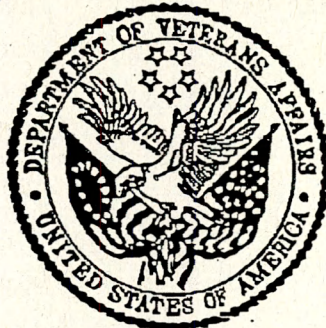


Office of Congressional Affairs



Department of Veterans Affairs

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PG Testimony

Number of pages
including cover:

Date:

3/1/95

Fax to number:

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on speech +
Advisory Cmte*

3RD DRAFT
3/2/95

STATEMENT OF
KENNETH W. KIZER, M.D.
UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
HOUSE VETERANS' AFFAIRS COMMITTEE
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

March 9, 1995

Mr. Chairman and Members of the Subcommittee,

Thank you for this opportunity to discuss the various research activities involving unexplained illnesses in Persian Gulf veterans. I am pleased to be here today and to have this opportunity to publicly state the Department of Veterans Affairs steadfast commitment to provide high quality compassionate care to Persian Gulf Veterans suffering with health problems and to back that clinical care with timely, peer reviewed scientific research. These men and women served valiantly under harsh conditions. They put their lives on the line, and we owe them and their families our very best efforts.

Since the focus of this hearing is research, I will describe the efforts to coordinate federal research and then describe the specific research conducted by the VA. In 1993, President Clinton named VA as the lead federal agency to coordinate government research efforts to find the causes of health problems facing Persian Gulf veterans. The VA, Defense, and Health and Human Services (HHS) Departments are engaged in both joint and separate research projects that include epidemiology; clinical

2

research, and basic research. Coordination is provided by the Interagency Research Coordinating Council (a working subcouncil of the Persian Gulf Veterans Coordinating Board). The Research Coordinating Council is chaired by VA with members from DoD, HHS, and the Environmental Protection Agency (EPA). The Council monitors the activities and ^{results} products of various research efforts and recommends future research directions.

In early 1992, only a few months after the end of the open conflict in the Persian Gulf, there were some reports of health complaints among veterans who served during the Gulf war. There were several immediate responses by VA and DoD to these complaints, which were primarily of an evaluative nature. These included (1) disease outbreak investigations; (2) population surveillance; (3) exposure inventory and assessment; (4) demographic analyses; and (5) clinical evaluations.

It became evident early in the initial disease outbreak investigations that many, [if not most, ^{delete?}] of the reported illnesses could be diagnosed and appropriately treated. However, there were veterans who reported symptoms of illness for which a medically accepted diagnosis could not be provided. When the number of these cases began to multiply VA and DoD initiated numerous surveillance activities and called in outside experts to look at this problem and provide consultation.

VA Research Efforts

The goals of research conducted by VA and other federal agencies are to:

1. Establish the prevalence of unexplained illnesses (i.e., illnesses for which an accepted diagnosis does not exist) in Persian Gulf veterans and their families, and compare the results to appropriate control populations.
2. Establish the prevalence of standard, diagnosable diseases (including adverse birth outcomes) in Persian Gulf veterans and their families, and compare the results to appropriate control populations.
3. Identify clinically and scientifically appropriate diagnoses for currently unexplained illnesses.
4. Identify potentially new presentations of recognized diseases.
5. Identify causative factors for unexplained illnesses.
6. Identify effective treatment modalities for unexplained illnesses.
7. Develop better understanding of previously unrecognized disease.

Reaching these goals requires a balanced combination of epidemiological, clinical, and basic research. As the ~~land~~ ^{lead} agency for federal-wide effort^s to achieve these goals, the

^

Department of Veterans Affairs is currently engaged in over 30 research projects related to the health problems of Persian Gulf veterans. The size and scope of these projects range from small, pilot projects conducted by individual investigators at VA medical centers, to large scale, epidemiologic studies, ^{and at} multidisciplinary research centers. Comprehensive information about all research projects related to Persian Gulf veterans in VA, and in other federal departments, is contained in Secretary Brown's annual report to the Veterans' Affairs Committees. The most recent report was provided to the Committee last week.

Sound epidemiological investigations are the foundation for our overall research program. VA is sponsoring several epidemiologic studies, as are DoD and HHS ^{the latter} through the Centers for Disease Control and Prevention. VA is initiating a major national survey of Persian Gulf veterans. This survey was highly recommended by the NIH Technology Assessment Workshop panel. It will involve selecting a random sample of 15,000 Persian Gulf veterans and 15,000 contemporaneous non-Persian Gulf veterans (referred to as Persian Gulf era veterans). The survey will utilize a mail-in health questionnaire to determine the prevalence of symptoms and certain health outcomes in veterans and their family members (including birth outcomes), as well as risk factors associated with these symptoms and illnesses. Investigators plan to include a physical examination component for a subgroup of those veterans, and their family members, included in the broader survey.

This national survey is a vitally important component of our overall research approach. The survey will help us determine whether the illnesses of these veterans are unique and/or more prevalent among Persian Gulf veterans, or are no different than those experienced by all veterans, or even by the general population of the United States.

VA is also commencing a study of mortality among Persian Gulf veterans. A preliminary analysis of the reported deaths of Persian Gulf veterans has revealed that the number of deaths is consistent with what would be expected in an appropriately matched population of Americans. However, we are not satisfied with that preliminary finding because it does not compare the Persian Gulf veteran population with a good control group, nor does it address the question of whether Persian Gulf veterans may have died from different causes than members of a well-matched control group. The VA Mortality Follow-up Study of Persian Gulf Veterans will review the death certificates of Persian Gulf veterans and compare these with a control group of Persian Gulf era veterans. Overall mortality rates among the two groups will be compared, along with case-specific death rates. The results of this study will tell us whether Persian Gulf veterans have been, or currently are, at a higher risk than veterans who didn't serve in the Gulf of contracting fatal diseases. This study can be extended to detect death from diseases which have a longer latency period, including most cancers.

Over the past year, there have been concerns expressed about the offspring of Persian Gulf veterans. Reports in the media of health problems and birth defects in these children have generated a considerable, and understandable, anxiety among veterans who want to have families. To date there is no scientific evidence to suggest that the children of Persian Gulf veterans have higher rates of health problems than the children in the ^{general} normal population. However, I want Persian Gulf veterans to benefit from the best research on this matter. VA is planning to undertake a major epidemiologic study of the offspring of Persian Gulf veterans. This study will be in addition to the reproductive data that are being collected by the National Survey, and by epidemiologic investigations undertaken by DoD and HHS.

Besides conducting epidemiologic investigations, VA scientists are engaged in research addressing possible causes of unexplained illnesses. A Request for Proposals was sent to VA medical centers in January 1994 to establish three Environmental Hazards Research Centers. Nineteen applications were submitted to the VA Medical Research Service. These applications were peer-reviewed for merit by a panel of outside experts and three centers were selected in July 1994.

The Environmental Hazards Research Centers are located at VA medical centers in Boston, MA, East Orange, NJ, and Portland, OR. Each of these centers ^{has} have been established in partnership with affiliated universities. The Environmental Hazards Research

Centers will be addressing the health issues of Persian Gulf veterans by taking a number of approaches including epidemiological, clinical, and basic research.

The Boston Environmental Hazards Research Center, in collaboration with Boston University, will conduct six Persian Gulf-related research projects aimed at determining health effects of environmental exposure to hazardous situations, with a particular emphasis on behavioral toxicology, immunotoxicology, cancer epidemiology, and behavioral psychopathology. The interdisciplinary work will extend current research at the Boston VA Medical Center that includes assessment of health, psychological well-being and neuropsychological function. Data shared among projects will allow investigators to examine such hypotheses as whether performance on psychological tests can be related to immune function, and whether there is a relation between pulmonary function test results and health symptom complaints. One project will examine the possible relationship between the experience of multiple symptom-based health complaints and such clinical phenomena as sensitivity to chemicals, Chronic Fatigue Syndrome, organic brain syndromes resulting from toxicant exposures, Post-Traumatic Stress Disorder, and somatization disorders. Other studies will investigate central and peripheral nervous system function in a group of veterans with potential environmentally related disorders while another will assess pulmonary and immune system function in the same study cohort. Other approaches at the

Boston Environmental Hazards Research Center will seek validation of neurobehavioral tests, a rodent study of immunologic changes thought to be related to petroleum products, a registry of cancer incidence in Persian Gulf veterans, and a study of a cellular receptor as a susceptibility biomarker for polycyclic aromatic hydrocarbon exposure.

