by Persian Gulf veterans.

As requested, I will also briefly review the findings of the recent IOM report which examined the adequacy of the Department of Defense's Comprehensive Clinical Evaluation Program and how those findings relate to similar programs administered by the Department of Veterans Affairs.

Dr. Ken Shine, the President of the IOM, regrets that he is unable to attend this hearing. However, he will make available him-

self, members of the Institute, and staff to provide information and testimony to the committee as necessary.

The Department of Veterans Affairs has requested that the IOM conduct a comprehensive review of the available scientific and medical literature regarding the association between exposures during the Persian Gulf War and adverse health effects experienced by Persian Gulf veterans.

This study will be conducted by a committee of experts drawn from a broad range of public health, scientific, and medical fields. Based on its review and findings, the committee will also make recommendations for additional scientific studies to resolve areas of continued uncertainty related to health consequences.

The IOM plans to conduct the study in three phases. During the first phase, the committee will develop criteria by which specific exposures and adverse health outcomes are to be chosen for study.

The committee will review different types of research findings from the scientific and medical literature; for example, data from animal studies, occupational exposures, and epidemiologic studies. They will conduct a review of the literature regarding prototypic exposures in order to develop methods for analysis and synthesis of findings. Scientific evidence concerning association of exposures and health effects will also be examined.

The committee will consider the strength of the scientific evidence and the appropriateness of those methods used to identify the association; the exposure levels of the study populations in comparison to Gulf War exposures; and whether there exists a plausible biological mechanism for a causal relationship between the exposure and the manifestation of the health effect.

During the second phase of the study, the remaining exposures will be subject to review and analysis. The final phase, to be conducted intermittently, will update the literature reviews and the associations that have been identified between exposures and adverse health outcomes. It is assumed that the IOM will begin this project this spring and complete the first phase by the Spring of the year 2000.

I would like to focus now on the findings of the recently released IOM report evaluating the adequacy of the Comprehensive Clinical Evaluation Program administered by the Department of Defense and how the report findings relate to similar programs administered by the Department of Veterans Affairs. I have appended a complete set of recommendations of the committee to my testimony but would like to summarize some of the findings for you.

The charge to this IOM committee was to examine the adequacy of the Comprehensive Clinical Evaluation Program diagnostic protocol as it relates to ill-defined and difficult-to-define conditions, and to stress and psychiatric disorders.

The committee chose based upon an examination of the conditions described as difficult-to-diagnose or ill-defined to refer to this spectrum of illness as medically unexplained symptom syndromes. Medically unexplained symptom syndromes are often associated with depression and anxiety. Yet, this does not imply that the syndromes are psychiatric disorders.

In addition, stress is a major issue in the lives of patients with this spectrum of illness and is a component of the patient's condi-

tion that cannot be ignored. With medically unexplained symptom syndromes, the potential for stress proliferation is great among both the persons deployed to the Persian Gulf and the family members.

Research has shown that stressors have been associated with major depression, substance abuse, and various physical health problems. Those deployed to the Gulf were exposed to a vast array of different stressors that carry with them their own potential health consequences.

It was the conclusion of that committee that "in cases where a diagnosis cannot be identified, treatment should be targeted to specific symptoms or syndromes."

The committee also recommended that "providers acknowledge stressors as a legitimate but not necessarily the sole cause of physical symptoms and conditions" and that providers should be educated to the fact that "conditions related to stress are not necessarily psychiatric conditions."

There is another committee of the Institute of Medicine that is currently completing its evaluation of the Department of Veterans Affairs Persian Gulf registry and uniform case assessment protocol for Persian Gulf veterans. Dr. Blazer is a member of that committee, whose charge is much broader than that of the CCEP committee because it includes an examination of the adequacy of: the protocol, its implementation and administration, outreach efforts to inform veterans of available services, and education of providers. The final report is due to be released later this year. We would be pleased to share copies of the report with you as soon as available.

Thank you for this opportunity to address you and the committee members. Dr. Blazer and I would be pleased to answer any questions that you might have.

[The prepared statement of Dr. Mattison, with attachment, appears on p. 83.]

Mr. SMITH. Dr. Mattison, thank you very much for your testimony.

Dr. Caplan, I'd like to ask you: In its report last October, the PAC recommended development of permanent legislation to, quote, "address the pervasive perception of government neglect in handling Gulf War veterans' illnesses." Is this proposal intended to help regain trust or is it a remedy, a gap, to provide a remedy for a gap, in legal authority as of right now?

Mr. CAPLAN. A little bit of the latter, a lot more of the former. Trust is a major issue in this area. And as you talk to veterans and listen to their complaints about lack of inattention from the DOD, failure to follow up on their symptoms, finding obstacles in their path about how best to find resources within the VA and other health care systems, I think there's a legacy of distrust here. And I believe that it really is going to take an independent authority with legal standing with veteran participation to oversight these investigations and keep tabs on what's going on.

The PAC that I served on no longer exists. And it is very important that something else be put in place with appropriate authority and representation to command that trust.

Mr. SMITH. Dr. Blazer, did you want to comment on that?

Dr. BLAZER. Yes. I have no comment specifically but would be happy to answer any questions.

Mr. SMITH. Okay. Doctor, your committee offered suggestions for treating Persian Gulf veterans' symptoms, such as fatigue and pain, even if their illnesses cannot be diagnosed. Does it matter that the treating physician doesn't know whether the symptoms are related to stress versus some other cause?

Dr. BLAZER. I think that the important issue is to recognize that stress and other causes can coexist. Stressors may relate to events that occur external to the individual.

For example, in the Persian Gulf, we heard testimony that individuals were exposed to hundreds of dead bodies, certainly an experience that would have been very stressful to them. At the same time, stress can arise from having a symptom that cannot be explained when one goes to a physician. So it may arise from that perspective as well.

I think the point we wish to make in our evaluation of the CCEP was that stress should not be ignored as part of the symptom complex going on. We do not suggest—it was mentioned earlier—that stress is the cause of every and all symptoms that we see.

Mr. SMITH. Dr. Caplan?

Mr. CAPLAN. Mr. Chair, just to follow up on that, I think one tendency in these discussions is to assume that if we eliminate certain causes and stress is put on the table, then everything in the way of illness is going to wind up in the stress bin. And that is false.

Stress is just being suggested as something that needs to be given consideration, but I think there is far more unknown about causes than there is known. And some of my skepticism about the complexity of what took place with respect to the health of the veterans is due to the fact that I'm not sure we're going to be able to tease all of that apart.

Mr. SMITH. Let me ask one final question.

In its testimony, Dr. Blazer, the GAO faulted the VA and the Department of Defense for failing to monitor Persian Gulf veterans' clinical progress after their initial examinations. Yet, the VA questions the feasibility of a monitoring effort in the absence of a well-defined illness. Can you comment on that?

Dr. BLAZER. I think there can be monitoring, and I think that monitoring can occur in a number of ways. One way that monitoring certainly could be improved would be to have good, solid, complete records from the individuals who were evaluated by the Veterans Administration. And this follows from a recommendation that we made regarding the CCEP.

A second would be to have a standardization of the way different symptoms are evaluated and whether they're recorded as being present or absent. Reliability across facilities without clear standards can be very poor. And improving reliability through training of physicians could go a long way toward improved monitoring.

I think also providing clear referral for follow-up would be another way that monitoring could take place.

Mr. SMITH. Thank you, Dr. Blazer.

Mr. Kennedy.

Mr. KENNEDY. Thank you. Thank you very much, Mr. Chairman.

First of all, I did want to just acknowledge your leadership on this issue, Mr. Smith. I appreciate you chairing this hearing today and the fact that we are following up on this Committee in a way that I think is appropriate given the lack of interest that took place for such a long period of time.

I want to just come back to the sort of general issue here that I spoke about in my opening statement. I think that because of the history of what's occurred, we're now in a situation where sort of almost every member of Congress and every different organization in the government has got some particular interest that they have developed and to a point where, as I mentioned, I couldn't believe we spent \$49 million on these studies. We have 103 of them, 103 studies going on right now.

I called the GAO and just asked them if they could—I looked at just the list of studies that have been requested. They cover everything under the sun.

So at a certain point, I began to get the impression from the veterans themselves that we can study this thing to death, but at a certain point, what they really need is treatment for their illnesses and that there is a sense I think at the moment that the veterans themselves, while they're getting treatment at the VA, they're not getting fixed. They're not getting better.

I'm sure that the Chairman and I would love to get together with you either at an appropriate time or whenever the Chairman decides that he'd like to ask you to come up, but——

Mr. QUINN (presiding). Mr. Kennedy?

Mr. KENNEDY. Yes?

Mr. QUINN. You may continue.

Mr. KENNEDY. Oh, I thought you were yelling at me. (Laughter.)

Mr. QUINN. I have a hammer if I need to deal with you.

Mr. KENNEDY. I've got some nails.

Anyway, what I want to come back to, though, is whether or not you feel right now that you have the necessary tools and information to be able to treat the illnesses that the veterans have.

Dr. BLAZER. I don't think that question could be answered "Yes" or "No." What I think we can say is that there are a number of symptoms that we do see. These may not fall into a clear, neat disease category, but these symptoms certainly can be treated. They're well-known to be treated.

There are many symptoms in medicine that are treated when we actually do not know the diagnosis or the cause of that particular symptom. Chronic pain is a certain example of that.

Mr. KENNEDY. But is there follow-up doc—I mean, the fact is that we're getting also information that the veterans come in. they get seen. They get sent back out.

They get some sort of treatment, but there isn't a sort of sustained kind of registry and follow-up so that people actually have—and, you know, I just ran into General Blanck the other day.

He said: Oh, you should see. We've got this tremendous health care initiative that's set up over at NIH, where you can come in and we treat you for free and everything is terrific.

And I said: Well, how many veterans actually take part? And I think he said like 109 or something. I mean, it was like compared

to the sheer number of people that you have with these ailments, it's a minuscule amount.

So what I'm driving at here is that there seems to be kind of a disconnect between the studies that we're asking for, on the one hand, but the treatment and whether or not the treatment is actually providing the kind of help and assistance that a bunch of sick veterans are actually facing.

Dr. BLAZER. I think that's a second question. First off, I think the question you asked initially was: Can these symptoms and some of the symptom complexes be treated? The answer to that is yes.

The second question, which I think is behind your first question, is: Are they being treated adequately right now? I think that is not well-known, and I think that's exactly one of the things that another Institute of Medicine task force will be looking into. It does need to be looked at.

Mr. KENNEDY. You know, it's pathetic that all we do is we study the studies, for crying out loud. I mean, come on, guys.

Yes, Doc?

Mr. QUINN. Dr. Caplan?

Mr. CAPLAN. Let me just say that one area where I think the veterans have complaints that this Committee and Congress could really do a better job on is not so much treatment but disability.

Time and time again when our Presidential Advisory Committee met, we heard people saying that when they sought disability and compensation for it, they encountered roadblocks.

And I will simply say based on what I listened to when I heard that the presumption, the benefit of the doubt ought to be going to the veteran. And I do not think that is taking place with respect to claims for disability. I think that's an area where movement is possible.

Mr. KENNEDY. Isn't it possible given the three of your sort of pre-eminent positions on this issue for the three of you to get together and to just give a very direct series of recommendations to this Committee on exactly what steps need to be taken?

You don't need to add. You don't need more studies here, gang. You just don't. What you should do is tell us to stop with the studies. You should say, "Listen, 103 studies. We're going to spend"—I don't know how many. If we spent 50 million bucks already, we're going to spend another 50 million on the remaining studies.

We ought to say, "Look, here are the two or three things we really need to study. Here's what we need in order to follow up on making certain the veterans are getting appropriate health care. And here is what we need to be making sure that they're getting appropriate disability payments." I mean, it's not that complicated.

Dr. MATTISON. That I think is the scope of the study that I referred to in my discussion, which was to look specifically at exposures. This is an—

Mr. KENNEDY. When is your study due?

Dr. MATTISON. The study would look at exposure—

Mr. KENNEDY. When is your study due?

Dr. MATTISON. When is the study due? The first phase of the study would be due in the Spring of 2000.

Mr. KENNEDY. It's just pathetic, you know? It's ridiculous. Don't you hear what you're saying? What do you think these guys are going to do behind you?

Mr. CAPLAN. I'll take a whack at that and say I think I can boil it down to at least three simple injunctions. One is let's make sure that veterans get the benefit of the doubt with respect to disability claims.

Secondly, we do need to make sure that we have the kind of monitoring and health surveillance that we don't for these veterans because, Congressman, we may not have heard the last of the health complaints. We haven't heard about long-term effects. And we need that infrastructure set in.

And, third, as I tried to suggest when I was giving my testimony, it is very important that we have the health infrastructure for pre-deployment, physicals for troops, to take health assessments, to monitor what's going on, and to have the appropriate chemical and biological weapons detectors be in place. If we deploy tomorrow, right now, we may be sitting here 2 years from now having this discussion.

Mr. QUINN. Yes. Thank you, Dr. Caplan, Dr. Mattison, and Dr. Blazer. Unfortunately, we're going to have to break for a vote now.

Mr. FILNER. Are we going to keep them here?

Mr. QUINN. They're going to stay, but we have 10 minutes to get to a vote.

Mr. FILNER. I have one question when we come back.

Mr. QUINN. Absolutely. We'll recess and be back in about 15 to 20 minutes.

[Recess.]

Dr. COOKSEY (presiding). If everyone will be seated, we'll get started. Mr. Filner, did you have a question?

Mr. FILNER. Yes, Mr. Chairman. Thank you very much. I'll try to be brief.

We apologize for this delay. I think that was the last vote. So we'll try to have some degree of efficiency here.

I think all of us and probably you all, too, share the frustration that was voiced earlier by Mr. Kennedy. When we see first studies of first phases of studies to be in the year 2000, when we have people who are now very sick, some very, very sick,—I have literally hundreds of constituents in San Diego who have some degree of illness from this, maybe thousands—and when we know, as I think, we are already inoculating our troops for possible deployment in the Gulf again, to say that studies might be available in 2000 does not help any of the current situation.

It seems to me that if I were in charge either of the Legislative or the Executive Branch, I would be looking at this with a lot more emotion and intensity and money and energy, what Dr. Caplan, your committee's report called bold action.

Mr. Kennedy was impressed with the amount of money budgeted. I'm very unimpressed. I don't think we have anywhere near the resources needed, given the problem and given the speed at which we have to do this.

I'm sure you would like to do your study faster. If you had more resources, you would do that. So, rather than getting frustrated at

you, it's our job to give you the resources that you need to complete your task quickly.

I have seen evidence—and I don't know if you're the people to ask or maybe a later panel—where at least some percentage of the cases could have been caused by the inoculations that we gave or tested. And here we are giving other inoculations. I mean, if I were in the armed forces, I would be scared to death to have my government inoculate me with anything, believe me.

We don't know what caused it. We don't know what we're doing. And we're proceeding again. Is that a fair fear that we ought to have, given what's going on?

Mr. CAPLAN. Well, unlike my colleagues on this panel, I'm not here to do further studies or request money for further studies. I'm kind of here from the look-see that this Presidential Advisory Committee took.

But I will say this, Congressman Filner, with respect to the vaccination issue, you don't need a study to understand that where we let down the troops who were over there before is not telling them that they were getting something new or untested and then not following them to see whether they became sick once they came back.

Mr. FILNER. Has that admission been in any public document from DOD or DVA?

Mr. CAPLAN. It's in our report.

Mr. FILNER. Your report, but has the Government of the United States ever said that?

Mr. CAPLAN. Sluggishly and grudgingly is the way I—

Mr. FILNER. I mean, that would be an important statement to make—

Mr. CAPLAN. And I think—

Mr. FILNER (continuing). And deal with it if that's the case.

Mr. CAPLAN. I think it's important that we understand that were we to use new agents, investigational agents tomorrow morning through vaccination or for anti-chemical or anti-biological warfare, I'm not convinced that we're not facing the exact same lack of infrastructure to tell them and monitor them.

As one veteran of the Gulf told me—he said: Look, informed consent isn't the issue. If you tell me someone is going to shoot a big canister of poison gas at my head and you might have something that could help me fend it off, I'll give you my informed consent, and you can give me the vaccine. It's not a big issue. But to follow me and study me and make sure that then I didn't get sick as a result of that, that's what we—

Mr. FILNER. But isn't it true that we do not have even the most basic vaccination records? I mean, were they not kept? Are they kept classified?

Mr. CAPLAN. They were kept sloppily.

Mr. FILNER. Do we have them but they have not been made public?

Mr. CAPLAN. No. I don't think they're kept in good order. They were not kept in good order.

Mr. FILNER. I mean, that's a pretty damning thing, and I would hope—

Mr. CAPLAN. What I would say is this—

Mr. FILNER (continuing). That we are doing it different this time around.

Mr. CAPLAN. We deployed—

Mr. FILNER. I see Dr. Rostker shaking his head yes. That scares me to death that we didn't keep these kinds of records and are not even admitting it, as far as I can tell.

By the way, did your committee look at the experiences of other nations in this regard? Because this was a multilateral effort. Are other countries experiencing the same thing?

Mr. CAPLAN. There certainly are other countries who have had veterans who report Gulf War illness. Specifically what you're asking about, recordkeeping and disclosure and follow-up and so on, I think our deployment and our presence was of a dimension that just isn't comparable.

Mr. FILNER. Is it true—I have heard this, and I'll ask this. The French had about 25,000 troops in there. I am told that there is not one case of the illnesses reported among the French who were there. Is that true or not? Has anybody heard that?

Dr. BLAZER. I've not heard.

Mr. CAPLAN. I've heard that, but I also did have occasion to talk with a few veterans from France who served in the Gulf. And they told me that the system for reporting, the way information is collected is not the same.

Plus, many of those who went in the French forces are still on active service. And it's a bit more difficult to report these kinds of symptoms when you're still active, as opposed to when you're out.

Mr. FILNER. I'm sorry to say that that may be the case here, too.

The reason I asked is that I understand they had a protocol treatment before their troops were deployed, which is, in fact, not allowed among our own troops. And if that is the case—and, again, I would like to find out, and I'm warning the other panelists I'm going to ask this if the French had a protocol that prevented the illness and we are not allowing the use of that same protocol, that would seem to me rather a disservice to our troops.

Dr. COOKSEY. Mr. Snyder, any questions?

Dr. SNYDER. No.

Dr. COOKSEY. Dr. Caplan, Dr. Snyder and I are both physicians. Let me ask you. You have a Ph.D.? In what?

Mr. CAPLAN. In philosophy, bioethics.

Dr. COOKSEY. Philosophy. Okay.

Let me ask you a couple of questions. The GAO report, of course, caused a little controversy and seemed to contradict that report from previous exports that I assumed were trained in the scientific method, including the PAC, the President's Commission, and stated that "A substantial body of research suggests that low-level exposure to chemical warfare agents or chemically related compounds is associated with delayed or long-term health effects." What's your assessment of that statement and the strength of the underlying scientific evidence?

Mr. CAPLAN. I would take issue with that statement, and I think it's not on a question of medical or scientific knowledge. It is actually on a question of logic and evidence.

What I think the GAO did was to say that you can't rule out chemical causes, chemical weapons causes, for these symptoms, as

we tried to do in our report, saying that whatever was going on, all of the illnesses and all of the people who had them couldn't be explained by low-level chemical weapons exposure. And they said: Well, you can't be sure of that.

My response would be to say the evidence that's available, what is known about the pattern of disease does not support that as the single cause of all the different illness complaints that veterans have. And I think the GAO, while wanting to keep the door open, if you will, is not consistent with what the evidence says about a single cause, chemical or otherwise, for all of these illnesses.

Mr. FILNER. Would you yield for one second, Doctor?

Dr. COOKSEY. Sure.

Mr. FILNER. But why? I mean, I'm sorry to point out a logical flaw in a philosophy professor, but I have a Ph.D., too. So I guess I can do it.

I don't understand why you kept saying a single cause. Why should that be the assumption?

Mr. CAPLAN. It isn't. I didn't mean to—

Mr. FILNER. If we were looking for a single cause and find no evidence of a "single" cause we should not conclude there are not multiple causes.

Mr. CAPLAN. I would prefer to call that an extension of what I said, rather than a contradiction. Yes, you are absolutely right. In fact, what the GAO was hinting toward was a single cause type of approach.

What we were trying to say again and again in this report is that low-level chemicals may have played a role in combinations of that, may have played a role in genetic differences. Plus, that may have played a role. But to simply say, "Well, you can't rule out this single agent as causing everything," even with the evidence, does not square with the evidence.

Mr. FILNER. Okay. I'm sorry, Doctor.

Dr. COOKSEY. Good point.

The GAO report seemed to reply heavily on the work of Dr. Robert Haley. And Dr. Haley indicated that his studies suggested that there were some subtle neurological findings that he attributed possibly to chemicals and chemical exposures. Did you and your colleagues review his report, number one? What is Dr. Haley's background?

Mr. CAPLAN. Physician, very expert researcher. I believe he was at Texas.

Dr. COOKSEY. One of the medical schools?

Mr. CAPLAN. Yes.

Dr. COOKSEY. Okay. Thank you.

Mr. CAPLAN. And the article did appear in the Journal of the American Medical Association. So it was subjected to peer review and so forth. We looked at it.

If you asked me personally, my impression of what my fellow panelists and I thought about his work was that it was very interesting, very important, should be credible but just an early report of something that needed more investigation.

Dr. BLAZER. I might be able to add something regarding the deliberations of our committee on the CCEP. In fact, Dr. Haley's findings actually were published just days before our first report was

released. But we did go back subsequently and look very carefully at this report.

One thing in reviewing the large literature that was evident to us is that there is very, very little data at the present time regarding the long-term effects of low-level exposure to toxins. That data is not there.

Dr. Haley's study may give us a beginning piece of that puzzle, but it's a puzzle that's far from complete. That study certainly should be replicated.

One person on our committee actually found a number of methodological flaws in the study. I think it was a good study. I think there are flaws. And I think you cannot jump to conclusions regarding that study, but I think it does reflect how little we know about long-term effects from some of these toxins that people may be exposed to in the Gulf War.

Dr. COOKSEY. Mr. Gutierrez.

Mr. GUTIERREZ. Thank you, Mr. Chairman.

Dr. Caplan, I'd like to read you a recommendation from Page 23 of the PAC special report and ask you to comment. It says, quote, "The Committee envisions legislation that directs VA to contract with an organization with the appropriate scientific expertise for a periodic review for benefits and future research purposes of the available scientific evidence regarding associations between illnesses and Gulf War service. The object of such an analysis would be to determine statistical association between service in the Gulf, morbidity and mortality, while also considering whether a plausible biological mechanism exists, whether research results are capable of replication and of clinical significance, and whether the data withstand peer review." Based on the external evaluation, the Secretary of Veterans Affairs would make a presumption of Service connection for positive associations or published reasons for not doing so.

I think that it's extremely important for the committee to make sure that we understand both the intent and the rationale for this recommendation. Does this recommendation mean that the PAC believes that symptoms that have a greater prevalence in the veterans' population deployed in the Gulf than in the non-deployed veteran population can provide a scientific basis for Service connection? And if not, please explain to us.

Mr. CAPLAN. I think it does. And I think that what we were trying to indicate there in my view was to try and lower the barriers that people have to claiming disability, what I was talking about in some earlier comments of mine. And I think it may be up to Congress to work with these agencies to create a program that they're satisfied does, in fact, lower those barriers.

But it is what we were saying. In the face of uncertainty, give the veteran the benefit of the doubt. In the face of uncertainty, it is the veteran who I think should in the end be the object of our empathy and compassion and that that recommendation is specifically targeted right to that goal.

I think even the message that those manning the gates, doctors doing the disability benefits, yield in the face of, other things being equal, to the presumption of the veteran is still not a message that

has percolated from these chambers out through the medical system.

Mr. GUTIERREZ. Do you know if the Secretary of Veterans Affairs or Department of Veterans Affairs say they're going to publish such a report or a recommendation in response to this report?

Mr. CAPLAN. I believe there was a contract—

Dr. MATTISON. Can I comment on that?

Mr. GUTIERREZ. Sure.

Dr. MATTISON. The study that I described as the proposed study that would be followed by the Institute of Medicine is, I think, a direct reflection of the Department of Veterans Affairs' response to this particular recommendation.

So I believe at least one component, the periodic review and the establishment of firm, credible scientific linkage between exposures and disease, will be specifically explored in that study. So at least that one component of that recommendation has been followed.

Mr. GUTIERREZ. So maybe what we should be doing as a Committee is making sure when the Veterans Affairs Department comes, make sure that that presumption is being given now as we continue testing because we're going to test ourselves to death here—well, actually, the veterans to death here, quite figuratively speaking and literally speaking, if we don't start giving them some presumption of the illness because it always seems to me that it's such a contradiction.

So I'm happy to hear Dr. Caplan's words and members of the committee, those members of the panel testify because, if my memory serves me correctly, we had the President of the United States of America, President Bush, and every member of Congress and senator talking about the brave, the intelligent, and the worthy men and women of this Nation, our best and our finest that were going off to fight and defend our Nation. And then they came back.

I was sitting here. I was elected in 1992. So I came here. And one of my first hearings was the people from actually the Department of Defense coming here and saying: Well, we think there's some malingering going on here and some people looking for pensions. Those were certainly the allegations that were made, and that's the only conclusion you could arrive at. They said: Well, you know, these guys are making up some strange stuff here, these men and women.

So I just want to make sure that we record for history that this just never happens again, that they are the finest, they are carrying out their duty, they are brave, they are everything we say they are, during war and after war, when they come back here.

You can't go to a bunch of parades all over the country, take photo ops, put them in your campaign literature, and then sit here in this Congress and say, "Well, you know, I'm sorry, but there might have been a malingerer in that parade with me that I was celebrating that day."

So I'm really happy and excited to hear your explanation to this answer, Dr. Caplan, because I think we've come a long way. Unfortunately, it has taken us 5 years to get here. And I think we have to make sure that we have that presumption. I think all veterans should have that presumption.

It's kind of like saying—you know what it reminds me of, Mrs. Chenoweth? It reminds me of that—you ever buy something and then you call up an 800 number and they said everything was covered but that? I'm sure everybody in this audience has. Everything was covered but that.

That's the way I would feel if I were a veteran. Everything was covered but this. You know, everything is covered is everything is covered. We should keep our bond to our word.

Thank you very much.

Mrs. CHENOWETH (presiding). I thank the gentleman from Illinois.

Does the gentleman from California have anything to add?

Mr. FILNER. Just briefly. By the way, I would take your analogy, Mr. Gutierrez, and say the 800 number generally doesn't answer and that is the real frustration. (Laughter.)

Mr. Kennedy before you were here, Madam Chair, voiced a lot of frustration and was asking for some more direct help.

We're all in professions, whether we're professors or doctors or bureaucrats or Congress people, in which we talk in a certain language and a certain format. And the format of these hearings adds to that. We talk in an understated, subdued way.

I want some emotion. I want you to tell us, "I don't have enough money. I'm angry. I'm frustrated. I'm saddened."

When I see the people in my district who are sick, I'm angry, but I'm trying to get them help. And I'm getting frustrated. I want some emotion in all of this, as opposed to these bureaucratic kinds of things that we're all involved in.

I see Dr. Rostker sitting in the front row just waiting to get here. I think part of the reason he was chosen for this job is he brings some of that emotion. Unfortunately, I think he's using his great skills still to cover up what the reality is.

But we need some of that emotion in this and not just bland statements, "In the year 2000, we're going to do the first phase." I mean, we've got real people here who are dying. We're sending them off to war again, and we don't know what the hell happened.

I want some action, and I think that's what we all have to talk about and get the kind of intensity here that lay behind the Manhattan Project and that kind of commitment of a Nation toward saving these young men and women.

Thank you.

Mrs. CHENOWETH. I thank you, Mr. Filner. Very well-stated.

I want to thank this panel very much for their valuable time and information. And, again, you know that you can supplement the record for a short period of time. And I want to thank you on behalf of the committee for your excellent participation.

Mrs. CHENOWETH. And the Chair will recognize the second panel now. The second panel consists of: Dr. Kenneth W. Kizer, M.D., the VA's Under Secretary for Health; Dr. Bernard Rostker, Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses, who is accompanied by Mr. Gary Christopherson, Acting Principal Deputy Assistant Secretary for Health Affairs at Department of Defense; and Dr. Donna Heivilin, Director of Planning and Reporting of the National Security and International Affairs Division at the U.S. General Accounting Office, who is accompanied by Dr.

Kwai Chan, Director of Special Studies and Evaluation of the National Security and International Affairs Division at GAO.

Welcome to all of you. And I know that you are experienced in offering your testimony and that you know for the record your testimony should be given in 5 minutes. And then you will be asked a series of questions by the committee.

The Chair would like to recognize Dr. Kizer first for his testimony.

Dr. KIZER. Thank you, Madam Chairman.

STATEMENTS OF KENNETH W. KIZER, M.D., M.P.H., UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY: FRANCES MURPHY, M.D., M.P.H., DIRECTOR, ENVIRONMENTAL AGENTS SERVICE, CHIEF CONSULTANT, OCCUPATIONAL AND ENVIRONMENTAL HEALTH; JOHN F. FEUSSNER, M.D., CHIEF RESEARCH OFFICER, DEPARTMENT OF VETERANS AFFAIRS; BERNARD ROSTKER, Ph.D., SPECIAL ASSISTANT TO THE DEPUTY SECRETARY OF DEFENSE FOR GULF WAR ILLNESSES, DEPARTMENT OF DEFENSE; GARY CHRISTOPHERSON, ACTING PRINCIPAL DEPUTY ASSISTANT SECRETARY FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE; DONNA HEIVILIN, Ph.D., DIRECTOR OF PLANNING AND REPORTING, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY KWAI CHAN, DIRECTOR, SPECIAL STUDIES AND EVALUATION, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE

STATEMENT OF KENNETH KIZER

Dr. KIZER. Let me introduce to you, for the record, the two other individuals who accompany me today: Dr. Jack Feussner, the Chief of Research and Development for the Veterans Health Administration; and Dr. Fran Murphy, who is in charge of the Occupational and Environmental Strategic Health Care Group.

Mrs. CHENOWETH. Welcome, Doctors.

Dr. KIZER. I thank you for this opportunity to continue our discussion of the health problems of Gulf War veterans. I have previously provided the committee a formal statement. That statement provides a much more complete review of VHA's efforts to provide health services to Gulf War veterans and our research efforts to find answers to the very complex medical and scientific questions related to Gulf War service than this brief opening statement, some of those difficult questions were touched upon by the last panel.

Before mentioning a few specific things, I think it is useful to note the context in which VA's response to the problems experienced by Gulf War veterans has developed.

No two wars in American history have been alike. The geography where the conflicts have occurred, the military tactics and weapons used; the ambient political, social, and cultural climate in which they occurred; the prevailing health technology at the time; and many other factors have been significantly different for each war in our history. Just as the Vietnam War differed from World War II, which was different from World War I, the environment of the Gulf War was unique. And, while it may be pointing out the obvi-

ous, I think it is often overlooked that much of what we are dealing with in Gulf War veterans is a medical frontier.

There is no model or standard formula about how to best respond to post-war health effects in general or Gulf War effects in particular. There simply is no textbook or standard reference that you can go to to find out what the best practices are to deal with the problem.

Indeed, when you consider the various environmental, technological, psychological, and other factors that collectively impact the soldiers who have fought the wars, and the state of the medical science at that time, it should be obvious that when you combine these factors this with the countless ways in which the human body can respond to those various stimuli, I think it should be clear how complex it is to determine cause and effect and the most effective medical interventions.

Because of these things, from the beginning of its response to Gulf War veteran problems, VA has sought broad scientific and other input to help inform us about the best course of action. As we have gained knowledge and information, we have continued to consult the best scientists available to help focus our efforts. Various groups, including the GAO; the congressional committees, such as this; the Presidential Advisory Committee; veterans themselves; and focus groups and other forums have reviewed our strategy and course of action. Those groups have provided their opinions and advice, and we have welcomed their opinions. We have tried to incorporate many changes in what we do, both in our health care programs and our research strategy based on that input.

Now, let me review a few things. And I am cognizant of the clock, so I am going to abbreviate much of what I was going to say.

Regarding VA's health programs, to date, almost 65,000 Gulf War veterans have completed registry examinations. More than 2,500,000 million ambulatory care visits have been provided to over 220,000 Gulf War veterans. More than 22,000 Gulf War veterans have been hospitalized at VA medical facilities for service-connected and non-service connected conditions. And more than 83,000 of these veterans have been counseled at our vet centers.

As we have discussed before at other forums such as this, Gulf War veterans participating in the Registry examination program have commonly reported that they suffer from a diverse array of symptoms, including fatigue and skin rash, muscle and joint pains, headache, memory problems, shortness of breath, sleep disturbances, diarrhea and other gastrointestinal symptoms, and chest pain. And the list of symptoms goes on considerably.

The diagnoses of our registry participants do not cluster in one organ system or disease category but, instead, thus span a wide range of illnesses and diagnostic categories.

A large majority of the veterans who have these symptoms and illnesses have been diagnosed and successfully treated. However, depending on the specific medical nomenclature that is used, somewhere between 10 and 25 percent of the veterans from the Registry who have been examined have unexplained illnesses.

I think it is useful in the way of context to again note that this frequency of unexplained symptoms among Gulf War veterans ap-

pears to be about the same as in a general medical practice outside of the VA or outside of a military setting.

It is important to note, however, that the medical scientists who are looking at this are far from completing their studies of these unexplained conditions. There continues to be considerable uncertainty about the character, natural history and potential causes of these conditions. It is essential if we are going to find effective treatments that this research continue into the underlying causes and the natural history and other aspects of these various conditions.

In the way of treatment, I think it's worthwhile to note that we have initiated clinical demonstration projects for multidisciplinary clinical care for Gulf War veterans as well as markedly expanding our case management efforts.

Case management as a routine clinical strategy for Gulf War veterans has already been implemented at 20—I think it is over 20 now—VA medical centers as part of a major initiative underway throughout the department. Indeed, as one of the Fiscal Year 1998 performance measures for our network directors, this has been targeted. They are focused specifically on this.

Likewise, in the area of compensation and pension examinations—and I know that there is another panel that will specifically address some of these issues later—but let me just say that we have been working with VBA, particularly with regard to clarifying the terminology and the protocols and the manner in which these examinations, particularly examinations for individuals with undiagnosed illnesses, would be conducted. We have developed some clear guidelines, which are being disseminated to the field, to help improve this effort. We expect that this will be an iterative process, and these will probably need to be refined over time as well, as just about everything else in this regard.

We are continuing our effort to expand health care education for our clinicians and care-givers. We have discussed our efforts in this regard at other forums like this, particularly for the registry physicians and those in Gulf War program per se, but we think that all of our clinicians should have a basic understanding of this. One step in that regard is a recently completed continuing medical education program that will be mailed and sent to every VA physician.

As an aside, I would also note that we will make this available for non-VA personnel at cost, as well.

In the interest of time, I am not going to discuss research programs per se other than to note that there is, as was commented before, a large number of research projects these underway and that a number of significant studies that are underway have reached critical points and are producing information that will be helpful as we move forward.

I think in my statement we also discuss in more detail our responses to the Presidential Advisory Committee's special report. I would note that many of the recommendations of that report have been implemented and are underway.

And, to respond to a question that Mr. Gutierrez asked before, we have indeed effected the contract with the National Academy of Sciences. As far as that specific recommendation which he asked about, the part that VA can do is completed.

I suspect there may be further discussion as far as the GAO report's recommendation, but in a very few words I would note that while we recognize the legitimacy of the recommendations and the inherent obviousness of what is recommended, this is a good example of how well-intentioned advice may be exceedingly difficult to complete.

There was some discussion before about efforts that are already underway with the Institute of Medicine to try to define health outcomes in a manner in which this can be tracked. I would go back to what I said very early in these comments, in that this is an area that certainly would be characterized as being on the frontier of medical science.

Let me just close by saying that there are some very real scientific conundrums which need to be worked out with Gulf War veteran issues. We are working with the National Academy of Sciences and others in trying to do this.

I think that we have made substantial progress in both furthering the understanding of Gulf War health issues and providing care for persons having health problems related to their service in the Gulf War. But, as I have testified at prior hearings, and I will reiterate today, that while we believe that our programs have been well-designed based on the current best available information, we also know that they are neither uniformly delivered nor perfect.

We also recognize that some of our veterans have not always received the kind of reception or the care at our VA medical facilities that we strive for, but I think we certainly have improved this, and we will continue to further improve in the future.

We are working diligently to improve the consistency and the predictability of care provided everywhere in this enormous system known as the veterans' health care system.

With that, let me close. I will be happy to try to answer your questions or respond to your comments as we move forward.

[The prepared statement of Dr. Kizer appears on p. 100.]

Mrs. CHENOWETH. Thank you, Dr. Kizer, for that very interesting testimony.

The Chair recognizes Bernard Rostker.

Mr. ROSTKER. Thank you, Madam Chairman, for the opportunity to appear before the committee today. With your permission, I would like to submit my written testimony for the record and provide the committee with brief remarks.

Mrs. CHENOWETH. Without objection, so ordered.

STATEMENT OF BERNARD ROSTKER

Mr. ROSTKER. Madam Chairman, members of the committee, you asked for a discussion of the Presidential Advisory Committee's special report. As you may know, the intergovernmental response is in the final stages of coordination. However, let me briefly comment in those aspects which fall under my purview.

In most respects, we agree with the PAC's findings. We concur with the recommendation to improve chemical warfare detection. And, in fact, the President's budget has an extra billion dollars to be spent over 6 years for chemical agent detection and protective equipment.

We agree that an objective standard that needs to be applied to all investigations and we strongly agree that independent oversight would dispel concerns regarding bias.

We disagree with two recommendations. First, at this time, we do not believe a low-level chemical exposure doctrine is needed, although we are funding research on what that doctrine would be. And the department will be announcing within the next 30 days the full-scale development of a fourth generation of chemical detector, which will include for the first time the ability to detect low levels of chemical agents.

Secondly, we disagree that notification of all personnel within the 300-mile radius of Khamisiyah is needed. We have already notified those people whom we believe may have been exposed. And, as our research continues, we will make further adjustments to that notification.

Let me also recognize the PAC. The members provided an invaluable service to our veterans and the American public. We appreciate their many constructive and relevant recommendations.

You also asked for my comments on the second report that the Committee has highlighted, the Committee on Government Reform and Oversight Subcommittee on Human Resources.

In testimony and response to requests for information, I provided that committee with a great deal of material. Needless to say, we were surprised and disappointed that the report published this past November included little of the information we provided.

Let me be more specific. The DOD has published 13 case narratives and information papers which were virtually ignored by the report. And we have for the Committee's inspection the 13 case narratives and information papers.

Several of these case narratives deal directly with issues raised by the committee and charges made by witnesses called before the committee. Our narratives were built upon the testimony of scores of Gulf War veterans. By ignoring facts presented in the case narratives, I believe that the committee's report is misleading about what happened in the Gulf.

Finally, in regard to the General Accounting Office report, I have included a copy of my response for the record. Virtually all of the facts and conclusions presented in that report were duplicates of previous reviews.

If it had been published a year earlier, the report would have been more accurate. As written, however, it does not present timely or accurate portrayals of work being performed by the Department of Defense.

And we have provided for the members' review—and I would ask that it be put in the record—the annual report from my office which covers the activities that have occurred since the office was established in November of 1996.

Looking ahead, this next year we will continue to investigate specific events concerning chemical agents. Our main focus will be on environmental issues, however. We will complete separate reports on pesticides, depleted uranium, and oil well fires. We look forward to working with Congress and our oversight agencies and remain committed to our veterans.

I would like to add one additional thing. I thank Congressman Filner for recognizing my passion. Part of that passion has been a willingness to go out and meet with veterans in town hall meetings, including in San Diego.

And it was at the town hall meeting in San Diego that I met the Dudleys. They discussed with me their concerns and particularly their concern that the government had stifled some of its premier researchers from looking at or positively reacting to the work of the Nicholsons.

I immediately came back to Washington and had a meeting at Walter Reed. In fact, Mr. Christopherson joined me at that point—where we reviewed with the researcher that the Dudleys asked us to as well as the Walter Reed staff the work that had gone on.

And based upon our review, we found that the protocols that we were establishing with the Nicholsons were correct in design but not adequately resourced and that we ordered additional resources and priorities be placed upon that effort. And at the committee's request, we're prepared to provide a complete report on our current status with the Nicholsons.

We take the veterans' concerns very seriously, both those concerns that come to us through our 800 hotline number as well as those that we gain in face-to-face contacts with the veterans. And this particular case is one where the Dudleys made certain representations which were very serious, and we took them very seriously.

So I thank the Chair for allowing me to make these comments. [The prepared statement of Mr. Rostker, with attachments, appears on p. 114.]

Dr. COOKSEY (presiding). Mr. Rostker, what is your Ph.D. in?

Mr. ROSTKER. I'm an economist.

Dr. COOKSEY. Oh, that's good, statistics and economy.

Mr. ROSTKER. Statistics is one of the fields that I have a specialty in.

Dr. COOKSEY. Good. Thank you. Thank you very much.

Dr. Filner, another Ph.D.

Mr. FILNER. At least there's a 50 percent chance that that occurred; right?

Dr. COOKSEY. I'm sorry. I'm sorry. We have another witness first, two more. So, if you could—

Mr. FILNER. I'm sorry.

Dr. COOKSEY. Mr. Christopherson is next. Thank you.

STATEMENT OF GARY CHRISTOPHERSON

Mr. CHRISTOPHERSON. Mr. Chairman, let me be very brief. I know time is short for the committee.

A couple of quick things. One is that let us be very clear from the point of view of the medical side of life that our concern here has been and will continue to be even more so taking care of our beneficiaries, the troops that come back from the Gulf War. It is our point as well to do the best research we can to try and understand what's going on. This is not an easy problem, as has been indicated by the previous panel.

What is important also to understand is from out of the Gulf War experience, there is no doubt that mistakes were made. We learned

a lot from the Gulf War. Recordkeeping was not what it should have been. Tracking of vaccinations was not what it should have been. A lot of the monitoring and surveillance we did at that time was not what it should have been as well. Again, we learned a lot from it. We are paying some prices, in fact, for not having those things in place. A lot of those things are now being moved forward.

If you look at the current experience and what we're doing there, Bosnia is kind of the case there. Bosnia is a case of making significant progress, but we're still not all the way home yet.

Some classic cases there are if you look at, for example, surveillance. We are doing a tremendous amount of surveillance in the environment, other kinds of hazards or the troops that are there to make sure we understand what went on there and after the fact, if necessary, to be the case figuring out what happened there.

It is also true that we have those things in place so that if something does come up, we are in a position as well to treat to take care of there. If you look, for example, at the experience with Bosnia, it is one of the lowest disease non-battle injury rates we have ever had.

And, again, a lot of it is because a lot of public health is in place. A lot of lessons have been learned again out of the Gulf War. Records have gotten better. We have introduced automatod record systems in the Bosnia situation, again, not perfect but, again, a lot of progress over that there, a lot of lessons learned out of Bosnia.

