

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. bio	re: Robert G. Claypool [Personally Identifiable Information] [partial] (1 page)	01/21/2000	b(6)

COLLECTION:

Clinton Presidential Records
First Lady's Office
Melanne Verveer
OA/Box Number: 20033

FOLDER TITLE:

Gulf War General

2013-0534-S

rc1868

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

FACSIMILE TRANSMITTAL SHEET

file Ruf War

**INTERAGENCY SUPPORT OFFICE
PERSIAN GULF AND MILITARY AND VETERANS HEALTH
COORDINATING BOARDS
(PHONE No. (202) 273-9897
(FAX No. (202) 273-9912)**

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TO:	Name	(HD= Hand Deliver)	Agency	Voice Phone	FAX
	Ms. Milann Verveer		Office of the First Lady	(202) 456-6266	(202) 456-6244

Number of Pages 19 + this page = 20; Date: 1/21/00

Ms. Verveer,

Attached are the documents that we discussed this morning concerning the establishment of the Military and Veterans Health Coordinating Board. This, hopefully, will provide background information for you on the Board, and will prepare you for Tuesday's meeting with our Executive Director, Dr. Robert Claypool.

If I can be of further assistance to you, please let me know.

Edwina Underwood

Military And Veterans Health Coordinating Board



Department of Defense



Department of Veterans Affairs



Department of Health and Human Services

For more information contact:
Military And Veterans Health Coordinating Board
202-273-9957
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NEWS RELEASE

FOR IMMEDIATE RELEASE
January 13, 2000

NEW MILITARY AND VETERANS HEALTH COORDINATING BOARD EXECUTIVE DIRECTOR NAMED

Washington, D.C. – The newly created Military and Veterans Health Coordinating Board (MVHCB) today announced its first executive director, retired Army Major General Robert G. Claypool, M.D.

President Clinton established the MVHCB to ensure a fully coordinated, interagency approach to protect the health of servicemen and women, veterans and families. The principal members and co-chairs of the board are the Secretary of Defense, the Secretary of Health and Human Services and the Secretary of Veterans Affairs. Appointees from each of the departments will serve on the board's work groups to accomplish the recommendations of Presidential Review Directive-5 (PRD-5).

PRD-5, "A National Obligation: Planning for Health Preparedness for and Readjustment of the Military, Veterans, and Their Families After Future Deployments," laid out a comprehensive set of goals, objectives and strategies addressing the areas of deployment health, research, recordkeeping, and risk communication that built upon lessons learned from past deployments.

- more -

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Claypool -- Page 2

The MVHCB is modeled after and collocated with the Persian Gulf Veterans Coordinating Board (PGVCB), which the President created in 1994 to work to resolve health concerns of Gulf War veterans. The mission of that board remains unchanged. Claypool will serve as the executive director of both boards.

Claypool joined the MVHCB following his Dec. 31 retirement from the military, where he served as the deputy assistant secretary of defense for health operations. Certified by the American Board of Internal Medicine, Claypool also has a subspecialty certification in rheumatology. His past Army assignments include service as commanding general of Brooke Army Medical Center at Fort Sam Houston, Texas.

He has served in the Army since 1965 in a variety of positions including commander of community hospitals and as an internal medicine residency program director. His assignment to the Office of the Secretary of Defense from 1997 to 1999 involved policy in various components of DoD's force health protection program.

A native of (b)(6) Claypool attended Northwestern University in [001] Evanston, Ill., where he earned a bachelor's degree in chemistry. He received his medical degree from Northwestern University in Chicago.

In taking the helm for administrative operations of both boards, Claypool will develop strategies to promote collaboration and information sharing among federal officials as well as improved risk communications among the departments, servicemembers, and veteran constituencies.

The collocation of the two boards will use the lessons learned from the Gulf War in developing and implementing a highly effective force health protection program for future military deployments.

###

Military and Veterans Health Coordinating Board (MVHCB) Update

On Nov 11, 1999, President Clinton announced the selection of Dr. [MG (Ret)] Robert G. Claypool as the first Executive Director of the Military and Veterans Health Coordinating Board. The Secretaries of Defense, Health and Human Services, and Veterans Affairs chartered the MVHCB and serve as its co-chairs. The role of the MVHCB is to ensure a fully coordinated, interagency approach is implemented to better protect the health of our Servicemen and women, our veterans, and families from the safety and health hazards associated with deployment. The genuine concern and recognition of the magnitude and consequences of the challenges associated with this endeavor are reflected by the Board's commitment to work in a productive and cooperative interagency manner exploiting individual Department's strengths and unifying them into a productive, responsive and fully integrated effort.

Creation of the MVHCB was a leading recommendation of the Presidential Review Directive-5 (PRD-5), National Science and Technology Council (NSTC) Report, *A National Obligation: Planning for Health Preparedness for and Readjustment of the Military, Veterans, and Their Families after Future Deployments*. The PRD-5 lays out a comprehensive set of goals, objectives and strategies addressing the areas of deployment health, research, recordkeeping, and risk communication that builds upon lessons learned from the Persian Gulf War as well as other major deployments.

The Board has a full time staff with one medical officer from the Army, Air Force, and Navy in addition to a VA Program Analyst and a DHHS Administrative Assistant. It is the staff's tasking to coordinate the efforts of the three interagency working groups: Deployment Health, Risk Communication, and Research as the recommendations of the PRD-5. The Board is currently in the process of standing up those working groups. The initial charge for the working groups will be the development of the first annual MVHCB Strategic Plan. Progress in the implementation of the strategic plan will be briefed on an annual basis to the President's assistants for science and technology and for national security.

The MVHCB which is focused on a prospective approach toward force health protection, will coexist with the Persian Gulf Veterans Coordinating Board (PGVCB), which was established in 1994 to examine in a retrospective fashion the illnesses associated with Gulf War service. The PGVCB has the same co-chairs and Dr Claypool will function as its executive director as well. The PGVCB has been a highly successful endeavor and is serving as a model for the MVHCB. Of particular note, is the interagency research effort mounted by the PGVCB to examine the health effects that may be associated with different exposure agents associated with Gulf Service. We now have a research portfolio of nearly 150 studies at a total cost of approximately \$150M that is examining these questions in depth. One of the initial areas of research that the MVHCB will be involved with is in the coordination of the design and approval of longitudinal health studies, as recommended by the Institute of Medicine, for military personnel subject to deployment in the future.

THE WHITE HOUSE
WASHINGTON

November 11, 1998

MEMORANDUM FOR THE SECRETARY OF DEFENSE
THE SECRETARY OF VETERANS AFFAIRS
THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Creation of Military and Veterans Health
Coordinating Board

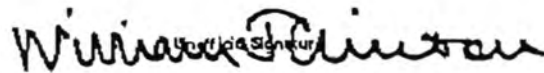
Our Nation is truly indebted to our active duty military, reservist, National Guard, and veterans for protecting America's interests around the globe. From small peacekeeping missions to large combat operations, these men and women put their lives on the line to ensure our peace and prosperity at home and abroad. We owe them and their families a great debt. We have an obligation to protect their health while they serve and to care for their service-connected injuries or illnesses for as long as they live.

Our experience with the Gulf War demonstrated that we were not adequately prepared to deal with the health consequences resulting from a large-scale combat deployment in the unique environment our soldiers faced. The aftermath of this conflict underscored the need to improve significantly our ability to address post-deployment health problems. Your extensive efforts to understand the causes and treat the illnesses experienced by Gulf War veterans have identified numerous deficiencies in the way we prepare for and deal with the health of our military, veterans, and their families. I am pleased that we are applying these lessons learned from the Gulf War and other recent military missions to current and future military deployments.

In its December 31, 1996, report, my Presidential Advisory Committee on Gulf War Veterans' Illnesses recommended that the National Science and Technology Council (NSTC) review existing Federal policies and programs and develop an interagency plan "to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions." The NSTC's plan, developed by your departments, identifies numerous actions, including improved health protection for military forces, which must be taken to avoid the mistakes of the past. One of the key recommendations contained in the plan is to establish a Military and Veterans Health Coordinating Board to continue improving the coordination among your departments and to oversee the implementation of the NSTC's plan.

Therefore, I direct you to establish the Military and Veterans Health Coordinating Board and report annually to the Assistants to the President for National Security Affairs and for

Science and Technology on its progress. Specifically, the Board should focus on issues associated with deployment health, research, and communications regarding health risks. In addition, the Board must ensure that record-keeping requirements linked to military and veterans health prepared-ness, health protection for military forces, disease prevention, and medical care are incorporated into your departments' relevant information technology and information management systems.

The image shows a handwritten signature in black ink. The signature is written in a cursive style and appears to read "William Clinton". There is a small, faint watermark or text visible in the background of the signature, which reads "U.S. Official Signature".

CHARTER FOR THE MILITARY AND VETERANS HEALTH COORDINATING BOARD

A. Official Designation

The Military and Veterans Health Coordinating Board ("Board").

B. Authority

On November 11, 1998 President William J. Clinton directed the establishment of an interagency body to ensure coordination among the respective agencies of the clinical, research, and health risk communication issues related to the health of military service members and veterans during and after deployments. The Secretaries of the Departments of Veterans Affairs, Defense, and Health and Human Services establish by this charter the Military and Veterans Health Coordinating Board as a permanent interagency body to ensure coordination on a broad range of health-related issues for military service members and veterans of military service.

C. Mission, Objectives and Scope of Activities

The primary mission of the Board is to ensure coordination among the Departments of Veterans Affairs, Defense, and Health and Human Services on a broad range of military and veterans' health matters to achieve the Nation's commitment to maintain, protect, and preserve the health of the men and women who serve in the U.S. Armed Forces. The Board addresses health matters that relate to military service with a primary focus on the health of military members, veterans, deployed civilians, and their families during and after future combat and other operations.

The Board addresses health matters related to current and past members of the Active and Reserve Components (including the National Guard) of the U.S. Armed Forces. The responsibilities of the Board include coordination of those responsibilities and activities that are statutorily prescribed for the participating agencies. The Board provides recommendations and coordination for deployment health and research activities as well as for outreach and health risk communication efforts with veterans, the public, other federal government entities, military and veterans' service organizations, health professionals, scientific professional societies, the media, and state, county, and local governments.

D. Membership

1. The Members of the Board are the Secretary of Veterans Affairs, Secretary of Defense, and Secretary of Health and Human Services. The three Secretaries are Co-Chairs of the Board.

2. The Principal Alternate Members are the Under Secretary for Health of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Assistant Secretary for Health of the Department of Health and Human Services.

3. Each Principal Alternate Member shall designate a primary liaison official to the Board staff.

E. Working Groups

The primary work of the Board is carried out through three Working Groups to address issues related to deployment health, health care, research, and health risk communication. Working Group membership is comprised of representatives of the respective Departments. The Co-Chairs of the Board shall select the Chair of each Working Group. The Working Groups have the following functions:

1. The Deployment Health Working Group (DHWG) monitors and coordinates interagency activities related to the force health protection and joint medical surveillance programs of the Department of Defense. The DHWG monitors the contingency and deployment health planning of the Armed Forces. With guidance from the military and civilian health care and health research community, the DHWG makes recommendations to enhance force health protection and medical surveillance programs, including: preventive countermeasures, pre- and post-deployment health assessments, medical surveillance during deployments, combat stress control, and individual and environmental exposure assessments. The DHWG defines interagency priorities for the assessment and prevention of deployment and post-deployment health issues. In addition, the DHWG makes recommendations to the relevant agencies on their preparations for post-deployment health evaluation and the health care needs of military members, veterans, deployed civilians, and their families. The DHWG provides recommendations to the agencies to ensure the appropriate integration of surveillance, research, and clinical findings into ongoing programs of prevention, diagnosis, and clinical care, and when appropriate recommends areas of research emphasis. The DHWG maintains an ongoing review of compliance with the recommendations of external review bodies and provides recommendations to the Board to ensure that "lessons learned" from combat operations and other military deployments and research findings are translated into effective preparation for future operations.

2. The Research Working Group (RWG) provides recommendations and coordination for research activities on deployment health issues affecting active duty members, veterans, deployed civilians, and their families. The RWG coordinates deployment health-related research studies developed from ongoing and new initiatives that receive federal funding. To prevent unnecessary duplication and to assure that resources are directed toward high priority studies, the RWG is the forum for information exchange from the research community at large and research coordination among the three participating Departments. The RWG encourages independent, scientific peer review of research in all its activities. The RWG assesses the state and direction of research on deployment and post-deployment health issues, identifies gaps in knowledge and understanding of issues relevant to service member and veteran health, proposes testable hypotheses, recommends research directions for participating agencies, reviews research concepts as they are developed, and collects and disseminates information on scientifically peer-reviewed research. The RWG monitors the medical and scientific literature regarding preventive measures and potential physiological, psychological, occupational, and environmental hazards to which service members may be exposed. The RWG will make recommendations concerning appropriate responses and actions to research findings. It maintains an ongoing review of the status of compliance with recommendations of external review bodies regarding research. If directed by the Co-Chairs of the Board, the RWG may, in areas of funded research on deployment health, set priorities and make final recommendations to participating federal agencies regarding research funding.

3. The Health Risk Communication Working Group (HRCWG) provides recommendations and coordination for the health risk communication efforts of the Departments of Veterans Affairs, Defense, and Health and Human Services for military members, veterans, deployed civilians, and their families. The HRCWG's focus is on health risk communication efforts before, during, and after combat operations and other deployments. The HRCWG coordinates interagency advice to the Department of Defense on health risk communication strategies and appropriate health risk communication research in areas of deployment-related preventive measures and potentially hazardous exposures. The HRCWG coordinates interagency activities to provide health care providers with up-to-date guidance on health risk communication about deployment and battlefield health risks, preventive measures, and treatments. One focus of this effort is Departments of Veterans Affairs and Defense health care providers, particularly those providing health assessments and health care services before, during, and after combat operations and other military deployments.

F. Military and Veterans Health Coordinating Board Staff and Executive Director

1. The Board is staffed by representatives of the Departments of Veterans Affairs, Defense, and Health and Human Services as designated by the Members or Principal Alternate Members. The Board staff assists in all functions of the Board and the Working Groups.

2. The Board staff serves as the focal point for information related to the Departments' cooperative and independent efforts concerning deployment and post-deployment health-related issues. The Board staff will coordinate development of interagency health risk communication and outreach programs on deployment and post-deployment military and veterans' health issues.

3. An Executive Director is appointed by the Principal Alternate Member for the Department of Veterans Affairs after concurrence with the other two Principal Alternate Members. The Executive Director is a full-time professional assignment to support the activities of the Board's and, as assigned, other interagency coordinating activities. For administrative purposes, the Executive Director reports to the Under Secretary for Health, Department of Veterans Affairs. The Executive Director develops an annual strategic plan for the Board subject to the approval of the Members, acts as a spokesperson for Board, provides oversight of Board staff activities; and serves as the Board's primary point of contact for the Secretaries, Principal Alternate Members, the White House staff, and the Working Group chairs.

4. Each Department provides appropriate staff to ensure efficient and effective functioning of the Board. At minimum, the Board staff includes: an Executive Director, three staff officers in the areas of military public health, health science, and health risk communication, and an administrator/program analyst. The Members or Principal Alternate Members in coordination may change the composition of the Board staff.

G. Administrative Support

Administrative support to the Board and Working Groups is a shared responsibility of the three Departments. The operational expenses of the Board shall be provided by the Department of Veterans Affairs.

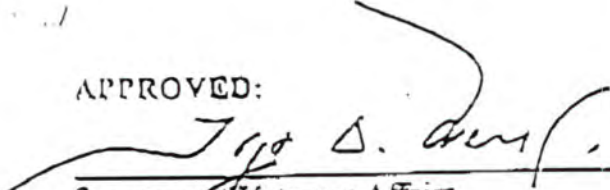
H. Reports

The Board shall coordinate or make reports to Congress or the President as may be directed by law or the President, and shall make such other reports as the three Members may direct.

I. Duration of Charter

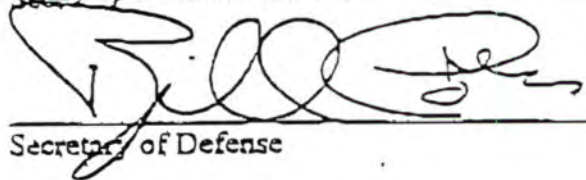
This Charter will expire December 31, 2000, subject to rechartering by the Members of the Board.

APPROVED:


Secretary of Veterans Affairs

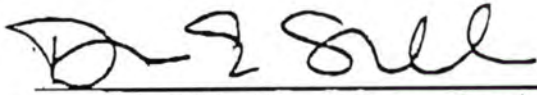
3/9/99

Date


Secretary of Defense

28 JAN 1999

Date


Secretary of Health and Human Services

December 11 1998

Date

Military and Veterans Health Coordinating Board

The Military and Veterans Health Coordinating Board's (MVHCB) mission is to improve the health protection and care of our armed forces, veterans, and their families as it relates to our contingency operations around the world. In November 1998, President Clinton announced the release of a National Science and Technology Council (NSTC) Report, "*A National Obligation, Planning for Health Preparedness for and readjustment of the Veterans, and their Families after Future Deployments.*" That report lays out an interagency plan for improving the Federal response to the health needs of our military, veterans, and their families. At that time he stated, "We have an enduring and special obligation to protect the health of those servicemen and women who protect our nation, and care for their service-connected injuries or illnesses for as long as they live." A key recommendation of that plan was to establish the MVHCB to promote interagency collaboration in the implementation of the plan; it officially stands up in Dec 1999. The PGVCB was established in 1994 to address health concerns in active duty, veterans, and their families associated with Gulf War service; it is slated to continue on with its mission of providing direction and coordination on Gulf War health issues within the Executive Branch of the Federal Government.

The Plan (PRD-5): A National Obligation

Q: What are the broad policy implications of the plan?

A: This plan, along with the President's directive, sets a course for improved cooperation and coordination among Federal agencies in addressing the health needs of our military, our veterans, and their families. Through the release of this report and the establishment of the Military and Veterans Coordinating Board (MVHCB), the President is directing the agencies to work together to achieve program synergy. Using the Persian Gulf Veterans Coordinating Board as a model, we will apply this approach to future deployments. We expect to see better-coordinated research program, record keeping initiatives, deployment health efforts, and health risk communication programs to address the force health protection requirements for future deployments

Q: What are the plan's major recommendations?

A: The interagency working group (IWG) that developed this plan identified the following essential recommendations:

- There must be ongoing coordination of all agencies involved in maintaining the health of military members (active duty, National Guard, and reservists), veterans, and their families. Therefore, the IWG recommends creation of a military and Veterans Health Coordinating Board (MVHCB).
- To succeed with many of the goals and objectives laid out in this plan, the government requires ongoing direction and coordination for the Departments' health and personnel information management and record-keeping activities, especially activities associated with deployments. The IWG recommends that DoD and VA, in consultation with DHHS, establish an ongoing interagency task force to coordinate and set standards for information management and technology efforts

- DoD should complete implementation of recently issued directives on joint medical surveillance and force health protection. DoD should proceed with its contract with the National Academy of Sciences (NAS) for a 3-yr program of scientific, technical, and policy analysis activities entitled "Strategies to Protect the Health of Deployed U.S. Forces."
- DoD, DHHS, Food and drug Administration (FDA), should accelerate their efforts not only to identify regulatory issues associated with the use of investigational products during military exigencies, but also develop strategies to resolve them. We're proud to say that an executive order has been recently issued which addresses the conditions under which investigational new drugs can be cleared for use by servicemen and women during future deployments.
- VA, DoD, and DHHS should develop and implement a coordinated interagency program to communicate health risk information related to current and future deployments, especially combat operations, to military members, veterans, and the public.
- DoD and VA should maintain a robust biomedical research, development, and testing, and evaluation program emphasizing research priority areas identified in this plan.
- DoD should ensure that military medical manpower requirements include medical scientists with expertise relevant to the health concerns associated with military deployments.

The MVHCB

Q: Who are the MVHCB members?

A: The principal members and co-chairs are the Secretary of Defense, the Secretary of the Veterans Affairs, and the Secretary of Health and Human Services. The Principal Alternate Members are the Under Secretary for Health of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Assistant Secretary for Health of the Department of Health and Human Services.

Q: By what mechanism will the MVHCB carry out its charter in implementing the recommendations of the plan?

A: The Board will have a full time staff with one medical officer from the Army, Air Force, and Navy in addition to a VA Program Analyst and a DHHS Administrative Assistant who will coordinate the efforts of the interagency working groups: Deployment Health, Risk Communication, and Research plus an Information Management/Information Technology (IM/IT) task force. Because DoD and VA are separate agencies and are governed by different statutes, great care has to be taken on the sharing of any health data. Working together in this interagency environment clearly benefits all veterans and their families in ensuring that a more seamless approach to care is implemented.

Q: How will the MVHCB report progress on its work in addressing the plan's recommendations?

A. The MVHCB will report its annual progress to both the Assistants to the President for Science and Technology and for National Security

Q: How will the establishment of the MVHCB effect the quality of care our military service members and veterans receive?

A: Our commitment to providing military members, veterans, their families, and our other health care beneficiaries with high quality health care remains unchanged. What the PRD-5 does reflect is our ongoing commitment and dedication to improving and protecting the health of military members, veterans, and their families and to improving the quality of the health care that they do receive.

Q: What will the MVHCB do that isn't currently being done?

A: The Coordinating Board will improve the level of coordination and communication between Federal agencies that have programs and expertise that can be brought to bear on the special needs associated with troop and veteran health. This has gone on in the past, but through the activities of the Board and its working groups, this will become a more focused and effective process. The MVHCB will ensure coordination among VA, DoD, and DHHS on a broad range of health care and research issues relating to past, present, and future military service in the U.S. Armed Forces. The MVHCB is modeled on the Persian Gulf Veterans Coordinating Board (PGVCB), which was established in 1994, which has been very successful in ensuring effective interagency coordination.

Q: What is the relationship between the MVHCB and the PGVCB?

A: The Persian Gulf Veterans Coordinating Board (PGVCB), established in January of 1994, has been an extremely successful interagency forum for coordinating efforts to address the health concerns of Gulf War active duty service members and veterans, which have come to be known as Gulf War illnesses. The PGVCB, which has the same co-chairs as the MVHCB (the Secretaries of DOD, VA, and HHS), will continue to exist along side the MVHCB. The PGVCB will continue the ongoing federal focus in providing direction and coordination on health issues related to the service in the Persian Gulf War. More specifically the PGVCB will continue to deal with issues related to the cause, diagnosis, and treatment of Persian Gulf illnesses. The MVHCB, on the other hand, will build on the lessons learned from the Persian Gulf War and other deployments in implementing a highly effective force health protection program for future deployment operations.

Q: What is Force Health Protection (FHP)?

A. Force Health Protection is a DoD program designed to provide a full spectrum of health protection for our servicemen and women, our DoD civilians, and their families. There are three important pillars to the FHP: Building a Healthy and Fit Force, Casualty Prevention, Casualty Care and Management. The MVHCB will address components of all three of these pillars with an emphasis on the first two – it will be very prevention oriented in its focus and will seek to reduce the occurrences of disease and nonbattle injury to the lowest practicable levels.

Q: What will be the relationship between the work of the MVHCB and the National Academy of Science review on improving deployment health in the future?

A: The National Academy of Sciences has undertaken a 3 year project to develop strategies to protect deployed United States forces during the future. DoD requested this study, which has just one year to go until completion. While the Academy study will draw on information from past deployments, it is future-oriented in its scope. The MVHCB will have access to the findings and recommendations of the Academy's work and will use them as a guide in the implementation of the PRD-5.

Q: What is being done to improve communication with our troops and their families?

A: Communication, and especially health risk communication, has become a visible part of our planning for force health protection efforts. Before and after deployments, health threat briefings are required parts of the military mission. A number of important efforts are occurring in support of enhanced communication with our active duty, veterans, families and health care providers. Some notable achievements include completion of a "Comprehensive Risk Communication Plan for Gulf War Veterans" by the Persian Gulf Coordinating Board. This plan will serve as a strategic plan and will guide the efforts of a Risk Communication Working Group to be established under the MVHCB. Recently a Research Advisory Committee supporting the efforts PGVCB Research Working Group was established for Veterans Service Organizations to become more active participants in determining areas of research for possible funding. A number of presentations to veterans designed to update them on the latest information on research and treatment trials have occurred. These include roundtable discussions in a number of settings, starting this past February at the CDC Conference on Gulf War-related Research held in Atlanta; continuing in June at the GW Illnesses Annual Research Conference in Crystal City, with yet another at the recent GW Veterans Conference sponsored by Veterans Organizations in Las Vegas. The Office of Special Assistant for Gulf War Illnesses (OSAGWI) has held, and continues to hold, public meetings around the country, which includes presentations by the VA. These meetings are open to veterans as well as active duty personnel further informing them on the results of the numerous investigations both completed and ongoing as well as a providing a forum for concerns to be raised to DOD and VA. In addition both the VA and DOD Web sites have continued to be made more effective and comprehensive in providing information to our Veteran's via the Internet.

Q: How are records being changed so that we have better information on future deployments and the health of the deployed troops?

A: Our ability to successfully, continually, and consistently meet the requirements of DoD, Joint Staff, and Service policies and Public Law 105-85 (Sec. 765) depends on medical information solutions that structure, capture, integrate, maintain, and retain the health and health-related data of all military members throughout their military service and into the period of retirement or post-separation where the VA becomes involved with the delivery of health care to these personnel. These requirements are being incorporated into the development of current and future medical information management and technology initiatives.

Information technology initiatives, including Composite Health Care System II (CHCSII) and the Preventive Health Care Application, are moving the DoD toward a complete computerized patient record that will capture and retain all health care information, improve the delivery of

preventive services and health care, and enhance our understanding of the health status and health needs of service members and their families. For the deployed military member, these systems will be able to share information with the Medical Personal Information Carrier (PIC) technology. The PIC is a small, rugged, device intended to store an individual's medical status and history, vaccination records and other essential information that will interface with the CHCSII and other existing medical tracking systems in use in theater. The PIC will be carried by Service members during deployment and updated by medical personnel using portable computers whenever the Service member is examined or treated. PIC information will be transmitted to consolidated databases to ensure that medical information is not lost if the PIC is lost or damaged. The DoD and the military are currently developing the concept of use and determining the specific information to be contained in the PIC.

Additionally, DoD is making special efforts to more effectively monitor the use of all vaccines and medicines given to service members to protect them from chemical and biological warfare agents as well as naturally occurring disease agents that they may be exposed to.

Q: What actions will be taken in the near future based on the plan set out by PRD-5?

A: The Department of Defense has established Surveillance, Clinical, and Research Centers for Deployment Health, which will support many of the objectives outlined in PRD-5. The Defense Authorization Bill for Fiscal Year 1999 authorized the Secretary of Defense to establish a center devoted to "...longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon their return from deployment..." The goal of the Centers will be to ensure identification of trends in diseases, illnesses, or injuries among such members that may follow such operations. The Center's mission will include: clinical research efforts to evaluate risk factors, etiologies, new treatments and prevention strategies; risk communication interventions; surveillance for patterns and risk factors for illnesses and injuries; planning, coordinating and conducting epidemiologic analysis of medical surveillance data relevant to specific deployments; epidemiological studies investigating the longitudinal health experience of previously deployed military personnel, and the development and evaluation of appropriate health surveillance strategies; and longitudinal clinical and epidemiological studies of symptoms, studies of hospitalizations, and studies of reproductive outcomes.

In response to a PRD-5 recommendation, the Department requested that the Naval Health Research Center in San Diego conduct a pilot study on methods of collecting health information for reproductive outcomes, including birth defects, among the offspring of military service members. Based on the results from this study, the Department established a program for national surveillance of birth defects among DoD beneficiaries. In addition, the Department has funded a pilot program to determine feasibility of establishing a Recruit Assessment Program as recommended in the PRD.

The VA has also been directed by the Congress to establish a National Center for Study of War-Related Illnesses. The IOM was commissioned to develop an operational plan for carrying out the implementation of the recommendations made by the National Academy of Sciences, which was presented to the VA on Nov 4, 1999. The DoD centers as well as the VA center will play a pivotal role in carrying out the recommendations of the PRD-5.

Q: How does the PRD-5 use "lessons learned" from the Gulf War to improve health care, deployment surveillance and record-keeping, research, communication for future combat veterans?

A. The Gulf War made clear how important it is to protect the health of troops over the long-term; to adequately respond to veteran's health concerns following redeployment; and to assist veterans and their families through difficult transitions. The primary goal of the MVHCB is to minimize or prevent post-conflict health concerns in the future.

In accordance with PRD-5, VA, DoD and HHS are working closely to improve service personnel's understanding of health risk information; improving delivery of health care services to Gulf War veterans and their families; enhancing government collection of health exposure data; and coordinating agency research programs.

These interagency efforts which result from lessons learned will include pre-deployment health screening in the form of a DoD/VA Recruitment Assessment Program; enhanced medical (and environmental) surveillance of troops during deployments; improved VA/DoD patient health record keeping to help prevent illness and efforts to identify and cure those that occur in a more timely manner; post-deployment health surveillance; and readjustment counseling.

This new approach for force medical protection will serve to safeguard military members and veterans from health hazards associated with future conflicts and peacekeeping missions.

Q: Can you give an example of how the lessons learned from the Gulf War are being applied to deployments in Bosnia?

Troops have been deploying to Bosnia for several years and that deployment has generated its own "lessons learned." The lessons from Bosnia have most recently been applied to the ongoing deployments to Southwest Asia and Kosovo. In February 1998, U.S. Central Command (CENTCOM) updated their deployment policy on implementing comprehensive joint medical surveillance measures, as outlined in the August 1997 Department of Defense Instruction 6490.3, Implementation and Application of Joint Medical Surveillance for Deployments. The CENTCOM policy requires completion of pre- and post-deployment health assessment questionnaires; daily and weekly disease and non-battle injury reporting; environmental monitoring of the air, water, soil, and radiation based on assessment of actual and/or potential health threats in deployed locations; oversight of individual and unit preventive medicine measures; and immunization tracking with enhanced focus on the anthrax vaccine. Joint medical surveillance teams (JMST) deployed to the CENTCOM area of operation closely monitor and report on disease and injury incidence, compliance with force medical protection/surveillance initiatives, including vaccinations administered in theater.

All personnel are assessed and determined to be physically and medically fit before deployment. This includes: 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 assessment questionnaire (to be filed in the medical record and a copy sent to DoD's Deployment Surveillance Team); and follow-up actions on any non-deployable conditions.

CENTCOM directed that a deployment medical record be prepared per Service policy and either carried by the service member or shipped with the medical element. CENTCOM requires documentation of all medically significant events that occur in theater. Guidance on vaccination programs and other force medical protection measures for the theater are explicit regarding the requirement to document, retain, and, if appropriate, archive individual medical information.

Q: How would you summarize the major differences now vs. during the Gulf War?

A: The U.S. military has incorporated many lessons learned from the Gulf War and subsequent hazardous deployments to Haiti, Rwanda, Somalia, Bosnia, and now Kosovo. The Department of Defense is committed to an aggressive program of Force Health Protection. A comprehensive approach to health care and prevention has been implemented that will coordinate the activities within DoD and among multiple federal agencies. The health of military personnel will be monitored and promoted from induction training to the end of military service, and then throughout their lives through medical care in the Department of Veterans Affairs. New DoD and VA deployment health research centers are being established that will actively investigate potential health risks and medical, psychological, and reproductive outcomes. DoD has recognized the need for proactive health risk communication as an essential part of the force health protection strategy.

Clearly the President and Congress have also heeded the lessons learned from the Gulf War. As early as 1992, Public Law 103-210 provided Gulf War veterans with priority health care in the VA; and, the "Veterans Programs Enhancement Act" of 1998 ensured that all future war veterans have access to health care.

Protecting the health of U.S. military forces is a national obligation. Americans who defend the vital interests of the nation deserve accurate health information and the finest medical care and preventive health measures available to protect their health, wherever they serve.

The PRD-5 also reflects our commitment to an interagency collaboration to address the current and future health issues of military members, veterans, and their families. The Military and Veterans Health Coordinating Board will help ensure this commitment is met.

Q: How will this new Coordinating Board help us understand unknown illnesses, or help us treat sick veterans?

The new Military and Veterans Health Coordinating Board (MVHCB) builds on the lessons learned about military and veterans health following recent conflicts including the Gulf War. Its mandate was spelled out in a Presidential Review Directive in August 1998 (PRD-5). Its mandate is a logical expansion of the interagency Persian Gulf Veterans Health Coordinating Board.

In the past, combat medicine was primarily focussed on casualty care. The MVHCB will look beyond battlefield casualties to concentrate on the prevention of post deployment illnesses experienced by veterans of past conflicts as well as those anticipated to occur as a result of future deployments. Key to this effort will be the establishment of the DoD Deployment Health Centers and the VA Center for War-related Illnesses. These centers of expertise will address improvements in clinical treatment, a wide range of research on the prevention and treatment of illnesses, and enhanced medical surveillance including the detection and monitoring of health hazards.

The new MVHCB will take a comprehensive, multi-agency approach to deployment health, record-keeping, research, and health risk communications.

Q: Did veterans (and other stakeholders including veterans' families) participate in establishing the new MVHCB? How?

Veteran's service organization representatives served on the Health Risk Communication Work Group and provided invaluable feedback on the mandate of the new MVHCB.

Q: Now that the MVHCB has an executive director, what are the immediate goals of the new MVHCB?

The three agencies participating in the MVHCB (VA, DoD and DHHS) will follow the recommendations established in the PRD-5 along with those provided by the NAS/NRC. The focus will be on improvements in the collection and maintain military personnel data, including demographic and occupational data, and longitudinal records of service member's military experiences, including pertinent data on health records, and the assessment and tracking of occupational and environmental exposures.

DoD has begun implementation of recently issued directives on joint medical surveillance and force health protection.

DoD contracted with the National Academy of Sciences (NAS) and the National Research Council (NRC) for a 3-year program of scientific, technical, and policy analysis activities entitled "Strategies to Protect the Health of Deployed U.S. Forces."

VA and DoD will, in consultation with DHHS, establish an ongoing interagency task force to coordinate information management/information technology efforts, including the development of functional requirements and standards.

A number of interagency work groups (Research, Risk Communication, and Deployment Health) will soon be established under the MVHCB to prioritize the goals, objectives and strategies contained in the plan and to develop implementation plans for those prioritized recommendations.

Q: How will this announcement effect the quality of care our Military service members and Veterans receive?

The new MVHCB will address quality of care and other force medical protection issues throughout the entire deployment continuum. In accordance with the PRD-5, VA and DoD are working cooperatively to:

- Streamline and better coordinate a more seamless medical service delivery to military service members and veterans.
- Create compatible, computer-based information management/information technology systems to ensure a smooth transfer of records between DoD and VA.
- Develop and publishing joint clinical practice guidelines for disease treatment resulting from deployment operations.
- Collaborate on the development of improved baseline health information databases and environmental monitoring during deployments. These activities will improve future medical surveillance, research and compensation efforts, and enhance the quality of healthcare our military service members and veterans receive.