The New Jersey Environmental Hazards Research Center at the East Orange VA Medical Center, along with scientists from the Robert Wood Johnson School of Medicine, UMDNJ, plans four projects to gather information about illnesses and environmental stress factors in Persian Gulf veterans for development of the most characteristic symptom profiles. Under the planned projects, an epidemiological study will compare two groups of Gulf veterans to describe symptoms and define illness and, through the case-control method, identify risk factors. It will compare veterans listed on VA's Persian Gulf Registry with Persian Gulf veterans who have not previously participated in VA's special health examination program. Study subjects who will be divided into three groups -- chronic fatigue, chemical sensitivity and asymptomatic -- ^{and} will participate in a series of studies in such areas as viral, immunological, neuropsychological and autonomic neural function. One project will examine chemical sensitivities through physiologic and cognitive reactivity to chemical challenges delivered nasally and through the skin. Those fulfilling Chronic Fatigue Syndrome criteria will be tested

to determine physiological and cognitive reactivity to exercise. An animal study will evaluate psychosomatic interactions.

The Portland, OR, VA Medical Center, in conjunction with University of Oregon, is planning four projects to examine health effects of exposure to selected environmental chemical and biological hazards related to military service. The center will identify exposures through intensive interviews and will study risk factors for unexplained illnesses through a case-control epidemiological study. The center will also screen veterans for medical, chemical, and biological markers of exposure and disease and act as a repository for data collection and analysis. Scientists from the VA medical center and university research center will work together to explore - at the whole organ and at the molecular level - key scientific issues involving epidemiology, neurobehavior, neuroendocrinology, dermatology, neurotoxicology, and parasitology. They hope to more accurately define relationships between illnesses in Persian Gulf veterans and post-traumatic stress disorder, or specific environmental, infectious or ~~warfare~~ chemical exposures. They plan to estimate future risks of developing symptoms in the population of exposed veterans and to begin devising appropriate treatments and intervention strategies.

do they mean "chemical warfare" here?

Review Activities

Pursuant to Public Law 102-585, VA and DoD engaged the Medical Follow-Up Agency (MFUA) of the Institute of Medicine (IOM) in the National Academy of Sciences (NAS) in a multiyear

contract to review the health consequences of service in the Persian Gulf and make recommendations regarding epidemiological study.

Another review activity was coordinated and co-sponsored by VA, DoD, HHS, and the EPA. The NIH Technology Assessment Workshop on Persian Gulf Health and Experience was held in April 1994. A panel of expert scientists and clinicians assembled by the Workshop was asked if a case definition for unexplained illnesses could be developed and whether any specific causes of illnesses could be identified.

Lastly, VA has established the VA Persian Gulf Expert Scientific Committee, composed of scientists, clinicians, and veteran representatives. The primary purpose of this committee is to review clinical and scientific findings related to Persian Gulf veterans and make recommendations to the Secretary.

In all of these review activities, we have sought to answer two important questions: (1) is there a disease process, previously unrecognized, that could account for the undiagnosed illnesses, and (2) could both the diagnosed and undiagnosed illnesses reported by Persian Gulf veterans, and their family members, be accounted for by ~~exposure to some agent or agents~~ ^{a particular environmental exposure or exposures} during the Persian Gulf conflict?

To date, all of the review panels have come to similar conclusions which are best summarized by a quotation from the NIH

Technology Assessment Workshop Report: "...no single or multiple etiology or biological explanation for the reported symptoms {of Persian Gulf veterans} was identified from the data available to the panel," and "...no single disease or syndrome was apparent, but rather multiple illnesses with overlapping symptoms and causes." Where do these findings leave us? It is clear that the answers to many questions about unexplained illnesses in Persian Gulf veterans will require a continuing federal scientific research effort.

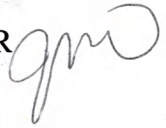
Secretary Brown and I are determined to find the nature and causes of unexplained illnesses in Persian Gulf veterans. As has become amply evident, research holds the key to finding these answers. While our research efforts are underway we are committed to provide the highest quality health care for veterans with these illnesses and to compensate them for their disabilities.

*Add something
from speech*

* * *

March 7, 1995

MEMORANDUM FOR ED SCOTT
SEILEEN MULLEN
SHARON KATZ

FROM: JENNIFER O'CONNOR 
CABINET AFFAIRS

SUBJECT: PERSIAN GULF TESTIMONY

Attached for your information is a transcript of the President's speech to the VFW, a set of the fact sheets and other materials we distributed to the press yesterday, and a set of questions and answers for your testifiers to use in the hearing on Thursday.

Please walk through the questions and answers with your testifier. As discussed, Dr. Jackson should probably defer to either Dr. Kizer and Dr. Joseph unless the questions are directed specifically to him. Please let me know ASAP if any of the testifiers has any comments on the Qs and As.

Finally, please fax me copies of the final testimony and/or oral statement as soon as they are completed.

You can reach me at 456-2572 with any questions or comments.

**PRESIDENTIAL ADVISORY COMMITTEE ON
GULF WAR VETERANS ILLNESSES
PRESS QUESTIONS AND ANSWERS**

Background: On Monday, the President will give a speech at the VFW Annual Washington Conference. In his speech, the President will discuss three issues: the importance of American leadership in the world and of rejecting the "new" isolationism; the importance of maintaining our commitments to veterans and of fighting rescissions; and the importance of leaving no stone unturned in helping Gulf War veterans who are ill. Among other things, the President will announce his intent to establish a Presidential Advisory Committee to review and provide recommendations on the full range of U.S. government activities related to Gulf War veterans' illnesses.

Nearly 700,000 U.S. personnel served in Operations Desert Shield/Desert Storm. Of these, some 55,000 Gulf War veterans have registered for free DOD and VA medical examinations. We do not know precisely how many Gulf War veterans are ill or precisely how many are suffering from undiagnosed illnesses. But, the majority of those who have been examined and are ill have been found to be suffering from diagnosable illnesses, and are being treated successfully. DOD and VA medical facilities are continuing to try to diagnose and treat the remaining veterans who are suffering from undiagnosed illnesses.

1. Who is going to be on this Presidential Advisory Committee?

- As the President indicated in his speech to the VFW, a number of distinguished scientists, doctors, veterans and others will be asked to serve on the Committee. We are not in a position to release any names today.

2. Why do this? You have had other panels. What is different or better than previous panels?

- This will be an independent Presidential Advisory Committee, reporting through the Secretaries of VA, Defense and HHS to the President on the full range of U.S. government activities related to the illnesses of Gulf War veterans.
- Previous expert panels have been more short term or had a more narrow focus.

-- For example, an NIH Workshop met for only three days; the Lederberg panel convened by the Defense Department focused only on DOD issues; the Institutes of Medicine panel is making recommendations about the types of research and data collection and coordination that are needed. No panel has looked at research, treatment, access to information and the full range of issues surrounding Gulf War veterans illnesses.

- The Presidential Advisory Committee the President announced today will also have a broader mandate than the Persian Gulf Coordinating Board, which was established in January 1994 and is comprised of officials from DOD, VA and HHS.
- The Depts. of Defense and Veterans Affairs have made unprecedented efforts to diagnose and treat these illnesses and to compensate veterans who are disabled by them. The President thinks this Presidential Advisory Committee will help ensure that our response to these veterans is as comprehensive and effective as possible.

3. What will the Presidential Advisory Committee do?

- Make sure we are doing everything possible to provide effective medical care to those who are ill.
- Make sure we are effectively coordinating research and other efforts aimed at determining the causes of their illnesses.
- Make sure that information about these issues is made publicly available regularly and as soon as possible.

4. Is there anything else new the President is announcing today other than the Presidential Advisory Committee?

- The President announced other new initiatives including:
 - Two new Defense Dept. specialized care centers for veterans who need additional testing and treatment.
 - \$8-13 million in new research this year including epidemiological research, research into the effects of drugs and vaccines given to the troops, research on the possible transmission of illnesses to spouses and children.
 - New plans to release information about reports of detections of biological and chemical weapons and about data on serious illnesses among Gulf War veterans.

(See Fact Sheets on Ongoing and New Initiatives for detailed information.)

5. When did the administration get interested in this issue?

- From the beginning of the administration, we promoted initiatives that resulted in legislation, which President Clinton signed in 1993 and again in 1994, to provide priority VA medical care for Gulf War veterans. In January 1994, the administration formed the Persian Gulf Coordinating Board, with the Departments of Defense, VA and HHS, to coordinate research, clinical care, and disability benefits. More than 30 research projects are underway to try to determine what made these veterans sick. And in February, the

administration began compensating disabled veterans, even if their illnesses are undiagnosed.

(See Fact Sheet on Ongoing Initiatives for more information.)