The final thing I guess I would come back to is obviously the concern here we have, including taking care of the troops, taking care of our Gulf War veterans, which we are doing, is: What are we doing for the future?

A lot of things I think for the future come down to a number. One, it is clear that when there are real threats out there, we need to prepare to provide the right kinds of protective measures, preferably licensed, most acceptably that we can possibly do out there.

And, secondly, we need good recordkeeping. We need to know exactly who got what and what happened with that so, again, we can trace back; if something pops up again the next time, we are in position and ready to do so.

It is also very important that we have in place surveillance plans so we can see what's going on in the environment in future deployments again so that we again can know what happened after the fact.

Better record systems. We're to put into place new computerized patient record systems there, which will be deployed in future deployments, personal information carriers. There's a way to track information all the way to the front. All of those things are in place.

Better research. Again, a need to do more in those areas there. We're working very closely with Veterans Affairs to do that. That's all, again, very important to trying to do what we need to do.

A lot more collaboration. I think what you've seen, especially in the last several years, in the VA and HHS is a lot of collaboration because no one agency can essentially do this all by themselves. It's a collaborative kind of effort.

Again, our commitment is to take care of the troops. And we're trying to do our best to do that. We'll do more in the future, our best to understand what's going on and more research, more epide-

miological kind of work, all part of trying to make this better for our troops.

Dr. COOKSEY. Thank you, Mr. Christopherson.

Dr. Heivilin, if I could ask, what is your Ph.D. in?

Ms. HEIVILIN. I have a doctorate in public administration.

Dr. COOKSEY. Okay. Thank you. Proceed.

Ms. HEIVILIN. Thank you, Mr. Chairman, members of the committee.

STATEMENT OF DONNA HEIVILIN

Ms. HEIVILIN. I am pleased to be here today to discuss two reports that were put out last summer. In the first one, we reported on the government's clinical care and medical research programs relating to Gulf War illnesses. In the second, we assessed the medical surveillance of the military personnel in Bosnia.

Our reports covered four issues: the adequacy of the mechanisms used by DOD and VA to monitor the quality, appropriateness, and effectiveness of Gulf War veterans' care and to follow up on their clinical progress over time; two, the government's research strategy for studying Gulf War veterans' illnesses and the methodological problems posed in the studies; three, the consistency of key official conclusions with available data on the causes of Gulf War veterans illnesses; and, four, the extent to which the DOD's efforts in Bosnia were successful in overcoming the medical surveillance problems that were seen in the Gulf War.

I'd like to mention that we are currently working on several related studies requested by other congressional committees and will be happy to share the results of this work once it is completed.

In one, we are looking at the incidence of tumors among Gulf War veterans. In a second study, we're looking at the possible presence of antibodies for synthetic squalene in blood samples of Gulf War veterans. In the third study, we're looking at the processes, methods, and criteria used by the Persian Gulf Veteran's Coordinating Board, DOD, and VA to approve or disapprove research protocols. And in a fourth study, we're looking at the extent to which ongoing research is likely to provide information on what caused Gulf War veterans' illnesses.

In our report on the Gulf War veterans' illnesses, we noted that while DOD and VA had provided care to eligible Gulf War veterans, they had no system for following up on their health to determine the effectiveness of the care after initial treatment. Also, because of the methodological problems and incomplete medical records on the veterans, research has not come close to providing conclusive answers on the causes of the illnesses. Given the data needed versus what is available, which is primarily anecdotal, we believe it will be very difficult, if not impossible, to determine the causes of the illnesses.

And, finally, the support for some official conclusions regarding stress, leishmaniasis, and exposure to chemical agents was weak or subject to other interpretations.

Regarding our report on the medical surveillance of Servicemen deployed to Bosnia, although we found that DOD had improved its capability to monitor and assess the effects of deployments on the Servicemen's health since the Gulf War, certain problems still

remained. One, the database containing deployment information was inaccurate. Not all the troops received post-deployment medical assessments. Many of the medical records we reviewed were incomplete.

In the first report, the one on Gulf War illnesses, we recommended that the Secretary of Defense and Secretary of Veterans Affairs set up a plan for monitoring the clinical progress of Gulf War veterans to help promote effective treatment and better direct the research agenda. And we ask that they give greater priority to research on effective treatment for ill veterans and on low-level exposures to chemicals and their interactive effects and less priority to further epidemiological studies.

I think in the earlier panel, they said that we said that it was a single cause. We did not say that. We said that it was a possible, one of the possible causes, and that there should be research in this area. To back that up, we had looked at 16 different studies which supported the fact that low-level effects are possible causes for the symptoms which are similar to these which are being seen in the Gulf War veterans.

We also recommended that the Secretaries of Defense and Veterans Affairs refine the current approaches of the clinical and research programs for diagnosing posttraumatic stress disorder consistent with suggestions recently made by the Institute of Medicine. The Institute had noted the need for improved documentation of screening procedures and patient histories and the importance of ruling out alternative causes of impairment.

Since our report, the agencies involved have taken a number of actions related to our recommendations. In December of 1997, DOD and VA asked the Institute of Medicine to establish a committee to assess the appropriate methodology for monitoring the health outcomes and treatment for Gulf War veterans.

Recently the coordinating board informed us that it had initiated a joint program with DOD to conduct multi-center treatment trials for fibromyalgia and chronic fatigue syndrome in Gulf War veterans. It is anticipated that the protocol will begin in late 1998 or early 1999.

As of January of this year, 23 studies had been added to the research portfolio, including research on the toxicology of low-level exposures to neurotoxins such as pyridostigmine bromide, insecticides, and chemical warfare nerve agents, with an emphasis on interactions among them.

In our report on the deployment and medical records for Service members deployed to Bosnia, we recommended that the Secretary of Defense ensure that a DOD-wide policy be expeditiously implemented on medical surveillance using lessons learned from Bosnia and the Gulf War.

We also recommended they have procedures developed to ensure that medical surveillance policies are implemented and also that they have procedures developed for providing accurate and complete medical assessment information to the centralized database.

In response to our recommendation, DOD established a new policy and implementing guidance in August of 1997. And we are told that they have plans to emphasize this to the field commanders, to emphasize to them the importance of this system.

Mr. Chairman, that concludes my summary. I will be happy to answer any questions you may have and provide the full statement for the record.

[The prepared statement of Ms. Heivilin appears on p. 134.]

Dr. COOKSEY. Thank you, Dr. Heivilin.

Dr. Chan?

Mr. CHAN. It's Mister.

Dr. COOKSEY. And, just to be equal with everybody, what is your Ph.D. in?

Mr. CHAN. I don't have a Ph.D. I have a Master's degree in mathematics and statistics.

Dr. COOKSEY. Statistics. I had a tough time in statistics when I went through my M.B.A. program. I'm anxious to hear from you. Go ahead.

Mr. CHAN. I don't have a statement to make, sir. Thanks.

Dr. COOKSEY. Oh, you have no testimony?

Mr. CHAN. No.

Dr. COOKSEY. Okay. Dr. Filner?

Mr. FILNER. Dr. Cooksey? Doctor, doctor, doctor, doctor, doctor. Thank you.

I would ask unanimous consent, Mr. Chairman, that all members of the committee may submit additional statements and questions for the record.

Dr. COOKSEY. So ordered.

Mr. FILNER. Dr. Kizer, are there any treatments that had been suggested for this illness that are not allowed to be delivered at the VA hospitals? Are there any banned treatments?

Dr. KIZER. I do not know of any that are banned. The reason I am hesitating a little, is that I was trying to interpret what you mean by "banned"?

Mr. FILNER. I have talked to doctors within the VA system and have seen some written memos that suggest that no doctor can deliver the antibiotic treatment that was developed by the researchers that Dr. Rostker mentioned earlier, the Nicholsons, that they are forbidden from providing their treatment. Is that the case or not?

Dr. KIZER. Well, I do not know of any such memo. My colleagues to my right tell me that there is no such thing. But I recognize that in a system as large as this, there may be pieces of paper that we do not know about. So if you do have in your possession or know of such, I would like to have a copy.

Mr. FILNER. If we had testimony by doctors in the VA system that they were, in fact, given orders not to give that antibiotic treatment, would you be surprised by that?

Dr. KIZER. I would be surprised, but also I think you raise a real interesting question. And it is one that you spoke to earlier today in your comments, as did a number of other members of the committee. Some very impassioned statements were made that it is absolutely essential that troops, and I take by extension veterans, not be given vaccines or other medications that are not approved for those uses; i.e., approved by FDA for those uses. To get that approval, they need a scientific evidentiary base to support their use.

The issue that you raise is whether we should apply that same standard to treatments or not. Should we require that the treat-

ment that is given to our patients have some evidentiary base or justification in the medical literature that would be accepted, at least by a significant number of practitioners, or should we encourage any type of treatment? I raise this merely as—

Mr. FILNER. Well, certainly the initial inoculations and testing from the DOD did not live up to that standard, unfortunately. I understand what you're saying, but you're also justifying a whole infrastructure, I'll have to say, the words that you're using, "evidentiary" this and "supported by" that, et cetera.

If, for example, there was a built-in bias against certain kinds of treatment by the very doctors who are making decisions on this, by the very ones who are testing out certain standards, your very infrastructure would end up leading to a conclusion that they are not worthy of use.

That is, if the whole system is biased against a certain protocol or a certain kind of evidence—and we have seen that in this situation. We have seen it with Agent Orange. We have seen it again and again.

The Chairman didn't ask what field my Ph.D. is in. I happen to be an historian and philosopher of science. Science is merely what most people who are called scientists say is science. It has nothing to do absolutely with truth. I see at least Dr. Rostker is agreeing with me. It has to do with what people think is the truth at a given set of time.

And if everybody in VA thinks, who have all those M.D.'s and Ph.D.'s beside their name, that a certain treatment is wrong, their whole methodology will end up proving that. And so the VA will end up with a very credentialed and very trustworthy, in their own view, system which has ended up being so biased that it precludes certain treatments that are out of the given mainstream.

Dr. KIZER. I am not sure that I would agree with that. I understand what you are saying, and I think that is a statement about the practice of medicine in general, not VA in particular.

Mr. FILNER. Right.

Dr. KIZER. But I think that one of the points that has been made at a number of forums like this that if we are going to pursue things that are not accepted by the prevailing scientific view, that the appropriate way to do that is through some sort of investigative protocol so that we have some clear understanding of what the outcomes are.

Mr. FILNER. I agree if you could do that fast enough to deal with the people who are dying or potentially dying. That is, you've got to do something. And, as we know with certain cancers and other treatments, if people are terminal, they're willing to take anything that has seemed to work by anecdotal evidence. And we have documented many cases of those working. Your whole system is set up to preclude certain ways of dealing with this issue.

Dr. KIZER. Could I just finish what I was going to say? The direction that the Congress has given the VA—and we are a public agency that is governed by the Congress—is that our treatments and the modalities that we utilize have to meet certain standards.

As a matter of public policy, if the Congress should espouse that we should not be taking that approach, then I think it needs to say so.

Mr. FILNER. Do you know who Dr. Lo is in the Defense Department?

Dr. KIZER. I don't personally know him, but Dr. Murphy does.

Dr. MURPHY. Dr. Shi Lo is a researcher at the Armed Forces Institute of Pathology—

Mr. FILNER. Right. Is he in a position to decide yes or no on certain research protocols? I mean, would he have that influence within the bureaucracy to do that?

Dr. MURPHY. No, not to my knowledge.

Mr. CHRISTOPHERSON. No.

Dr. MURPHY. Mr. Christopherson may be able to answer that.

Mr. CHRISTOPHERSON. I think that's correct. I mean, again, all of the research that is done in either organization has to go underneath a certain amount of peer review, partly to protect the troops and the veterans that we're talking about there.

On the other hand, they're encouraged, obviously, to look for new and innovative ways to try and deal with very difficult issues, this being clearly one of those.

Mr. ROSTKER. Sir, if I might, Dr. Lo was, in fact, the doctor who was cited by the Dudleys, whom Mr. Christopherson and I spent a full day with. He educated us on it. We reviewed with him—

Mr. FILNER. I'm sorry. Dr. Lo did or—

Mr. ROSTKER. Dr. Lo. We presented to him the statements that had been presented to me about the protocols. He said they did not represent his view, that he was in full accordance with the progress we were making, the approach we were making to take several hundred random blood samples and submit them to a number of laboratories. He is a world-class researcher in the area of mycoplasma, and he has been fully on board.

To the best of my knowledge,—and I have asked him directly—what we are doing is in line with what his recommendations are.

Mr. FILNER. Yes, that's the problem.

Dr. COOKSEY, my time is up. I would—

Dr. COOKSEY. I will have some latitude. I'm not a tough—

Mr. FILNER. Thank you, Mr. Chairman.

By the way, Dr. Rostker, I appreciate your confronting directly in your testimony the issue of the Nicholsons. You said that if the committee requested, you would give a more full report on that. I would so request.

Mr. ROSTKER. Okay.

Mr. FILNER. When did that change or the new support for that research take place?

Mr. ROSTKER. We had the meeting last spring. And within I would guess a week of coming back from San Diego, Mr. Christopherson and I and members of our staff, our physicians went to Walter Reed, met with Dr. Lo, met with the physicians there, directed that any question of financial priority be put aside, and that this took the highest priority, and to push forward.

Mr. FILNER. So is he being funded at a—

Mr. ROSTKER. Yes.

Mr. FILNER (continuing). Level that he sees as sufficient? I don't know.

Mr. ROSTKER. Well, the agreed-upon task, with the involvement of the National Institutes of Health, was to test out his techniques for identifying the mycoplasma.

I would be happy to have Colonel Riddle provide you right now with an update on where we are.

Mr. FILNER. I'll get back to that in a second. What I heard in my initial round of questions was that we are all open to this, we're doing this, we're doing everything we can. It just is in conflict with all the anecdotes or many anecdotes that we hear across the country.

So we have to figure out why that is the case, why you feel—and I don't dispute that you're honest—that your systems are open and honest and subject to peer review and all of that when we all know from history and from experience that any bureaucracy—I don't care if it's big or small; I don't care if it's VA, Defense, or my own office—has built-in biases and turfs and jealousies that the upper people might not be aware of. And I think that's a possibility here, but that's something that we're not going to figure out today.

Let me just ask you, Dr. Rostker: It's fair to assume, I think, that this Nation has stores of chemical and biological weapons. I mean, we are yelling at Saddam Hussein, but it would be unlikely to assume that we would not have such weapons?

Mr. ROSTKER. We are a signator of the chemical treaty. And we have been in the process for years of destroying those weapons.

Mr. FILNER. But obviously we have research into those weapons. We have tested those weapons, I suspect. We have tested antidotes to those weapons.

Mr. ROSTKER. Yes, sir.

Mr. FILNER. Would you find it unlikely or impossible that that very production, development, testing of weaponry and its antidotes could have caused some of this illness? I mean, is that a possibility that you would exclude?

Mr. ROSTKER. We have looked very hard. It's really been the major function of my office compared to our colleagues, whom we have worked with consistently, to understand what happened in the Gulf.

And we are all aware of the events at Khamisiyah. We have spent a great deal of effort.

Mr. FILNER. I asked you about our own. Friendly fire is what I'm talking about.

Mr. ROSTKER. To the best of my knowledge, we had no chemical weapons in the Gulf.

Mr. FILNER. I'm not talking about the Gulf. You're purposely narrowing my question. I asked: Is it possible that any of our troops could have gotten what we call Persian Gulf illness from our own inoculations, from our own testing, from our own development of these kinds of weapons, in the Gulf or elsewhere?

Mr. ROSTKER. No, sir.

Mr. FILNER. You don't think that's a possibility?

Mr. ROSTKER. I have absolutely no facts before me that would lead me in any way to that conclusion.

Mr. FILNER. All right. In terms of possibilities here, is it possible that some percentage of what we call Gulf War illness is contagious?

Mr. ROSTKER. I'm not a physician, and there's no way I would be able to make—

Mr. FILNER. Would you exclude that, as a statistical expert, as a possibility?

Mr. ROSTKER. To the best of my knowledge, there was no biological agent that our troops were exposed to. Whether there were other things in the Gulf, I can't tell you, but we—

Mr. FILNER. Well, why do family members seem to be able to come down with this or pets seem to come down with it? How would you explain that?

Mr. ROSTKER. I have no explanation, sir.

Mr. FILNER. It seems to me that contagion is a possibility there. Dr. Kizer?

Dr. MURPHY. Yes. We've looked at this issue very carefully. It is a concern to us, especially since the Gulf War veterans brought the concern to VA shortly after leaving the Gulf, that they felt that their family members were suffering from similar symptoms.

We've looked. We've found no current rigorous scientific evidence that supports a contagious or an infectious illness being transmitted either to family members or to the general population.

Mr. FILNER. Let me just tell you—Dr. Cooksey, I'll end with this—the history of dealing with this issue, as the history with Agent Orange and some other incidents in this Nation, every time somebody made a suggestion such as I had just done—7 years ago when someone said there is an illness, someone up there testified there is no evidence that there is such an illness.

When the evidence built up that there was some possibility of an illness, somebody like me asked: Is it possible they were exposed to chemical or biological weapons in the Gulf? And someone like you said: There is no possibility. There is no evidence that that occurred.

Then knowledge that somebody had about Khamisiyah and other such incidents occurred. I said: Well, how many people were exposed? Could it have been thousands? And someone like you said: There is no evidence that more than a few hundred people were exposed to this. Now we know 100,000.

At every stage in this thing—this is what gets me most angry. At every stage in our inquiry, the public's inquiry, people have said with the credentials that you have, with the positions that you have, that there is no evidence for what someone who has acquired that evidence from anecdotal means, from testimony, from conversations—you know, Congress people are not dumb.

And just because we're not scientists, although I happen to have a degree there, doesn't mean that what we come up with is not truth. Our antennae are out there with talking to people, with testimony, with anecdotes, with letters, with calls, with all of this evidence. We were the first ones who said there was an illness when everybody there said there wasn't any.

So I just have trouble with your saying there is absolutely no evidence and no possibility or nothing of this—

Dr. MURPHY. If I could continue for just a moment? Because I think it's important that you hear the rest of my statement. In the past, I've been on the front lines taking care of Gulf War veterans. I've seen their pain. I've talked with their family members. And I

can be as passionate about this as you are. I also have lots of anecdotes. But our job now is to look at all Gulf War veterans and how we can help them.

VA has taken the issue of contagiousness very seriously. DOD has begun to do the scientific work that will answer the specific questions that you have asked in a non-anecdotal way. And, in addition, VA is evaluating carefully the Gulf War veterans' illnesses and any potential association association with the illnesses of their families. We're beginning the physical examination phase of the national survey, which will allow us to address the scientific questions that you're asking.

Mr. FILNER. I'm going to tell you now that, again, I have been in the homes. I have seen the pets. I will tell you that it's a fact. Three years from now someone there is going to say, "Oh, yeah. Now we know that it's contagious."

Given the lack of knowledge that you all seem to have about this—you know, we're inoculating troops today against anthrax or something. I don't know what it is that we're inoculating troops against. Why are we doing something that nobody can tell me what it actually is, the impact it has, or what effect it's going to have there?

Mr. ROSTKER. Let me first say that you know that as many as 100,000 troops may have been exposed because the Department of Defense did the work that developed that——

Mr. FILNER. How many years after they knew it?

Mr. ROSTKER. We did the work to develop that——

Mr. FILNER. Because you couldn't cover it up, because somebody leaked it basically.

Mr. ROSTKER. We did the work. We have not been satisfied. We pushed back the frontiers of knowledge. And as we pushed back the frontiers of knowledge and we bring that information to you, we're accused of a coverup or: Why have you changed your mind?

We are not static. We see the same people that you see. We work in their behalf just as much as members of the Congress. And we are trying as hard as we can to push back the frontiers of knowledge, whether it be on the medical side or whether it be to uncover what happened in the Gulf.

And you know this information because they're contained in this stack of reports that examine this and are answering the questions that people are asking.

Mr. CHRISTOPHERSON. Let me also pick up on that because you opened up a line of avenue I think we need to talk about for a second here: the issue of vaccination. And we all have to be very careful. We walk a very fine line here between protecting people from, in quotes, in terms of "consequences" of something and protecting them from real threats in real wartime situations here.

When you're looking, for example—and the issue obviously that's in the back of your mind is the issue of anthrax vaccination. Let me be very clear. On anthrax vaccination, we have a fully licensed vaccine that's safe and effective against what can be a very real threat that kills people.

We would be irresponsible were we not to use these things. At the same time, which is also our responsibility, is the need to track what happens, to make sure that we understand that there are

other consequences there, even though it's fully licensed, safe, used for many years, and this kind of thing.

The commitment of the Department of Defense is that for those kinds of measures, which we do need to use because we have this Hobson's choice between, in quotes, "doing or not doing" there, we have to step forward and provide those things.

At the same time, the lessons learned from the Gulf War, which are applied now, is to better understand if something comes out of that that nobody expects. But we would be irresponsible not to protect our troops in those kinds of situations.

Mr. FILNER. And, finally—and I appreciate your patience, Dr. Cooksey. this conversation can go on for a long, long time. Several reports, the Shays Committee report, to some degree the PAC report, said: Look, basically all of this has to be put in the hands of an independent group.

I would go further: not contracted by the VA, not contracted by the DOD. Someone—I hate to say this because I don't like the independent counsel legislation—who has the authority to delve into both bureaucracies and come up with things that bureaucratic inertia or turf battles or cautiousness or whatever you want to call it is not able to come to grips with. And that's what I would recommend to the Congress of the United States.

Mr. ROSTKER. I would just point out that your colleagues in the Senate have a special investigative committee looking exactly at that. And we have had the pleasure of jointly going overseas. I had a number of trips overseas to the countries you were talking about and many more. And we invited members of congressional committees' staffers to join us, and we had members from the Senate investigative committee of the Veterans Committee. So we have done that.

And I would only add to the extensive GAO reviews that GAO is living with us. They're in the process of reviewing all of our work in great detail. And we offer that to anyone who wants to come in.

We believe oversight is an important part of the process. So does the administration. And that's why they're standing up a new oversight board, which will have full access to everything we're doing.

Mr. FILNER. I don't want oversight. I want insight.

Mr. CHRISTOPHERSON. Let me go back because I think what you need to remember, by the way—go back to the previous panel. The Institute of Medicine is not here on their own. They came here because we contracted with them to provide oversight, independent review, the best science minds in this country here to do exactly what you're asking to do.

We agree that independent oversight and the outside reviews is very critical not only in terms of trying to get the right answers but, going back to the early discussion on, about trust.

And we've got to try and get the best minds working with us to understand these things who can step back from where we are standing at a given moment in time and tell us what's best clinically, what's best in terms of research.

Mr. FILNER. Why don't you give them enough money to do it in 3 months, instead of 5 years, though?

Dr. COOKSEY. I have some questions of my own, but I think it's interesting to observe that we are all sitting here today because of

one man, one demagogue, one dictator, who is not elected. He got where he is at the end of a gun barrel. He is a coward. He hid during the Gulf War. He hides at night. He kills people with his own handgun but when he's surrounded by people.

And I understand Mr. Filner's frustration because as congressmen, we do have people that come to us and say, "I've got symptoms." As a physician, I think I get more of them than the average congressman. And it is frustrating.

A few questions. Of 700,000 vets that were in the Gulf War, how many have come forward with symptoms that have been categorized as Gulf War illness? Dr. Murphy, if I could ask you? You're an internist, Dr. Murphy?

Dr. MURPHY. I'm a neurologist, sir.

Dr. COOKSEY. A neurologist?

Dr. MURPHY. Yes.

Dr. COOKSEY. Great.

Dr. MURPHY. Approximately 100,000 veterans have come either to the DOD CCEP program or to the VA Registry program. We have approximately 12 to 15 percent over time who have come in with no symptoms. They're feeling well. They just want the examination. And they want to be able to talk to a physician about their concerns. Of those—

Dr. COOKSEY. Can I clarify that? You're saying about 12 percent of the 700,000 have no symptoms?

Dr. MURPHY. No. I'm sorry. Of the 66,000 that VA has examined, about 12 percent have come in with no symptoms.

Dr. COOKSEY. Okay. That's a significant number.

Dr. MURPHY. Yes. And I think it speaks to some of the confidence that the veterans, at least some of them, have in the VA system to provide answers.

Of the symptomatic veterans, we have not been able to find a diagnosis in anywhere from 10 to 25 percent depending on how you determine what an unexplained illness is. And we have used two different methods depending on whether it was our original registry program or the revised.

DOD has approximately the same number of individuals who have a category of conditions which, in the International Classification of Diseases, is called: Signs, Symptoms, and Ill-defined Conditions. These are not diagnoses so much as symptoms that have been described by the veterans.

So that's where we are with unexplained illnesses among the people that we have examined.

Dr. COOKSEY. Okay. Mr. Christopherson?

Mr. CHRISTOPHERSON. Yes, Mr. Chairman?

Dr. COOKSEY. What do you think, and just very briefly, what are the five lessons that you think we have learned or should have learned from this experience, the Gulf War illness and the symptoms of the war, the symptoms, the complaints?

Mr. CHRISTOPHERSON. That's a good question to be putting. One is clearly medical records. We've got to do a much better job of keeping track of records of what's going on health-wise there.

Second is clearly surveillance, knowing what's going on in the environment around the troops as they are deployed out there, and understanding that part of it as well.

Third is clearly education, the need to risk communication, other kinds of education of the troops, so they know better what they're getting into and are better abler to handle it when the time comes.

Fourth is clearly the institution very early on of a clinical evaluation and treatment program so that if something does appear in this thing, we can quickly figure out what it is, especially when it's fresh in people's minds, they understand what's going on. When you ask them what may have happened to them in the Gulf, there's a better chance of getting an accurate answer.

The final thing is the need for some clear research to be done on things we do not understand as well. Clearly in the area of chemical and biological, there's a lot of work that needs to be done there. There are certain other kinds of environmental hazards. Research still needs to be done as well.

But on a rough count, I'd say that's probably the five I would put forward as lessons learned and lessons being applied.

Dr. COOKSEY. Good. That's a good brief answer.

You know, one of our warfare installations was in Pine Bluff, Arkansas. Was that chemical or biological? I think it's closed now, but—

Mr. CHRISTOPHERSON. I'm not sure.

Dr. COOKSEY (continuing). One of them was there because I live not too far. I'm not an Arkansan. Don't label me with that. I'm from Louisiana. But there was one of them that's in Pine Bluff.

Mr. CHRISTOPHERSON. The consensus, by the way, seems to be chemical is what we believe.

Dr. COOKSEY. Chemical? Okay. I know it's been closed.

Let me ask you this: What do you think is the most serious deficiency that still is not addressed?

Mr. CHRISTOPHERSON. Serious deficiency? I probably have a few candidates, actually, for that, but I think very honestly the one that we are probably wrestling with the most—and it kind of goes back to your opening remarks about certain persons in certain other parts of the world—has to do probably with the chemical and biological area.

There's just a number of things we need to understand better, both in terms of preventive measures, protective measures for the troops there, better detectors. It sort of all glums around that issue of trying to do it. It's the one we spent the least time figuring out, but there's a lot of research now committed to trying to figure this out.

Dr. COOKSEY. Dr. Kizer, do you know: Have we had any exchange of research with some of our former enemies, like the Soviet Union?

Dr. KIZER. If I might just defer that for one second because I'd like to also respond to your former question if that's agreeable.

Dr. COOKSEY. Sure, sure.

Dr. KIZER. It occurs to me as one looking at a system that is taking care of people at the tail end, after all of this has happened, that one of the biggest problems we see in dealing with problems post-service, is: What was the extent of health or illness pre-service, and we need a more complete assessment of what the individual status was before?

And I know that efforts are underway towards this, but I just want to underscore that it would be critically important in the future to better know what people started off with when you end up trying to figure out what they have at that later time, and especially with regard to what the conditions may be due to.

Also, I would underscore a point that I have made at quite a number of other hearings in this regard, and that is the importance of a very concerted effort to look at the effects of chemical warfare agents and the fact that those problems are the same issues that are being wrestled with in other committees—e.g., in individuals who live near toxic waste dumps or Superfund sites and the questions of low-level chemical exposure from environmental contamination. The same is true from an occupational safety point of view. Whether they are farm workers in California or people who work in factories, they are the same generic issue in a number of forums.

And the one, of course, on the horizon is what happens if there should be a terrorist incident in this country that affects a small or large number of civilians. Are we going to have the information to address their concerns at that time?

I would again underscore the point that I have made on a number of prior occasions that if we are going to do this, if we are going to have those answers, it will take a very large and concerted effort with substantial funding needs.

To try to best respond to your question, I would ask if you would repeat it.

Dr. COOKSEY. Okay. My question is: Has our government been able to obtain any information from our former enemies or even allies that have done research on chemical warfare and biological warfare that maybe we could either have already exchanged information that's been done or could we do it in the future that would help answer some of these questions?

Dr. KIZER. Let me answer that in three ways or a three-part answer in brief. And others I think will probably also shed some light on it. One, I don't know a specific incident of exchange of information from former adversaries or at least potential adversaries. That may well be occurring that I'm unaware of.

Secondly, we are working with some other foreign governments on incidents and the evaluation of those; for example, a joint research project with the Japanese is looking at the Tokyo subway incident involving sarin and the effects of that.

And, third, I am aware from my pre-federal government life of some efforts to work with the former Soviet Union countries on issues having to do with nuclear materials.

Mr. ROSTKER. The answer is yes in all counts. My team has not been to Russia, but we have been to Prague, France, England, Kuwait, Saudi Arabia, Egypt, and Israel and have compared notes both on health effects to the indigenous population, on health effects among troops who were in the Persian Gulf, as well as basic research on chemical agents, pesticides, and pyridostigmine bromide, and a whole range of factors which may impact the central nervous system in ways that are of interest to this topic.

We have been again joined in that research by members of the Senate, staff from the Senate investigative committee.

Mr. FILNER. Can you comment on the French situation that I asked about earlier?

Mr. ROSTKER. Sure. We know of no protocol that the French used. I think the best comment was the senior French colonel on the general's staff, who said: We are most interested in what you are doing because, as far as we're concerned, there but for the grace of God go we.

They have no idea and no hypothesis of why their troops have not made claims except that their whole health bureaucracy and health insurance system is quite different and their general relationship of the population to the government and these kinds of claims are different.

We explored with them the theory that they did not take PB, which had been presented. It was widely understood. And they dispelled that, that elements of their force did, in fact, take PB. And, as one French colonel said: PB? I took it every day for a month, and no problem.

So we have explored with the French all aspects of their program, and they have no hypotheses as to why they may not have reporting veterans.

Mr. FEUSSNER. Dr. Cooksey?

Dr. COOKSEY. Yes, sure.

Mr. FEUSSNER. If I might follow on that, in March of last year, the VA sponsored in collaboration with the Society of Toxicology an international symposium in Cincinnati. During that meeting, the investigators from Japan, the investigators who were involved in the sarin subway episode, a number of European investigators, Israeli investigators attended the meeting.

In addition to that, this past summer, we sent the director of our environmental epidemiology center in Boston to Europe for a 6-month period of time. We have been collaborating with the British, the Danish. And on the research working group, there is official and consistent representation with a British person and a Canadian person.

Dr. COOKSEY. Good. That's very good. The British do some very good work. They've come up with some great medications and solutions to problems.

Believe it or not, the great plague of my youth was polio. Dr. Kizer fortunately, is young enough. He assured me yesterday he was in high school when I was in medical school. Of course, Dr. Salk and Dr. Sabin found the solution for that.

And the great plague of this period is AIDS. And the protease inhibitors are beginning to save lives. I know this comes as a shock to some of you in this room, but trial lawyers did not find the solutions and politicians did not find the solutions.

Ms. HEIVILIN, a quick question: Do you know the incidence of Gulf War illness among the women veterans of the Gulf War/Persian War?

Ms. HEIVILIN. No, I do not.

Dr. COOKSEY. I don't either. Does anybody know? Dr. Murphy?

Dr. MURPHY. We actually looked at that jointly with DOD, and we have published an article in Military Medicine I'd be happy to provide you a copy.

In fact, it looks like the rates of illness are very similar in men and women. We found very few differences in the types of diseases that are being reported.

There is a slightly higher rate of genitourinary problems. That was reported while women were stationed in the Gulf and also after they returned. And that isn't terribly surprising, since GU problem among women patients.

Dr. COOKSEY. Sure. Dr. Heivilin, I noticed that in some of your previous work, you had disagreed with some of the experts, some of the scientists, these Ph.D.'s who had done some work and basically thrown off their work. And these were some people from the Institute of Medicine and the President's Advisory Committee.

With respect to your comments regarding the risk factors, it seems that you seemed to throw theirs off, their ideas off, and that you seemed to know better. Who peer-reviewed your work?

Ms. HEIVILIN. We have a very extensive quality assurance program, an internal peer review. We also show our work to outside experts when we're doing that, when we're going through that process.

Dr. COOKSEY. Who are your peer reviewers?

Ms. HEIVILIN. Who are our peer reviewers?

Dr. COOKSEY. Yes. What's their background?

Ms. HEIVILIN. What are their backgrounds? We had professors in pharmacology, epidemiology, toxicology, and neurology who peer-reviewed our work.

Dr. COOKSEY. Okay. That's good. Thank you.

I have no further questions of this panel. And so we appreciate your coming, and we'll hear the next panel.

Dr. COOKSEY. We'll now start with Panel 3. Mr. Thompson, Under Secretary of Benefits, DAV.

Mr. THOMPSON. Thank you, Mr. Chairman.

STATEMENTS OF JOSEPH THOMPSON, UNDER SECRETARY FOR BENEFITS, DEPARTMENT OF VETERANS AFFAIRS; STEPHEN BACKHUS, DIRECTOR, VETERANS' AFFAIRS AND MILITARY HEALTH CARE ISSUES, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, U.S. GENERAL ACCOUNTING OFFICE; AND KRISTINE MOFFITT

STATEMENT OF JOSEPH THOMPSON

Mr. THOMPSON. I am pleased to provide a status report on the adjudication of Gulf War claims. I have submitted our full statement for the record, which I'd like to briefly summarize.

Dr. COOKSEY. Go ahead. Proceed.

Mr. THOMPSON. Regarding the redistribution of claims work from processing centers to regional offices, we were aware of concerns that the regional offices lack the expertise to handle these claims efficiently and accurately. Many members of Congress were anxious that we develop procedures to assist regional offices and monitor their progress. I'd like to summarize what we've done.

In May 1997, the Compensation and Pension Service conducted satellite broadcast training on Gulf War issues for our regional offices. This was followed by training sessions in June at the Cleveland Regional Office. Members of the Compensation and Pension

Service also participated in several Gulf War workshops during the month of June.

The service established a rapid response team consisting of the most knowledgeable headquarters people to provide immediate assistance to regional offices with Gulf War claims when they had questions. The service also conducted weekly Gulf War conference calls—this has been going on since June of 1997—where guidance is provided to regional offices who need to make a decision on these claims.

Every month each regional office is required to review a sample of Gulf War claims as part of its quality improvement program and to provide those reports to headquarters. These reviews provide the regional offices with a snapshot of the accuracy of what they're doing and identify areas for improvement.

The service has also conducted, in headquarters, a number of comprehensive reviews of Gulf War cases and will begin another one later this month. We use these cases to assess the current status of claims processing and give us some idea of what regional offices are doing.

Mr. Chairman, I am deeply committed to improving both the technical accuracy and the processing time for compensation and pension claims involving Gulf War. In pursuing this goal, I have established a special workgroup to study how we handle the workload issues in the regional offices today. I will use these findings to improve the accuracy of claims processing in general, and Gulf War claims in particular.

A major area of concern in Gulf War claims is the adequacy of medical exams. We have been working with VHA to produce guidelines for conducting the exams involving undiagnosed illnesses. These guidelines will ensure that all issues are fully addressed during the exam process. Implementation is imminent. To supplement this, a joint VBA-VHA satellite broadcast on Gulf War exams will take place early next month.

Since the redistribution of Gulf War claims, the regional offices have submitted weekly status reports on cases that have been adjudicated and readjudicated and or cases affected by the extension of the presumptive period for undiagnosed illnesses.

Last October, the Compensation and Pension Service asked the regional offices to make every effort to complete them by December 31. We did not do that. There are approximately 600 cases yet to be finalized. I have asked the service to provide me a monthly status report until all the cases are complete.

However, I believe the regional offices have done extremely well with these cases. They have worked very hard to get this done under very pressing workload conditions. And I commend them for their efforts.

An issue of continuing interest, of course, is how many Gulf War veterans receive compensation. Last summer, we discovered that some of the statistics we used to report on Gulf War business were not accurate. In response to these concerns, the Deputy Secretary asked the Office of Policy and Planning to coordinate all Gulf War information for the department. We have been working with that office to identify Gulf War veterans and ensure the information we provide is accurate. But I'll say at this point in time this is still

a work in progress and the data still has an awful lot of areas that are shaky at best.

In my full testimony, I have provided the most recent numbers available, fully recognizing that the limitations of our information systems may impact on their accuracy. However, let me assure the Committee that we are working constantly to refine and improve them.

Mr. Chairman, that concludes my statement. I will be happy to answer any questions.

[The prepared statement of Mr. Thompson appears on p. 162.]

Dr. COOKSEY. Thank you, Mr. Thompson.

Mr. Backhus.

STATEMENT OF STEPHEN BACKHUS

Mr. BACKHUS. Good afternoon, Mr. Chairman, Mr. Filner. I'm pleased to be here today.

My statement focuses on two issues: first, VA's efforts to improve claims processing for Gulf War undiagnosed illnesses; and, second, the effect of these efforts on VA's reexamination of claims that they previously denied.

As you may know, back in May of 1996, we reported on deficiencies with the claims processing for these undiagnosed illness. And, as a result, VA is now readjudicating those denied claims. Our work is based on a statistical sample of the 11,000 denials as well as discussions with VA and VSO officials.

In summary, our examination indicates that VA has, in fact, taken a number of efforts to improve the processing of the Gulf War claims. And its reexamination has, in fact, followed its new procedures. As a result, more veterans have been granted compensation.

Specifically, the VA procedures call for the examiners to inform veterans of the types of evidence they need that can be used in adjudicating their claim. They seek out both medical and nonmedical evidence, and they use all of the evidence obtained, including lay statements, in their decisions.

You heard Mr. Thompson speak of the decentralization to their 58 regional offices. The purpose of that was to provide better customer service and faster processing, to spread the workload from 4 offices to 58.

It's too early for me to sit here and to tell you how well that's worked, but preliminarily based on the folks we've talked to, the results are mixed. There are more examiners, but there are potentially more inconsistencies as well with the decisions.

Considerable training has taken place, though, in the form of workshops, conference calls, teams of experts that are available to help the people adjudicate the claims, et cetera. The adjudicators we spoke with felt comfortable in when it came time to process these claims.

Turning to VA's reexamination of the denied claims, as I mentioned, VA followed its procedures and has granted benefits to 8 percent of the veterans who had previously been denied for undiagnosed illnesses. They're now receiving compensation and/or medical care. Another 5 percent, we estimate, are receiving benefits for diagnosed conditions. These were veterans who had made a

claim under undiagnosed illness. When the case was reviewed, it was discovered they had a diagnosis and are now receiving benefits.

VA has provided veterans with information on the evidence they need to support their claims. A review of the files indicates they have, in fact, attempted to obtain all of the evidence that was necessary, and have considered all of the evidence in their decisions.

Two factors, though, still account for the majority of claimants being denied a second time. One-third of the claimants who reported an undiagnosed illness or thought it was undiagnosed wound up with a diagnosis. However, the diagnosis was either a noncompensable illness or had exceeded the presumptive period. Therefore, they were denied. And another third just lacked the evidence to sustain a claim.

That concludes my statement, Mr. Chairman. I will be glad to answer any questions you may have.

[The prepared statement of Mr. Backhus appears on p. 172.]

Dr. COOKSEY. Thank you, Mr. Backhus.

Ms. Moffitt?

Ms. MOFFITT. Yes?

Dr. COOKSEY. Do you have a statement?

Ms. MOFFITT. No, I don't. I'll be happy to answer any questions you have.

Dr. COOKSEY. Okay. Mr. Filner.

Mr. FILNER. Thank you, Mr. Chairman.

Just briefly, you mentioned, Mr. Thompson, data problems that you are trying to correct now, but I couldn't tell from either your written or your oral testimony what kind of problem, what numbers were wrong, what kinds of things were we given wrong or you received wrong information on.

Mr. THOMPSON. Well, it's inconsistent information. Probably the best example is the number of undiagnosed illnesses we're actually compensating. If you look in our payment system, the benefits delivery network, it would show up as around 1,500 or so claims, 15 to 16 hundred claims.

The system is very old. It was designed strictly to pay claims, carries very little additional information, and has a number of limitations, which I won't bore you with, but it doesn't necessarily capture all of the information.

Another figure, which is from our tracker system, which we maintain in the local regional offices manually, would show 2,400 claims. There's roughly an 800-claim difference in the number paid. That is, again, a manual system handled by scores of people. And the data also could be in error.

Mr. FILNER. The Chairman had asked in the previous panel some questions of statistics, how many veterans, what percentage for this or that. And we had very precise answers. Were they subject to that same data problem? I mean, could they be in error?

Mr. THOMPSON. I would say any data that's extracted from our current computer systems is subject to misinterpretation.

Mr. FILNER. Why didn't they say that when they gave us the answers?

Mr. THOMPSON. Well, I'm not sure about the particular information they provided, but I'll give you an example. These systems

were designed 30 to 40 years ago. And, again, they keep minimum information.

We limited the number of conditions that it will track to six. After six conditions, we start dropping the diagnostic codes. If the veteran has a zero percent rating for undiagnosed illness, that could well be dropped. You may have a record, but we would not know it.

These are longstanding problems that are related to our information technology infrastructure. And I don't want to make excuses for them, but I don't want to misrepresent the information.

Mr. FILNER. I appreciate that. I wish that when someone said that 12 percent, that is based on the data we have, in fact, and we are now in the process of checking out the accuracy of that data. I mean, somebody could say that.

That's the kind of thing that leads to the skepticism that I have been showing all day here. But I appreciate your openness about that, and I'll remember that when I ask similar questions in the future.

Thank you very much.

Dr. COOKSEY. Good news is that we are in the information age. Bad news is that the health profession, my profession, has not quite caught up. But there is technology out there.

So in the future when you go in to see your physician, you'll have a card. And on that card, you'll have a chip. And he or she—my associate is a woman. So I've learned to be politically correct. Anyway, they will have your full medical history. And you should be able to network this information. And it should transfer to military records, too.

A couple of questions. Mr. Thompson, could you give us your latest claims data?

Mr. THOMPSON. Yes, I can.

Dr. COOKSEY. How current is this?

Mr. THOMPSON. This morning.

Dr. COOKSEY. That's very good. Thank you.

Mr. THOMPSON. It has not been, let's say, scrubbed. So if I could put one codicil on that, it's subject to some change, but I think these are fairly accurate numbers.

There are three ways of looking at Gulf veterans we have: folks who are in the conflict, in the Gulf during the conflict; folks who were in the Gulf after the conflict; and then everyone who has been in the Gulf War era, which is from August 2, 1990 to the present.