- Ensure the implementation of a comprehensive and well-coordinated interagency program to communicate health risk information related to the Gulf War and future deployments, and especially combat operations, to military members, veterans, family members, and the public.
- Sponsor research to identify risk factors for development of post-war illnesses, develop health promotion and disease prevention programs for members of future military deployments and sponsor treatment trials for Gulf War and other era veterans.

file Gulf War

0324

January 20, 1998

ACTION

MEMORANDUM FOR SAMUEL R. BERGER

FROM: PHILLIP J. HEYL */S/*

SUBJECT: Status of DOD Efforts Regarding Medical Countermeasures for Chemical Warfare/Biological Warfare (CW/BW) Reported in The Washington Post

Attached at Tab I is an information memorandum in response to the President's questions about Patrick Pexton's January 12 article in The Washington Post. The Pexton article starts with the incorrect premise that DOD has requested broad authority to give out Investigational New Drugs (INDs) drugs to civilians during or after a domestic terrorism incident. This is not true, although DOD has said that they would provide medical products from their stockpiles to the Office of Emergency Preparedness in accordance with the President's emergency response directive.

However, the article raises issues relating to the use of INDs and waiver of informed consent to use medical countermeasures for CW/BW threats to our troops. Both issues need to be resolved in a timely manner. My memorandum addresses the issues raised by Pexton and the heavy lift ahead.

Concurrence by: Joe Bouchard, Anne Luzzatto, Steve Simon

RECOMMENDATION

That you sign and forward the informational memorandum to the President at Tab I.

Attachments

Tab I Memorandum to the President
Tab A January 12, 1998 The Washington Post article
(annotated)

cc: John H. Gibbons
Thurgood Marshall, Jr.
Melanne Verveer

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: SAMUEL R. BERGER

SUBJECT: Status of DOD Efforts Regarding Medical Countermeasures for Chemical Warfare/Biological Warfare (CW/BW) Reported in The Washington Post

Patrick Pexton's January 12, 1998 article, attached as Tab A, starts with the incorrect premise that DOD has requested broad authority to give out Investigational New Drugs (INDs) to civilians during or after a domestic terrorism incident. This is not true, although DOD has said that they would provide medical products from their stockpiles to the Office of Emergency Preparedness in accordance with your emergency response directive.

However, the article does raise issues regarding DOD's use of INDs and waiver of informed consent to use medical countermeasures for CW/BW threats. These issues, which were carefully considered by your Advisory Committee on Gulf War Illnesses (PAC), need to be resolved. This memorandum addresses the issues raised by Pexton, and the heavy lift ahead to balance the concerns of FDA and DOD.

Use of INDs

The medical response to chemical or biological terrorism--whether against military or civilian targets--may include the use of products not approved by the FDA for general commercial marketing. The ability to use INDs in this context may be critical to saving lives. In a large emergency response operation, as in a large military combat operation, compliance with all of the normal FDA rules for INDs--rules primarily for clinical research trials--may be infeasible.

With regard to statements in the article about pyridostigmine bromide (PB) and botulinum toxiod (BT) vaccine, both used during

cc: Vice President
Chief of Staff

the Gulf War as INDs, the DOD concluded at the time--and the FDA concurred--that the best medical protection against CW/BW threats included the use of these drugs; that the safety profile of these products was acceptable; that effectiveness was suggested by research data; and that there were no satisfactory alternatives. DOD's position was that failure to provide those products during that time would have put our troops at an unacceptable risk. As the article points out, DOD did have difficulties in carrying out recordkeeping, providing troops with information, and other implementation actions. However, these problems do not undermine the primary determination that, had the enemy used soman or botulinum toxin against U.S. forces, available scientific evidence strongly supported that the drug PB and BT vaccine would have provided the best protection.

The PAC has pointed out, and DOD has acknowledged, there were problems with recordkeeping of IND use during both the DESERT STORM and JOINT ENDEAVOR (Bosnia) deployments. It is also true, however, that the FDA inspector who reviewed DOD's use of the Tickborne Encephalitis (TBE) vaccine concluded that DOD "conducted its activities in Bosnia without significant deficiencies noted." Since there is no TBE threat in the U.S., the vaccine is not FDA approved, however, the vaccine is commonly used in Europe.

In Bosnia, DOD did considerably better than the Gulf War, but still failed to meet all of the FDA's standards. For example, 20,000 troops deployed to Bosnia were briefed on the threat of TBE and the availability of the vaccine. Consent forms are available for all but 14 of the 3,981 personnel who were considered high risk and were given the vaccine. Of the 15,600 doses of vaccine sent to Bosnia, only 242 doses were not accounted for.

In its latest report, the PAC recommended that DOD and the Joint Chiefs of Staff place a higher priority on medical surveillance before, during and after deployments. In November, you directed the DOD to initiate a unified force health protection program to address these hazards. Significant progress has been made since the Gulf War to mitigate risks inherent in military deployments. DOD's civilian and military leadership is actively involved in this process. The non-battle disease and injury rate for U.S. forces deployed to Bosnia has been the lowest in history--76 cases per 1,000 service members per year.

As for Pexton's discussion of PB use as a "trigger" for Gulf War Illnesses, the scientific community is studying this

possibility, as well as the effects of other compounds and interactions, including stress.

Waiver of Informed Consent

During the Gulf War, DOD was permitted a waiver of informed consent by FDA for the use of INDs under an Interim Final Rule. The PAC has recommended that the issues associated with informed consent be resolved by September 30, 1998. The FDA will propose two new rules. The first proposed rule will address the interim Final Rule that permitted the waiver of informed consent in the Gulf. The second proposed rule will establish criteria for the kind of evidence needed to demonstrate the effectiveness of drug and biological products used to treat or prevent the toxicity of potentially devastating chemical or biological substances when effectiveness studies in humans are not feasible. DOD and FDA have formed a working group to resolve the waiver of informed consent issue. Also, DOD has agreed to identify those products that may provide protection, submit appropriate drug development plans for each product, and establish a timeframe for completion. As recommended by the PAC, DOD will seek an assessment of its policies from your National Bioethics Advisory Commission or other appropriate independent body.

What Should Be Done?

DOD's use of INDs and informed consent is currently subject to FDA approval. The heavy lift ahead is to balance the concerns of the responsible Federal agencies: DOD's concern to allow medical personnel to use the best prophylactic and therapeutic products available to protect military members against chemical and biological weapons, and FDA's concern that we are giving our troops the appropriate drug in an approved way. We shouldn't let DOD "off the hook," but ensure that the appropriate mechanism is in place to balance these two concerns. Because of the importance of this issue, the working group process must be made to work. We will be monitoring the process and will elevate the decisions to the appropriate level in order to resolve differences in a timely manner. We also have encouraged DOD to respond to the Pexton article to set the record straight.

Attachment

Tab A January 12, 1998 The Washington Post article
(annotated)

Really

What are we doing
about this? Should
Pentagon request be granted?
PK

Patrick B. Pexton

A Promise to Do Better Is Not Enough

In a recent letter to the Food and Drug Administration, the Pentagon asked for broad authority to distribute to U.S. civilians—during or after a domestic terrorism incident—some of the same experimental drugs and vaccines used on troops to unknown effect in the Gulf War. In most cases these are drugs, or sets of drugs and vaccines, that have never been tested in a clinical trial for effectiveness or side effects and that are not at present for sale commercially.

The Pentagon is seeking not only broad authority to give out these drugs during terrorist emergencies but also to waive FDA rules meant to ensure the safest use of experimental drugs: requirements such as keeping track of who gets what drugs, proper labeling, monitoring of side effects and fully informing patients of possible complications before they give their consent.

The FDA is concerned, because as it and the Presidential Advisory Committee on Gulf War Veterans recently documented, the Pentagon has a terrible record in using such drugs and vaccines both in Desert Storm and more recently in Bosnia.

Just before Desert Storm, the FDA allowed the Pentagon to give troops several experimental drugs and vaccines not approved for commercial sale. Among them were pyridostigmine bromide (PB), a drug believed to be effective in lessening off the effects of chemical and nerve agents; botulinum vaccine and antitoxin medicine to combat biological weapons other than anthrax; and anthrax post-exposure treatments. The FDA also allowed the Pentagon to waive informed consent, in some cases making it mandatory that the troops take the pills or

vaccines without full knowledge of possible risks.

Early research suggests that the interaction of PB with wartime stress, pesticides and other hazardous materials present in Desert Storm may be a trigger for "gulf war illness." PB may have been taken by as many as 500,000 troops and botulinum vaccine by about 8,000, although some information still is classified.

After the war, the FDA, in reviewing the Pentagon's compliance with the minimal wartime conditions the agency had laid down, found that "deviations" from the rules "pointed out an underlying inability for the Defense Department to carry out its obligations" under the rules for handling experimental substances. For example, only about half of the troops surveyed by the Pentagon received required information about PB; no records were kept of troops who had adverse reactions to the PB pills; and no notation in permanent medical records was made of those who took botulinum vaccine, making it impossible to study its long-term effects.

The Pentagon, chastised, promised the FDA it would do better next time. Bosnia was that next time.

In Bosnia, the Army was authorized to dispense an experimental vaccine for tick-borne encephalitis, a disease common in the Balkans. In its recent review of that program, the FDA criticized the Pentagon for failing again to document immunizations in soldiers' permanent medical records and for touting the vaccine in handouts given to troops as "very safe and extremely effective" when the FDA never authorized such glowing language.

The FDA at last is considering rescinding its permission for the Pentagon to use some experimental drugs on troops in wartime without their consent.

The President's Committee on Gulf War Illnesses was even more critical of the Pentagon's performance with unapproved drugs in the Gulf War and Bosnia, saying the Pentagon "currently is incapable" of handling such drugs, and that its poor performance has hampered research into the causes of Gulf War illness.

Against this background, the head of defense health affairs boldly is requesting from the FDA more authority to use some of these same substances not only on troops but on civilians in case of domestic terrorism involving chemical and biological weapons, with the same protocol waivers that the FDA already has noted the Pentagon is incapable of honoring.

The Department of Defense, understandably and correctly, wants as much flexibility as it can have during times of national emergency to protect troops and civilians at home from these weapons of mass murder.

But if Americans are in imminent danger of dying by the thousands from biological and chemical weapons at home, then the Pentagon and the White House should do a better job leveling with the people and Congress about the precise nature of the threat and how imminent it may be, and then begin a debate on how far the Pentagon should go in injecting itself into civilian emergency care.

The writer is a managing editorial at Army Times Publishing Co.

SANDY

WHAT ARE WE
DOING ABOUT THIS?
Should Pentagon
request be granted?
PK

To Defense

Please prepare
short memo to Pexton
on response

PLEASE STAFF

FM: LA Times/Washington Post

k0000

^bc-drugs-comment<

^(wap) (ATTN: Editorial Page editors)<

^Pentagon's Experimental Drug Policy Puts Troops in Peril<

^Pexton is a managing editor at Army Times Publishing Co.<

^By Patrick B. Pexton=

^(c) 1998, The Washington Post=

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LAWP 01/13/98 02:45:00

File Gulf War

*• pre home POTUS letter
• into folder w/ fitness report*

• fitness report

• get it to Phil

June 11, 1997

DRAFT *• begin off in by...*

Dear Admiral Kramek:

One of the most important and difficult problems our ^{Country} Administration has confronted is the legacy of the Persian Gulf War for veterans of that conflict. Concern over unexplained illnesses among veterans and the reports of possible exposure to chemical agents led me to appoint a Presidential Advisory Committee to look into these and other related matters.

The Committee's work over the last two years and intensified efforts by the Departments of Defense, Veterans Affairs, HHS, and the CIA has resulted in a great deal of additional information coming to light.

The National Security Council created a Directorate for Gulf War Illnesses to ensure that the Committee's findings and recommendations were pursued and that the intensified work of the Departments continued. RADM Paul Busick has been assigned since November as my Special Assistant to head that Directorate.

I want to express my appreciation for Admiral Busick's service and commend his outstanding performance over the last seven months as he has worked within the White House and with the Departments and agencies toward achieving four fundamental goals:

- Improving care of those Gulf War veterans who are sick,
- Investigating every Gulf War event that might help to explain the undiagnosed illnesses,
- Capturing lessons learned to reduce the likelihood of similar issues arising in future deployments, and
- Restoring the credibility of the government's efforts to address Gulf War Illness.

I realize this assignment falls outside the traditional mission of the Coast Guard, and thus, am particularly grateful for your willingness to detail Admiral Busick to the National Security Council and for allowing him to continue to serve.

While much more work is required, I am convinced that Admiral Busick's leadership has been critical in shaping a strategy that will make it possible to meet these goals. His skillful handling of this complex and difficult assignment is a great credit to him and to the Coast Guard.

Please accept my personal thanks for all you and the Coast Guard continue to do in service to our country.

Sincerely,

*• let's get this signed
• send to [signature]
Kramek;
copy in report
cc Slater,
from Kitty*

File Half Vae

66

November 1, 1996

NOTE TO JACK GIBBONS, KITTY HIGGINS, SANDY BERGER, MELANNE
VERVEER, ELISA HARRIS, PAUL BUSICK, JULIA MOFFITT, AND ANNE MCGUIRE

FROM: CLIFF GABRIEL

SUBJECT: REVIEW OF PAC'S DRAFT FINAL REPORT

Attached is a draft copy of the final report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses. As stated in Robyn's memo, this is our opportunity to provide comments on the report's factual content. In order to provide the PAC with a unified EOP response by noon 8 November, I'll need your comments by COB on 6 November. Please note that along with your comments you must return to me your numbered copy of the manuscript. Please call (6-6127) if you have any questions.



Presidential Advisory Committee on Gulf War Veterans' Illnesses

Chair

Joyce C. Lashof, M.D.

John Baldeschwieler, Ph.D.
Arthur Caplan, Ph.D.
Major Thomas P. Cross
Admiral Donald Custis, M.D. (Ret.)
David A. Hamburg, M.D.
James A. Johnson
Major Marguerite Knox, M.N.
Philip Landrigan, M.D.
Elaine L. Larson, Ph.D.
Rolando Rios, Esq.
Andrea Kidd Taylor, Dr.P.H.

Executive Director
Robyn Y. Nishimi

Deputy Director/Counsel
Holly L. Gwin

TO: Reviewers

FR: Robyn Y. Nishimi, PhD

RE: Agency Reviews of Draft Final Report

DA: October 31, 1996

Enclosed for your review is a copy of the Advisory Committee's draft Final Report. I greatly appreciate your reviewing the document for factual content. You will notice that portions of the document have been reproduced on Copisafe® paper: Such pages cannot be photocopied or faxed successfully. Your copy also has been numbered and otherwise marked, and it must be returned to us at the end of the review period.

As previously discussed with the interagency working group, this document is being delivered for you to review and then transmit comments to your agency's review coordinator, who will assemble a single, consensus review to be forwarded to the Committee. Any requests I receive to obtain the manuscript from individuals at the agencies will be referred to my points of contact: Cliff Gabriel, Scott Harris, Mary Beth Donahue, and Harold Gracey. Additionally, any calls or communications with comments or reviews from individuals will be similarly handled.

The single, consensus review of the draft from each contact MUST be, without exception, returned to the Committee's office no later than 12 noon (not 1,2,3 or close of business) on Friday, November 8, 1996. Again, your copy of the draft also must be returned, intact, to the Committee offices; a pre-addressed *Federal Express* label is enclosed.

I cannot overemphasize the importance and firmness of the 12 noon, November 8th deadline. We appreciate the difficulties associated with the short timeframe, but such a schedule is necessary if the Committee is to deliver the Final Report to the President by the end of the year. For your information, the Committee will hold its final meeting on November 13, 1996, 9:00 am - 5:00 pm, ANA Hotel, 2401 M Street, NW.

Many thanks in advance for your assistance. The Committee and staff greatly appreciate your efforts. If you have questions about the review process, please do not hesitate to contact me at 202/761-0066, FAX: 202/761-0310.

Verveer

**Presidential Advisory Committee on Gulf War
Veterans' Illnesses**

DRAFT FINAL REPORT -- Copy 066

October 31, 1996

*Distribution of this draft has been limited to invited external reviewers only.
This manuscript must be returned, intact, by November 8, 1996 to:*

**Dr. Robyn Y. Nishimi
Executive Director
Presidential Advisory Committee on Gulf War Veterans' Illnesses
1411 K Street, NW #1000
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202/761-0066

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Appendixes are not included. References currently are organized by chapter but collated into a series of documents at the end of this draft. In the published document, they will be enumerated and placed at the end of each chapter or the document.

PURPOSE AND ORGANIZATION OF THE FINAL REPORT

This document builds on the analyses of the *Interim Report* and reexamines that work in light of information gathered since its publication. Most importantly, the *Final Report* encompasses ground not previously covered—reviewing the full range of the government's efforts to address issues related to Gulf War veterans' illnesses.

This *Final Report* represents the Committee's best judgment on how to improve government programs targeted to Gulf War veterans' health that are, in the main, addressing the concerns of veterans. Our review of outreach, medical and clinical issues, research, and coordination resulted, principally, in findings and recommendations to help the government fine-tune its efforts. The notable exception to our generally positive report comes from our evaluation of the government's efforts to investigate possible exposures to chemical and biological warfare agents. In this instance we intend our recommendations to be constructive, but the Committee's findings are harsh and unequivocal.

The Committee's conclusions appear in three broad chapters. Within each chapter, the Committee outlines the framework that shaped its inquiry; describes background material it has uncovered through testimony, document reviews, and interviews; makes findings based on its investigations; and offers recommendations we believe can improve the government activities under review. The Executive Summary distills our findings and presents all of our recommendations.

In chapter 2, we present our evaluation of the government's outreach, clinical, research, investigative, and coordination efforts. Chapter 2 includes an assessment of the government's

CHAPTER 1: INTRODUCTION

Caring for veterans is not a national option or a partisan program. It is a national tradition and a national duty. . . . There are thousands of veterans . . . who served their country in the Gulf War and came home to find themselves ill. . . . Just as we relied on these men and women to fight for our country, they must now be able to rely on us to try to determine what happened to them in the Gulf and to help restore them to full health. We will leave no stone unturned.

*-- President Clinton
March 6, 1995*

Approximately 697,000 men and women served in Operations Desert Shield/Desert Storm (table 1-1) from August 1990 to June 1991. Americans who fought the Gulf War differed from any force in U.S. history: there were more racial and ethnic minorities, more women, more parents, more individuals—activated members of the Reserves and National Guard—uprooted from civilian jobs.

During the war, U.S. troops suffered 148 combat deaths and 145 deaths due to disease or accidents, and 467 individuals were wounded. Even in the face of these relatively low casualty rates, national leaders anticipated some post-conflict health concerns and initiated programs to address them. The first programs focused on helping veterans readjust to civilian life and cope with the stresses of war. Lessons learned from the Vietnam era prompted officials in the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to provide counseling services (from family therapy to treatment for post-traumatic stress disorder) throughout the war and through the return stateside.

Despite these efforts, some men and women began to experience debilitating illnesses soon after returning from the Gulf. Commonly reported symptoms included fatigue, muscle and joint pain, memory loss, and/or severe headaches. When several Gulf-deployed members of an Indiana Army National Guard unit reported these symptoms in early 1992, DOD sent in a research team to conduct an epidemiologic study; the team found no evidence of an outbreak of disease. VA contemporaneously established a health registry where Gulf War veterans could report their symptoms. Reports came in, but answers about the nature and cause of the illnesses remained elusive.

THE GOVERNMENT'S INITIAL RESPONSE

Well aware of the problems generated by mishandling Vietnam veterans' health concerns, the government took several actions, including the following, to address questions about health and Gulf War service:

- VA and DOD established medical programs to identify and treat Gulf War veterans' illnesses.
- Congress and the Executive branch worked together to provide disability compensation for veterans whose illnesses could not be diagnosed.
- VA and DOD joined with the Department of Health and Human Services (DHHS) to conduct research on the prevalence, nature, and possible causes of Gulf War veterans' illnesses.

By early 1995, the clinical evaluation programs had enrolled more than 49,000 veterans and the research portfolio included more than 30 studies. Many medical and scientific experts—from inside and outside the government—had reviewed the government’s efforts (figure 1-1). Still, a substantial number of Gulf War veterans did not have the answers they sought—about what kind of illnesses they had, about exposures in the Gulf region that might have made them sick, or about the strength of the country’s commitment to its veterans.

To make sure the government was doing all it could as quickly as it could to get answers, President Clinton issued Executive Order 12961 on May 26, 1995, to establish the Presidential Advisory Committee on Gulf War Veterans’ Illnesses (appendix A). For the first time, a single body would conduct an independent, open, and comprehensive review of all facets—risks, diagnosis, treatment, and research—related to health issues and Gulf War service.

THE ADVISORY COMMITTEE

Securing a healthy future for Gulf War veterans is important to all Americans. As First Lady Hillary Rodham Clinton noted at the Committee’s first meeting in Washington, DC, on August 14-15, 1995, “We owe them that much, and more.” The President charged the Committee to review the full range of government activities relating to Gulf War veterans’ illnesses, including:

- research,
- coordinating efforts,
- medical treatment,
- outreach,

- reviews conducted by other governmental and non-governmental bodies,
- risk factors, and
- chemical and biological weapons (appendix B).

The Committee—a 12-member panel made up of veterans, scientists, health care professionals, and policy experts (appendix C)—has been directed to issue its findings and recommendations to the President through the Secretaries of Defense, Health and Human Services, and Veterans Affairs.

The President made clear his belief that only an open government is a responsive government. The Committee has operated under the Federal Advisory Committee Act, conducting its business in open meetings and providing the opportunity for comment from members of the public at each event. Additionally, the Committee received written submissions for consideration throughout its process.

With the assistance of a full-time staff and consultants (appendix D), the Committee held ten full Committee meetings and eight focused panel meetings around the country from August 1995 through November 1996 (appendix E). We heard invited testimony at each meeting, and transcripts of our proceedings, and other relevant information, were posted on the Committee's homepage on the World Wide Web. Staff held inhouse consultations, received briefings, conducted literature surveys, interviewed veterans, and reviewed government records throughout our tenure.

On February 15, 1996, we delivered our *Interim Report*. In accordance with our mandate, this *Final Report* is being delivered by December 31, 1996.

Table 1-1—Key Dates during Operations Desert Shield/Desert Storm

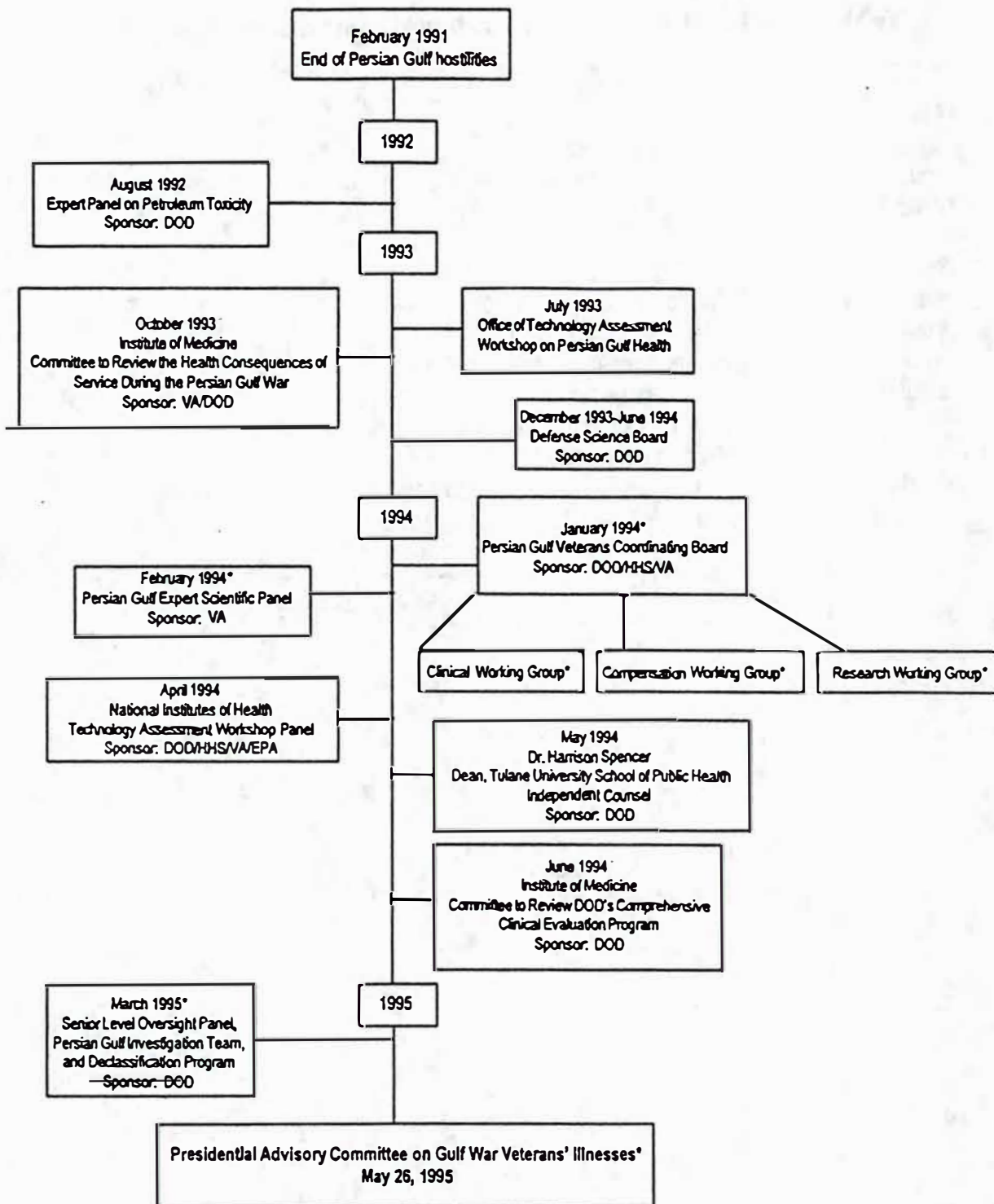
1990

August 2	Iraq invaded Kuwait
August 8	U.S. Air Force planes arrived in Saudi Arabia
August 9	U.S. ground forces arrived in Saudi Arabia

1991

January 17	First irretrievable hostile fire
January 20	Oil fires started in Kuwait
January 27	Coalition forces declared air supremacy
February 24	Ground war began
February 25	U.S. troops killed during a Scud attack in Dhahran
February 28	Offensive operations ceased
June 13	Last U.S. service members who participated in the ground war returned to the United States

Figure 1-1 – Key Committees on Gulf War Veterans' Illnesses



* Current Committee/Group

CHAPTER 2: THE GOVERNMENT'S RESPONSE

The President assigned the Committee two principal tasks:

- determine whether the government is doing all it can to discover the causes of Gulf War veterans' illnesses; and
- determine whether the government is delivering quality care to those veterans who are ill.

We initially addressed these questions in our *Interim Report*, which was delivered in February 1996. In the sections of this chapter on outreach, medical and clinical issues, research, and chemical and biological weapons, we include an assessment of how the government has responded to the Committee's *Interim Report* recommendations.

To complete our work, the Committee continued evaluating outreach regarding benefits and services available to Gulf War veterans and also evaluated the departments' risk communication efforts. Committee and staff also conducted a series of site visits to DOD and VA medical facilities, and evaluated the government's ability to respond to reproductive health concerns and the stresses of war. For this *Final Report*, the Committee has assessed the scope of the federally funded research portfolio and the award-making process.

We make recommendations for improvement in each of these areas—outreach, medical and clinical issues, and research. Overall, however, the Committee commends the government's response to the range of health-related problems experienced by Gulf War veterans. Lessons were learned from our country's experience with the Vietnam War and the health effects of exposure to Agent

1 success of these programs. Our analysis revealed some relatively simple ways for DOD and VA to
2 receive feedback on the utility of various outreach programs and a critical need to present information
3 more clearly to veterans. We made the following recommendations:

- 4 • Operators at the DOD Medical Registry Hotline, DOD Incident Reporting Line, and VA
5 Helpline should be instructed to ask “How did you find out about this number?” as a
6 method of qualitatively measuring the success of the different methods for publicizing the
7 numbers.
- 8 • In the next Comprehensive Clinical Evaluation Program end-of-evaluation questionnaire,
9 which participants answer when the initial evaluation is completed, DOD should include a
10 question about satisfaction with the referral provided by the Persian Gulf Medical Registry
11 Hotline.
- 12 • DOD and VA should utilize more refined performance measures to determine how well
13 outreach services are reaching concerned parties. Caller volume data are not adequate.
- 14 • To assist the general public in interpreting the declassified intelligence documents on
15 GulfLINK [a DOD site on the World Wide Web], DOD should prepare a user’s guide.
16 This guide should explain in general terms the various sources of intelligence information,
17 how they may differ in quality and reliability, and how intelligence analysts compile and
18 evaluate reports from a variety of sources in the field to obtain corroboration before
19 preparing a final assessment. This guide should be featured prominently on the GulfLINK
20 home page.
- 21 • In its outreach campaign, VA should forego use of the term “priority care.” VA should
22 state clearly that Gulf War veterans are entitled to receive the Persian Gulf Health Registry
23 examination free of charge, including any diagnostic testing found to be medically
24 necessary and counseling regarding findings.
- 25 • VA should make its broadcast public service announcements (PSAs) about the toll-free
26 Helpline more explicit. The PSAs should include brief explanations of the purpose of the
27 Helpline and the referral process for the Persian Gulf Health Registry.
- 28 • Future conflicts are likely to generate controversial and unexplained health concerns, and
29 DOD and VA should anticipate the need and plan for outreach services and implement
30 them expeditiously.

1 Departmental Responses

2 The departments have been responsive to these recommendations, though full implementation will
3 require a long-term commitment that the Committee is not in a position to evaluate.

4 Issues New to This Report

5 To complete our work, the Committee continued the evaluation of outreach to Gulf War veterans
6 concerning benefits and medical services. In addition, we examined the issue of risk communication
7 and whether DOD and VA are communicating effectively with Gulf War veterans about the health
8 risks associated with service in Southwest Asia.

9 Outreach Concerning Benefits and Medical Services

10 For this report, the Committee evaluated outreach efforts (i.e., education and publicity) associated
11 with special government-sponsored readjustment programs, outreach to specific populations of Gulf
12 War veterans, and military broadcasts.

13 **Outreach component of readjustment programs.** Immediately following the Gulf War, VA's Vet
14 Centers and Persian Gulf Family Support Program (PGFSP) provided services to assist Gulf War
15 veterans and their families in the post-conflict readjustment process. VA's staff for these programs
16 performed a significant amount of outreach about the readjustment services available to active duty
17 and veteran populations. As veterans began to report illnesses and as the government established
18 clinical procedures to evaluate Gulf War veterans, the outreach aspects of Vet Centers and PGFSP
19 continued to educate the public. Both programs quickly mobilized comprehensive outreach efforts

1 and offered a more targeted and directed approach than subsequent DOD or VA efforts, which
2 focused on hotlines and public service announcements (PSAs).

3 Vet Centers. Congress authorized Vet Centers in 1979. The centers initially offered a range of services
4 to Vietnam veterans, including psychotherapy and counseling, referral and aftercare for substance
5 abuse, crisis intervention for acute symptoms, employment and educational counseling, assistance with
6 upgrade of military discharge, education of community professionals and the public, consultation and
7 input into VA assessments and service decisions at VA Medical Centers (VAMCs), and intensive
8 networking and referral interactions with other community agencies.¹ VA's Readjustment Counseling
9 Service (RCS) administers the Vet Center program.

10 All veterans of conflicts are eligible for Vet Center services. In 1991 RCS directed Vet Center
11 staff to educate themselves about the Gulf War experience by setting up briefings with recent active
12 duty and veteran returnees. Information gathered via the briefings was presented to an RCS
13 committee, which decided to place programmatic emphasis on meeting the special needs of women
14 veterans and families of veterans. Vet Center staff have seen more than 69,000 Gulf War clients since
15 May 1991. Gulf War clients comprise the largest percentage of the post-Vietnam era group of clients
16 during this period (RCS 6/96).

17 Vet Centers operate with considerable autonomy. Each center is staffed by a team leader—
18 typically a social worker or clinical or counseling psychologist—two or three counselors, and an office

¹ These services were designed to manage PTSD, which was the primary readjustment concern.

1 manager. Most centers are nonthreatening spaces located away from the local VAMC (which
2 continues to provide administrative support in the form of supplies, personnel, fiscal processing, and
3 other logistical services). Most staff at Vet Centers have military experience.

4 Persian Gulf Family Support Program. Congress established an additional resource for readjustment
5 counseling through Public Law 102-405, which directed that VA provide readjustment assistance
6 specifically to Gulf War veterans; the department established PGFSP on October 1, 1992. VA's
7 Social Work Service designed and implemented PGFSP based on recommendations from a task force
8 of officials from VA, DOD, the American Red Cross, and the National Guard. The task force
9 recommended PGFSP include: aggressive community outreach and coordination with National
10 Guard and Reserve Units; case management of clinical services² available at VAMCs, Vet Centers,
11 community agencies, and through contract services not provided by VAMCs; staff training and
12 education components; program evaluation; and national clinical coordination. Acknowledging the
13 essential role families play in the readjustment process, PGFSP architects included marriage and
14 family counseling in the program and provided these services to spouses and children of veterans
15 (Campbell et al.).

16 Congress appropriated \$10 million per year for PGFSP for a two-year period. VA initiated
17 the program at 36 VAMCs in the 26 states with the largest populations of formerly activated National
18 Guard and Reserve troops. The size of the Gulf War veteran population within a VAMC region and
19 empirical projections of the regional need for post-conflict readjustment counseling dictated staffing

² Initially, treating post-traumatic stress disorder (PTSD) was the primary focus of clinical services.

1 and funding at each site. A member from each participating VAMC's social work staff was
2 designated PGFSP Coordinator and attended a one-week training session. Training emphasized
3 developing effective working relationships with community agencies, establishing clinics appropriate
4 for the client population, creating outreach goals and strategies, developing assessment and treatment
5 goals, using therapies based on clients' needs, and providing counseling services to veterans and their
6 families. Following training, coordinators integrated PGFSP into their VAMC infrastructures and
7 educated hospital personnel about the evolving policies pertinent to Gulf War veterans.

8 Initially, the program provided services to assist veterans with readjustment difficulties, but in
9 response to concerns about emerging illnesses among Gulf War veterans, coordinators conducted
10 regional Gulf War illness-related outreach and enrolled clients into VA's Persian Gulf Health
11 Registry (1-800-PGW-VETS). In conducting regional outreach, coordinators briefed Guard and
12 Reserve units, local veterans service organization (VSO) chapters, state veterans services offices, and
13 grassroots family support groups. Coordinators focused on general information about PGFSP, the
14 illnesses experienced by some Gulf War veterans, and VA's Registry. They also prepared PSAs and
15 gave interviews to local civilian and military media.