6. **What about the USA Today article and charges that there is evidence of chemical and biological weapons exposure?**

- There was nothing new in the USA Today article that appeared last week. There have been anecdotes about possible exposures, and military logs about initial reports of possible exposures. To take these as a confirmed fact, no matter how well intentioned, is incorrect. These reports were previously reviewed and discounted as a direct result of the investigations by on-site officers-in-charge and later investigations.
- Based on the Defense Department's own reviews and the reviews of the experts they have had look at the situation, no one has been able to find compelling evidence of the use of chemical or biological weapons in the Gulf War. This issue will be examined again by the President's Advisory Committee.
- In the meantime, we will continue to try to answer the question of what made these veterans sick. More than 30 research projects are underway to try to find out -- and we have not ruled out any explanations, including possible exposure to chemical or biological weapons, as we look for causes and for treatments.
- And as announced today, we will continue to make more information available about reports of the detection of chemical or biological weapons. (Refer to Fact Sheet on New Initiatives.)

7. **What about the charge reported in USA Today that the Defense Department withheld information from Senator Riegle?** [Note -- we should try to avoid getting into this -- if we look defensive, it will ruin the message for the event.]

- There is no basis for the charge that DOD tried to hide the logs in response to Senator Riegle's March 1994 request. In its "initial interim" response to the request, the Department described the search being conducted throughout DOD and noted that Central Command had, after one search, found no documents meeting the description in the request. DOD invited Senator Riegle to "provide a more specific description" of the documents sought, and offered to "repeat the search using the new description." Senator Riegle's office did not respond to this offer.
- The whole reason the logs are in the public now is that last June, DOD announced it would declassify all material related to the potential causes of Gulf War veterans' illnesses. Thus far, the Department has reviewed more than 400 linear feet of records as part of its effort to declassify and release these records.

8. Why has it taken so long to help these sick veterans and their families?

- What these veterans and their families want is to get well and to find out what made them sick. Many of these illnesses are complicated and difficult to diagnose. Despite the government's research efforts -- and there are more than thirty research projects underway -- we have not yet been able to determine the causes of all the veterans' illnesses. But until we do, we are taking unprecedented steps to compensate these veterans even when we can't diagnose their illnesses, and DOD and VA have special, priority care programs to make sure they get the treatment they need.

9. How can you be sure the experimental drugs and vaccines given to the troops didn't make them sick?

- Pyridostigmine bromide is a treatment that protects troops against the possible use of chemical agents. At the beginning of the war, policymakers believed that Iraq would use chemical weapons and that it was important to provide this protection. Could it have made them sick? Some of the \$8-13 million in new research that the President announced today will be used to look into this very question -- the effect of this drug, particularly when combined with other environmental exposures like pesticides. We won't know the answer to this question for sure until some of this research is completed.

10. Are birth defects among children of Gulf War veterans related to Persian Gulf service?

- Results of a small study conducted by the Mississippi Health Department in conjunction with the Centers for Disease Control showed no increase in birth defects among children born to Persian Gulf veterans in two National Guard Units. But this issue requires extremely careful review. Some of the new research announced today will look into this question.

Add to Testimony

VA and DOD have made unprecedented efforts to diagnose and treat these illnesses, and to compensate veterans who are disabled from them. However, the President believes that more must be done, and believes that a fully independent Presidential Advisory Committee is the best way of assuring that our response to these veterans is as comprehensive and effective as possible.

The Advisory Committee will review and make recommendations on all the major activities of the government on this issue. The Committee will submit an interim report within 6 months of beginning its work and a final report by December 1996.

Some have asked how this expert panel is different from previous efforts. Previous expert panels have been more short-term or had a more narrow focus. For example, the NIH workshop was a three-day workshop intended to develop a case definition of "Gulf War Syndrome." The experts decided that there was no clear evidence of a single syndrome, and therefore could not develop a case definition.

The IOM is a longer term effort that focuses on data gathering and research. In its interim report, the IOM recommended that Federally funded research be peer reviewed and that the Departments do a better job of coordinating their data sets and research. We agree, and had in fact already made plans to do so, even before the IOM report was released. For example, this spring DOD will request research proposals by independent scientists to conduct a wide range of research projects including epidemiological research, clinical trials, and research on pesticides and anti-nerve gas pills. At least \$5 million will be spent on this research this year.

When the Departments first asked outside experts for advice, we believed that it would be possible to easily follow-up on their suggestions. We now know that the constellation of symptoms are more complicated to assess than was previously believed. As a result, research, diagnosis, and effective treatment is more complicated, and coordinating our efforts is more of a challenge. We believe that a Presidential Advisory Committee can help us by overseeing the work that is being done and by ensuring that the efforts of various departments are well coordinated and responsive to new information as it becomes available.

The Presidential Advisory Committee will:

- make sure that we are doing everything possible to provide effective medical care to those who are ill;

- make sure we are effectively coordinating research and other efforts aimed at determining the causes of their illnesses
- make sure that information about these issues is made publicly available as soon as possible

MEMORANDUM

To: Jennifer O'Connor
From: Diana Zuckerman
Re: The PGW letter that was quoted in the President's Speech
Date: March 7, 1995

In the President's speech yesterday, he quoted a letter from Dylan and Theresa Callahan, of Hampton, NH, who wrote "Our lives may be in your hands." I had called ahead of time to ask permission to quote their letter, and Dylan was enthusiastic. After the speech, Theresa called to thank the First Lady and the President for their interest in the Callahans' situation, but also to complain about his efforts to get compensation and medical care.

The good news is that they praise Dylan's doctor at the Manchester VA, Dr. Victor Gordon. However, they have several problems. First, when her 25-year old husband was rushed to the VA hospital last July and almost died due to blood loss, the VA was unable to treat him immediately. He had to be flown to the University of Massachusetts Medical Center, where he received emergency care that apparently should have been reimbursed by the VA. They now have thousands of dollars of bills that VA has not yet reimbursed. Dylan also applied for disability compensation last summer, which he has not yet received.

The Callahans have been waiting for approximately eight months, which is not particularly long by VA compensation standards (I don't know how long reimbursements usually take). However, since they were singled out in this speech, it would be a good idea to ask VA to try to expedite this case. (I would not have chosen it if I had been told of this problem when I called. Fortunately the Callahans are very happy about the President's announcement and not planning to criticize the Administration. They may, however, criticize the Manchester VA Medical Center; they believe the administrator there is not responsive to requests for assistance.) I am hopeful that the VA can respond to this individual case rather quickly, and also determine whether there is a systemic problem in Manchester that needs to be addressed.

In their letter, Theresa and Dylan had mentioned that their VA doctor, Dr. Gordon, wanted to conduct research on Gulf War illnesses but had been unable to obtain VA funding. I don't know if his proposal has merit, so I just pass that fact along in hopes that someone will look into it.

TALKING POINTS TO RESPOND TO HEARING QUESTIONS RE PRESIDENTIAL ADVISORY COMMITTEE

- The Administration has several new initiatives that are aimed at improving the government's efforts to address the needs and concerns of Gulf War veterans.
- The major new initiative is a Presidential Advisory Committee on Gulf War Veterans' illnesses, that will review and make recommendations on all the major activities of the government on this issue. For the first time, a fully independent expert panel will be created to make sure that the government's response is as comprehensive and effective as possible. The Committee will submit an interim report within 6 months of beginning its work and a final report by December 1996.
- Previous expert panels have been more short-term or had a more narrow focus.
- In contrast, the Presidential Advisory Committee will:
 - make sure that we are doing everything possible to provide effective medical care to those who are ill;
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- VA and DOD have made unprecedented efforts to diagnose and treat these illnesses, and to compensate veterans who are disabled from them. The President believes that this independent Advisory Committee is the best way of assuring that our response to these veterans is as comprehensive and effective as possible.
- The President also announced other new initiatives, such as:
 - two new DOD specialized care centers for veterans who need additional testing and treatment
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THE WHITE HOUSE
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FAX #

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OF PAGES (including cover)

4

COMMENTS

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Office of Congressional Affairs



Department of Veterans Affairs

To:

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PG Testimony

Number of pages
including cover:

Date:

3/7/95

Fax to number:

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3/2/95

STATEMENT OF
KENNETH W. KIZER, M.D.
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March 9, 1995

Mr. Chairman and Members of the Subcommittee,

Thank you for this opportunity to discuss the various research activities involving unexplained illnesses in Persian Gulf veterans. I am pleased to be here today and to have this opportunity to publicly state the Department of Veterans Affairs steadfast commitment to provide high quality compassionate care to Persian Gulf Veterans suffering with health problems and to back that clinical care with timely, peer reviewed scientific research. These men and women served valiantly under harsh conditions. They put their lives on the line, and we owe them and their families our very best efforts.