Of the total number of veterans who have been in service from August 2, 1990, until the present, there are 3.3 million veterans. Approximately 10 percent, or 326,000, of those are receiving disability compensation.

Of the conflict, the folks who were actually in the Gulf during the war, 670,000 are veterans today. Approximately 77,000 of them are receiving benefits, so about 11 and a half percent.

Of the ones who were in the theater,—they served after the war was over—360,000 in number, about 5 percent of them, or 18,000, are receiving service-connected disability.

And of the era—these are the veterans who were not in the theater or in the conflict—2.2 million, about 10 percent, or 231,000 of them received compensation.

Dr. COOKSEY. I was in the Air Force during the Vietnam period, 1967, 1968, 1969, and a little bit afterwards. How does the incidence of claims for the Gulf War compare with my generation's war or the Korean War or World War II?

Mr. THOMPSON. We're just starting to compile those statistics, but I would say that the number of claims being filed by veterans is on the increase. The number of conditions filed in each claim as well is on the increase.

I saw some very preliminary data yesterday that would suggest that from an original compensation claim, just slightly less than five conditions are claimed. That is very preliminary information. We hope within the next month or two to be able to tickle some more information out of that.

But greater numbers file. And when they file, they have more issues at play.

Dr. COOKSEY. Let me ask you: Of those claims from the Gulf War, how many of them were claims for, say, combat injury, like a land mine, a bullet wound, the traditional wounds from weapons?

Mr. THOMPSON. I don't know what the number would be. Chris might have the number. It would be very low, though.

Ms. MOFFITT. We don't track what those issues come from. We don't track combat claims versus non-combat.

Dr. COOKSEY. Would DOD have that?

Ms. MOFFITT. I don't think they'd have a record of the claims filed with the Department of Veterans Affairs, no. I don't think so.

Mr. THOMPSON. We may be able to compare our records against DOD's. We could at least investigate that and get back to you.

Dr. COOKSEY. You know, in my congressional office, we really get a lot more claims from people that have non-combat-related injuries than we do people that had combat injuries.

I have treated patients with land mine injuries. This was after I was out of the military. It was when I was doing some mission work in East Africa, in Mozambique, at the end of that civil war. In the Air Force, we didn't see those injuries, but I had seen people who had injuries, eye injuries, from the Vietnam War.

And I feel like people who have an actual bullet wound, weapon type of injury should probably be paid twice or compensated twice or three times what they're being compensated. I at times get a little bit concerned that that's underdone.

Another quick question: What do you think you can do to improve your information technology, your information systems to avoid some of the problems we've gotten right now as to a person's previous medical history and wartime history and so forth and future history?

Mr. THOMPSON. Old Betsy has about seen the end of her service. It was initially built in the late 1950s and through much of the Vietnam era. It really can't be improved much beyond what it is doing today. It really needs to be replaced. We're in the process of attempting to do that.

Of course, as you well know, that's an extraordinary commitment for the agency. And, frankly, we have not been as successful as we could be.

Dr. COOKSEY. So these are trade computers or IBMs? They're surely not PCs?

Mr. THOMPSON. No. These are large mainframe batch systems. They're run primarily in Chicago and Austin. They have millions of lines of code in them, all COBOL programs. We need to get them in a modern database environment. That's part of the efforts that we're undertaking now, but that will not come quickly.

Dr. COOKSEY. Well, in closing, I feel that we are all very committed to the veterans. And I have just been in Congress a year now, a year and two or three weeks. I feel good about the things that were done in this time period for the veterans. As a veteran, I am very heavily committed to veterans. And, yet, if there's more that needs to be done, I want the veterans to know that this Committee is committed to them, as obvious by Mr. Filner's comments.

And I think that the whole Congress is committed to veterans. But we've got to base all of our decisions on facts as we find them from research data and find solutions that will be real solutions once we find the etiology of the illness.

I appreciate all of you coming today. It's been a long meeting, but we're always glad to hear from you. Thank you very much.

[Whereupon, at 4:13 p.m., the committee was adjourned.]

APPENDIX

Statement Chairman Bob Stump

Today is the Veterans' Affairs Committee's 15th hearing regarding Persian Gulf War veterans' illnesses.

Members should take pride in the words of American Legion National Commander Anthony Jordan last September, when he commended this Committee for convening "the most comprehensive and important hearings on Gulf War veterans since the end of the Gulf War."

Indeed, both our oversight and legislative record amply demonstrate this Committee's unwavering determination to help these veterans and resolve their questions.

Many Persian Gulf veterans, including some who are healthy, have had profound concerns over their well-being. Many have been understandably alarmed by the endless speculation about potential causes of a so-called mystery illness. Importantly, however, we have broad scientific consensus that there does not appear to be a single Gulf War illness, but many illnesses within this large population with no single cause. Some of these illnesses cannot be diagnosed; but their symptoms can usually be treated.

Over the years, Congress has generously supported scientific research and inquiry on these illnesses. Yet the findings and insights that have emerged have often been ignored when they don't fit preconceptions. We owe it to our veterans to listen when expert scientists and physicians who have studied these questions share their findings. But we must also appreciate science's limitations.

A great deal of research involving Persian Gulf veterans has been done, and more is underway. This Committee helped craft a law passed in 1992 to have the National Academy of Sciences (NAS) provide VA and DoD with recommendations on research into Persian Gulf veterans illnesses. NAS's recommendations and those of the Presidential Advisory Committee on Gulf War Veterans Illnesses have helped shape what is now an extensive research effort.

With hindsight, one can debate the merits of certain research initiatives or the delay in pursuing others. One can fault the missteps along the way.

We would do well, however, to remember the important message of The American Legion's national commander who stressed what is most important to our veterans – insuring that they are provided effective health care and timely adjudication of their compensation claims.

STATEMENT OF HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
HOUSE COMMITTEE ON VETERANS' AFFAIRS

OPENING STATEMENT
HEARING ON PERSIAN GULF WAR VETERANS ISSUES
FEBRUARY 5, 1998

Thank you, Mr. Chairman. I commend you for scheduling this hearing and I look forward to the testimony. As a result of this proceeding, our Committee should have a better understanding of the current health status of Persian Gulf veterans - the care they are now receiving and the care they still need to receive. We should also better understand the research being conducted to help answer vexing questions about the cause and treatment of persistent Gulf War veteran illnesses and VA's response to the claims for compensation filed by Persian Gulf War veterans.

When our Committee first examined the health care problems and concerns of Gulf War veterans, VA was literally denying care to Persian Gulf veterans. VA's response to claims for service-connected disability compensation, if possible, was worse.

While our Committee has not sought the spotlight, it has responded to legitimate concerns and problems of Persian Gulf veterans. We have enacted legislation and authorized VA health care for Persian Gulf veterans. Research is being conducted to seek answers to the many questions which remain concerning Persian Gulf War veterans' illnesses and effective treatment. A presumptive period was established for service-connected disability compensation claims for Persian Gulf War veterans with undiagnosed illnesses. This progress is important, but more - much more - needs to be done. I trust this Committee will stay the course and continue to enact needed legislation.

Undiagnosed illnesses, lack of effective treatment and compensation for service-connected disabilities are clearly among the most disturbing problems related to Gulf War service.

Why are these problems so difficult and frustrating? To begin with, there is a potentially bewildering array of exposures and manifestations of disease and disabilities which could be linked to establish service-connection. Specifically, VA references about 80 different hazards and 270 various disabilities, it presently deems "acceptable" as a basis for adjudicating service-connected disability compensation claims made by veterans who served in the Persian Gulf theater. Given the currently identified number of hazards and disabilities, without considering possible synergistic effects, it could well be years, and more likely decades if then, before science can provide definitive, indisputable explanations.

Former Secretary Jesse Brown recommended that the presumptive period for compensation for Gulf War veterans with undiagnosed illnesses be extended on March 7, 1997, President Clinton approved the recommendation and extended the presumptive period through December 31, 2000. In doing so, the President stated, "Gulf War veterans who fell ill as a result of service to their country should receive the compensation they earned, even if science cannot yet pinpoint the cause of their illnesses." Similarly, then Secretary Brown stated, "Gulf War veterans served honorably, and some are now suffering. It will take time for us to find all the answers, but until we do, we must provide them with the disability compensation they deserve." I cannot agree more strongly.

Recognizing that the termination date of the current presumptive period is approaching, I am now preparing legislation to provide a basis for granting claims for service-connected disability to those who served in the Persian Gulf theatre as well as those who were prepared to be deployed. While a number of details are now being finalized, I expect to introduce this measure in the very near future. Prior to introduction, I will invite all members of our Committee to become original cosponsors of this measure.

In general, this legislation will provide a scientific basis for Persian Gulf compensation, but it does not presume that answers exist today to all the questions veterans still have about why they are sick. We cannot demand or mandate that science provide definitive, unequivocal answers to cause and effect questions within six, eight, ten or twenty years. How

long has it taken to learn about the consequences of human exposure to ionizing radiation? It has taken decades and there are still important questions to be answered. In some cases, available science can make clear links to exposures. In other cases the evidence linking specific causes to specific conditions is more controversial and in still other cases there is little or no available science. In addition, some scientists have indicated that some agents may combine to create synergies that produce adverse health effects. To further complicate matters, existing data may not allow inferences about causality to be made.

As time passes, additional information may become available. For example, in 1997, six years after the war, the government publicly acknowledged nearly 100,000 U.S. ground troops may have been exposed to low level chemical warfare agents when an Iraqi munitions bunker was destroyed after the ground war had ended. What does this exposure mean? How long will it take to learn what it means?

Whereas, the science does not always exist to link specific exposures to specific symptoms or medical conditions, an independent scientific entity should identify those symptoms or conditions that are more prevalent in the population of veterans who served in or prepared to be deployed to the Persian Gulf theatre than in a matched group of their veteran peers who were neither deployed or prepared to be deployed. Those symptoms or medical conditions, found to be more prevalent in the Persian Gulf veteran population should be presumed "service-connected" This does not necessitate a definitive link between a specific agent and the symptoms or diagnosis, but does provide a firm grounding in science. No less important, it also will provide Gulf War veterans who are suffering today - years after their service, the benefit of the doubt - a benefit which they have earned.

Thank you, Mr. Chairman. I look forward to hearing from the witnesses before us today.

**Congress
of the
United States
House of Representatives**

JOHN F. TIERNEY
MASSACHUSETTS
SIXTH DISTRICT



February 2, 1998

The Honorable Lane Evans
Ranking Member
Committee on Veteran Affairs
Room 334
Cannon House Office Building
Washington, DC 20515-6335

Dear ~~Mr.~~ ^{Carl} Evans:

Ms. Venus Hammack is a Desert Storm veteran and constituent who suffers from a "Gulf War Illness." She has requested that the attached statements be included in the official hearing that the Committee will hold on Feb. 5, 1998. Thank you for your consideration of this matter

Sincerely,


John F. Tierney
Member of Congress

JFT/hh

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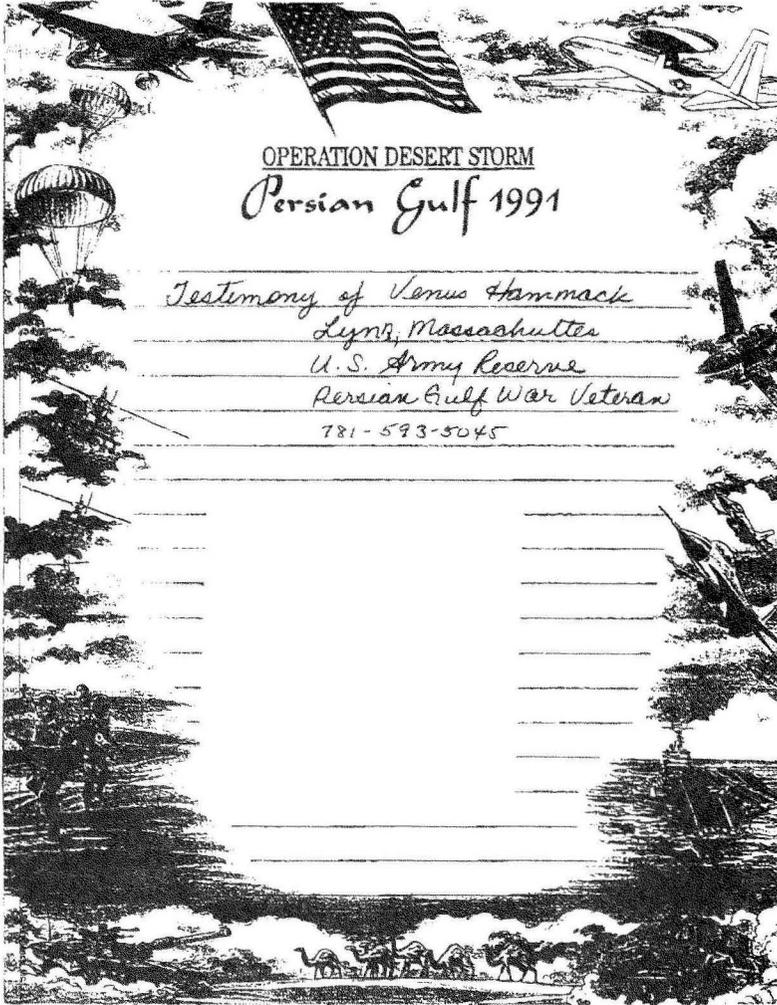
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To: Harry R. Hoglander From: Venus-val Hammack
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Message:

1. I and members of the Persian Gulf War Era Veterans appreciated Representative Tierney hard work and support of issues that effects us. gain we thank you.
2. We ask that you add my attached remarks as testimony at the House Committee on Veterans Affairs Meeting on Gulf War Illness scheduled currently for Feb,98. 10 AM, 334 Cannon Bldg.
 - *See attachment 1, titled Move Gulf Illness Outside of Pentagon
 - *See attachment 2, titled How good Gulf Clinic to sick Veterans ?

55:\letters\tierney.up

Persian Gulf Era Veterans INC

MOVE GULF ILLNESS STUDIES OUTSIDE OF PENTAGON

105th Congress, 1st Session House Report 105-388
**GULF WAR VETERANS' ILLNESSES: VA, DOD CONTINUE TO RESIST STRONG
 EVIDENCE LINKING TOXIC CAUSES TO CHRONIC HEALTH EFFECTS**

SECOND REPORT November 7, 1997

"We find those efforts hobbled by institutional inertia that mistakes motion for progress. We find those efforts plagued by arrogant incuriosity and a pervasive myopia that sees a lack of evidence as proof. As a result, we find current approaches to research, diagnosis and treatment unlikely to yield answers to veterans' life-or-death questions in the foreseeable, or even far distant, future."

1. Congress should enact a Gulf War Toxic Exposure Act.
2. The VA should contract with an independent scientific body composed of non-Government scientific experts like National Environmental Medicine Center, Maryland and the center for Disease Control and Prevention, Georgia
3. The VA Gulf War Registry and the DOD Comprehensive Clinical Evaluation Program should be re-evaluated by an independent scientific body.
4. The VA should refer all Phase II Registry examinations to Gulf War Referral Centers.
5. The VA should add toxicological and environmental medicine expertise to the staff resources dedicated to Gulf War illnesses.
6. VA and DOD clinicians should be encouraged to pursue, and be trained in, new treatment approaches to suspected neurotoxic exposure effects.
7. The diagnoses for somatoform disorders and Post Traumatic Stress Disorder [PTSD] should be refined to insure that physiological causes are not overlooked.

Compensation

8. Denials of Gulf War veterans' compensation claims attributable in any way to missing medical records should be reviewed and veterans given the benefit of any doubt regarding the presumptive role of toxic exposures in causing post-war illnesses and disability.
9. For purposes of compensation determinations, disabilities associated with presumed exposures should be deemed service-connected without any limitation as to time.
10. We GULF WAR VETERANS support all of other recommendation made in this COMMITTEE session.

How good is Gulf War Clinic to sick Gulf War Veteran?

The Gulf War Clinic at Boston VA Medical Center:

- is directed by an Internal Medicine Physician
- mission only to run exams for the Gulf Registry.
- patient conditions and treatments are not follow up by this clinic!

MODEL of Exposures and Health Consequences to Veterans

- multiple vaccines
 - endemic infections
 - depleted uranium
 - pesticides/organophosphates
 - biological warfare agents
 - chemical warfare agents
- ie. anthrax & botulinum toxin
 - ie. Leishmaniasis, parasitic
 - ie. DEEF

Synergistic Interaction
with any or all of the above

Where is the clinicians and specialists supplying treatment?

- There are no Neuroimaging consults given by the Gulf War Clinic
- There are no Neuroimmunology consults given by the Gulf War Clinic
- There are no Metabolic Neurology consults given by the Gulf War Clinic

The Gulf War Clinic needs doctors who see and treat veterans in:

- industrial hygiene
- environmental medicine
- behavioral toxicology
- respiratory toxicology
- environmental toxicology

RESEARCH ALONE IS NOT ENOUGH

HELP VETS GET WELL

**OPENING STATEMENT OF
REP. CHRIS SMITH (R-NJ)**

HOUSE COMMITTEE ON VETERANS' AFFAIRS

**FULL COMMITTEE HEARING ON RESEARCH RELATING TO
PERSIAN GULF WAR VETERANS' ILLNESSES**

February 5, 1998

For more than six years, there have been questions about the health conditions of Persian Gulf War veterans. The Committee on Veterans' Affairs has been diligent in investigating these concerns. In fact, today marks the 15th time this Committee has heard testimony on this matter, and I expect that with the vigorous leadership of our Chairman, Bob Stump, it will not be the last.

This Committee has also been at the forefront in formulating legislation designed to assist Persian Gulf veterans. For example, through the work of this Committee, any Persian Gulf veteran – whether sick or not – can now go to a VA facility for an examination and counseling. Also, a veteran who exhibits any condition which may be associated with the veteran's service in the Gulf is now eligible for priority care through the VA. Last year, Veterans Benefits Act of 1997 – signed into law in November – created a \$5 million competitive grant program under which up to ten VA facilities would establish demonstration projects to test new approaches to treating, and improving the satisfaction of Persian Gulf veterans suffering from undiagnosed illnesses.

As Vice Chairman of the National Security Committee, Chairman Stump felt an obligation to attend the DoD budget hearing at which Secretary Cohen is testifying. Chairman Stump wanted this important hearing to go forward, however, and has asked that I open the proceedings.

About this time last year, the Committee held a hearing to examine the progress of Persian Gulf illness-related research. Today, we follow up on that issue by bringing in government officials, academicians, and scientists to provide us an update on what we hope is significant progress over the past year.

Persian Gulf veterans' illnesses have raised difficult scientific questions. It is vital, accordingly, that we gain the benefit of the insight of scientific and other experts who have studied these questions.

We realize that many important research studies are still underway and that our state of knowledge remains incomplete; however, real and accurate answers do not come overnight.

Residents from across my district answered the call and served in the Persian Gulf. Through my continued contacts with them, I know first hand that many still suffer from undiagnosed, service-connected illnesses. For instance, Mark Panzara, who my office has worked with closely, still has undefined, non-compensated medical problems with his kidneys, lungs, and liver. He still awaits answers to his grave concerns over depleted uranium exposure. I ask the witnesses on the panels here today to address for my constituent, and the many others like him, what the government has learned in the past six years -- and especially the past year -- with respect to exposure to uranium.

Along with Mark Panzara, thousands of veterans are still suffering from illnesses that in many cases have no name or diagnosis. These veterans deserve to know that their government is doing its best to help them, and I hope that this hearing serves to underscore that this Committee will continue to provide aggressive oversight -- and initiate appropriate legislation -- relating to this serious matter.

I thank our witnesses for their testimony, and particularly want to thank those of you from the academic community, who have given generously of your time as members of expert panels to help answer the pressing questions that have brought us here today.

In deference to our witnesses, some of whom have tight travel schedules, I would like to avoid interrupting this hearing to the extent possible, and would ask members' indulgence in the event there are votes this afternoon. [For the same reason, I ask that members refrain from making opening statements.] Without objection, any opening statements will be made a part of the record. Before calling our first panel, however, I do want to call on our ranking member for any opening remarks he may wish to make.

Statement by Rep. Luis V. Gutierrez
Committee on Veterans' Affairs
U.S. House Of Representatives
February 5, 1998

Thank you Mr. Chairman.

Your commitment to ensuring that this committee continues to honor its responsibilities to Gulf War veterans is commendable.

I entered Congress in 1993. Since my tenure began on this committee that year, we have been listening to and addressing the concerns of Gulf War veterans.

It has been five years.

In this time, we have conducted an average of two hearings on this issue per year. We have heard from the Defense Department, the VA, even the CIA, and of course the President's Advisory Committee.

Nor are we alone in this institution in pursuing a resolution to what can only be called a crisis of governmental inertia.

Five years. Lots of studies, lots of paper, lots of questions.

We have passed legislation to authorize the VA to provide compensation and priority medical care to the men and women who served in Desert Storm.

We have expanded the qualification period for these benefits from two to ten years.

These are very positive steps. These are signs of progress.

But it has been five years and we are still left without an adequate ability and procedure to research these illnesses and provide presumptive compensation and quality care to all the veterans who came back from the Gulf sicker than when they left to defend our nation.

For too many veterans the Gulf War still has not ended.

We must respond now.

A little more than a year ago I challenged the members of this committee to seek a comprehensive approach to the treatment and compensation of the victims of Persian Gulf War Syndrome.

I asked my colleagues to pass legislation that would give the benefit of doubt to our veterans based on statistical evidence suggesting a link between environmental risk factors and the illnesses suffered by these brave men and women.

The statistical evidence is mounting, the clock is ticking and our veterans remain in need.

I challenge this committee again to achieve this goal.

We should authorize and fund a program that will guarantee the presumption of service connection for all Gulf War veterans for injuries and ailments related to chronic neurological and immunological diseases.

We should fund an independent study into the causes and consequences of the multiple possible causes of these illnesses.

We should ensure that epidemiological studies that fully consider the statistical connections between service in the Gulf and these illnesses are used to guide our policy.

The VA has contracted with the Institute of Medicine to conduct epidemiological research. But this research must be used to expand our care and compensation for veterans and not solely the knowledge of their suffering.

These are the next steps we should take.

We must end the waiting and rebuild trust.

I believe one of the most important recommendations issued by the Presidential Advisory Committee in their supplemental report regarded trust.

Trust.

The people of this nation simply do not trust that our government is doing all we can to inform and assist the veterans of Desert Shield and Desert Storm.

Without the trust of the American people we cannot resolve this crisis.

We must regain the confidence of our veterans and all Americans. Only dramatic wholesale change of our response to Gulf War syndrome will achieve this goal.

The Presidential Advisory Committee finds fault with the manner in which the Pentagon conducted their investigations of the Gulf War.

They have joined others in calling for these investigations to be taken out of the Pentagon's hands.

If this is what is required to move this issue forward and regain the trust of the veterans of America than let us not hesitate to move in this direction and do so quickly.

I am hopeful that this will finally be a year of action.

Thank you Mr. Chairman.

Statement of Rep. Corrine Brown
Full Committee Hearing/Persian Gulf Veterans Illnesses
2/5/98

Mr. Chairman I wish we could say that we have made some progress in treating the illnesses affecting many Gulf War Veterans, but I cannot. Just a few evenings ago, I heard yet another story of a Veteran, who just a few years ago, was in marathon shape, and who now has a body that's failing him in virtually all functions.

I am glad that last year we were able to increase funding for research into Gulf War Veterans illnesses, but I also want to hear about the treatment. I am anxious

to hear from our invited guests, how the research will help the veterans, especially with becoming healthy enough to conduct normal every day lives.

I also would like to find out about how coordinated our Federal efforts are in the research. I know that VA and DOD have several research initiatives, and I would like to get a sense that this is a coordinated research approach.

One very important issue also of concern is how the VA is doing in processing and granting claims for Gulf War illness. I know that this was a very important

priority of former Secretary Jesse Brown, and I would look forward to GAO's data about how these claims are coming along.

I know that this is a complex issue, and I know that the this Congress and this Administration have listened to the veterans when they say that they are really sick. I believe they are really sick, and I will continue to charge VA and DOD with caring for them adequately.

REMARKS BY CONGRESSMAN FRANK MASCARA
HEARING ON PERSIAN GULF VETERANS' ILLNESSES
FEBRUARY 5, 1998

MR. CHAIRMAN, THANK YOU FOR GRANTING ME
PERMISSION TO INSERT MY REMARKS IN THE
RECORD.

I REGRET I AM UNABLE TO ATTEND THIS
IMPORTANT HEARING IN PERSON. SADLY, MY
BROTHER AUGUST DIED YESTERDAY MORNING AND I
MUST TEND TO FAMILY MATTERS.

AS MANY OF YOU KNOW, A NUMBER OF MY
CONSTITUENTS SERVED IN THE PERSIAN GULF
CONFLICT AND SUFFER FROM GULF WAR ILLNESSES.

ON SEVERAL OCCASIONS, I HAVE PERSONALLY
GONE TO BAT FOR THEM, WINNING TWO WOMEN
SOLDIERS SOME OF THE FIRST GULF WAR BENEFITS
AWARDED BY THE VA.

LIKE MY COLLEAGUES, I HAVE BEEN TERRIBLY DISTURBED BY THE LACK OF DOD CANDOR ABOUT THIS MATTER. WHILE SOME PROGRESS HAS BEEN MADE, I THINK BOTH VA AND DOD OFFICIALS STILL MUST DO A GREAT DEAL MORE TO ENSURE ADEQUATE, COMPETENT RESEARCH IS BEING CONDUCTED.

OUR GOAL MUST BE TO GET TO THE BOTTOM OF THESE ILLNESSES AND START OFFERING OUR VETERANS SOME SOUND TREATMENT AND HOPE FOR A HEALTHIER TOMORROW.

I HAD AN OPPORTUNITY TO LOOK OVER SOME OF THE TESTIMONY AND I THINK DOCTOR CAPLAN'S RECOMMENDATION THAT AN INDEPENDENT AGENCY BE CHARGED WITH COORDINATING AND OVERSEEING RESEARCH INTO GULF WAR ILLNESSES IS A SOUND ONE THAT SHOULD BE ADOPTED.

HE IS A WELL RESPECTED AND RENOWNED
MEDICAL ETHICIST CURRENTLY WORKING AT THE
UNIVERSITY OF PENNSYLVANIA AND FOR THE SAKE
OF OUR VETERANS I THINK WE OUGHT TO HEED HIS
CONCERNS ABOUT LAPSES IN DOD'S INVESTIGATION.

I MUST SAY I AM PLEASED WE ARE APPARENTLY
GOING TO BE CONDUCTING A SERIES OF FOLLOW-UP
HEARINGS THIS YEAR. IT IS OUR JOB TO KEEP ON TOP
OF THIS MATTER AND TO MAKE SURE OUR VETERANS
WHO SERVED SO ABLY IN THE GULF CONFLICT
RECEIVE THE HEALTH CARE BENEFITS AND
COMPENSATION THEY CERTAINLY HAVE EARNED.

FOR THE SAKE OF ALL THOSE YOUNG PEOPLE
FROM MY DISTRICT WHO SO WILLING HELPED OUR
COUNTRY IN ITS TIME OF NEED, LEAVING BEHIND
SMALL CHILDREN AND SPOUSES, WE MUST NOT

**BACK DOWN FROM OUR DEMAND THAT BOTH DOD
AND VA OFFICIALS TRULY PUT THEIR INTERESTS
AND NEEDS FIRST. I, FOR ONE, INTEND TO KEEP
FIGHTING TO SEE THAT IS THE CASE!**

**AGAIN, THANK YOU MR. CHAIRMAN FOR
LETTING ME SUBMIT MY REMARKS.**

--THE END--

**Statement of Representative Helen Chenoweth
Committee on Veterans Affairs
334 Cannon House Office Building
February 5, 1998**

Thank you Mr. Chairman. I would like to commend the committee for holding this hearing on this important topic.

I would like to thank the various members of the panels for their participation in this hearing and for their insight into this issue which is so important to our Persian Gulf veterans.

In light of the current situation in the Middle East and the continued involvement of American soldiers in Bosnia, it is more important than ever that our nation firm up its commitment to our men and women in uniform who make the sacrifices that guarantee freedom and democracy in places where it is threatened.

It is important that we continue to investigate the possible and resulting symptoms of the conditions that our soldiers were subject to in the Middle East. The issue of Gulf War Illness should not be swept aside or forgotten, especially when we consider that American troops could again be subjected to unfamiliar conditions in the future.

It is my hope that the VA, led by Dr. Kizer and Dr. Rostker, will continue to lead the way in determining the fairest

and most efficient ways for the VA health system to diagnose and treat veterans of the Persian Gulf. This includes the public availability of facts and a continual process of comment and input by the veterans themselves. I am disturbed by reports from my constituents that active duty personnel are not given the same opportunities as others to participate in the various *Town Hall Meetings* being held in various parts of the country.

I would like to commend Dr. Caplan and the Presidential Advisory Committee, Under Secretary Kizer and Dr. Rostker, for their efforts to ensure that our veterans receive proper treatment and are rewarded for the sacrifices that they have made. I hope, Mr. Chairman, that the Advisory Committee, the Department of Defense, and the VA will continue to work together to come up with fair and just solutions for the health care of our veterans. Additionally, I am confident that research and investigation will continue so that we will learn more about Gulf War Illnesses and other disorders which affect veterans.

Thank you Mr. Chairman, and thank you to the panelists, for your efforts on behalf of our Persian Gulf veterans. Please keep this committee informed as to how we can continue to provide quality care for our veterans.

Testimony of Arthur L. Caplan

Trustee Professor and Director, Center for Bioethics

University of Pennsylvania

Philadelphia, PA

It is an honor to have the opportunity to offer testimony to this committee. My name is Arthur Caplan and I am a professor at the University of Pennsylvania in Philadelphia. My field is ethics, specifically ethical issues in medicine and the life sciences. But, more importantly for this committee, I was a member of the Presidential Advisory Committee on Gulf War Veterans' Illnesses which completed its work last October 31st.

I want to be clear that the testimony I am presenting, while based on my service on the Presidential Advisory Committee only represents my own views and opinions. I would not presume to speak for my fellow committee members.

I am very, very proud of the work that this committee did and of the devotion those who served with me on the committee showed in their efforts to examine why some veterans returned from their service in the Persian Gulf conflict with health problems, what might have caused those problems, what could be done to help these veterans, whether it was possible to determine a cause or causes for their illnesses and, what lessons the health and medical problems those who served in the Gulf can teach

about future conflicts and deployments in an age of technological warfare fought in distant battlefields.

I would like to offer my opinions to you about a number of issues your committee must address. What needs to be done to find answers to questions about Gulf War Illness, what needs to be done to attend to the health problems of veterans from the Gulf War and what lessons must be learned and zealously applied to future possible deployments in the Gulf or other areas of the world where American military personnel and support personnel might go.

Mr. Chairman I feel obligated to begin my testimony to you by reaffirming something that our committee noted in its interim report, final report, and when our tenure was extended in January of 1997 for another nine months, a special report. There should be no doubt that some veterans returned home from the Persian Gulf War ill. Some of these illnesses are clearly service-connected.

The questions of what exactly Gulf War Illness is has proven to be a most vexing one. No single set of symptoms, no classic presentation of complaints has emerged which encompasses all of the health problems that veterans told us about in an extensive period of public hearings and that have been amply documented in numerous scientific studies and assessments. This has led to repeated pronouncements over the years, to our committee and in the media that there is no such entity or disease as Gulf War Illness. But, the lack of a clearcut set of criteria that permits easy

diagnosis or a single clearcut disease shared by all with complaints and ailments should not obscure or detract from the fact that some veterans became sick and some remain sick as a consequence of service in the deployment and conflict that constituted the Persian Gulf War. Gulf War illness is a very real phenomena. No one on this committee should doubt that for a moment.

The obvious question which follows is why did some veterans become sick. Mr. Chairman I spent many long hours reviewing scientific studies and overviews provided to us by a most competent staff. I listened to hours and hours of testimony from dozens of experts. I have had the opportunity to question many of those who served in the war and who came home with various medical problems about what they thought had made them sick. And I have heard testimony from representatives of scientific and medical professional societies, veterans organizations, scholars, researchers and experts in our armed forces and department of veterans affairs. While many have advanced hypothesis about this or that agent as being the factor responsible for Persian Gulf veterans' illnesses including, pesticides, chemical warfare agents, biological warfare agents, vaccines and pills that some troops received to protect them against biological and chemical weapons, depleted uranium, oil fires, silica dust, fleas, cleaning agents, bad water, microbial infections and stress, my own view is that none of these factors individually was or could have been responsible for the scope or variety of illness complaints that veterans have reported.

The range of complaints and ailments, differences in the degree to which military personnel exposed to the same agents were effected by them, an absence of obvious patterns in the overall distribution of illness complaints makes it most unlikely that any single agent or cause was responsible. My own opinion is that Gulf War Illness may actually constitute more than one illness which may have more than one cause and may also include illnesses brought on by exposure to multiple factors in the Gulf War environment.

One factor on my list is worthy of special note--stress. Our committee called special attention to the role of stress as an important contributing factor to the problems that beset those who were in the Gulf. The identification of stress has led some to conclude that our committee felt that Gulf War Illness is all in the minds of veterans, that some veterans must be making up their symptoms or that only those too weak, or frail or unfit for service would succumb to the psychological impact of deployment in an alien environment and exposure to combat fought with terrible technological weapons. I want to state to this committee that I find these reactions to the citing of stress as a contributing factor to Gulf War Illness absurd and at times offensive.

Stress can effect health. This is a well documented fact from both studies of animals and studies of human beings who work or live in stressful environments. To pretend that stress is something that influences our health in peacetime but not in war is patently silly.

That said it is my opinion that stress is one of a number of factors that probably contributed to the illness symptoms and disabilities that affected and still afflict many veterans. It is not the sole cause of Gulf War Illness.

Nor is it even the primary contributing cause. It is simply one of a number of factors that probably was at work in bringing about ill health in some of those who served in the Persian Gulf War.

The obvious question that arises is what can be done then to determine answers to the questions of causation. Many of my colleagues on the Presidential Advisory Committee were and remain optimistic that focused, carefully conducted, peer reviewed research will lead us to answers. The Department of Veterans Affairs, the Department of Defense, the Department of Health and Human Services, the President and this Congress have all been urged to review all available data and literature on the health status of veterans and to pursue clinical and basic science investigations into the causes of Gulf War Illnesses. These are noble efforts. I am not sure they will give the answers that are sought.

The Gulf War was fought under unusual circumstances. Large numbers of reservists were called into action at a rapid pace. For the first time many women served at or near the front lines. The war itself was prosecuted with lightning speed. Technology was deployed during this war that thankfully kept American casualties to an absolute minimum while causing great devastation to our enemy. Environmental hazards were omnipresent on the battlefield--some endemic to the desert environment, some brought

there as a necessary component of modern technological warfare, some deliberately released into the environment in acts of ecological terrorism by our enemy and some through accident or the nature of warfare when chemical weapons were put into the environment through their inadvertent destruction and release both in combat and in the effort to disarm the enemy after the most active part of the conflict had ended.

American military personnel entered into this new form of warfare with relatively little information having been obtained about their health prior to deployment. Moreover, specific information on which individuals were exposed to particular hazards is almost impossible to obtain.

To think that it is possible to pinpoint the causes of illnesses, note the plurals in both cause and illness, is in my view optimistic. To believe that simple answers will be obtained whatever the effort given the passage of time is in my view exceedingly optimistic.

The definitive answer to the question of why did some veterans become sick may never be forthcoming. What should be forthcoming however is an unwavering commitment from this Congress and this administration to provide the health and disability benefits to all those who became sick when they came back from the Gulf. In the face of uncertainly doubt must be resolved in favor of the veteran.

Should the hunt for causes then be abandoned? Is the mystery of Gulf War Illness a harsh reality to which this Congress and the American people must simply resign themselves? No.

The Gulf War has a lesson to teach us. As the Presidential Advisory Committee noted in its final and special reports and as I will say to you even more firmly today, the single most important lesson of the Gulf War is that the only way to prevent another tragedy is to redouble our efforts into research to establish the health effects of the agents and factors that were in play in the Persian Gulf Theater. We must study the long-term health effects of exposure to pesticides and chemical warfare agents and oil fires. It is essential to understand more about the effect of stress and depleted uranium and pyridostigmine bromide pills on the human body.

Just as important it is vital that Congress insist that the armed services and the Department of Defense make a concerted effort to establish uniform standardized policies for predeployment in depth health assessments as well as demobilization policies. These did not exist at all in Desert Storm and Desert Shield. Despite the injunction that health monitoring and assessment receive a top priority from the military in an era of technological wars fought rapidly in alien environments in all of the reports issues by the Presidential Advisory Committee this has not happened. There still is insufficient attention to issues of adequate physicals, in depth health assessments for a sample of active and reserve troops, comprehensive and usable records, standardization of medical information, storage of tissue samples for assessment pre and post a conflict, adequate monitoring of vaccine use and other preventive measures for deployed

troops, environmental monitoring and sampling of the battlefield and deployment areas, or standardized follow up assessment for demobilized forces and personnel. The experience in Bosnia should alert anyone who cares that the steps needed to avoid the need to create another commission and to convene another set of hearings about yet another spate of mysterious illnesses post a conflict in the Persian Gulf or other combat theater have not been taken.

It is also the case that chemical warfare detection equipment deployed in the Gulf War did not work as expected. An thorough investigation of why this was so and what is being done to improve monitoring and surveillance in this crucial area is a crucial responsibility for this committee and Congress.

There is little glamour or glory in epidemiology. No one has ever been awarded a medal for coming up with a useful system for recording that health status of soldiers pre and post a conflict. But that is partly because no nation has faced the prospect of war using the kinds of weapons at our disposal deployed at a pace and with a fury unrivaled in human history. Modern warfare requires that every effort be made to assess the cost of conflict after the actual battle is fought. Until that lesson is learned, until Congress insists that the lesson be applied, the danger continues to exist the questions why some who serve in contemporary conflicts return sick, ill or disabled and what might be done to prevent their illnesses will remain unanswerable.

**Statement of Donald Mattison, M.D.
National Academy of Sciences
Institute of Medicine
to the
Committee on Veterans' Affairs
U.S. House of Representatives**

February 5, 1998

Mr. Chairman, members of the committee, my name is Donald Mattison. I am Dean of the Graduate School of Public Health of the University of Pittsburgh and Chair of the Institute of Medicine's Board on Health Promotion and Disease Prevention. I am accompanied today by Dr. Dan Blazer who is Dean of Medical Education at Duke University Medical Center and Chair of the IOM Committee on the Evaluation of the Comprehensive Clinical Evaluation Program for Persian Gulf veterans. We appreciate the opportunity to provide testimony to you regarding a new IOM study. This study will evaluate the available scientific and medical literature regarding an association between exposures during the Gulf War and potential health effects as experienced by Persian Gulf veterans. As requested, I will also briefly review the findings of the recent IOM report which examined the adequacy of the Department of Defense's (DoD) Comprehensive Clinical Evaluation Program (CCEP), and how those findings relate to similar programs administered by the Department of Veterans' Affairs (DVA). Dr. Kenneth Shine, President of the IOM, regrets that he is unable to attend this hearing, however, he will make himself, members of the Institute, and staff available to provide information and testimony to the committee as necessary.

The DVA has requested that IOM conduct a comprehensive review of the available scientific and medical literature regarding the association between exposures during the Persian Gulf War and adverse health effects experienced by Persian Gulf War Veterans. This study will be conducted by a committee of experts drawn from a broad range of public health, scientific, and medical fields. Based on its review and findings, the committee will also make recommendations for additional scientific studies to resolve areas of continued scientific uncertainty related to health consequences.

The IOM plans to conduct the study in three phases. During the first phase, the committee will develop criteria by which specific exposures and adverse health outcomes are to be chosen for study. The committee will review different types of research findings in the scientific and medical literature, for example, data from animal studies, occupational exposures, and epidemiologic studies. They will conduct a review of the literature regarding prototypic exposures in order to develop methods for analysis and synthesis of findings. Scientific evidence concerning association of exposures and health effects will be examined. The committee will consider the strength of the scientific evidence and the appropriateness of the methods used to identify associations; the exposure levels of the study populations in comparison to the Gulf War exposures; and whether there exists a plausible biological mechanism for a causal relationship between the exposure and the manifestation of a health effect.

During the second phase of the study, the remaining exposures will be subject to review and analysis. The final phase, to be conducted every two to three years, will update the literature reviews and the associations that have been identified between exposures and adverse health outcomes. It is assumed that the IOM will begin this project in the Spring of 1998 and complete the first phase by Spring of 2000.

I would like to focus now on the findings of the recently released IOM report evaluating the adequacy of the Comprehensive Clinical Evaluation Program (the CCEP) administered by the Department of Defense, and how the report findings relate to similar programs administered by the DVA. I have appended a complete set of recommendations of the committee to my testimony but would like to summarize some of the findings for you. The charge to the IOM committee conducting the evaluation was to examine the adequacy of the CCEP diagnostic protocol as it relates to ill-defined and difficult-to-diagnose conditions, and to stress and psychiatric disorders.

The committee chose, based upon an examination of the conditions described as difficult-to-diagnose or ill-defined, to refer to this spectrum of illnesses as medically unexplained symptom syndromes. Medically unexplained symptom syndromes are often associated with depression and anxiety, yet this does not imply that the syndromes are psychiatric disorders. In addition, stress is a major issue in the lives of patients within this spectrum of illness and is a component of the patient's condition that can not be ignored. With medically unexplained symptom syndromes, the potential for stress

proliferation is great among both the person deployed to the Persian Gulf and the family members.

Research has shown that stressors have been associated with major depression, substance abuse, and various physical health problems. Those deployed to the Gulf were exposed to a vast array of different stressors that carry with them their own potential health consequences. It was the conclusion of the committee that, "in cases where a diagnosis cannot be identified, treatment should be targeted to specific symptoms or syndromes (e.g., fatigue, pain, depression)." The committee also recommended that "providers acknowledge stressors as a legitimate but not necessarily the sole cause of physical symptoms and conditions" and that providers should be educated to the fact that "conditions related to stress are not necessarily psychiatric conditions."

There is another committee of the IOM that is currently completing its evaluation of the DVA Persian Gulf Registry and Uniform Case Assessment Protocol for Persian Gulf veterans. Dr. Blazer is a member of that committee whose charge is much broader than that of the CCEP committee because it includes an examination of the adequacy of (1) the protocol, (2) its implementation and administration, (3) outreach efforts to inform veterans of available services, and (4) education of providers. The final report is due to be released in March of this year. We would be pleased to share copies of the report with you as soon as it is available.

Thank you for this opportunity to address the committee. Dr. Blazer and I would be pleased to answer any questions you may have.

Donald R. Mattison, MD, MSc.
Biographical Sketch

Dr. Mattison is currently Dean of the Graduate School of Public Health at the University of Pittsburgh. His medical specialty is obstetrics/gynecology and he is particularly interested in reproductive and developmental toxicology; human risk assessment nuclear magnet resonance imaging and spectroscopy. He has numerous publications and has served on the editorial boards of the journals *Risk Analysis* (1988), *Developmental Pharmacology and Therapeutics* (1987), *Reproductive Toxicology* (1987), and *Pediatric Pharmacology* (1980-87).