16 Most coordinators appeared to develop a close relationship and personal knowledge of the
17 veterans and active duty community within the region. They tailored appropriate outreach efforts,
18 such as periodic newsletters, brochures distributed throughout the area, and hotline numbers for
19 contacting the local PGFSP. Coordinators also organized "Persian Gulf Health Days" for veterans
20 and the general public, holding them on weekends to maximize attendance. These day-long events

1 often offered educational seminars on illnesses, traumatic stress, and VA benefits, and brought in
2 representatives from VSOs, state and municipal veterans affairs offices, and interested community
3 groups. Participating veterans had the opportunity to enroll in VA's Registry and, at some sites, the
4 Registry examinations were conducted on the weekend as well.

5 PGFSP coordinators at the 36 sites closely monitored the services provided under the
6 program's initial two-year period. More than 2,800 outreach briefings were conducted for
7 approximately 70,000 persons, and approximately 22,000 PGFSP outpatient visits were made by
8 veterans and family members nationwide. Funding for the program ended September 30, 1994
9 (Murphy et al.). Some VAMCs continued to fund aspects of PGFSP, incorporating them into the
10 facility's general budget. Most coordinators, however, returned to their original positions, and after
11 the program ended, spouses and children had to contact Vet Centers to receive free counseling
12 services.

13 **Transition Assistance Program.** The National Defense Authorization Act of 1991 (Public Law 101-
14 510) authorized DOD, VA, and the Department of Labor (DOL), to provide comprehensive transition
15 assistance for service members separating from active duty. The departments developed a
16 Memorandum of Understanding (MOU) that established the three-day Transition Assistance Program
17 (TAP) and assigned each department responsibilities for its implementation: DOL coordinates
18 implementation; DOD arranges the participation of service members and provides logistical support;
19 and VA presents veterans benefits information. TAP workshops continue to be held periodically at

1 major U.S. military institutions in the United States and overseas, and service members are directed
2 to attend within a 180-day period before separation.

3 TAP's main objective is to prevent and reduce long-term unemployment problems among
4 veterans by educating them about goal setting, decisionmaking, labor market information, and job
5 search techniques. The interdepartmental MOU, however, also established a high priority for
6 informing veterans about VA benefits. Benefits briefings typically take four hours, during which
7 benefits and application procedures are discussed; there is no standard syllabus for this discussion. It
8 is plausible that briefings include information about DOD and VA clinical programs designed for
9 evaluating Gulf War veterans and their families, but no evidence exists to suggest these programs are
10 mentioned.

11 **Outreach to women veterans.** More than 40,000 women served in the Kuwaiti Theater of Operations
12 (KTO). Cognizant of the increased role of women in the armed forces and specific medical needs
13 they could have, Congress authorized new and expanded services for women veterans at VAMCs and
14 Vet Centers in the Women Veterans Health Program Act of 1992 (Public Law 102-585). Every
15 VAMC has a Women Veterans Coordinator who coordinates outreach as well as clinical services.
16 Vet Centers also are active in providing outreach about specific VA programs for women and in
17 building referral networks for non-VA medical and social services. RCS has a Women Veterans
18 Working Group that has published information on specific health issues related to women veterans
19 and guidance for outreach to this population (RCS 1995b).

1 **Outreach to Latino veterans.** New Mexico, Texas, California, Arizona, Florida, and Illinois, as well as
2 the metropolitan areas of Boston, New York City, Chicago, and Milwaukee, have large Latino
3 veteran communities. Vet Centers and VAMCs in these regions typically have a Spanish-speaking
4 staff member who can bridge potential language difficulties and potential cultural barriers to full
5 utilization of the Vet Centers by the Latino veterans community. VA outreach unique to this
6 population includes establishing relations with Latino VSOs, working with Spanish language media
7 to publicize VA programs, and acting as a liaison with other VSOs and VA personnel for assistance
8 in filing disability compensation claims (RCS 1995a).

9 **Military Media**

10 The American Forces Information Service (AFIS) and its broadcasting arm, the Armed Forces Radio
11 and Television Service (AFRTS), comprise the bulk of DOD's internal information services. AFRTS
12 delivers radio and television programming for service members overseas and aboard ships. AFIS
13 oversees the European and Pacific editions of the *Stars and Stripes* newspapers and the
14 approximately 1,100 military-funded newspapers in the United States and overseas. AFIS also has
15 produced several media products on Gulf War veterans' health issues. Military media activity have
16 undertaken the following activities related to Gulf War veterans' illnesses:

- 17 • Since early 1992, *Stars and Stripes* has printed 118 stories with headlines related to Gulf
18 War veterans' health issues. The coverage appears to be similar to the civilian media,
19 intermittently covering topics as issues evolve. Circulation for the papers is 75,000
20 worldwide, with readership estimates at 175,000.

1 • Since early 1994, the AFRTS has broadcast 19 television and 43 radio spots on Gulf
2 War-related health issues to an audience estimated at one million people stationed
3 overseas and aboard ships. Although a few print stories and broadcast spots
4 communicate how to register for either the DOD or VA clinical programs, most are
5 general news stories on research efforts.

6 • AFIS also produces an *Internal Information Plan*—a collection of single-page briefs on
7 topics of interest to military personnel, such as voter registration, drug and alcohol
8 abuse, equal opportunity, and military benefits. The *Plan* is distributed to Public Affairs
9 Officers at all units throughout the military, and they are encouraged to disseminate this
10 information to service members. In 1996, a “Persian Gulf Illnesses” brief explaining
11 DOD’s Comprehensive Clinical Evaluation Program (CCEP) was added to the *Plan*, but
12 the toll-free hotline for this service was not listed (1-800-796-9699).

13 **Risk Communication**

14 The Committee first examined the government’s outreach programs designed to inform veterans
15 about their benefits. Outreach cannot stop there, however, when veterans have so many questions
16 about the health risks of service in the Gulf. The next phase of outreach examined by the Committee
17 is risk communication.

18 Risk communication is a multi-step process that involves building a communication plan with
19 specific short- and long-term objectives and using language understandable to lay persons. Risk
20 communication also requires analyzing the affected community to determine effective methods of

1 presenting health information, sustaining the communication process over a period of time to give the
2 community an opportunity to increase its awareness and understanding, and establishing an open
3 process of information exchange between the communicating agency and the affected community.
4 Finally, any strategy must include evaluation of the performance of particular programs (Burke, Dan,
5 Doble, Schulte, Tinker).

6 Risk communication is a challenge, but there is a broad theoretical and experience base on
7 which DOD and VA can draw. Several federal agencies, including the Environmental Protection
8 Agency (EPA) and DHHS's Agency for Toxic Substances and Disease Registry (ATSDR), have
9 developed programs for risk communication with the public about environmental issues and health
10 risks (Chess). The National Institute for Occupational Safety and Health (NIOSH) conducts a
11 function of risk communication known as worker notification, in which at-risk industrial workers
12 participating in epidemiologic studies are informed of the study results. This step provides the
13 participants probabilistic information regarding the possibility or *risk* of experiencing health effects
14 from exposures (Schulte). The National Academy of Sciences (a private sector body that often
15 prepares reports for the government) has published several theoretical and practical guides that
16 emphasize the importance of risk communication in public health (NRC '83, '89, '96).

17 The scenario of Gulf War participants who were subjected to various potential risk factors
18 during a specific length of time is comparable to an industrial setting where workers are exposed to
19 potentially hazardous agents. Additionally, the epidemiologic and clinical studies designed for Gulf
20 War veterans are analogous to studies in which appropriate worker notification measures would be

1 considered. Although a military conflict may be a far more complicated operation than the typical
2 industrial setting, the risk communication experiences of several federal agencies and private
3 institutions provide a suitable framework against which risk communication efforts for Gulf War
4 veterans can be evaluated and compared.

5 **Federal risk communication with Gulf War veterans.** Most DOD and VA outreach efforts concentrate
6 on publicizing the clinical evaluation programs and then referring participants to them. While serving
7 a valuable function, these efforts do not fully educate the veterans or sufficiently build their trust that
8 the government's efforts to help them are comprehensive.

9 In addition, the target population for risk communication related to Gulf War veterans'
10 illnesses extends beyond military service members. Members of the affected community also include
11 family members, civilians who served in the Gulf in support roles, state veterans service officials, and
12 national and local VSOs. Individuals who provide services to the affected community, including
13 social workers and health care providers who come into contact with Gulf War veterans and their
14 families and support groups, are also important risk communication targets.

15 Some of the departments' outreach efforts provide educational information to veterans. For
16 example, VA publishes the *Persian Gulf Review*, a quarterly newsletter sent to those veterans who
17 have participated in the VA Health Registry or received other health services from a VAMC. The
18 newsletter carries brief segments (one or two paragraphs) covering recently released information from
19 reports and studies of Gulf War veterans' illnesses, developments concerning eligibility for medical
20 services and disability compensation regulations, and common questions and answers about how to

1 receive medical care. VA's Persian Gulf Veterans' Illnesses Internet site also provides brief and
2 general information similar in content to the newsletter. Neither the newsletter nor Internet site,
3 however, provide comprehensive risk communication information about exposures or epidemiologic
4 studies underway.

5 DOD's Internet site, GulfLINK, attempts to provide more salient information, such as an
6 assessment of health effects from organophosphate exposures and reports of detections of chemical
7 agents during the Gulf War. However, DOD has been slow to post information, and the tone of some
8 of the posted reports is patronizing and dismissive of veterans' concerns. DOD's growing lack of
9 credibility, attributable largely to chemical warfare (CW) agent exposure investigations (discussed
10 below), compounds its difficulties with effective risk communication with Gulf War veterans and
11 others. DOD faces a complex challenge in conducting investigatory activities that require contacts
12 with individuals who may face health risks associated with their service in the Gulf. Early efforts,
13 such as the initial Khamisiyah telephone survey, sorely neglected the risk communication element of
14 DOD's responsibilities.

15 Effective risk communication requires a dialogue—a two-way flow of information, opinions,
16 and perceptions (Tinker). DOD and VA have not established clear pathways for veterans to provide
17 feedback about clinical programs and/or about concerns regarding exposures; nor have they
18 canvassed the Gulf War veterans' community regarding better methods of communication. It appears
19 the only way in which a veteran could provide feedback would be through contact with the clinical
20 personnel at local VAMCs or military hospitals. This, however, does not appear to be a likely route

1 for transmitting concerns to decisionmakers. VA does conduct periodic interactive video
2 teleconference sessions on Gulf War health topics for clinical and social work staff, but this format is
3 designed for staff education, not as a formal, publicized mechanism of interaction with veterans and
4 other members of the public.

5 Likewise, the telephone hotlines also are designed for a one-way flow of information. The
6 VA and DOD health care hotlines are for referrals only. DOD's Incident Reporting Line (1-800-472-
7 6719) and Khamisiyah investigation telephone survey are used to collect—not disseminate—
8 information. For example, there often is no follow-up response from DOD to Incident Line callers
9 about reported incidents, nor is there adequate disclosure through any existing outreach methods
10 concerning the overall progress of the investigation into CW and biological warfare (BW) incidents.

11 Another opportunity for DOD and VA to interact with members of the affected community is
12 in the design and execution of epidemiologic studies. In the *Interim Report*, this Committee found
13 that public advisory committees might improve communications with veterans who are asked to
14 participate in epidemiologic studies, and we recommended DOD, DHHS, and VA urge their principal
15 investigators to use public advisory committees in epidemiologic studies of Gulf War veterans' health
16 issues. Departmental response to this recommendation has been half-hearted, at best.

17 DOD and VA need to emphasize feedback procedures in their outreach programs. Creating a
18 dialogue with disparate veteran populations is central to effective risk communication and warrants
19 increased attention from the departments.

1 There appears to be a role for VSOs in DOD's and VA's development and implementation of
2 risk communication strategies, since many VSOs have extensive networks in place throughout the
3 country. VSOs represent veterans in social and legislative matters at the national, state, and local
4 levels. Many VSOs—including the American Legion, Veterans of Foreign Wars, and Vietnam
5 Veterans of America—have been chartered in public law by Congress. VSOs already have an
6 established working relationship with VA in many areas, including working with Vet Centers on
7 readjustment issues, sitting on the Persian Gulf Expert Scientific Committee, and providing advocates
8 for the disability compensation claims process. Currently, some VSOs are working on behalf of Gulf
9 War veterans, mostly with assistance in the disability compensation claims process. Several VSOs
10 recently have emerged in various regions of the country specifically to serve Gulf War veterans, and
11 their interests are represented in Washington, DC, by the National Gulf War Resource Center, which
12 was organized in 1995.

13 An example of VSOs implementing useful risk communication is the *Self Help Guide for*
14 *Veterans of the Gulf War* (NVLSP) developed by the National Veterans Legal Services Program
15 (NVLSP) and distributed by the American Legion. The *Guide* provides an overview of the nature of
16 Gulf War veterans' illnesses, explains some health risk factors associated with Gulf War service, and
17 describes eligibility requirements for receiving VA medical benefits. In a different vein, an example
18 of VSOs as a credible resource for veterans is their work in the complicated disability compensation
19 process: Concerned about the 95 percent denial rate for undiagnosed illness claims, the American
20 Legion developed an undiagnosed illnesses application addendum for the VA disability compensation

1 claims process. When completed, the addendum provides a comprehensive description of the
2 veterans' clinical profile and military operational history, which are important in the claims process.

3 The issue of risk communication will only increase in relevancy as studies with specific
4 findings about the nature of Gulf War veterans' illnesses are released. These findings might be
5 unclear to the veterans and, indeed, some conclusions could offer a message some veterans would
6 prefer be different. In such cases, trust, credibility, interaction, and community involvement are key
7 to successful risk communication—but it is unknown whether DOD or VA will have personnel in
8 place to conduct effective risk communication when findings from various reports are ready for
9 dissemination. VA has Persian Gulf Coordinators assigned to each medical center, but these
10 personnel have other responsibilities and typically are more involved with clinical case management.

11 To date, DOD and VA have not devised a plan with specific objectives for effective health
12 risk communication (Roswell 1996a&b). There are many messages to exchange in a health risk
13 communication process, especially one as complicated as the possible health consequences of service
14 in the Gulf War. A process that adequately addresses risk communication in this area would by
15 necessity involve the following: educating members of the community about the known and
16 unknown of risk assessment, using the media as a conduit of information, having frequent and
17 sustained contact with the affected community, and validating the information and the source of
18 information with appropriate external reviews.

Findings Regarding Outreach

Based on its analysis of the government's programs for outreach concerning services available to Gulf War veterans and for communicating with veterans about the risks of Gulf War service, the Committee makes the following findings:

- In their geographic areas, Vet Center staffs have established working relationships with the veterans community, veterans service organizations, local municipal and state veterans liaison offices, in-region Guard and Reserve units, community social services organizations, local VA medical center personnel, and military establishments. These relationships enable Vet Centers to provide education and outreach to local communities about issues and clinical programs concerning Gulf War veterans, and a significant number of Gulf War veterans use their services.
- The outreach initiative of VA's Persian Gulf Family Support Program was an effective method of communicating information about Gulf War veterans illnesses—in particular the established government clinical programs—to veterans, Reservists, National Guard members, and local communities. The outreach component used trained, knowledgeable personnel in the field to establish a communication network with the community and deliver specific information directly to Gulf War veterans.
- Ninety percent of separating active duty service members attend Transition Assistance Program (TAP) workshop briefings conducted jointly by DOD, VA, and DOL. VA benefits briefings during the TAP workshop could be an effective method of outreach about DOD and VA programs for evaluating Gulf War veterans illnesses, yet there is no evidence their clinical programs receive mention.
- Through the initiatives of the Women Veterans Health Programs, VA has implemented a range of efforts to inform women veterans about available health services.
- In regions with significant Latino populations, Vet Centers and VAMCs attend to delivering bilingual, cross cultural outreach and services.
- While newspaper articles and television and radio broadcasts disseminated by DOD's American Forces Information Service provide adequate media coverage of Gulf War illnesses-related issues, few of the media products perform the outreach functions of publicizing government-sponsored Gulf War veterans clinical programs and methods of referral into them.

- DOD's 1996 *Internal Information Plan—Persian Gulf Illnesses* describes its Comprehensive Clinical Evaluation Program, yet fails to provide the most basic information on how to register for it.
- Effective risk communication is essential to the government's credibility on Gulf War veterans' illnesses, but DOD and VA have not seriously attempted to educate veterans about health effects of service in the Gulf War or to establish a dialogue concerning research programs relevant to veterans' concerns.
- Several federal agencies have developed, tested, and validated techniques for health risk communication that could be adopted by DOD and VA.

MEDICAL AND CLINICAL ISSUES

In our *Interim Report*, the Committee focused on medical treatment issues that surfaced during the deployment and demobilization of troops. We found DOD's policies and procedures were not adequate in all cases to prevent service members with preexisting conditions from being deployed or to identify health problems extant at the time of demobilization; we noted these conditions could have contributed to some current health concerns. The Committee also found that DOD and the Food and Drug Administration (FDA) deliberated carefully before enabling, through rulemaking, DOD to require troops to take pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine as pretreatments for possible CBW agents without FDA approval of the products for that purpose. We were concerned that FDA had failed, in the five years since the Gulf War, to devise better long-term methods governing military use of drugs and vaccines for CBW defense. We also found DOD's inability to produce records of who received PB or BT indicative of much need for wholesale improvement in the government's performance on medical recordkeeping during military engagements. As a result, our *Interim Report* made the following recommendations:

- 1 • DOD should regularly review and update the policies and procedures that govern the pre-,
2 during, and postdeployment medical assessment of the Ready Reserve to ensure they are
3 current and adequate.
- 4 • DOD should establish a quality assurance program to ensure compliance with pre-, during,
5 and postdeployment medical assessment policies.
- 6 • Prior to any deployment, DOD should undertake a thorough health assessment of a large
7 sample of troops to enable better postdeployment medical epidemiology. Medical
8 surveillance should be standardized for a core set of tests across all services, including
9 timely postdeployment followup.
- 10 • Given that FDA's Interim Final Rule permitting waiver of informed consent for use of
11 unapproved products in a military exigency is still in effect, DOD should develop
12 enhanced orientation and training procedures to alert service personnel they may be
13 required to take drugs or vaccines not fully approved by FDA if a conflict presents a
14 serious threat of chemical and biological warfare.
- 15 • If FDA decides to reissue the Interim Final Rule as final, it should first issue a Notice of
16 Proposed Rule Making. Among the areas that specifically should be revisited are:
17 adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term
18 followup of individuals who receive investigational products; review by an institutional
19 review board outside of DOD; and additional procedures to enhance understanding,
20 oversight, and accountability.
- 21 • DOD should assign a high priority to dealing with the problem of lost or missing medical
22 records. A computerized central database is important. Specialized databases must be
23 compatible with the central database. Attention should be directed toward developing a
24 mechanism for computerizing medical data (including classified information, if and when
25 it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure
26 continuity.

27 DOD's Response

28 DOD has been responsive to Committee recommendations about medical treatment policies
29 governing pre-, during, and postdeployment of U.S. troops. DOD has not been responsive, however,
30 to the Committee's recommendation that prior to any deployment, DOD should undertake a thorough
31 health evaluation of a large sample of troops to enable better postdeployment medical epidemiology.

One of the overriding difficulties of research on Gulf War veterans' illnesses is the absence of baseline data—on health and on exposure to environmental hazards. DOD testified that it has improved its approach to gathering such data and has incorporated new policies and procedures in its medical surveillance and environmental monitoring programs (DeFraites; Resta). Although DOD has introduced these techniques in the Bosnia peacekeeping mission, they have not been tested in a large-scale conflict. Laying the groundwork for post-conflict medical surveillance might be perceived by some as a low priority in a war-fighting environment. There is no evidence that a standardized set of tests or physical examination procedures has been identified and applied to a large sample of troops across all services to ensure that medical epidemiology can be conducted in the aftermath of conflict.

With regard to using investigational new drugs, DOD has made the effort in Bosnia to provide information about the risks of tick borne encephalitis (TBE) and the investigational TBE vaccine being administered, with informed consent, to U.S. troops in that region. However, DOD has made no specific response to the Committee's recommendation that, given that the Interim Final Rule is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they could be required to take investigational drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of exposure to CBW agents.

With respect to our *Interim Report* recommendation concerning medical recordkeeping, the Committee observes that DOD has made progress in working toward improving medical recordkeeping in theater and stateside. However, increased commitment from DOD's Joint Chiefs of Staff and Commanders in Chief is essential for increasing the priority of this effort.

1 **FDA's Response**

2 FDA has testified that it is now considering the Interim Final Rule in conjunction with guidelines for
3 CBW agent prophylaxis approval; it is also considering how it should address military and civilian
4 use (Lee). The Committee remains concerned, however, about the amount of time FDA is taking to
5 move forward with opening up the Interim Final Rule—which was issued more than five years ago—
6 for public comment.

7 **Issues New to This Report**

8 To complete its work on medical and clinical issues, the Committee assessed whether Gulf War
9 veterans currently receive access to quality medical care under programs established by the
10 government for their care. We specifically examined the availability of reproductive health care
11 because of the high degree of concern expressed by Gulf War veterans and their families in this
12 regard. Finally, the increasingly obvious role of stress in the illnesses of Gulf War veterans and their
13 families led us to give particular scrutiny to this clinical care issue.

14 **Access to Health Care**

15 Beginning with our first meeting in August 1995, the Committee heard frequent public comment
16 about the difficulty of gaining access to health care in VAMCs and, to a lesser degree, DOD medical
17 facilities. Inadequate information, delays in scheduling appointments, insensitive personnel, and
18 inadequate followup topped the list of complaints. The Committee decided a series of site visits and
19 interviews could help inform our deliberations in determining whether problems with access to care
20 persist or largely preceded establishment of VA's Registry and DOD's CCEP. Facilities for site

visits were selected to vary geographically and represent both initial evaluation sites (Phases I and II) and referral centers. Between November 1995 and February 1996, Committee members and staff visited the following sites:

- VA Medical Center, Washington, DC (Referral Center; Phases I and II)
- VA Medical Center, Durham, NC (Phases I and II)
- VA Medical Center, Houston, TX (Referral Center; Phases I and II)
- VA Medical Center, Indianapolis, IN (Phases I and II)
- Naval Medical Center, San Diego, CA (Referral Center; Phases I and II)
- Walter Reed Army Medical Center, Washington, DC (Specialized Care Center; Phases I and II)
- Eglin Air Force Base, Ft. Walton Beach, FL (Phases I and II)
- University of Louisville Medical Center, Louisville, KY (CCEP contractor for Fort Knox; Phases I and II)

Site visits included interviews with medical facilities' commanders or chiefs of staff, Registry or CCEP coordinators, medical and non-medical staff assigned to the program, and veterans undergoing evaluation. Committee members and staff also took walking tours of dedicated facilities and reviewed randomly selected medical records of Gulf War veterans.

Clinical evaluation programs. In August 1992, VA established its Registry for veterans who had returned to civilian life. DOD established the CCEP in June 1994 for Gulf War veterans remaining on active duty. These clinical programs are available, free of charge, to any Gulf War veteran. Both

1 the Registry and CCEP are treatment programs, not research protocols, but the data have been used to
2 generate research hypotheses.

3 VA and DOD maintain databases for their clinical care programs. The databases for the
4 Registry and CCEP can generate information useful for patient care—both for diagnosis and for risk
5 communication.

6 **Quality of care.** The VA Registry originally consisted of a medical history, a thorough physical
7 examination, and basic laboratory tests. If indicated, participants received specialty consultations as
8 Phase II of the evaluation. While the Phase I and Phase II examinations essentially were equivalent
9 to a good internal medicine evaluation, initially no uniform protocol existed for the assessment of
10 participants in the Registry. As the program developed, VA established requirements for certain
11 specialty examinations for all participants and standard questions regarding possible exposures while
12 in the Gulf. By early 1994, a uniform assessment protocol, which is in use today, was in place
13 systemwide. To date, more than 57,000 Gulf War veterans have participated in VA's Registry
14 program. The most frequently cited symptoms, which have remained consistent over time, include:
15 fatigue, headache, skin rash, muscle and joint pains, and memory loss. The majority of participants
16 receive a diagnosis, but approximately 20 percent of veterans who describe symptoms during the
17 physical examination(s) complete the Phase I and/or Phase II examinations without receiving a
18 diagnosis.

1 DOD uses the same examination protocol for its CCEP.³ Initially, any CCEP participant who
2 wanted a Phase II evaluation was given one without a specific referral from his or her physician.
3 DOD modified this policy in January 1995, and now requires a physician referral for Phase II. In
4 April 1996, DOD published information derived from more than 18,000 CCEP examinations (CCEP
5 4/96), and the findings are similar to those for VA's Registry. The most frequently cited symptoms
6 have been fatigue, headache, skin rash, joint pain, and memory loss. All CCEP participants receive a
7 diagnosis, but approximately 18 percent of the primary diagnoses fall into the category "ill defined
8 signs and symptoms," with no specified cause.

9 VA designated medical centers in Washington, DC, Houston, TX, Los Angeles, CA, and
10 Birmingham, AL, as Referral Centers for evaluating veterans who have unexplained illnesses after
11 the Phase I and II examinations. DOD established a Specialized Care Center at Walter Reed Army
12 Medical Center for the evaluation, treatment, and rehabilitation of Gulf War service members with
13 chronic debilitating symptoms.

14 **Appointment scheduling.** VA offers the Phase I examination at any VA medical facility; Phase II
15 examinations are performed at any secondary or tertiary care facility. Phase I evaluations through the
16 CCEP may be done at any military treatment facility. DOD's Phase II evaluations can be conducted
17 at any tertiary care facility with the required specialty staff, but DOD has specified one treatment

³ At DOD's request, the Institute of Medicine (IOM) evaluated the CCEP, and IOM judged the clinical protocol (also used by VA) excellent for the diagnosis of illness.

1 facility for Phase II referrals in each of 14 geographic regions and prefers individuals use these
2 facilities.

3 When VA's Registry began in 1992, veterans often encountered significant delays throughout
4 the system in scheduling appointments—chiefly because of the large number of veterans requesting
5 examination, the newness of the program, and the need to reassign space and personnel within
6 facilities. Experience gained over time, the development of streamlined procedures, and the
7 decreasing rate of veterans entering the Registry largely have eliminated major delays in scheduling
8 an initial examination. Delays—usually less than 30 days—can occur in scheduling Phase II
9 evaluations depending on the availability of specialists. Evaluations at one of VA's four Referral
10 Centers entail administrative delays associated with necessary medical records preparation and
11 consultations with referring primary care physicians. The Referral Centers follow a more rigorous
12 protocol that requires a greater commitment of time and specialty resources and limits the number of
13 participants at any one time. Delays of three months or more are not uncommon.

14 The Committee heard fewer complaints about initial appointment scheduling in the CCEP
15 program and found that delays in scheduling Phase II referrals seldom exceed two weeks. The
16 Specialized Care Center at Walter Reed, a rigorous 30-day program, requires advance scheduling and
17 consultation, but at the time of our visit we heard of no scheduling delays.

18 **Personnel and space.** By the time Committee members and staff initiated our site visits in November
19 1995, all facilities had a designated Gulf War Veterans Program coordinator and support staff who
20 were responsible for scheduling participant visits and conducting the evaluations. Committee and

1 staff interviewed these individuals and found them knowledgeable about the Registry or CCEP
2 programs and their individual responsibilities. Staffing at the facilities we visited is currently
3 sufficient to conduct Phase I and Phase II evaluations, although differing numbers of available
4 specialists to conduct portions of the Phase II evaluation causes some delays in a few of the facilities
5 visited.

6 The large numbers of soldiers at Fort Knox who registered in the CCEP initially threatened to
7 overwhelm the resources of the Internal Medicine Department. A large backlog of participants
8 awaiting Phase I evaluation existed in February 1995, when DOD mandated that all requested work-
9 ups nationally would be completed by April 22, 1995. Because Fort Knox had only three internists at
10 the time, CCEP registrants consumed all their clinic time. In response, two physicians from Wright-
11 Patterson Air Force Base were detailed to Fort Knox to assist with the evaluations. Contract
12 arrangements also were made with the University of Louisville to conduct Phase I evaluations from
13 Fort Knox beginning July 26, 1995. Participants requiring Phase II evaluations formerly were
14 referred to the U.S. Air Force Hospital at Wright-Patterson Air Force Base, Dayton, OH, but Phase II
15 evaluations now also are conducted at the University of Louisville.

16 The Fort Knox example of clinic overload was the most extreme example of clinical
17 disruption at facilities visited by the Committee. Eligible beneficiaries, other than Gulf War veterans,
18 who requested appointments at the Fort Knox Internal Medicine Clinic in the spring 1995 were
19 referred to civilian care under DOD's Civilian Health and Medical Program of the Uniformed
20 Services (CHAMPUS). All other facilities we visited maintained they had extended hours and

1 worked harder to avoid interfering with the usual hospital routine. In conversations with clinic and
2 program staff, they noted there had been some disruption in the early part of both clinical care
3 programs, but that the problems had not been severe. The most frequently mentioned effect was the
4 pressure on clinical and program staff to complete the evaluations in a timely manner, particularly at
5 the DOD facilities during January to May 1995.

6 Most facilities did not designate a separate clinic space for the Phase I evaluations, seeking to
7 mainstream participants as much as possible and reduce the possibility of symptom sharing. Some
8 facilities (e.g., VAMC, Durham, NC), have set aside specific clinic hours for the Gulf War
9 evaluations and report no evidence of symptom sharing among their group of veterans. With the
10 significant reduction in numbers of Gulf War veterans seeking evaluation, all clinical spaces we
11 visited are more than adequate to handle current demand.

12 **Staff education.** In contrast to the extensive knowledge of staff assigned directly to Gulf War-related
13 programs, the knowledge level of staff not specifically assigned to the Registry or CCEP at both VA
14 and DOD medical facilities was problematic. For example, the existence of the CCEP was widely
15 unknown among staff at the VA facilities we visited. Moreover, it was astonishing in one instance to
16 find that a physician treating Gulf War veterans in his VA post-traumatic stress disorder (PTSD)
17 research was unaware of the VA Registry. There have been scattered Continuing Medical Education
18 (CME) programs for DOD and VA medical facility staff about the government's Gulf War programs,
19 but these are intermittent, usually limited to a single department, and not well attended.

1 At the time of the site visits, some staff at the VA medical facilities complained they were
2 receiving less information about the program from VA Central Office than they felt they needed.
3 While recognizing the educational outreach concerning the Registry program undertaken by the
4 Central Office, they wanted more information about results of the Registry evaluations and about
5 research being undertaken. Staff at DOD's facilities expressed general satisfaction with the feedback
6 they received.

7 **Staff attitudes.** The Committee heard public comment at each meeting citing insensitive attitudes on
8 the part of staff at both VA and DOD medical facilities. Frequently, these reports by veterans and
9 their families centered on a dismissive or cynical approach to the veterans' problems—i.e., the
10 message received was that his or her problems were “not real” or “all in your head.” Veterans who
11 sought care after the Gulf War but before the establishment of the Registry and CCEP appeared to
12 suffer most from this treatment.

13 In our interviews with staff at the eight medical facilities, we encountered a range of views
14 about the problems being experienced and reported by Gulf War veterans. Some VA and DOD staff
15 members expressed the belief that the thorough, structured evaluations in the Registry and CCEP
16 were overkill and were exacerbating any problems that existed through the reinforcement of a sick
17 role. Others felt constrained by the rigidity of the evaluation protocol—that it did not allow for
18 flexibility of clinical judgment—and felt this was “not the way I would practice medicine.” No VA
19 or DOD staff members interviewed stated they believed that these veterans were not actually ill.

1 Patient satisfaction surveys carried out at several of these facilities find a greater than 80
2 percent approval rate for all patients, including for Gulf War veterans.

3 **Adequacy of medical records.** Medical records of Registry and CCEP participants at each facility are
4 maintained separately from other patient records, and there is a final, common pathway for
5 determining when the records were complete and certified by a physician's signature. When
6 completed, patient data are reported to either VA Central Office or DOD Health Affairs.

7 Committee staff reviewed a 10 percent sample of randomly selected medical records of Gulf
8 War veterans at each facility visited. Records were reviewed for completeness, adherence to protocol
9 and, particularly, documentation of diagnoses by specialty consultation and/or laboratory reports.

10 In its reviews, staff found only minor deviations from completeness and adherence to
11 protocol. In each instance where Committee staff noted missing documentation for a discharge
12 diagnosis, facility staff was able to locate the necessary documentation. It appears that, overall,
13 medical records for these veterans are complete.

14 **Follow-up treatment.** After completing a Registry or CCEP examination, Gulf War veterans are, in
15 most instances, returned to their local medical facility for follow-up care. Despite the general
16 medical adequacy of the VA and DOD evaluation programs, follow-up treatment—particularly where
17 mental health visits are involved—are problematic. Staffing constraints often occasion long delays in
18 scheduling appointments in some specialties. Psychiatric staffing is particularly overloaded at some
19 sites.

1 Many Registry and CCEP participants are receiving follow-up care from a number of
2 physicians, both federal and private sector. No single case manager is guiding their care. The
3 absence of a case manager can lead to confusion and, in some cases, over medication of patients.

4 Follow-up treatment of active duty veterans also is made more difficult by command
5 resistance to granting the necessary time off to maintain an adequate treatment program. This is true
6 for all chronic illnesses, but especially so for psychiatric diagnoses.

7 **Reproductive Health Services**

8 The birth of a child with a disabling, disfiguring, or lethal condition is devastating to the parents and
9 family of that child. Likewise, the inability to produce a wanted child is usually unexpected and
10 almost always anguishing. Most people want to know why this has happened to them and their
11 family. Understanding what caused, or at least did not cause, the problem can often bring relief.

12 **Care provided to active duty service members.** When a couple experiencing infertility, a woman in a
13 high risk pregnancy, or an infant with a birth defect enters the military health care system, a
14 comprehensive range of services—from primary to tertiary care—are available. Beneficiaries who
15 experience fertility problems can use their benefits to obtain a variety of reproductive health services,
16 including infertility testing and treatment. A child with special health needs receives a full range of
17 medical and related health care benefits to the full extent of his or her disability. In addition, a child
18 with a disability and incapable of self-support remains eligible for care in under the military's

1 medical services system as a family member of an active duty member or retiree, even after the age of
2 majority (Tabler, 1996).

3 **Care provided to veterans who have separated from service.** Reproductive-related medical care and
4 counseling for individuals no longer on active duty stands in stark contrast to coverage for active duty
5 service members. With the exception of children with spina bifida born to in-country Vietnam
6 veterans, VA currently lacks the authority to provide benefits or services on the basis of adverse
7 health effects in children—even if the effects are shown to result from their parents' service
8 experience. Evaluation and treatment for infertility of veterans is limited to a small number of
9 situations in which the cause of the infertility could have been detected and treated while on active
10 duty (e.g., diabetes in women or service-related spinal cord injury in men). In general, obstetrical
11 services are not offered to female veterans through the VA medical system—except for care relating
12 to a pregnancy that is complicated, or in which the risks of complication are increased by a service-
13 connected condition. VA has no policies in place to systematically address the concerns of Gulf War
14 veterans regarding reproductive health.