Since the focus of this hearing is research, I will describe the efforts to coordinate federal research and then describe the specific research conducted by the VA. In 1993, President Clinton named VA as the lead federal agency to coordinate government research efforts to find the causes of health problems facing Persian Gulf veterans. The VA, Defense, and Health and Human Services (HHS) Departments are engaged in both, joint, and separate, research projects that include epidemiology; clinical

research, and basic research. Coordination is provided by the Interagency Research Coordinating Council (a working subcouncil of the Persian Gulf Veterans Coordinating Board). The Research Coordinating Council is chaired by VA with members from DoD, HHS, and the Environmental Protection Agency (EPA). The Council monitors the activities and products of various research efforts and recommends future research directions.

In early 1992, only a few months after the end of the open conflict in the Persian Gulf, there were some reports of health complaints among veterans who served during the Gulf war. There were several immediate responses by VA and DoD to these complaints which were primarily of an evaluative nature. These included (1) disease outbreak investigations; (2) population surveillance; (3) exposure inventory and assessment; (4) demographic analyses; and (5) clinical evaluations.

It became evident early in the initial disease outbreak investigations that many, if not most, of the reported illnesses could be diagnosed and appropriately treated. However, there were veterans who reported symptoms of illness for which a medically accepted diagnosis could not be provided. When the number of these cases began to multiply VA and DoD initiated numerous surveillance activities and called in outside experts to look at this problem and provide consultation.

VA Research Efforts

The goals of research conducted by VA and other federal agencies are to:

1. Establish the prevalence of unexplained illnesses (i.e., illnesses for which an accepted diagnosis does not exist) in Persian Gulf veterans and their families, and compare the results to appropriate control populations.
2. Establish the prevalence of standard, diagnosable diseases (including adverse birth outcomes) in Persian Gulf veterans and their families, and compare the results to appropriate control populations.
3. Identify clinically and scientifically appropriate diagnoses for currently unexplained illnesses.
4. Identify potentially new presentations of recognized diseases.
5. Identify causative factors for unexplained illnesses.
6. Identify effective treatment modalities for unexplained illnesses.
7. Develop better understanding of previously unrecognized disease.

Reaching these goals requires a balanced combination of epidemiological, clinical, and basic research. As the lead agency for federal-wide effort to achieve these goals, the

Department of Veterans Affairs is currently engaged in over 30 research projects related to the health problems of Persian Gulf veterans. The size and scope of these projects range from small, pilot projects conducted by individual investigators at VA medical centers, to large scale, epidemiologic studies, and multidisciplinary research centers. Comprehensive information about all research projects related to Persian Gulf veterans in VA, and in other federal departments, is contained in Secretary Brown's annual report to the Veterans' Affairs Committees. The most recent report was provided to the Committee last week.

Sound epidemiological investigations are the foundation for our overall research program. VA is sponsoring several epidemiologic studies, as are DoD and HHS through the Centers for Disease Control and Prevention. VA is initiating a major national survey of Persian Gulf veterans. This survey was highly recommended by the NIH Technology Assessment Workshop panel. It will involve selecting a random sample of 15,000 Persian Gulf veterans and 15,000 contemporaneous non-Persian Gulf veterans (referred to as Persian Gulf era veterans). The survey will utilize a mail-in health questionnaire to determine the prevalence of symptoms and certain health outcomes in veterans and their family members (including birth outcomes), as well as risk factors associated with these symptoms and illnesses. Investigators plan to include a physical examination component for a subgroup of those veterans, and their family members, included in the broader survey.

This national survey is a vitally important component of our overall research approach. The survey will help us determine whether the illnesses of these veterans are unique and/or more prevalent among Persian Gulf veterans, or are no different than those experienced by all veterans, or even by the general population of the United States.

VA is also commencing a study of mortality among Persian Gulf veterans. A preliminary analysis of the reported deaths of Persian Gulf veterans has revealed that the number of deaths is consistent with what would be expected in an appropriately matched population of Americans. However, we are not satisfied with that preliminary finding because it does not compare the Persian Gulf veteran population with a good control group, nor does it address the question of whether Persian Gulf veterans may have died from different causes than members of a well-matched control group. The VA Mortality Follow-up Study of Persian Gulf Veterans will review the death certificates of Persian Gulf veterans and compare these with a control group of Persian Gulf era veterans. Overall mortality rates among the two groups will be compared, along with case-specific death rates. The results of this study will tell us whether Persian Gulf veterans have been, or currently are, at a higher risk than veterans who didn't serve in the Gulf of contracting fatal diseases. This study can be extended to detect death from diseases which have a longer latency period, including most cancers.

Over the past year, there have been concerns expressed about the offspring of Persian Gulf veterans. Reports in the media of health problems and birth defects in these children have generated a considerable, and understandable, anxiety among veterans who want to have families. To date there is no scientific evidence to suggest that the children of Persian Gulf veterans have higher rates of health problems than the children in the normal population. However, I want Persian Gulf veterans to benefit from the best research on this matter. VA is planning to undertake a major epidemiologic study of the offspring of Persian Gulf veterans. This study will be in addition to the reproductive data that are being collected by the National Survey, and by epidemiologic investigations undertaken by DoD and HHS.

Besides conducting epidemiologic investigations, VA scientists are engaged in research addressing possible causes of unexplained illnesses. A Request for Proposals was sent to VA medical centers in January 1994 to establish three Environmental Hazards Research Centers. Nineteen applications were submitted to the VA Medical Research Service. These applications were peer-reviewed for merit by a panel of outside experts and three centers were selected in July 1994.

The Environmental Hazards Research Centers are located at VA medical centers in Boston, MA, East Orange, NJ, and Portland, OR. Each of these centers have been established in partnership with affiliated universities. The Environmental Hazards Research

Centers will be addressing the health issues of Persian Gulf veterans by taking a number of approaches including epidemiological, clinical, and basic research.

The Boston Environmental Hazards Research Center, in collaboration with Boston University, will conduct six Persian Gulf-related research projects aimed at determining health effects of environmental exposure to hazardous situations, with a particular emphasis on behavioral toxicology, immunotoxicology, cancer epidemiology, and behavioral psychopathology. The interdisciplinary work will extend current research at the Boston VA Medical Center that includes assessment of health, psychological well-being and neuropsychological function. Data shared among projects will allow investigators to examine such hypotheses as whether performance on psychological tests can be related to immune function, and whether there is a relation between pulmonary function test results and health symptom complaints. One project will examine the possible relationship between the experience of multiple symptom-based health complaints and such clinical phenomena as sensitivity to chemicals, Chronic Fatigue Syndrome, organic brain syndromes resulting from toxicant exposures, Post-Traumatic Stress Disorder, and somatization disorders. Other studies will investigate central and peripheral nervous system function in a group of veterans with potential environmentally related disorders while another will assess pulmonary and immune system function in the same study cohort. Other approaches at the

Boston Environmental Hazards Research Center will seek validation of neurobehavioral tests, a rodent study of immunologic changes thought to be related to petroleum products, a registry of cancer incidence in Persian Gulf veterans, and a study of a cellular receptor as a susceptibility biomarker for polycyclic aromatic hydrocarbon exposure.

The New Jersey Environmental Hazards Research Center at the East Orange VA Medical Center, along with scientists from the Robert Wood Johnson School of Medicine, UMDNJ, plans four projects to gather information about illnesses and environmental stress factors in Persian Gulf veterans for development of the most characteristic symptom profiles. Under the planned projects, an epidemiological study will compare two groups of Gulf veterans to describe symptoms and define illness and, through the case-control method, identify risk factors. It will compare veterans listed on VA's Persian Gulf Registry with Persian Gulf veterans who have not previously participated in VA's special health examination program. Study subjects who will be divided into three groups -- chronic fatigue, chemical sensitivity and asymptomatic -- will participate in a series of studies in such areas as viral, immunological, neuropsychological and autonomic neural function. One project will examine chemical sensitivities through physiologic and cognitive reactivity to chemical challenges delivered nasally and through the skin. Those fulfilling Chronic Fatigue Syndrome criteria will be tested

to determine physiological and cognitive reactivity to exercise. An animal study will evaluate psychosomatic interactions.

The Portland, OR, VA Medical Center, in conjunction with University of Oregon, is planning four projects to examine health effects of exposure to selected environmental chemical and biological hazards related to military service. The center will identify exposures through intensive interviews and will study risk factors for unexplained illnesses through a case-control epidemiological study. The center will also screen veterans for medical, chemical, and biological markers of exposure and disease and act as a repository for data collection and analysis. Scientists from the VA medical center and university research center will work together to explore - at the whole organ and at the molecular level - key scientific issues involving epidemiology, neurobehavior, neuroendocrinology, dermatology, neurotoxicology, and parasitology. They hope to more accurately define relationships between illnesses in Persian Gulf veterans and post-traumatic stress disorder, or specific environmental, infectious or warfare chemical exposures. They plan to estimate future risks of developing symptoms in the population of exposed veterans and to begin devising appropriate treatments and intervention strategies.