Dr. Mattison now serves as Chair of the Board on Health Promotion and Disease Prevention of the Institute of Medicine. He was formerly a member of the Board on Environmental Studies and Toxicology, NAS/NRC (1986) and of the Semiconductor Industry Science Advisory Panel (1987). Dr. Mattison has received no federal grant or contract relative to the subject matter of the testimony during the current or previous two fiscal years.

Dan G. Blazer, II, M.D., Ph.D., M.P.H.
Biographical Sketch

Dr. Blazer is currently Dean of Medical Education and Professor of Psychiatry and Community and Family Medicine at Duke University Medical Center. His medical specialty is psychiatry and he holds a Ph.D. in epidemiology. His primary research interests are psychosocial epidemiology and geriatric psychology. Dr. Blazer has served on the editorial boards of numerous journals including *Contemporary Psychiatry* (1980-1988), *Behavior, Health and Aging* (1989-present), and *American Journal of Psychiatry* (1992). He has published extensively.

Dr. Blazer is Chair of the Institute of Medicine Committee on the Evaluation of the DoD Comprehensive Clinical Evaluation Program, serves on the IOM Committee on the Evaluation of the Persian Gulf Registry and Uniform Case Assessment Protocol, and is a member of the Board of the Medical Follow-up Agency of the IOM. Dr. Blazer has received no Federal grant or contract relative to the subject matter of the testimony during the current or previous two fiscal years.

**Institute of Medicine
Federal Contracts Related to Testimony Subject Matter**

The Institute of Medicine, Division of Health Promotion and Disease Prevention has held two federal contracts during the current and previous two fiscal years related to the subject of the testimony. The first was a contract from the Department of Defense for the purpose of evaluating the Comprehensive Clinical Evaluation Program for Persian Gulf veterans as regards the adequacy of its diagnostic evaluation for (1) difficult-to diagnose and ill-defined conditions, (2) stress and psychiatric disorders, and (3) health problems of veterans who may have been exposed to low levels of nerve agents. The total amount of the contract was \$475,000. The second contract was from the Department of Veterans Affairs for the purpose of evaluating the Persian Gulf Registry and Uniform Case Assessment Protocol. The total award was \$280,815.

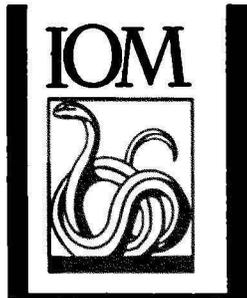
Adequacy of the Comprehensive Clinical Evaluation Program

A Focused Assessment

**Committee on the Evaluation of the Department of Defense
Comprehensive Clinical Evaluation Program**

**Division of Health Promotion and
Disease Prevention**

INSTITUTE OF MEDICINE



**NATIONAL ACADEMY PRESS
Washington, D.C. 1997**

Executive Summary

On August 2, 1990, Iraq invaded Kuwait. Within 5 days the United States had begun to deploy troops to the Persian Gulf in Operation Desert Shield. In January 1991, UN coalition forces began intense air attacks against the Iraqi forces (Operation Desert Storm), on February 24, a ground attack was launched and within 4 days, Iraqi resistance crumbled. Almost 700,000 US troops participated in the Persian Gulf War. Following the fighting, the number of US personnel began to decline rapidly.

Most troops returned home and resumed their normal activities. Within a relatively short time, a number of those who had been deployed to the Persian Gulf began to report health problems they believed to be connected to their deployment. These problems included the symptoms of fatigue, memory loss, severe headaches, muscle and joint pain, and rashes.

In 1992 the Department of Veterans Affairs (VA) developed a Persian Gulf Registry to assist in addressing questions about health concerns of Persian Gulf veterans. Exposures, particularly those associated with oil well fires, were included as part of the history taking. By 1994, with continuing concern about potential health consequences of service in the Persian Gulf, the Department of Defense (DoD) implemented a clinical evaluation program similar to the VA's and named it the Comprehensive Clinical Evaluation Program (CCEP).

Also in 1994, DoD asked the Institute of Medicine (IOM) to assemble a group of medical and public health experts to evaluate the adequacy of the CCEP. This committee concluded that although overall "the CCEP is a comprehensive effort to address the clinical needs of the thousands of active-duty personnel who served in the Gulf War," specific recommended changes in

the protocol would help to increase its diagnostic yield. (See Appendix D for a complete set of recommendations.)

Late in 1995, DoD asked the IOM to continue its evaluation of the CCEP with special attention to the adequacy of the protocol as it related to (1) difficult-to-diagnose individuals and those with ill-defined conditions; (2) the diagnosis and treatment of patients with stress and psychiatric conditions; and (3) assessment of the health problems of those who may have been exposed to low levels of nerve agents. It is important to note what was not included in the committee charge. It was *not* the committee's charge to determine whether or not there is such an entity (or entities) as "Persian Gulf Illness" nor was it this committee's charge to determine whether or not there are long-term health effects from low-level exposure to nerve agents. These questions are more properly the subject for extensive scientific research.

Given the urgency surrounding the last question—the health problems of individuals with possible exposure to low levels of nerve agents—the committee addressed this issue first and separately, releasing its report, *Adequacy of the Comprehensive Clinical Evaluation Program: Nerve Agents*, in April 1997. The committee concluded that although the CCEP continues to provide an appropriate screening approach to the diagnosis of disease, certain refinements would enhance its value. A complete set of recommendations is found in Appendix F.

To complete the remaining portions of its charge, the committee convened two workshops on the relevant topics, heard presentations, reviewed written material, and received comments from leading scientific and clinical experts, representatives of DoD and the VA, the Presidential Advisory Committee, the General Accounting Office, and representatives of veterans groups.

A great deal of time and effort has been expended evaluating DoD's Comprehensive Clinical Evaluation Program. It has been reviewed by the President's Advisory Committee, the General Accounting Office, the Office of Technology Assessment, the Institute of Medicine, and many other organizations. As more is learned, it becomes easier to focus on the kinds of questions the CCEP should be asking. As Dr. Penelope Keyl said in her workshop presentation on the development of good screening instruments, progress made over time will necessitate new generations of screening instruments. This does not imply that the first instrument developed is bad, but rather that time leads to new knowledge, which leads to the ability to improve the instrument.

Such is the case with the CCEP. Over time, the CCEP and other programs have generated information that has increased our understanding and led us to focus on areas of importance for those concerned about the health consequences of Persian Gulf deployment. This information has enabled us to take a closer look, to make a more thorough examination of the system, and to identify areas in which change will be of benefit. The committee believes that such change is

healthy, that it reflects growth, and that it should be a natural part of any system having as one of its goals the delivery of high-quality health care services.

Change also occurs with individuals. It may be that as time passes or new information is released, some of those who have already participated in the CCEP will develop new concerns or problems. The committee hopes that DoD will encourage these individuals to return to the CCEP for further evaluation and diagnosis if they so desire.

CONCLUSIONS AND RECOMMENDATIONS

Medically Unexplained Symptom Syndromes

The committee spent time deliberating on the precise meaning of “difficult to diagnose” or “ill defined” as a description of a category of conditions. Difficult to diagnose is generally used to describe a condition for which special expertise is required to arrive at a diagnosis, but some of the conditions under consideration do not require such expertise. Chronic fatigue syndrome (CFS), fibromyalgia, and multiple chemical sensitivity are symptom complexes that have a great deal of overlap in the symptoms present in each condition. They are symptom-based, without objective findings. However, they are actually fairly well defined by operational criteria, even if they are medically unexplained. Despite the fact that they are medically unexplained, they may cause significant impairment, and they are conditions that are better understood through time (i.e., adequate evaluation of these disorders requires a longitudinal perspective that includes knowledge of previous services and responses to treatment). The committee decided, therefore, to refer to this spectrum of illnesses as *medically unexplained symptom syndromes*. This spectrum of illnesses may include those which are etiologically unexplained, lack currently detectable pathophysiological changes, and/or cannot currently be diagnostically labeled.

Medically unexplained symptom syndromes are often associated with depression and anxiety, yet this does not imply that the syndromes are psychiatric disorders. There remains a debate about how to distinguish these syndromes from psychiatric diagnoses. However, since most of the recommended treatments for medically unexplained symptom syndromes overlap with the pharmacological and behavioral treatments for psychiatric diagnoses, the committee believes that it is important to identify and evaluate the symptoms associated with these conditions and then treat those symptoms.

- The committee recommends that when patients presenting with medically unexplained symptom syndromes are evaluated, the provider

must have access to the full and complete medical record, including previous use of services.

In the area of medically unexplained symptom syndromes, it is sometimes not possible to arrive at a definitive diagnosis. It may be possible, however, to treat the presenting complaints or symptoms.

- The committee recommends that in cases where a diagnosis cannot be identified, treatment should be targeted to specific symptoms or syndromes (e.g., fatigue, pain, depression).

- The committee recommends that the CCEP be encouraged to identify patients in this spectrum of illnesses early in the process of their disease. In addition, primary care providers should identify the patients' functional impairments so as to be able to suggest treatments that will assist in improving these disabilities.

Stress

Stress is a major issue in the lives of patients within this spectrum of illness. Stress need not be looked at so much as a causative agent, but rather as a part of the condition of the patient that cannot be ignored. With medically unexplained symptom syndromes, the potential for stress proliferation is great among both the person deployed to the Persian Gulf and the family members.

Research has shown that stressors have been associated with major depression, substance abuse, and various physical health problems. Those deployed to the Gulf were exposed to a vast array of different stressors that carry with them their own potential health consequences. The current collection of exposure information does not adequately address an investigation of traumatic events to which the deployed soldier may have been exposed. In addition, media attention and reports by the military to Gulf War veterans that toxic exposure could have occurred are very stressful events. The stress associated with these reports needs to be recognized and addressed.

- The committee recommends that the CCEP contain questions on traumatic event exposures in addition to the exposure information currently being collected. This would include the addition of open-ended questions that ask the patient to list the events that were most upsetting to him or her while deployed. Positive responses to questions regarding such events, as well as to other exposure questions, should be pursued with a *narrative inquiry*, which would address such items as the specific nature of the exposure; the duration; the frequency of repetition; the dose or

intensity (if appropriate); whether the patient was taking protective measures and, if so, what these measures were; and the symptoms manifested.

- The committee recommends that DoD providers acknowledge stressors as a legitimate but not necessarily sole cause of physical symptoms and conditions.

Every soldier who goes to war will be subjected to major disturbing events since war involves death and destruction. There are certain jobs undertaken in the midst of war that, by their very nature, result in high stress (e.g., grave registration duty). The effect of stress associated with these jobs can be mitigated if approached properly. Such efforts, however, require time for the provider and the patient to interact. It is not possible to hand the patient a pamphlet or a questionnaire and expect that all necessary information will be revealed or understood.

- The committee recommends that DoD provide special training and debriefing for those who are engaged in high-risk jobs such as jobs associated with the Persian Gulf experience.

- The committee recommends that DoD provide to each about-to-be deployed soldier, risk or hazard communication that is well developed and designed to provide information regarding what the individual can expect and the potentially traumatic events to which he or she might be exposed.

- The committee recommends that adequate time must be provided during initial interactions with patients in the CCEP in order to insure that all pertinent information is forthcoming.

Screening

Depression is a condition that is common in primary care. Most individuals who experience depression continue to function, but if they are left untreated, their condition may deteriorate. Unlike many of the medically unexplained symptom syndromes, there are accepted and effective treatments for depression.

- The committee recommends that there be increased screening at the primary care level for depression.

- Every primary care physician should have a simple standardized screen for depression. If a patient scores in the significant range, this person should be referred to a qualified mental health professional for further evaluation and treatment.

- If depression is identified, there has to be more questioning on exposure to traumatic situations.

- **The committee recommends that any individual who reports any significant symptoms of posttraumatic stress disorder (PTSD) and/or a significant traumatic stressor should be referred to a qualified mental health professional for further evaluation and treatment.**

Substance abuse or misuse problems are prevalent in primary care. In addition, individuals under stress and/or with untreated depression or medically unexplained symptom syndromes may be at increased risk for substance abuse.

- **The committee recommends that every primary care physician have a simple, standardized screen for substance abuse. Every individual who screens positive should be referred for further evaluation and treatment.**

There are certain areas in which baseline assessments are of immense value in the clinical evaluation of an individual patient's status (e.g., pulmonary function and neurobehavioral testing). Changes in neurocognitive and peripheral nerve function are measured by comparing the individual's current status to a baseline measure. Individual baseline information is necessary because the variability across individuals is too great to identify a generalized "normal" screening level.

- **The committee recommends that DoD explore the possibility of using neurobehavioral testing at entry into the military to determine whether it is feasible to use such tests to predict change in functioning or track change in function during a soldier's military career.**

Program Evaluation

Most patients in the CCEP receive a diagnosis after completing a Phase I examination; some are referred to Phase II for evaluation; and a few have gone on to participate in the program at the Specialized Care Center (SCC). Information presented to the committee indicates that there is great variation across regions in the percentage of patients who are diagnosed with primary psychiatric diagnoses and medically unexplained symptom syndromes. A determination should be made as to why this variation exists. Although there may be many reasons, one explanation could relate to the consistency with which procedures for diagnosis and referral are implemented from facility to facility.

- **The committee recommends that an evaluation be conducted to examine (1) the consistency with which Phase I examinations are conducted across facilities; (2) the patterns of referral from Phase I to Phase II; and**

(3) the adequacy of treatment provided to certain categories of patients where there is the potential for great impact on patient outcomes when effective treatment is rendered (e.g., depression).

The SCC has provided evaluation and treatment to 78 patients since it was begun. A great deal of effort and thought has gone into the development of a program designed to help the patient understand his or her conditions and engage in behaviors most likely to result in improvement. The committee was asked to assess the effectiveness of this center, but realized that such an assessment depended on a number of factors that have not been well defined. What is the goal of the center—is it treatment, research, or education? Should a major consideration in the center's evaluation be cost-effectiveness? Should the numbers of those receiving care be taken into consideration and, if so, what are the barriers to patients accessing this level of care? What is the triage process by which individuals get referred to the SCC?

- The committee recommends that a short-term (perhaps 5-year) plan be developed for the Specialized Care Center that would specify goals and expected outcomes.

Coordination with the VA

Given that many now receiving services in the DoD health care system will eventually move to the VA health care system, it is important for there to be good communication between DoD and the VA. This may be particularly true in the areas of medically unexplained symptom syndromes and psychiatric disorders, where accurate diagnosis and/or assessment of response to treatment is important for positive patient outcomes.

- The committee recommends that DoD explore ways to increase communication with the VA, particularly as it relates to the ongoing treatment of patients.

Both providers and patients would benefit from increased educational activity regarding Persian Gulf health issues. Provider turnover within DoD is a factor that must be taken into consideration when examining the special health needs and concerns of active-duty personnel who were deployed to the Persian Gulf. Although efforts to educate providers were extensive at the time the CCEP was implemented, 3 years have passed and many new providers have entered the system. These individuals should be oriented to the special needs, concerns, and procedures involved, and all providers should be updated regularly.

The VA has developed a number of approaches to provider education which could serve as useful models. Interactive satellite teleconferences are available for medical center staff to discuss particular issues of concern. The VA conducts quarterly national telephone conference calls, directs periodic educational mailings to Persian Gulf Registry providers in each health facility, and conducts an annual conference on the health consequences of Persian Gulf service.

In addition to providers, there is a great need for education of and communication with individuals (and their families) who were deployed to the Gulf. These individuals are concerned about the potential impact of Persian Gulf deployment on their health, whether or not their health concerns will affect their military careers, their ability to obtain health insurance once they leave the service, and a number of other issues that need to be addressed.

- The committee recommends that DoD examine the activities and materials for provider education developed by the VA to determine if some of the items might be used as educational approaches for DoD providers.

- The committee recommends that DoD mount an effort designed to educate providers to the fact that conditions related to stress are not necessarily psychiatric conditions. The committee recommends that depression be a topic of education for all primary care providers, with emphasis on the facts that depression is common, it is treatable, and individuals who experience depression can continue to function.

- The committee recommends that CCEP information be used to develop case studies that will help educate providers about Persian Gulf health problems.

- The committee recommends that DoD develop approaches to communication and education that address the concerns of individuals deployed to the Persian Gulf and their families.

Determining the etiology(ies) of health problems experienced by those deployed to the Persian Gulf War may not always be possible. However, it is possible that treatment can be provided for many of the symptoms or conditions associated with some of these problems. The committee wishes, therefore, to emphasize the importance of adequate assessment of medically unexplained symptom syndromes and of traumatic event exposure, as well as screening for depression and for substance abuse. Such additions to the CCEP will enhance its ability to identify and, ultimately, treat the health problems being experienced by those who served in the Persian Gulf War.

Table 1 provides a summary of the committee's recommendations.

TABLE 1 Summary of Committee Recommendations

Topic	Recommendation
Medically unexplained symptom syndromes	<ul style="list-style-type: none"> • The provider evaluating these patients must have access to the complete medical record including prior treatment. • Rather than attempting to fit a treatment to a diagnosis, treatment should target specific symptoms or syndromes (e.g., pain, fatigue, depression). • A patient's functional impairments should be identified early to facilitate treatment.
Stress	<ul style="list-style-type: none"> • The initial CCEP examination should include questions regarding traumatic event exposure. Any positive response should be followed up with a narrative inquiry. • Stressors must be acknowledged as a legitimate but not necessarily sole cause of physical symptoms and conditions. • DoD should provide special training and debriefing for those engaged in high-risk jobs during deployment, e.g., graves registration. • DoD should provide risk or hazard communication to each about-to-be deployed soldier. • Adequate time must be provided for provider/patient interaction during CCEP examinations.
Screening	<ul style="list-style-type: none"> • There should be increased screening for depression at the primary care level. • Every physician should employ a simple, standardized screen for depression (e.g., BDI, Zung Scale, CES-D, IDD). • Patients who screen positive for depression should be referred for screening, further evaluation, and treatment. • Patients diagnosed with depression should be interviewed regarding traumatic exposure. • Patients identified with any significant PTSD symptoms and/or a significant traumatic stressor should be referred to a qualified mental health professional for further evaluation and treatment. • Every physician should employ a simple standardized screen for substance abuse (e.g., CAGE, brief MAST, T-ACE, TWEAK, AUDIT). • Every patient who screens positive for substance abuse should be referred for further evaluation and treatment. • DoD should explore feasibility of neurobehavioral testing at entry into military for usefulness in measuring change in function.

Continued

TABLE 1 *Continued*

Topic	Recommendation
Program evaluation	<ul style="list-style-type: none"> • An evaluation should be conducted to examine: (1) the consistency of Phase I examinations across facilities; (2) the patterns of referral program from Phase I to Phase II; and (3) the adequacy of treatment provided to certain categories of patients where the potential for positive impact is great (e.g., depression). • DoD should develop a short-term plan for the Specialized Care Center that specifies goals and expected outcomes.
Education	<ul style="list-style-type: none"> • DoD should explore ways to increase communication with the VA, particularly as it relates to the ongoing treatment of patients. • DoD should examine the provider education materials and programs developed by the VA to determine if they might serve as models for DoD approaches. • Education is needed to emphasize that conditions related to stress are not necessarily psychiatric conditions. • Education should emphasize that depression is common and treatable, and that patients with depression can continue to function. • CCEP information should be used to develop case studies which will help educate providers about Persian Gulf health problems. • DoD educational efforts should also address the concerns of Persian Gulf-deployed individuals and their families.

**Statement of
Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
Department of Veterans Affairs
Before the
Committee on Veterans' Affairs
U. S. House of Representatives
regarding
Gulf War Veterans Programs**

February 5, 1998

Mr. Chairman and members of the Committee, thank you for this opportunity to discuss VA's response to the health problems of Gulf War veterans and to comment on recent reports that assess our efforts.

Before discussing our current healthcare and research efforts, I will provide background information about VHA's overall response to Gulf War veterans' healthcare needs.

BACKGROUND

On August 2, 1990, Saddam Hussein invaded Kuwait, and American military personnel were deployed to Southwest Asia soon thereafter. Ultimately, nearly 700,000 U.S. troops were deployed to the Persian Gulf in Operations Desert Shield and Desert Storm. It was clear to the military leaders planning this action that military personnel engaged in these actions would be exposed to a variety of risks, including the possible exposure to chemical and biological warfare agents. A number of preventive measures were taken to provide potential protection for military personnel against these agents, including the administration of a licensed vaccine, an experimental drug, and an experimental vaccine.

After months of tense military build-up in a foreign desert environment, coalition military forces fought a successful air war, followed by a four-day ground war. For some Gulf War military personnel, however, the trauma and pain of war did not end with the cease-fire. Veterans returned home, and began to come to VA for help with a variety of symptoms and illnesses. They reported a long list of environmental exposures that occurred during their service in the Gulf War. We listened to the veterans' concerns and utilized the increasing knowledge gained to design and implement special healthcare programs to serve their needs. These special Gulf War programs are a supplement to the full-range of healthcare services VA provides for the nation's veterans of other conflicts.

VA's Persian Gulf Registry Health Examination Program was the first component of VA's comprehensive Gulf War response. VA developed the Registry in 1991, and implemented it in 1992. The Gulf War Registry was established primarily to assist Gulf War veterans to gain entry into the continuum of VA health care services by providing them with a free, complete physical examination with basic laboratory studies; and to act as a health screening database. As such, VA staff are instructed to encourage all Gulf War veterans, symptomatic or not, to get a Registry examination. The Registry's database, which in addition to allowing VA to communicate with Gulf War veterans via periodic newsletters, provides a mechanism to catalogue prominent symptoms and report exposures and diagnoses. This record of symptoms, diagnoses and exposures makes the Registry valuable for health surveillance purposes; however, the voluntary, self-selected nature of the database means that the experiences, illnesses and health profile of those in the Registry cannot be generalized to represent those of all Gulf War veterans. The Registry was neither designed nor intended to be a research tool. It was also not envisioned to be a "stand-alone" healthcare program, nor a mechanism to monitor the health outcomes of Gulf War veterans through longitudinal follow-up. Another significant limitation is that it records the results of a single evaluation of veterans examined over a variable time period since their Gulf War service.

Since the Registry examination program was initiated, VHA's Gulf War programs have grown to encompass a comprehensive approach to health services, addressing relevant medical care, research, outreach and educational issues. In 1993, at the request of VA, Congress passed legislation later enacted as Public Law 103-210, giving Gulf War veterans special eligibility (priority care) for VA healthcare. This law gave VA the authority it requested to treat Gulf War veterans who have health problems which may have resulted from exposure to a toxic substance or environmental hazard during Gulf War service. We are also pleased that Congress passed legislation subsequently enacted as P.L. 105-114, which expands Gulf War veteran's eligibility for health care for any condition that might be associated with the veteran's service in the Gulf War. VA now provides Gulf War Registry health examinations and hospital and outpatient follow-up care at its medical facilities nationwide, specialized evaluations at four regional Referral Centers, and readjustment and sexual trauma counseling at Vet Centers and VA Medical facilities nationwide to Gulf War veterans. To date, almost 65,000 Gulf War veterans have completed Registry examinations; more than 2.5 million ambulatory care visits have been provided to 221,225 veterans; more than 22,000 veterans have been hospitalized at VA medical facilities; over 470 veterans have received specialized Referral Center evaluations; and more than 83,000 Gulf War veterans have been counseled at VA's Vet Centers.

REGISTRY EXAMINATIONS

Gulf War veterans participating in the Registry examination program have commonly reported that they suffer from a diverse array of symptoms, including fatigue, skin rash, headache, muscle and joint pain, memory problems, shortness of breath, sleep disturbances, gastrointestinal symptoms, and chest pain. Veterans experiencing these multi-system symptoms have been treated seriously, and veteran patients have received medical evaluations, as appropriate. Of note, 12 percent of the VA Registry examination participants have had no specific health complaints but have wished to participate in the examination because they were concerned that their future health might be affected as a consequence of their service in the Gulf War. Overall, while 26 percent of the Registry participants rated their health as poor, 73 percent receiving this examination reported their health as all right to good.

An examination of all the diagnoses of Registry participants indicates that they do not cluster in one organ system or disease category. Instead, the diagnoses span a wide range of illnesses and diagnostic categories. A large majority of symptomatic Gulf War veterans evaluated in the VA Registry suffer from symptoms or illnesses that have been successfully diagnosed. Depending on the particular nomenclature used, between 10 and 25 percent of veterans from the Registry who have been examined have unexplained illnesses. While some symptoms of Gulf War veterans are difficult to diagnose and remain unexplained, there is consensus among government and non-government physicians and scientists alike that current evidence does not support the conclusion that these illnesses represent a single, unique illness that can explain every Gulf War veteran's symptoms. As such, the unexplained illnesses of Gulf War veterans do not meet the clinical definition of a medical syndrome, per se.

As previously stated, the majority of Gulf War veterans have a wide spectrum of diagnosed medical conditions, spanning the range of known medical conditions. We agree with the consensus of the scientific community, including prior findings of the Institute of Medicine, that Gulf War veterans' illnesses appear to be a heterogeneous group of disorders, exhibiting widely varying manifestations and not amenable to a single unifying case definition. The overall frequency of unexplained symptoms among Gulf War veterans appears to be about the same as in a general medical practice (i.e., a non-VA or non-military general medical practice). However, medical scientists have not completed their study of these unexplained conditions and much is uncertain about their character, natural history and potential causes. VA is working hard to better understand these important health problems and develop effective treatments for the symptomatic veterans receiving care at VA facilities.

We recognize that the wide variety of medical conditions diagnosed in Gulf War veterans and the lack of a unique set of characteristics representing a

single illness or "Gulf War Syndrome" per se has created significant challenges for VA clinicians. We believe that Gulf War veterans who seek care from VA are suffering from genuine illnesses and, as indicated already, we are providing a substantial amount of healthcare and treatment for these veterans.

HEALTH STATUS OF GULF WAR VETERANS

At present, we do not have a valid mechanism to determine the health outcomes of all Gulf War veterans from VA, DOD, or other existing health care databases. However, we are committed to developing a better understanding of the natural history of Gulf War veterans' illnesses and in overcoming the barriers that have precluded this ability to date.

In the meantime, as a surrogate, we have looked at our existing systems to get a snapshot of Gulf War veterans health status over time. First, we looked at the self-reported health status of 18,938 Gulf War veterans on their original Registry exam and on a later survey response. The characteristics of those Gulf War veterans who responded to the survey were somewhat different from the overall VA Registry participants. Relatively more Reserve and National Guard unit members (44.2% vs. 39.2%), whites (66.8% vs. 64.3%) and older veterans (32.5 vs 30.4, mean age as of 1991) responded to the 1996 survey. At the time they participated in the Registry examination, the self-reported health status of those Gulf War veterans who responded to the survey was similar to that of the overall Registry examination participants. Among the 18,938 Gulf War veterans who participated in the Registry and subsequently responded to the 1996 follow-up survey, self-reported health status was unchanged for 8443 (45%), better for 3589(19%) veterans and worse for 6906 (36%) veterans. As the time interval increased between the Registry exam and the follow-up survey response dates, a greater proportion of veterans reported worsening health status. This data is limited by a poor response rate (less than 50%) and by inability to assess the contribution of other confounding factors. However, we feel that the results merit further assessment. In this regard, we intend to look at self-reported health status longitudinally on our annual customer satisfaction survey. This additional report should be available in April 1998.

CASE MANAGEMENT AND DEMONSTRATION PROJECTS

In response to Public Law 105-114, VA will initiate clinical demonstration projects for case management and multidisciplinary clinical care for Gulf War veterans.

Last year, I implemented a new case management initiative aimed at improving services to veterans with complex medical problems. In their *Special Report*, the Presidential Advisory Committee on Gulf War Veterans Illnesses supported our efforts to implement case management. Significant progress has already been made. Case management as a routine clinical strategy for Gulf War

Veterans has already been implemented at nearly 20 VA medical centers. In addition, performance measures for the Network Directors have been established to ensure that the appropriate resources are devoted to these efforts at all facilities.

The demonstration projects are an important component of this effort. The projects will use objective outcome measures to assess whether health care for Gulf War veterans is improved by multidisciplinary clinics or case management approaches. Awards for the demonstration projects will be made before the end of this fiscal year. These projects will be funded as two-year studies. We look forward to reviewing their conclusions.

COMPENSATION AND PENSION EXAMINATIONS

VHA is committed to providing quality compensation and pension examinations for all veterans. I have recently appointed a Director of Forensic Medicine to spearhead these efforts within VHA. Of particular concern is assuring improvement in examinations of Gulf War veterans with undiagnosed illnesses. We recognize that there have been problems in this area and have worked cooperatively with VBA to develop clearer guidelines to the physicians performing these examinations. These guidelines will be supplemented by a focused training program for regional office and medical center staff who are involved in working Gulf War veterans' compensation cases. A copy of these enhanced guidelines has been provided to the Committee.

INFORMATION MANAGEMENT

In response to congressional concerns about Gulf War information management issues, the Department has taken the following steps: First, the Acting Secretary has designated the Assistant Secretary for Policy and Planning to serve as the Department's focal point and responsible official for coordination and release of all departmental data pertaining to Gulf War veterans issues. Secondly, the Assistant Secretary has been charged with assessing and evaluating all current data sources relative to Gulf War veterans and to determine any associated data gaps or vulnerabilities. As a result, an electronic match of disparate data sets maintained by Veterans Benefits Administration (VBA), Veterans Health Administration (VHA) and the Department of Defense (DoD) will be accomplished and a Gulf War Management Information System will be established as part of the Department's Corporate Information Repository. It is hoped that these efforts will provide a mechanism for more consistently recording and reporting accurate information regarding the VA healthcare and benefits statistics regarding Gulf War veterans.

EDUCATION

In order to maintain the quality of health care provided to Gulf War veterans and keep our healthcare providers informed about the latest

developments related to Gulf War veterans' health, VHA has utilized a wide array of communication methods, including periodic nationwide conference calls, mailings, satellite video-teleconferences and annual on-site continuing medical education (CME) conferences. In 1995 and 1996, we broadcast teleconferences on undiagnosed illnesses and on the evaluation and management of chronic fatigue syndrome. A 1996 CME conference was comprised of workshops focused on evaluation and management of common symptoms and medical conditions identified in Gulf War veterans. The most recent national training program, Gulf War CME Conference, was held on June 3-4, 1997, in Long Beach, California.

VA's past internal educational efforts have been primarily aimed at developing a cadre of well-informed Registry physicians and staff, who in turn provide a source of education and consultation to other healthcare providers at their facilities. However, with the universal implementation of primary care and the growing recognition that the health problems of Gulf War veterans span all medical subspecialties, we are expanding our educational programs to encompass other medical personnel. Our goal is that all VA healthcare providers will have a working understanding of Gulf War exposures and health issues and will be able to discuss with their Gulf War patients how these issues could impact on their current or future health status. The Presidential Advisory Committee also concluded that we needed to expand our educational efforts to all direct care providers. As a first step to meet this challenge, the Veterans Health Administration is publishing a self-study Gulf War CME program in March of 1998 that will then be distributed to every VA physician. We will make this educational tool available to non-VA physicians, at cost, as well.

STATUS OF GULF WAR RESEARCH

In order to get the best assessment of the health status of Gulf War veterans, a carefully designed and well-executed research program is necessary. VA, as lead agent for federally sponsored Gulf War research, has laid the foundation for such a program. Under the auspices of the Persian Gulf Veterans Coordinating Board Research Working Group, VA has developed a structured research portfolio to address the currently recognized, highest priority medical and scientific issues. Over 120 federally sponsored research projects are pending, underway or have been completed. VA's own research programs related to illnesses of Gulf War veterans include more than 40 research projects amounting to a cumulative expenditure of research dollars projected from FY 1994 through FY 1998 of approximately \$27 million. Federally funded researchers have, to date, published approximately 60 papers in the peer reviewed literature, including nearly 40 from VA investigators alone. The research portfolio of VA encompasses a variety of research approaches, including epidemiology, basic research, clinical research, and applied research, applied to a vast array of potential exposures and health outcomes. Issues studied by VA researchers include epidemiology surveys, mortality studies,

studies of the health effects of exposure to petroleum products, including the oil well fires, pesticides, the parasitic infection Leishmaniasis, and chemical warfare agents. In addition, VA research is embarking on some important steps toward the assessment of effective treatments for Gulf War veterans' illnesses.

The Research Working Group is preparing its Annual Report to Congress for federally sponsored research on Gulf War veterans' illnesses. This report will provide significant detail about the research efforts of VA and the other participating federal departments. There has been significant progress on a number of key VA research studies. The Office of Research and Development has awarded funding for Phase III of the National Health Survey of Persian Gulf Veterans and preliminary site selection has begun. It is expected that physical examinations will begin in the near future. As you may recall, the National Survey is designed to determine the prevalence of symptoms and illnesses among a random sampling of Persian Gulf veterans across the nation. The Survey is being conducted in three phases. Phase I was a population-based mail survey of the health of 30,000 randomly selected veterans from the Persian Gulf era (15,000 Persian Gulf veterans and 15,000 non-Persian Gulf veterans, males and females). The data collection phase is complete and analysis of the data continues. Phase II consisted of a telephone interview of 2,000 non-respondents from Phase I (1,000 from each group) to determine if there are any response differences between respondents and non-respondents. Additionally, 1,000 veterans from each group will be selected for a telephone interview to validate their responses from the mail survey. Phase II is nearing completion. In Phase III the 2,000 veterans who responded to the postal survey and underwent a telephone interview will be invited, along with their family members, to participate in a comprehensive physical examination protocol. These examinations will be conducted at 18 VA medical centers nationwide and involve specialized examinations including neurological, rheumatological, psychological, and pulmonary evaluations. Completion of data collection is anticipated around mid-1999. When the National Survey is complete we will have a much clearer picture of the prevalence of symptoms and illnesses among Gulf War veterans.

The VA Office of Research and Development has initiated the planning stages for a multi-site randomized clinical trial to assess the effectiveness of treatments for Chronic Fatigue Syndrome (CFS) and Fibromyalgia (FM) in Gulf War veterans. These conditions appear to significantly overlap with the types of symptoms and illnesses reported by many Gulf War veterans. Such a study is possible because these conditions have clearly defined case definitions along with proposed treatments that have undergone preliminary evaluation. This study will be carried out in collaboration with the Department of Defense and conducted at multiple VA and DoD health care facilities. VA and DoD are investing up to \$5 million each to conduct this trial. Because of its experience and research on the characteristics of these diseases, we plan to consult with NIH in the development of these research protocols. In addition, the VA Office of Research and Development has issued a Program Announcement, or general

invitation to VA clinicians/scientists, to propose additional multi-site trials to evaluate the effectiveness of different treatment strategies. The planned treatment trial, along with any trials proposed in response to the Program Announcement, will undergo rigorous scientific peer review by VA's federally chartered Cooperative Studies Evaluation Committee.

VA has been concerned about the adequacy of research on the neurobiological effects of stressors. The Office of Research and Development has taken some new steps to address this issue.

VA and DoD have issued a request for intramural proposals valued at \$5 million for research on the neurobiology of stress and stress-related disorders. Proposals will undergo scientific review by a joint VA/DoD appointed panel of experts, and programmatic review by the Research Working Group. Proposals will undergo peer review this spring, with the award and funding of projects expected by July 1, 1998.

In June 1997, VA funded a multi-center cooperative study examining the effectiveness of a computerized battery of neuropsychological tests that could improve the accuracy of the diagnosis of PTSD by enabling the clinician to rule out organic central nervous system dysfunction.

In July 1996 VA funded a new multi-center treatment trial investigating the efficacy of trauma-based group therapy in the treatment of PTSD. In addition VA issued a Program Announcement in August 1997 requesting proposals for additional multi-center trials of PTSD treatment. Methodologies being sought include new, non-pharmacologic approaches to treatment, and focus on targeted subpopulations such as women and Persian Gulf veterans.

PAC SPECIAL REPORT

The PAC Special Report recommends that "All research on Gulf War veterans' illnesses that is funded by the government should be subjected to external competition and independent peer review." The Report acknowledges the necessity for some rare exceptions, but the message is clear. VA agrees with the PAC on this matter. The policy of VA's Office of Research and Development is to fund only competitively peer-reviewed projects. It applies this same concept in its coordination of its research portfolio for Gulf War veterans' illnesses. The Research Working Group, chaired by VA, has always promoted competitive peer review as a means for all member agencies to obtain the best research. Indeed the Research Working Group has played a major role in the selection process of peer reviewed, competitively funded research for all of the member Departments or agencies. However, it must be emphasized that the Research Working Group only makes funding recommendations to member Departments. It does not direct them to fund particular projects.

The PAC also recommended that "The White House and VA should work with Congress to establish a permanent, statutory program for Gulf War veterans' illnesses. The Committee envisions legislation that directs VA to contract with an organization with the appropriate scientific expertise—e.g., the National Academy of Sciences (NAS)—for a periodic review, for benefits and future research purposes, of the available scientific evidence regarding associations between illnesses and Gulf War service. The object of such an analysis would be to determine statistical association between service in the Gulf War and morbidity and mortality, while also considering whether a plausible biological mechanism exists, whether research results are capable of replication and of clinical significance, and whether the data withstand peer review." VA agrees with this PAC recommendation. Gulf War veterans who are suffering with health problems deserve to know what happened to them in the Gulf War and whether evidence exists that their illnesses could be related to service. VA believes that this review by the NAS would ensure that the best scientific minds would be brought to bear on the complex array of Gulf War veterans health problems and that a consistent, continuous and equitable effort is sustained. Earlier this week I approved the NAS contract proposal and we have provided a copy of the contract to the committee. I would welcome any input that the Committee members have regarding this effort.

OTHER REPORTS

Besides recommendations from the PAC, the Institute of Medicine, and other panels of experts, there have been other reports on the government's research programs for Gulf War veterans' illnesses. The General Accounting Office (GAO) has issued reports and is currently engaged in ongoing reviews of issues centering on Gulf War veterans' illnesses including research. In June 1997, the GAO issued their report, Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis are Needed. VA provided a detailed response to the GAO report, which is contained in the report's appendix.

The House Appropriations Committee Report 105-175 states, "GAO recently found that DoD and VA did not have a systematic approach to monitoring the health of Gulf War veterans after their initial examination and consequently could not provide information on the effectiveness of the treatment they had received or whether they were better or worse than when first examined." The report goes on to say that "DoD and VA should develop and implement a plan to provide: (1) data on the effectiveness of treatments received by these veterans, and (2) longitudinal information on the health of veterans who reported illnesses after the war." The review, according to the report, should be "focused on resolving those conditions that have proven intractable or resistant to current therapies."

We agree that the goal of identifying improved therapies for veterans is an important one. In the traditional view of treatment outcomes research such ill-defined, symptom-based illnesses are not amenable to outcomes research

because one or all of the following requirements for a treatment trial are lacking: a clearly defined definition of the disease, a measurable health outcome result, and a single treatment aimed at a biologically plausible etiology. Treatment trials are the foundation of evidence-based medicine, which is changing the way clinicians carry out their mission by informing them of the best, most effective approaches to treatment and care.

The issues raised by the GAO and House reports are not simple. Gulf War veterans have experienced a wide variety of diagnosed and undiagnosed medical conditions, which span the entire range of medical experience. The methodology for evaluating health outcomes and treatment efficacy in such a complex situation has not been developed by the health research community. The task of designing a protocol for acquiring and analyzing longitudinal information to provide an accurate assessment of hundreds of health outcomes and the effectiveness of thousands of treatments in Gulf War veterans poses a significant challenge. VA and DoD have asked the National Academy of Sciences Institute of Medicine to conduct a workshop and provide us with advice and recommendations on valid scientific methods to collect this information. Based on this advice, we will design a program to carry out this activity.

Additionally, a report entitled, Gulf War Veterans' Illnesses: VA, DoD Continue to Resist Strong Evidence Linking Toxic Causes to Chronic Health Effects, was released last fall by the House Committee on Government Reform and Oversight. This report resulted from a series of hearings conducted by the Subcommittee.

The Committee's report included several findings and recommendations. Some of these findings and recommendations warrant a response on the part of VA. There are strong negative assertions made in the report about the management of the government's research on Gulf War veterans' illnesses. These are even reflected in title of the report. The title implies the existence of two facts: (1) there is strong scientific evidence linking toxic causes to chronic health effects; and (2) VA and DoD have resisted this strong evidence in setting their research agendas. These assertions do not comport with the facts. VA has not resisted the possibility that exposures to toxic agents in the Gulf War are responsible for veterans' illnesses. VA and the Research Working Group are committed to continuing the pursuit of the health effects of toxic exposures. The combined efforts of all agencies have resulted in approximately \$20 million alone on research directly related to the potential health consequences of exposure to toxic substances. These exposures include oil well fires, chemical warfare nerve agents, pesticides, and pyridostigmine bromide. This figure does not include all of the epidemiological health studies on Gulf War veterans that acquire self-report exposure data in an attempt to identify potential links between toxic exposure and outcome. One of VA's initial major investments in research on Gulf War veterans' illnesses was the three environmental hazards research centers located at Boston VAMC, East Orange VAMC, and Portland VAMC.

This evidence clearly counters the notion that we have resisted exploring potential linkages.

Evidence linking toxic exposures to chronic health effects in Gulf War veterans is incomplete at this time. However, VA, and the Research Working Group which it chairs, has continued to pursue all leads with respect to potential causes of Gulf War veterans' illnesses. However, at this time, research reports claiming a causal relationship between toxic exposures and health outcomes in Gulf War veterans are incomplete. We face two problems in this area of causation: (1) quantitative exposure data, which are necessary ingredients for establishment of causation, have been difficult to obtain beyond self-reported exposures; (2) it is still too early in the research cycle to make definitive research-based claims about causation.

In the Committee's report itself, there are three research-related findings, and five research-related recommendations. The findings contained in the report restate the previous assertion that the federal research strategy has disregarded evidence of causal links between toxic exposures and health outcomes. As stated before, this is simply untrue.

The report findings also suggest that "institutional and methodological constraints make it unlikely that the current research structure will find the causes and effective treatments for Gulf War veterans' illnesses". We acknowledge the possibility that we may never definitively know the precise cause, or causes, of Gulf War veterans' illnesses. However, as discussed before, the limitations to finding a cause are not due to constraints imposed on research by the government, but are due, in part, for example, to the inherent methodological problems imbedded in the difficult job of acquiring accurate, quantitative exposure data that can be linked to health outcomes. Despite this, we continue to strive to ascertain the cause or causes through innovative methods of exposure ascertainment.

The notion put forward in the report that current research will not identify effective treatments is also inaccurate. Much of the current research is directed at establishing working case definitions for Gulf War illnesses. This is a prerequisite for conducting treatment trials. As stated earlier, the VA Office of Research and Development is proceeding with planning for multi-site treatment trials that will initially rely on standard case definitions for CFS and FM. When, and if, better case criteria can be established, VA will be prepared to use those in future trials.

The report recommends that Congress create or designate an agency independent from VA and DoD to coordinate research and allocate research funds. Panels of scientists and experts such as, the IOM, have commended the Research Working Group on its research directions and processes for selecting research. The direction of research should be based on accurate, expert, and

independent assessments of existing data. We strongly disagree with this report recommendation because it is inconsistent with other expert opinion and has no basis.