15 **Prevention of Combat-related Stress**

16 Building on research on veterans of Korea, Vietnam, and the Gulf, DOD has undertaken an ambitious
17 program to proactively address combat-related stress. The U.S. Army, through the Department of
18 Military Psychiatry, Walter Reed Army Institute of Research, has instituted a Human Dimensions
19 Research Program. One important observation has been that strong leadership and unit cohesion are

1 strongly associated with reduced severity of stress reactions. U.S. Army doctrine embraces this
2 finding and emphasizes it in its field manuals.

3 Combat Stress Control Detachments have been established (six in the Active Army and nine
4 in the Reserve), each consisting of a psychiatrist, psychologist, social worker, psychiatric nurse,
5 clinical nurse specialist, occupational therapist, and two enlisted technicians. These detachments
6 provide predeployment briefings that address all known health hazards, including stress, that
7 individuals might face during the deployment. During deployment, members of the detachments are
8 instructed to be highly visible to the commanders and troops. One of these detachments has been
9 deployed to Bosnia.

10 Combat Stress Control Detachments provide briefings for units newly arrived, provide special
11 training in stress management techniques and, most important, they conduct unit survey interviews
12 throughout the deployment. Unit interviews are a systematic tool for gathering information from the
13 troops and then reporting to the command what is troubling the troops and how well leadership is
14 functioning. When critical events occur, the trained individuals in the detachments debrief personnel
15 directly involved, provide consultation to the leaders and chaplains, and provide any special
16 education that could be needed. At the end of a deployment, all units, including those in which no
17 critical events occurred, receive an end of tour debriefing by the Combat Stress Control Detachment.
18 Those units exposed to particular critical events receive special attention to ensure that unit members
19 have a chance to talk through events and reach appropriate closure prior to returning home.

1 Follow-up plans for the Bosnia deployment include studies that will take place six months
2 after veterans return. Plans also are under discussion to continue to follow the same individuals, with
3 appropriate informed consent, over the long term.

4 Tertiary prevention programs, such as Vet Centers within the VA medical system, also can
5 help minimize psychiatric conditions before they become too severe. As noted earlier in this chapter,
6 Vet Centers were established after the Vietnam War to provide support for Vietnam veterans with
7 PTSD and other mental health disorders. There are 205 centers located around the United States, and
8 since 1991, more than 66,000 Gulf War veterans in over 210,000 visits have availed themselves of
9 these centers (Batres)

10 Findings Regarding Medical and Clinical Issues

11 Based on the government's response to the recommendations in the Committee's *Interim Report* and
12 additional interviews, site visits, briefings, and testimony, the Committee makes the following
13 findings regarding medical and clinical issues:

- 14 • DOD has not been responsive to the Committee's recommendation that prior to any
15 deployment, DOD should undertake a thorough health evaluation, including a core set of
16 diagnostics, of a large sample of troops to enable better postdeployment medical
17 epidemiology along with timely postdeployment followup.
- 18 • FDA is moving toward finalizing the Interim Final Rule related to permitting a waiver of
19 informed consent for use of unapproved products during military exigencies. The
20 Committee remains seriously concerned about the amount of time—currently exceeding
21 five years—FDA is taking to open the process to public comment.
- 22 • DOD has not been responsive to the Committee's recommendation that it should routinely
23 inform recruits and troops, through orientation and training procedures, about the possible
24 use of investigational drugs or vaccines for chemical and biological warfare agent
25 purposes. DOD's lack of response in this highly sensitive area contributes to the

1 perception of many that U.S. troops were inappropriately subjected to investigational
2 drugs or vaccines during the Gulf War.

- 3 • DOD has made progress in improving medical recordkeeping in-theater and stateside, but
4 increased and sustained commitment from DOD's Joint Chiefs of Staff and Commanders
5 in Chief will be necessary for current prototypes and plans to be fully and successfully
6 integrated and implemented.
- 7 • Clinical staff not directly involved in VA's Registry and DOD's CCEP are not well
8 informed about the programs.
- 9 • Follow-up treatment, particularly when mental health visits are involved, is problematic
10 within both VA and DOD. Staffing constraints occasion long delays in scheduling
11 appointments. Commanders are sometimes resistant to making sufficient time off
12 available for active duty veterans to maintain an adequate treatment program.
- 13 • Reproductive health care benefits available to active duty service members and their
14 families through the Military Health Services System are comprehensive and the standard
15 of care.
- 16 • Reproductive health concerns are addressed on a case-by-case basis within DOD, and no
17 evidence exists that they are addressed at all within the VA medical system. Neither DOD
18 nor VA have widespread or systematic policies in place to address the concerns and
19 questions of Gulf War veterans concerning reproductive health.
- 20 • DOD and VA have implemented innovative programs to help veterans cope with combat-
21 related stress.

22 **RESEARCH**

23 In our *Interim Report*, the Committee found most of the major epidemiologic studies sponsored by
24 DOD, VA, and DHHS to be well designed and appropriate to determine if Gulf War veterans have
25 mortality, symptoms, or diseases that could be attributable to service in the Gulf War. We were
26 concerned, however, that inadequate response to scientific peer review, disregard for the importance
27 of allocating scarce research dollars to the best designed studies, and inattention to the need to
28 communicate effectively with veteran participants were undermining the effectiveness of the

government's research efforts. Finally, we found that the lack of data about exposure to various risk factors was hampering ongoing research. The Committee made the following recommendations following its preliminary analysis of the government's research programs:

- All epidemiologic studies aimed at Gulf War veterans' health issues should incorporate external scientific review and ongoing interaction with appropriate outside experts throughout the study process, from study design through analysis of results.
- The Persian Gulf Veterans Coordinating Board should play an active role in allocating the limited resources available for research on Gulf War veterans' illnesses. The Research Working Group of the Coordinating Board should monitor the findings and recommendations of scientific peer review committees. If scientific reviews draw into question the usefulness of particular studies to the overall research strategy, the Research Working Group should, via the Coordinating Board, recommend appropriate actions to the Secretaries of the three departments involved.
- DOD, DHHS, and VA should recommend their principal investigators use public advisory committees in designing and executing epidemiologic studies of Gulf War veterans' illnesses.
- For those questions that are common to different epidemiologic surveys, coordination between principal investigators and survey design experts should take place to arrive at common wording. The Persian Gulf Veterans Coordinating Board's Research Working Group should take responsibility for this coordination.
- The Persian Gulf Registry of Unit Locations should be made available to qualified government and private researchers as quickly as possible, within the constraints of confidentiality.
- DOD should make reasonable and practical efforts to collect and record better troop exposure data during future conflicts and to make those data available as quickly as possible to health care researchers.

Departmental Responses

The government has been responsive to these recommendations in general, but the Committee notes continuing problems in two areas: the use of public advisory panels for epidemiologic studies and the utility of the Persian Gulf Registry of Unit Locations.

Public advisory panels. While VA and DOD have encouraged their principal investigators to convene and consult scientific advisory committees, they have not taken serious steps to encourage the formation and use of public advisory committees. Although public advisory committees will be recommended for epidemiologic studies recently funded by DOD and VA, their use is given low priority by program administrators. The Committee believes this practice is unfortunate because public advisory committees can greatly facilitate incorporation of veterans' concerns into study design, dissemination of results, and risk communication.

Persian Gulf Registry of Unit Locations. DOD has made its congressionally mandated Persian Gulf Registry of Unit Locations available to government and private researchers, but the database lacks the precision and detail necessary to be an effective tool in the investigation of exposure incidents. More to the point, the unit locator database has failed in its application to the single CW agent incident investigated by DOD in any detail to date—i.e., Bunker 73 and the pit at Khamisiyah.

In its Khamisiyah investigation, the Persian Gulf Veterans' Illnesses Investigation Team (PGIT) has not relied on reports provided from the database because the assumption on which the database is premised—that individuals remain with their units—was the exception rather than the rule

1 in the theater of operations. Instead, PGIT went back to the operational records and engaged in a
2 series of interviews to try to piece together a more accurate picture of troop locations. They found
3 that in the field individuals performed duties while assigned to discrete groups that might or might
4 not be represented by one of the database's unit identification codes. In addition, records of unit
5 locations, which are still maintained manually, were sometimes incomplete and/or inaccurate. For
6 these reasons, the Committee concludes the unit locator has not proved to be a valuable tool for
7 investigating exposure incidents. The effort has been no more successful than the effort to compile
8 similar information following the Vietnam War to examine possible exposures to Agent Orange.
9 Regrettably, DOD raised expectations about the potential utility of the database far beyond reason,
10 given the data available to developers of the computer database. Better data—whether acquired
11 through rigorously enforced manual methods or new technologies such as devices that interact with
12 the Global Positioning Satellite system—should receive higher priority from DOD.

13 **Issues New to This Report**

14 To complete its evaluation of federally funded research on Gulf War veterans' illnesses, the
15 Committee assessed whether the federally funded research portfolio is well managed and whether the
16 federally funded research addresses an appropriate range of questions relevant to Gulf War veterans'
17 illnesses.

Management of the Federally Funded Research Portfolio

The Committee focused on four areas related to the government's management of federally funded research in Gulf War veterans' illnesses: coordination, research centers, prioritization, and external review.

Coordination. The Persian Gulf Veterans Coordinating Board (Coordinating Board) manages the government's Gulf War veterans' health research. Established in January 1994, the interagency Coordinating Board is comprised of the Secretaries of Defense, Health and Human Services, and Veterans Affairs, and its Research Working Group (RWG) has primary responsibility for research related to possible health consequences Gulf War service. RWG's tasks include coordinating studies to avoid unnecessary duplication, ensuring a focus on high priority research, assessing the status and direction of federally funded research, identifying possible gaps in understanding Gulf War veterans' health issues, recommending future research directions, and generating periodic reports to Congress. Oversight of individual projects within the government's portfolio rests within the funding agency. Each department has its own established funding and management procedures for its intra- and extramural research programs.

DOD and VA have historical roles in research on the health of active duty service members and veterans, and they take the lead in the RWG partnership. DHHS has historical strengths in public health that are brought to bear in this effort. However, DHHS's many basic biomedical research intramural activities (e.g., the National Institutes of Health (NIH)) and extramural projects that could

1 contribute substantial expertise to Gulf War health issues are peripherally involved in RWG's
2 activities, if at all.

3 **Research centers.** The government has developed some innovative approaches to address Gulf War
4 veterans' health research. For example, in October 1994 it launched three Environmental Hazards
5 Centers in Portland, OR, East Orange, NJ, and Boston, MA. At the outset, the goal was to bring
6 together teams of highly qualified researchers with relevant expertise in veterans' health issues. The
7 centers are joint VA-university endeavors—each funded at approximately \$500,000 per year for five
8 years—and they support interdisciplinary collaborations and interactions between VA and academic
9 scientists.

10 Testimony before the Committee and staff site visits indicate the centers each bring a different
11 array of expertise to the broad set of questions relevant to Gulf War veterans' illnesses. To date, the
12 center approach already has produced some well-designed studies. Moreover, the range and depth of
13 research at the centers suggests these studies will provide useful contributions to understanding Gulf
14 War-specific health concerns, as well as those that could arise with future conflicts.

15 More recently, VA decided to adopt the multidisciplinary center approach for reproductive
16 health issues; the possibility that reproductive health problems and birth defects might be tied to
17 service in the Gulf War is of special concern to many veterans and their families. In part to address
18 these concerns, VA solicited applications in May 1996 to establish a research center for
19 epidemiologic, clinical, and basic science studies of environmental hazards and their effects on
20 reproductive and developmental outcomes. The proposed center will collaborate with federal and

state agencies that collect birth outcome data and that have experience with relevant chemical exposures. The center will not be specific to reproductive issues related to Gulf War veterans, but will have the broader mission of analyzing reproductive health research for all veterans.

Prioritization. In addition to developing the center-based approach, RWG also established priorities for federally funded research on Gulf War veterans' illnesses. Research priorities were first published in August 1995. These evolved over the next few months, and in response to questions from the Committee in May 1996, the RWG identified and ranked priority research areas. In order of priority, these were:

- reproductive health, including male contribution to adverse reproductive health outcomes (e.g., burning semen)
- mortality follow-up studies;
- stress;
- illnesses in non-U.S. coalition forces and indigenous populations;
- toxicology of pesticides, CW agents, and PB (alone and in combination with other factors);
- toxicology of depleted uranium (DU), solvents, and fuels; and
- infectious diseases, especially leishmaniasis and BW agents.

The Committee commends the effort to set priorities and notes these priorities were applied to the most recent round of research awards overseen by the RWG. However, the Committee has identified a more narrow range of priorities specific to Gulf War veterans' health concerns, specifically: the long-term health effects from stress, the long-term health effects from low-level

1 exposure to CW nerve agents, the long-term health effects from exposure to known carcinogenic and
2 mutagenic compounds (such as mustard agent), and the long-term health effects of interactions
3 between PB and other agents as the principal uncertainties about Gulf War veterans' illnesses. We
4 conclude, therefore, that further, new research in several of the RWG's priority areas will have
5 minimal impact on understanding Gulf War veterans illnesses. Such research could be important,
6 however, for future conflicts.

7 **External review.** The departments have incorporated external scientific merit review into their
8 research selection processes. Proposals for funding through DOD's fiscal year 1995 Broad Agency
9 Announcement (BAA) were reviewed for scientific merit and relevancy by the American Institute of
10 Biological Sciences.

11 To maximize the validity and interpretability of study findings and as recommended in the
12 Committee's *Interim Report*, external scientific review has been incorporated—at least for studies
13 funded at more than \$100,000 per year. External scientific review for smaller, VA-sponsored studies
14 is more variable.

15 Each agency of the RWG has its own standing advisory committees charged with overseeing
16 research, including VA's Persian Gulf Expert Scientific Committee, the Armed Forces Epidemiology
17 Board, the Defense Science Board (DSB), and NIH study groups. However, none of these groups has
18 interagency appointments and/or responsibilities. Moreover, none is charged specifically with
19 overseeing post-conflict health research.

Content of the Research Portfolio

The U.S. government funds a broad range of research in Gulf War veterans' illnesses. Figure 2-1 illustrates the distribution (by numbers of studies) of the federal research commitment specifically dedicated to Gulf War veterans' health. These studies are not equivalent in terms of cost, number of participants, or likely contribution to understanding Gulf War veterans' health. Table 2-1 categorizes the research portfolio by type of study and lists the funding agency, health issue(s) under investigation, location and affiliation of the research institution, anticipated completion date, and publications to date.

Epidemiologic studies. As of Fall 1996, the federal government has funded 18 epidemiologic studies (23 percent of the total number of studies). These projects are intended to evaluate the occurrence of disease in Gulf War veterans and the factors that influence their occurrence, severity, and outcome. Individual studies examine different groups of veterans and different diseases and health outcomes. For example, subgroups include women veterans, servicemen and women from countries other than the United States, veterans who have enrolled in the VA registry, veterans who now live in specific states, veterans who have been hospitalized, and specific veteran groups such as the Seabees. Health outcomes under investigation include cancer rates; rates of infertility, birth defects, and miscarriages; causes of death since return from the Gulf War; general well-being; current health status; and operational case definitions that have been empirically developed for specific subgroups of veterans. The body of major federally funded epidemiologic studies was reviewed in the Committee's *Interim Report*.

Upon completion, this epidemiologic research aims to answer some fundamental questions about the health of Gulf War veterans. Are Gulf War veterans as a population exhibiting specific symptoms, diseases, and death at a greater rate than seen in veterans who did not serve in the Gulf War? If so, what are the specific diseases or causes of death that are increased? Results from the epidemiologic research will be crucial for identifying future research needs, as well as which risk factors should receive additional research attention.

Gulf War risk factors and health outcomes. Health outcomes for Gulf War veterans under investigation in Fall 1996 included reproductive health; diarrhea and gastrointestinal disorders; irritable bowel-like disorders; immunological function; respiratory function; fibromyalgia; musculoskeletal symptoms; sensitivity to chemicals; fatigue, stress, mental health, and neurophysiologic and neuropsychologic status (including PTSD and Chronic Fatigue Syndrome). Many of the projects on specific health outcomes also are based on epidemiologic approaches.

Currently, stress is the risk factor funded for the greatest fraction of total studies—23 studies (28 percent). Other federally funded research investigating possible health effects of specific Gulf War risk factors—often involving animal models—include projects assessing mustard agent; organophosphorus (OP) nerve agents; DU; infectious disease, especially leishmaniasis; oil-well fire smoke; leaded fuels; and PB in combination with insecticides and other agents (figure 2-1).

As summarized in figure 2-1 and table 2-1, the government's research portfolio on possible health consequences related to Gulf War service has directed significant effort at addressing uncertainties specific to Gulf War veterans. Other portions of the research portfolio, however, can

1 only be justified as anticipating health issues in future conflicts—i.e., the general health consequences
2 of military service.

3 **Low-level effects of chemical warfare agent exposure.** Newly released information has affected the
4 relative importance of certain risk factors. Prior to June 1996, DOD ignored calls from its own DSB
5 and others for research on the possible long-term health consequences of low-level exposure to CW
6 agents. DOD's intransigence in refusing to fund such research until Summer 1996 has done veterans
7 and the public a disservice.

8 The recent revelations about possible exposure of some U.S. service personnel to low levels of
9 CW agents during the destruction of Iraqi chemical munitions at Khamisiyah have elevated this
10 research issue, however, and altered DOD's posture toward funding such projects. Currently, the
11 RWG is preparing to fund research proposals in this area. The RWG will need to consult with experts
12 in and out of government to ensure that difficulties such as institutional barriers, inadequate access to
13 expertise, and lack of a clear management strategy do not impede progress in this important research
14 area.

15 DOD recently committed \$5 million from fiscal year 1996 funds for collaborative DOD/VA
16 research—as identified by the RWG—on possible low-level effects from CW agents. Projects initially
17 slated to receive funds (\$2.5 million) include three previously unfunded proposals based on animal
18 model experiments. Current plans are to identify and fund additional clinical and epidemiologic studies
19 on this topic with the remaining \$2.5 million.

Findings Regarding Research

Based on the government's response to the recommendations in the Committee's *Interim Report*, a review of the federally funded research portfolio for Gulf War veterans' health, and a parallel, but independent, review of potential health risk factors that could be associated with service in the Gulf War, we make the following findings:

- DOD and VA have not taken serious steps to encourage their principal investigators to convene and use public advisory committees for its Gulf War veterans' epidemiologic health research.
- DOD's Persian Gulf Registry of Unit Locations lacks the precision and detail necessary to be an effective tool for the investigation of exposure incidents. The effort has been no more successful than the effort to compile similar information following the Vietnam War to examine possible exposures to Agent Orange.
- Overall, 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.
- Research on Gulf War veterans' illnesses is treated, appropriately, as a subset of the government's broader research portfolio on the health consequences of military service. However, current priorities for new research specifically directed toward concerns about the effects of Gulf War service are cast too broadly. Any new research funds should be directed toward the principal uncertainties, which are: long-term health effects from stress; long-term health effects from low-level exposure to chemical weapons; long-term health effects from exposure to known carcinogenic and mutagenic compounds, such as mustard agent; and long-term health effects of interactions between pyridostigmine bromide and other agents.
- Stress appears to be a major contributing factor to illnesses being reported today by Gulf War veterans. Stress, however, is not well understood in terms of diagnoses, physiological sequelae, and effective prevention and treatment strategies. Additional attention to basic and applied research on stress-related disorders across the entire federally funded biomedical research portfolio would benefit DOD's and VA's capabilities to manage combat stress and its effects.
- The efforts of the Coordinating Board's Research Working Group would benefit from the active participation of additional representatives from other federal agencies with relevant

1 expertise, such as the National Institutes of Health and the Agency for Toxic Substances
2 and Disease Registry.

- 3 • VA's May 1996 solicitation to establish a new Environmental Hazards Center focused on
4 reproductive health and developmental outcomes from environmental exposures is an
5 important step forward in developing policies for the treatment of veterans and addressing
6 their concerns.

7 CHEMICAL AND BIOLOGICAL WEAPONS

8 At the time the Committee issued its *Interim Report*, we were still in the initial stages of reviewing
9 information gathered about Iraq's advanced CBW capabilities by the United Nations Special
10 Commission on Iraq (UNSCOM) since the end of the Gulf War. UNSCOM's work, which continues
11 today, has played a critical role in discovering the extent of possible exposures of U.S. troops to
12 CBW agents during the Gulf War (UNSCOM rpts).

13 In our *Interim Report*, we found the decisions of DOD and the Central Intelligence Agency
14 (CIA) to reopen their investigations of chemical and biological weapons in the Gulf War to be
15 constructive steps and urged DOD and CIA to draw fully on their resources to answer some of the
16 war's most controversial questions. We stated our intention to monitor their progress carefully.
17 Additionally, we found that improved technology to detect the presence of CBW agents would
18 improve the health surveillance of troops involved in future conflicts. The Committee made the
19 following recommendations related to chemical and biological weapons in the *Interim Report*:

- 20 • CIA and DOD should coordinate their analyses to ensure a comprehensive review of the
21 complete record of the Gulf War. Each agency should make full and prompt disclosure of
22 all findings.
- 23 • DOD should devote more attention to monitoring low-level (subacute) exposures to
24 chemical warfare (CW) agents. One possible basis for such a system is the automated air-
25 sampling system developed by the U.S. Army Edgewood Research, Development and
26 Engineering Center for UNSCOM, which is using it to monitor emissions from Iraqi

chemical plants. Another approach might be to modify the detection system the U.S. Army uses to monitor for leaks at chemical weapons storage depots.

- DOD should continue to invest in the development of a biological point detector/alarm system that can detect and identify biological warfare agent aerosols rapidly enough to enable troops to take protective measures before being exposed.

DOD and CIA Responses

As described more fully later in this chapter, CIA has systematically reviewed classified and open source information related to CBW agent exposures during the Gulf War. In contrast, DOD has failed to take advantage of its unique access to both classified and routine military records. DOD has not accepted nor implemented the Committee's recommendation to develop and implement low-level CW agent monitoring. DOD has not made substantial progress in fielding a real-time biological agent detector.

The Committee notes that in a series of studies since the end of the Gulf War in 1991, the U.S. General Accounting Office (GAO) has identified several inadequacies in the U.S. military's preparedness for chemical or biological attacks, and GAO has briefed the Committee on these matters (GAO '91; GAO '96; Gebicke). While DOD has agreed with virtually all of GAO's findings and recommendations, the Committee is concerned that the equipment, training, and medical shortcomings still persist and could result in needless casualties and a degradation of U.S. war fighting capability.

Issues New to This Report

To complete its evaluation of information related to reports of possible detections of CW or BW agents during the Gulf War, the Committee focused on two questions:

- What conclusions can be drawn about exposures given the evidence collected to date?
- How vigorously has the government pursued the search for evidence?

The Committee purposefully separated these issues from its assessment of the possible health effects of CBW agents, which is discussed in chapter 4.

Evidence of Exposure

Drawing from a number of sources, including interviews with veterans, operational and intelligence logs, UNSCOM reports, and testimony, briefings, and reports from CIA and DOD, the Committee reviewed evidence of exposure to CBW agents. Ultimately, we identified three possible exposure scenarios for analysis: intentional use of CBW agents by the Iraqis; theater-wide contamination from air war bombings in Iraq; and site-specific exposures related to bombings or demolition activities (DSB; Senate Banking). The Committee has drawn its conclusions with full knowledge that ongoing investigations could disclose additional evidence and does not intend to foreclose full consideration of new information.

Exposure to biological warfare agents. The Committee's review of U.S. Army hospital admissions records identified only one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning. Stateside laboratory analyses also have not indicated BW agents were present in the KTO. Reports of dead animals that could have succumbed to biological warfare agents have been investigated by DOD and UNSCOM, and the evidence does not implicate biological warfare. Finally, Iraqi officials have denied any use of biological weapons during Operations Desert Shield/Desert Storm. Thus, the best evidence available to the Committee indicates U.S. personnel

1 were not exposed to biological warfare agents during the Gulf War (CIA 1996, Copeland, Duelfer,
2 Dunn, Koenigsberg, J. Martin).

3 This conclusion is based on imperfect information. For instance, UNSCOM cannot verify the
4 quantities and weaponization status of Iraqi BW agents because Iraq claims that it unilaterally
5 destroyed all of its biological weapons (Duelfer; Mitrokhin). Additionally, the United States did not
6 deploy a real-time BW agent detection system to the Gulf.

7 **Intentional Iraqi use of chemical warfare agents.** Iraq successfully used chemical weapons in its war
8 with Iran, with massive casualties not seen in the Gulf War. A DOD review of U.S. Army hospital
9 admissions records identified no admissions for CW agent exposures. The U.S. Army officer
10 responsible for CBW agent medical surveillance during the war has testified to the Committee that
11 only one, accidental casualty was treated (discussed in a later section). Additionally, UNSCOM
12 reported to us that Iraqi officials have denied to them any use of chemical weapons during the war.
13 Lastly, veterans groups testifying before this Committee concede there were no widespread chemical
14 attacks. Based on information compiled to date, there is no persuasive evidence of intentional Iraqi
15 use of CW agents during the war (CIA 1996, Copeland, Duelfer, Dunn, Koenigsberg, J. Martin,
16 Sullivan, Tuite).

17 Again, though based on the best available information, our analysis necessarily relies on less
18 than ideal information. Iraqi representations cannot always be taken at face value. And, some
19 veterans have not received satisfactory explanations for wartime incidents they believe involved
20 chemical weapons (Grass; Lyons; Sullivan; Wages).

1 Theaterwide chemical warfare agent contamination from air war bombings of Iraq. During the Gulf
2 War, Coalition forces conducted air attacks on suspected Iraqi CW agent manufacturing and storage
3 facilities. Some veterans and independent researchers have suggested that fallout from Coalition
4 bombing of these sites led to large-scale nerve agent contamination in the KTO (Senate Banking;
5 Tuite). Three key pieces of evidence suggest that such theaterwide contamination is highly unlikely.
6 First, Coalition airstrikes damaged chemical munitions at only 2 of the 11 Iraqi sites where such
7 munitions were stored. Second, quantities of agents released by successful strikes on chemical
8 munitions sites were limited. And third, locations of those releases were remote. (CIA; Copeland)

9 In late January and February 1991, Coalition forces conducted aerial bombings that damaged
10 chemical munitions stored at two sites in central Iraq: Muhammadiyat and Al Muthanna.
11 Subsequent UNSCOM investigations indicate these are the only sites where Coalition airstrikes
12 actually damaged or destroyed chemical agents. At Muhammadiyat, munitions containing 2.9 metric
13 tons of sarin/cyclosarin and 15.2 metric tons of mustard were damaged during the air war. At Al
14 Muthanna, munitions containing 16.8 metric tons of sarin/cyclosarin were damaged during the air
15 war.

16 To assess possible hazards to U.S. forces from CW agent releases at Muhammdiyat and Al
17 Muthanna, atmospheric modeling was conducted for the CIA for all possible bombing dates at each
18 site. This modeling indicates that on the bombing date when southerly winds were most pronounced,
19 Muhammdiyat releases, at worst, would have resulted in downwind contamination for up to 300
20 kilometers (km) at general population exposure levels established by DOD. This modeling also

1 indicates that on the bombing date when southerly winds were most pronounced, Al Muthanna
2 releases, at worst, would have resulted in downwind contamination for up to 160 km at general
3 population exposure limits. (The general population exposure is a threshold at which one would not
4 expect to see characteristic signs and symptoms of CW agent exposure.) During the air war, the
5 nearest U.S. personnel were in Rafha, Saudi Arabia—more than 400 km from Muhammadiyat and Al
6 Muthanna. Figure 2-2 depicts the locations of the damaged munitions and the closest U.S. forces
7 during the Gulf War (CIA 1996, Copeland, Duelfer, J. Martin, McNally, Mitrokhin).

8 *Figure 2-2 (not included): CIA downwind plumes imposed on map; circles added to indicate*
9 *failure to capture U.S. troops*

10 The Committee frequently heard the suggestion that air strikes on An Nasiriyah caused CW
11 agent contamination as far away as King Khalid Military City (Senate Banking; Tuite). Onsite
12 inspections by UNSCOM, however, found no evidence that chemical munitions were damaged at An
13 Nasiriyah. Iraqi officials also have stated to UNSCOM that chemical munitions stored there were
14 moved to Khamisiyah when An Nasiriyah was first subjected to airstrikes (Duelfer). Although the
15 Iraqis have not cooperated fully with the UNSCOM investigations, the best evidence available
16 indicates theaterwide contamination with CW agent fallout from the air war is highly unlikely (CIA;
17 Copeland; McNally; PGIT Czech report).

18 **Site-specific chemical agent exposures.** During the period U.S. forces were deployed in the KTO,
19 incidents occurred at specific sites that resulted in confirmed exposure, detections, or release of CW
20 agents. In testimony and submissions to this Committee, DOD has taken the position that chemical

1 agent exposures can only be confirmed through physical symptoms (Koenigsburg; J. Martin). The
2 Committee believes, however, that this approach is analytically flawed and that medical symptoms
3 should not drive a determination of presumed exposure/nonexposure.

4 **Confirmed mustard agent exposure.** On March 1, 1991, a soldier exploring a captured bunker in
5 southern Iraq suffered a burn DOD now confirms was caused by mustard agent. Two mass
6 spectrometer tests by Fox vehicles detected mustard agent on the flak jacket worn by U.S. Army
7 Sergeant Fisher, who was diagnosed as suffering from a chemical agent burn. DOD does not view
8 negative results from subsequent laboratory tests on the jacket and urinalysis as inconsistent with the
9 signs of low level exposure exhibited by the soldier. DOD now acknowledges the site-specific
10 exposure of mustard agent of this individual. (Blanck, DSB, Dunn, J. Martin, Wages).

11 **Confirmed nerve and mustard agent detections.** On January 19, 1991, shortly after the beginning of
12 the air war, Czech units reported detecting nerve agent at two locations northeast of Hafir al Batin,
13 Saudi Arabia. On January 24, 1991, Czech units also reported detecting mustard agent at a site 10 km
14 north of King Khalid Military City, Saudi Arabia. DOD has verified the reliability of the Czech
15 equipment and regards these detections as valid, but cannot identify a source of the CW agents for
16 either detection (Blanck; J. Martin; PGIT Czech report). Thus, the Czech detections represent
17 un rebutted evidence of the presence of CW agents at these sites and low level exposure—at the
18 detection sights—must be presumed.

19 As noted earlier in this section, worst-case modeling of hypothetical releases centered at An
20 Nasiriyah indicates potential contamination would not have reached the Czech forces, as does

1 modeling for known CW agent releases at Muhammadiyat and Al Muthanna—i.e., evidence indicates
2 An Nasiriyah, Muhammadiyat, and Al Muthanna were not the CW agent sources for the positive
3 Czech findings. This inability to identify a source for the CW agents precludes modeling the range of
4 exposures around the Czech detection sites. CW agents also were not detected by U.S. troops sent to
5 confirm the Czech findings. Currently, it is not possible to identify low-level exposure of any U.S.
6 troops associated with these two Czech detections (Blanck, CIA 1996, Copeland, Duelfer, J. Martin,
7 McNally; PGIT Czech rpt.).

8 **Confirmed nerve agent releases at Khamisiyah.** In the ceasefire period after the ground war
9 concluded, U.S. personnel used explosives to destroy captured munitions and other materiel
10 throughout occupied areas of southern Iraq so that enemy forces could not use them to rearm. One
11 such site was a major storage depot at Khamisiyah, where more than 100 large bunkers containing
12 artillery rounds, rockets, and other munitions were destroyed in March 1991 (Koenigsburg; J. Martin;
13 B. Martin).

14 DOD has testified to the Committee that on March 4, 1991, U.S. personnel destroyed
15 munitions containing 8.5 metric tons of sarin/cyclosarin housed in Bunker 73 at Khamisiyah. On
16 March 10, 1991, U.S. personnel destroyed an as yet unknown number of sarin/cyclosarin rockets at a
17 pit area at Khamisiyah (Koenigsburg; J. Martin).

18 Atmospheric modeling conducted for CIA indicates CW agent release from Bunker 73 would
19 result in downwind contamination for up to 25 km at general population exposure limits (Copeland,
20 McNally) (figure 2-3). U.S. personnel with the 37th Engineering Battalion, 307th Engineering

Battalion, 60th Explosive Ordnance Detachment, 146th Explosive Ordnance Detachment, 450th Civil Affairs Battalion, and other components of the 82nd Airborne Division were within 25 kms of Khamisiyah (Koenigsberg, J. Martin, B. Martin; Ford). The footprint of the March 10, 1991, release at the Khamisiyah pit area is still under investigation.

[Figure 2-3 (not included): CIA footprints of Bunker 73 and the pit imposed on a map w/circle encompassing unit locator data points]

The evidence of CW agent release at Khamisiyah is overwhelming. The Committee concludes that for nearby troops exposure should be presumed, although the exact levels are unknown.

Search For Evidence

The U.S. government has relied on CIA and DOD internal investigations to report evidence of exposure of U.S. troops to CBW agents. CIA was assigned two responsibilities: reviewing intelligence information relevant to possible CBW agent exposures and performing downwind hazard modeling for possible CW agent releases (Copeland). DOD's investigatory efforts have been led by PGIT, which reports to the Assistant Secretary of Defense (Health Affairs). PGIT's scope spans the broad range of issues related to Gulf War veterans' illnesses. Additionally, a DOD Senior Level Oversight Panel for Gulf War veterans' illnesses coordinates the declassification and release of documents related to CBW agents and other potential risk factors (Joesph, Koenigsburg, Wallner).

The releases at Khamisiyah suggest the need for a thorough investigation of other sites for which reliable detections exist or where information indicates CW agents could have been present.

1 Comprehensive inquiries based on positive detections by M256 kits and Fox vehicles recorded in unit
2 logs should be initiated immediately.

3 **CIA's investigation.** In March 1995 CIA began its re-review of intelligence related to CBW agents and
4 the Gulf War; its work in atmospheric modeling began in early 1996. To date, CIA has aggressively
5 pursued information related to possible CBW agent exposures from classified and open sources.

6 With respect to downwind hazard modeling, CIA has been responsive to concerns about potential
7 low-level contamination and has modified modeling assumptions and parameters to reflect these
8 concerns. In August 1996, CIA reported on the bulk of its analysis, but the agency has yet to
9 complete atmospheric modeling for the March 10, 1991, destruction at the pit at Khamisiyah (CIA
10 1996, Copeland, McNally).

11 **DOD's investigations.** Since 1991, DOD's public position has been that there was no use or presence
12 of chemical weapons in the KTO and that no U.S. troops were exposed to CBW agents during the
13 Gulf War. DOD maintained that position throughout a series of congressional investigations in late
14 1993 and early 1994. In June 1994, a DSB Task Force concluded there was "no evidence that either
15 chemical or biological warfare was deployed at any level against us, or that there were any exposures
16 of U.S. service members to chemical or biological warfare agents in Kuwait or Saudi Arabia." The
17 DSB Task Force was silent on the issue of exposures to service members in Iraq, but its conclusion
18 was interpreted by DOD as inclusive (DSB; Koenigsburg; Senate Banking).