Review Activities

Pursuant to Public Law 102-585, VA and DoD engaged the Medical Follow-Up Agency (MFUA) of the Institute of Medicine (IOM) in the National Academy of Sciences (NAS) in a multiyear

contract to review the health consequences of service in the Persian Gulf and make recommendations regarding epidemiological study.

Another review activity was coordinated and co-sponsored by VA, DoD, HHS, and the EPA. The NIH Technology Assessment Workshop on Persian Gulf Health and Experience was held in April 1994. A panel of expert scientists and clinicians assembled by the Workshop was asked if a case definition for unexplained illnesses could be developed and whether any specific causes of illnesses could be identified.

Lastly, VA has established the VA Persian Gulf Expert Scientific Committee, composed of scientists, clinicians, and veteran representatives. The primary purpose of this committee is to review clinical and scientific findings related to Persian Gulf veterans and make recommendations to the Secretary.

In all of these review activities, we have sought to answer two important questions: (1) is there a disease process, previously unrecognized, that could account for the undiagnosed illnesses, and (2) could both the diagnosed and undiagnosed illnesses reported by Persian Gulf veterans, and their family members, be accounted for by exposure to some agent or agents during the Persian Gulf conflict?

To date, all of the review panels have come to similar conclusions which are best summarized by a quotation from the NIH

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Technology Assessment Workshop Report: "...no single or multiple etiology or biological explanation for the reported symptoms {of Persian Gulf veterans} was identified from the data available to the panel," and "...no single disease or syndrome was apparent, but rather multiple illnesses with overlapping symptoms and causes." Where do these findings leave us? It is clear that the answers to many questions about unexplained illnesses in Persian Gulf veterans will require a continuing federal scientific research effort.

Secretary Brown and I are determined to find the nature and causes of unexplained illnesses in Persian Gulf veterans. As has become amply evident, research holds the key to finding these answers. While our research efforts are underway we are committed to provide the highest quality health care for veterans with these illnesses and to compensate them for their disabilities.

* * *

CDC*DZ comments*

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Persian Gulf War veterans from two National guard units in Mississippi. CDC and the Mississippi Department of Health assisted the VA Medical Center in Jackson, Mississippi in an investigation of this reported cluster. This investigation found no increase in expected rates in the total number of birth defects, or the frequency of premature birth and low birth weight. The frequency of other health problems such as respiratory infections, gastroenteritis, and skin diseases among children born to these veterans also did not appear to be elevated. Due to the small number of births investigated, this study was not able to examine individual categories of birth defects. In addition, this study was not able to account for confounding by all the well-known factors than can increase the risk for conceiving and giving birth to a baby with a congenital malformation. Such factors include family history, maternal age and health, alcohol use and smoking during pregnancy, medications taken during pregnancy, and hazardous exposures.

Since this was not conclusive it's safer to omit

Pennsylvania Epidemiologic Investigation

On November 15, 1994 Dr. Katherine Leisure, the Persian Gulf coordinator for the Lebanon Pennsylvania VA Medical Center, made a presentation to the VA Persian Gulf Expert Scientific Committee. She reported that at least 60 members of the 193rd

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and nongovernmental oversight committees have also reviewed research and clinical activities relating to Persian Gulf War veterans, including the Defense Science Board Task Force on the Persian Gulf War Health Effects, the National Institutes of Health Technology Assessment Workshop Panel, and the Institute of Medicine Committee on the Health Consequences of Service During the Persian Gulf War. These committees have also been unable to find evidence for the existence of a ^{single} "Persian Gulf Syndrome" that can explain the variety of symptoms Persian Gulf War veterans are experiencing. ✓

Future Research Needs

The DOD and VA Persian Gulf registries have added useful information on the spectrum of health concerns among Persian Gulf War veterans, however these registries are of limited value as a data base for determining the actual prevalence of illness among the population of Persian Gulf War veterans. Persian Gulf War veterans who have come forward to participate in the DOD and VA registries represent 6% of the almost 700,000 military personnel who participated in Operations Desert Shield and Desert Storm. It is essential that studies be conducted on representative samples of Persian Gulf War veterans with complete assurance of confidentiality to alleviate any potential veterans' concerns.

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Obtaining data on a comparable control group of veterans who were not deployed to the Persian Gulf is also essential as the symptoms cited most frequently by Persian Gulf War veterans are symptoms that are common in the general population. For example, data from the National Institute of Mental Health's Epidemiologic Catchment Area study, a multi-site, collaborative study of the prevalence and incidence of psychiatric disorders and the associated use of health services, found a high lifetime prevalence of joint pains (37%), headache (25%) and fatigue (25%) among community samples.

✓ Hearings by the Senate Committee on Veterans Affairs in August ~~1993~~¹⁹⁹⁴ and recent reports from the General Accounting Office and the Institute of Medicine (IOM) have highlighted the need to examine adverse reproductive outcomes among Persian Gulf War Veterans. The IOM report also emphasizes the need for population-based surveys of Persian Gulf War veterans.

Studies utilizing representative samples of Persian Gulf War veterans with adequate comparison groups are currently underway. The VA is planning a mail survey of a nationally representative sample of Persian Gulf War veterans. CDC's Iowa study will complement the VA study and will provide more in depth information on Persian Gulf War veterans health status. The

CENTERS FOR DISEASE CONTROL AND PREVENTION
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SUBJECT: Dr. Jackson's (HHS) testimony for
3/9/95 hearing

PAGES TO FOLLOW: 18

COMMENTS:

TESTIMONY OF

RICHARD JACKSON, M.D., M.P.H.

NATIONAL CENTER FOR ENVIRONMENTAL HEALTH
CENTERS FOR DISEASE CONTROL AND PREVENTION
PUBLIC HEALTH SERVICE

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON VETERANS' AFFAIRS

MARCH 9, 1995

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I am Dr. Richard Jackson, Director of the National Center for Environmental Health at the Centers for Disease Control and Prevention (CDC). CDC is pleased to have this opportunity to meet with the Subcommittee on Hospitals and Health Care to review our efforts and those of the Department of Health and Human Services in evaluating the health status of Persian Gulf War veterans. As you may know, CDC has a long history of involvement in veterans issues, dating back to the formation of CDC as a public health agency. In fact, CDC evolved from an agency established during World War II to help control malaria among soldiers training in the South.

Background

Shortly after returning from the Persian Gulf, some U.S. military personnel began to complain of a variety of symptoms, such as fatigue, muscle and joint pain, and headaches, for which no medical diagnosis could be found. Veterans are concerned about the potential impact of a variety of exposures that occurred while in the Persian Gulf, including environmental and occupational pollutants such as sand, petroleum products, pesticides, and smoke from oil-well fires. Not only are these veterans concerned about their own health, but they are also concerned that their military service may have affected the

health of their children. This fear has been heightened by extensive media coverage of stories of reported birth defects among some children born to Persian Gulf War veterans.

The preponderance of current knowledge on the prevalence of illnesses among Persian Gulf War veterans has come from registries established by Departments of Veterans Affairs (VA) and Defense (DOD). However, these registries were designed to provide clinical evaluation and treatment for veterans with health concerns, not to provide epidemiologic data.

Role of the Department of Health and Human Services (HHS):

Assessment of Oil Well Fires

The Department of Health and Human Services (HHS) has taken a very active role in evaluating the health of veterans who participated in the Persian Gulf War. Our initial involvement began in response to concerns about the health impact of exposure to burning oil. More than 600 oil wells were set on fire or damaged throughout Kuwait in February 1991. In response to a request from the State Department regarding concerns about the health impact of burning oil fields, the Public Health Service (PHS) issued a preliminary health advisory in March 1991 stating that the emissions from oil fires were a varied mixture of unburned materials and combustion products, many of which were

toxic. The combustion by-products of burning crude oil are similar in nature to what is found in the exhaust of a poorly functioning automobile. The smoke produced by the burning of crude oil is a mixture of heated, potentially noxious gases and coated carbon particles representing products of combustion. The most obvious constituents of the smoke are carbonized particles of unburned material. The hazards posed by these particles depend on both their size and composition.

Beginning in April 1991, researchers from CDC, the Agency for Toxic Substances Disease Registry, the Environmental Protection Agency, and the National Oceanic and Atmospheric Administration went to the Persian Gulf to assist officials from the Government of Kuwait to design and undertake monitoring and research projects to assess the health effects of the air pollution created by the burning oil fields. These projects included the initiation of a health alert system for public health authorities, physicians, and the public, and the initiation of emergency room surveillance at two local hospitals and five clinics.

Air monitoring data from the Kuwait Environmental Protection Department demonstrated that the quality of air during April 1991 in Kuwait City was comparable to many American cities. In other

words, the pollutants were not elevated to levels that would be associated with acute adverse health effects.