The report recommends that research focus on evaluation and treatment of disorders such as Chronic Fatigue Syndrome and Fibromyalgia. As noted earlier, VA has undertaken efforts to develop effective treatment strategies for these disorders. Included in the report's recommendation, however, are disorders identified as "Gulf War Syndrome" and "Multiple Chemical Sensitivity". As we have often stated before, there is no collection of signs and symptoms manifested by Gulf War veterans that can be uniquely ascribed to a single novel disease pathology that could be given a name as specific as "Gulf War Syndrome". We know Gulf War veterans are suffering, and we believe that their illnesses are associated in some way with their service in the Gulf War.

Multiple Chemical Sensitivity is another condition that does not have an accepted case definition. We in the medical and environmental health community have long acknowledged that health consequences can arise from exposures to chemicals alone or in combinations. These health consequences are generally well described medically and include such conditions as peripheral neuropathy, pulmonary fibrosis, occupational asthma, cancer, and many others. The condition that goes by the name "Multiple Chemical Sensitivity", however, has eluded accurate case definition, which is a prerequisite to the development of treatment trials. However, VA supports peer reviewed research on Multiple Chemical Sensitivity that is scientifically credible. In the current government research portfolio on Gulf War veterans' illnesses there are seven projects examining different aspects of Multiple Chemical Sensitivity. Thus VA, as well as other federal Departments and agencies, support research on Multiple Chemical Sensitivity that meet criteria of scientific merit.

Another recommendation of the Committee's report suggests that VA and DoD medical systems augment their research and clinical capabilities with regard to women's health issues and the health effects of combat service in women. We agree with this recommendation and will continue to encourage more research on women's health issues. The VA Office of Research and Development has already identified women's health as a priority research area within its program of Designated Research Areas. VA researchers are currently carrying out nine research projects, valued at \$1.3 million, specifically targeted at the health consequences of the military experience of women. VA and other federal agencies are sponsoring this research. The Health Services Research Service in the VA Office of Research and Development has also issued a Program Announcement inviting submissions of proposals to study the impact of gender differences in health.

Finally, the report recommends that VA join with other federal agencies to create an interdisciplinary research and clinical program on the prevention,

intervention and treatment of environmental neuropathies. We agree with the report that prevention, intervention, and treatment of environmentally induced neuropathies is important. We also encourage the merging of research expertise from different federal agencies to tackle vexing health problems. VA has done this in a number of health areas already. Consequently, we will build on prior efforts to work with other federal agencies in exploring the feasibility of creating such an interdisciplinary program. In addition, VA will issue a request for applications (RFA) within VA for research proposals on the prevention, intervention, and treatment of environmental neuropathies.

IMPROVING CARE AND RESEARCH

VA has been a leader in the development of veterans' healthcare programs, improvement of understanding concerning Gulf War health issues and dissemination of knowledge on Gulf War-related health issues. As we have previously testified, we believe that our programs have been well designed; we also know that they are neither uniformly delivered nor perfect. We also recognize that some veterans have not received the kind of reception or care at VA medical facilities that we strive for. To both the Committee and those veterans here today, I want you to know that the Veterans Health Administration is working diligently to improve their satisfaction with our services. One of the new initiatives aimed at improving services to veterans with complex medical problems is implementation of case management.

VHA has also conducted Gulf War focus groups and developed a new customer satisfaction survey, which includes a large sample of Gulf War veterans. This national survey was sent to veterans in the fall of 1997. It will provide us the specific opinions of Gulf War veterans. The survey will produce adequate statistical power from which to draw valid conclusions about these data. These programs will allow us to collect data for quality improvement of VA programs and support our goal of providing the highest quality care to veterans. The analysis of the survey results will be available in March 1998. A final report will be forwarded to the Committees at that time.

I have just described VA's extensive treatment and research efforts on behalf of Gulf War veterans. You should know that we continue to take steps to improve the program when weaknesses have been identified. We believe the approaches being pioneered for these veterans will benefit others in the future.

Research related to the illnesses of Gulf War veterans is highly complex, and this is equally true of outcomes research. VA is committed to meeting these challenges and providing quality healthcare and the most effective treatments to Gulf War veterans. We will continue to solicit the advice of scientific experts, oversight groups and this Committee to improve our programs for veterans. VA healthcare providers are dedicated to providing compassionate care and

answering important medical questions. President Clinton has made it clear that no effort should be spared in this regard.

Mr. Chairman, that concludes my prepared statement. We welcome your specific suggestions for how VA care can be improved and how VA can be more responsive to those whom it serves. I will now be happy to respond to any questions the Committee may have.

Statement by Dr. Bernard Rostker, Special Assistant to
the Deputy Secretary of Defense for Gulf War Illnesses
Before the House Committee on Veterans' Affairs.
February 5, 1998

Thank you, Mr. Chairman, for the opportunity to appear before your Committee today. In my two previous appearances before this Committee, I discussed my mission, DoD's resource commitment, our investigative methodology and our increased medical research effort. Today, you have requested that I discuss the Special Report of the Presidential Advisory Committee on Gulf War Veterans Illnesses (PAC), the Second Report by the Committee on Government Reform and Oversight, and the report by the United States General Accounting Office: "Gulf War Illnesses—Improved Monitoring and Re-examination of Research Emphasis Needed." Additionally, I will tell you our direction for the coming year.

First, with respect to the PAC Special Report, the intergovernmental response is in the final stages of coordination. As soon as the coordinated response is released, I will provide a copy to the Committee.

The PAC Special Report had a number of recommendations for the Department of Defense which cover a wide range of topics. Many are health related and do not fall under my purview. Therefore, I will only comment on the five specific recommendations concerning: Technologies, Doctrine, Exposure Modeling of Khamisiyah Pit Demolition, Bias in Fact Finding and Analysis, and Objective Standards.

First, in the area of technologies, we concur with the PAC's recommendation to pursue technological improvements for chemical warfare (CW) agent detection. For example, the Department has approved production and fielding of the Automatic Chemical Agent Detector and Alarm which will provide improved detection capabilities. Our ongoing developmental programs are striving to lower detection limits and increase the range of agents detected.

Second, we continue to review doctrine and policy. At this time, we do not believe there is a need for doctrine concerning low-level chemical exposure. However, if research indicates a need for modification, we will consider taking such action.

Third, as a result of our efforts on exposure modeling of the Khamisiyah pit demolition, we notified more than 97,000 veterans of their potential exposure to low-levels of chemical warfare agents. The PAC recommended that all other individuals within a 300 mile radius of Khamisiyah be notified that they were not exposed. At this time, we disagree. We conducted extensive, sophisticated modeling to ascertain the size of the low-level chemical agent plume and the area of potential exposure and announced the results last summer. These are our best estimates of the exposed area. However, through ongoing efforts, we continue to refine our model and the unit location data base to determine any health implications. As new information is developed, we will identify and notify additional veterans as appropriate.

Fourth, the PAC suggested that independent oversight would dispel concerns regarding bias in fact finding and analysis. We strongly agree. Our investigation has been subject to full public accountability and independent oversight. We developed an extensive case narrative and briefing process which involves both veterans and military

service organizations, Congressional staffs, the media and the public. All our case narratives are interim reports as we continually solicit veterans to provide additional factual information. Since this is a totally open process, we welcome independent oversight and look forward to the anticipated appointment by President Clinton of a special oversight board.

Finally, we agree with the PAC that an objective standard needs to be applied to all investigations. We have developed a methodology, based on international protocols, which is thorough in considering all information, evidence and data. Furthermore, the analysts conducting the investigations operate freely within the construct of this methodology. We make an assessment for each case and provide our sources to allow any other reader to make his/her own assessment. Our assessment is solely based on the facts available, not on any presumptions, preconceptions or pre-judgments and is not related to any potential determination of benefits or outside influence.

Although we have been disappointed with the characterizations of our relationship, we recognize the PAC's invaluable service to our veterans and the American public by mobilizing the Government's efforts. We appreciate the many constructive and relevant recommendations they have made which have assisted us in fulfilling our heartfelt responsibility to our Gulf War veterans.

As you may know, I have testified three times before the Committee on Government Reform and Oversight Subcommittee on Human Resources and have enclosed, for the record, our response to Chairman Shays. In those sessions, I discussed the whole spectrum of effort, from my mission to DoD's expanded resource commitment. I explained our case narrative process, provided detailed information on our case narratives, explained our outreach programs and interactions with veterans and their involvement in the investigative process, and provided detailed answers to all questions asked by the Subcommittee and met with the Subcommittee staff on numerous occasions. Needless to say, in early November, when the Committee published its report, we were disappointed that it contained little of the information we provided.

Let me be more specific. The DoD has published 13 case narratives and information papers which are virtually ignored by this report. Several of these case narratives deal directly with issues raised by the Committee and charges made by witnesses called by the Committee. Our narratives were built upon the testimony of scores of Gulf War veterans. By ignoring facts presented in the case narratives, I believe that the Committee's report is misleading about what happened in the Gulf.

The third report I was asked to discuss is the report by the United States General Accounting Office, "Gulf War Illnesses—Improved Monitoring and Re-examination of Research Emphasis Needed". I have also enclosed our response to this report for the record. If this report had been published a year earlier, it would have been right on the mark concerning the DoD. We are concerned, however, that this report did not provide a timely or accurate status of the work being performed or progress made within the DoD at the time it was published. Virtually all of the facts and conclusions were previously identified by other reviews from both inside and outside the government and were addressed by a number of new programs not considered by the GAO in their report.

For the record, a full accounting of the activities of my office is in my annual report to the Deputy Secretary of Defense. I have enclosed this Annual Report and ask that it be made part of the record.

This year we continue to investigate specific events concerning chemical agents and will publish additional narratives on that subject. However, our main focus will be on environmental issues. We will complete and publish separate environmental reports on pesticides, depleted uranium and the oil well fires. We look forward to the challenges ahead and welcome the opportunity to work with the Congress and oversight agencies. We are responsible to our veterans to provide them with a full accounting of what went on during and after the war. The investigations we undertake provide the information we need to modify our doctrine, procedures, equipment and systems so that we can learn from this experience. No other agency can fulfill this responsibility.



SPECIAL ASSISTANT
FOR
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JAN 30 1998

Honorable Christopher Shays
Chairman, Subcommittee on Human Resources
Committee on Government Reform and Oversight
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Subcommittee on Human Resources report entitled *Gulf War Veterans Illnesses: VA, DoD Continue to Resist Strong Evidence Linking Toxic Causes to Chronic Health Effects*, unfavorably compared my testimony regarding the occurrence of Amyotrophic Lateral Sclerosis (ALS) in Gulf War veterans to a letter from Dr. Robert H. Brown. I believe that, when viewed in their proper context, my and Dr. Brown's statements are both accurate and in complete agreement.

Testifying before your subcommittee, I stated since the Gulf War nine veterans registered with the Comprehensive Clinical Evaluation Program and the VA Registry have been identified as having ALS. Further, I noted that, given the size and age of the deployed population, this number is consistent with the anticipated rate of occurrence.

Dr. Brown noted that the annual rate of new cases for the American population is 1 per 100,000. Since people under 40 years of age would constitute 20-25% of the total, he believes that there would be between 1.4 and 1.7 new cases each year. Our research, and my testimony, does not contradict Dr. Brown's analysis. His estimate was based on a single year's projection, DoD was looking at a six year period. Multiplying Dr. Brown's rate by six yields a range of 8.4 to 10.2 cases; DoD had confirmed nine cases of ALS in the registries.

I hope this information is helpful and clears up any misunderstanding concerning my testimony before your committee.

Sincerely,

Bernard Rostker



SPECIAL ASSISTANT
FOR
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NOV 21 1997

The Honorable Christopher Shays
Chairman, Subcommittee on Human Resources
Committee on Government Reform and Oversight
House of Representatives
Washington, DC 20515-6143

Dear Mr. Chairman:

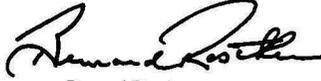
I am pleased to respond to the Oversight Report of the Subcommittee on Human Resources and the House Committee on Government Reform and Oversight. While I concur with many of the findings and recommendations of the report, I disagree with the selective handling of facts on several issues discussed in the report. Moreover, DoD has completed thirteen information papers and case narratives which are ignored by this report. The scores of veterans that provided testimony to us deserve to be heard just as much as those called by the Committee. As a result, the report appears to be biased in its presentation.

By ignoring facts presented in the case narratives, I believe the report is misleading about what has or has not been done, or what is fact and what is presumption. The use of generalities, but lack of factual and provable details, leads to many misleading conclusions. In many instances, the reported facts are true, but by failing to describe the circumstances or the follow-up, the report again leads the reader to incorrect conclusions. Finally, several factual errors and misinterpretation of the facts presented misstate the intent, meaning, or truth of several issues. Enclosed are specific examples of my concerns.

I want to emphasize that I have not ruled out any potential cause for our veterans' illnesses, nor have I limited our investigation in any way. I agree that it is important to seek a solution to Gulf War illnesses and provide a dialogue and answers to our Gulf War veterans' concerns and health problems. To this end, we are conducting a comprehensive examination that includes: investigations of more than 50 incidents regarding possible chemical exposure; a detailed analysis of the Khamisiyah plume model; a thorough review of medical literature on Pyridostigmine Bromide, depleted uranium, oil well fires, pesticides, and other related subjects; and an extensive dialogue with veterans through outreach programs. There are more than 90 projects and clinical evaluations underway to find explanations for the symptoms reported by our Gulf War veterans. In this work, we strive to identify and present all relevant facts, which we then assess to present an interim conclusion subject to modification by additional facts. We

welcome your review of our work and comments, as well as that of other interested committees of the Congress and will continue to conduct as objective and thorough an investigation into potential exposures during the Gulf War as is possible.

Sincerely,

A handwritten signature in black ink, appearing to read "Bernard Rostker". The signature is fluid and cursive, with the first name "Bernard" and last name "Rostker" clearly distinguishable.

Bernard Rostker

Enclosure

Comments on Oversight Report

Page 16 We are providing additional comments about ALS in a separate letter.

Page 18, para 7 (and at least 2 other references in the paper): Report alleges that the Czech detections on January 19th occurred along the border “where hundreds of thousands of U.S. troops were massed for the invasion.” Actually, there was only one U.S. unit within 10km of Hafir Al Batin on January 19th when and where the detection was reported.

Page 21, para 3 CIA undertook a worst case analysis of the bombing campaign and demonstrated that fall-out was unlikely. We are redoing this analysis with the expanded model used in Khamisiyah.

Page 23, para 1: MAJ Johnson testified that he did not know what happened to the tapes he made at the Kuwaiti Girl's School. One copy of the tapes was returned to the United States and evaluated by Edgewood. Another copy was provided to the British authorities. The copy from Edgewood was lost, but the British provided DoD with a copy of theirs. This copy of the Fox tapes from the Girls' school incident is in the possession of OSAGWI who is having it evaluated by independent agencies.

Page 23, para 3: GySgt Grass testified that the EOD team “...verbally acknowledged the presence of chemicals weapons in the storage area.” The report ignores the letter written to Congressman Shays by a member of the EOD team that denies (as have all EOD members) the events as relayed by Grass. They stated strongly that no chemical munitions were in that ASP. In addition, the report fails to acknowledge or account for all information brought forward in the case narrative and it should be noted, that GySgt Grass' testimony was given without inviting DoD to testify on the same incidents.

Page 23, para 6: In paragraphs 3,4 and 5, GySgt Grass testifies about the chemical agent detections he reported at ASP Orchard and Al Jaber Airfield. In fact, the Marine Breaching narrative, cited in para 6, covers different events than ASP Orchard or Al Jaber. Again, the report fails to even acknowledge the case narrative.

Page 24, para 4 The report treats Dr. Tucker as an expert but fails to subject his claims to the same review it has given to DoD. This shows an anti-DoD bias.

Page 24, para 4: Dr Tucker states that “A declassified Marine report stated that 221 respondents (about 13%) reported some contact with or detection of Iraqi chemical weapons during the ground war.” The declassified Marine report mentioned is probably the Manley Report. The Manley Report survey question, “did you encounter chemical munitions or agent threats?” is significantly different from Dr. Tucker's reported question. Nowhere in the Manley Report is there a survey question related to “Iraqi chemical weapons”

Page 25, para 1: Dr Tucker implies that a captured Iraqi document giving detailed instructions on the destruction of 31 oil wells implies that chemicals would be released in conjunction with the destruction. Iraqis were instructed to wear chemical protection gear when setting the oil wells on fire. There is nothing in the instruction about the release of chemical agents

Page 25, para 3: GySgt Grass reported that, while monitoring the oil well fires, the alarm went off and detected S Mustard. The Committee failed to interview Fox MM1 experts who could explain the Fox has difficulty on the initial pass in discriminating between the multiple ion combinations possible in the oil well fires and could mistake them for Mustard or several other CWAs. Only full spectrum analysis (and maybe a series spectrum) would identify the actual chemical warfare agents present.

Page 25, para 4: Dr Morehouse states that metal cylinders were placed downwind of the oil well fires to "...mask the plume from the canisters." The author is careful not to state what was in these "canisters or metal cylinders." It is presented in such a way as to imply chemical warfare agents, but without evidence or proof. The Committee fails to account for the destructive nature of the heat of the oil well fires.

Page 27, para 2: The report accurately states the number of US troops possibly exposed, but avoids the facts about general population limit exposure (not much more than daily living).

Page 27, para 3: Fails to provide all the details of the warning received by "the Army" from the CIA concerning the possibility of chemical weapons at Khamisiyah.

Page 27, para 5: Correctly reports UNSCOM's testimony to the PAC, but fails to report that their testimony goes on to state that they found no evidence of chemical munitions movement into Kuwait (or south of Khamisiyah).

Page 29, para 1 & 3: It appears that we take the Iraqis at their word when "they admit the existence" of a BW or CW program, but "Iraq's denials ... should not be taken at face-value." By selectively choosing what we want to believe and what we don't, the report is able to paint any picture it wants. The report fails to acknowledge the biological testing of the Navy Forward Lab which tested for and found no biological agents.

Page 36, paragraph 1. The report notes that the first fires were set around 17 January, 1991. This is a true statement. The implication that large numbers of U.S. troops were exposed to high levels of contaminants for an additional month is inaccurate. While some exposure to oil fire smoke occurred as the result of the January fires, these fires involved a limited number of wells (about 60) and the release of airborne contaminants paled in comparison to the levels reached as the result of the destruction inflicted on over 900 wells, the vast majority of which occurred in the February 24 - 28, 1991 time-frame.

Page 37, paragraph 1. Scott Russell states that U.S. troops were ill-equipped in terms of personal protective equipment available to protect against exposure to oil fire smoke, but that civilian contractors were well equipped. Military-issued personal protective equipment other than MOPP was limited and varied, and there appeared to be no consistent policy or directive on how and when to use the equipment that was available. It is incorrect to suggest, however, that civilian contractors brought in to fight the fires were any more protected than the troops. Conversations with numerous fire fighters who fought the blazes in Kuwait indicated that while more specialized equipment may have been available, the only protective equipment that was used included Nomex fire retardant suits and hard hats. Fire-fighters did not, as general practice, wear "chemical" suits nor did they use self-contained breathing apparatus because of its tendency to obstruct the wearer's vision when the lenses became coated with spraying oil, soot, and other debris from the burning wells. [We have pictures available to substantiate this.]

Page 38 - 39. Statement by Mr. Craig Stead. Mr. Stead's comments regarding the shortcomings of the USAEHA 1994 Final Report are correct. The health risk assessment conducted was based on data collected from May to December 1991, and did not include an assessment of risk for troops exposed during the period of February to April 1991 when the oil fires were at their peak and the climatic/atmospheric conditions the worst. Furthermore, and this point was not noted in Mr. Craig's comments, the USAEHA report only included a risk assessment for those troops stationed or located near the sites where the air monitoring/sampling was conducted. These limitations in the USAEHA analysis was known at the time of publication and were noted in the report. Mr. Craig's comments fail to note, however, that current investigations and analyses being performed by this organization and supported by USCHPPM (U.S. Army Center for Health Promotion and Preventive Medicine), formerly known as USEAHA, are addressing these issues. Ongoing analyses will predict troop exposures and associated risks, based on accepted modeling techniques, for the entire period in which troops were in Kuwait and Saudi Arabia. In addition the investigation will include an estimate of risk for all troops in theater, regardless of location, and not solely those who were in the vicinity the air monitoring sampling locations.

Page 39, para 2. The USAEHA study did not conclude, as Mr. Stead suggests, that the oil field fires presented no health hazards to the troops. The report states: "The results of this HRA indicate the potential for significant long-term adverse health effects for the exposed DOD troop or civilian employee populations is minimal." Further, the USAEHA report did not deny the fact that short-term acute health responses (e.g., coughing, sneezing, vomiting, black nasal discharges, etc.) to oil fire smoke did occur.

Page 39, para 3. The report states that the U.S. Army Intelligence Agency January 1991 study (correct citation: "Kuwait: Serious Oil fire, Gas and Smoke Dangers", Applied Technologies Branch, Science Division, FSTC Author, AST-2660Z-148-90, January 9, 1991) refutes the findings of the USAEHA report. The Army Intelligence Agency report discusses the *physical* hazards associated with exposure to oil well fires. It speaks to the dangers of fire, heat, explosions, shock, and poisons associated with burning and

damaged well heads. The USAEHA report, on the other hand, addresses the *health* hazards from the inhalation, ingestion, and dermal adsorption of oil fire contaminants. It predicts expected increases in the incidence of cancer cases and hazards to the body's internal system (e.g., heart, respiratory, kidney, etc.). The subject matter of the two reports are different and do not warrant direct comparison. In other words, the writer is attempting "to compare apples and oranges".

Page 75, para 3: The report states that DoD has focused on case narratives "...to disprove specific chemical detection incidents reported by military specialists...." DoD has focused its efforts on determining the facts associated with reported chemical incidents. There is no preconceived outcome of our investigation. If the facts prove or disprove the reported incidents, then that is what DoD reports. In addition, it is the Committee's report that has failed to account for all the information developed in the case narratives and has even ignored letters from service members sent to the Committee when the letters present new information that does not fit the bias of the Committee.

Page 87, para 4: Report cites as proof of chemical weapons in Kuwait UNSCOM testimony of the movement of chemical weapons to Khamisiyah. However, Khamisiyah is not in Kuwait. In fact, UNSCOM reports that chemical weapons (122/155 mm) never went south of Khamisiyah which implies that they were not in the Marine section.

Page 87, para 3: Report correctly reports GySgt Grass's report of Fox chemical alerts. There is nothing in GySgt Grass' testimony that he "added any doubt he may have had as to the accuracy of the readings was eradicated when he noticed the international symbol for poison - the skull and crossbones - emblazoned on yellow tape, boxes of ammunition, and posted signs." In fact, his testimony is that he saw yellow tape with skull and crossbones but, he never claimed to have linked the tape to "the international symbol for poison." he never stated that the skull and crossbones were on the boxes of ammunition, only on the yellow tape, and he never doubted the accuracy of his readings.

Page 88, para 4-6: Mr Tuite claims that the 19 January, 1991, bombings resulted in widespread exposure to U.S. Troops to chemical warfare agents. The possibility of a chemical detection on 19 January, 1991, is addressed in OSAGWI's Czech-French case narrative (not yet released). We are aware of no "widespread exposure" because only one U.S. unit was at Hafir Al Batin, where the detection was reported. The detection was for a very low level of chemical for a very short period of time. There was never a U.S. confirmation with an M256 kit or any other detection. Additionally, OSAGWI is investigating and will model the plumes resulting from the coalition bombing campaign, including bombings on 19 January, 1991.

Page 93, para 8: Report states that "oxidized particles [of DU] are ... absorbed through the skin." DU is not absorbed through the skin. It must be ingested or enter as a result of a wound.

Page 129 last para - Page 130 first para: The proposals in the committee's report would provide a means for anyone to establish, and thereby automatically validate, his/her own medical record of treatment and of vaccines received exclusive of any subsequent documentation. Once established the veteran could then file for compensation citing as proof the very records that he/she established. Medical records are never created *de novo* several years after the fact.



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

JUL 8 1997

Mr. Henry L. Hinton, Jr.
 Assistant Comptroller General
 National Security and International Affairs Division
 U.S. General Accounting Office
 Washington, DC 20548

Dear Mr. Hinton:

This is the Department of Defense (DoD) response to the General Accounting Office (GAO) draft report, "GULF WAR ILLNESS(sic): Improved Monitoring of Clinical Progress and Re-examination of Research Emphasis Needed," dated May 19, 1997 (GAO Code 713002), OSD Case 1364. The DoD only partially concurs with the draft report. While the thrust of some of the recommendations has merit, the report suggests some misunderstanding of both DoD clinical and research programs and the role these programs play in understanding Gulf War veterans' illnesses. More importantly, the recommendations do not fully take into account the complex set of health outcomes related to the Gulf War and fail to recognize the significant accomplishments of the Department as noted by the Institute of Medicine and Presidential Advisory Committee.

Preceding this GAO report, there have been several independent assessments of Gulf War veterans' illnesses and the DoD and VA research and clinical programs. The Institute of Medicine, in independent reviews, concluded that: "The DoD has made conscientious efforts to build consistency and quality assurance into this program at the many medical treatment facilities and regional medical centers across the country. This nationwide effort was implemented relatively quickly. The committee commends the DoD for its efforts to provide high-quality medical care in the Comprehensive Clinical Evaluation Program (CCEP) and the success it has achieved to date in developing the infrastructure necessary to efficiently contact, schedule, refer and track thousands of patients through the system." "...Signs and symptoms without diagnosis or apparent cause are found in every medical practice; clinical medicine is neither perfect nor all-knowing. Although physicians may fail to provide a medical reason for some of these signs and symptoms, the illnesses and related disability have to be addressed as well as possible, independent of efforts to understand causes. All of us in the health care and public health fields are committed to using the scientific study methods available to us in an attempt to understand and better explain what is presently known. Only in this way can we make progress in defining, preventing and treating disease."

Appointed by President Clinton, the Presidential Advisory Committee on Gulf War Veterans' Illnesses concluded that: "...the government is...providing appropriate medical care to Gulf War veterans and has initiated research in the areas most likely to illuminate the causes of their illnesses." "...for the most part, the government has acted in good faith to address veterans'

health concerns." "...the government's current research portfolio on Gulf War veterans' illnesses is appropriately weighted toward epidemiologic studies and studies on stress-related disorders that are more likely to improve our understanding of Gulf War veterans' illnesses. For the most part, the government's prioritization process has worked."

This report differs from these independently derived findings, upon which much of the DoD and VA research and clinical programs are based, without having carried out the level of careful and thoughtful assessments carried out by the Institute of Medicine Committees and the Presidential Advisory Committee.

The detailed DoD comments on the GAO recommendations are provided in the enclosure. The DoD appreciates the opportunity to comment on the GAO draft report.


Edward D. Martin, M.D.

Acting Assistant Secretary of Defense

Enclosure:
As stated

GAO DRAFT REPORT - DATED MAY 19, 1997
OSD CASE 1364, GAO CODE 713002

**"GULF WAR ILLNESS(sic): IMPROVED MONITORING OF CLINICAL
PROGRESS AND RE-EXAMINATION OF RESEARCH EMPHASIS NEEDED"**

**DEPARTMENT OF DEFENSE COMMENTS ON
THE GAO RECOMMENDATIONS**

RECOMMENDATION 1: The GAO believes that efforts to monitor Gulf War veterans' clinical status are necessary to provide direction to the research agenda and to ensure that veterans are receiving appropriate and effective treatments. Moreover, the Institute of Medicine and at least one veterans' service organization have also highlighted the importance of monitoring the progress of Gulf War veterans. We agree with these organizations and recommend that the Secretaries of Defense and Veterans Affairs develop and implement plans to monitor the clinical progress of veterans who have participated in their postwar examination programs. (p.13 / GAO Draft Report)

DoD RESPONSE: Partially concur. The DoD established the Comprehensive Clinical Evaluation Program (CCEP) as a clinical rather than a research program to provide health care to veterans who may be experiencing health problems possibly related to their service in the Persian Gulf. The CCEP process has been reviewed by a series of nationally recognized expert panels including the Presidential Advisory Committee and groups from the Division of Health Promotion and Disease Prevention - Institute of Medicine (IOM). Each of the panels included distinguished clinicians, scientists, and scholars across multiple disciplines. The IOM committees specifically commended the DoD for "its efforts to provide high quality medical care and success in developing the infrastructure necessary to efficiently contact, schedule, refer and track thousands of patients through the system." The IOM further concluded that there is "no clinical evidence in the CCEP for a previously unknown illness among Persian Gulf veterans." In addition to the IOM Committees, the Final Report of the Presidential Advisory Committee on Gulf War Veterans' illnesses noted, "The committee agrees with the IOM's conclusion that the clinical evaluation programs of the DoD and VA are excellent for the diagnosis and care of Gulf War veterans' illnesses." Therefore, the Department continues to operate the CCEP and to actively collaborate with VA to share information and to plan accordingly.

In keeping with the spirit of the GAO recommendation, in November 1996, the DoD requested a draft feasibility proposal to evaluate the current health status of CCEP participants. The proposal shall specifically address measures of health outcomes of CCEP participants. A proposal has been received and is currently being reviewed. Our goal is to find health outcome measures that can reflect current health status of Gulf War veterans compared with Gulf War era veterans and other appropriate comparison groups. Some of the outcome measures may include active duty attrition rates, hospitalizations,

Enclosure

ambulatory visits, medical and physical evaluation board rates, promotion rates, and mortality rates.

Relative to the Gulf War, significant information is known regarding the nature of veterans' illnesses. In April 1994, a non-Federal, independent panel of experts sponsored by the National Institutes of Health concluded that veterans appeared to be "experiencing no single disease or syndrome, but rather multiple illnesses with various overlapping symptoms and causes." This conclusion is consistent with the subsequent clinical experience of the DoD in providing systematic clinical examinations to veterans through the Comprehensive Clinical Evaluation Program (Mil Med 1997; 162(3):149-155). Over 90,000 Gulf War veterans, approximately 13 percent of the deployed force, have elected to participate in the medical programs conducted by the Departments of Defense and Veterans Affairs.

The Department embraces the contemporary approaches to utilization management, quality management, and risk management found in civilian health care and applies these approaches to all DoD beneficiaries including Gulf War veterans. Such an approach provides a more than adequate mechanism for the oversight of care provided. Whatever uncertainties may exist about the causes of Gulf War veterans illnesses, veterans are receiving appropriate and effective treatment according to standards currently in place for all patients within the DoD medical treatment facilities. The vast majority of CCEP participants have the types of diagnoses commonly seen in military and civilian primary care settings. Indeed, as in any clinical setting, the treatment of veterans in the CCEP has been according to their clinical presentation as is typical of medical practice. Finally, the fact that CCEP participants have multiple diagnoses and may see multiple providers is consistent with the experience of other health care beneficiaries. Gulf War veterans have been treated according to the same high standards of care provided to all beneficiaries within the Military Health Services System.

Nonetheless, many conditions such as chronic fatigue syndrome or depression are chronic and do not lend themselves to time-limited resolution. Civilian as well as military patients suffering from these conditions may have symptoms that persist for years. It should be noted that the DoD provides intensive follow-up to those individuals from the CCEP who require care beyond the CCEP evaluation. Specifically, at the Walter Reed Army Medical Center's Specialized Care Program, follow-up occurs at the 3, 6, 9, and 12 month intervals upon completion of the program.

All military personnel are afforded high quality comprehensive health care and follow-up in the Military Health Services System. This system of care and follow-up ensures that quality care, based on the best available medical services, is provided. The DoD has an established policy for the consolidation and expansion of centralized databases which will assess health outcomes, health care utilization patterns, and both ambulatory visits and in-patient trends. Furthermore, DoD is constructing an automated information system to monitor any medical consequence and other health-related events within individuals before, during, and after a deployment. This system will ensure

targeted prevention and control programs for those at greatest risk of deployment-related injuries or illnesses in future deployments.

The underlying theme of the GAO Report appears to be that there is a single or a few large scale Gulf War-related illnesses for which there are specific correct treatments. That conclusion is contrary to scientific evidence to date and the conclusions of at least three independent, expert scientific panels.

RECOMMENDATION 2: The GAO recommended that the Secretary of Defense, in conjunction with the Secretary of Veterans Affairs, give greater priority to research on treatment for ill veterans and on low-level exposures to chemicals and their interactive effects and less priority to further epidemiological studies. (p. 13-14 / Draft GAO Report)

DoD RESPONSE: Partially concur. This recommendation appears to be inconsistent with basic clinical and research principles. Research for effective treatment(s) or clinical trials almost always follows rather than precedes the identification of illness and epidemiological studies. Clinical and epidemiologic studies in the current research portfolio have provided and shall continue to provide appropriate information for further research that shall benefit the population in question. The Medical Follow-up Agency of the IOM said specifically on page 25 of their final report, "Even when considering the difficulties and cautions in interpreting research as described above, the committee believes that there is a sound basis for epidemiologic studies...." The GAO fails to acknowledge that research results thus far have provided accurate and conclusive results regarding causes of mortality (JAMA 1996; 275 and NEJM 1996; 335), rates and causes for hospitalizations (NEJM 1996; 335), rates and types of adverse birth outcomes (Mil Med 1996; 161 and NEJM 1997; 336), as well as many other health outcomes. Well designed clinical and epidemiologic studies that compare specific health outcomes within distinct groups of individuals with appropriate comparison or control groups are extremely important and remain a valid approach to better understanding Gulf War health issues. These studies do not lose their importance if validated exposure data are difficult to obtain. The findings from these studies can help identify areas for future research.

In keeping with the GAO recommendation, however, DoD and VA are committed to better understanding the possible health effects of exposure to sub-clinical levels of chemical warfare agents and other environmental hazards. As of December 1996, more than \$15 million was allocated in the area of subclinical exposures to chemical warfare nerve agents and health effects from other hazardous exposures including possible interactive effects. As with all Persian Gulf-related health research managed by DoD, scientific proposals are formally solicited by an announcement in the Commerce Business Daily. All proposals are then anonymously peer-reviewed by experienced panels of independent experts and rated for scientific merit. The Research Working Group of the Persian Gulf Veterans' Coordinating Board then selects the best proposals based on scientific merit and program relevance, ensuring a balanced research portfolio across multiple fronts. We do agree that research into environmental factors is critical. Our current research effort for 1997 includes \$10 million extramural research targeted at

possible health effects of exposure to chemical warfare agents or other toxins, as well as combinations of inoculations and investigational new drugs. An additional \$5 million of joint DoD and VA research money is committed to study stress, somatization disorders and possible health effects of exposure to subclinical chemical warfare agents.

Throughout this report, GAO has criticized the findings and recommendations of a committee of nationally recognized experts, called together by the President of the United States, to better understand the health issues of Gulf War veterans. While it would be inappropriate for the Department to comment on the GAO findings related to the Presidential Advisory Committee, we are surprised that several key Presidential Advisory Committee findings were dismissed since this expert panel conducted an extensive, 18-month investigation that included multiple field hearings.

RECOMMENDATION 3: The GAO recommended that the Secretaries of Defense and Veterans Affairs refine the correct approaches of the clinical and research programs for diagnosis of post-traumatic stress disorder consistent with suggestions recently made by the Institute of Medicine. (p. 14 / GAO Draft Report)

DoD RESPONSE: Partially concur. Both organizations have already designed and initiated clinical and research programs to better understand Post-Traumatic Stress Disorder (PTSD), as well as other stress-related health outcomes. Multiple expert panels including the Defense Science Board, National Institutes of Health Consensus Panel, two IOM panels and the Presidential Advisory Committee have all recognized that stress is an important contributing factor to the broad range of illnesses, including PTSD, being reported by Gulf War veterans. Replicated studies have shown an association between stress and PTSD and other conditions in both clinical and population studies. Given the clinical nature of the CCEP, it is not surprising that approximately 5% of CCEP participants have a diagnosis of PTSD and that this observation is higher than that reported in population based studies. In 1997, DoD and VA will publish a solicitation and commit at least \$5 million for both basic and applied stress-related research. Furthermore, DoD and VA have nationally recognized experts at medical referral centers to assist clinicians in the diagnoses and treatments related to PTSD.

The CCEP uses state-of-the-art instruments for the diagnosis of Post-Traumatic Stress Disorder and other psychological conditions. The Clinician-Administered PTSD Scale (CAPS) is the structured interview used to assess for the presence and severity of PTSD. Empirical research has shown that the CAPS is a valid and reliable instrument for this purpose and is the instrument of choice among scientists studying individuals with PTSD. The Structured Clinical Interview derived from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) is used extensively in psychiatric research to measure psychological conditions. It was selected for use in CCEP because it provides the most accurate, comprehensive, and reproducible diagnostic assessment for psychological conditions currently available. These measures are used for all CCEP patients warranting the phase II multispecialty assessment. Patients referred for

psychological assessment undergo similarly extensive and validated neuropsychological and psychological testing.



OFFICE OF THE SECRETARY OF DEFENSE

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17 JUN 1987

Mr. Henry L. Hinton, Jr.
Assistant Comptroller General
National Security and International Affairs Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Hinton:

As was discussed with your staff, we are providing additional input for GAO's report, "Gulf War Illness - Improved Monitoring and Re-examination of Research Emphasis Needed", beyond that provided in our June 9th letter. (See attachment.) Our intention in providing this input is to assist GAO in producing a factually correct and useful report for the Congress. However, its value, especially to Gulf War veterans, is heavily dependent upon being factually correct and drawing supportable conclusions from those facts. Its added value is heavily dependent upon the extent to which it builds upon and rises above the foundation laid by many preceding efforts. As for the current draft, unfortunately, very little is new.

Virtually all of these facts and conclusions, in the draft we have for review, have been surfaced before by efforts inside and outside the government. We understand well the shortcomings of the past. We have owned up to them on many occasions. But most importantly, we have taken the lessons learned and applied them both to caring for our Gulf War veterans and protecting our troops in the future.

Over the past several years, much work has been done to ensure that we take care of our Gulf War veterans, understand Gulf War illnesses and their causes, and protect our troops during future deployments. Many parties have played a constructive role in that effort, including Departments of Defense (DoD), Veterans Affairs (VA) and Health and Human Services, the Institute of Medicine (IOM) and the Presidential Advisory Committee (PAC). While much more remains to be done, much more of this multiagency effort needs to be recognized by the GAO.

With respect to the factual basis for the GAO study and the subsequent conclusions, we want to make several points.

- Since the beginning of the VA and DoD clinical programs, we have had in place systems to ensure that quality care, using the best available medical science, is being provided to our Gulf War veterans. What we are adding, as we advised the PAC some time ago, is a strategy to look at a sample of our patients and their progress over time.
- Both epidemiological studies and studies on potential causes need to be pursued aggressively. The GAO study mistakenly assumes that the difficulty in carrying out Gulf War epidemiological studies reduces their importance and continuing contribution.

- Working through the Persian Gulf Veterans Coordinating Board, the three Departments have had a coherent research plan, reviewed positively by the PAC and IOM and shared with the Congress, for quite some time. The GAO study fails to recognize that fact.
- In GAO's criticisms of "government conclusions", GAO discounts the considerable work done by the PAC and by the three Departments and overstates the extent to which the government has arrived at "conclusions." As we have stated on many occasions, our work on determining the causes of Gulf War veterans illnesses continues.

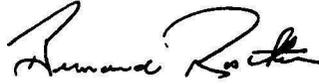
Even in the title of the report, there is no recognition of progress or commitments already made.

Again, focusing on the past and failing to acknowledge the enormous progress made does not serve well either the Congress or Gulf War veterans. We hope you will make the changes necessary for a report that is to serve well the Congress and our Gulf War veterans and their families.

Sincerely,



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Enclosure
As Stated

United States General Accounting Office

GAO

Testimony
Before the Committee on Veterans Affairs, House of
Representatives

For Release on Delivery
Expected at
1:00 p.m., EST
Thursday,
February 5, 1998

GULF WAR ILLNESSES

Research, Clinical Monitoring, and Medical Surveillance

Statement of Donna Heivilin, Director of Planning and
Reporting, National Security and International Affairs Division



Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss two recent GAO reports that responded to congressional mandates¹ regarding health care issues of military personnel deployed for military operations overseas. In the first, we reported on the government's clinical care and medical research programs relating to illnesses suffered by Gulf War veterans.² For the second, we assessed the medical surveillance³ of military personnel in Bosnia.⁴ Based on these two reports, I will discuss four issues:

- the adequacy of the mechanisms used by the Department of Defense (DOD) and Veterans Affairs (VA) to monitor the quality, appropriateness, and effectiveness of Gulf War veterans' care and to follow up on their clinical progress over time;
- the government's research strategy for studying Gulf War veterans' illnesses and the methodological problems posed in its studies;

¹National Defense Authorization Act for Fiscal Year 1997 (P.L. 104-201, sec. 744, Sept. 23, 1996).

²Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed (GAO/NSIAD-97-163, June 23, 1997).

³Medical surveillance involves the regular or repeated collection, analysis, and dissemination of uniform health information.

⁴Defense Health Care: Medical Surveillance Improved Since Gulf War, but Mixed Results in Bosnia (GAO/NSIAD-97-136, May 13, 1997).

- the consistency of key official conclusions with available data on the causes of Gulf War veterans' illnesses; and
- the extent to which DOD's efforts for Operation Joint Endeavor in Bosnia were successful in overcoming the medical surveillance problems encountered during the Gulf War.

We are currently working on several related studies requested by other congressional committees. For example, we are looking at the incidence of tumors among Gulf War veterans; the possible presence of antibodies for synthetic squalene³ in blood samples of Gulf War veterans; the processes, methods, and criteria used by the Persian Gulf Veteran's Coordinating Board (PGVCB),⁴ DOD, and VA to approve or disapprove research protocols; and the extent to which ongoing research can provide information on what caused Gulf War veterans' illnesses. We will be happy to share the results of this work with you once it is completed.

RESULTS IN BRIEF

I will first summarize our findings on the four issues and then provide detailed information on them. In our report on Gulf War veterans' illnesses, we noted that while DOD and VA had provided

³Squalene is an acyclic hydrocarbon that is widely distributed in nature but is unhealthful to humans in synthetic form.

⁴The PGVCB, which comprises the Secretaries of Defense, Veterans Affairs, and Health and Human Services, was charged with coordinating the federal response to Gulf War veterans' illnesses.

care to eligible Gulf War veterans, they had no system for following up on their health to determine the effectiveness of their care after initial treatment. Also, because of methodological problems and incomplete medical records on the veterans, research has not come close to providing conclusive answers on the causes of the illnesses. Given the data needed versus what is available, which is primarily anecdotal, it will be very difficult, if not impossible, to determine the causes of the illnesses. Finally, the support for some official conclusions regarding stress, leishmaniasis (a parasitic infection), and exposure to chemical agents was weak or subject to other interpretations.

Regarding our report on the medical surveillance of servicemembers deployed in Bosnia, while we found that DOD had improved its capability to monitor and assess the effects of deployments on servicemembers' health since the Gulf War, certain problems remained: the database containing deployment information was inaccurate, not all troops received postdeployment medical assessments, and many of the medical records we reviewed were incomplete.