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1 Persian Gulf Veterans' Illnesses Investigation Team. PGIT's 12-member staff includes intelligence
2 officers, members of the Chemical Corps, pilots, chemists, physicians, and one trained investigator.
3 Reflecting its staffing, PGIT has devoted substantial resources to literature reviews and scientific
4 studies, rather than collecting first-hand evidence of possible CBW agent exposure incidents from eye
5 witnesses, battlefield intelligence, unit logs, diaries, and other original documents. By doing so,
6 PGIT has failed to take advantage of its singular unique access to classified and routine military
7 records to fully investigate and help answer the public's questions about possible CBW agent
8 exposures (Koenigsberg, J. Martin, Moldenhauer, Nalls). PGIT's investigation of the Khamisiyah
9 incidents represents the sole exception to this situation.

10 Khamisiyah first appeared on PGIT's list of incidents under investigation in October 1995
11 material supplied to the Committee. Yet, PGIT conducted no interviews with possible eyewitnesses
12 until June 1996. PGIT had or should have had knowledge of documents, including UNSCOM reports
13 and declassified intelligence reports posted to GulfLINK (though subsequently removed), that
14 suggest a sufficient basis to initiate investigatory interviews long before UNSCOM confirmed its
15 initial reports in May 1996 about the presence of CW agents. PGIT's recent eyewitness interviews
16 and its efforts to ascertain troop locations have been valuable, however, in trying to find answers
17 about the Khamisiyah incidents.

18 More importantly, other possible CW agent incidents also merit a thorough review and full
19 investigation. Chief among these are positive readings recorded by two types of detectors fielded to
20 verify chemical agent alarms: Fox reconnaissance vehicles equipped with mobile mass spectrometers

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1 posted testimony before this Committee on GulfLINK, but the department has not posted status
2 reports on its investigations that it prepared for the Committee in August 1996. Public access to more
3 information could only enhance DOD's reputation among parties interested in these issues.

4 DOD's pledge to post copies of relevant declassified documents to GulfLINK has also proved
5 problematic. In November 1995, DOD officials instructed that before declassifiers posted sensitive
6 documents, they should forward the material to PGIT "to allow the investigation Team time to begin
7 preparation of responses on particular 'bombshell' reports" (Wallner memo). Separately in early
8 1996, more than 300 declassified documents were removed from GulfLINK, and while DOD has
9 reported that the documents have not been reclassified, these 300 items have not been reposted.
10 These actions clearly have created the impression that DOD has failed live up to repeated assertions
11 and commitments to openness in its work related to CBW agent investigations and the Gulf War.
12 Nationwide there has been an increasingly strongly held view that DOD is still withholding relevant
13 information from concerned veterans and members of the public (Koenigsberg, Lyons, Moldenhauer,
14 Sullivan, Wallner).

15 Findings Regarding Chemical and Biological Weapons

16 Based on interviews with veterans, review of operational and intelligence logs, UNSCOM reports,
17 testimony, briefings, and reports from CIA and DOD, the Committee makes the following findings:

- 18 • In the face of credible evidence of the presence or release of chemical warfare agents, low-
19 level exposure of U.S. personnel at the affected site must be presumed while efforts to
20 develop more precise measures of exposure continue.

- 1 • to provide all veterans the complete range of health care services necessary for medical
2 problems that might be related to deployment in Operations Desert Shield/Storm;
- 3 • to develop a research program that will result in the most accurate and complete
4 understanding of the types of health problems being experienced by Gulf War veterans
5 and the factors that have contributed to these problems; and
- 6 • to develop clear and consistent guidelines for the evaluation and compensation of
7 disabilities related to Gulf War service (Beach 1995).

8 The Coordinating Board established a working group to oversee each primary mission. As a
9 preliminary matter, the Committee found the assistance of the Coordinating Board and its staff and
10 working groups invaluable. In addition, we recognize the difficulty of integrating the activities of
11 large departments with disparate missions to achieve a whole greater than the sum of its parts. The
12 Committee commends the dedication of the Board's staff.

13 **Clinical Working Group.** The CWG oversees delivery of care to Gulf War veterans. The Committee
14 found that, overall, high quality health care is provided. We recommend, however, some
15 improvements in CME and a regular review of staffing requirements to ensure adequate access to
16 follow-up care.

17 VA introduced its clinical Registry program in 1992 and refined the physical examination and
18 associated questionnaires over the next two years; DOD and civilian medical professionals were
19 consulted as the program matured. DOD adopted VA's standardized evaluation protocol for its

1 CCEP in 1994, and both departments continue to use the same protocol. This Committee and others
2 have judged the protocol to be an excellent tool for diagnosing illness.

3 The CWG serves as a useful counterpart to the RWG by ensuring coordination of the research
4 plan with interesting hypotheses that might emerge from the clinical programs. The CWG also has
5 an important role to play in disseminating information about the clinical programs and in
6 communicating the results of the research program to health professionals in DOD and VA medical
7 facilities.

8 **Research Working Group.** In its *Interim Report*, the Committee identified the need for a more
9 aggressive stance by the RWG in emphasizing the importance of utilizing peer review committees
10 when planning and conducting research and in coordinating the design of epidemiologic surveys.
11 Overall, the RWG has been responsive to our recommendations. A peer review process was used to
12 identify scientifically meritorious proposals that were funded in 1996 (in response to DOD's BAA
13 issued in 1995). Ongoing government-sponsored epidemiologic surveys of Gulf War populations
14 include a core set of similar questions regarding symptoms and exposures that should enable
15 appropriate comparisons among study groups. The RWG has developed a set of core questions that
16 future investigators will be encouraged to incorporate.

17 The RWG has set priorities for new research on Gulf War veterans' illnesses. And the group
18 has overseen the publication of research compendiums and efforts to cooperate with U.S. allies in the
19 Gulf War in future health research.

1 **Disabilities and Benefits Working Group.** The DBWG initially addressed itself to a broad range of
2 issues, including case definitions for disabilities with vague symptoms, care for family members of
3 Gulf War veterans, and DOD's outreach program on Gulf War veterans' health issues. Late in 1994,
4 this working group took as its primary responsibility coordination of the executive branch response to
5 Public Law 103-446, which authorized compensation to Gulf War veterans for disabilities resulting
6 from undiagnosed illnesses. VA issued an implementing regulation (38 C.F.R. 3.317) in February
7 1995. DBWG continued to meet through June 1995 to discuss the impact of the new legislation and
8 regulation. The only meeting in 1996 (to date) occurred for the purpose of briefing this Committee's
9 staff on pay and benefits for individuals separated from service, DOD's disabilities evaluation
10 process, military retirement and separation for disability, comparison of the departments' use of VA's
11 schedule for rating disabilities, and VA's compensation and evaluation procedures.

12 VA currently is reviewing how effectively it has managed its program of compensation for
13 undiagnosed illnesses. A randomized case review by VA's Compensation and Pension Service
14 (prompted, in part, by a GAO report (GAO 1996b)) disclosed frequent instances of miscategorization
15 in the tracking system and failures to develop evidence—particularly lay observations—that might
16 affect the outcome of a claim. As a result of this review, VA reported to the Committee that as of
17 July 1996, it had undertaken a complete second review of all 11,000 cases in the tracking system to
18 ensure full evidentiary development, correct adjudication, and accurate coding in the tracking system.
19 VA also issued more detailed instructions emphasizing these points. VA expected the review of
20 11,000 cases to take six months and reported its intent to work closely with DOD.

1 **Anticipating Post-conflict Health Concerns**

2 Several issues identified during the Committee's examination of Gulf War veterans' illnesses—issues
3 related to research, outreach, and clinical programs—have surfaced after previous conflicts (e.g.,
4 effective epidemiology in the absence of baseline exposure and health information; risk
5 communication with veterans concerned about environmental hazards; and uncertainties about the
6 health consequences of environmental exposures). Responsibility for resolving concerns that
7 invariably arise in the aftermath of military conflicts lies within the domain of several departments,
8 yet appears to be a principal focus of no agency. Following a military operation, effort is exerted in a
9 reactive, rather than proactive, manner.

10 The departments principally involved in Gulf War veterans' illnesses—DOD, VA, and
11 DHHS—have had historical responsibilities for other, similar post-conflict issues, but a number of
12 other agencies also have important expertise and interest. These entities include EPA, CIA, the
13 Department of Energy, the National Science Foundation, the Department of Commerce, and the
14 Department of State. Along with DOD, VA, and DHHS, all are members of the National Science and
15 Technology Council (NSTC), an interagency coordinating body established to ensure cross-agency
16 attention to matters of critical national importance.

17 The lessons learned from the Committee's analyses of Gulf War veterans' health concerns
18 point toward post-conflict health needs of veterans as precisely such a matter. A Presidential Review
19 Directive to the NSTC could be used to ensure the government formulates a comprehensive strategy
20 to deal with key concerns that arise following significant military operations, including:

- health (e.g., stress prevention, treatment, research; medical surveillance adequacy, coordination; mental health; interventions for families);
- outreach and risk communication;
- recordkeeping (e.g., accountability, timeliness, cross-agency coordination, application of new technologies);
- research (e.g., adequacy, quality, coordination, dissemination of results);
- biological and chemical weapons preparedness and research;
- application of emerging technologies (e.g. telemedicine, technology transfer); and
- international cooperation and coordination, especially on research and technology matters.

Any plan developed by NSTC should be reviewed by appropriate nongovernmental experts to ensure that these recurring concerns receive attention at the highest national levels.

Committee Findings Regarding Coordination

Based on its analysis of the government's efforts to coordinate the response to Gulf War veterans' illnesses, the Committee makes the following finding:

- Many issues related to post-conflict health concerns of Gulf War veterans are common to the aftermath of other military engagements. Governmental responsibility to address such concerns spans the missions of several federal departments and agencies, but is a priority for no agency. Resolving these issues in a timely and effective manner requires interagency coordination at the highest levels of government.

SUMMARY

As noted in the Committee's *Interim Report*, the President asked that we review the full range of government activities relating to Gulf War veterans' illnesses (appendix B). In the *Interim Report*, we organized our analyses of the government's efforts into four broad areas: outreach, medical and clinical issues, research, and chemical and biological weapons. In this document, we make additional findings and recommendations to complete our initial assessments; we also address coordination for the first time.

With the exception of DOD's investigations in matters related to incidents involving chemical weapons and possible exposure to U.S. troops, we believe the government has acted in good faith and drawn on a somewhat checkered experience with Agent Orange to significantly improve how it has addressed Gulf War veterans' health issues. Hence, we note that although our recommendations are many, they are offered to improve the government's generally commendable response: Their number and scope should not be viewed as a wholesale condemnation or cause for a complete overhaul of the government's approach to addressing the health concerns of Gulf War veterans.

RECOMMENDATIONS

The Committee's evaluation of the government's response to concerns about Gulf War veterans' illnesses led us to findings in outreach, medical and clinical issues, research, chemical and biological weapons, and coordination. Based on our analyses and these findings, the Committee makes the following recommendations:

1 Outreach

- 2 • DOD and VA should follow the model of field-based outreach demonstrated in the Vet
3 Centers and the Persian Gulf Family Support Program when developing health education
4 and risk communication campaigns for active duty service members, Reserve and Guard
5 personnel, and other veterans. General, less specific outreach methods—e.g., hotlines and
6 public service announcements—should be viewed as an important supplement, but not a
7 replacements.
- 8 • VA should direct its Transition Assistance Program workshop benefits counselors to
9 specifically mention DOD and VA programs related to Gulf War veterans' illnesses.
- 10 • VA should ensure that its initiatives under the Women Veterans Health Programs
11 specifically provide information about Gulf War-related programs.
- 12 • VA should ensure that its outreach to Latino populations specifically provides information
13 about Gulf War-related programs.
- 14 • As the Committee stated in its *Interim Report*, DOD and VA should develop and utilize
15 more refined performance measures to determine how well outreach services are reaching
16 concerned parties. DOD and VA officials (specifically those in the American Forces
17 Information Service and its broadcasting arm, the Armed Forces Radio and Television
18 Service) using media products for outreach initiatives should be aware of the difficulty in
19 enumerating the actual readership and viewership figures and be concerned about how
20 effectively their message saturates the targeted population.
- 21 • DOD should reissue its *Internal Information Plan* on Gulf War-related illnesses. It should
22 make a special effort to note the revision provides the toll-free number and that individuals
23 are encouraged to register for its Comprehensive Clinical Evaluation Program (CCEP). It
24 also should take this opportunity to provide updated information.
- 25 • In an attempt to increase veterans' and the public's awareness and understanding of the full
26 range of the government's commitment to addressing the nature of Gulf War veterans'
27 illnesses, DOD and VA should reevaluate the goals and objectives of their risk
28 communication efforts. DOD and VA should develop effective methods that provide the
29 affected community with comprehensive information concerning possible exposures to
30 environmental hazards, potential health effects from risk factors, and explanations of
31 ongoing and completed clinical and epidemiologic studies.
- 32 • DOD and VA should immediately develop and implement a comprehensive risk
33 communication plan. This effort should move forward in close cooperation with agencies
34 that have a high degree of public trust and experience with risk communication, such as the

Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health.

- Because health risk information and education applies to service members who remain on active duty and veterans no longer in military service, DOD and VA should closely coordinate the federal government's risk communication effort for Gulf War veterans and other members of the affected community. Departmental commitments to any plan should be viewed as continuous and long-term; a sustained effort is particularly critical in light of veterans' and public skepticism arising from the recent revelations related to chemical weapons.
- In its coordinated risk communication plan, DOD and VA should engage veterans service organizations as intermediaries—and include personnel in leadership positions, such as senior enlisted personnel (for active duty military) and state veterans' service officials—in the effort to establish an efficient information exchange process where veterans receive accurate information and the departments receive valuable feedback on clinical programs, health concerns, and communication efforts.

Medical and Clinical Issues

- Given that the Food and Drug Administration's (FDA) Interim Final Rule permitting a waiver of informed consent for use of unapproved products in a military exigency is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- FDA should solicit public comment on the Interim Final Rule. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.
- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.
- The Clinical and Research Working Groups of the Persian Gulf Veterans Coordinating Board should be charged to develop a protocol to implement the following recommendation, which was made in the Committee's *Interim Report*: Prior to any

1 deployment, DOD should undertake a thorough health evaluation of a large sample of
2 troops to enable better postdeployment medical epidemiology. Medical surveillance should
3 be standardized for a core set of tests across all services, including timely postdeployment
4 followup.

- 5 • VA and DOD should, in their educational outreach programs, specifically target staff
6 members not directly involved in the care of Gulf War veterans.
- 7 • DOD and VA should include timely updates on the CCEP or Registry, respectively, in their
8 Continuing Medical Education programs.
- 9 • VA and DOD should regularly brief their staffs on the Gulf War research portfolio and on
10 the results of research studies as they become available.
- 11 • VA and DOD should regularly review staffing needs, particularly in mental health, and
12 increase recruitment and retention of adequate numbers of medical professionals to satisfy
13 patient needs. Staffing reviews should consider that, despite increased medical surveillance
14 and better preventive measures, future deployments also will generate a significant number
15 of veterans who will need care for illnesses that are difficult to diagnose.
- 16 • Since 1986, U.S. service members with certain chronic illnesses, e.g., asthma and diabetes,
17 have been allowed to remain on active duty when regular medical monitoring is necessary.
18 Veterans of the Gulf War with chronic illnesses are no different. Troop commanders
19 should be reminded that adequate time off for follow-up medical appointments is a
20 necessity and a priority.
- 21 • VA should conduct a thorough review of its policies concerning reproductive health and
22 continue to seek statutory authority to treat veterans and their families for service-
23 connected problems. When indicated, genetic counseling should be provided—either via
24 VA treatment facilities or referral—to assist veterans and their families who have
25 reproductive concerns stemming from military service.
- 26 • DOD should continue and intensify its efforts to develop stress reduction programs for all
27 troops, with special emphasis on deployed troops.
- 28 • Since leadership and unit cohesion are so important in managing stress, DOD should
29 specifically involve senior commanders and senior non-commissioned officers in stress
30 management programs.

31 Research

- 32 • The Research Working Group of the Coordinating Board should require that any proposals
33 for new, large-scale Gulf War veterans' epidemiologic health research describe a plan to

1 incorporate a public advisory committee into the study design, dissemination of results, or
2 both. The Research Working Group should consider justifying a waiver of such a
3 committee only under rare circumstances.

- 4 • DOD should develop more accurate methods of recording troop locations to facilitate
5 post-conflict health research in the future. DOD should make full use of global positioning
6 technologies.
- 7 • DOD, through the Coordinating Board's Research Working Group, should plan for further
8 research on possible long-term health effects of low-level exposure to organophosphorus
9 agents such as sarin, soman, or various pesticides, based on studies of groups with well-
10 characterized exposures, including:
 - 11 ◇ cases of U.S. workers exposed to nerve agent pesticides;
 - 12 ◇ civilians exposed to the chemical warfare agent sarin during the 1994 and 1995
13 terrorist attacks in Japan; and
 - 14 ◇ an appropriate subset of any U.S. service personnel who were exposed during
15 the Gulf War.

16 The Research Working Group should begin by consulting with appropriate experts, both
17 governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of
18 human populations with well-characterized exposures will be much more revealing than
19 studies based on animal models, which should be given lower priority.

- 20 • Since a number of Gulf War risk factors are potential human carcinogens that could result
21 in increased rates of cancer beginning decades after exposure, VA should continue to
22 monitor Gulf War veterans through its ongoing mortality study for increased rates of lung,
23 liver, and other cancers.
- 24 • Because depleted uranium munitions are likely to be used in future conflicts involving U.S.
25 service personnel, VA should continue research that monitors closely the health status of
26 individuals with embedded fragments of depleted uranium (DU) shrapnel to fully elucidate
27 the health effects of DU munitions.
- 28 • To facilitate future research, DOD should continue to collect and archive serum samples
29 from U.S. service personnel when feasible.
- 30 • The Research Working Group should more thoroughly consult with other federal agencies
31 with relevant expertise—such as the National Institutes of Health, National Institute of
32 Environmental Health Sciences, and ATSDR—on basic, clinical, and epidemiologic
33 research and on risk communication.

Chemical and Biological Weapons

- All U.S. service personnel assigned to units within 25 km of the Khamisiyah demolition activity should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DOD's Comprehensive Clinical Evaluation Program.
- All reports of positive M256 kits and Fox detections must be thoroughly investigated. Where unit logs record positive detections by either type of equipment, members of that unit should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DOD's Comprehensive Clinical Evaluation Program.
- To ensure credibility and thoroughness, any further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD.

Coordination

- A Presidential Review Directive (PRD) should be issued to instruct the National Science and Technology Council to develop an interagency plan to address health preparedness and readjustment of veterans and families following future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues.

Figure 2-1. Distribution of Federally Funded Research on Gulf War Veterans Illnesses (number of projects in parenthesis)

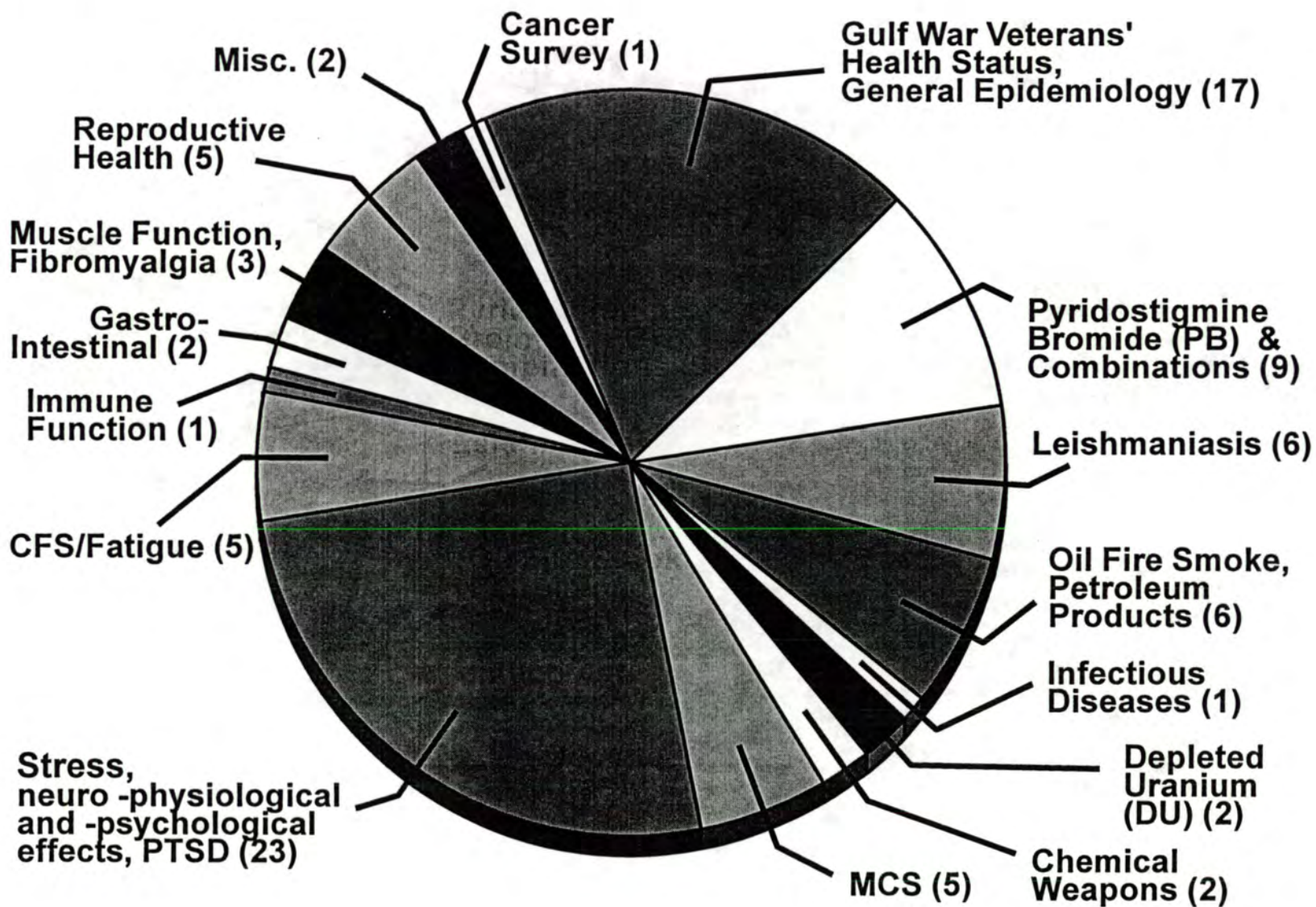


Table 2-1: Summary of Federally Funded Research on Gulf War Veterans' Health Issues, Including Research Funded Through Fiscal Year 1996

GROUP I: Federally Funded Exploratory and Epidemiologic Research on Gulf War Veterans' Health, Rates of Diseases and Death, and Possible Association with Risk Factors			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Health and Exposure Survey of Persian Gulf Veterans</i> (general health symptoms, CFS, MCS, exposures)	VAMC East Orange/VA	complete	manuscript in preparation
<i>Gulf War and Vietnam Veterans Cancer Incidence Surveillance</i>	VAMC Boston/VA	9/99	none
<i>A Controlled Epidemiological and Clinical Study into the Effect of Gulf War Service on Servicemen and Women of the United Kingdom Armed Forces</i> (BAA 1996) (general health symptoms, CFS, psychiatric conditions, neuropsychological outcomes, respiratory function)	King's College School of Medicine, UK	6/99	none
<i>Epidemiological Studies of Persian Gulf War Illnesses, Persian Gulf Women's Health Linkage Study</i> (BAA 1996) (general health symptoms, reproductive outcomes, cancer, psychological conditions)	Klemm Analysis Group, Inc., Washington, DC	1/99	none
<i>Risk Factors Among US Army Soldiers for Enrolling on the Department of Veterans Affairs Gulf War Registry</i> (demographics, aptitude test scores, hospitalizations, self-reported health behaviors)	Walter Reed Army Institute of Research/DOD	complete	in internal review
<i>The General Well-Being of Gulf War Era Service Personnel from the States of Pennsylvania and Hawaii: A Survey</i> (general symptoms, PTSD, and other psychological conditions)	Walter Reed Army Institute of Research/DOD	complete	USAMRMC, 1994; Stretch 1995; 1996a&b; Wright 1996
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors: Study 6: A Comparison of Nonfederal Hospitalization Experience Among Veterans in California who have separated from active service: PGW vs. EV</i>	Naval Health Research Center/DOD	6/97	none
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors: Study 5: Seabee mail survey</i> (chronic disease outcomes)	Naval Health Research Center/DOD	survey in OMB review	none
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors: Study 2: A Comparative Study of Hospitalizations among Active-duty Personnel Who Participated in the Gulf War and Similar Personnel Who Did Not</i>	Naval Health Research Center/DOD	complete	Coate 1995; Gray 1996

GROUP I: Federally Funded Exploratory and Epidemiologic Research on Gulf War Veterans' Health, Rates of Diseases and Death, and Possible Association with Risk Factors			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Investigation of Disease Cluster in a Pennsylvania Air National Guard Unit</i> (general health symptoms, psychiatric outcomes, infectious diseases)	CDC & Pennsylvania State/DHHS	phases 1 and 2 complete, phase 3 analysis ongoing	CDC 1995
<i>Health Assessment of Persian Gulf Veterans from Iowa</i> (CFS, fibromyalgia, psychiatric conditions, cognitive dysfunction, reproductive outcomes)	CDC & Iowa State/DHHS	1/97	manuscript submitted for publication
<i>CORE Project Portland Environmental Hazards Research Center: Environment, Veterans Health, and the Gulf War Syndrome. Core: Clinical and Epidemiology Research</i> (general health symptoms and diseases, reproductive outcomes, stress, psychological conditions)	VAMC Portland/VA	9/99	none
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors: Study 1: A Study of Symptoms Among 1500 Seabees</i> (general health symptoms, handgrip strength, respiratory function)	Naval Health Research Center/DOD	complete	Kaiser 1995
<i>National Health Survey of Persian Gulf Veterans</i> (a survey of general health status of Gulf War veterans examining general health symptoms and diseases, reproductive outcomes, stress, psychological conditions)	Environmental Epidemiology Service/VA	5/98, phase 1 complete	none
<i>Mortality Follow-up Study of Persian Gulf Veterans</i>	Environmental Epidemiology Service/VA	complete, long-term follow-ups planned	Kang 1996
<i>Comparative Mortality Among US Military Personnel Worldwide During Operations Desert Shield/Storm</i>	Walter Reed Army Institute of Research/DOD	complete	Writer et al, 1996
<i>Physical and Emotional Health of Gulf War Veteran Women</i>	Ann Arbor, MI/DOD		Pierce, 1996 a&b
<i>Exploratory Data Analysis with the CCEP Database</i>	Naval Post-Graduate School, MO/DOD	9/97	none
<i>A Statistical Study Correlating the Reported Cases of Gulf War Syndrome to Battlefield Locations of Afflicted U.S. Army Personnel During the Iraq-Kuwait War, Part I: Method to Relate Troop Deployment and the Reported Cases of Gulf War Syndrome and Probable Incidence of Maladies Defined by the ICD-9-CM</i> (statistical techniques)	Aberdeen/DOD	complete	Army Research Laboratory Technical Report ARL-TR-800, July 1995

GROUP II: Federally Funded Research on Health Outcomes from Service in the Gulf War			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors Study 4: Infertility and Miscarriage in Gulf War Veterans</i>	Naval Health Research Center/DOD	9/97	none
<i>Feasibility of Investigating Whether There is a Relationship Between Birth Defects and Service in the Gulf War (BAA 1996) (birth defects in Gulf War veterans living in California)</i>	March of Dimes, California Birth Defects Monitoring Program	6/98	none
<i>Suspected Increase of Birth Defects and Health Problems Among Children Born to Persian Gulf Veterans in Mississippi</i>	Jackson VAMC/DHHS	complete	Penman and Tarver, 1996.
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors: Study 3: A Comparative Study of Pregnancy Outcomes among Gulf War Veterans and Other Active-duty Personnel</i>	Naval Health Research Center/DOD	complete	Cowan, 1995
<i>Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors Study 7: Prevalence of Congenital Anomalies Among Children of Persian Gulf War Veterans</i>	Naval Health Research Center/DOD	6/97	none
<i>Investigation of Seminal Plasma Hypersensitivity Reactions (immunological analysis of semen)</i>			none
<i>Diarrhea in Persian Gulf Veterans: An Irritable Bowel-Like Disorder</i>	VAMC Gainesville/VA		none
<i>Chronic Gastrointestinal Illness in Persian Gulf Veterans</i>	VAMC Boston/VA	complete	Sostek 1996
<i>Immunological Evaluation of Persian Gulf Veterans</i>	VAMC Birmingham/VA	complete	none
<i>Assessment of Genomic Instability via Chromosome 7 Inversion Frequency in a Gulf-War Syndrome Cohort vs Selected Control Groups (immunology)</i>	Armed Forces Institute of Pathology/DOD	5/97	none
<i>Evaluation of Respiratory Dysfunction Among Gulf War Veterans (Kuwait oil-well fire effects)</i>	VAMC Boston/VA	9/99	none
<i>Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome: Project II. Clinical and Neuroendocrine Aspects of Fibromyalgia</i>	VAMC Portland/VA	9/99	none
<i>Musculoskeletal Symptoms in Gulf War Syndrome</i>	VAMC Long Beach	1/99	none
<i>Evaluation of Muscle Function in Persian Gulf Veterans (BAA 1996) (causes of chronic fatigue and muscle weakness)</i>	University of Pennsylvania	11/99	none

<i>Fatigue in Persian Gulf Syndrome-Physiologic Mechanisms</i> (BAA 1996) (physiology of muscle fatigue)	Institute for Exercise and Environmental Medicine, University of Texas	7/98	none
<i>Markers of a Persian Gulf War Syndrome with Fatigue</i> (measurements of CNS function, cognition)			none
<i>The Symptomatic Persian Gulf Veterans Protocol: An Analysis of Risk Factors with an Immunologic and Neuropsychiatric Assessment</i>	VAMC Birmingham		Kotler-Cope, 1996
<i>Initial Contact Interview with Marine Reservists in Operation Desert Storm and 3-year follow-up</i> (stress and PTSD outcomes)	VAMC Mountain Home/VA	3/97	Sloan 1992; 1993; 1995a&b; 1996a&b;
<i>Neurobehavioral Aspects of Persian Gulf War Experiences: A Pilot Study</i> (stress, neuro - physiological and -psychological effects, PTSD outcomes)	VAMC Pittsburgh/VA	complete	Goldstein 1996
<i>Neuropsychological Functioning in Veterans</i> (stress and PTSD outcomes)	VAMC New Orleans/VA	complete	Vasterling 1994; 1996; Vasterling, manuscript submitted
<i>A Comparison of PTSD Symptomology among Three Army Medical Units Involved in ODS</i>	VAMC Phoenix/VA	complete	DVA 1996
<i>Combat Stress Diagnosis, PTSD Prevention</i>	Ft. Detrick/DOD	9/98	Glass 1995; Oleshansky 1992
<i>Desert Storm Reunion Survey</i> (stress, PTSD outcomes)	VAMC Boston/VA	ongoing	Wolfe 1992a; 1992b; 1993; 1996
<i>Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome: Project 1. Psychosocial, Neuropsychological, and Neurobehavioral Assessment</i> (stress, neuropsychological, PTSD outcomes)	VAMC Portland/VA	9/99	Kovera in press
<i>Memory and Attention in PTSD</i> (neuropsychological outcomes)	VAMC New Orleans/VA	9/98	Vasterling 1994; Vasterling 1996; Vasterling, manuscript submitted
<i>Evaluation of Cognitive Functioning of Persian Gulf Veterans</i> (stress, depression, general health symptoms, PTSD outcomes)	VAMC Boston/VA	9/99	Proctor 1994; Wolfe 1992a; 1992b; 1993; 1996
<i>Psychological Assessment of Operation Desert Storm Returnees</i> (stress and PTSD outcomes)	VAMC New Orleans/VA	9/97	Sutker 1992; 1993; 1994a&b; 1995a&b

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<i>Female Gender and Other Potential Predictors of Functional Health Status Among Persian Gulf Veterans</i> (stress, MCS, PTSD outcomes)	VAMC Boston/VA	3/98	Proctor 1994; Wolfe 1992b;1993; 1996
<i>Physiological and Psychological Assessments of Persian Gulf Veterans</i> (stress, viral/immunological and neuro -physiological & -psychological assessments, CFS, MCS outcomes)	VAMC East Orange/VA	3/97	none
<i>Effects of Exertion and Chemical Stress on Persian Gulf Veterans</i> (CFS, MCS outcomes)	VAMC East Orange/VA	9/99	none
<i>Evaluation of Neurological Functioning in Persian Gulf Veterans</i> (stress, CFS, MCS, PTSD outcomes)	VAMC Boston/VA	9/99	none
<i>Validity of Computerized Tests</i> (assessment of neurophysiologic damage)	VAMC Boston/VA	9/99	Krengel 1996; White 1996
<i>Evaluation of Cognitive Functioning In Persian Gulf Veterans Reporting War-Related Health Problems</i> (stress, neuropsychological and PTSD outcomes)	VAMC New Orleans/VA	complete	Sutker 1993
<i>Psychological and Neurobiological Consequences of Gulf War Experience</i> (BAA 1996) (stress outcomes and PTSD)	West Haven VAMC, Connecticut	7/99	Southwick 1993; 1995
<i>Neuropsychological Functioning in Persian Gulf War Era Veterans</i> (BAA 1996) (stress outcomes, cognitive impairments and CNS damage compared to controls)	Boston University Medical Campus, Boston, MA	6/99	none
<i>Dysregulation of the Stress Response in the Persian Gulf Syndrome</i> (BAA 1996) (abnormalities in neurohormones related to stress response)	Georgetown University Medical Center, Washington, DC	6/99	none
<i>Acute and Long-Term Impact of Deployment to Southwest Asia on the Physical and Mental Health of Soldiers and their Families</i> (stress outcomes)	Ft. Detrick/DOD	9/98	none
<i>Stress Symptoms and Their Causal Attribution in Desert Storm Veterans</i>	VAMC Clarksburg/VA	12/96	none
<i>Psychological Adjustment In Operation Desert Shield/Storm Veterans</i> (stress outcomes)	VAMC Gainesville/VA	complete	Sohler 1992

GROUP III: Federally Funded Research on Risk Factors and Gulf War Veterans' Health			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Persian Gulf Veterans Health Tracking System</i> (Kuwait oil fire smoke and other environmental exposures)	CHPPM/DOD	12/97	none