Data analysis of emergency room admissions at two hospitals in Kuwait City showed a small increase in the proportion of visits for gastrointestinal illnesses and psychiatric illnesses during the period after the oil well fires. However, we saw no increase in the proportion of visits for such expected conditions as acute upper and lower respiratory infections or asthma in the period when the oil fires were burning.

Following a review of air monitoring activities from April through July 1991, the PHS issued a revised health advisory for Kuwait and Saudi Arabia on October 9, 1991. The health advisory provided the following information: two major pollutants, sulfur dioxide and nitrogen dioxide, never reached harmful levels; levels of carbon monoxide exceeded the U.S. alert level on rare occasions, possibly due to increased vehicular traffic; levels of particulate matter on a number of occasions exceeded U.S. alert levels, but this occurs regularly in Kuwait even in the absence of oil well fires due to sand and dust storms. In the revised health advisory, PHS recommended precautions for populations at risk, including asthmatics, individuals with chronic respiratory conditions, children, the elderly, and pregnant women. These

recommendations were similar to those given in U.S. cities on days when air pollution levels are high.

We conducted cross-sectional surveys of workers in Kuwait City in May 1991 and of firefighters in the oil fields in October 1991. Blood samples were tested for 31 volatile organic compounds (VOCs) and compared to a referent group of persons living in the United States collected as part of CDC's third National Health and Nutrition Examination Survey III. As would be expected, the median concentration of VOCs among the firefighters was quite elevated. These chemicals remain in the blood for only a short period of time before being excreted. We do not know the long-term health effects of very short term exposures such as these. Among the non-firefighting personnel, VOC concentrations were equal to or lower than the levels found among the reference group. This suggests that smoke from the oil well fires did not pose a significant health threat to individuals working in the Kuwait area.

In addition, our laboratory collaborated with the Department of Defense in a study of 30 members of the 11th Armored Cavalry regiment. Blood from these military personnel was tested for VOCs at three points in time, while the troops were in Germany prior to leaving for Kuwait, after two months in Kuwait, and upon

returning to Germany. Only one compound, tetrachloroethylene, was found to be elevated. This compound is not associated with emissions from oil fires, but rather is a substance found in degreasing agents and may have been used to clean equipment or personal weapons.

Laboratory Testing for *Leishmania*

Another area in which CDC has been involved in evaluating the health of Persian Gulf War veterans is in our testing for evidence of *Leishmania* infection. Leishmaniasis is a disease caused by intracellular parasites that are transmitted by sand flies. The cutaneous form of leishmaniasis typically is manifested by characteristic skin sores. Leishmaniasis rarely causes a chronic systemic disease characterized by fever, swollen glands, enlargement of the spleen, weight loss, and weakness. Leishmaniasis occurs primarily in rural areas of developing countries. In the United States, it occurs in immigrants and persons who have lived in or traveled to areas of the world where the disease is endemic.

After military personnel returned from Operation Desert Storm, CDC published an article in the February 1992 issue of the *Morbidity and Mortality Weekly Report* (MMWR 1992;41:131-4) that described cases of leishmaniasis identified in persons who had

served in the Persian Gulf region. The article provided information identifying Federal organizations to contact for information regarding leishmaniasis. CDC worked with staff of the Walter Reed Army Medical Center and others to distribute information to medical, public health, and lay communities about the risk of leishmaniasis in persons who had been in the Middle East.

From December 1991 through February 1995, 1,632 serum specimens from persons who served in the Persian Gulf region were referred to CDC from State health departments and other sources for testing for evidence of antibody to the parasite that causes leishmaniasis. Most (93.5%) of the serum specimens were negative; 6.5% demonstrated low levels of reactivity. In addition, during this same period, CDC cultured 9 bone marrow, 3 liver/spleen, and at least 15 skin specimens. Two of the skin cultures grew *Leishmania* parasites, thus confirming the diagnosis of cutaneous leishmaniasis in these two persons.

Assessment of Birth Outcomes

Another area in which CDC has been involved is in assessing birth outcomes among Persian Gulf War veterans. In December 1993, CDC met with Congressman Sonny Montgomery regarding reports of a cluster of infant health problems among children born to

Persian Gulf War veterans from two National guard units in Mississippi. CDC and the Mississippi Department of Health assisted the VA Medical Center in Jackson, Mississippi in an investigation of this reported cluster. This investigation found no increase in expected rates in the total number of birth defects, or the frequency of premature birth and low birth weight. The frequency of other health problems such as respiratory infections, gastroenteritis, and skin diseases among children born to these veterans also did not appear to be elevated. Due to the small number of births investigated, this study was not able to examine individual categories of birth defects. In addition, this study was not able to account for confounding by all the well-known factors that can increase the risk for conceiving and giving birth to a baby with a congenital malformation. Such factors include family history, maternal age and health, alcohol use and smoking during pregnancy, medications taken during pregnancy, and hazardous exposures.

Pennsylvania Epidemiologic Investigation

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Pennsylvania Air National Guard were ill. All of the ill persons had deployed to the Persian Gulf during Operations Desert Shield/Desert Storm. She characterized the illness as consisting of irritable bowel syndrome, large joint polyarthralgia (joint pain), skin rash, and several other symptoms. She indicated that the illness was associated with exposure to sand and sand flies.

Subsequent to her report, Drs. James T. Rankin, Jr., State Epidemiologist, Pennsylvania Department of Health; Kenneth Kizer, Undersecretary for Health, Department of Veteran's Affairs; and, Steven Joseph, Assistant Secretary of Defense for Health Affairs, Department of Defense, requested CDC conduct an investigation of the reported cluster. Primary responsibility for the investigation was assigned to the National Center for Infectious Diseases (NCID). Within NCID the Division of Viral and Rickettsial Diseases (DVRD) Chronic Fatigue Syndrome Research Group was assigned responsibility for developing overall study strategy and supervising field work.. The Chronic Fatigue Syndrome Research Group will also coordinate collaborations with other groups within CDC (for example the Division of Parasitology, the National Center for Environmental Health, and the Epidemiology Program Office).

The investigation is being conducted in three logical

phases. Phase-1 will describe the clinical manifestations and health concerns among a sample of ill Persian Gulf War veterans served by the Lebanon Veterans Administration Medical Center (VAMC). The objective is to verify and characterize the existence of illness and search for possible risk factors. Phase-2 is a survey of the index Air National Guard unit and comparison military units to document the prevalence of health problems. The objective is to determine if rates are unusually high in the 193rd Air National Guard Unit and if this is related to Persian Gulf War service, devise a case definition, and identify possible risk factors. Phase-3 is a case control study. The objective is to define risk factors if an unusual cluster of disease is identified through the first two phases.

Field work for Phase-1 was conducted in December by a CDC field team in Lebanon, PA. They interviewed and examined 59 patients and reviewed medical records, interviewed Dr. Leisure and other VAMC staff, and surveyed local and regional health care providers. Analysis of these data is ongoing. Field work for Phase-2 was conducted in January and February by CDC field teams who surveyed approximately 4,000 members of the 193rd and 171st Pennsylvania Air National Guard units, the 919th Florida Air Force Reserve and the 16th Air Force Special Operations Wing in

Florida. Data processing and analysis is in process. Phase-3 field work will begin in April.

**Assessment of Health Status of Persian Gulf War Veterans
From Iowa**

At the request of Congress, CDC is implementing a survey of Persian Gulf War veterans who listed Iowa as their home of record. This study, being conducted in collaboration with the Iowa Department of Public Health and the University of Iowa, includes a detailed assessment of Persian Gulf War veterans' health concerns as well as questions about the health of the veterans' family members. The study will consist of a random sample of 2,000 military personnel who served in the Persian Gulf theater of operations and 2,000 Persian Gulf-era military personnel who served at sites other than the Persian Gulf. We expect to begin data collection in July and to have a final report prepared by Summer 1996.

Interagency Coordination

In addition to these studies, CDC has been an active participant in the Persian Gulf Veterans Coordinating Board. As you know, this Board is co-chaired by the secretaries of the Departments of Veterans Affairs, Defense, and Health and Human Services and is tasked with overseeing research on Persian Gulf

War veterans. The Coordinating Board co-sponsored a scientific panel convened by the National Institutes of Health (NIH). The NIH Technology Assessment Workshop on the Persian Gulf Experience and Health was held in Washington, D.C., on April 27-29, 1994.