After I have provided details on the findings of our reports, I will discuss our reports' recommendations, the relevant agencies' comments on them, and our evaluation of those comments.

BACKGROUND

Before providing you details on the results of our work, let me briefly provide some background information. During service associated with the Gulf War, many of the approximately 700,000 veterans might have been exposed to a variety of potentially hazardous substances. These substances include compounds used to decontaminate equipment and protect it against chemical agents, pesticides, vaccines, and drugs to protect against chemical warfare agents (for example, pyridostigmine bromide). Following the postwar demolition of Iraqi ammunition facilities, some veterans might also have been exposed to the nerve agent sarin.

Over 100,000 of the approximately 700,000 Gulf War veterans have participated in DOD and VA health examination programs established between 1992 and 1994. Of those veterans examined by DOD and VA, nearly 90 percent have reported a wide array of health complaints and disabling conditions, including fatigue, muscle and joint pain, gastrointestinal complaints, headaches, depression, neurologic and neurocognitive impairments, memory loss, shortness of breath, and sleep disturbances. Some of the veterans fear that they are suffering from chronic disabling conditions because of exposure during the war to substances with known or suspected health effects.

In 1992, VA established a program through which Gulf War veterans could receive medical examinations and diagnostic services. Participants received a regular physical examination with basic laboratory tests. In 1994, VA established a standardized examination to obtain information about exposures and symptoms related to diseases endemic to the Gulf region and to order specific tests to detect the "biochemical fingerprints" of certain diseases. If a diagnosis was not apparent, veterans could receive up to 22 additional tests and additional specialty consultations. In addition, if the illness defied diagnosis, the veterans could be referred to one of four VA Persian Gulf referral centers.

In 1994, DOD initiated its Comprehensive Clinical Evaluation Program, through which it used a clinical protocol and provided diagnostic services similar to those of the VA program.

In examining the causes of Gulf War veterans' illnesses, the Presidential Advisory Committee on Gulf War Veterans' Illnesses and the Institute of Medicine confirmed the need for effective medical surveillance capabilities. They found that research efforts to determine the causes of the veterans' illnesses were hampered by incomplete data on (1) the names and locations of deployed personnel, (2) the exposure of personnel to environmental health hazards, (3) changes in the health status of personnel while deployed, and (4) immunizations and other health services for personnel while deployed.

Subsequently, in May 1997, we reviewed the actions DOD had taken since the Gulf War to improve its medical surveillance capabilities. Specifically, we determined what medical surveillance procedures DOD had used in Operation Joint Endeavor, which was conducted in the countries of Bosnia-Herzegovina, Croatia, and Hungary, and whether DOD had corrected the problems that surfaced during the Gulf War.

DOD AND VA HAD NO SYSTEMATIC APPROACH TO MONITORING
GULF WAR VETERANS' HEALTH AFTER INITIAL EXAMINATION

DOD and VA officials claimed that regardless of the cause of Gulf War veterans' illnesses, the veterans had received appropriate and effective symptomatic treatment. Both agencies tried to measure or ensure the quality of veterans' initial examinations by training health care specialists and maintaining standards for physicians' qualifications. However, these mechanisms did not ensure a given level of effectiveness for the care provided or help to identify the most effective treatments.⁷

Beyond the initial examination, neither DOD nor VA had mechanisms for monitoring the quality, appropriateness, or effectiveness of these veterans' care or clinical progress, and they had no plans to establish such mechanisms. VA officials told us that they regarded

⁷See VA Health Care: Observations on Medical Care Provided to Persian Gulf Veterans (GAO/T-HEHS-97-158, June 19, 1997).

monitoring the clinical progress of registry participants as a separate research project, and officials from DOD's Clinical Care and Evaluation Program made similar comments.

We noted that such monitoring was important because (1) undiagnosed conditions were not uncommon among ill veterans, (2) treatment for veterans with undiagnosed conditions was based on their symptoms, (3) veterans with undiagnosed conditions or multiple diagnoses might see multiple providers, (4) follow-up could provide a better understanding of the clinical progression of the illnesses over time, and (5) the success or failure of physicians' treatments of Gulf War veterans could be identified. Without follow-up of their treatment, DOD and VA cannot say whether these ill veterans are any better or worse today than when they were first examined.

MOST OF THE FEDERALLY FUNDED RESEARCH WAS ONGOING.
AND SOME HYPOTHESES WERE NOT INITIALLY PURSUED

Federal research on Gulf War veterans' illnesses and factors that might have caused their problems was not pursued proactively. Although these veterans' health problems began surfacing in the early 1990s, the vast majority of research was not initiated until 1994 or later, and much of that responded to legislative requirements or external reviewers' recommendations. This 3-year delay complicated the researchers' tasks and limited the amount of completed research available. Of the 91 studies receiving federal

funding, over 70 had not been completed at the time of our review. The results of some studies will not be available until after 2000.

While research on exposure to stress was emphasized in earlier studies, research on low-level chemical exposure was not pursued until legislated in 1996. The failure to fund such research could not be traced to an absence of proposals. According to DOD officials, three recently funded proposals on low-level chemical exposure had previously been denied funds because, at the time, DOD did not believe that U.S. troops had been exposed to chemical warfare agents.

We found that additional hypotheses were pursued in the private sector. A substantial body of this research suggests that low-level exposure to chemical warfare agents or chemically related compounds, such as certain pesticides, is associated with delayed or long-term health effects. For example, animal experiments, studies of accidental human exposures, and epidemiological studies of humans offer evidence that low-level exposures to certain organophosphorus compounds,⁸ including sarin nerve agents to which some of our troops may have been exposed, can cause delayed, chronic neurotoxic effects.

⁸Organophosphates are used in many pesticides and chemical warfare agents, and sarin has been used as a chemical warfare agent since World War II, most recently during the Iran-Iraq war and by terrorists in Japan.

It was suggested that the ill-defined symptoms experienced by Gulf War veterans might be due in part to organophosphate-induced delayed neurotoxicity. This hypothesis was tested in a privately supported epidemiological study of Gulf War veterans.⁹ The study clarified the patterns among veterans' symptoms through the use of statistical factor analyses and demonstrated that vague symptoms of the ill veterans were associated with brain and nerve damage compatible with the known chronic effects of exposures to low levels of organophosphates. It further linked the veterans' illnesses to exposure to combinations of chemicals, including nerve agents, insect repellents, and pyridostigmine bromide tablets.

Toxicological research indicates that pyridostigmine bromide, which Gulf War veterans took to protect themselves against the immediate, life-threatening effects of nerve agents, may alter the metabolism of organophosphates in ways that activate their delayed, chronic effects on the brain. Moreover, exposure to combinations of organophosphates and related chemicals like pyridostigmine bromide has been shown in animal studies to be far more likely to cause morbidity and mortality than any of the chemicals acting alone.

Aside from the hypotheses being emphasized in the research being done, we found that the bulk of ongoing federal research on Gulf War veterans' illnesses was focused on the epidemiological study of

⁹This research, conducted at the University of Texas Southwestern Medical Center, has been supported in part by funding from the Perot Foundation.

the prevalence and cause of the illnesses. It is important to note that to conduct such studies, investigators must adhere to basic, generally accepted principles.

First, investigators must specify diagnostic criteria to (1) reliably determine who has the disease or condition being studied and who does not and (2) select appropriate controls (people who do not have the disease or condition). Second, they must have valid and reliable methods of collecting and relating data on past exposure(s) of those in the study to possible factors that may have caused the symptoms. The need for accurate, dose-specific exposure information is particularly critical when low-level or intermittent exposure to drugs, chemicals, or air pollutants is possible. It is important not only to assess the presence or absence of exposure but also to characterize the intensity and duration of exposure.

The epidemiological federal research we examined had two methodological problems: the lack of a case definition (that is, a reliable way to identify individuals with a specific disease) and the absence of accurate exposure data. Without valid and reliable data on exposures and the multiplicity of agents to which the veterans were exposed, researchers will likely continue to find it difficult to detect relatively subtle effects and to eliminate alternative explanations for Gulf War veterans' illnesses. Prevalence data can be useful, but it requires careful interpretation in the absence of better information on the factors

to which veterans were exposed. While multiple federally funded studies on the role of stress in the veterans' illnesses have been done, basic toxicological questions regarding the substances to which they were exposed remain unanswered.

The ongoing epidemiological research cannot provide precise, accurate, and conclusive answers regarding the causes of veterans' illnesses because of these methodological problems as well as the following:

- Researchers have found it extremely difficult to gather information about exposures to such things as oil-well fire smoke and insects carrying infection.
- Medical records of the use of pyridostigmine bromide tablets and vaccinations to protect against chemical/biological warfare exposures were inadequate.
- Gulf War veterans were typically exposed to a wide array of agents, making it difficult to isolate and characterize the effects of individual agents or to study their combined effects.
- Most of the epidemiological studies on Gulf War veterans' illnesses have relied only on self-reports for measuring most of the agents to which veterans might have been exposed.

- The information gathered from Gulf War veterans years after the war may be inaccurate or biased. There is often no straightforward way to test the validity of self-reported exposure information, making it impossible to separate bias in recalled information from actual differences in the frequency of exposures. As a result, findings from these studies may be spurious or equivocal.

- Classifying the symptoms and identifying veterans' illnesses have been difficult. From the outset, the symptoms reported have been varied and difficult to classify into one or more distinct illnesses. Moreover, several different diagnoses might provide plausible explanations for some of the specific health complaints. It has thus been difficult to develop a case definition.

SUPPORT FOR KEY GOVERNMENT CONCLUSIONS WAS
WEAK OR SUBJECT TO ALTERNATIVE INTERPRETATIONS

Six years after the war, little was conclusively known about the causes of Gulf War veterans' illnesses. In the absence of official conclusions from DOD and VA, we examined conclusions drawn in December 1996 by the Presidential Advisory Committee on Gulf War Veterans' Illnesses. In January 1997, DOD endorsed the Committee's conclusions about the likelihood that exposure to 10 commonly cited chemical agents contributed to the explained and unexplained

illnesses of these veterans. We found the evidence to support three of these conclusions to be either weak or subject to alternative interpretations.

First, the Committee concluded that stress was likely a contributing factor to Gulf War veterans' illnesses. While stress can induce physical illness, the link between stress and these veterans' physical symptoms has not been firmly established. For example, a large-scale, federally funded study concluded that stress and exposure to combat or its aftermath bear little relationship to the veterans' distress. The Committee also stated that "epidemiological studies to assess the effects of stress invariably have found higher rates of posttraumatic stress disorder (PTSD) in Gulf War veterans than among individuals in nondeployed units or in the general U.S. population of the same age."

Our review indicated that the prevalence of PTSD among Gulf War veterans might be overestimated due to problems in the methods used to identify it. Specifically, the studies on PTSD to which the Committee referred did not exclude other conditions, such as neurological disorders that produce symptoms similar to PTSD and can also elevate scores on key measures of PTSD. Also, the use of broad and heterogenous groups of diagnoses (e.g., "psychological conditions"--ranging from tension headache to major depression) in data from DOD's clinical program might contribute to an

overestimation of the extent of serious psychological illnesses among Gulf War veterans.

Second, the Committee concluded that "it is unlikely that infectious diseases endemic to the Gulf region are responsible for long term health effects in Gulf War veterans, except in a small known number of individuals." Similarly, the PGVCB concluded that because of the small number of reported cases "the likelihood of leishmania tropica as an important risk factor for widely reported illness has diminished." While this is the case for observed symptomatic infection with the parasite, the prevalence of asymptomatic infection is unknown. Such infection could reemerge in cases in which the patient's immune system becomes deficient. As the Committee noted, the infection could remain dormant up to 20 years. Because of this long latency, the infected population is hidden, and because even classic forms of leishmaniasis are difficult to recognize, we noted that leishmania should be retained as a potential risk factor for individuals who suffer from immune deficiency.

Third, the Committee concluded that it is unlikely that the health effects reported by many Gulf War veterans were the result of (1) biological or chemical warfare agents, (2) depleted uranium, (3) oil-well fire smoke, (4) pesticides, (5) petroleum products, and (6) pyridostigmine bromide or vaccines. However, our review of the Committee's conclusions indicated the following:

- While the government found no evidence that biological weapons were deployed during the Gulf War, the United States lacked the capability to promptly detect biological agents, and the effects of one agent, aflatoxin, would not be observed for many years.

- Evidence from various sources indicated that chemical agents were present at Khamisiyah, Iraq, and elsewhere on the battlefield. The magnitude of exposures to chemical agents has not been fully resolved. As we reported in June 1997, 16 of 21 sites categorized by Gulf War planners as nuclear, biological, and chemical (NBC) facilities were destroyed. However, the United Nations Special Commission found after the war that not all the possible NBC targets had been identified by U.S. planners. The Commission investigated a large number of the facilities suspected by the U.S. authorities as being NBC related. Regarding those the Commission had not inspected, we determined that each was attacked by coalition aircraft during the Gulf War.¹⁰

- Exposure to certain pesticides can induce a delayed neurological condition without causing immediate symptoms.

¹⁰Operation Desert Storm: Evaluation of the Air Campaign (GAO/NSIAD-97-134, June 12, 1997), p. 2.

- Available research indicates that exposure to pyridostigmine bromide can alter the metabolism of organophosphates in ways that enhance chronic effects on the brain.

SUCCESS IN IMPROVING MEDICAL SURVEILLANCE WAS
MIXED FOR SERVICEMEMBERS DEPLOYED TO BOSNIA

In 1994, DOD began developing a directive and implementing instruction to address the problems experienced in the medical surveillance of Gulf War veterans. Although DOD had not issued this guidance when Operation Joint Endeavor began, it did develop a comprehensive medical surveillance plan in January 1996 for the Bosnia deployment. The plan included establishing a system to identify which servicemembers deployed to the theater, assessing environmental health threats, monitoring diseases and nonbattle injuries, and conducting postdeployment medical assessments.

In examining medical surveillance in Bosnia in late 1996 and early 1997, we found many remaining problems, despite DOD's attempts to implement its plan. These problems are as follows:

- First, DOD had not developed a system for accurately tracking the movement of individual servicemembers in units within the theater. Such a system is important for accurately identifying exposures of servicemembers to health hazards where they are located.

- Second, predeployment blood samples were not available for many servicemembers who deployed to Bosnia, and of the blood samples that were available in the repository for servicemembers who deployed, many were quite old.

- Third, many Army personnel did not receive required postdeployment medical assessments. Moreover, when the assessments were done, they were done much later than required.

- Fourth, the centralized database for monitoring the extent to which required medical assessments were done was incomplete for the 618 servicemembers whose medical records we reviewed. More specifically, it omitted 12 percent of the in-theater medical assessments and 52 percent of the home unit medical assessments.

- Finally, many of the medical records that we reviewed were incomplete regarding in-theater postdeployment medical assessments done, servicemembers' visits to battalion aid stations for medical treatment during deployment, and documentation of personnel being vaccinated against tick-borne encephalitis (a health threat in the theater).

METHODOLOGY

To address our first objective--the extent of DOD's clinical follow-up and monitoring of treatment and diagnostic services--we reviewed literature and agency documents and conducted structured interviews with DOD and VA officials. We asked questions designed to identify and contrast their methods for monitoring the quality and outcomes of their treatment and diagnostic programs and the health of the registered veterans.

To examine PGVCB's research strategy, we conducted a systematic review of pertinent literature and agency documents and reports. We also interviewed representatives from PGVCB's Research Working Group and officials from VA, DOD, and the Central Intelligence Agency. We surveyed primary investigators of ongoing epidemiological studies.

Because different methodological standards apply to various types of research and because the overwhelming majority of federally sponsored research is categorized as epidemiological, we limited our survey to those responsible for ongoing epidemiological studies. With the help of an expert epidemiological consultant, we devised a questionnaire to assess critical elements of these studies (including the quality of exposure measurement, specificity of case definition, and steps to ensure adequate sample size) and to identify specific problems that the primary investigators might

have encountered in implementing their studies. We interviewed primary investigators for 31 (72 percent) of the 43 ongoing epidemiological studies identified by PGVCB in the November 1996 plan. We also reviewed and categorized descriptions of all 91 projects identified by April 1997, based on their apparent focus and primary objective. Finally, to review the progress of major ongoing research efforts, we visited the Walter Reed Army Institute of Research, the Naval Health Research Center, and two of VA's Environmental Hazards Research Centers.

To address the third objective, we reviewed major conclusions of the PGVCB and the Presidential Advisory Committee on Gulf War Veterans' Illnesses to determine the strength of evidence supporting them. The purpose of this review was not to critique the efforts of PGVCB or the Presidential Advisory Committee but rather to describe the amount of knowledge about Gulf War illnesses that had been generated by research 6 years after the war. We reviewed these conclusions because they were the strongest statements that we had found on these matters by any official body. The Presidential Advisory Committee's report was significant because the panel included a number of recognized experts who were assisted by a large staff of scientists and attorneys. In addition, the Committee conducted an extensive review of the research. Thus, we believed that evaluating these conclusions would provide important evidence about how fruitful the federal research had been. We addressed this objective by reviewing extant

scientific literature and by consulting experts in the fields of epidemiology, toxicology, and medicine.

Because of the scientific and multidisciplinary nature of this issue, we ensured that staff conducting the work had appropriate backgrounds in the field of epidemiology, psychology, environmental health, toxicology, engineering, weapons design, and program evaluation and methodology. In addition, we used in-house expertise in chemical and biological warfare and military health care systems. Also, medical experts reviewed our work. Moreover, we held extensive discussions with experts in academia in each of the substantive fields relevant to this issue. Finally, we talked to a number of the authors of the studies that we cited in our report to ensure that we correctly interpreted their findings and had independent experts review our draft report.

Finally, regarding our fourth objective, we interviewed key agency officials, examined relevant information from the DOD Deployment Surveillance Team's database, and reviewed the medical records of active duty servicemembers in selected Army units in Germany who were deployed to Operation Joint Endeavor.

Our work was completed between October 1996 and April 1997 in accordance with generally accepted government auditing standards.

Appendix I contains a bibliography of research material referred to in our testimony.

RECOMMENDATIONS TO DOD AND VA

Because of the numbers of veterans who have experienced illnesses that might be related to their service during the Gulf War, we recommended in our report that the Secretary of Defense, with the Secretary of Veterans Affairs, (1) set up a plan for monitoring the clinical progress of Gulf War veterans to help promote effective treatment and better direct the research agenda and (2) give greater priority to research on effective treatment for ill veterans and on low-level exposures to chemicals and their interactive effects and less priority to further epidemiological studies.

We also recommended that the Secretaries of Defense and Veterans Affairs refine the current approaches of the clinical and research programs for diagnosing posttraumatic stress disorder consistent with suggestions recently made by the Institute of Medicine. The Institute noted the need for improved documentation of screening procedures and patient histories (including occupational and environmental exposures) and the importance of ruling out alternative causes of impairment.

While DOD agreed with the thrust of our recommendations, VA believed they "reflected a lack of understanding of clinical research, epidemiology, and toxicology." The Presidential Advisory Committee disagreed with our findings, particularly that the support for some of its conclusions was weak. Despite these disagreements with our report, none of the comments we received provided evidence to challenge our principal findings and conclusions.

In response to our recommendation regarding the treatment of Gulf War veterans, in December 1997, DOD and VA asked the Institute of Medicine to establish a committee to assess the appropriate methodology for monitoring the health outcomes and treatment efficacy for Gulf War veterans. On February 2, 1998, PGVCB informed us that it had initiated a joint program with DOD to conduct multicenter treatment trials for fibromyalgia and chronic fatigue syndrome in Gulf War veterans. It is anticipated that such a protocol will begin in late 1998 or early 1999.

In response to our recommendation on research programs, as of January 1998, according to the research working group of PGVCB, 23 studies had been added to the research portfolio, including research on the toxicology of low-level exposures to neurotoxins such as pyridostigmine bromide, insecticides, and chemical warfare nerve agents, with an emphasis on interactions among them.

In our report on the deployment and medical records for servicemembers deployed to Bosnia, we recommended that the Secretary of Defense direct the Assistant Secretary of Defense for Health Affairs, along with the military services, the Joint Chiefs of Staff, and the Unified Commands, as appropriate, to

- expeditiously complete and implement a DOD-wide policy on medical surveillance for all major deployments of U.S. forces, using lessons learned during Operation Joint Endeavor and the Gulf War;
- develop procedures to ensure that medical surveillance policies are implemented, to include emphasizing (a) the need for unit commanders to ensure that all servicemembers receive required medical assessments in a timely manner and (b) the need for medical personnel to maintain complete and accurate medical records; and
- develop procedures for providing accurate and complete medical assessment information to the centralized database.

In response to our recommendation, DOD established a new policy and implementing guidance in August 1997 and has emphasized to field commanders the importance of the system. The guidance mandated medical surveillance of servicemembers before, during, and after

military deployments and specified procedures for conducting such surveillance.

It is important to note that GAO has not evaluated DOD's, VA's, and the PGVCB's proposed plans regarding the treatment and research for Gulf War veterans' illnesses. Also, while we have reviewed DOD's new medical surveillance guidance, we have not evaluated the implementation of it. Nonetheless, we believe that if the guidance is properly implemented, DOD's medical surveillance system would be greatly enhanced.

A number of other actions--particularly legislative actions--have taken place to help ailing Gulf War veterans. In a law sponsored by this Committee (P.L. 105-114, sec. 209, Nov. 21, 1997), the Secretary of Veterans Affairs is required to set up a program, by July 1, 1998, to test new approaches to treating those veterans suffering from undiagnosed illnesses and disabilities. Also, recent defense authorization legislation (P.L. 105-85, Nov. 18, 1997), requires DOD and VA to (1) prepare a plan, by March 1, 1998, for providing appropriate health care to Gulf War veterans and (2) establish a program of clinical trials at multiple sites to assess the effectiveness of protocols for treating the veterans.

In addition to the legislation, on October 31, 1997, the Presidential Advisory Committee issued a special report in which it noted that (1) VA should move quickly to incorporate Gulf War

veterans into its case management system and (2) DOD should place a higher priority on medical surveillance to ensure that the health data problems that occurred during the Gulf War do not recur in future military operations.

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Mr. Chairman, that concludes my prepared remarks. I will be happy to answer any questions you may have.

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APPENDIX I

APPENDIX I

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(713017)

STATEMENT OF
JOSEPH THOMPSON
UNDER SECRETARY FOR BENEFITS
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

FEBRUARY 5, 1998

Mr. Chairman and Members of the Committee:

I am pleased to be here with you today to provide a status report on the adjudication of Gulf War veterans' claims and to discuss the efforts we have made to improve Gulf War programs.

On May 14, 1997, the Director of the Compensation and Pension Service testified before the Subcommittee on Benefits on the status of Gulf War claims. At that time we were halfway through a readjudication of over 10,000 Gulf War cases previously considered under the provisions of 38 CFR 3.317, governing compensation for undiagnosed illnesses. This initiative had been undertaken in July 1998 to ensure that less traditional types of evidence, specifically lay evidence, had been accorded proper weight and that information about completed claims was being correctly entered into the Gulf War

tracking system maintained by the Compensation and Pension Service.

Shortly before the May 14 hearing we had published the final regulation implementing the Secretary's decision to extend the presumptive period for undiagnosed illnesses through December 31, 2001. In our testimony, we stated that we expected a significant number of additional grants of service connection for undiagnosed illnesses because of the extended presumptive period. As of the end of April 1997, there were 4,435 cases requiring review. These cases were originally coded in the Gulf War tracking system as disallowed because of the previous 2-year presumptive period.

We also reported that the Secretary had approved VBA's recommendation to redistribute adjudication of Gulf War claims from four Area Processing Offices (APOs) to all regional offices.

Mr. Chairman, I would now like to bring the Committee up to date on where we now stand with regard to Gulf War claims adjudication.

Issues Arising from the Redistribution

At the May 14 hearing, we were aware of serious concerns that the regional offices lacked the expertise and resources to handle these claims efficiently and accurately. Many members of Congress

were understandably anxious that we develop procedures to assist the regional offices and monitor their efforts and progress in adjudicating Gulf War veterans' claims. Let me summarize the assistance we have provided.

On May 29, 1997, the Compensation and Pension Service conducted a 2-hour satellite broadcast on Gulf War issues for all offices. This was followed by an in-depth training session on June 2 and 3 at the Cleveland Regional Office for representatives from all offices. Members of the Compensation and Pension Service subsequently participated in Gulf War issue workshops on June 3 and 4 for our Eastern Area offices, on June 4 and 5 for Central Area offices, and during the week of June 23-27 for the Southern and Western Areas.

After the redistribution, the Compensation and Pension Service established a Rapid Response Team of individuals highly proficient in Gulf War issues and rating procedures. The members of this team are available to provide immediate answers to general or claims-specific questions and technical support in evaluating Gulf War disabilities. Under the leadership of the Rapid Response Team, the Compensation and Pension Service has been conducting weekly Gulf War conference calls. At these calls, information is provided on such issues as how to deal with specific disabilities, the kinds of development most useful in obtaining evidence necessary to

adjudicate a claim, how to distinguish between symptoms and actual diagnoses, and how to obtain complete physical examinations addressing the unique concept of undiagnosed illnesses. The Compensation and Pension Service held 29 Gulf War conference calls from June 25, 1997, through January 28, 1998. Additional calls have been scheduled for each Wednesday through March 25, and they will continue beyond that date unless there is a consensus that they have fully served their purpose.

The effectiveness of the regional offices in handling Gulf War cases is monitored not only by the Rapid Response Team, but also through evaluation of the results of local quality reviews conducted monthly at the regional offices. Each office is required to review a sample of its Gulf War claims as part of the local Quality Improvement program. The focus is on the areas of examinations and development, decision-making, and notification. Each office has provided a monthly report of its findings to the Compensation and Pension Service since July 8, 1997. The local Quality Improvement review provides each station a good snapshot of the technical accuracy of its claims processing and identifies areas for improvement and training. The Compensation and Pension Service shares the cumulative findings of these local reports with all offices in periodic special letters.

The Compensation and Pension Service also has undertaken several comprehensive reviews of Gulf War cases to ensure that all

required procedures and instructions are being followed by the regional offices. The Service will begin another review of 100 cases in February as part of its ongoing oversight of these cases. We expect that the review and analysis of the findings will be complete by mid-April, and we will be happy to share them with the Committee at that time. The Service uses the results of their own quality reviews, together with the local Quality Improvement reviews and feedback from the Rapid Response Team, to assess the current status of Gulf War claims processing and to determine particular areas where future training would be beneficial.

Mr. Chairman, I am deeply committed to improving the technical accuracy and processing time of compensation and pension claims adjudication to ensure that our nation's veterans receive the best service possible. As one way of pursuing this, I have established a special work group to study Compensation and Pension workload issues. One of the key areas of their study will be accuracy of claims adjudication. Gulf War claims involving undiagnosed illnesses are unique, generally more difficult than others, and have their own special requirements. Over the past three years, we have devoted a considerable amount of training to develop the expertise needed to ensure proper processing of Gulf War claims. This same degree of commitment will continue. Furthermore, I will use the findings of the special work group to achieve improvements in the accuracy of claims processing in general and Gulf War claims in particular.

A major area of concern identified through our reviews of Gulf War cases and questions from the field offices is the adequacy of medical examination reports. Thorough medical examinations are essential for accurate adjudication of these claims. Staff of the Compensation and Pension Service have been working with staff of the Under Secretary for Health to produce guidelines for conducting examinations involving undiagnosed illnesses. There is agreement that physicians who conduct C&P examinations must be familiar with the regulatory requirement that existence of an undiagnosed illness is established only when an acceptable clinical diagnosis has been ruled out through medical history, physical examination, and laboratory tests. The guidelines being developed will ensure that all issues are fully addressed during examinations. A draft of the guidelines is now under review in both VBA and VHA. Final agreement should be reached very shortly. As a supplement to these guidelines, a joint satellite video broadcast on Gulf War examinations for VHA and VBA employees will take place in early March. The tentative date is March 3.

Readjudication and Extension of Presumptive Period

At the beginning of the readjudication in July 1996, there were 10,736 cases to be reviewed, in which service connection for undiagnosed illnesses had been denied. As I stated earlier, 4,435 cases were later identified as requiring an additional review under the amended regulation extending the presumptive period for

undiagnosed illnesses. In June 1997, following the Secretary's decision to redistribute Gulf War cases from the 4 APOs, 8,477 cases were sent to the regional offices. This number included readjudication cases, presumptive-period cases, and original and reopened claims that had been filed by Gulf War veterans in the interim. Priority was given to completion of the readjudication and presumptive-period cases, and shortly after the redistribution of claims from the APOs, the regional offices began submitting to the Compensation and Pension Service weekly status reports on the progress they were making on these cases. In October 1997, the Service asked the regional offices to make every effort to complete them by December 31, 1997. However, the Service recognized that due to the extensive development and overall complexities involved in these cases, some claims would in all likelihood remain uncompleted at that date. As of February 3, there were approximately 600 cases yet to be finalized. The Compensation and Pension Service will be monitoring the regional offices' progress on these cases and will provide me with a status report each month until all cases have been completed. Let me go on record as stating that I believe the regional offices have done extremely well in reducing the number of review cases. I commend them for their efforts.

Gulf War Data

An issue of continuing interest, to VA, Congress, veterans' service organizations, and others, is "How many Gulf War veterans

are receiving service-connected compensation?" Last summer, we discovered that certain Gulf War numbers provided each month to Congress and to others were not accurate. This information cast doubt on all Gulf War numbers that emanated from our data bases. In response to growing concerns, Deputy Secretary Gober designated VA's Office of Policy and Planning as the focal point within the Department for coordinating all information pertaining to the Gulf War conflict. Under that office's guidance, the Department began to assess and evaluate VA's Gulf War data sources, determine existing gaps in the data, and establish procedures to match electronically disparate sets of data maintained by VBA, VHA, and DOD. The Department remains committed to providing the most accurate and complete data possible.

For our own part, we in VBA have been working closely with the Office of Policy and Planning and the Defense Manpower Data Center to identify all veterans who served in the Gulf War Theater and to ensure that those who have filed claims with VA are properly recorded in existing information systems. We also want to ensure that the indicators used to identify Gulf War veterans records in our data bases are not removed through accident or mistake. Because our efforts are still a "work in progress," we provide the following numbers recognizing that each of our information systems has limitations that may impact on accuracy.

These remarks being made by way of caveat, preliminary data from our Gulf War Management Information System, dated October 15, 1997, showed that we are paying compensation to 90,665 veterans who served in the Gulf War Theater at some point during the Gulf War era (which runs from August 2, 1996, through the present). Of the 90,655 veterans receiving compensation, 74,133 served in the Gulf theater during the period of hostilities, defined as lasting through July 31, 1991. Another 45,630 Gulf War Theater veterans had service-connected disabilities for which no compensation is being paid. Of these 45,630 veterans, 37,253 served in theater during the period of hostilities.

Let me also say a few words about data on Gulf War veterans who are have service-connected disabilities due to undiagnosed illnesses, which I know is a subject of particular interest to this Committee. On the basis of information from the Gulf War tracking system as of January 27 of this year, 2,306 veterans have been granted service connection for disabilities resulting from undiagnosed illnesses. Information from our benefits delivery network extracted on January 15, shows 1,590 veterans have been service connected for undiagnosed illnesses. Because of the differences and limitations of the two systems, we expect some discrepancies in the date extracted. We are currently matching these two groups of records and reviewing a sample of each to explain in detail the differences and correct any errors that are not legitimate. We will provide you an interim report on this effort by March 15. This report will contain a timetable for

complete resolution of these data issues. Let me assure you, Mr. Chairman, that in this matter as in all matters involving Gulf War data, we are working constantly with VA's Office of Policy and Planning to refine and improve the information we provide to ensure that it is as accurate and complete as possible.

Mr. Chairman, this concludes my testimony. I will now be happy to answer any questions that you and other members of the Committee might have.

GAO

**United States General Accounting Office
Testimony**

**Before the Committee on Veterans' Affairs,
House of Representatives**

**For Release on Delivery
Expected at 1:00 p.m.
Thursday, February 5, 1998**

VETERANS' BENEFITS

**Improvements Made to
Persian Gulf Claims
Processing**

**Statement of Stephen P. Backhus, Director
Veterans' Affairs and Military Health Care Issues
Health, Education, and Human Services Division**



Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss the Department of Veterans Affairs' (VA) adjudication of veterans' claims for compensation for undiagnosed illnesses that resulted from their service in the Persian Gulf War. As you know, in November 1994, the Congress enacted legislation allowing VA to pay compensation benefits to veterans for Persian Gulf-related undiagnosed illnesses. In May 1996 we reported deficiencies in VA's processing of the nearly 8,000 undiagnosed illness claims VA had evaluated.¹ More specifically, we reported that VA did not provide clear and useful information to veterans about the types of evidence needed to support a claim. We also stated that VA did not always provide veterans with required assistance by obtaining relevant evidence for the claims. In response to our report and concerns raised by others, VA made the decision to readjudicate previously denied Persian Gulf claims related to undiagnosed illness.

My comments today will focus on information we have gathered at your request on VA's efforts to improve Persian Gulf claims processing and its effect on the readjudication of claims previously denied. Our information is based on analyzing a statistical sample of the approximately 11,000 undiagnosed illness claims that VA had initially denied and is now readjudicating as well as discussions with officials at VA headquarters and regional offices, and veterans service organizations.

In summary, VA has taken steps to help improve its processing of Persian Gulf claims. Specifically, in July 1996, VA issued guidance to help ensure that procedures for processing Persian Gulf claims are followed by requiring claims processors to provide veterans with clear and useful information regarding the types of evidence that could be used to support their claims. Such evidence includes records of medical exams and time lost at work. The guidance also requires claims processors to properly consider these pieces of evidence and thoroughly follow up on information that may support the claims. Also, to help improve the timeliness of VA's actions on Persian Gulf claims, in May 1997, VA decentralized the processing of those claims from 4 to all 58 of its regional offices and began providing training to regional office staff on processing the claims.

Because VA only recently began some of the initiatives to help improve the processing of Persian Gulf claims, the full impact of the initiatives is uncertain at this time. However, our follow-up review indicates that VA, for the most part, has followed its procedures in readjudicating the previously denied cases. For example, in all the cases we reviewed, VA had provided veterans with a written description of the types of evidence Persian Gulf veterans could use to support their claims. As a result of VA's

¹Veterans' Compensation: Evidence Considered in Persian Gulf War Undiagnosed Illness Claims (GAO/HEHS-96-112, May 28, 1996).

readjudication of denied claims completed to date, VA granted benefits to about 8 percent of the veterans whose claims were previously denied for undiagnosed conditions. Benefits could include compensation and/or medical care.

BACKGROUND

Following the return of U.S. forces from the Persian Gulf region, some veterans began exhibiting symptoms that could not be attributed to known clinical diagnoses. At that time, section 1110 of title 38, U.S.C., authorized VA to compensate for disabilities arising from disease or injury incurred or aggravated in the line of duty during military service. However, since many of the symptoms reported by Persian Gulf veterans could not be attributed to a known disease or injury, VA had no authority to compensate for them.

In response to the needs and concerns of Persian Gulf veterans, the Congress enacted the Persian Gulf War Veterans' Benefits Act (P.L. 103-446, Nov. 2, 1994) to allow VA to pay disability compensation to veterans who experienced undiagnosed illnesses. Some examples of compensable conditions under this legislation include fatigue, headaches, joint and muscle pains, and respiratory disorders. In order to be compensated under this legislation, veterans must provide objective evidence of a chronic disability. Objective evidence includes medical information such as medical records from the military, VA, or private physicians. Objective evidence also includes nonmedical information such as records of time lost from work and lay statements from persons such as family members or friends who are knowledgeable about changes in the claimant's physical appearance, physical abilities, and mental or emotional attitude. Claimants must also prove that the undiagnosed illness is chronic—present for 6 months or longer—and was either present during service in the Persian Gulf or during the eligibility period. Initially the eligibility period was defined as 2 years after a veteran's departure from the Gulf. However, based on a consensus within the veteran community concerning the adequacy of the 2-year presumptive period and the continuing medical and scientific uncertainty about the nature and causes of these illnesses, VA extended the eligibility period to December 31, 2001.

STATUS OF VA'S EFFORTS TO IMPROVE PERSIAN GULF CLAIMS PROCESSING

Since our 1996 report, VA has taken a number of steps to improve its processing of Persian Gulf claims. These steps include issuing guidance to ensure that procedures for processing Persian Gulf claims are followed, decentralizing claims processing to all 58 regional offices to improve timeliness, and providing training on the processing of Persian Gulf claims.

In July 1996, VA issued guidance that clarified its procedures for processing Persian Gulf claims. For example, the guidance identified the importance of using a standard letter for all claims involving undiagnosed illnesses of Persian Gulf veterans informing the veterans of the types of evidence that could be used to support a claim. The guidance also discussed the importance of nonmedical evidence, such as lay statements, in deciding a claim and in determining the duration and severity of the illness.

In addition, the guidance discussed the importance of obtaining all evidence, including medical and nonmedical statements. For instance, if a veteran's lay statement describes the year the condition arose, but the month is not specified and that information is necessary for a successful resolution of the claim, VA staff should attempt to obtain this missing information.

With the additional readjudication workload imposed on the initial four regional offices, VA found the operations of those offices increasingly strained. Thus, in May 1997, VA decided to decentralize the processing of Persian Gulf claims and began redistributing undiagnosed illness claims from the 4 offices to VA's 58 regional offices. VA officials said that the purpose of VA's decision to decentralize the processing of Persian Gulf claims was to give better service to claimants, reduce the workload created by the readjudication, and improve the timeliness of claims resolution.

While there may be advantages to the decentralization, there may also be disadvantages. VA officials and veterans service organization representatives said that advantages include more rating specialists being available to process the claims, a faster VA response to inquiries, and immediate access for claimants and their veterans service representatives to claim files and claim processors if the claim file is located at the regional office. The officials and representatives said that the disadvantages include the loss of expertise as a result of using staff less experienced in processing Persian Gulf claims, an increase in average claims processing time while the new staff are trained and become familiar with processing Persian Gulf claims, and the potential for inconsistency because of the vastly increased number of regional offices processing the claims.

VA officials said that the redistribution of claims has resulted in an unequal distribution of cases and backlogs in some regional offices. While some regional offices have received few additional Persian Gulf claims, others have received over 600 claims. For example, one regional office director said that decentralization had caused a slowdown in all claims processing in his office.

As a part of VA's decentralization effort, in late May 1997, VA began preparing each regional office to process undiagnosed illness claims. To accomplish this, VA developed a variety of methods to train and assist rating specialists as they processed claims. Specifically, shortly after the claims were redistributed, VA sponsored a satellite broadcast to all regional offices to discuss rating issues for Persian Gulf claims.

Following the broadcast, VA conducted a 2-day training conference to reinforce the information provided in the broadcast. Following the conference, additional training was provided in each VA area—eastern, central, southern, and western. Attendees from this and the 2-day conference then trained staff in their regional offices. In addition to classroom training, VA created a team of experts referred to as the Rapid Response Team. The members of this team are available to respond to questions or address any Persian Gulf issue. Moreover, VA's central office conducts weekly conference calls with regional office staff to share information obtained through the Rapid Response Team and to address issues or concerns. Rating specialists and adjudicators we spoke with at the regional offices said that, generally, the training was effective and they felt comfortable as they began processing undiagnosed illness claims. (See app. I for details about the training and assistance provided to regional claims processors.)

VA FOLLOWS PROCEDURES IN READJUDICATING CLAIMS AND GRANTS ADDITIONAL APPROVALS

In our 1996 report, we found that VA did not adequately implement its claims processing procedures. Specifically, VA did not always inform the veterans of the type of evidence needed to support undiagnosed illness claims, nor did it always attempt to obtain all medical and nonmedical evidence identified by claimants, including lay statements. Our analysis of a statistical sample of readjudicated claims showed that VA has followed its processing procedures during the readjudication of undiagnosed illness claims.

On the basis of our analysis of readjudicated cases, we found that, for the most part, VA provided veterans with information on the types of evidence needed to support undiagnosed illness claims and followed up on medical and lay statements. Specifically, in all cases, VA provided the veteran with a written description of the types of evidence Persian Gulf veterans could use to support their claims. And, in nearly all cases, VA attempted to obtain all medical and nonmedical records. Table 1 shows the percentages of cases in which VA followed its procedures in the readjudication of Persian Gulf undiagnosed illness claims.

Table 1: Percentages of Cases in Which VA Followed Procedures in Readjudicating Persian Gulf Undiagnosed Illness Claims

Claims processing procedure	% of cases in which procedure was followed
VA provided claimant a letter describing evidence to support a claim	100
VA tried to obtain medical records identified by the claimant	96
VA tried to obtain nonmedical records identified by the claimant	100

For the claims included in our sample where VA's readjudication process was complete, we estimate that 8 percent resulted in veterans receiving benefits for undiagnosed conditions, although previously they had been denied those benefits.² These veterans are now receiving compensation or free medical care, or both, for their conditions. In our sample of readjudicated claims, we found that two major factors account for about 70 percent of the denied claims. About 34 percent of the cases were denied because physicians were able to diagnose the condition. These would then be assessed under different compensation requirements. Another 36 percent of the cases were denied for lack of objective medical evidence to support a claim.

CONCLUSIONS

The Congress enacted the Persian Gulf War Veterans' Benefits Act to allow VA to pay disability compensation to veterans suffering from undiagnosed illnesses attributed to their service in the Persian Gulf. As we reported in 1996, VA had not properly followed its procedures to adequately inform and assist veterans in processing their claims for Persian Gulf-related undiagnosed illnesses. In response to our report and concerns raised by others, VA has taken steps to help improve its processing of claims for Persian Gulf undiagnosed illnesses. VA's issuance of clearer guidance on its processing procedures appears to have resulted in claims processors following the procedures. In addition, to help improve the timeliness of VA's actions on Persian Gulf claims and better serve claimants, VA decentralized processing of Persian Gulf claims from 4 to 58 regional

²Sampling errors range from ± 6 to ± 16 percentage points at the 95-percent confidence level.

offices and began training claims processors in handling Persian Gulf undiagnosed illness claims. Because VA only recently began these efforts, their impact is yet to be determined.

Mr. Chairman, this concludes my prepared statement. I will be glad to answer any questions you or Members of the Committee may have.

TRAINING AND OTHER ASSISTANCE
PROVIDED TO REGIONAL CLAIMS PROCESSORS

- On May 29, 1997, VA provided a satellite broadcast to its regional offices that primarily discussed rating issues for Persian Gulf claims. VA stated that the broadcast was the first in a series of initiatives that the Compensation and Pension Service plans to undertake to prepare claims processors in each regional office for processing Persian Gulf claims.
- On June 2, 1997, VA conducted a 2-day training conference that expanded on the training provided in the May broadcast. Each regional office sent one representative (usually a hearing officer or rating specialist) to the training. The representatives were responsible for going back to their regional offices to train other staff that would be working on Persian Gulf cases.
- After the June training, additional training was provided in each VA area that focused on using examples of actual cases to show how they should be processed. For example, the staff from the Louisville regional office conducted training for regional offices in the central area on June 4. The southern area training was conducted by staff from the Nashville regional office for 3 days at the end of June.
- Claims processors also receive less formal training through participation in weekly national conference calls and interaction with the Rapid Response Team, a team of experts created by the VA central office to address questions or issues raised by claims processors. Every Wednesday, the VA central office holds a conference call with all regional offices. During these calls, knowledgeable staff members address any Persian Gulf-related issue.