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GROUP III: Federally Funded Research on Risk Factors and Gulf War Veterans' Health			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Portland Environmental Hazards Research Center: Environment, Veterans Health, and the Gulf War Syndrome: Project IV. DNA Damage from Chemical Agents and Its Repair</i> (nitrogen mustard effects in human skin cultures)	VAMC Portland/VA	9/99	Kisby 1995
<i>Chronic Organophosphorus Exposure and Cognition</i> (chemical weapon effects in lab. animals)	University of Georgia/DOD	5/98	none
<i>Carcinogenicity of Depleted Uranium Fragments</i>	ITRI, Albuquerque, NM/DOD	10/98	none
<i>Health Risk Assessment of Embedded Depleted Uranium: Behavior, Physiology, Histology, and Biokinetic Modeling</i>	AFFRI, Bethesda, MD/DOD	9/97	none
<i>Forward Deployable Diagnostics for Infectious Diseases</i>	Ft. Detrick/DOD	9/01	Kelly 1995; Weddle 1995
<i>Kuwait Oil Fire Health Risk Assessment</i>	CHPPM, Aberdeen, MD/DOD	complete	USAEHA 1994
<i>Kuwait Oil Fires Troop Exposure Assessment Model TEAM</i>	CHPPM, Aberdeen, MD/DOD	12/96	USAEHA 1994
<i>The Aromatic Hydrocarbon Receptor AhR as a Biomarker of Susceptibility</i> (exposure to Kuwaiti oil well fires and petroleum products)	VAMC Boston/VA	9/99	none
<i>Biomarkers of Susceptibility and Polycyclic Aromatic Hydrocarbon PAH Exposure in Urine and Blood Cell DNA from U.S. Army Soldiers Exposed to Kuwaiti Oil Well Fires</i>	NIH/DHHS	1/97	USAEHA 1994
<i>Characteristics of Emissions from Heaters Burning Leaded Diesel Fuel in Unvented Tents</i> (BAA 1996)	Lovelace Biomedical & Environmental Research Inst., Albuquerque, NM	7/98	none
<i>Identification of the Genetic Factors Which Control Tropism in Leishmania</i>	Ft. Detrick/DOD	7/98	Callahan 1995; Callahan in press
<i>Protective Immunity in Experimental Visceral Leishmaniasis</i>	VAMC San Antonio/VA	9/97	none
<i>Vaccine-mediated Immunity Against Leishmaniasis</i>	VAMC Cleveland/VA	9/99	Heinzel 1993; 1994a&b;
<i>Development of a Leishmania Skin Test Antigen (LSTA)</i>	Walter Reed Army Institute of Research/DOD	1/00	Stitler 1994; 1995
<i>Serologic Diagnosis of Viscerotropic Leishmaniasis (VTL)</i>	Walter Reed Army Institute of Research/DOD	complete	Dillon 1994a&b; 1995

GROUP III: Federally Funded Research on Risk Factors and Gulf War Veterans' Health			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Diagnostic Antigens of Leishmania tropica</i> (BAA 1996)	Infectious Disease Research Institute, Seattle, WA	6/98	none
<i>Study of Mycoplasmal Infections in Gulf War Veterans</i>	Walter Reed Army Medical Center/DOD	8/97	none
<i>Combat Stress Pharmacotherapy</i>	Walter Reed Army Institute of Research/DOD	9/99	Hebert 1994; 1996; Potegal, 1992; 1993; 1996a&b
<i>Neurobehavioral and Immunological Toxicity of Pyridostigmine, Permethrin and DEET in Males and Females</i> (BAA 1996) (immune and neurobehavioral effects of PB, DEET, and permethrin in rats)	University of Florida, Gainesville	5/99	none
<i>Effects of Genetics and Stress on Responses to Environmental Toxins</i> (interaction with stress, PB, and aromatic hydrocarbons)	VAMC East Orange/VA	9/97	Natelson, 1996
<i>Effects of PB in Flinders Line Rats Differing in Cholinergic Sensitivity</i> (BAA 1996) (effects of PB on rats)	University of North Carolina, Chapel Hill, NC	7/98	none
<i>Physiological and Neurobehavioral Effects in Rodents from Exposure to Pyridostigmine, Fuels, and DEET</i> "Toxicity of Simulated PGW Exposure"	Ft. Detrick/DOD	10/97	Nelson, 1995
<i>Possible Relationship Between Multiple Chemical Sensitivity of Insect Repellent DEET and Carbamate Pyridostigmine in Gulf War Veterans' Illnesses; Study of Variability in Pyridostigmine Inhibition of Blood Cholinesterases in Healthy Adults</i> (interactions of PB with various pesticides in humans)	Walter Reed Army Institute of Research/DOD	12/96	abstract presented in May-seeking details of authorship
<i>Pyridostigmine Synergistic Toxicity Study</i> (interaction of PB and various pesticides)	CHPPM Aberdeen, MD/DOD	complete	USACHPPM 1995; McCain 1997
<i>Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome: Project III. Neurotoxicity of Environmental Pollutants and Warfare Agents</i> (effects of PB and hydrocarbon solvents on rodent nervous system)	VAMC Portland/VA	9/99	Drake-Baumann, 1996
<i>Male/Female Differential Tolerances to Pyridostigmine Bromide</i>	South Florida/DOD	complete	
<i>Retrospective Studies Involving Military Use of Pyridostigmine as a Pretreatment for Nerve Agent Poisoning</i>	Ft. Detrick/DOD	complete	

GROUP IV: Miscellaneous Research on Gulf War Veterans Health Issues			
Study Title/Focus (highlighted)	Facility/Agency	Est. Finish Date	Reports
<i>Effects of Persian Gulf War Service on Military Working Dogs</i>	Ft. Detrick/DOD	12/98	none
<i>Use of Roster of Veterans Who Served in Persian Gulf Area</i>	VA	complete	none

CHAPTER 3: NATURE OF GULF WAR VETERANS' ILLNESSES: DATA TO DATE

Currently, quantitative documentation and analysis of the extent of Gulf War veterans' health remains elusive. Nevertheless, the clinical programs of VA and DOD, along with preliminary information from several federally funded epidemiologic studies, provide some data that can begin to place Gulf War veterans' illnesses in context. This chapter provides an overview of available data and the Committee's findings and recommendations about the nature of Gulf War veterans' illnesses.

DATA FROM CLINICAL PROGRAMS

As of August 1996, more than 60,000 individuals had requested an examination in VA's Persian Gulf Health Registry, and VA has reviewed results for the first 52,216 veterans (Kang, et. al., 1996b). More than 21,000 individuals had requested an examination in DOD's CCEP as of April 1996; information for the first 18,075 military personnel have been reported by DOD (DOD, 1996).

Information derived from these data sets has clinical utility, and DOD and VA have used the information to address several concerns from a descriptive perspective. The data also have provided guidance in the formulation of certain epidemiologic research approaches. However, results from analyzing the Registry and the CCEP—two self-selected case series—cannot be generalized to the entire population of Gulf War veterans. As described later, scientifically valid, generalizable knowledge is the expected outcome of epidemiologic research currently underway.

1 **Data From DOD's CCEP and VA's Registry**

2 Gulf War veterans who have participated in the CCEP and Registry represent a broad cross-section of
3 service members who deployed to the Gulf War (table 3-1). To provide a qualitative snapshot of the
4 clinical status of the Gulf War veterans who have participated in the government's clinical evaluation
5 programs, the following sections summarize information—based on material published by DOD and
6 VA (DOD, 1996; Kang, et al., 1996b)—for several key descriptive parameters.

7 **Reported symptoms.** CCEP participants report a broad range of symptoms that span a variety of
8 organ systems (table 3-2). The most common primary symptoms reported are joint pain, fatigue,
9 headache, rash, and memory loss. Ten percent of participants are asymptomatic. The most frequent
10 symptoms in the CCEP also are common in the general adult population in the United States.

11 The most common symptoms reported by VA Registry participants (table 3-2) nearly match
12 the most common symptoms reported by CCEP participants. Asymptomatic individuals comprise
13 about 12 percent of the Registry population.

14 **Diagnoses.** Approximately 10 percent of CCEP participants are found to be healthy. The other most
15 common primary diagnostic categories of CCEP participants are psychological conditions;
16 musculoskeletal system diseases (MSDs); and symptoms, signs, and ill-defined conditions (SSIDC)
17 (table 3-3). Combined, the three categories account for more than 50 percent of primary diagnoses.
18 Other primary diagnoses in the CCEP do not concentrate in any single organ system.

For VA's Registry, the most common diagnostic categories are the same as in the CCEP: psychological conditions; MSDs; and SSIDC (table 3-3). Like the breakdown for CCEP participants, beyond these three categories the diagnoses do not center in a single organ system.

Morbidity/Disability. To approximate disability due to illness, DOD asks CCEP participants about the number of work days missed due to illness in the 90 days prior to the initial examination. Most individuals (80 percent) reported no missed days of work due to illness during this time period. Among those reporting one or more lost work days, the median number of lost days was five. This level of lost workdays in the past 90 days exceeds that found for the general U.S. population of civilian employees.

CCEP data on lost workdays, however, cannot be viewed as an estimate of the overall prevalence of disability due to Gulf War service. Many individuals—some of whom could have disabilities—have left active service since the Gulf War and are not eligible for participation in the CCEP. No estimates of the degree of disability have been reported for individuals enrolled in VA's Registry.

Musculoskeletal system diseases. MSDs account for 18.3 percent of primary diagnoses in CCEP participants. DOD reports the occurrence of MSDs in the CCEP is about two times higher in male CCEP participants and three times higher in female CCEP participants than the rate of occurrence of MSDs in the general U.S. population aged 20 to 40 (DOD, 1996). Whether the rate of MSDs for

CCEP participants differs from that for the general military population is unknown, however, due to the paucity of baseline information on the health status of active duty personnel.

Military personnel must maintain certain levels of physical fitness, and many are required to participate in demanding physical training programs, placing considerable stress on joints and muscles. DOD reports that the majority of MSDs diagnosed in CCEP participants are wear-and-tear disorders—e.g., recurrent strains, sprains, and degenerative arthritis due to trauma on a joint—that could be expected in a physically active populace; occupational and recreational overuse injuries also frequently occur as a consequence of the physical activities of military training and operations (DOD, 1996).

MSDs are the most prevalent diagnostic category among participants in VA's Registry (Kang, et al., 1996b). Additionally, as of September 1995 more than 15,000 Gulf War veterans had been admitted for inpatient treatment to a VA hospital; MSDs account for 21.3 percent of the total diagnoses received by these inpatients.

Infectious diseases. Infectious diseases are not a frequent cause of illness among CCEP participants. DOD reports 470 individuals have a primary diagnosis of an infectious disease, and about half of these are infections of the skin due to fungi that are common in the United States. VA's Registry reports similarly low occurrences of infectious diseases among its participants; 7.1 percent have a primary or secondary diagnosis of an infectious disease (Kang, et al., 1996b). Athlete's foot, a fungal

1 infection of the skin, was one of the most common infectious diseases—occurring in 1.4 percent of
2 the Registry population.

3 Infectious diseases have affected a variety of organ systems in Gulf War veterans without any
4 observable patterns. The majority of infectious diseases identified through the clinical programs
5 represent minor conditions common among the general population; such conditions do not explain
6 serious, persistent, systemic complaints. To date, few individuals have demonstrated characteristic
7 physical signs and laboratory abnormalities that indicate a chronic infectious process (Gasser, 1995;
8 Hyams, et al., 1995; PGVCB, 1995). Moreover, it is unlikely that Gulf War veterans have infections
9 that have evaded the systematic diagnostic efforts mandated by the standardized protocol.

10 **Cancer.** Cancer is rare among CCEP enrollees. A primary diagnosis of cancer has been made in 52
11 individuals (0.3 percent), and the types and frequencies are shown in table 3-4. Lymphomas are the
12 most frequent cancer diagnosed in CCEP participants; lymphomas also are the most common types of
13 cancer among 20 to 40 year-olds in the general U.S. population. The second most frequent cancer
14 diagnosis is skin cancer—again, one of the most common malignancies in the age-matched U.S.
15 general population. Clinical evaluation through the CCEP identified four individuals with testicular
16 cancer, which is a common type of cancer among young men in the U.S. general population.

17 As with CCEP participants, cancer also is rare among individuals in VA's Registry. There
18 does not appear to be an unusual incidence of any specific type of cancer in this population. A
19 primary diagnosis of cancer was made in 226 individuals (0.4 percent; table 3-4) (Kang, et al., 1996).

1 The same three types of cancer most common among CCEP participants are the most frequently
2 diagnosed in VA's Registry population: lymphomas, skin cancer, and testicular cancer.

3 **Data from Great Britain and Canada.** Great Britain implemented a systematic medical evaluation
4 program for Gulf War veterans in late 1993. To date, about 500 individuals have enrolled in the
5 medical program, and the clinical results for 284 individuals are available (Coker, 1996). Canada
6 began its medical evaluation program for Gulf War veterans in early 1995, and the clinical
7 information for 49 veterans is available (Scott, 1996). Both programs are thorough, and the
8 procedures resemble Phase II of the U.S. protocol (see ch. 2). Because the proportion of eligible Gulf
9 War veterans who have enrolled in these programs is small, physicians involved in both programs
10 view results as preliminary. The Committee draws no conclusions based on the available data.

11 Great Britain. Approximately 45,000 British troops were deployed to the Gulf War. In late 1993, the
12 Ministry of Defense set up a medical evaluation program for these individuals, and in September
13 1994, a modified version of the U.S. protocol was adopted. About 20 percent of participants remain
14 on active duty.

15 Information about the first 284 participants (0.6 percent of British troops deployed) was
16 presented publicly in August 1996 (Coker, 1996). Table 3-5 presents the most frequently reported
17 symptoms, which are similar to the symptoms reported by U.S. Gulf War veterans. The most
18 common primary diagnoses in the British participants are also common among U.S. Gulf War
19 veterans (table 3-6). Fifteen percent of diagnoses for British participants are coded under the SSIDC
20 category. A small percentage of these cases meet the Oxford criteria for chronic fatigue syndrome

(CFS) which are slightly less stringent than the criteria developed by the U.S. Centers for Disease Control and Prevention (CDC) (Coker, 1996). There was a clear relationship between service in the Gulf War and the onset of psychiatric illness in a number of participants in the British evaluation (Revell, 1995).

Canada. Canada established its medical evaluation program for Gulf War veterans in early 1995 and had enrolled about 60 veterans as of Summer 1996. A compilation of the evaluations for the first 49 participants (about 1.0 percent of the 4,500 Canadian troops deployed to the Gulf) were presented publicly in August 1996 (Scott, 1996).

Table 3-7 presents the ten most frequent symptoms among Canadian participants; these symptoms are nearly identical to the most frequent symptoms reported by U.S. Gulf War veterans. Table 3-8 reports the frequencies of the major diagnostic categories in the 49 Canadian participants (Scott, 1996). Most of the MSD cases in the Canadian population are mechanical low back pain, osteoarthritis, and degenerative disc disease. Eight percent of the diagnoses are SSIDC (Scott, 1996).

DATA FROM EPIDEMIOLOGIC STUDIES

As noted in the Committee's *Interim Report*, epidemiologic studies are crucial for better understanding of the extent and nature of Gulf War veterans' illnesses. Any large population will include people who are experiencing a variety of different illnesses. While clinical programs provide valuable information, they cannot provide answers to whether and how rates of illnesses or death in the whole Gulf War veteran population differ from those that would be expected in any similar large

population. Answers to these questions could focus attention on the most useful and relevant interventions or treatments.

Unfortunately, carefully designed epidemiology studies are time-consuming, and many were not initiated until several years after the Gulf War. Thus, many important studies addressing the general characteristics of Gulf War veterans' illnesses are still underway or preliminary results are not yet publicly available. These include such studies as VA's National Health Survey and the Health Assessment of Persian Gulf War Veterans from Iowa, as well as several studies at VA's Environmental Hazards Centers. The following sections review data from completed epidemiology studies for which results have been published in the peer-reviewed literature, government reports, or publicly released by the investigators in a preliminary form (table 3-9).

Mortality Studies

Mortality studies examine deaths among the selected population. Research in this area has focused on deaths that occurred during and after the Gulf War.

Mortality during the Gulf War. Two epidemiologic studies have been completed on service member deaths that occurred during the Gulf War. One study reported on mortality during the six weeks from January 17, 1991, through February 28, 1991. It found that battle and nonbattle casualty rates were the lowest experienced by the United States in any major 20th century conflict (Helmkamp, 1994).

A more detailed mortality study covered the time period of August 1, 1990 through July 31, 1991, spanning the entire Operations Desert Shield/Desert Storm campaign and the post-war recovery

(Writer, 1996). This study examined the cause of each death and compared cause-specific mortality rates of troops in the Gulf region with those of U.S. troops serving elsewhere during this time period. Of the 372 deaths among active duty service members stationed in the region during this 1-year period, 147 (40 percent) were a direct result of combat, 194 (52 percent) resulted from nonbattle injuries, and 30 (8 percent) were the result of illness.¹ An excess of unintentional injury (accident) deaths—e.g., from motor vehicle and aircraft accidents—was identified in the Gulf campaign participants compared to the nondeployed population. No excess mortality from illness or unexpected/undefined causes was observed, nor were there clusters of the deaths in timing or location.

Mortality since the Gulf War. A study of mortality among Gulf War veterans and a comparison population of era veterans since the Gulf War has been conducted by VA's Environmental Epidemiology Service (Kang, 1995; Kang, 1996a). Mortality in all people who served in Operations Desert Shield/Desert Storm between August 1990 and April 1991 was compared to era veterans matched to study subjects by branch and unit status. During the study's timeframe (Gulf War through September 1993), 1,765 deaths occurred among Gulf War veterans, and 1,729 deaths occurred among the era veterans sampled.

Preliminary results of the study indicate that the higher number of deaths among Gulf veterans was statistically significant. The excess of deaths compared to era veterans resulted from external

¹ Since this paper was published, some of these casualties have been reclassified. The current official count of deaths from hostile action in Operation Desert Storm is 148 persons.

causes such as accidents. The mechanism underlying the excess deaths due to external causes among war veterans is not well understood.

Among active duty Gulf War veterans, the mortality rate was 15 percent higher than in active duty veterans from the same era. Most of the excess mortality came from external causes, such as motor vehicle and other accidents, while rates for natural causes such as infectious diseases, cancers, and other diseases were lower in the Gulf War veterans. Veterans who served in activated Reserve units had the same overall mortality rate as non-deployed reservists, but also had higher mortality rates from external causes, including motor vehicle accidents and suicides. Women Gulf War veterans had a crude mortality rate 47 percent higher than era veteran women, with excess mortality from accidents.

Summary of mortality studies. The completed mortality studies reveal no excess of deaths from natural causes during either Operations Desert Shield/Desert Storm or in the two years that followed. Death rates from all illnesses, including infectious diseases and cancers, have been lower in the population deployed to the Gulf than those deployed elsewhere. Death rates from external causes have been elevated among Gulf War veterans.

Elevated mortality from external causes, particularly from motor vehicle accidents, is consistent with trends observed in populations of combat veterans from other wars. Studies of mortality in Vietnam veterans document an increased mortality rate from external causes such as accidents (Bullman; CDC 1987; Thomas; Watanabe).

Morbidity Studies

To answer fundamental questions about disease prevalence, epidemiologic studies must be population-based, meaning they must draw information from samples representative of the entire population of interest. Currently, there remains a paucity of information from population-based studies on Gulf War veterans. However, we have reviewed findings from epidemiologic studies on Gulf War veterans' illnesses for which investigators have published results or publicly presented preliminary results. The studies undertaken most quickly after reports of illnesses in Gulf War veterans surfaced were investigations of clusters of reported illnesses or analyses of health databases of subgroups of the Gulf War veteran population.

123d Army Reserve Command investigation. In Spring 1992, an interdisciplinary team interviewed and examined 79 members of the 123d Army Reserve Command at Fort Benjamin Harrison, Indiana, after a number of members reported a variety of symptoms (DeFraites et al, 1992). After physical and psychiatric examinations, the team found no evidence of an outbreak or cluster of any unique disease process. The most frequently reported symptom was fatigue (71 percent), which most commonly had its onset within several weeks of return from the Gulf. Physical examinations and laboratory screenings yielded limited positive objective findings similar to those seen in nondeployed soldiers. The group was self-selected and therefore the results cannot be generalized to the larger Reserve or Gulf War veteran population.

Seabee study. A cluster study to investigate health complaints in Gulf War veteran reservists was carried out in the 24th Naval Mobile Construction Battalion between 1993 and 1994 (Berg, 1994).

1 Two detachments, in which media reports had indicated a large degree of symptomatic illness, were
2 evaluated with a standard questionnaire and a review of medical records to verify diagnoses and
3 obtain additional information. No physical examinations or laboratory tests were performed. One
4 year later, these detachments and two additional detachments were visited and surveyed again. Types
5 and frequencies of diagnosed illnesses did not seem unusual for this age group, but no control group
6 was analyzed. The symptoms did not suggest a pattern or particular illness to the investigators. As in
7 the previously described study, the study group was self selected and therefore the results cannot be
8 generalized to the larger Reserve or Gulf War population.

9 **Study of women veterans.** A study on health symptoms in women Air Force Gulf War veterans was
10 carried out with a survey questionnaire from 1991 to 1993 (Pierce, 1996a&b); preliminary results
11 were presented publicly and await review for publication. A randomized sample of Air Force women
12 from the active duty, Reserve, and Guard were asked to report any conditions or symptoms for which
13 they sought medical care since beginning service in the armed forces. The sample of 525 women
14 included those deployed to the Gulf and those deployed elsewhere during the same time period.

15 The rates of baseline symptoms (i.e., those experienced prior to the Gulf War) did not differ
16 between the two populations. However, results indicated a higher prevalence after the Gulf War of
17 skin rashes, depression, unintentional weight loss, and headaches in those deployed to the Gulf
18 compared with those deployed elsewhere. Reported health problems in general were higher in those
19 deployed to the Gulf, and highest among those reporting they were no longer in the military.

1 A follow-up survey carried out between 1994 and 1995 on the same group also found higher
2 levels of reported skin rashes and headaches among those deployed to the Gulf region. It also found
3 increased reports of cough, memory problems, lumps or cysts in the breast, and abnormal Pap test
4 results in Gulf-deployed women veterans. Differences between the two groups in reported
5 depression, unintentional weight loss, and insomnia no longer were statistically significant. An
6 additional follow-up survey is planned to see if these reported differences persist.

7 Increases in self-reported health symptoms in this small, but representative, sample of Air
8 Force women are consistent with the increased reports of health symptoms seen in cluster
9 investigations. Since this study did not involve physical examinations or evaluate medical records, it
10 cannot assess the extent to which increased concern or vigilance in Gulf-deployed service members
11 could contribute to higher levels of reported symptoms.

12 **Pennsylvania Air National Guard study.** CDC's Infectious Disease Center has carried out a study of
13 illnesses reported among Gulf War veterans in a Pennsylvania Air National Guard unit. This three-
14 stage study began in late 1994 as a rapid response to reports of an outbreak of illnesses in the unit. At
15 this time, findings from the first two stages have been published or presented publicly (CDC, 1995;
16 Reeves, 1995).

17 The first stage involved standardized interviews and physical examinations of 59 Gulf War
18 veterans reported to be symptomatic. Most frequently reported symptoms were fatigue, joint pain or
19 stiffness, nasal or sinus congestion, diarrhea, gas, difficulty remembering, muscle pains, headaches,
20 abdominal pain, general weakness, and impaired concentration. All study participants reported

1 several symptoms that had persisted at least six months. No consistent abnormalities were identified
2 through standardized physical examination or by review of medical records and laboratory tests.

3 In the study's second stage, unit members and three comparison units (a total of 3,927
4 individuals) were surveyed to determine the prevalence of selected symptoms identified in stage 1. In
5 all units, the prevalence of 13 chronic (lasting 6 months or more) symptoms was significantly higher
6 among individuals who had deployed to the Gulf.

7 The operational case definition developed for the illness in this population is similar to the
8 definition recently developed by CDC for CFS, but lacks a requirement of severity of symptoms.
9 Criteria for the case—as defined for the purposes of this study—were met in 45 percent of the
10 veterans surveyed who had been deployed to the Gulf, but were also met in 15 percent of the
11 nondeployed veteran respondents and in 12 percent of a San Francisco civilian population surveyed—
12 suggesting that the causes of the problems are not unique to Gulf War service. Symptoms were not
13 associated with the place of service in the Gulf, the number of deployments to the Gulf, or the timing
14 of deployment to the Gulf.

15 The study's final stage explored associations between having the symptoms defined in the
16 study as being a "case" and selected infectious, behavioral, and environmental risk factors for
17 developing the illness (Reeves, 1996). No physical or laboratory abnormalities were associated with
18 being defined as a case. Despite the absence of physical findings, veterans who fit the definition of a
19 severe case had measurable deficits in reported functioning. Veterans in this group also were more

likely to meet screening levels for PTSD on the Mississippi Scale for PTSD. Data from this study stage are still preliminary and undergoing additional analyses.

Because the Pennsylvania Air National Guard study relied on volunteers who were a minority of the target population, the potential for bias exists in the research findings. Furthermore, the generalizability of the results from this study to the entire Gulf War veteran population is limited: subjects were all members of the Air National Guard or Air Force and were not chosen to reflect the makeup of the larger Gulf War service member population.

DOD hospitalization study. Preliminary data from an exploratory study of hospitalizations of active duty military personnel through 1993 indicated that the only differences in hospitalization rates observed between active-duty personnel who had been deployed to the Gulf and non-deployed were that the deployed experienced more hospitalizations with mental disorder or genitourinary diagnoses (Coate, 1995). This study has important shortcomings that make it difficult to generalize to the Gulf War veteran population at large. Data were only collected for those deployed to the Gulf who remain on active duty, so it failed to capture hospitalizations of those who had separated from the military since the war or veterans from Reserve or National Guard populations. Since 40 percent of Gulf War veterans had left the military by the end of the data collection period in 1993, this study omits an important population--and possibly those with most health problems. The research team has refined their analyses since the preliminary data were presented, and the results will be published soon.

Cognitive testing studies. Some small epidemiologic studies have been carried out in Gulf War veterans to assess complaints of cognitive difficulties such as memory problems. Comprehensive,

1 structured neuropsychological testing is used clinically to evaluate subtle cognitive difficulties.
2 Typical dimensions that are evaluated by these tests include: intellectual functioning (i.e., estimated
3 pre-morbid IQ), attention, concentration, language, visuospatial processing, learning/memory, and
4 motor skills (Vasterling, 1996).

5 Results of cognitive testing of four populations of Gulf War veterans have been published or
6 presented at national medical conferences (Goldstein, et al, 1996; Vasterling, et al., 1996; Vasterling,
7 1996; Kolter-Cope, et al., 1996). Although these four studies were small--groups of Gulf War
8 veterans ranging in size from 19 to 149 people--several consistent findings emerged. On objective
9 testing, memory and concentration performances were the same or only slightly decreased in groups
10 of Gulf War veterans compared to control participants. Perceptions of memory dysfunction,
11 however, were greater among the groups of Gulf War veterans. A small minority of Gulf War
12 veterans who were significantly distressed due to PTSD or other psychiatric diseases did have
13 objective memory and concentration impairment. These data are preliminary and require replication
14 in additional studies.

15 **Summary of morbidity studies.** Completed morbidity studies show an increase in symptoms—such as
16 fatigue, joint pain, memory problems, and headaches—in individuals who were deployed to the Gulf.
17 The study results, however, do not indicate consistent abnormal laboratory or physical findings in
18 these groups. Until results from some of the larger, population-based epidemiologic studies become
19 available, conclusions cannot be generalized from these studies about the extent of illnesses in the
20 Gulf War veteran population as a whole.

DATA ON STRESS-RELATED DISORDERS

Physicians have observed in many previous wars that physical and psychological stress can lead to the development of higher rates of psychiatric illnesses than are observed in the general population. PTSD and depression are particularly prevalent problems in combat veterans. Stress is also known to affect the endocrine, cardiovascular, immune, and central nervous systems, i.e., to cause serious biological problems that are in no way trivial. As expected from experiences in previous wars, some Gulf War veterans have symptoms that frequently can be manifestations of psychological stress, including fatigue, headaches, loss of appetite, sleep problems, and cognitive difficulties (such as memory problems and difficulty in concentration).

Psychiatric Diagnoses in Clinical Programs

Psychological conditions are either the primary or secondary diagnosis in 36.0 percent of CCEP participants (DOD, 1996). The most common conditions are: major depressive disorder; neurotic depression (also called dysthymia); depression (not otherwise specified); PTSD; anxiety disorders; adjustment disorders; alcohol related disorders; and substance related disorders (table 3-10).

Among participants in VA's Registry, 15.1 percent of the top three diagnoses for each patient were psychological conditions, with the most common: depression (not otherwise specified), PTSD, and anxiety disorders (table 3-10). Additionally, 15,486 Gulf War veterans had been admitted for treatment to a VA hospital as of September 1995, and psychological conditions were the most common diagnosis for these inpatients (43 percent of total diagnoses). Specific psychological

conditions included: PTSD and adjustment disorders; alcohol dependence; and drug dependence (Kang, et al., 1996).

The psychological conditions diagnosed among Gulf War veterans also are common in the general population. The best estimates of the prevalence of psychiatric disorders in the general population are based on the National Comorbidity Survey (NCS), a comprehensive, highly structured, population-based survey of 8,098 adults, aged 15 to 54 years (Kessler, et al., 1994; Kessler, et al., 1995). The diagnostic criteria used in this national study are basically the same as that used by DOD and VA.

The percentage of individuals who met diagnostic criteria for several disorders in the 12 months preceding NCS interviews was: major depressive disorder, 10.3 percent; dysthymia (neurotic depression), 2.5 percent; generalized anxiety disorder, 3.1 percent; alcohol related disorders, 9.7 percent; and substance related disorders, 3.6 percent (Kessler, et al., 1994). The lifetime prevalence of PTSD was 7.8 percent (Kessler, et al., 1995). Among the age groups encompassing 15 to 54 years, these serious psychiatric diseases peaked during 25 to 34 years; there was a significant decline in lifetime prevalence with increasing age (Kessler, et al., 1994).

Treatment for Psychiatric Disorders

Stress-related illnesses are real, often debilitating illnesses for which treatment interventions are available. Treatment for stress-related disorders is, by necessity, case-specific and symptom-oriented. No one treatment regimen is appropriate for the overlapping range of problems for tension headaches, chronic fatigue, fibromyalgia (FM), depression and anxiety disorders. Despite some variability in

1 therapeutic approaches to depression, anxiety disorders, and other psychiatric conditions, there is a
2 relatively narrow range of treatment options.

3 Testimony before the Committee and interviews during site visits clearly indicate a significant
4 stigma remains associated with psychiatric diagnoses, and this perception often interferes with
5 veterans receiving or accepting adequate care. In many instances, veterans report meeting command
6 resistance to granting the necessary time off to maintain an adequate treatment program. This is true
7 of all chronic illnesses, but especially so for veterans with psychiatric diagnoses—despite the fact that
8 since 1986, service members with certain chronic illnesses that require medical monitoring have been
9 allowed to remain on active duty (Friedman, 1996).

10 Frank PTSD is particularly difficult to treat because alcoholism or other comorbidities
11 frequently are present. Nevertheless, there has been some agreement on the basic approaches to
12 treating PTSD. The Director of VA's National Center for PTSD describes three phases of treatment:
13 stabilization-establishing trust and safety; trauma-focused therapy-therapy targeting the traumatic
14 event—i.e., what happened and how one deals with and makes sense of what happened; and moving
15 from the past to present reintegration into society by disconnecting from the trauma and reconnecting
16 with the present.

17 In randomized clinical trials, cognitive-behavioral therapy (CBT) has been the most
18 successful treatment for PTSD. CBT centers on two psychological theories—learning theory and
19 how one appraises a situation and develops a more adequate coping response—and there are a variety
20 of CBTs. Among these are exposure therapies that include systematic desensitization, imaginal and

1 in vivo exposure, and anxiety management training therapies (e.g., stress inoculation training,
2 biofeedback, cognitive therapy, and relapse prevention). Often, exposure therapy and anxiety
3 management are combined; they can be used either individually or within group settings.

4 Several additional types of psychotherapy ranging from peer counseling to marital counseling
5 to long-term dynamic therapy exist. Some are designed to be short-term and problem focused, while
6 others are long-term and ongoing. Other disorders should be treated concurrently, although substance
7 abuse usually must be treated first.

8 Some pharmacological treatments with drugs developed for depression (e.g., Prozac and
9 Zoloft) also can be successful for PTSD. A fruitful area for research and development will be drugs
10 that act on the neurobiological systems most implicated in PTSD and other stress-related disorders—
11 e.g., corticotropin releasing factor antagonists, N-methyl-D-aspartate antagonists, and neuropeptide
12 antagonists.

13 **Symptoms Associated With Stress Reported in the Clinical Programs**

14 Headaches are a frequent symptom reported by Gulf War veterans who have received clinical
15 evaluations through DOD and VA (39 percent of the top seven symptoms for CCEP and 18 percent of
16 the top three symptoms in the Registry) (DOD, 1996; Kang, et al., 1996b). Tension headaches are
17 coded under the diagnostic category “Psychological Conditions” and were diagnosed in 11.3 percent
18 of CCEP participants and 2.3 percent of Registry participants. Other types of headaches are coded
19 under “Nervous System Diseases” (migraine headaches) and “SSIDC” (nonspecific headaches).
20 Migraine headaches were the primary diagnosis in 2.7 percent of CCEP participants, and nonspecific

1 headaches were the primary diagnosis in 2.7 percent of this group. The frequency of headaches
2 among Gulf War veterans does not appear to be unusual, since headaches are one of the most
3 common reasons for seeking medical care (Linnet, et al., 1989; Kroenke and Price, 1993).

4 Gulf War veterans commonly report cognitive difficulties. These symptoms can be caused by
5 psychological distress, which is associated with diseases such as major depression and PTSD. For
6 the CCEP, 34 percent of participants report memory loss and 27 percent report difficulty
7 concentrating (DOD, 1996). Fourteen percent of Registry participants report memory loss (Kang, et
8 al., 1996b).

9 To date, DOD reports that only a few CCEP participants have demonstrated cognitive deficits
10 following neuropsychological testing. That is, such testing generally has eliminated an underlying
11 neurologic etiology for the reported memory problems (DOD, 1996). Organic brain syndrome (OBS)
12 is a generic medical term for brain damage due to several diseases, such as head trauma or
13 Alzheimer's disease. OBS is the primary diagnosis in 0.6 percent of the CCEP participants. The
14 extent of OBS in the VA Registry population has not been reported.

15 The major symptoms (diagnostic criteria) of common psychiatric conditions overlap with
16 some of the symptoms that are frequently reported by Gulf War veterans. As noted earlier in this
17 section such conditions include major depression, PTSD, and anxiety disorder. As an example of the
18 extent of overlap, diagnostic criteria for major depression are provided in table 3-11 (APA-DSM-IV,
19 1994). Comparison to table 3-2, which lists some of the symptoms frequently reported by the first
20 18,075 CCEP participants, reveals that symptoms relevant to major depression are: Criteria 1-

1 depression (23 percent of CCEP participants); Criteria 3-weight loss (7 percent); Criteria 4-sleep
2 disturbance (32 percent); Criteria 6-fatigue (47 percent); Criteria 8-memory loss (34 percent); and
3 Criteria 8-difficulty concentrating (27 percent).

4 **Epidemiologic Studies of Stress-related Conditions**

5 The need to understand the effects of stress and psychiatric diseases in Gulf War veterans was
6 recognized in 1991, and several epidemiologic studies focused on these issues were launched.