The purpose of the NIH Technology Assessment Workshop was to bring together an independent, non-governmental panel to review the scientific evidence regarding the health effects of the Gulf War experience and to make recommendations as to what future research is necessary to determine the types and magnitude of the health problems that are associated with military service in the Persian Gulf War. After 1½ days of medical and scientific presentations and testimony by Gulf War veterans, the expert panel concluded that an accurate estimate of health problems among Gulf War veterans was not available. To address this lack of data, the panel recommended that a health survey of all (or a large representative sample of) Gulf War veterans be conducted. The panel also recommended that the health survey should query for illnesses in veterans' family members as well. Such a national survey is being planned by the Department of Veterans Affairs. The panel recommended that once a better understanding of the types and extent of illnesses among Persian Gulf War veterans was obtained, then more rigorous diagnostic, medical,

and epidemiologic studies could be conducted.

In addition to participating in the NIH Technology Assessment Workshop, HHS has been very involved in fostering coordination and communication among the Federal agencies involved in Persian Gulf research. One of our staff has been detailed to the Persian Gulf Veterans Coordinating Board. This person will serve as a liaison from the Coordinating Board to the Department of Health and Human Services and will be responsible for working with the Departments of Veterans Affairs and Defense to together assure that there is adequate coordination of Federal research efforts and that there are no significant gaps in this research. Additional CDC staff participate in the Department of Veterans Affairs Persian Gulf Expert Scientific Committee.

Issue of a Single Persian Gulf War Syndrome

Considerable effort has been directed towards establishing a single case definition for illnesses among Persian Gulf War veterans. However, to date, no physical signs or laboratory findings have indicated that a single disease is responsible for the unexplained symptoms reported by some Persian Gulf War veterans. In addition, data from the VA and DOD registries has been unable to identify any demographic, exposure, or geographic risk factors for the unexplained illnesses. Several governmental

and nongovernmental oversight committees have also reviewed research and clinical activities relating to Persian Gulf War veterans, including the Defense Science Board Task Force on the Persian Gulf War Health Effects, the National Institutes of Health Technology Assessment Workshop Panel, and the Institute of Medicine Committee on the Health Consequences of Service During the Persian Gulf War. These committees have also been unable to find evidence for the existence of a "Persian Gulf Syndrome" that can explain the variety of symptoms Persian Gulf War veterans are experiencing.

Future Research Needs

The DOD and VA Persian Gulf registries have added useful information on the spectrum of health concerns among Persian Gulf War veterans, however these registries are of limited value as a data base for determining the actual prevalence of illness among the population of Persian Gulf War veterans. Persian Gulf War veterans who have come forward to participate in the DOD and VA registries represent 6% of the almost 700,000 military personnel who participated in Operations Desert Shield and Desert Storm. It is essential that studies be conducted on representative samples of Persian Gulf War veterans with complete assurance of confidentiality to alleviate any potential veterans' concerns.

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Obtaining data on a comparable control group of veterans who were not deployed to the Persian Gulf is also essential as the symptoms cited most frequently by Persian Gulf War veterans are symptoms that are common in the general population. For example, data from the National Institute of Mental Health's Epidemiologic Catchment Area study, a multi-site, collaborative study of the prevalence and incidence of psychiatric disorders and the associated use of health services, found a high lifetime prevalence of joint pains (37%), headache (25%) and fatigue (25%) among community samples.

Hearings by the Senate Committee on Veterans Affairs in August 1993 and recent reports from the General Accounting Office and the Institute of Medicine (IOM) have highlighted the need to examine adverse reproductive outcomes among Persian Gulf War Veterans. The IOM report also emphasizes the need for population-based surveys of Persian Gulf War veterans.

Studies utilizing representative samples of Persian Gulf War veterans with adequate comparison groups are currently underway. The VA is planning a mail survey of a nationally representative sample of Persian Gulf War veterans. CDC's Iowa study will complement the VA study and will provide more in depth information on Persian Gulf War veterans health status. The

determination of whether Persian Gulf War veterans are experiencing a higher than expected prevalence of illnesses awaits the results of these studies.

Recommendations

All of these studies will contribute to our understanding of the effects of military service in the Persian Gulf theater of operations. However, most of these studies are limited by their retrospective nature. This was also true of previous CDC studies of military personnel. In most instances, CDC has been called in only after an environmental health problem is suspected, usually following a congressional inquiry. As a result, we often lack baseline data on the health of military personnel and the ability to conduct definitive studies is limited.

We do not believe that this is the last time that CDC will be called in after the fact to evaluate exposures that may have occurred during military conflicts. The only way to rectify this problem is to increase our collaboration with the Departments of Defense and Veterans Affairs and to take a more proactive approach to evaluating veterans' health concerns. Such an approach could include collaborating with the DOD and VA on gathering baseline data on the health of military personnel, establishing surveillance systems for adverse health outcomes,

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and identifying risk factors for stress-related reactions. We believe the health of our veterans should be a very high priority and we are taking steps towards increasing our collaboration with other Federal agencies who deal with veterans issues.

FAX**Date** 03/7/95**Number of pages including cover sheet****TO:** Jennifer O'Connor, WH**Phone****Fax Phone** 202-456-6704**CC:****FROM:** Gary A. Christopherson
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the Assistant Secretary of
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Washington, DC 20301**Phone** 703-697-2111**Fax Phone** 703-614-3537**REMARKS:**

Jennifer,

This is the final version of Dr. Joseph's testimony for the VA hearing on Thursday. As you will see, we associate it closely with the President's remarks at both the opening and closing of the testimony. If you have any questions, give me a call.

Thanks.

Gary

Please
xerox and
deliver ASAP
to Elisa 376A
Diana 102
original to me

STATEMENT BY**STEPHEN C. JOSEPH, M.D., M.P.H.****ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS****BEFORE THE****SUBCOMMITTEE ON HOSPITALS & HEALTH CARE****COMMITTEE ON VETERANS' AFFAIRS****U.S. HOUSE OF REPRESENTATIVES****FIRST SESSION, 104TH CONGRESS****PERSIAN GULF VETERANS' MEDICAL RESEARCH ISSUES****March 9, 1995****NOT FOR PUBLICATION****UNTIL RELEASED BY****COMMITTEE ON VETERANS' AFFAIRS****U.S. HOUSE OF REPRESENTATIVES**

STEPHEN C. JOSEPH

HOUSE VETERANS AFFAIRS

Mr. Chairman and Distinguished Members of the Committee, it is an honor for me to come before you today as the Assistant Secretary of Defense for Health Affairs to discuss the Department's Medical and Research Programs concerning illnesses related to the Persian Gulf War.

Mr. Chairman, let me first provide some assurances to you, the American public, and our troops and their families. For the past two years, the Clinton Administration has been heavily engaged in caring for our Persian Gulf troops and in solving the difficult puzzle known as Persian Gulf Illness. Just this Monday, the President, in a speech before the Veterans of Foreign Wars, described the very aggressive program of research and care already under way. But we need to go further. For the future, the President announced that we will "step up our treatment efforts and launch new research initiatives." The Departments of Defense, Veterans Affairs and Health and Human Services will be funding millions of dollars in new research initiatives. New specialized care centers are being opened for those troops whose illnesses are difficult to diagnose or treat. But the President went even further. In stressing his personal commitment on the issue, the President announced the creation of a Presidential Advisory Committee, a committee that will report to President and the American public and focus on government efforts to find the causes of these illnesses and improve care available to Gulf War Veterans.

With a firm Clinton Administration commitment to research and care firmly in place, I believe it is important to frame our efforts by providing some background information. Approximately 697,000 service members were deployed to the Persian Gulf in 1990/1991 in support of Operation Desert Shield/Desert Storm.

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Very importantly, the vast majority of soldiers, sailors and airmen returned from this large deployment healthy and remain fit for duty today. Since the war with Iraq, most Gulf War veterans seeking medical care have had readily diagnosable illnesses, the same types of illnesses that would be expected in such a large population of adults. However, there are service members who have suffered illnesses that are not easily explained. It is this group on which we are focusing our medical research efforts.

To better understand why some veterans were reporting diverse symptoms that were not readily explained, I established the Comprehensive Clinical Evaluation Program (CCEP) on June 7, 1994. The CCEP was launched to provide a systematic, in-depth, medical evaluation for all military health care beneficiaries who are experiencing illnesses that may be related to the Persian Gulf deployment. Since June 7, 1994, the Department of Defense (DoD) has enrolled approximately 15,000 participants in the CCEP. Of the 4,674 people with completed evaluations, 2,074 patients' records have been reviewed and validated and have been entered into the CCEP database. The CCEP is a systematic program, that allows us to accomplish several objectives. As I have said from the beginning, first and foremost, the CCEP is really all about taking care of our people. It makes the medical care of Persian Gulf Veterans and their family members a high priority. It allows us to identify patterns of health problems across this group of patients. Finally, the CCEP is the first and necessary step to understanding the illnesses related to the Persian Gulf deployment.