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GAO/T-HEHS-98-89

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

CONGRESSMAN EVANS TO DR. BERNARD ROSTKER, SPECIAL ASSISTANT TO THE DEPUTY SECRETARY OF DEFENSE FOR GULF WAR ILLNESSES

1. It's fair to say that the PAC's Special Report was critical of DOD's Investigations into possible chemical warfare exposures. The PAC believes that DOD is skeptical of any exposure and is predisposed to neglect evidence that contradicts its belief that no exposures took place. The Special report states that DOD's contractor, MITRE, uncovered new evidence supportive of exposures in some incidences that DOD Ignored. Do you plan to release other sections of the MITRE report? They also believe that DOD has established too high a threshold for concluding that exposure to chemical weaponry is likely. Will you respond to these allegations?

Answer:

Last year, Chapter 11 of the d ran MITRE report and supporting material was forwarded to my office for review and inclusion in our case narratives, as appropriate. Following a careful review of the material, some of the information was incorporated into various narratives. However, the chapter received by my office should be viewed as "incomplete" and does not, in our judgment, present an accurate picture of what went on before, during, or after the Gulf War. The chapter basically presents a series of unsubstantiated claims and speculations which are only one of many pieces of information needed to meet the internationally recognized standards for chemical incident assessments. MITRE put much weight on the 1991 Manley study, "Marine Corps NBC Defense in Southwest Asia." We also appreciate the Manley study, especially his admonition not to treat the issue categorically. Our detailed case narratives are exactly the opposite of categorical; the facts associated with each case narrative are fully explored and assessments are made on the specific facts as presented.

Any reader of this chapter must understand that it is not a definitive treatment of any of the incidents they report on. The MITRE Chapter 11, as presented, does not bring together all available information associated with each event, as the case narratives do, and thus, the material presented is not by itself useful in drawing any conclusions about the presence of chemical weapons on the battlefield. For example, MITRE cites the U.S. Central Command Chemical Log reporting the discovery of a chemical weapons supply on February 28, 1991. Clearly, if true, this is a major event. Unfortunately, the report does not tell the reader that the following day's U.S. Central Command logs also show that the same reporting officers determined, based on a thorough survey of the site, no chemical weapons were present. Neither does MITRE mention that each member of the explosive ordnance disposal unit who examined the bunkers had also testified that no chemical weapons were found. The full accounting of this incident is in the case narrative, Fox Detections in an ASP/Orchard. Unfortunately, this is just one example of many where the information presented in Chapter 11 is incomplete and where a reading of Chapter 11 alone would result in an incomplete picture and the possible drawing of erroneous conclusions.

Similarly, Chapter 11 continues to speculate about the existence of chemical mines. Without any evidence, the chapter speculates the possibility that the contractors who cleared over 300,000 land mines from Kuwait might not have known if they were clearing chemical mines. In fact, the cataloging and destruction of munitions in the US sector of Kuwait was carried out methodically over a three year period and no chemical mines were found.

To reiterate, MITRE's Chapter 11 is not a complete picture of any of the events it reports on. The material presented is largely uncorroborated accounts of and speculations about possible chemical events. The remainder of the MITRE report is controlled by the Assistant to the Secretary of Defense (Intelligence Oversight). We have not addressed the release of the remainder of the report.

The assertion that DOD has established too high a threshold for concluding that exposure to chemical weaponry is "Likely" is inaccurate. Since embarking on our series of investigations, we have used internationally accepted standards for determining what events constitute chemical weapons exposure. Accordingly, our investigative methodology is designed to provide a thorough understanding of each suspected chemical exposure incident. By following our methodology and applying accepted standards, we are able to appropriately weigh the often conflicting evidence that we find and support an assessment on a five point scale ranging from "Definitely" to "Definitely Not."

2. Several reasons have been cited for the difficulties encountered in identifying the causes of Gulf War illnesses. These have included difficulties in knowing where service members were located within the theater, lack of documentation such as missing/lost tapes from FOX vehicles, and the lack of effective medical surveillance systems to track and identify service members exposure to various health hazards.

Answer:

Gulf War illnesses are the varied group of symptoms in Gulf War veterans which cannot be medically explained after extensive history, physical examination and laboratory evaluation. Individuals comprising this cohort are about 20 percent of Gulf War veterans who have registered in the DOD or the VA Registries. The reason(s) for the symptoms in these individuals becomes a matter of considering all possible theoretical causes. Knowing where each individual was located through out the deployment would aid in determining if there were a location in common (place and/or time) which could then be evaluated for a possible common source exposure to a health hazard.

The Fox chemical detection vehicles were designed to alarm if the ground sampled indicated anything consistent with chemical agents. The design of the alarm was to assure there were no false negatives—that is, no alarm when a chemical agent was present at a concentration to cause medical effects. This meant that there were many false positive alarms. When Fox tapes were discarded, it meant we could not produce evidence to validate the tapes were negative. The Fox chemical detection vehicles did not detect at low-levels because these levels were not considered to be a hazard to personnel and military operations.

During the deployment to the Gulf, there were medical surveillance systems in place for monitoring food and water supplies, air quality and to monitor for biological warfare agents in soil, food, water and air. This sort of surveillance assures that whatever is sampled was okay at the time was sampled. There are no "medical surveillance" badges that people can wear to record all the health hazard exposures over time, similar to a radiation badge an X-ray technician can wear to measure exposure over time.

3. OSAGWT's investigations involve the collection of all relevant documentation associated with Gulf War illnesses. We realize that this process has been a massive undertaking. What level of confidence do you have that you have identified all relevant documentation and that the intelligence agencies have provided all of the relevant documentation?

Answer:

We are still identifying and gathering all relevant documentation. The Department has collected more than 6.4 million classified documents, more than 54,000 of which are identified as health related and are being used in my team's investigations. We do not have all relevant documentation from the Air Force or the intelligence agencies. We have collected the bulk of the relevant documentation from the Army, the Navy, and the Marine Corps. but continue to declassify smaller numbers of documents as they are identified.

4. OSAGWI has been in operation for about a year. Given the difficulties of doing investigations six years after the incidents, describe the extent to which DOD is closer to identifying the causes of Gulf War illnesses?

Answer:

The Special Assistant's office has made great headway in clarifying and defining what events did or did not occur during the Gulf War. For the veterans who have come forward with medical symptoms, only 20 percent have medically unexplained illnesses. Those with medically explained illnesses are being treated. The Special Assistant's office has contributed to the extensive federally-funded research program evaluating scientifically plausible causes or contributing factors. The lessons learned from our investigations are being applied to protect military personnel deployed today.

5. What are OSAGWT's plans to bring closure to its investigations? How can the OSAGWI investigations be expedited?

Answer:

As I expressed in the annual report in November, the office has a robust list of planned and on-going activities taking us into our second year. However, I expect that by the end of this year we will have completed the bulk of our investigations into possible chemical and biological exposures and a number of significant environmental hazards. The President charged us with leaving no stone unturned in our investigation into what happened in the Gulf and what may be making our veterans sick. We are searching for complex and often elusive answers on a number of fronts, but each inquiry will be complete, thorough and methodical. To do less would be a disservice to the brave men and women who served in the Gulf.

This year, we will complete and publish as "interim reports" 12 additional chemical case studies, three additional information papers and updates to two previously published case narratives. We expect to complete and publish three reports each on pesticides, depleted uranium and the fallout from oil well fires.

We expect to complete our investigation of the Air Campaign, including a detailed analysis of possible fallout with the same models used to estimate the fallout from the Khamisiyah demolitions.

We will conduct an analysis of Army in-theater hospital records.

We will conduct an extensive inquiry into the possibility that Iraq used biological warfare agents.

We will be monitoring programs in place as a result of lessons learned to date, for example the depleted uranium training by the Services, as well as the continuing effort to archive and declassify health related Gulf War documents.

The Institute of Defense Analyses (IDA) will complete research into low level chemical doctrine and publish several papers applicable throughout DOD.

RAND will complete and publish eight medical reviews, as well as two papers on management of our medical program. Also, several medical research projects we have been monitoring closely will report during our second year.

The S3/G3 operations officer's conferences will be completed early this year, and as a result, we will be better able to determine the number of personnel who may have been exposed to low level chemical agents at Khamisiyah. We will also incorporate information about the location of Air Force personnel.

If our first year is any guide, additional reviews will come up during the year that cannot be anticipated that will require our review and investigation.

6. OSAGWT's initial emphasis was placed on investigating possible incidents of chemical weapons exposure. Have you identified ways to improve your investigative process which can be used for subsequent investigations into other areas such as the use of biological weapons, environmental factors (pesticides, oil well fires), and immunizations?

Answer:

We are improving the investigative process in a number of diverse areas. Specifically, we have increased productivity and thoroughness by taking advantage of database technology and automation. We have also learned data must be shared. With multiple cases under investigation, the need for sharing data is magnified—sharing

leads, sharing sources, sharing lessons learned, and continuous process improvement. Automated information sharing is critical. The value of an encompassing contact database cannot be overstated. We developed our own internal procedures and greatly improved our ability to find, track, and use data. We are also using resources from other government agencies with key expertise, including the intelligence agencies, weather collection and analyses organizations, explosive ordnance disposal units, CHPPM, and academic modelers.

The most important lesson we have learned is the importance of establishing an encompassing methodology as we did in our chemical investigations. The office's chemical investigation methodology was developed to provide a common framework for investigations into the allegations of chemical warfare agent exposure and reports of chemical detection during the Gulf War. It was designed as a general template for each incident investigation to formalize the process of how we conduct our investigations and ensure that all the pertinent information is gathered and assessed. Each investigation may deviate to suit the circumstances, but the foundation of the methodology is corroboration from multiple sources—logs, records' veterans' interviews and source material, intelligence sources, and medical records.

7. Could you characterize the level of support you have received from the Central Intelligence Agency in your search for documentation concerning possible incidents of exposure to chemical weapons agents? Do you have any thoughts on how we can do a better job of coordinating intelligence so it gets to the right people in conflicts in the future?

Answer:

DOD has enjoyed unprecedented access and cooperation from the CIA during the conduct of its investigation into Gulf War illnesses. On a daily basis, through strong personal relationships formed between Dr. Rostker and the Intelligence Community, this office has been able to cut through years of bureaucracy and look where no "outside agency" has been permitted to look before. We have enjoyed direct access to limited distribution documents, Special Access Programs, and Director of Operations files in order to follow every trail and lead. Cooperation continues to this day and has helped DOD insure that "no stone has been left unturned."

For further information regarding improved coordination between the intelligence community and field commanders, I refer you to the enclosed SECDEF Report on Coordination of Access of Commanders and Deployed Units to Intelligence Collected and Analyzed by the Intelligence Community.

8. How has OSAGWI followed through on transmitting to DOD and the separate services recommendations it has made to avoid some of the mistakes made during the Persian Gulf War? Are the services institutionalizing recommendations that you have made?

Answer:

We have learned a number of lessons as a result of our operations during the Gulf War. Those lessons learned have resulted in changes that have either been made or recommended. These can be categorized in three groups:

Chemical and Biological Equipment—Especially Detectors and Alarms

There has been a successful consolidation of the individual service development programs into a joint Chemical-Biological Defense program. The program was authorized an additional \$1 billion over the next five years and duplicative program elements were removed. With the added funding and consolidation, we can move forward in the development and fielding of advanced chemical-biological equipment and incorporate refinements based on our Gulf War experiences.

Medical Force Protection

Prior to the Gulf War, medical force protection initiatives lacked inter-Service standardization. After the war, the Assistant Secretary of Defense for Health Affairs and the Joint Staff undertook a complete review of doctrine, policy, oversight and operational practices for medical surveillance and force medical protection. A number of changes were incorporated for subsequent deployments to Somalia, Rwanda, Haiti and Bosnia. Currently, joint publications are being rewritten to include changes in

doctrine. Additionally, theater operations plans are being revised to include new force medical protection measures. A promising new change will be the implementation of the new Personnel Information Carrier (PIC). This dog-tag-like computer storage device will greatly improve medical records keeping to include vaccinations, treatment and patient history.

Another problem being addressed is the incompatibility of individual health information. A joint VA/DOD Executive committee is currently working to get a number of initiatives underway. Some of the improvements being sought are: setting up procedures for transfer of health information, agreeing on a common discharge physical, and acquiring a computerized patient record system that can be used by both Departments.

Education Concerning the Handling of Hazardous Material

During our investigation into the potential health hazards of depleted uranium, we discovered deficiencies in training. While technicians in nuclear-chemical-biological specialties and safety fields were well informed on the dangers posed, our combat troops or those handling contaminated equipment such as enemy tanks, did not understand how to reduce unnecessary risks.

To remedy this problem, we wrote to the chiefs of the Air Force, Navy and Marines on September 9, 1997, encouraging them to "ensure that all Service personnel who may come in contact with depleted uranium, especially on the battlefield, are thoroughly trained in how to handle it." The Joint Chiefs of Staff and my office are currently working together to ensure all personnel who might come in contact with depleted uranium receive appropriate training on how to handle depleted uranium and depleted uranium—contaminated equipment. We especially want the services to sensitize their personnel to what the DU-related hazards are, and how to avoid them.

9. It is my understanding that the Oversight board to be chaired by former Senator Rudman has still not been appointed. Why is this taking so long? When do you expect the members and staff of the board to begin operations?

Answer:

The Special Oversight Board For Department of Defense Investigations of Gulf War Chemical and Biological Incidents was formally established by Executive Order on February 9, 1998. President Clinton announced his intent to appoint former Senator Warren B. Rudman to chair the Special Oversight Board on the same day. We expect to know more in March about the operation of the board.

**Congressman Evans to Gary Christopherson, Acting Principal Deputy
Assistant Secretary for Health Affairs, Department of Defense**

House Veterans' Affairs Committee

February 5, 1998

Research, Investigations, and Programs Involving Persian Gulf War Veterans' Illnesses

Mr. Gary Christopherson

Question 1

Question: In past hearings, this Committee has heard experts repeatedly recommend that troops should have a pre-deployment physical examination to establish a baseline for health effect that may arise as a consequence of some exposure during deployment. If troops are deployed soon, would the mechanisms be in place to ensure that troops could have a pre-deployment physical? Will DOD implement this recommendation? How long will it take?

Answer: All personnel are assessed and determined to be physically and medically fit prior to deployment. This includes the following: a medical threat briefing; distribution of medical information; DNA sample collected and on file; demonstration that a pre-deployment serum specimen is either on file or has been drawn; HIV test within 12 months prior to deployment; immunizations as required; a physical exam if not current; completion of a pre-deployment health questionnaire; and follow-up actions on any non-deployable conditions. Medical personnel address any discrepancy for deployment. Specific disqualifiers for deployment include the following: unresolved health problems mandating light duty or requiring a category 4 profile; pregnancy; HIV seropositivity; or dental readiness category III or IV.

Chairman Stump Questions for the Record
Arthur Caplan, Ph.D.
Hearing on Persian Gulf Issues
February 5, 1990

1. What is your view on the quality and scope of the ongoing Federal research effort, and the process by which that research agenda is set? Did the PAC consider the concept (which has since been advanced as a proposal) of having Congress create or designate an agency other than the Departments of Defense and Veterans Affairs to serve as the lead federal agency responsible for coordinating, and allocating funds for, all research into Gulf War veterans' illnesses? (The proponent of this view has not explained what role, if any, the two departments would play vis a vis a research agenda which they would neither set nor help fund.) Did the PAC, or do you, have a view on the merits of this proposal?
2. There has been criticism that the Federal research effort on Gulf war illnesses lacks a coherent approach. Given the number of risk factors under review and the uncertainty regarding the health effects experienced by veterans, are there comparable situations or models to which Government should have looked in developing its research plans?

NATIONAL ACADEMY OF SCIENCES
Institute of Medicine

Response to Post-Hearing Questions of
Chairman Bob Stump
Veterans Affairs Committee
U.S. House of Representatives

Questions for Donald Mattison, MD

Question 1: How formidable is the scientific task IOM is about to undertake? How complex a task is it likely to be to find independent, objective experts to address the large number of risk factors under consideration? What difficulties, if any, do you foresee? VA and IOM developed a contract (as had been proposed by the Presidential Advisory Committee) without any specific statutory directive. Is the IOM satisfied with the terms of the contract, from a scientific perspective? If so, there is no further need for legislation on this matter to meet any scientific concern on the part of the IOM, is there?

Response to Question 1: The scientific task of reviewing, evaluating, and summarizing the available scientific and medical information regarding the association between exposures during the Persian Gulf War and adverse health effects experienced by Persian Gulf veterans is quite formidable. The numbers of possible exposures is large and includes such items as depleted uranium, pesticides, chemical and biologic warfare agents, vaccines, heat stress, solvents, paints, fuels, smoke from oil-well fires, sand, and pyridostigmine bromide. In addition, the actual exposures and dose of exposures experienced by Persian Gulf veterans is unknown.

Further complicating the task is that there may be little human or animal data related to the exposures chosen for study, the health effects related to exposure to multiple chemicals is largely unknown, the synergistic effects related to different chemical exposures may be unknown, it may be difficult to extrapolate animal data to man, the dose-response may not be linear (there may be a threshold effect related to some of the biologic and chemical exposures), and the scientific data may not be sufficient to determine whether or not an association exists between an exposure and an adverse health outcome.

However, the obstacles listed above are not specific to Persian Gulf veterans' exposures, and those difficulties are generic problems when trying to link possible exposures to adverse health outcomes. Scientists often rely on modeling and mechanistic data to determine the biologic plausibility for the association between exposure and health outcomes. The IOM committee will consider biologic plausibility during the upcoming study.

Finding independent, objective experts to address the large number of risk factors under consideration will be time consuming task. There are a number of individuals who are well qualified to provide expertise on these topics from a scientific and medical perspective. However, the task is complicated by the need to ensure that the experts chosen are not DoD or VA funded, and that they have not already taken a position on the likelihood of association between the exposures and the health outcomes under study. It is expected that assembling the independent, expert committee will require several months of activity and search. Assembling such expert panels is, however, at the core of how the IOM functions. We have a great deal of experience in this type of effort and a large pool of leading scientists and clinicians from which to select volunteers for this project.

From a scientific perspective, the IOM is satisfied with the terms of its proposed study with VA. The VA was very cooperative and receptive to IOM suggestions as the process evolved. As you are aware, the entire project described to your committee is a three

phase project. The current proposal between IOM and VA is for the first phase only. While the next two phases have been generally described, it may be fruitful to reexamine the proposed project and to make any necessary adjustments based on the findings of the first phase. Such negotiations would be based on the scientific findings of the IOM committee work.

Question 2: VA and DoD have reportedly asked IOM to develop a workshop to examine how they might do research on treatment outcomes. When would that workshop take place?

Response to Question 2: The Department of Veterans Affairs and the Department of Defense have asked the IOM to establish a committee for the purpose of developing a research design and methods that could be used to measure the health of Persian Gulf veterans. The committee will explore the feasibility, given existing databases, of conducting research on treatment outcomes, health outcomes and health status.

During the 18 month study period the committee plans to meet 5 times, one meeting of which will include a workshop. It is likely that the workshop will be held in Spring, 1998. The workshop will include presentations on research planned or conducted to-date on Persian Gulf veterans' health; a review of existing databases for the conduct of such research; and exploration of methodological issues regarding the conduct of such research. The committee will determine which of these approaches it is feasible to pursue given existing data and will produce a final report describing a research design and methods that could be implemented by VA and DoD.

Question 3: There has been criticism that the Federal research effort on Gulf war illnesses lacks a coherent approach. Given the number of risk factors under review and the uncertainty regarding the health effects experienced by veterans, are there comparable situations or models to which Government should have looked in developing its research plans?

Response to Question 3: The Persian Gulf veteran experience is different in at least two significant ways from previous situations or models where the government has funded research on veterans' health. Instead of exposure to one agent (as was the case with the atomic veterans, those exposed to chemical agents at the Edgewood Arsenal or Vietnam veterans), there are many vastly different exposures which need to be investigated. There is also the need to investigate possible synergistic effects of these agents. In addition, it has not been possible to determine, for each of the potential agents of exposure, which veterans were exposed at what level. Nor has there been sufficient passage of time to allow for the development of the longer-term possible health effects such as cancer.

For these reasons, it is very difficult to identify previous comparable situations or models that can be used to guide the development of the Federal research effort on Gulf War illnesses.

Questions for Dan G. Blazer, MD

Question 1: Regarding undiagnosable conditions in Persian Gulf veterans, is your report saying in essence that regardless of the etiology of such conditions there are ways these conditions can be treated? Would you comment?

Response to Question 1: The committee report states that "in cases where a diagnosis cannot be identified, treatment should be targeted to specific symptoms or syndromes (e.g., fatigue, pain, depression)." The committee believes that while it may not be possible to arrive at a definitive diagnosis in all cases, it may be possible to treat the veterans' presenting complaints or symptoms.

Question 2: Your committee's findings regarding difficult-to-diagnose conditions among Gulf veterans apply to VA as well as DoD. What practical steps can Dr. Kizer as VA's Under Secretary for Health take to change the way his physicians provide care to their patients.

Response to Question 2: IOM review of the VA implementation and use of the diagnostic protocol for Persian Gulf veterans has been completed and the final report was released on Monday, March 16, 1998. I have included a copy of that report for your information. It provides thorough and reasoned recommendations based on site surveys and analysis of the VA system for diagnosis of Persian Gulf veterans' health problems, as well as input from scientific experts and clinicians, VA providers, veterans, the General Accounting Office, the President's Advisory Committee on Persian Gulf Illnesses, and the expertise of the IOM committee members themselves. I would refer you to the recommendations of this expert Committee on the Evaluation of the Department of Veterans Affairs Uniform Case Assessment Protocol to provide an answer to your question.

Question 3: In its testimony today, the GAO faults VA and DoD for failing to monitor Persian Gulf veterans' clinical progress after their initial examinations. VA questions the feasibility of a monitoring effort in the absence of a well-defined illness. Are there measures short of formal outcomes studies by which the Departments can meaningfully monitor or assess clinical progress or improvement in the care of undiagnosed or ill-defined health problems in Persian Gulf veterans?

Response to Question 2: There are a variety of levels of evaluation that one can undertake in any health care setting. First, one can assess whether there are sufficient resources to provide care, e.g., appropriate licensed practitioners and adequate resources and equipment. The next level of assessment is to determine whether these resources are being used, that is, do the physicians see patients, do patients have their blood pressure taken, are laboratory tests ordered and done.

The third level of evaluation would be to determine whether these resources are being used appropriately. In order to conduct this third level of evaluation, it is necessary to determine what is appropriate given the presenting symptoms and complaints of the patient. One can refer to medical textbooks for the answer of what is appropriate and adequate diagnosis and treatment for defined conditions. One can use clinical practice guidelines that have been developed by AHCPR, the American Society of Internal Medicine, and many other medical and health groups (including the VA) for well defined diagnoses and procedures. For those conditions for which no clinical practice guidelines have been developed, one can develop those guidelines as the VA did for PTSD, Major Depressive Disorder (MDD) and MDD with substance abuse.

Actual practice can then be compared to the clinical practice guideline to determine the extent to which the practice of medicine is consistent with the guideline for practice.

However, when there is not a scientific body of knowledge that, through well-designed and replicated research, documents what treatments work to improve the health of patients with particular complaints or problems, it is necessary to conduct formal treatment outcomes studies. This requires well-defined treatment and control groups, a well-defined treatment protocol, and well-measured health outcomes.

Question 4: Given the view that current scientific evidence does not support a link between environmental risk factors in the Gulf and reported illnesses, can veterans who have remained in good health since their Gulf service feel reasonably confident that they are not likely to develop unexplainable, undiagnosable illness in the future because of their Gulf service?

Response to Question 4: Given information available today, it does appear that Gulf War veterans who do not currently have unexplained or undiagnosed illnesses are

unlikely to develop those illnesses as a result of their past Gulf War service. To thoroughly and adequately explore the issue of association between exposure during the Persian Gulf War and adverse health effects experienced by Persian Gulf veterans, however, requires a massive effort of review of all scientific and medical literature and assessment of the biological plausibility that these exposures, or synergistic effects of combinations of exposures, are associated with illnesses experienced by Gulf War veterans. The VA has contracted with the IOM to conduct this review of associations between exposures and health outcomes.

Question 5: A controversial GAO report appears to contradict the findings of previous expert panels, including the PAC, in stating that “a substantial body of research suggests that low-level exposure to chemical warfare agents or chemically related compounds. . . is associated with delayed or long-term health effects.” What’s your assessment of that statement and of the strength of the underlying scientific evidence?

Response to Question 5: The strength of the underlying scientific evidence for association between low-level exposure to chemical warfare agents or chemically related compounds and delayed or long-term health effects will be assessed in the new study which IOM will be conducting on the Health Effects Associated with Service in the Persian Gulf War. The IOM committee evaluating the adequacy of the CCEP for diagnosing Persian Gulf veterans did not find “a substantial body of research” that conclusively indicated the existence of long-term health effects of low-level exposure to nerve agents.

Question 6: The GAO, in its work appears to rely heavily on research conducted by Dr. Robert Haley. Dr. Haley apparently found that Persian Gulf veterans whom he tested had subtle neurological problems which he attributed to chemical exposures; did you or your colleagues review that research and reach any conclusions regarding its strength?

Response to Question 6: The Committee on the Evaluation of the DoD Comprehensive Clinical Evaluation Program did review the work of Dr. Haley as it was published in the JAMA. The committee concluded that additional research was needed to determine the clinical significance of the work conducted by Dr. Haley and his colleagues.

Question 7: There has been criticism that the Federal research effort on Gulf war illnesses lacks a coherent approach. Given the number of risk factors under review and the uncertainty regarding the health effects experienced by veterans, are there comparable situations or models to which Government should have looked in developing its research plans?

Response to Question 7: I would concur with Dr. Donald Mattison’s response to this question, that is the Persian Gulf veteran experience is different in at least two significant ways from previous situations or models where the government has funded research on veterans’ health. Instead of exposure to one agent (as was the case with the atomic veterans, those exposed to chemical agents at the Edgewood Arsenal, and Vietnam veterans), there are many vastly different exposures that need to be investigated. There is also the need to investigate possible synergistic effects of these agents. In addition, it has not been possible to determine, for each of the potential agents of exposure, which veterans were exposed at what level. Nor has there been sufficient passage of time to allow for the development of the longer-term possible health effects such as cancer.

For these reasons, it is very difficult to identify previous comparable situations or models that can be used to guide the development of the Federal research effort on Gulf War illnesses.

**Post-Hearing Questions
Concerning the February 5, 1998
Hearing to Receive Updates on Research,
Investigations, and Programs Involving
Persian Gulf War Veterans' Illnesses**

**For Dr. Kenneth Kizer
Under Secretary for Health
Department of Veterans Affairs**

**From The Honorable Bob Stump
Chairman, Committee on Veterans' Affairs
U.S. House of Representatives**

1. A November 1996 Persian Gulf Coordinating Board report entitled "A Working Plan for Research", cites a need in the near future to explore "more longitudinal studies of the health of Persian Gulf veterans." No new longitudinal studies have been mounted since then. What are your plans for starting such a study this year?

Response: There are a number of projects in the government's research portfolio on Gulf War veterans' illnesses that have longitudinal components. The outcomes being looked at in longitudinal studies are varied in their nature.

The VA Mortality Study is a longitudinal study of the mortality of Gulf War veterans. The first examination of mortality in Gulf War veterans was published by VA scientists in the New England Journal of Medicine in November 1996, and reported on deaths among Gulf War veterans and their non-deployed counterparts through 1993. That study found no significant differences in the disease-specific death rate among deployed Gulf War veterans compared with non-deployed veterans. There was, however, an observed increase in the death rates of Gulf War veterans due to accidents, and motor vehicle accidents in particular. This study has since undergone its first follow-up, reviewing deaths through 1995. Preliminary findings indicate results that are similar to the first study. VA is committed to continuing to follow the mortality experience of Gulf War veterans well into the future because delayed onset diseases, such as cancer, have latency periods of many years.

Another relevant study, Phase III of the VA National Survey of Gulf War Veterans, is expected to begin in the spring of 1998. Phase III involves physical examination follow-ups on veterans who participated in Phase I and Phase II of the survey. The same questions asked in Phases I and II will be repeated in Phase III which will be two to three years following the initial questionnaire. Thus, Phase III, in addition to providing objective clinical findings to accompany self-reported symptoms and illnesses, will also provide a measure of longitudinal progress of a population-based sample of Gulf War veterans.

Likewise, investigators at the University of Iowa who conducted a telephone survey of Gulf War veterans in the state of Iowa (results published in JAMA, January 1997) will be conducting follow-up physical examinations on participants in the original survey in two separate projects funded by HHS and DOD. Specific outcomes that will be examined include asthma (in the HHS funded project), and depression, cognitive dysfunction, and multi-systemic conditions (in the DOD funded study). Again, this will provide an opportunity to examine the health of a population-based sample of Gulf War veterans and to compare their health with the original survey findings.

Projects A and B of the VA's Boston Environmental Hazards Research Center are examining the cognitive and neurological function of participants in the so-called Fort Devens reunion study. These veterans were first studied when they were processed through Fort Devens in Massachusetts upon their return from

the Gulf War in 1991. They have now been studied at two additional time points following the initial evaluation in 1991. Publications in progress include evaluation of reported health symptoms by this cohort of Gulf War veterans at Time 2, examination of reported sexual harassment by the women surveyed, and a longitudinal assessment of PTSD and psychological symptomatology between Time 1 and Time 2. In addition, researchers at the Boston Environmental Hazards Center are developing, in cooperation with states in the New England area, a Gulf War veterans cancer registry that will provide a means of monitoring cancers among veterans in those states over many years.

Additionally, the VA East Orange Environmental Hazards Research Center has been conducting physiological, psychological, and neuropsychological evaluations of veterans with fatiguing illnesses from the VA Persian Gulf Registry. Originally, this group was only to evaluate these veterans at a single time point. They have modified their protocol to include a second time point and have already begun to bring back veterans for follow-up evaluation.

Further, the Department of Defense recently funded three projects on Gulf War veterans' illnesses that have longitudinal components. One study funds a VA investigator to continue studies of the psychological and neurobiological consequences of the Gulf War experience on a cohort of veterans that have been followed since the Gulf War. An important aspect of this study is the use of magnetic resonance imaging to examine the functional correlates of the psychological health outcome in these veterans. Two other studies are conducting longitudinal evaluations of the physical and psychological health of women Gulf War veterans.

Finally, VA and DOD recently announced a collaborative effort to conduct a major multi-site treatment trial of Gulf War veterans with Chronic Fatigue Syndrome (CFS) and Fibromyalgia (FM). These two conditions bear many similarities to the symptom complexes experienced by some other Gulf War veterans and, thus, such a treatment trial could shed light on effective treatments for these other Gulf War veterans. It is likely that such a treatment trial will involve a longitudinal component to evaluate treatment efficacy over time.

As can be seen, VA, DOD, and HHS have been engaged in a number of studies involving longitudinal follow-up of Gulf War veteran participants. Several new studies have been initiated since the 1996 *Working Plan*. At the present time, the Research Working Group of the Persian Gulf Veterans Coordinating Board does not recommend funding additional longitudinal research studies. This recommendation does not, however, apply to future clinical follow-up examinations of Gulf War veterans.

2. Some criticize the Federal Persian Gulf research for lack of timeliness. For example, in 1992, Congress directed VA and DOD to contract with the National Academy of Sciences to get recommendations for Persian Gulf research. NAS didn't provide initial recommendations until 1995, and issued its final report in 1996. Doesn't that experience raise questions regarding the means by which the Government gains timely, independent guidance for future research?

Response: The federal government has been managing the research portfolio for Gulf War veterans' illnesses in a measured, scientifically expedient, and effective manner.

VA, DOD, and HHS have used a number of vehicles to obtain advice on research directions, including the NAS Institute of Medicine (IOM) panel on the Health Consequences of Service in the Persian Gulf War. The IOM panel was contracted in FY '93 following the legislative direction, and it began work in early FY '94. Between the signing of the contract and the commencement of work, IOM had to recruit appropriate panel members to perform the required work. Besides the IOM panel, advice was obtained from the NIH Technology Assessment Conference held in April 1994; the Defense Science Board then

produced its findings and recommendations in July 1994. The advice of the IOM panel was not restricted to its interim and final reports. The ongoing meetings of the panel and its interactions with VA, DOD, and HHS officials provided numerous opportunities for interim, informal advice. Thus, at no time did the government wait to proceed with research plans as these committees met; there simply was no need to wait. This applies as well to the activities of the Presidential Advisory Committee (PAC) on Gulf War Veterans' Illnesses. The bimonthly public meetings of the PAC provided opportunities for VA, DOD, and HHS officials to interact with the expert members of the PAC.

3. GAO believes VA needs to develop a mechanism to monitor Persian Gulf veterans' clinical progress or the effectiveness of their care. Your testimony expresses agreement in principle, but suggests that ascertaining whether patients have improved can only be determined through the conduct of outcomes research (whose feasibility you've asked the Institute of Medicine to explore). Is it your position that treatment trials are the only mechanism that could reasonably be considered to assess whether VA Persian Gulf veteran patients (or any subsets thereof) have improved under VA care?

If so, is there an inconsistency between, on the one hand, the Department's willingness to track longitudinally self-reported data from veterans on their health status, and its apparent unwillingness to consider any other unscientific measures for reviewing overtime health status or clinical progress?

Response: The Research Working Group is in basic accord with all of the research recommendations of the PAC and IOM and have been striving to carry out these recommendations.

As you may know, during the past seven years, VA has provided outpatient care for more than 221,000 Gulf War veterans. More than 22,000 Gulf War veterans have been hospitalized and cared for as inpatients in VA medical centers. More than 67,000 Gulf War veterans have completed the Gulf War Registry health examination at VA facilities. These veterans suffer from the entire range of diagnosable medical conditions and some have unexplained symptoms. Little is known about the natural history of the ill-defined conditions experienced by Gulf War veterans.

It is possible to get a partial estimate of health outcome for certain subsets of veterans or for a single parameter of interest (such as customer satisfaction, self-reported health status, or functional status) without designing a comprehensive research study. However, obtaining a valid and complete assessment of health outcomes in Gulf War veterans requires well-designed research. Furthermore, valid assessment of treatment efficacy requires design of randomized clinical trials.

I understand and sincerely share your concerns about the health consequences of Gulf War service. At first blush, the questions raised by GAO seem simple and straightforward. However, when one attempts to develop a specific strategy for answering the questions, the complexity and knottiness of the problem quickly becomes apparent. There is extreme difficulty in ascertaining whether the health status of the entire cohort of Gulf War veterans is better or worse as a result of VA treatment. This difficulty is related to the wide variety of medical conditions that have been experienced coupled with the large number of possible medically-accepted pharmacologic and non-pharmacologic treatments for each individual diagnosis. In addition, numerous studies suggest that many Gulf War veterans suffer not one, but multiple illnesses.

An example might be helpful in illustrating the problem. Hypothetically, let's say that Gulf War veterans suffer from one hundred possible conditions and Gulf War veterans average two conditions each. What is the possible number of outcomes that would need to be assessed if 100 illnesses were suffered in combinations of

two? A quick calculation demonstrates that 4,950 analyses would need to be performed to describe the health condition of these veterans. If the same one hundred conditions occurred five at a time, the possible number of combinations is 75,287,520. Now add to your calculation that each combination of medical conditions can be treated with five possible combinations of therapy and the analysis becomes virtually mind-boggling!

Determination of appropriate, standardized, quantifiable outcome measures is another vital issue that VHA must consider in developing a methodology to assess the health outcomes of Gulf War veterans. Patient satisfaction, functional status as determined by SF-36, symptom burdens, exacerbation rates, scales of disease progression, healthcare utilization rates, pharmacy usage, and cost of healthcare are examples of potential variables of interest. However, each addresses a different aspect of health status and would be more or less appropriate depending on the medical condition being studied. In fact, VHA is currently performing a longitudinal analysis of Gulf War veterans' satisfaction with VA care and functional status. These results are partially responsive to the questions you've asked. I should be able to report these results to you by May 1998.

As you noted, we have contracted with the Institute of Medicine (IOM) to explore the feasibility of methodologies to measure the clinical progress and effectiveness of our treatment efforts and to advise us on methods to collect and analyze longitudinal information concerning the effectiveness of treatment and health outcomes in Gulf War veterans. We look forward to their advice on this issue. It is our view, at this time, that well-designed research studies is the best (and perhaps only scientific) mechanism to assess treatment effectiveness. VA is establishing a program of multi-center clinical trials to address the effectiveness of protocols for treating Gulf War veterans who suffer ill-defined or undiagnosed conditions. Of course, we will share the IOM findings and recommendations with you and the other members of the Committee, as soon as the report is available.

We understand that you perceive an apparent inconsistency between our willingness to perform a longitudinal analysis of self-reported health status of veterans from the Registry and what you called our "unwillingness" to consider any other unscientific measures for reviewing health outcomes or clinical progress. Our report on veterans' self-reported health status grew out of an open-minded attempt to be responsive to the GAO recommendations and use our existing national databases to provide partial answers. We found the self-reported health status data interesting, but not especially enlightening. As stated previously, we will also be reporting self-reported functional status and satisfaction measures. However, we continue to believe that scientific answers are needed in addition to these exploratory or more anecdotal efforts. We want to assure you, Mr. Chairman, that we are not unwilling to consider novel approaches. VHA has been a leader in research, and we are positioning ourselves to be the national benchmark for health outcome studies. We have contracted with IOM because we are genuinely interested in getting valid answers to veterans' concerns and in improving the state-of-the-art for outcome studies.

4. Please provide for the record a list of the nearly 20 VA medical centers at which "case management" has been implemented as a routine clinical strategy for Gulf War veterans (as reported in your testimony).

For those nearly 20 centers, what specific implementation actions have been taken, and how many Persian Gulf veterans' cases are being managed at those facilities?

Also, please provide the specific performance measures aimed at ensuring that appropriate resources are devoted to these efforts which have been established for network directors.

Response: The following VA medical centers are utilizing the "case management" approach to patient care: Big Spring, TX; Birmingham/Huntsville, AL; Boston, MA; Columbia, MO; Dayton, OH; Fayetteville, NC; Grand Junction, CO; Houston/Beaumont/Lubbock, TX; Lake City/Tallahassee, FL; Marion/Evansville, IL; Northampton, MA; Oakland Park, FL; Omaha, NE; Palm Beach/Rivera Beach, FL; Providence, RI; San Antonio/Kerrville, TX; St. Louis, MO; Tampa, FL; Seattle/American Lake, WA; and West Haven/Newington, CT.

The FY '96 performance measure for case management is attached for your information. The specific performance measures utilized are to ensure the availability of adequate resources. For a fully successful program, VISNs must improve the score on the overall coordination of care customer service standard by five percent; and for the exceptional program, a ten percent increase. Specific implementation actions and a progress report will be part of the VISN Directors' performance assessment. We will share that information with the Committee when it becomes available. Since this approach is relatively new at most of these facilities, we anticipate that the numbers of veterans currently served by case management is still rather low, but increasing.

5. Your testimony discusses many initiatives you have underway. Are there recommendations directed at VHA which the PAC, IOM, or other expert scientific bodies have made that you have rejected and NOT carried out?

If so, what are they, and what are the reasons for not implementing these recommendations?

Response: To the best of our knowledge, VA has seriously considered and implemented (at least in part) almost all the recommendations offered by the numerous scientific advisory committees that have evaluated our efforts on behalf of ill Gulf War veterans. The exception to this principle is related to the Presidential Advisory Committee recommendation advising VHA to offer genetic counseling services to veterans and their families. This recommendation remains under review. Genetic counseling requires reproductive evaluations of both the veteran and spouse. If VA decides to provide genetic counseling services, new legislative authority would be required to do an evaluation of the veteran's spouse.

VA Care Management

Definition:

Care management in VA is a process for increasing the likelihood that a patient receives easily accessible, coordinated, continuous, high quality healthcare. Care management is that aspect of primary care that coordinates care across all settings, including the home. VA care management is patient-centered rather than disease-specific; coordination of care for all diseases and all episodes of illness is carried out by the care manager assigned to a particular patient. VA care managers especially focus on the patient in the context of family and community by integrating an assessment of living conditions, family dynamics, and cultural background into the patient's plan of care.

Recognizing that not all patients need care management, and the extent of care management: required by any one patient will vary over time, the VA care manager is responsible for screening and determining the intensity of care management required for a panel of patients, typically belonging to one primary care provider (physician, nurse practitioner, or physician assistant). The care manager is then responsible for providing the appropriate intensity of care management for his or her panel. It is recognized that manageable panel sizes will vary depending on the case-mix of the provider. Care management is focused primarily on providing more coordinated and higher quality care; it may or may not lower the cost of care.

Goals:

Fully Successful: Improve VISN score on the overall coordination of care customer service standard (FY 98 national ambulatory care survey report) by 6%.

Exceptional: Improve VISN score on the overall coordination of care customer service standard (FY 98 national ambulatory care survey report) by 10%.

Data Source: Self report, NCFC surveys.

Issues:

1. VA care managers are from a variety of disciplines, although social work and nursing are most common. VA care management emphasizes competency in prioritizing, organizing, and coordinating services. Advocacy and communication skills are critical. The ability to negotiate and mediate with all levels of the health care system as well as other community organizations to support optimal service delivery is essential.
2. Care managers are members of the 502g primary care team, which typically consists of a primary care provider, a staff nurse, a care manager, and a health technician. The specific primary care setting (outpatient clinic, nursing home, home-based primary care, etc.) will broaden team composition, but the concept that patients and care managers are team-specific is constant. It is envisioned

that as patient needs and preferences change, patients may change teams (and thus care managers). For example, a patient may be followed by an outpatient clinic-based team with coordination of home health services by the team care manager for years until a team decision is made, *with the patient or caregiver*, that the patient requires more intensive support. At that time, the patient's care may be assumed by a home-based primary care team, or the nursing home primary care team if the patient moves to that setting. Team changes described typically occur only once in a single patient's life.

3. The following terms describe broad nursing initiatives encouraged and supported by VHA that are frequently confused with Care Management:

Nurse-Managed Care: Nurse managed care is a term used to describe two separate concepts: 1) case management performed by nurses who are typically baccalaureate trained, and 2) advanced nurse practices by masters-prepared clinical nurse specialists and nurse practitioners. Nurse Practitioners function as PCPs. Clinical Nurse Specialists typically function as consultants for particular diseases or issues.

Nurse-Managed Clinics: Nurse managed clinics can be run by nurses of any educational and certification level, depending on the nature of the clinic. Vaccination clinics might be run by LPNs, while a Community Based Outpatient Clinic (CBOC) would probably require a Nurse Practitioner. The CBOC could potentially be staffed by a primary care team comprised entirely of nursing personnel (Nurse Practitioner, PCP, staff nurse, nurse care manager, and nurse aide).