7 Among the completed studies, the results primarily address the prevalence of psychiatric conditions
8 and the role of risk factors and protective factors.

9 **Large epidemiologic investigations on effects of stress.** Research targeted to increase knowledge
10 about how stress could contribute to Gulf War veterans' illnesses involves several large-scale efforts.
11 Studies with generalizable results are briefly described in the following sections. Other studies with
12 similar, though not generalizable, results include the West Haven, CT, VA study of the 142d medical
13 unit and the 143rd military police unit of the Connecticut National Guard (Southwick, et al., 1993 and
14 1995), the Little Rock, AR, VA study of U.S. Army and Air National Guard and Reserve personnel
15 (USDVA, 1992; West, et al., 1993), and the Mountain Home, Johnson City, TN, VA study of the
16 24th Marines, Third Battalion, Company H (Sloan, et al., 1995a, 1995b, and 1996). Only one
17 significant study has included large numbers of active duty troops—the Walter Reed Army Institute
18 of Research (WRAIR) study of units from Pennsylvania and Hawaii (WRAIR, 1994; Stretch et al.,
19 1995, 1996a, and 1996b). Regrettably, the response rate in the WRAIR study was too low to
20 extrapolate results to the overall Gulf War veteran population, but the study did find elevated rates of

1 physical and mental distress among survey respondents who were deployed to the Gulf compared to
2 those who were not.

3 Fort Devens, Massachusetts VA study. Still in progress, the Fort Devens study involves 2,344 Gulf War
4 veterans who have been followed by a research team at the Boston VAMC since 1991 (Wolfe, et al.,
5 1996a and 1996b). Comparisons between the study sample and the overall Fort Devens population
6 indicated that the study subjects were representative of the military population that was processed
7 through this base during that time. The study population included 46 units with a wide range of
8 military occupational specialties from several regions in the United States. Hence, its results are
9 relevant to the health status of the larger population of Gulf War veterans who were in the U.S. Army
10 Reserve and National Guard.

11 Men and women in the Fort Devens sample had equivalent levels of combat exposure (Wolfe,
12 et al., 1993). Fifty-six percent of both genders reported little or no direct combat exposure.
13 However, if combat exposure was held constant, certain types of stressors appeared to affect people
14 differently. For women, witnessing death and serious accidents significantly predicted poorer
15 psychological adjustment; while for men, marital strife or being placed on chemical/biological alert
16 or SCUD alert were more strongly associated with the development of psychiatric symptoms. Sexual
17 assaults and harassment were the most important factors that explained the different rates of PTSD
18 symptoms between women and men (Wolfe, 1996b). This group of veterans has been evaluated at
19 three time points, starting with five days from their return.

1 Using the Mississippi Scale for Combat Related PTSD, investigators found that
2 approximately nine percent of women and four percent of men had PTSD-like symptoms that likely
3 would qualify them for a positive diagnosis at Time 1 (five days after return; Wolfe, et al., 1993). At
4 Time 1 and Time 2 (18 to 20 months after return), women reported more PTSD symptoms than men
5 (Wolfe, et al., 1996a). At Time 2, both men and women reported higher levels of PTSD symptoms
6 than at Time 1 (11 percent for men and 21 percent for women). At Time 3 (approximately three years
7 after return), however, rates of PTSD symptoms declined to approximate levels for Time 1, so there
8 appears to be some recovery (Wolfe, 1996b).

9 To provide context for the rates of PTSD in Gulf War veterans, the best estimates of the rates
10 of PTSD in the general U.S. population are based on the NCS, as described earlier (Kessler, et al.,
11 1994; Kessler, et al., 1995). Based on NCS data, lifetime prevalence of PTSD in men was 5 percent,
12 and it was most commonly associated with combat experience during a war or witnessing someone
13 being badly injured or killed. The lifetime prevalence of PTSD in women was 10.4 percent, and it
14 was most commonly associated with a history of rape or sexual molestation.

15 During the follow-up examination at Time 4 (begun late 1996), actual functional status will be
16 examined, such as days of work lost and quality of life. Continued funding for the Fort Devens study
17 is being provided as part of the Boston VA Environmental Research Center. A parallel study
18 assessing psychological status in a group of Gulf War-era military personnel who did not deploy was
19 recently funded by DOD.

1 New Orleans, Louisiana VA study. In 1991, the New Orleans VAMC developed a psychological
2 assessment program as part of a series of programs set up at VAMCs nationwide (USDVA, 1992).
3 The New Orleans research team evaluated 1,520 Reserve and National Guard troops who were
4 mobilized for Gulf War duty. Because this larger study sample included Reserve and National Guard
5 troops in the U.S. Army, Navy, Air Force, and Marines, study results are relevant to the health status
6 of the larger population of Gulf War veterans who were members of the Reserve or National Guard.

7 The initial assessment took place within a few months of the end of the war (Sutker, et al.,
8 1993; Sutker and Vasterling, 1996). Compared to nondeployed troops, individuals from deployed
9 units reported more physical symptoms and had more negative mood states, including depression,
10 anger, and anxiety. The two groups differed in prevalence of reported headaches, general aches and
11 pains, lack of energy, and sleep disturbance. Twenty-three percent of war-zone-deployed troops
12 reported at least mild levels of clinical depression, while 14 percent reported clinically significant
13 levels of PTSD. Individuals diagnosed with PTSD also displayed less proficient cognitive
14 performances in neuropsychological functioning, pertaining mostly to attention and new learning
15 (Sutker and Vasterling, 1996). Deployed troops who reported higher levels of war-zone stress
16 exposure were characterized by more depression, anxiety, anger, hostility, physical symptoms, and
17 PTSD symptoms.

18 Women reported more physical symptoms than men, regardless of war-zone assignment
19 (Sutker, et al., 1995). Ethnic minorities reported more depression than nonminorities, regardless of
20 war-zone assignment. No gender differences existed for measures of PTSD or psychological distress

1 among deployed troops. Minorities among deployed troops were at greater risk for developing
2 symptoms of PTSD than nonminorities among deployed troops.

3 Highland Drive, Pittsburgh, Pennsylvania VA study. Starting in July 1991, the PTSD team at the Highland
4 Drive VAMC in Pittsburgh conducted mental health screening and outreach programs for about 620
5 Reserve personnel from deployed and nondeployed units in the U.S. Army, Navy and Marines in
6 western Pennsylvania, eastern Ohio, and West Virginia (USDVA, 1992; Perconte, et al., 1993a).
7 Because the study included individuals in the U.S. Army, Navy, and Marines, results can be viewed
8 in context of the larger population of Reserve personnel who served in the Gulf War. In addition, a
9 wide variety of stressors were encountered by the units evaluated, ranging from simple unit activation
10 for groups that stayed in the United States to the deaths and injuries suffered by the 14th
11 Quartermasters (QM) Unit when its barracks were destroyed by a SCUD missile.

12 The 439 reservists who were deployed to the Gulf region demonstrated significantly higher
13 rates of psychological symptoms than individuals sent to Europe or who stayed in the United States
14 (Perconte, et al., 1993a). Gulf War veterans reported higher rates of PTSD, depression, and global
15 psychological distress.

16 **Focused, small-scale epidemiologic studies on stress.** Researchers also have investigated stress
17 responses in certain veterans who performed specific duties (e.g., grave registration) or experienced
18 significant combat trauma (e.g., a SCUD missile attack). Because these research subjects

1 experienced more extreme levels of stress than the average Gulf War veteran, data from these studies
2 are not generalizable.

3 U.S. Army unit that experienced SCUD missile attack. The PTSD Clinical Team at the Highland Drive
4 VAMC (Pittsburgh) developed an early treatment intervention program for the members of the 14th
5 QM Detachment, whose barracks were destroyed by an Iraqi SCUD missile on February 25, 1991
6 (Perconte, et al., 1993b). When the SCUD missile struck their barracks, 28 soldiers were killed, and
7 99 were wounded. Blast effects on survivors included extensive shrapnel wounds and ruptured
8 eardrums.

9 The PTSD Clinical Team initially contacted members of the 14th QM during the week of
10 March 18, and treatment continued until April 24, 1991. Five of the 20 soldiers who were onsite at
11 the time of the missile attack were judged to have met the criteria for PTSD during the initial
12 assessments. Testing revealed these onsite soldiers reported distress from nearly twice as many
13 symptoms related to war stress as the four soldiers who had been on guard duty three miles away at
14 the time of the attack. Nine of these 24 soldiers reported an increase in their alcohol consumption
15 since their return home.

16 At the end of treatment, the 20 soldiers who had been onsite showed significant decreases of
17 symptoms related to PTSD and depression. One patient was judged to continue to meet full criteria
18 for the diagnosis of PTSD, while the other four patients who had previously met the PTSD criteria
19 were still showing significant, though decreased, stress symptoms. Alcohol consumption was
20 reported as decreased for most of those interviewed.

1 A follow-up study of the 14th QM in 1993 revealed about half of the treated patients were
2 continuing to show improvement, and about half of the patients were returning to pretreatment levels
3 of symptoms (Pontius, et al., 1994). The PTSD team at the Highland Drive VAMC continues to
4 follow and treat the surviving members of the 14th QM.

5 U.S. Army units that performed graves registration duties, New Orleans studies. Among the sample of 1,520
6 military personnel studied by the New Orleans VA, were 194 members of QM units assigned graves
7 registration duties that encompassed handling, identification, and processing of bodies and body
8 parts. In one unit (24 people), investigators found the prevalence of PTSD was 46 percent. They also
9 reported a high incidence of psychiatric diagnoses concurrent with PTSD, including depression (33
10 percent) and alcohol abuse/dependence (13 percent) (Sutker et al., 1994a).

11 A second study compared 40 service members who performed graves registration duties with
12 20 individuals from the same units who were not deployed to the Gulf War and who did not perform
13 graves registration duties (Sutker, et al., 1994b). Current diagnoses of PTSD were made in 48
14 percent of the deployed troops, compared to none for nondeployed service members. Diagnoses
15 concurrent with PTSD included depressive disorder (18 percent) and alcohol dependence (10
16 percent). After one year, 42 percent of the service members who had performed graves registration
17 continued to meet criteria for PTSD (Sutker and Vasterling, 1996). The New Orleans research team
18 continues its followup of both groups who performed graves registration duties.

1 U.S. Army units that performed graves registration duties, Walter Reed Army Institute of Research study.

2 Researchers at WRAIR's Department of Military Psychiatry also studied units with graves
3 registration duties. They found consistent, but milder, symptoms compared to the New Orleans
4 groups (McCarroll, et al., 1993; McCarroll, et al., 1995).

5 **Summary of epidemiologic data on stress.** Epidemiologic studies to assess the effects of stress
6 invariably have found higher rates of PTSD in Gulf War veterans than among individuals in
7 nondeployed units or in the general U.S. population in the same age group. It also appears groups
8 with the most severe stress, such as the group injured by the missile attack, have a greater risk of
9 PTSD than other Gulf War veterans.

10 In the large epidemiologic studies performed in Boston and New Orleans, the rates of PTSD
11 and other psychological conditions had increased at the one-year follow-up evaluation, rather than
12 ameliorating over time. Longer-term followup to determine the effectiveness of treatment and
13 outreach efforts is indicated in these study groups. The long-term effects of stressors of the Gulf War
14 on active duty troops remain largely unexplored.

15 **DATA ON UNDIAGNOSED ILLNESSES**

16 A significant number of Gulf War veterans who have participated in the government's clinical
17 programs report symptoms that do not fall into standard diagnostic categories. The epidemiologic
18 studies also have identified a many veterans who report symptoms of illness, but who do not show
19 abnormalities on physical examinations or standard diagnostic tests. Congress has authorized VA to

1 provide disability compensation to Gulf War veterans with undiagnosed illness (P.L. 103-446; 38
2 CFR 3.317), but the impetus to determine the underlying cause of the problem remains.

3 **Data from the CCEP**

4 More than 40 percent of CCEP participants have a primary or secondary diagnosis of SSIDC. This
5 diagnostic category includes an extremely heterogeneous group of miscellaneous symptoms that do
6 not fit elsewhere in the diagnostic coding system. As shown in table 3-12, the category encompasses
7 generalized symptoms, such as malaise and fatigue; isolated abnormal laboratory results (i.e., a
8 nonspecific reaction to the tuberculin test or an elevated sedimentation rate); and symptoms that
9 prove to be transient (e.g., an episode of seizures or a rash, by history only) (DOD, 1996). Overall,
10 no significant anatomical, physiological, biochemical, or pathological abnormalities are detectable in
11 individuals whose symptoms are coded in the SSIDC category. DOD has reported that the frequency
12 of symptoms coded under SSIDC for CCEP participants is about five times higher than the frequency
13 of coding of SSIDC in the general U.S. population, aged 20 to 40 years (DOD, 1996).

14 Of VA's Registry participants, 10,391 individuals (19.9 percent) reported some symptoms,
15 but they did not have a characteristic set of signs and laboratory test abnormalities that allowed a
16 medical diagnosis to be made (Kang, et al., 1996b). This group of Registry participants is
17 comparable to the group of CCEP participants who were coded with a primary diagnosis of SSIDC,
18 and their symptoms are similar. Table 3-13 presents the most common symptoms among these VA
19 participants.

Comparison to Symptom-based Diagnoses

The Committee noted the interest of many veterans in possible links between their illnesses and recognized diagnoses—such as CFS and FM—that are based on symptoms reported by the patient rather than on physical abnormalities evident to a physician or laboratory findings. Veterans also expressed a need to know more about Multiple Chemical Sensitivity (MCS), which is not currently a recognized diagnosis in U.S. medical practice.

Chronic Fatigue Syndrome. The CDC consensus case definition for CFS (1994 revision) requires both:

- Clinically evaluated, unexplained, persistent, or relapsing fatigue for at least six months that is of new or definite onset; is not the result of ongoing exertion; is not substantially alleviated by rest; and results in substantial reduction in previous levels of occupational, educational, social, or personal activities. In practical terms, most CFS patients are unable to work full-time.; and
- Four or more of the following concurrent symptoms on a persistent or recurrent basis during six or more consecutive months of illness, none of which may predate the fatigue:
 - ◊ self-reported severe impairment in short-term memory or concentration;
 - ◊ sore throat;
 - ◊ tender cervical or axillary lymph nodes;
 - ◊ muscle pain;
 - ◊ multi-joint pain without joint swelling or redness;
 - ◊ headaches of a new type, pattern, or severity;
 - ◊ unrefreshing sleep; or
 - ◊ postexertional malaise lasting more than 24 hours.

The 1994 CDC case definition lists many medical and psychiatric conditions that exclude the diagnosis of CFS. CFS is strictly a diagnosis of exclusion, and no confirmatory lab test exists (Fukuda et al., 1994).

The prevalence of CFS in Gulf War veterans is unknown. VA diagnoses patients with CFS, but it has not reported the proportion of veterans in the Registry with this diagnosis. DOD has reported that 42 of the first 10,000 participants in the CCEP (0.42 percent) met the 1994 CDC case definition for CFS (DOD, 1995); its report on 18,075 participants did not provide this breakout.

Fibromyalgia. The 1990 American College of Rheumatology consensus case definition of FM requires both of the following:

- chronic widespread pain in all four quadrants of the body (“pain all over”); and
- pain in at least 11 of 18 tender point sites on digital palpation.

Other symptoms in FM patients frequently report include sleep disturbance, fatigue, morning stiffness, anxiety, headache, and depression. No exclusions are made for the presence of concomitant X-ray or lab abnormalities. Therefore a patient may be diagnosed with FM and another disorder simultaneously, such as rheumatoid arthritis, osteoarthritis, or major depression. There is no confirmatory lab test.

The prevalence of FM in Gulf War veterans is unknown. VA diagnoses patients with FM, but it has not reported the proportion of veterans in the Registry who have FM. DOD has reported that approximately 1.5 percent of CCEP participants have received a primary or secondary diagnosis of FM (DOD 1996).

Multiple Chemical Sensitivity. There is no consensus case definition for MCS, although two recent government-sponsored conferences have attempted to develop one. MCS patients report many symptoms, including tiredness or lethargy, fatigue, memory difficulties, difficulties concentrating, dizziness or lightheadedness, and depressed feelings when exposed to low levels of common, everyday substances. Symptoms relevant to many different organ systems have been linked to MCS in the clinical ecology literature; symptoms related to the central nervous system are the most common.

The majority of patients that clinical ecologists diagnose with MCS have no objective abnormalities on physical examination or on routine laboratory testing. Clinical ecologists use a variety of nontraditional diagnostic and treatment techniques, none of which have been validated in a controlled trial.

One physician who specializes in MCS has consulted on 75 patients at the Houston VA Persian Gulf Referral Center. She reported that among her first 59 consultations, 46 patients (78 percent) reported a variety of symptoms, referred to as intolerances, when exposed to various chemical inhalants, such as traffic exhaust, perfume, or tobacco smoke (Miller). No other data on chemical intolerances in Gulf War veterans exist.

Overlap of symptom-based diagnoses. Several studies have demonstrated that symptoms of CFS, FM, and MCS overlap. A 1994 Seattle study evaluated three groups with 30 patients each who had been diagnosed with CFS, FM, or MCS. Researchers for this study concluded that symptoms typical of each disorder were prevalent in the other two conditions, and that “with the exception of tender

1 points, other physical examination findings appear to be prominent by their absence in CFS, FM, and
2 MCS” (Buchwald et al., 1994). The symptoms of CFS, FM, and MCS also are common among
3 CCEP and Registry participants with undiagnosed illness. The government is sponsoring research on
4 each of these conditions.

5 **Deficits in peripheral nerve function.** At least one researcher has suggested a link between unexplained
6 illnesses among Gulf War veterans and measurable deficits in peripheral nerve function attributable
7 to one or more Gulf exposures (Jamal). Published data, however, reports on a small population that
8 was not randomly selected, so data are not generalizable to the entire Gulf War service population.
9 Reported results also revealed no objective differences between Gulf War veterans and civilian
10 participants, and there was no evidence for a clinically demonstrable peripheral neuropathy in any of
11 the Gulf War veterans who participated in the study.

12 **ILLNESS AMONG FAMILY MEMBERS**

13 Some veterans and their family members, scientists, and physicians have voiced concern that
14 Gulf War veterans’ illnesses could or does affect the health of their families. The potential for
15 adverse reproductive outcomes—infertility and birth defects—and new hypotheses regarding
16 communicable diseases have generated the most anxiety.

17 **Overview of Clinical Data**

18 Since CCEP’s inception in 1994, spouses and children of active duty personnel have been eligible for
19 enrollment. DOD’s recent report discussed its evaluation of 332 spouses and 191 children (DOD,
20 1996). Additionally, VA began a similar program for the spouses and children of veterans in April

1 considerable design advantages over previous studies assessing the reproductive health of Gulf War
2 veterans.

3 A substudy of this investigation involves an evaluation of the prevalence of
4 oculoauricularvertebral spectrum (Goldenhar syndrome) among children born or hospitalized in DOD
5 medical treatment facilities. To date, five cases of Goldenhar have been identified among offspring
6 of 34,067 Gulf War veterans, and three cases were identified among offspring of 41,220 nondeployed
7 veterans. Although the rate per 100,000 of the Gulf War veteran group is seemingly twice that of the
8 nondeployed group, the difference is not statistically significant (Olney 1996).

9 One problem that plagues all studies of reproductive outcomes among Gulf War veterans is
10 the absence of baseline data on military populations. The birth defects surveillance programs
11 operated and coordinated by CDC have helped to diminish this problem in the civilian sector. The
12 primary purpose of the National Survey of Family Growth, performed by the National Center for
13 Health Statistics (NCHS), is to collect national data on factors affecting pregnancy and birth rates in
14 the United States. Conducted five times since 1973, NCHS uses widely accepted sampling and
15 survey methods to estimate rates of infertility, pregnancy loss, and birth defects. The samples are
16 representative of the civilian noninstitutionalized population of women aged 15 to 44. Selected,
17 proximate risk factors that might affect infertility and pregnancy loss also are collected (Chandra,
18 1994).

19 In addition to being used to search for increases in the incidence of specific malformations,
20 surveillance systems can be used to develop baseline data, provide timely rates, identify geographic

1 areas of concern for cluster investigations, and provide the basis for ecological investigations and
2 follow-up studies to identify causes or risk factors such as drugs, nutritional factors, environmental
3 exposures, maternal illnesses, and genetic factors (Lynberg, 1992). No such baseline data collection
4 system specific to the reproductive health of military personnel currently exists.

5 In April 1996, VA established the Examination Program for Spouses and Children of Persian
6 Gulf Veterans to fulfill a legislative mandate (P.L. 103-446, Section 107). This program could
7 eventually yield some data about reproductive outcomes among the families of Gulf War veterans.
8 Under this authority, VA may provide examinations to any individual who: is the spouse or child of
9 a veteran who is listed in VA's Registry and is suffering from illness or disorders; is suffering from,
10 or could have suffered from, an illness or disorder (including a birth defect, miscarriage, or stillbirth)
11 that cannot be disassociated from the veteran's service in the Southwest Asia theater of operations; or
12 has granted VA permission to include in the Registry relevant medical data from the evaluation.

13 The program initially was funded at \$2 million and was open to the first 4,500 individuals
14 who called VA's Helpline. It has been extended to September 30, 1998. Examinations are provided
15 by university-affiliated physicians at 32 VAMC coordinating centers, and participants are examined
16 at one of these contractor sites. The program does not pay for travel or reimburse for incurred
17 expenses. Examinations are similar to VA's Phase I Registry examination, including a standardized
18 history and physical examination. The protocol for the children of veterans involves a detailed
19 medical history, including symptoms and a developmental history. VA is not authorized to provide
20 medical followup or treatment of conditions diagnosed by the medical examination. The program

currently is not designed to provide useful research results, but could be used to identify areas needing further evaluation.

INFECTIOUS DISEASES

Infectious diseases are a special concern to Gulf War veterans and their family members. Based on its CCEP, DOD reports no clinical evidence that Gulf War veterans have transmitted an infectious disease endemic to the Gulf to their spouses or children. Among 332 spouses of veterans who have been evaluated, 23 individuals (7.0 percent) have a primary or secondary diagnosis of an infectious disease (table 3-14; Kinty, 1996). These include 14 cases of fungal skin infections, six cases of vaginal yeast infections, two cases of warts, and one case of tuberculosis—all of which are common infectious diseases in the general U.S. population.

Among 191 children of veterans who have been evaluated in the CCEP, 17 children (8.9 percent) have a primary diagnosis of an infectious disease (table 3-15; DOD, 1996). Nine children have an upper respiratory infection, six children have otitis media (ear infection), one child has tinea capitis (fungal skin infection), and one child has chronic pneumonia. All of these diagnoses are common childhood infectious diseases in the general U.S. population, with the exception of chronic pneumonia.

Three other microorganisms have been hypothesized as possible etiologies for illnesses in some Gulf War veterans and their families: *Mycoplasma* infections, microsporidia infections, and occult, systemic streptococcal infections. Each hypothesis awaits systematic, controlled research to confirm it as a potential cause of morbidity in Gulf War veterans.

- Dr. Garth Nicolson, an eminent, non-physician cancer researcher has suggested that many symptomatic Gulf War veterans have illness caused by *Mycoplasma fermentans* (*incognitus* strain) (Nicolson 1996), resulting in a broad range of symptoms and organ dysfunctions that encompass nearly every system (Nicolson 1995). A systematic description of the symptoms, abnormalities on physical examination, or abnormalities on routine testing for patients believed to be infected with this organism has not been presented, and so a case definition is not possible. CDC has approached Dr. Nicolson about funding a case-controlled study to evaluate *Mycoplasma* presence in the Pennsylvania National Guard unit study described earlier (Blanck 1996a). As of Fall 1996, Dr. Nicolson had continued to defer this collaborative research.
- In 1995, a microbiologist at the VAMC in Mountain Home, TN, reported he found small round bodies, which he identified as microsporidia, in the stool specimens of some Gulf War veterans. Microsporidia are parasites that can cause diarrhea and wasting (Weiss). Following his report, VA collected several stool specimens along with gastrointestinal (GI) biopsy material from individuals identified as having a positive histochemical stain. The samples were evaluated by experts at several institutions; no microsporidia-like organisms or other known intestinal protozoans were detected in the stool samples, and the histology of the GI material was normal. In addition, CDC found no evidence of microsporidia among the stool specimens from subjects in the Pennsylvania National Guard unit study (Blanck 1996b).

- Dr. Edward Hyman, a primary care physician in New Orleans, states he has diagnosed a streptococcal bacteremia that he calls “systemic coccal disease,” in about 10 Gulf War veterans and 10 of their family members (Hyman 1994, 1995, and 1996). He describes this syndrome as manifesting “almost universally as chronic fatigue, but with pains in muscles and fibrous tissue or FM, with nerve and mental findings, neuritis and brain loss, with lung impairment, with arthritis of one kind or another, with skin rashes that usually itch, with blood changes, etc.” Dr. Hyman has treated the Gulf War veterans and their families, and he reports that, initially, all veterans improved noticeably, but then most of them soon relapsed. No research approved by an institutional review board has been initiated on this hypothesis.

Based on available evidence, the Committee believes it is unlikely these microorganisms are responsible for widespread disease among Gulf war veterans or their families.

SUMMARY

In the absence of generalizable, quantitative information about the extent of Gulf War veterans’ illnesses, only a qualitative range of symptoms and illnesses being reported by Gulf War veterans can be described. This general picture derives from information about participants in DOD’s and VA’s clinical evaluation program and preliminary data from several federally funded epidemiologic studies.

The Committee believes that the most significant findings about the nature and extent of Gulf War veterans’ illnesses—and recommendations for followup—must await the conclusion of the population-based epidemiologic studies. These results will come in well after the Committee

disbands. However, based on in-house expert consultations, literature reviews, briefings, and testimony, the Committee makes the following findings and recommendations.

FINDINGS

- Gulf War veterans have experienced no excess mortality from natural causes during or after the war. Gulf War veterans have experienced excess mortality from external causes, such as accidents, which is consistent with the experience of veteran populations from previous conflicts.
- Information from the clinical programs indicates musculoskeletal conditions and ill-defined conditions are common components of Gulf War veterans' illnesses.
- Data from the clinical programs and epidemiologic studies indicate stress-related disorders are common components of Gulf War veterans' illnesses.
- Among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf. Currently, the extent of service-connected illness in the population is unknown.
- Stigmatization of psychosomatic illness seriously interferes with some veterans seeking care.
- It is unlikely that exposures in the Gulf War theater are responsible for the birth defects of children born to veterans.
- VA's examination program for spouses and children of Gulf War veterans has little or no value as a research program and offers no incentive for participation, thus raising expectations about the government's ability to respond to health care needs in veterans and their families that are impossible to meet.
- The absence of baseline data regarding the reproductive history and health of military personnel makes determinations of the effects of exposures during deployment more complex and difficult.

RECOMMENDATIONS

- Research on possible causes and methods of prevention of excess mortality from external causes among veterans should receive high priority.
- Research on Gulf War veterans' illnesses should emphasize investigating the causes and methods of prevention and treatment of musculoskeletal conditions and stress-related disorders.
- Since the stigmatization of mental illness continues to be a problem for society at large, the DHHS should place a priority on developing public education outreach programs that note the indissoluble association between the mind and the body. DOD and VA should make a special effort to address and target such needed educational outreach to their communities.
- Since Congress has extended VA's examination program for spouses and children of Gulf War veterans, VA should formulate what it intends to do with the results and consider mechanisms to reimburse travel and other costs.
- DOD should consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, DOD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.

**Table 3-1: Demographic Characteristics of Gulf War Participants
Enrolled in DOD's CCEP and VA's Registry**

<u>Characteristic</u>	<u>Total Gulf War Participants</u> (N = 697,000)	<u>CCEP Participants</u> (N = 18,075)	<u>Registry Participants</u> (N = 52,216)
<u>Gender (%)</u>			
Male	93	88	90
Female	7	12	10
<u>Race (%)</u>			
White	70	57	64
Black	23	32	23
Hispanic	5	6	---
Other/Unknown	2	5	13
<u>Age (Years)</u>			
Mean (in 1990)	26	30	29
<u>Branch</u>			
Air Force	12	10	7
Army	50	81	72
Marines	15	4	12
Navy	23	4	8
Other/Unknown	---	1	1
<u>Status (in 1991)</u>			
Active-Duty	83.3	83	54
Reserve	10.4	13**	20
National Guard	6.3	---	19
Other/Unknown	---	4***	6

--- means information is unavailable.

** Reserve and National Guard are combined.

*** Includes eligible civilians who went to Gulf War.

Table 3-2: Frequency of the Ten Most Common Symptoms Reported by Participants Enrolled in the CCEP and in the VA Registry

<u>Reported Symptom</u>	<u>CCEP Participants</u> <u>(% of 18,075)</u>		<u>Registry Participants</u> <u>(% of 52,216)</u>
	<u>Chief Complaint</u>	<u>Any of Top Seven Symptoms</u>	<u>Any of Top Three Symptoms</u>
No Symptoms	10	10	12
Joint Pain	11	49	17**
Fatigue	10	47	20
Headache	7	39	18
Memory Loss	4	34	14
Sleep Disturbance	2	32	6
Rash/Dermatitis	7	31	18
Difficulty Concentrating	<1	27	---
Depression	1	23	---
Muscle Pain	1	21	**

--- means information has not been reported.

** Muscle and joint pain are 17% combined in the VA Registry

**Table 3-3: Frequency Distribution of Major Diagnostic Categories (ICD-9-CM)
in Participants in CCEP and Registry**

<u>Diagnostic Categories</u> <u>(ICD-9-CM Code)</u>	<u>CCEP Participants (% of 18,075)</u>		<u>Registry Participants</u> <u>(% of 52,216)</u>
	<u>Primary Diagnosis</u>	<u>Any of Top Seven</u> <u>Diagnoses</u>	<u>Any of Top Three</u> <u>Diagnoses</u>
Psychological Conditions	18.4	36.0	15.1
Musculoskeletal System Diseases	18.3	47.2	25.3
Symptoms, Signs & Ill-Defined Conditions	17.9	43.1	19.9
Healthy	9.7	10.2	---
Respiratory System Diseases	6.8	17.5	14.4
Digestive System Diseases	6.3	20.4	11.4
Skin Diseases	6.2	19.9	13.5
Nervous System Diseases	5.7	17.8	8.3
Infectious Diseases	2.6	9.0	7.1
Circulatory System Diseases	2.2	8.0	7.1
Endocrine Disorders	2.0	7.9	---
Genitourinary System Diseases	1.3	5.4	3.4
Injury and Poisoning	0.8	3.2	4.8
Neoplasms	0.8(0.3**)	2.9	0.4**
Blood and Blood Organ Diseases	0.5	3.0	---

--- means information has not been reported.

** Malignant neoplasms (cancer) only.

**Table 3-4: Frequency of Primary Diagnoses of Cancer (Malignant Neoplasms)
in Participants in the CCEP and Registry**

<u>Type of Cancer</u>	Number of Cases in CCEP (N=52)		Number of Cases in VA Registry (N=226)	
	<u>Male</u>	<u>Female</u>	<u>Male</u>	<u>Female</u>
Malignant Melanoma	3	0	11	2
Other Skin Cancer	6	0	44	1
Hodgkin's Disease	8	0	19	1
Non-Hodgkin's Lymphoma	4	1	15	0
Multiple Myeloma	0	0	2	0
Leukemia	6	1	8	0
Soft Tissue	0	0	8	0
Brain and Meninges	5	0	6	1
Thyroid	1	1	6	0
Prostate	1	0	2	0
Testicular	4	0	20	0
Colon	1	0	7	0
Breast	0	2	0	5
Cervix Uteri	0	1	0	5
Ovary	0	1	0	1
Vagina	0	0	0	1
Stomach	0	1	0	0
Lung	3	0	8	1
Bladder	1	0	4	0
Kidney	1	0	2	2
Other Types	<u>0</u>	<u>0</u>	<u>40</u>	<u>4</u>
TOTAL	44	8	202	24

**Table 3-5: Frequency Distribution of Symptoms
Reported by 284 Gulf War Veterans in Great Britain**

<u>Reported Symptom</u>	<u>% of 284 Patients</u>
Tiredness	55
Muscle and Joint Pain	35
Irritability	29
Sleep Disturbance	24
Short Term Memory Loss	22
Breathlessness	21
Skin Problems	16
Tingling Limbs	11

Table 3-6: Frequency Distribution of Major Diagnostic Categories Among 284 Gulf War Veterans in Great Britain

<u>Primary Diagnostic Category</u>	<u>% of 284 Patients*</u>
Psychological Conditions	35
SSIDC (including CFS)**	15
Respiratory Diseases	9
Skin Diseases	8
Digestive Diseases	7
Musculoskeletal Diseases	6
Nervous System Diseases	6
Circulatory System Disease	3
Genitourinary Diseases	2
Infectious Diseases	1
Endocrine Conditions	1
Cancer	1

* Note some patients were healthy.

** Symptoms, Signs and Ill-defined Conditions; Chronic Fatigue Syndrome

**Table 3-7: Frequency of the Ten Most Common Symptoms
Reported by 49 Gulf War Veterans in Canada**

<u>Reported Symptom</u>	<u>Chief Complaint (%)</u>	<u>Any Symptom (%)</u>
Fatigue	10	86
Memory Problems	14	77
Headaches	8	67
Sleep Disturbance	12	65
Joint Pain	8	61
Difficulty Concentrating	0	59
Depressed Mood	0	55
Rash	4	49
Muscle Pain	4	35
Diarrhea	3	31

**Table 3-8: Frequency Distribution of Major Diagnostic Categories
in 49 Gulf War Veterans in Canada**

<u>Diagnostic Category</u>	<u>Primary Diagnosis (%)</u>	<u>Any Diagnosis (%)</u>
Psychological	45	77
Dermatological	6	53
Digestive System	4	53
Musculoskeletal	16	49
Nervous System	6	41
Ear, Nose and Throat	4	28
Ophthalmology	2	20
Respiratory	2	14
Ill-Defined (SSIDC)*	2	8
Genitourinary	2	8

* Symptoms, Signs and Ill-defined Conditions.