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I should issue a word of caution, here. The CCEP was designed to provide medical care and was not designed as a formal research project. Further, because the CCEP results are derived from a self-selected population of patients, the distribution of illnesses cannot, of course, be directly related to the overall population of 697,000 Gulf War Veterans nor can the specific distribution of diagnoses be compared directly to the VA registry because of differences in demographic characteristics between the two registries. Although qualified by these factors, the CCEP nevertheless provides very accurate and specific information about the types of symptoms and illnesses that are affecting Gulf War veterans presenting for medical evaluation because it provides a systematic, comprehensive, medical evaluation.

Preliminary findings, based on the review of 2,074 CCEP patients with validated evaluations, include the following:

1. 84 percent of the first 2,074 CCEP patients have a clear diagnosis or diagnoses which explains their condition. These diagnoses represent a very broad range of known clinical entities for which these patients are receiving treatment and are responding favorably.
2. Infectious diseases account for relatively few diagnoses, about 4 percent, and do not represent a major cause of illness among CCEP patients. Based on information from the CCEP and other sources, we are aware of about 30 patients who were diagnosed with Leishmaniasis as a result of the Persian Gulf deployment.

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3. 21 percent of these patients have psychologically related medical conditions. Most of these conditions are relatively common in the general population and include such diagnoses as depression, anxiety, tension headache, and stress related disorders. These patients have been provided appropriate treatment and many have responded well. I think it is important to understand that these people are hurting as much from their symptoms as if they had diabetes or arthritic knees. The good news is, as with most of all the CCEP patients, we are able to provide treatment and offer these patients relief.

4. About 16 percent of patients with completed CCEP evaluations have ill-defined symptoms, also commonly seen in civilian medical practice, such as fatigue, headache and sleep disturbances. These patients will receive further evaluation by DoD.

5. Based on the CCEP experience to date, there is no clinical evidence for a new or unique agent causing illnesses among Persian Gulf veterans.

Although the specific distribution of illnesses in this nonrandomly selected sample cannot be generalized to the entire Gulf War veteran population, the preliminary results of the CCEP are consistent with conclusions of a National Institutes of Health Technology Assessment Workshop that "no single disease or syndrome is apparent, but rather multiple illnesses with overlapping symptoms and causes". Likewise, the Defense Science Board determined that there was insufficient evidence that supported a coherent 'syndrome'.

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To better understand the nature of these difficult diagnoses, DoD has established two national Specialized Care Centers for those individuals who require further evaluation and, especially, care for conditions possibly related to environmental, psychosocial, biological or medical factors associated with deployments. The Specialized Care Centers are located in Washington DC, and San Antonio, Texas. The Centers offer the full array of specialty evaluations and coordinated, patient-centered care for referred Persian Gulf veterans and their family members.

For as long as is needed, the CCEP will continue to provide Gulf War Veterans and their families with the diagnostic tools and medical care they deserve. In addition to medical care, the CCEP will undoubtedly identify scientific hypotheses for future medical research. I want to emphasize that the cornerstone of our medical approach is to keep an open mind, to foreclose no possibilities prematurely, and to "let the chips fall where they may."

In conjunction with the CCEP, the Department continues to work closely with the Departments of Veterans Affairs and Health & Human Services in a coordinated and intensive scientific research effort to assess the health consequences of military service members deployed to the Persian Gulf. In FY94, DoD alone dedicated more than \$4 million to medical research focused on Persian Gulf health issues.

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Along with providing high quality medical care, the Departments of Defense, Veterans Affairs, and Health & Human Services have initiated numerous scientific research studies to evaluate the health consequences of serving in the Persian Gulf. Further, DoD is engaged in a number of collaborative research projects with the VA and HHS. Each project assesses the health consequences of military service as a result of the Persian Gulf War. Although the research activities span a broad range of areas, I'd like to mention some of the critical studies.

- The Navy is conducting several large epidemiologic studies which will compare morbidity and mortality among Persian Gulf veterans with military personnel who were not deployed to the Persian Gulf. Results are expected late this year. The goal is to determine whether the incidence of diagnosable illnesses and non-specific complaints, like fatigue, are different from what would be expected.
- Studies will assess reproductive health and birth outcomes using hospitalization records of Gulf War veterans compared to a non-deployed control group. The analyses should be complete by this Fall.
- Additionally, DoD is collaborating with the VA to conduct a large, randomized epidemiologic study of 30,000 veterans. Again, Gulf War veterans will be compared to a non-deployed military population. Data collection is expected to begin late this summer.
- Studies in progress include infectious disease projects (especially tropical disease research).

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- Research is also underway to identify the health effects of exposure to depleted uranium. Early results are encouraging, although long-term follow-up is necessary to fully evaluate such as exposure.
- Research is currently progressing to identify possible interactive effects of certain chemical compounds used during the Gulf War with pyridostigmine. For those who may not be familiar with pyridostigmine bromide, it is a pill that, when used as a pretreatment, provides meaningful, therapeutic enhancement to injectable treatment of nerve agent exposed patients.

These studies will evaluate the health consequences of the Persian Gulf War and will contribute to the development of programs to protect the health of military personnel during future deployments.

There are two sets of funds that we are using to fund Persian Gulf related research. In both cases, we are working with the Persian Gulf Veterans Coordinating Board. The Board, headed by the Secretaries of DoD, VA, Department of Health and Human Services, was established to coordinate clinical care, research and compensation issues.

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With respect to the first set of funds, the Department is working with the Persian Gulf Veterans Coordinating Board to help identify DoD funded medical research proposals totaling approximately \$5 million in FY95. DoD will disperse this money to agencies and institutions external to the Federal Government. Research proposals will be selected after the projects have been independently peer reviewed for scientific merit; the proposals will also be competitively bid. We will work closely with the Departments of Veterans Affairs and Health & Human Services, through the Coordinating Board to select the best scientific research studies in three specific areas: epidemiologic studies, studies involving pyridostigmine bromine, and other clinically related research projects. The broad agency announcements and the request for proposals is currently in the coordination process. We expect the call for research proposals to be published and on the street by the end of this month.

With respect to the second set of funds totaling about \$5 million in FY95, DoD will supplement the research mentioned above. To help DoD determine what research to fund, the Persian Gulf Coordinating Board will identify research gaps with respect to the Persian Gulf and prioritize protocols based on scientific merit and value. Projects supported by these funds could potentially come from agencies both external to and within the Federal Government and will be directly funded by DoD based upon the recommendations of the Coordinating Board.

Now there is one area, chemical and biological exposure, which has been the subject of intense media coverage and public interest. Let me summarize what we know of the exposure of our troops to chemical and biological weapons. Hundreds of false chemical alarms that were activated due to dust, heat, smoke and low batteries have led many to believe that chemical agents were used.

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General Schwartzkopf's experience was that these alarms were taken seriously and immediately investigated and that never was there confirmation of actual chemical presence. Just last week, he was quoted in USA Today in reference to Iraq's using of chemical or biological weapons. What General Schwartzkopf said was, "There's absolutely no evidence that we ever ran into during the war, or anything that's come up since the war, that I know of, that says they used them."

Two independent agencies with distinguished scientists, environmental health experts, and physicians from the leading universities in this country, have addressed the chemical and biological weapons/warfare issue. These groups were the Defense Science Board and the Institute of Medicine (a body of the National Academy of Sciences). Both of these groups arrived at essentially similar conclusions about the lack of evidence on chemical and biological weapons as being causative factors in the symptoms seen in Persian Gulf Veterans.

Now we all know how difficult it is to prove the negative, to prove that there was no exposure to chemical or biological weapons. On the other hand, there is no persuasive evidence of such exposure, even after much scrutiny. But we are not done. It is our intention to find the answer whatever it may be. The Department has declassified a substantial number of military documents which might offer some insights. The Department is engaged in an ongoing effort of research, clinical work and investigation of anecdotes and theories. It is our sincere hope that all of this together can provide us the answers being sought by our troops and their families.

IN CLOSING

In closing, let me again turn to the President's personal commitment to our Persian Gulf Veterans and quote his words to the Veterans of Foreign Wars,

" We must listen to what the veterans are telling us, and respond to their concerns. We will leave no stone unturned. And we will not stop until we have done everything that we possibly can for the men and women who -- like so many veterans in our history -- have sacrificed so much for the United States and our freedom."

Mr. Chairman, the Department of Defense is fully committed to providing high quality, compassionate medical care to Gulf War veterans and their families no matter what the cause. This remains our number one priority. But that is not enough. Parallel to providing outstanding medical care, we will continue to seek answers for our troops and their families from the research community. The aim of our research program is to evaluate and understand the health consequences for our people serving in the Persian Gulf. But beyond that, we are determined to enhance our current programs to protect the health of our troops and their families during future deployments.

Let me express my deep appreciation for your interest and concern for the health of the Veterans of the Persian Gulf War and your active support of military medicine as we continue to use science to provide the answers to a very complex set of health questions.