**Post-Hearing Questions
Concerning the February 5, 1998
Hearing to Receive Updates on Research,
Investigations, and Programs Involving
Persian Gulf War Veterans' Illnesses**

**For Dr. Kenneth Kizer
Under Secretary for Health
Department of Veterans Affairs**

**From The Honorable Lane Evans
Ranking Democratic Member
Committee on Veterans' Affairs
U.S. House of Representatives**

Question 1: Dr. Donald Mattison spoke about the contract VA has developed with the Institute of Medicine (IOM) which establishes an advisory role on research undertaken by VA. IOM also produced a report on the Health Consequences of Persian Gulf War in 1996. Please describe how the recommendations made in that report affected the research or health agenda for VA's treatment of Persian Gulf veterans.

Answer: The Institute of Medicine's Final Report on their study "Health Consequences of Service During the Persian Gulf War" has been a valuable tool to guide the research efforts of VA specifically, and the government generally.

With respect to VA research efforts, several research activities were undertaken or given additional emphasis as a result of the IOM report. The Final Report recommended that mortality studies on Gulf War veterans be extended out to at least 30 years. In 1996, VA published its study of Gulf War veterans' mortality experience through 1993 in the New England Journal of Medicine. This study showed that although there were more deaths among deployed Gulf War veterans than among their non-deployed counterparts, this excess in deaths was due to accidental causes (primarily from motor vehicle accidents). VA has followed that study up by extending the time period of deaths through 1995. The results of this follow-up are consistent with the earlier results. VA is committed to updating the mortality study on a periodic basis far into the future because excess deaths due to such causes as cancer may not become evident until much later.

Because of the excess deaths among deployed Gulf War veterans due to motor vehicle accidents, IOM recommended that a study be conducted to understand the risk factors for those excess deaths. VA researchers examined in greater detail the circumstances surrounding each motor vehicle accidental death using Department of Transportation databases. Preliminary results indicate that the excess deaths due to motor vehicle accidents may be associated with certain behavior patterns such as speeding and failure to wear a seatbelt. Additional research can hopefully determine why such behavior patterns may have occurred.

The IOM report urged improved DOD record keeping for epidemiological purposes, and enhancement of DOD epidemiologic capabilities. VA, DOD and HHS have been working together to develop a strategic plan for future deployment health that includes research to improve prevention, intervention, and treatment of deployment related health problems; improved record keeping; improved health surveillance; and improved risk communication. The initiative is in response to a Presidential Review Directive, NSTC-5, that was prompted by a recommendation of the Presidential Advisory Committee on Gulf War Veterans' Illnesses. However, this activity is also consistent with the recommendation of the IOM to continue and extend the Defense Medical Epidemiological Database (DMED). An integral part of this plan is continued improvement of capabilities and capacities to systematically collect medical and health data of active duty service members, as well as to enhance epidemiologic capabilities where needed. The quality of these data elements should significantly enhance epidemiological research capabilities.

The IOM report recommended that gender issues be addressed when assessing health effects of deployment. The VA Office of Research and Development has identified women's health as a priority research area within its program of Designated Research Areas. VA researchers are currently carrying out nine research projects, valued at \$1.3 million, specifically targeted at the health consequences of the military experience of women. The Health Services Research Service in the VA Office of Research and Development has also issued a Request for Applications inviting submissions of proposals to study the impact of gender differences in health. In the federal government's research portfolio for Gulf War veterans' illnesses, there are, in addition to the projects mentioned above, 10 projects that approach gender issues and the impact of service in the Gulf War from a variety of perspectives ranging from reproductive health to psychological health. The IOM report reinforced our view that this was an important area to investigate.

The IOM urged the completion and publication of the Naval Health Research Center epidemiology studies. These studies continue to progress at a steady pace. In the past year, major publications on reproductive outcomes and hospitalizations have been published in the New England Journal of Medicine. These have contributed significantly to our assessments of Gulf War veterans' illnesses.

The IOM recommended completion and publication of the VA National Survey of Gulf War Veterans. Phase I of the Survey is complete, and Phase II is nearing completion. Phase III involving detailed physical examinations of Gulf War veterans, spouses, and children is expected to commence this spring.

In accord with one of the IOM recommendations, a study of predictors of VA and DOD registry enrollment has been completed, and the results of that study should be published this spring.

Lastly, the IOM strongly recommended that all research results be published in a timely manner in peer-reviewed scientific publications. This has been a long-standing policy of the Research Working Group (RWG) of the Persian Gulf Veterans Coordinating Board and continues as such. Part of the charge to the RWG is to ensure scientific peer-review of all research on Gulf War veterans' illnesses research.

The 1996 IOM report also made recommendations concerning the collection and maintenance of health exposure information to improve the evaluation of Gulf War service-related conditions, and it gave considerable attention to improving medical information systems that would be used in future conflicts. Also, the report stressed the need for VA and the Department of Defense (DOD) to collaborate on the development of a computerized patient information system that would create a single, uniform health record for each service person. The recommendations made in the IOM report influenced VA's health agenda for Gulf War veterans, largely by focusing our attention on correcting gaps in systems that were already in place. We have made a considerable amount of progress improving these areas since the report was published.

An executive council of senior VA and DOD healthcare officials is improving communication between the two Departments, finding ways in which their health-care systems can work together, and reducing or eliminating overlap in the services each Department provides. For example, late last year, the two Departments agreed to conduct joint discharge physical exams that fulfill both DOD and VA requirements. Previously, DOD conducted an exit physical exam before separation, and VA would conduct another exam if the veteran applied for disability compensation afterwards. VA's compensation and pension protocol requirements are now incorporated into DOD exit physical exams. The exam will meet VA requirements for claims determinations, as well as DOD needs for a separation medical examination. When fully implemented, this new national policy will allow separating or retiring military service members expecting to file a claim for VA disability compensation, to undergo a single physical exam prior to discharge.

The VA/DOD executive council is working on other initiatives to improve VA/DOD healthcare coordination including: (1) Creating compatible, computer-based patient records to ensure a smooth transfer of information between DOD and VA healthcare systems, and provide every service member with a single, comprehensive VA/DOD healthcare record; (2) Working on ways the two Departments can share existing automation and technological products and collaborate in the ongoing and future development of medical automation and technology; (3) Creating and publishing joint clinical practice guidelines for disease treatment; (4) Collaborating in or combining laboratory and pathology programs; and (5) Developing a long-term effort that builds on the accomplishments of the interagency Persian Gulf Veterans Coordinating Board, through the establishment of a multilateral Military and Veterans Health Coordinating Board. These efforts will improve future medical surveillance, healthcare, compensation and research efforts.

Question 2: VA has four national referral centers for Persian Gulf War illnesses which have seen about 400 veterans since VA established them. What has and what can do to provide access to a level of diagnostic and treatment commensurate to what is available through the centers for greater numbers of veterans?

Answer: While fewer than 500 veterans have received care at the Gulf War Referral Centers, many more Gulf veterans with unexplained symptoms have received appropriate diagnostic evaluations and treatment at their local VA medical facilities. For the veteran's convenience, we encourage local VA medical centers to provide as many medical evaluations as possible. However, we have found that some Gulf War veterans have medical conditions that require referral. In some cases, this is due to lack of ability to provide subspecialty consultation or diagnostic technology at the smaller centers. In other instances, the case is medically complex and requires a second opinion. VA established Gulf War Referral Centers in West Los Angeles, Houston, Birmingham and Washington, DC to assist these veterans. The decision to send a veteran with unexplained symptoms to a referral center is made by the local VA physician in consultation with the referral center. No Referral Center has denied a veteran's admission when it has been requested.

Efforts are being undertaken to evaluate the effectiveness of Gulf War Referral Centers, and Gulf War veteran's satisfaction with VA health care. We have obtained some preliminary results about Referral Center patient satisfaction from the National Health Survey of Gulf War Era Veterans, but have not yet completed the formal review or data analysis. Appropriate adjustments will be made to the program after the review.

Question 3: There are many research projects taking place in VA investigating Persian Gulf War illnesses. VA has four environmental research centers -- please describe how these centers were selected, how their projects are selected and funded, and the focus of their research to date.

Answer: The first three Environmental Hazards Research Centers (EHRC) at Boston VAMC, Portland VAMC, and East Orange VAMC were the result of a competitive peer-review process resulting from a specific call for proposals issued January 10, 1994. Nineteen proposals from VA medical centers and their academic affiliates were reviewed for scientific merit in late spring 1994. Funding was announced in July 1994 and the three centers were funded beginning October 1, 1994. Each of these centers is receiving \$500 thousand per year for up to five years. Each EHRC has approached Gulf War veterans' illnesses with an overarching perspective that environmental exposures may have played a significant role. In this context, environmental exposures is taken to include a wide range of possibilities (i.e., smoke from oil well fires, chemical warfare agents, pesticides, and stress, among other things). Possible outcomes being investigated include neurological, neurophysiological, neuropsychological, psychological, pulmonary, and rheumatological. Specific putative diagnoses are being explored, including Chronic Fatigue Syndrome (CFS) and chemical sensitivities (which lacks a precise case definition).

In the summer of 1996, per my instruction, VA Office of Research and Development issued a request for proposals for an additional EHRC with a focus on reproductive

outcomes with an initial focus on Vietnam veterans. Seven proposals were submitted and reviewed by a scientific peer-review panel of experts in fall 1996. The Louisville VAMC, in collaboration with the University of Louisville, was selected based on scientific merit. Funding for the Louisville EHRC began in early 1997. The Louisville EHRC is conducting a broad range of research on reproductive outcomes. The EHRC is also conducting basic research into the reproductive toxicology of several specific compounds including dioxin. Lastly, it is developing a reliable biomarker for exposure to mustard gas that may be very valuable in future deployments.

Question 4: In past hearings, this Committee has encouraged VA to work more closely with DOD in researching probable causes of Persian Gulf War illnesses and identifying successful treatment models to serve their two beneficiary populations. The Institute of Medicine has also made this recommendation. What steps have you taken to more closely work with DOD?

Answer: At my request, the VA Office of Research and Development has entered into an agreement with DOD to jointly plan multi-center treatment trials for Gulf War veterans' illnesses. VA and DOD have initiated the planning process for a treatment trial for Gulf War veterans with Chronic Fatigue Syndrome (CFS) and Fibromyalgia (FM). VA and DOD are now exploring a possible joint effort to conduct an antibiotic treatment trial to ascertain whether Gulf War veterans' illnesses may have an infectious origin. In addition, VA has issued a Program Announcement soliciting proposals for additional treatment trials. Where appropriate and feasible, such trials could be conducted jointly by VA and DOD.

Question 5: On June 19, 1997, you testified, many veterans, and certainly the most complex Gulf War cases, need a system of care which utilizes case management. Has this been achieved?

Answer: One of our initiatives aimed at improving services to all veterans with complex medical problems is implementation of case management. In their Special Report (October 1997), the Presidential Advisory Committee on Gulf War Veterans Illnesses supported our efforts to implement case management. Significant progress has been made. Case management as a clinical strategy for Gulf War Veterans has been implemented at approximately 20 VA medical centers. Performance measures for the Network Directors have been established to ensure that the appropriate resources are devoted to these efforts at all facilities. In addition, in response to Public Law 105-114 (November 1997), VA will initiate clinical demonstration projects for case management and multidisciplinary clinical care for Gulf War veterans. The demonstration projects will use objective outcome measures to assess whether health care for Gulf War veterans is improved by case management approaches or multidisciplinary clinics. Awards for the demonstration projects will be made before the end of this fiscal year. These projects will be funded as two-year studies. We look forward to reviewing their conclusions.

Question 6: Given the scope of this problem and its apparent origin in wartime service, it is incumbent on VA to design and test alternative treatment models with an eye to improving the care afforded these veterans and their satisfaction with that care. Describe VA's efforts and results to improve both the care provided these veterans and their satisfaction with that care.

Answer: The VA Office of Research and Development has initiated plans for a multi-site randomized clinical trial to assess the effectiveness of multidisciplinary treatments for Chronic Fatigue Syndrome (CFS) and Fibromyalgia (FM) in Gulf War veterans. These conditions appear to significantly overlap with the types of symptoms and illnesses reported by many Gulf War veterans. Such a study is possible because these conditions have clearly defined case definitions along with proposed treatments that have undergone preliminary evaluation. This study will be carried out in collaboration with the Department of Defense (DOD) and conducted at multiple VA and DOD health care facilities. VA and DOD are investing up to \$5 million each to conduct this trial. Because of its experience and research on the characteristics of these diseases, we plan to consult with the National Institutes of Health (NIH) in the development of these

research protocols. In addition, the VA Office of Research and Development has issued a Program Announcement, or general invitation to VA clinicians/scientists, to propose additional multi-site trials to evaluate the effectiveness of different treatment strategies. The planned treatment trial, along with any trials proposed in response to the Program Announcement, will undergo rigorous scientific peer review by VA's federally chartered Cooperative Studies Evaluation Committee. In addition, VA is contracting for a study of what is commonly known as alternative or complementary medicine use and potential applications among VA patients. A copy of the statement of work is attached.

Question 7: The final report of the Presidential Advisory Committee on Persian Gulf War Veterans' Illnesses noted that neither VA nor DOD have "widespread or systematic policies in place to address the concerns and questions of Gulf War veterans concerning reproductive health." Has VA conducted a review of its policies for reproductive health and instituted a policy to allow genetic counseling for veterans with concerns about conditions that may be associated with military service as recommended by the PAC? What are the results of this review?

Answer: I understand that Department policy on the provision of reproductive healthcare, including genetic counseling and other related issues, is currently under review by VHA officials. It is my further understanding that to perform adequate and complete reproductive genetic counseling, one needs to perform a reproductive evaluation of the couple, i.e., of both the veteran and the veteran's spouse. However, VA has no authority to provide genetic counseling to Gulf War veterans' spouses (non-veterans). VHA officials must thus consider this significant limitation in their ongoing policy deliberations.

Question 8: Section 107 of the Veterans' Benefits Improvements Act of 1994 required VA to conduct a study to evaluate the health status of spouses and children of Persian Gulf War veterans. Provide the status, results and findings of this study.

Answer: VA implemented the Spouses and Children Examination Program on April 8, 1996. This program was to originally terminate on September 30, 1996. As you know, Congress extended the authority to conduct examinations until December 31, 1996. As of December 31, 1997 approximately 2,750 requests for examinations had been received. We have completed approximately 800 spouse or children exams and 730 exams are pending. The remaining 1,220 requested exams were not conducted because the individual to be examined canceled or did not appear for the exam. VA has developed a database to capture the medical findings and other related information. However, at this time, there are insufficient entries to draw any findings or conclusions. Upon termination of the program, we will perform a detailed analysis. The results of that analysis will be forwarded promptly to you and the Committees.

**Attachment
Honorable Lane Evans Question No. 6
to Dr. Kenneth Kizer**

Title of Project: Alternative Medicine Therapy: Assessment of Current VHA Practices and Future Opportunities.

Authority of Project: Subpart 37.2 of Title 48, CFR prescribes policies and procedures for acquiring services by contract and regulating these contracts with individuals and organizations for both personal and non-personal services.

Purpose: The purpose of conducting this study is to assist the Veterans Health Administration (VHA) to answer the question, "Should VHA offer what is often referred to as alternative medicine treatment?" "If so, as a publicly funded national organized system of care that is extensively involved in health professional training and research, how can VHA ensure that any alternative medicine therapies that it offers to supplement or complement traditional therapies are appropriate, of high quality and equitably available throughout the system?"

Background: The VHA in the Department of Veterans Affairs provides medical care and social support services to veterans in a wide range of inpatient, outpatient, home and community settings. It does this in a system of 173 hospitals, nearly 600 ambulatory care and community based outpatient clinics, 131 nursing homes, 73 home healthcare programs, 40 domiciliaries, 206 readjustment counseling centers, and various contract programs that are administered through 22 integrated service network offices, a national headquarters and other support offices. VHA facilities are located in each of the fifty states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam and Manila.

VHA care is delivered to veterans who present with a wide range of medical, surgical, mental and social problems. In addition to the diseases/illnesses seen in the general U.S. adult population, VHA has special interests and needs in geriatrics and long-term care. VHA also serves a number of special populations of veterans who are disadvantaged by spinal cord injury/dysfunction; limb loss; post-traumatic stress disorder; chronic mental illness; homelessness; blindness; substance abuse; and exposure to environmental hazards associated with their military service.

In addition to providing a full continuum of clinical care services to veterans, VHA has education and research programs that are major national assets. VHA's education program includes affiliations with 107 medical schools and over 1200 allied and associated health education programs representing over 40 professional disciplines. It has provided training to over two-thirds of the nation's physicians. The VHA research program conducts basic, clinical, epidemiological and behavioral studies across the entire spectrum of scientific disciplines. VHA researchers continually make major and landmark contributions to the advancement of medical science and the improvement of national health care.

VHA's major stakeholders include Congress; veterans; veterans service organizations; academic institutions; professional healthcare organizations that represent providers and clinical specialties; organized labor and research organizations.

This project is expected to provide VHA with information about and analysis of "alternative medicine" treatments that have been judged to: 1) be safe for patients, 2) be clinically effective and 3) contribute to patient satisfaction. These judgments are expected to be predicated on published, valid and reliable evidence obtained through methodologically sound studies. This must be done, and reported, in a manner that allows VHA to make determinations about what it will add to its armamentarium of care to meet the goal of providing the most appropriate and best possible care to each veteran.

Scope and Methodology.

Assessment and Analysis. VHA is proposing to have a contractor: 1) provide a working definition of "alternative medicine" for use in this project; 2) assess and catalogue its current use of what are commonly known as "alternative medicine" treatments, 2) prepare a listing of the universe of available "alternative medicine" therapies currently in use for/by VA patients and those that are both potentially useful in the care of VA patients and available in the U.S.; and then, 3) make recommendations about those treatments that should be considered for continued use, or addition to available treatments based on:

- the evidentiary base supporting the "alternative medicine" treatment;
- identification of VA patient need/potential benefit;
- analysis of patient risk associated with use of the therapy, at least in terms of the direct risk of the therapy and the risks of using it rather than other potentially more efficacious traditional therapies; and
- cost-effectiveness.

It is understood by both VA and the contractor that recommendations about therapies that should receive consideration will be subject to additional internal and external review.

To answer the question under **Purpose** above it is expected the contractor will;

1. Develop an understanding of the major diagnoses of veterans served by VHA, including women and those in VHA's special emphasis programs.

Associated VA actions: Provide information about the VA patient population related to major diagnoses and special patient populations to the contractor.

2. Submit to VHA, for approval, the working definition of "alternative medicine" treatment to be used for this project indicating from what sources it was drawn.

Associated contractor actions: In construction/selection of the definition, review relevant databases including National Institutes of Health definitions available through Medline.

3. Assess and analyze the degree to which "alternative medicine" therapies are offered within VHA system-wide, to include providing information about type of therapies offered, the purposes for which offered and the specific programs, locations in which offered and outcomes of such interventions.

Associated contractor actions:

- a. Develop a list of "alternative" or "complementary medicine" therapies in general use in the U.S.; e.g., acupuncture, biofeedback, etc., that have been applied to problems/conditions/illnesses of the VA patient population. Each treatment identified will be accompanied by summary information about the scientific and experiential evidentiary base supporting its use and the extent and primary application(s) of its use. To do this, the contractor will work with the Office of Alternative Medicine at the National Institutes of Health and other appropriate entities as well as members of VHA offices including Patient Care Services, Public and Environmental Health, Readjustment Counseling, and Research.
- b. Conduct quantitative assessment of use of "alternative medicine" treatments across the entire system that provides detail about each of the offered therapies in terms of 1) programs/settings in which a therapy is used; 2) diseases/problems for which used; 3) reason for using it; e.g., patient request, prior success with its use, primary vs. adjunct treatment etc.; and frequency of use in comparison to traditional methods; 4) availability of the treatment across the system; e.g., limitations on availability and use in terms of settings, access, etc.; and 5) clinicians who provide the therapies; e.g., MD, RN, psychologist, social worker, etc.

It is anticipated that the contractor will develop a survey tool and 1) obtain VHA pre-approval of its use; 2) pretest the instrument at a minimum of one facility; 3) make indicated changes to the survey; 4) obtain VA approval of the final survey; 5) survey all VHA healthcare facilities for quantitative information and 6) follow this with an in-depth review of approximately ten representative facilities. (The tool/method must provide for accuracy and comparability of data that is approved by VA prior to use.) Representative facilities will be identified by the contractor using results of the initial survey and consultation with VHA staff. Alternative approaches to this method can be proposed by the contractor and will be considered based on ability to meet the goals.

- c. Develop a set of criteria, and obtain VA approval of same, by which therapies should be judged appropriate for inclusion in VHA's array of clinical care treatments. Such criteria would be expected to discern evidence that a treatment had been proved safe, efficacious for the condition for which used, and cost-effective

Associated contractor actions: Contractor will provide a detailed description of the process by which the validity of the selected criteria was determined.

d. Develop, in consultation with VHA officials the definition of "applicable universe of available alternative medicine treatments" using information gained in steps a-c.

4. Using the criteria and list of treatments of potential use in treatment of VA patients, develop recommendations about "alternative medicine" treatments that should be considered by VA for discontinuation, continuation, or addition. Treatments recommended for continued use or for addition are to be arrayed based on strength of evidence in support of each treatment; associated costs, benefits and risks to patients, availability of qualified practitioners and receptivity or barriers to offering each treatment. It is further expected that a) conclusions reached by the contractor will compare use of "alternative medicine" treatments for particular problems/diseases to their use by "benchmark" organizations (to be identified in advance by the contractor and approved by VA) and b) that recommendations will address the full range of the contractor's assessments and analyses.

Associated contractor actions:

a. Identify to VHA any "alternative medicine" treatment options that should be of particular interest to VA for control of symptoms – e.g., pain or for subjective symptom management. As noted earlier, it is expected this would be based on a review of major diagnoses/problems experienced by VA's overall patient population and sub-populations – e.g., Gulf War veterans with undiagnosed or hard-to-diagnose conditions, veterans diagnosed with PTSD, those with addictive conditions, AIDS patients, etc. Each identified option should include an assessment of the cost or financial impact of implementation of the option. To do this, VHA will make available to the contractor demographic information about its patient populations and expects that the contractor would also collect additional information through its review and interviews.

b. For those therapies that should be of particular interest because of usefulness in the VA patient population, provide information regarding the availability of evidence reports from the Agency for Health Care Policy and Research (HHS) and of other governmental agency assessments or evaluations, from organizations such as the Swedish Office of Health Technology Assessment (SBU), the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), as well as reports from private sector organizations such as the Emergency Care Research Institute (ECRI)

c. Assess and analyze the receptivity and barriers to the use of the various "alternative medicine" treatments from the perspectives, at a minimum, of culture (medical and VA), academic affiliates; VA policy, regulation or statute; access to practitioners qualified in their use. In its analysis of the findings, VHA should be provided information about the extent to which facilitators and barriers found in VA are mirrored in the larger health care arena. To do this, it is anticipated that the contractor will use its

survey tool; conduct subsequent in-depth review of representative facilities and interviews with appropriate VA patients or patient advocacy groups such as Veterans Service Organizations and VA staff including General Counsel attorneys as well as review practices of other health care organizations (as part of its initial preparation of the list of therapies) directly, or through relevant published information.

Tasks and Associated Deliverables.

The successful bidder will provide documentation of ability and experience in conducting studies that require scientific rigor in evaluating medical therapies and their evidentiary bases.

1. Written project plan with timelines.
2. Benchmarking activities and consultation with VA officials as noted above
3. List of "alternative medicine" treatments.
4. Alternative medicine treatment evidence assessment, including process used for evidence assessment
5. Survey instrument (or other alternative method acceptable to VA)
6. Written interim report at conclusion of assessment phase, with briefing.
7. Written final report. (A briefing with the Under Secretary for Health may also be required.)
8. Verbal summary of report and recommendations, with appropriate documentation, for key executives
9. Regular interaction with TOPM throughout course of contract.

Term of the Contract. Begin not later than February 10, 1998 and be completed within 180 work days.

Description of Tasks and Associated Deliverables.

Task 1. Meeting with VHA project manager and other key officials to outline project and clarify subsequent timelines and tasks. This would include proposing an approach (for example - for the survey or alternative approach; methods planned to facilitate selection of an appropriate sample of facilities for more in-depth assessment and analysis) and reaching agreement on methods that would allow maximum usefulness and ability to apply recommendations across the VHA system. Following this meeting, the contractor's project leader and other appropriate staff will maintain telephone, personal or other contact with the TOPM on weekly basis for first month and biweekly thereafter during entire project to assure VA is aware of status of the work on an ongoing basis.

Task 2. Benchmarking activities and consultation with VA officials as noted above.

Task 3. List of "alternative medicine" treatments.

Task 4. "Alternative medicine" treatment evidence assessment product, including process used for assessing the evidentiary base.

Task 5. Survey instrument or other acceptable tool/method.

Task 6 Complete assessments as outlined under Scope and Methodology and provide a briefing and interim written report of findings and preliminary recommendations to Under Secretary for Health.

Task 7. Provide complete written report that incorporates assessment and recommendations in a manner that meets the approval of the TOPM and Office of the Under Secretary for Health.

Task 8. Provide verbal summary of finding and recommendations to an audience that includes appropriate Headquarters, VISN and facility staffs.



United States
General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

March 20, 1998

The Honorable Bob Stump
Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
335 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Stump:

We have enclosed our responses to questions you posed following our testimony before the Veterans Affairs Committee on Feb. 5, 1998.

Please refer any questions about this material to Mr. Kwai-Cheung Chan, Director, Special Studies and Evaluations, on 512-3092.

Sincerely yours,

A handwritten signature in cursive script, reading 'Donna M. Heivilin'.

Donna M. Heivilin
Director of Planning and Reporting

Enclosure

**Responses to Post-Hearing Questions for Ms. Heivilin
Director of Planning and Reporting
National Security and International Affairs Division
U.S. General Accounting Office**

- Q:** Do you concur with the views of the PAC that as a general rule the government should sponsor only research that has been subject to peer-review and competition?
- A:** To the extent that independent peer review and competition act to improve the credibility, quality, and efficiency of research efforts, we agree that these approaches should be strongly encouraged.

- Q: There is a perhaps-unintended implication in your testimony that government sponsored research on Gulf War illnesses is suspect, and that privately sponsored research is inherently more reliable. Did you intent to convey such an implication? If so, please explain.
- A: We did not intend to imply that 'government sponsored research on Gulf War illness is suspect, and that privately sponsored research is inherently more reliable.' We reported the following facts in our report: (1) federal research on Gulf War veterans' illnesses has not been pursued proactively; (2) much of this research was begun in response to congressional mandate, earmarked funding, or external reviewers' recommendations, indicating that the executive branch agencies were slow in responding to Gulf War veterans' health concerns; (3) while federal research is currently centered on studies of the prevalence, nature, and risk factors associated with veterans' illnesses, few studies are focusing primarily on identification and improvement of treatments for these illnesses; (4) most of the epidemiological studies have been hampered by data problems and methodological limitations and consequently may not be able to provide conclusive answers in response to their stated objectives, particularly in identifying risk factors or potential causes; (5) some hypotheses (for example, that veterans' current symptoms are due to exposure to stress) were pursued more aggressively than others (for example, that symptoms are due to low-level exposure to chemical warfare agents) and some hypotheses that were initially rejected by the federal government (for example, that symptoms are due to delayed chronic effects of exposure to organophosphates) were pursued with private sector funding; and (6) a substantial body of privately funded research suggests that low-level exposure to chemical warfare agents on chemically related compounds, such as certain pesticides, is associated with delayed or long-term health effects. Regarding delayed health effects of organophosphates, the chemical family used in many pesticides and chemical warfare agents, there is abundant evidence from animal experiments, studies of accidental human exposures, and epidemiologic studies of humans that low-level exposure to certain organophosphorus compounds, including sarin nerve agents to which our troops were exposed, can cause delayed and chronic neurotoxic effects.¹

¹Sarin has been used as a chemical warfare agent since World War II, most recently during the Iran-Iraq war, and by terrorists in Japan.

Q: I note that a substantial number of highly regarded independent scientists and physicians have worked on these issues for years – first with the Institute of Medicine and then on the Presidential Advisory Committee. Your conclusions implicitly and explicitly disagreed with scientific judgments made by those bodies. You testified that you "showed your work to outside experts" who "reviewed our work." In the context of your testimony, the implication is that unnamed "experts" agreed with your findings and conclusions, but in responding to our pre-hearing questions, you failed to identify who those experts were. Please identify for the record by name and affiliation the "outside medical experts [who] reviewed [your] work." Your answers to our prehearing questions indicate that you did not solicit or receive written responses from those "experts." Why not? Did you receive comments from those experts at all? Did you receive any comments expressing disagreement with assertions of fact, findings or conclusions in your draft report? In preparing the report on which you testified before our Committee, you solicited comments on your draft report from VA, DOD, and the PAC. Despite substantial critical responses from each, you concluded that none of the comments received provided evidence to challenge your principal findings and conclusions. With respect to the soundness of the findings and conclusions made in your report and your testimony, particularly those with which the PAC, VA, and DOD disagree, precisely what conclusions do you intend to have the Committee draw from your testimony that you "show[ed] your work to outside experts"?

A: Comments from PAC, VA, and DOD are acknowledged and reprinted in our report for the review of interested readers. None of the comments we received provided evidence to challenge our principal findings and conclusions that (1) DOD and VA had no means to systematically determine whether symptomatic Gulf War veterans were better or worse than when they were first examined and (2) ongoing epidemiological research would not provide precise, accurate, and conclusive answers regarding the causes of the Gulf War veterans' illnesses. All of the comments we received sought to shift the onus of identifying and substantiating the causes of Gulf War illnesses to us, when in fact we merely reviewed the sufficiency and persuasiveness of the evidence behind the administration's conclusions. In some instances, we found it to be weak or open to alternative interpretation.

In the absence of official conclusions from DOD and VA, we examined conclusions drawn in December 1986 by the President's Advisory Committee on Gulf War Veterans' Illnesses, and endorsed by DOD in January 1997, about the likelihood that exposure to 10 commonly cited agents contributed to the explained and unexplained illnesses of these veterans. We found that the evidence to support several of these conclusions is open to challenge or subject to different interpretation. We reviewed the extent and validity of official conclusions on key issues through review of extant scientific literature; and consulted experts in the field of epidemiology, toxicology, and medicine. We consulted these experts to ensure that we were correctly presenting the results of the scientific literature. For epidemiological research, we consulted Dr. D.A. Henderson, Dean Emeritus and Dr. L. Gordis, Professor Emeritus, School of Hygiene and Public Health, Johns Hopkins University. For toxicological and medical research, we consulted Dr. F. H. Duffy of Harvard University; Dr. M. B. Abou-Donia of Duke University; Dr. S. Somani and Dr. K. Husain of the University of Southern Illinois; Dr. R. W. Haley of the University of Texas Southwestern Medical School; and Dr. P. Spencer of Oregon Health Sciences University. However, it is important to note that GAO is solely responsible for the conclusions drawn in its reports; it does not rely on experts to draw these. It is our practice to consult individuals with a variety of viewpoints in the expectation that they will not always agree; we do so largely to help ensure that all the relevant facts and factors are adduced, not to seek their views on what GAO should find or recommend.



United States
General Accounting Office
Washington, D.C. 20548

Health, Education, and
Human Services Division

B-279446

March 18, 1998

The Honorable Bob Stump
Chairman, Committee on Veterans' Affairs
House of Representatives

Subject: Veterans' Benefits: Improvements Made to Persian Gulf Claims Processing

Dear Mr. Chairman:

The enclosed information responds to your follow-up questions concerning our testimony before the Committee on February 5, 1998. In our testimony, we noted that VA has taken steps to improve the processing of Persian Gulf claims for undiagnosed illnesses. However, because VA only recently began some of these initiatives, their full impact is uncertain at this time. The enclosed information supplements our testimony before the Committee and specifically clarifies information on our review of readjudicated Persian Gulf claims.

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If you have any questions or would like to discuss this information further, please contact me on (202) 512-7101. We will make copies of this correspondence available to other interested parties on request.

Sincerely yours,

Stephen P. Backhus
Director, Veterans' Affairs and
Military Health Care Issues

Enclosure

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SUPPLEMENTAL INFORMATION ON PERSIAN GULF CLAIMS

This enclosure details your questions and our responses, which supplement information in our testimony before your Committee, Veterans' Benefits Improvements Made to Persian Gulf Claims Processing (GAO/T-HEHS-98-89, Feb. 5, 1998).

1. **You mentioned the potential for inconsistencies in adjudicating these claims. With the sample you studied, have you noticed a significant difference in allowance rates between the regional offices?**

Our sample of Persian Gulf claims does not permit us to draw conclusions or provide an indication of the differences in allowance rates by regional office. We drew our sample from a nationwide pool of Persian Gulf claims, and it was not designed to estimate such differences by regional office. In addition, the results of our analysis were based on a sample drawn shortly after VA decentralized its claims processing from four area processing offices to the 58 regional offices. VA began redistributing claim files around June 1997, and we drew our sample as of July 31, 1997. Two-thirds of the claims in our sample were readjudicated by a former area processing office. The remaining claims in our sample were readjudicated by 16 different regional offices, and 11 of these offices processed only one claim.

2. **Is there one thing you can suggest that is the key to improving the rating and timeliness of these Persian Gulf claims?**

Persian Gulf claims are extremely complex, often requiring claims processors to develop and rate multiple medical conditions. As noted in our testimony, our review focused on VA's readjudication of claims that were previously denied. We reviewed the claims to ensure that VA followed its procedures in addressing all evidence in a veteran's claim file but did not assess the adequacy of the medical examinations.

One area that may warrant closer inspection, however, is the adequacy or quality of VA's medical examinations required in undiagnosed illness claims. Thorough medical examinations are essential for accurate and timely adjudication of these claims, according to our review. Physicians who conduct compensation examinations must be familiar with the regulatory requirement that an undiagnosed illness is potentially compensable only when an acceptable clinical diagnosis has been ruled out through medical history, physical examination, and laboratory test. This approach is somewhat contrary to the way most compensation examinations are conducted because in those cases a diagnosis is expected. In limited discussions with rating specialists and compensation and pension physicians, we learned that some medical examiners still believe that a diagnosis is expected from them and they generally provide one. VA's Undersecretary for Benefits acknowledged in his testimony that the adequacy of medical examination reports are a major concern. To address this issue, VA has developed guidelines for conducting examinations involving undiagnosed illnesses and conducted a joint satellite video broadcast on Gulf War examinations for Veterans Health Administration and Veterans Benefits Administration employees.

3. **Have you found that other veterans' claims are being cast aside in favor of readjudicating the Persian Gulf claims?**

As part of its decentralization process, VA instructed its regional offices to give the readjudication of previously denied Gulf War claims the highest priority. Regional offices therefore assigned up to 30 percent of their adjudication staff to Persian Gulf claims processing, which allowed 70 percent of the staff to handle non-Persian Gulf claims. According to regional officials we spoke with, if their office's workload increased beyond its capability, they transferred cases to other regions to be

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processed or worked overtime to reduce the workload. These strategies were used for both Persian Gulf and non-Persian Gulf cases.

4. In your review of the various regional offices, did you note any large mismatches between Gulf War claims and the resources to handle them?

Because our review of Persian Gulf claims processing did not include an analysis of regional office resources, we cannot address mismatches between claims and resources in regional offices. We did note, however, that due to the decentralization, regional offices located in VA's southern areas received most of the Persian Gulf claims for readjudication. Specifically, 10 of the 14 regional offices that received 250 or more of the redistributed Persian Gulf claims were located in the southern area. Officials at two of the four southern regional offices whom we spoke with stated that the decentralization had increased processing time or backlog. For example, one regional office stated that in a 6-month period in 1997, the percentage of cases pending over 180 days increased from 10.5 to 16 percent. Officials at the other two southern offices stated that they mitigated the decentralization's impact by transferring cases to other regions to be processed or worked overtime to reduce the workload. Thus, the impact on a regional office's resources depends on the number of cases they receive and the regional office's existing workload.

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**Honorable Jack Quinn Questions for the Record
Honorable Joseph Thompson
Under Secretary for Benefits
Department of Veterans Affairs
Hearing on Persian Gulf Issues
February 5, 1998**

QUESTION 1: On page 2-55 in Volume 4 of the VA budget submission, there is a very candid description of the results of a December 1997 review of 384 claims. The section reads, "of the 384 cases reviewed, 139 had at least one error for a national baseline accuracy rate of 64%." First, how do those findings compare with the monthly reports filed by each RO since July 8, 1997, as mentioned in your testimony? Second, this review does not engender great confidence in how VA is processing Persian Gulf claims and even more disturbing, how VA is handling all of its claims. Does VBA intend to continue the STAR Program, and when will you begin similar audits at each of the Regional offices?

ANSWER: The quality improvement reports on Gulf War claims for the months June through December 1997, indicate an approximate 70% accuracy rate. While we have seen some improvement during the latter months of the reporting period and the overall percentage is somewhat better than that found on the STAR review, it is still not good enough for the quality service we expect for the processing of Gulf War claims. For this reason the Compensation and Pension Service's (C&P) Gulf War Rapid Response Team continues to provide assistance functioning as a full time program information resource and by conducting weekly telephone conferences with Regional Office staff throughout the country. We continue to work with VHA to improve the sufficiency of disability examinations which are so critical to the overall accuracy of the processing of Gulf War claims.

We understand that we need to improve the accuracy of all the compensation and pension claims processing. For this reason, the Director of the C&P Service formed a special work group last year to study the quality review program that was in place. The work group developed the prototype Systematic Technical Accuracy Review (STAR) program, which we tested with a special review in December. The purposes of the test were to validate the methodology and review instrument of the STAR program and to better define the baseline national accuracy rate for the core adjudicative work which was limited to the more complex and more difficult rating related work. It is essential to understand that the STAR protocol tested is more rigorous and demanding than the review program currently in place. Under the STAR protocol, a case is reviewed from the point of initial development, through the decision, to the notification sent. If a critical service or decision error is identified at any point in the processing of the claim, the entire case is considered to be in error.

As I noted in my statement, I am committed to improving the technical accuracy of compensation and pension claims adjudication to ensure that our nation's veterans receive the best service possible. The STAR program will play a critical role in documenting service. We are now developing a plan to implement STAR on a national and station level. I expect an interim program to start by June of this fiscal year and a final version by October 1, 1998.

QUESTION 2: In your testimony, you state that guidelines for C&P exams are now being finalized between VBA and VHA. Do you find it disturbing that it has taken several years for VBA and VHA to develop and ensure a complete and ratable exam?

ANSWER: The guidelines for C&P exams, jointly approved on February 6, 1998, are not new guidelines, but rather a refinement of the examination guidelines that have been in place since the Gulf War legislation was first enacted in 1994. The legislation was designed to address a unique set of illnesses. As a result, we find we are dealing with the kinds of claims we have never before experienced. As with any new process, it is important to update and refine field guidelines as we learn more about undiagnosed illnesses. A satellite video teleconference was conducted on March 3, 1998, to provide training on the newly revised guidelines. The broadcast was well received by both VBA and VHA personnel. We look forward to continued collaboration with VHA.

QUESTION 3: You note that among the roughly 91,000 Gulf theater veterans who are receiving service-connected compensation, either 1,590 or 2,306 veterans are receiving compensation for undiagnosed illness. What are you doing to rectify that large variation in the data?

ANSWER: Attached is a White Paper addressing this issue.

White Paper on Gulf War Reporting

ISSUE: Data from the Gulf War Tracking System (Tracker) and the Gulf War Management Information System (GWMIS) do not match with respect to the number of Gulf War veterans who are service-connected for an undiagnosed illness.

BACKGROUND: On February 5, 1998, the Under Secretary for Benefits noted in testimony before the House Veterans' Affairs Committee that discrepancies between the Tracker data and the GWMIS data for service-connected undiagnosed illnesses needed to be resolved.

The Tracker showed 2,306 veterans with service-connected undiagnosed illnesses whereas the GWMIS showed only 1,590. Tracker data is collected from manual input by Adjudicators in the field offices as they identify disability decisions for veterans claiming undiagnosed illnesses. The GWMIS uses Defense Manpower Data Center (DMDC) data on Gulf War veterans and matches it with the VA Benefits Delivery Network (BDN) for veterans with undiagnosed illness rating codes.

REASONS FOR DISCREPANCY:

There are vulnerabilities in both of the reporting systems for Gulf War illness claims which preclude the ability to track these cases with 100% accuracy. In general, the use of stand alone tracker systems that are not tied into the payment and award system (the Benefits Delivery Network) are inherently flawed. These tracker systems must rely on an adjudicator to update a separate system that has no impact on the veteran's claim or the decision making process. This extra step is prone to being overlooked and/or recorded inaccurately when workload is heavy.

Ideally, we would be able to capture this type of data in the BDN. Unfortunately, the BDN was designed and developed in the late 60's and early 70's when system capacity (memory) was expensive and therefore limited. Consequently, the BDN only holds a maximum of 6 diagnostic codes and does not retain any information on 0% SC cases when no payments are being made. Since 1991, if payments were not made, we captured 0% SC in BIRLS (the Beneficiary Identification and Records Locator Subsystem) in Austin which also holds 3 additional diagnostic codes. The Tracker system was an attempt to capture all of the data associated with Gulf War claims (i.e., all diagnostic codes, 0% SC cases, as well as all denials) without matching data from multiple systems. The tracker system, however, has not proved to be a reliable data source and we plan to discontinue its use as soon as we can develop a subsystem that is tied to the BDN.

The GWMIS represents the best data we have available from several sources including the Defense Manpower Data Center. The GWMIS was developed at the Department level and includes information derived from both VHA and VBA. The vulnerabilities of the system which include the limitations of the BDN are clearly cited. One of the limitations includes the reporting lag in DMDC data which is 4 months older than the current data used by VBA. This lag can affect the Era and Theater numbers but does not affect the Conflict data which represents a closed period and is not subject to change except for some minor corrections that VBA has discovered in processing individual claims. These minor corrections are required, since the DMDC's distinctions of Era, Theater, and Conflict service rely on reports that tracked the locations of various military units rather than specific individuals. Consequently, the precise assignments of some individuals are not always accurately reflected in the DMDC data. When there is a discrepancy, VBA has been providing DMDC with corrections in an ongoing joint effort to improve our data integrity.

CORRECTIVE ACTIONS:

The IRM staff and the C&P staff are in the process of designing a new BDN subsystem which will capture data on all special issue claims. The system will be designed so that it will prompt adjudicators to make an entry to identify whether a claim involves any special issues. The accuracy of these entries will be reviewed as part of our performance management system and STAR reviews. Our target date for implementing this new subsystem is September 30, 1998.

In the short term, we are modifying BDN procedures to prioritize undiagnosed illness rating codes so that they are retained, where possible, as one of the 6 codes the system can hold.

The longer term solution involves the development of VETSNET which will replace the BDN and provide not only enhanced processing functionality but also a management information subsystem to meet our data reporting needs which will encompass the data needs of our key stakeholders.

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ISBN 0-16-057306-8



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