Table 3-9: Summary of Epidemiologic Data to Date from Federally Funded Studies

Study Type	Studies completed or reporting results	Limitations and generalizability	Results
Mortality studies	- United States Military Casualty Comparisons During the Persian Gulf War (Helmkamp, 1994) - Comparative Mortality Among US Military Personnel in the Persian Gulf Region and Worldwide During Operations Desert Shield and Desert Storm (Writer et al 1996) - The Effect of Persian Gulf War Service on Subsequent Mortality Among 700,000 U.S. Military Veterans (Kang et al, 1996)	- studies have included entire deployed Gulf War service population and thus encompass the experience of the complete population of interest - follow-up since the Gulf War has only been carried out through September 1993	- both battle and nonbattle casualty rates were low during the war, but excess mortality from accidents was observed - since the war, Gulf veterans have experienced excess mortality from external causes such as accidents, while rates for natural causes such as diseases have been lower in Gulf veterans
Morbidity studies	123rd Army Reserve Command Investigation (DeFraithe et al, 1992) 24th Naval Construction Battalion Investigation (Berg, 1994) - Health Effects of Gulf War Veteran Women (Pierce 1996a&b) - Pennsylvania Air National Guard Study (CDC 1995; Reeves, 1995, 1996) - The Postwar Hospitalization Experience of US Persian Gulf War Veterans (Gray et al, 1996)	- studies have varied in populations examined and their generalizability to the Gulf War veteran population as a whole - studies have differing strengths and limitations	- increased symptoms are reported by those deployed to the Gulf, compared to other veterans - no consistent abnormal laboratory or physical findings in groups with increased symptoms
Studies on the effects of stress	- Fort Devens Study (Wolfe et al, 1993, 1996a&b) - New Orleans Study (USDVA, 1992; Sutker 1993, 1995, 1996) - West Haven, CT Study (Southwick et al, 1993, 1995) - Little Rock VA Study (USDVA, 1992; West et al 1993) - Highland Drive (Pittsburgh) VA Study (USDVA 1992, Perconte et al, 1993a) - Mountain Home, Johnson City, TN study (Sloan et al, 1995a&b, 1996) - The General Well-Being of Gulf War Era Service Personnel from the States of Pennsylvania and Hawaii (WRAIR 1994, Stretch 1995, 1996a&b) 14th Quartermaster Detachment Study (Perconte et al, 1993b; Pontius, 1994) - New Orleans study of Army units carrying out graves registration duty (Sutker et al, 1994a&b; Sutker and Vasterling, 1996) - Walter Reed Army Institute of Research study of units	- studies vary in size and study populations - almost all have been carried out only in Reserve and National Guard populations	- studies indicate higher rates of PTSD in Gulf War veterans compared to non-deployed veterans or general US population - groups with the most severe stress during the war appear to have greater risk of PTSD than other Gulf War veterans

Study Type	Studies completed or reporting results	Limitations and generalizability	Results
	performing graves registration (McCarroll et al, 1993, McCarroll et al, 1995)		
Reproductive outcome studies	• Mississippi National Guard Study (Penman and Tarver, 1996) • Record-based evaluation of the risk of birth defects and military service in the Gulf War (Cowan 1995a&b, 1996) • Prevalence of congenital anomalies among children born to GW veterans; a substudy of Goldenhar syndrome (Olney, 1996)	• studies vary in size, populations examined, and generalizability • large record-based study included only births to active duty veterans	• risks of birth defects, either broadly or narrowly categorized, were not different among the Gulf-deployed and non-deployed troops • ongoing population-based study has not shown a statistically significant elevation in the rate of Goldenhar syndrome

Table 3-10: Most Frequent Psychological Conditions Among Participants in the CCEP and Registry

<u>Psychological Condition **</u>	<u>CCEP Participants</u> (% of 18,075)		<u>Registry Participants</u> (% of 52,216)
	Primary Diagnosis	Any of Top 7 Diagnoses	Any of Top 3 Diagnoses
Major Depressive Disorder	1.8	3.0	---
Neurotic Depression (Dysthymia)	1.1	3.0	---
Depression, Not Otherwise Specified	2.9	6.2	2.5
Post Traumatic Stress Disorder	2.8	5.2	2.9
Anxiety Disorders	0.7	2.2	1.6
Adjustment Disorders	1.3	2.5	---
Alcohol Related Disorders	0.4	1.7	---
Substance Related Disorders	0.3	2.0	---

-- means information has not been reported.

** Tension headache is also coded under the category of Psychological Conditions. It was diagnosed in a total of 11.3% of CCEP participants and 2.3% of VA Registry participants.

Table 3-11: Criteria for Major Depressive Episode*

A.	Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning: at least one of the two symptoms is either (1) depressed mood or (2) loss of interest or pleasure. Note: Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.
(1)	depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful). Note: In children and adolescents, can be irritable mood.
(2)	marked diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
(3)	significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month) or decrease or increase in appetite nearly every day. Note: In children, consider failure to make expected weight gains.
(4)	insomnia or hypersomnia nearly every day
(5)	psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
(6)	fatigue or loss of energy nearly every day
(7)	feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
(8)	diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
(9)	recurrent thoughts about death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide
B.	The symptoms do not meet criteria for a Mixed Episode.
C.	The symptoms can cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
D.	The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).
E.	The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

* Table from DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, 4th Ed., 1994.

Table 3-12: Proportion of Primary Diagnoses in the Category of Symptoms, Signs, and Ill-Defined Conditions among 3,239 CCEP Participants

<u>Diagnosis (ICD-9-CM Codes 780-799)</u>	<u>Percent (of 3,239)</u>
Malaise and Fatigue	27
Sleep Disturbances	18
Headache	15
Other General Symptoms*	9
Dyspnea and Painful Respirations	6
Rash	5
Syncope, Seizures, and Vertigo	3
Other Chest Pain	2
Abdominal Pain	1
Nonspecific Reaction to Tuberculin Test	1
Cough	1
Other	12

* Nearly all of the complaints coded under "Other General Symptoms" are reported problems with memory.

**Table 3-13: Ten Most Common Symptoms Among 10,391 Registry Participants
Who Have Symptoms* But No Diagnosis**

<u>Symptom</u>	<u>Percent (of 10,391)</u>
Fatigue	29
Headache	22
Skin Rash	20
Muscle, Joint Pain	16
Loss of Memory and Other General Symptoms	15
Shortness of Breath	10
Sleep Disturbances	7
Chest Pain	5
Cough	4
Diarrhea and Other GI Symptoms	4

* Note that the top three symptoms are computerized for each patient in the VA Registry.

Table 3-14: Distribution of Primary Diagnoses and All* Diagnoses for Spouses in the CCEP (N=332)

Diagnostic Categories	Spouses	
	Primary Diagnosis (%)	All Diagnoses (%)*
Psychological Conditions	20.8	39.5
Musculoskeletal System Diseases	9.9	33.7
Symptoms, Signs, and Ill-Defined Conditions	14.5	42.2
Healthy	9.9	5.4**
Respiratory System Diseases	4.2	15.7
Digestive System Diseases	4.8	23.5
Skin and Subcutaneous Tissue Diseases	7.8	22.6
Nervous System Diseases	8.7	18.1
Infectious Diseases	1.5	7.2
Circulatory System Diseases	1.8	7.2
Endocrine Disorders	5.1	12.3
Genitourinary System Diseases	8.4	17.8
Neoplasms	0.6	3.6
Injury and Poisoning	0.3	2.4
Blood and Blood Organ Diseases	0.9	4.5
Congenital Abnormalities and Conditions of the Prenatal Period	0.3	1.5

* All diagnoses include the top seven diagnoses.

** Includes spouses having a healthy primary and no secondary diagnoses.

**Table 3-15: Frequency Distribution of Primary Diagnosis
for Children of Gulf War Veterans in the CCEP (N=191)**

Diagnosis	Number
Healthy (Normal Exam)	72
Congenital Abnormalities*	35
Dermatitis, Eczema, Folliculitis, Acne	14
Other	11
Upper Respiratory Infections	9
Asthma, Reactive Airway Disease	6
Psychosis, Depression, Obsessive/Compulsive Disorder	6
Otitis Media	6
Attention Deficit/Hyperactivity	5
Seizures	5
Developmental Delay	4
Gastroesophageal Reflux	4
Nephritis, Vesicoureteral Reflux, Hydrocele	4
Dermoid Cysts, Hemangiomas	3
Rash	2
Anemia	1
Choroid Plexus Carcinoma	1
Chronic Pneumonia	1
Insomnia	1
Tinea Capitis	1
TOTAL	191

* Specific diagnoses include: congenital heart disease (3); cleft lip or palate (5); chromosomal abnormalities (4); hydrocephalus (5); minor congenital defects (11), including duplicated toe and pectus excavatum; and others (7).

1 CHAPTER 4: SCIENTIFIC ANALYSIS OF GULF WAR RISK FACTORS

2 U.S. service members potentially were exposed to a broad range of risk factors during the Gulf War.
3 As specified by the charter, the Committee has evaluated the potential health effects of several
4 suspected risk factors. We have also attempted to analyze the extent and likelihood of exposure to
5 these risk factors during the Gulf War. In most instances, however, exposure data have been difficult
6 to obtain or nonexistent. The Committee identified risk factors for assessment based on its charter,
7 previous reports on Gulf War veterans' illnesses, and expert and stakeholder testimony at meetings
8 held nationwide. This chapter reports the Committee's findings on the following risk factors:

- 9 • pesticides,
- 10 • chemical warfare agents,
- 11 • biological warfare agents,
- 12 • vaccines,
- 13 • pyridostigmine bromide,
- 14 • infectious diseases,
- 15 • depleted uranium,
- 16 • oil-well fire smoke,
- 17 • petroleum products, and
- 18 • psychological and physiological stress.

19 The chapter first reports what is known currently about possible U.S. troop exposure to each
20 risk factor. Following this analysis, we discuss health effects known to date, and we present our
21 findings and recommendations in the final section of this chapter.

22 EXPOSURE TO RISK FACTORS IN THE GULF

23 As described in the Committee's *Interim Report*, few exposure data exist on many key Gulf War risk
24 factors. In fact, for most of the risk factors we analyzed, the only exposure information available

1 today is anecdotal recollections of Gulf War veterans. As a consequence, it will be difficult to link, in
2 a scientifically valid manner, any adverse health outcomes detected by ongoing research to specific
3 exposures or risk factors. As noted in chapter 2, the Committee has concluded that DOD's Persian
4 Gulf Registry of Unit Locations will be of little use for investigating questions about Gulf War
5 veterans' health issues and is certainly an inadequate substitute for missing exposure data.

6 **Exposure to Pesticides**

7 Precise records exist for pesticides DOD shipped to the Gulf region (table 4-1). All pesticides
8 shipped were approved by EPA or FDA for general use in the United States at the time of the Gulf
9 War. U.S. consumers can purchase these at grocery, gardening, and other stores in products such as:
10 OFF® and Cutters® (DEET), Raid® Ant and Roach Killer Spray and Raid® Yard Guard (permethrin),
11 Black Flag® Insect Spray (Baygon), permethrin spray for treating clothes, and a variety of Ortho®
12 brand and other name brands of gardening products containing carbaryl, diazinon, malathion,
13 chlorpyrifos, and permethrin.

14 While DOD can document what pesticides were shipped—and how much—there are virtually
15 no records available today on how these pesticides were used in the Gulf region. DOD made no
16 provisions for collecting or keeping distribution or use records of U.S.-shipped and approved
17 products. Reports from a few veterans about the use of other, locally obtained, unapproved pesticides
18 are impossible to follow up.

19 Assuming DOD adhered to its policies on pesticide use, its programs closely parallel those
20 established by EPA and FDA regulations for domestic pesticide use. According to DOD policy, the

1 majority of U.S. service members had access to two pesticides: permethrin in a spray can (for
2 treating uniforms) and DEET liquid or stick as a personal mosquito and fly repellent. DOD reports
3 about 2.2 spray-cans of permethrin and 2.0 tubes of DEET (33 percent formulation) were shipped to
4 the Gulf for each U.S. service member; according to DOD, U.S. troops were not provided with
5 permethrin pretreated uniforms. All other pesticides shipped to the Gulf region were to be used only
6 by specifically trained individuals or for special applications. For example, lindane apparently was
7 used nearly exclusively on Iraqi prisoners of war as a delousing agent.

1

Table 4-1: Major Pesticides Shipped by DOD for Use During the Gulf War ¹	
<i>Pesticide (common name) and form</i>	<i>Class</i>
Carbaryl (Sevin®) insecticide dust and spray 10- and 4-lb bags	Methyl carbamate
Chlorpyrifos (Dursban®) insecticide spray 1- and 5-gal cans	Organophosphorus
DEET insect repellent for clothing/personal use 2-oz bottles/tubes and 1-oz sticks (Cutter), 33% DEET	Other
Diazinon insecticide spray and dust 25-lb and 1-gal cans	Organophosphorus
Dichlorvos (Vapona®) insecticide plastic strips	Organophosphorus
Lindane (gamma-benzene-hexachloride) insecticide dust 2-oz cans	Chlorinated hydrocarbon
Malathion insecticide spray 1- and 5-gal cans	Organophosphorus
Methomyl (Lannate®) insecticide fly bait 5-lb cans	Methyl carbamate
Permethrin insect repellent for clothing use 6-oz aerosol can	Pyrethroid
Propoxur (Baygon®) insecticide roach and ant spray 1-gal cans, 28-oz aerosol cans	Methyl carbamate
Pyrethroid insecticides ² 20-, 12-, and 11-oz aerosol cans	Pyrethroids other than permethrin
Rodenticide baits 5- and 11-lb cans	(Variety)

2

3

4

5

6

¹Pesticides shipped in small amounts were pentachlorophenol, boric acid, Combat® cockroach bait, bendiocarb insecticide, and pyrenone mosquito capsules. Including d-phenothrin, d-trans-allevethrin, resmethrin, or pyrethrins with synergists.

²Including d-phenothrin, d-trans-allevethrin, resmethrin, or pyrethrins, with synergists.

1 samples of particulate matter, levels of PAHs and toxic metals were low (USAEHA 1994, Heller
2 1996).

3 Samples were collected during at least one instance when the smoke plume had touched
4 down, providing “worst case” exposure data. Although airborne contaminants were detectable, they
5 were low compared to current U.S. occupational standards for these contaminants, even within the
6 plume touchdown (USAEHA 1994, USAEHA 1996, Heller 1996).

7 Various biological samples from troops or other personnel working in Kuwait while the fires
8 burned were also collected. In a CDC study, blood levels of volatile organic compounds (VOCs) in
9 firefighters were significantly higher than those in a U.S. reference population (Etzel and Ashley,
10 1994), but individuals in Kuwait City about 20 km from oil fires had VOC levels approximately that
11 of the reference group. These data are limited by small sample size and the short half-life of VOCs in
12 service members’ blood, but they suggest the oil-well fire smoke did not significantly increase VOC
13 exposures in troops in the Kuwait City area when most of the fires were active.

14 Blood and urine samples collected from a group of U.S. service members before, during, and
15 after their 1991 deployment to Kuwait were analyzed for VOCs, PAH-DNA adducts, metals, and
16 sister chromatid exchange (SCE) frequency in lymphocytes (USAEHA, 1994). Pulmonary function
17 tests and questionnaires also were administered. Levels of metals, VOCs, and PAH-DNA adducts
18 showed no changes or showed decreases in troops living in Kuwait compared to troops living in

1 Germany, with few exceptions. Lead levels in blood were not statistically significantly altered during
2 deployment to the Gulf region.²

3 **Exposure to Petroleum Fuels**

4 Little specific data exist about possible exposures of U.S. service members to petroleum fuels or their
5 combustion products. Operating the vehicles and machinery used in the Gulf War involved exposure
6 to petroleum based material. Petroleum fuels also were used for burning wastes and trash, dust
7 suppression, and fueling stoves and tent heaters. None of these uses are unique to the Gulf War, but
8 they probably led to increased petroleum vapor and combustion product exposures. Thus, some U.S.
9 service members were exposed to petroleum materials including benzene, toluene, xylene, ethyl
10 benzene, and combustion products including carbon monoxide, sulfur dioxide, nitrogen dioxide,
11 particulates, lead, and other pollutants.

12 The U.S. Army's air monitoring (and blood monitoring done by CDC in a small study) found
13 no evidence of elevated exposure to volatile organic compounds (including petroleum materials)
14 (USAEHA 1996; Etzel and Ashley 1994).

15 Some service members, however, clearly experienced short-term, elevated exposures to
16 petroleum fuels. For example, diesel was sprayed on the ground to suppress dust from the fine sand
17 found in the Gulf region. A U.S. Central Command document lists crude oil/waste oil as the least

² As noted, individuals in this group also were assessed for SCEs, which were found to increase with deployment to Kuwait and remain high even after the return to Germany (McDiarmid 1995). SCEs are a sensitive measure of DNA damage and repair and occur at a background rate in normal cells, but increase with exposures to DNA damaging agents. It is not clear what exposures in Kuwait could have led to the observed increases, since elevated SCEs are a nonspecific measure that can reflect exposure to infections and vaccinations, or to dietary, occupational, or environmental mutagens.

desirable option for dust suppression, but does not mention diesel fuel (Doc 87 Dust Control, undated). One U.S. Army sanitary engineer testified to the NIH Technology Assessment Panel in 1994 that units used water or diesel fuel for dust suppression during the war (Johnson 1994). He described one brigade dumping 30,000 gallons of diesel fuel on the roads daily, and said U.S. service members living in tents near the roads—and particularly truck drivers carrying out the spraying—complained of nausea from breathing the resulting fumes. As a result, the preventive medicine person to whom they complained obtained respirators for the drivers' use (Johnson 1996). Another occupational group that could have experienced some risk of elevated exposures to petroleum products during the Gulf War were those who worked at military "Petroleum, Oils, and Lubricants" points where these materials were distributed.

The fuel used most widely during the war for both vehicles and equipment was Jet A-1, an internationally used kerosene-based aviation fuel provided at no cost by the Saudi Arabian government. Of the 1.8 billion gallons of fuel used during Operations Desert Shield/Desert Storm, roughly 75 percent was jet fuel (mostly Jet A-1), 24 percent was diesel fuel, and one percent was gasoline (Stucker et al.). The gasoline used during Operations Desert Shield/Desert Storm was commercial leaded gasoline refined to Saudi Arabia's national standard (Lepera 1996).

Combustion products from heaters used in poorly ventilated areas also are a general exposure concern for Gulf War participants. Burning leaded fuels indoors without proper ventilation—e.g., heaters in tents—could have caused increased lead exposure. Kerosene heaters, widely used in the United States, also could have been significant sources of exposure to nitric oxides, sulfur dioxide,

1 inorganic combustion gases, carbon monoxide, and particles when used with inadequate ventilation
2 (Mumford et al., 1992). During the war, four hospitalizations in U.S. Army field hospitals occurred
3 because of asphyxiation from carbon monoxide.

4 **Exposure to Psychological and Physiological Stress**

5 U.S. service members encountered many stressors during the Gulf War, including short deployment
6 notice, uncertainty about length of deployment, isolation and separation from family, a polluted
7 environment, poor living conditions with little privacy or social outlets, prolonged work hours,
8 decreased income and worry about job retention, fear of SCUD missile and chemical and biological
9 weapon attacks, anticipation of high casualty rates and torture, frequent CW agent alarms that often
10 required a defensive posture and full chemical gear, and dealing with casualties and dead bodies.

11 Even when the war was over, many veterans experienced post-deployment stress on their
12 return from the Gulf. These included financial and employment difficulties, unresolved military pay
13 issues, the revelation of cases of leishmaniasis and the consequent temporary ban on blood donations,
14 the apparent increasing numbers of health complaints and “unexplained illnesses,” and media reports
15 of apparent increased numbers of birth defects and cancer.

16 **HEALTH EFFECTS OF GULF WAR RISK FACTORS**

17 Even though exposure data are sparse, the Committee undertook a comprehensive analysis of the
18 health effects of the 10 Gulf War risk factors for which we examined possible exposures. Our
19 analysis of possible health effects was performed independently of whether exposures were

undocumented, imprecise, or known. That is, we considered the possible health consequences of a range of exposure scenarios from high-level to low-level exposure and from single to multiple event and chronic or continuing exposure. The Committee also considered short-term and long-term health effects, including symptoms that might have appeared while service members were still in the theater of operations and symptoms that might not have appeared until sometime after the service members left the Gulf. The Committee's search for possible health effects extended to all organ systems and to both cancer and noncancer outcomes.

Our examination of health effects draws on three types of sources: scientific literature; briefings and workshops with recognized experts; and information presented at Committee meetings. The Committee reviewed human exposure (mostly occupational) data and laboratory animal data. We found extensive scientific literature describing the human health effects for all the risk factors investigated, including CW agents, where we had anticipated significant data gaps. The breadth and depth of information were generally sufficient to make conclusions about the short- and long-term health effects that would be anticipated for U.S. service members exposed to a particular risk factor during the Gulf War. The information available in these sources, however, represents the boundaries of the Committee's investigation: We conducted no primary research and elected not to base our findings on research not yet subjected to peer review.

Finally, the Committee drew conclusions about the role of each risk factor in Gulf War veterans' illnesses based on comparison of the known health effects of the risk factor to the

symptoms reported by Gulf War veterans. Symptoms reported by Gulf War veterans used in these comparisons were based on DOD's CCEP and VA's Persian Gulf Health Registry (see chapter 3).

Pesticides

As noted earlier in this chapter, pesticides DOD shipped for use during the Gulf War fell into five major categories: OP pesticides, methyl carbamate pesticides, organochlorine pesticides (lindane), pyrethroid pesticides (permethrin), and DEET.

Organophosphorus pesticides. Several OP pesticides were used, including chlorpyrifos, diazinon, dichlorvos, and malathion. When administered in high doses, OP pesticides cause irreversible inhibition of acetylcholinesterase, an enzyme crucial to normal nerve and nerve/muscle function.

Inhibiting acetylcholine esterases leads to unique and highly characteristic poisoning symptoms.

Immediate symptoms of OP poisoning in humans usually develop within 4 hours of exposure and include narrowing of the pupil of the eye (miosis), headache, nausea, dizziness, anxiety, and restlessness. Severe and rapid onset poisoning symptoms include muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps, diarrhea, sweating, salivation, tearing, runny nose, and production of phlegm. Life-threatening symptoms include unconsciousness, incontinence, convulsions, and depression of breathing function. According to DOD, their medical monitoring and surveillance efforts reported no cases of immediate and severe OP pesticide poisoning symptoms in U.S. military personnel during the Gulf War.

1 Some individuals who recover from immediate and severe OP pesticide poisoning show long-
2 term (lasting more than a year), subtle, neurophysiological abnormalities that can be detected using a
3 battery of standardized neuropsychological tests. In an epidemiologic study of such long-term
4 effects, severely poisoned individuals showed clear but subtle differences in intellectual functioning,
5 academic skills, abstraction and flexibility of thinking, and simple motor skills. For example, about a
6 five-point difference in IQ was measured in severely poisoned versus control subjects.
7 Neurophysiologic effects were less apparent; abnormalities were found only in measurements of
8 memory, abstraction, and mood and on one test of motor reflexes (Savage). These effects could not
9 be detected, however, in a subset of the same worker population that had been exposed to doses of
10 OP pesticides that were too low to cause the symptoms of immediate and severe poisoning
11 (Steenland). Other studies of low-level occupational exposures reinforce the finding that these types
12 of long-term effects present solely in the aftermath of severe and immediate OP agent poisoning
13 (Ames et al.; Steenland et al.).

14 Some OP pesticides that are no longer sold in the United States have been associated with
15 human cases of a second type of delayed toxic effect called organophosphate-induced delayed
16 neurotoxicity (OPIDN, sometimes referred to as delayed neuropathy). Initial symptoms are muscular
17 incoordination progressing to numbness, tingling, fatigue or a cramp-like pain in the calf muscles,
18 and even moderate to severe muscular weakness and paralysis (Barrett and Oehme; Klaassen).
19 Typically, effects occur 7 to 14 days following recovery from immediate and severe poisoning by the
20 OP pesticide and involve neuropathologic lesions and degeneration of the nerve axon and myelin

nerve sheath in both the central and peripheral nervous systems (Klaassen); these effects are easy to measure in a clinical setting. In general, OPIDN caused by OP pesticide poisoning is associated with immediate poisoning symptoms.

All OP pesticides sold in the United States today are routinely screened for OPIDN toxicity with a standardized hen assay used by EPA; the hen is a laboratory animal especially sensitive to OPIDN effects. For some OP agents, these effects only can be observed by giving the hen extremely high doses that would rapidly lead to death, but then keeping the hen alive through the use of protective drugs such as atropine. Many investigators conclude that any OP agent theoretically could cause this effect at sufficiently high doses, but that in fact, their immediate toxic effects would cause death before delayed effects could be seen (Klaassen). None of the pesticides DOD shipped to the Gulf War generally cause OPIDN in humans. At doses that cause nearly lethal, immediate, and severe toxic effects, some of the OP pesticides shipped might lead to OPIDN in humans.

Methyl carbamate pesticides. Methyl carbamate insecticides shipped for use during the Gulf War included propxur (Baygon®), carbaryl (Sevin®), and methomyl (Lannate®). These insecticides reversibly inhibit the enzyme acetylcholine esterase, which leads to poisoning effects similar to OP poisoning. Poisoning with methyl carbamates tends to be of much shorter duration—with a greater margin of safety between symptom-producing and lethal doses—compared to OP pesticides, which bind permanently with acetylcholine esterase.

1 **Pyrethroid pesticides.** DOD shipped the pyrethroid insecticide permethrin to the Gulf for use as an
2 insect repellent. Permethrin is used widely in the United States as the active ingredient in personal
3 care products, such as shampoos and lotions, and for treating clothes to make them insect repellent.
4 There are few reported poisonings of humans by permethrin, probably because such a large dose is
5 required to cause poisoning. Humans rapidly detoxify and excrete permethrin. Clinical signs of
6 immediate permethrin poisoning following large oral doses become evident within 2 hours and
7 include incoordination, ataxia, hyperactivity, and convulsions, followed by prostration, paralysis, and
8 death (NRC 1994). Unlike OP pesticides, the Committee found no reports of long-term effects from
9 permethrin poisoning in humans.

10 A National Research Council (NRC) subcommittee that reviewed possible health problems
11 for military personnel wearing permethrin-treated military clothing concluded it is unlikely that
12 soldiers using such uniforms would experience adverse health effects at the suggested exposure
13 levels. The subcommittee concluded, “the weight of evidence shows that permethrin is unlikely to be
14 a skin irritant or skin sensitizer for military personnel who are exposed to it dermally from wearing
15 permethrin impregnated [uniforms].” The estimated “no observable adverse effect level” for
16 immediate neurotoxic effects in humans from daily exposure is 200 mg/kg, which is approximately
17 3 million times greater than estimated dermal exposure from permethrin treated uniforms (NRC
18 1994). NRC’s worst-case estimate of lifetime carcinogenicity risk for humans wearing permethrin
19 treated uniforms was less than 2 in 1,000,000.

1 In laboratory animal studies, dermal absorption of permethrin is low, although scientists
2 observe neurotoxic effects if the substance is injected (EPA 1989, NRC 1994). Most, but not all,
3 studies have reported that permethrin does not cause damage to genetic material in a wide variety of
4 standard measurement systems. Permethrin is neurotoxic to laboratory animals at high oral doses.
5 Rats fed permethrin at 6,000 mg/kg for 14 days showed fragmented and swollen sciatic nerve axons
6 and myelin degeneration. However, nerve conduction studies in 23 permethrin workers showed no
7 evidence of nerve impairment associated with permethrin exposure (NRC 1994). Rodent bioassays
8 of chronic exposure to permethrin showed carcinogenic effects, such as liver and lung adenomas and
9 lung carcinomas in mice, but data on human carcinogenicity of permethrin are lacking.

10 **Organochlorine pesticides.** DOD shipped one organochlorine pesticide, lindane, to the Gulf region.
11 Lindane, once widely used as an agricultural insecticide in the United States, is still available as a
12 lotion to treat head and body lice and scabies (EPA 1989; ATSDR 10/92). Lindane is dermally
13 absorbed, stored in body fat, and only slowly leaves the body. Reports document that a few people
14 who have used large amounts of lindane on their skin have had blood disorders and even seizures.
15 Under conditions of extremely high exposure, lindane can cause liver and kidney disease.

16 Some pregnant laboratory animals orally treated with the maximum tolerated dose (the dose
17 just below that causing immediate and severe toxicity) showed a statistical increase in the number of
18 fetuses with extra limbs, indicating that lindane is a teratogen for this laboratory animal strain.
19 Lindane has not been shown to be a human carcinogen, although long-term oral exposure of lindane

1 to certain species and strains of laboratory rodents has been reported to cause liver cancer (ATSDR
2 10/92). Hence, DHHS has determined that lindane should be viewed as a human carcinogen.

3 DEET. DEET, first introduced in 1955, continues to be a widely used liquid insect repellent in the
4 United States and DOD shipped approximately two 2-oz tubes per U.S. service member during the
5 Gulf War. According to EPA, 50 to 100 million Americans use DEET-containing insect repellents
6 annually. Relative to most pesticides, DEET has notably low immediate toxicity (EPA 1989; Osimitz
7 & Grothaus). Although generally well tolerated when used as an insect repellent applied to human
8 skin, about five to nine percent is absorbed through skin, and reports of tingling, mild irritation, and
9 occasional skin peeling following repeated application exist (EPA 1989). Topically applied DEET is
10 rapidly eliminated, mostly in the urine. In the past 35 years there have been a few reports in medical
11 literature suggesting rare neurotoxic effects (Osimitz). In adult humans, ingestion of enormous doses
12 of DEET has been associated with immediate toxic effects including tremors, generalized seizures
13 and coma, although no long-term effects of poisoning have been reported (Verschoyle 1991). (See
14 the section on PB for discussion of possible toxic interactions.)

15 Rats continuously fed DEET up to the maximum tolerated dose over three generations
16 showed a slight increase in the high-dose animals in a single neurological abnormality—a slight
17 increase in exploratory locomotor activity—and no histopathologic central nervous and peripheral
18 nervous system changes of significance (Osimitz). Other reports indicate that rats fed the maximum
19 tolerated dose of DEET can show severe and often fatal prostration accompanied by a brain
20 myelinopathy (Verschoyle 1991).

1 **What do we conclude about the risks of pesticides to Gulf War veterans?** According to DOD, after-
2 action reports from the in-theater medical personnel did not reveal any U.S. troops complaining of
3 symptoms that would indicate pesticide poisoning. Evidence from studies of humans poisoned by OP
4 pesticides suggests that low-level exposures to these agents that do not cause immediate and severe
5 poisoning signs and symptoms will not result in long-term health effects. Thus, the Committee
6 concludes it is unlikely that health effects and symptoms reported today by Gulf War veterans are the
7 result of exposure to pesticides during the Gulf War. Lindane is an animal liver carcinogen, but it is
8 too early to see an elevated liver cancer rate in Gulf War veterans.

9 **Chemical Warfare Agents**

10 At the time of the Gulf War, the U.S. military believed Iraq had weapons that could deliver OP nerve
11 agents, including sarin, soman, and VX, and mustard (blister) agents. Hence, U.S. forces were
12 supplied with protective gear, detectors, and prophylactic drugs to protect against the known
13 consequences of exposure.

14 **Immediate signs and symptoms of nerve agent poisoning.** OP nerve agents are designed to
15 incapacitate and kill humans. Inhalation exposure to these agents leads to immediate effects
16 including miosis, runny nose, and increased salivation. Immediate effects following skin exposure
17 include local sweating and muscle twitching. Eye exposure rapidly produces miosis, which often is
18 associated with eye pain, headache, and blurred vision. In fact, miosis is the most sensitive and
19 specific immediate response to acute poisoning in humans, and this reaction has served as the basis
20 for establishing allowable occupational concentrations for CW nerve agents. Higher doses of these

agents cause more severe effects, including convulsions, neuromuscular blockage, profuse airway obstruction and apnea—developing within one to two minutes of exposure (Gunderson). Death occurs due to respiratory paralysis. The effects of nerve agent poisoning are virtually identical to those of severe OP-pesticide poisoning.

Data on human effects of CW nerve agent poisoning derive largely from human experiments carried out by the U.S. Army from the 1940s to the 1960s. Table 4-2 illustrates the type of information on immediate poisoning effects from low-level exposures to the OP nerve agent sarin.

Table 4-2—Reactions of Human Volunteers Who Had Various Immediate Effects From Low-level Inhalation Exposure to Sarin (McNamara and Leitnaker)				
Air concentration of sarin (mg min/m ³)				
	1	2	4	6
Effect	Percentage of exposed human volunteers showing the effect			
Miosis	7	50	50	100
Runny nose	17	80	100	100
Tight chest	4	80	100	100
Headache	20	7	5	50
Eye pain	17	0	0	54
Eye-lid twitch	0	4	4	4
Throat irritation	3	0	11	23
Sweating	0	0	0	18
Flu-like symptoms	10	0	27	59

Immediate signs and symptoms of mustard agent poisoning. With mustard agents, poisoning symptoms are severe irritation and tissue damage to eyes, skin, and respiratory and gastrointestinal (GI) tracts. Usually the onset of symptoms is delayed for some hours after exposure.

One report of Iraqi use of mustard agent against Iranian troops in 1984 documented health effects in more than 5,000 Iranian casualties. Affected individuals had first to third degree burns over 20 to 70 percent of the total skin surface. Eye exposure caused tearing, severe conjunctivitis, and temporary loss of vision. Corneal abrasion was nearly always present, and photophobia and blurred vision developed in some cases. Upper airway involvement due to chemical burning of the throat led to pharyngitis and tracheobronchitis. These effects were quite severe, and this group suffered approximately 15 percent mortality. Those who survived the initial symptoms later experienced various GI complaints, including nausea, vomiting, and diarrhea. After 5 to 7 days, hematologic problems were the greatest health threat to survivors (Kadivar and Adams 1991).

Long-term health effects of high-level exposure to CW nerve agents. Two NRC reports addressed possible long-term morbidity and mortality in about 1,400 servicemen intentionally exposed to CW nerve agents in experiments conducted over a 20-year period ending in 1975. The possibilities of excess cancer risk and adverse mental, neurologic, hepatic, and reproductive effects were reviewed. Both NRC analyses concluded that no evidence exists that CW nerve agents cause long-term, adverse human health effects at the doses tested. The doses were nonlethal, but were high enough to cause clinical effects (such as miosis). NRC reported that both analyses had the power to detect any major health effects had they been present. A statistically significant increase in admissions to VA hospitals

for malignant neoplasms was detected, with the caveat that admission numbers were small, showed no dose relationship, and no clustering of specific chemicals in relation to tumor site (NRC 1982; NRC 1985).

Numerous studies in humans and animals report that survival from severe, immediate poisoning by OP nerve agents (including OP pesticides) can be associated with measurable, long-term neurological effects. One study of 77 industrial workers exposed to levels of sarin that caused immediate toxicity showed slight alterations in electroencephalograms (EEGs) one year after exposure. The study also reported, however, that trained experts could not distinguish EEGs of exposed individuals from EEGs for controls, and that no clear relationship existed between alterations in EEG frequency spectrum and alterations in brain function (Burchfiel). A 1975 review by Lohs of the effects of CW agents in humans similarly reported long-lasting effects following severe, immediate OP pesticide and CW agent poisoning (Lohs).

CW nerve agents do not show OPIDN toxicity as measured in EPA's standardized hen bioassay for evaluating OP pesticides, except with extremely high doses (10 to 100 times the lethal dose) where immediate and severe toxic effects, including death, are seen. Because OP CW nerve agents are chemically similar to OP pesticides and affect the same enzyme system in the body, similar long-term health effects would likely occur in the aftermath of immediate, severe poisoning with sarin, soman, or VX—i.e., the subtle, but measurable, neurophysiological and neurological effects described earlier in this chapter. Again, these health effects did not occur in populations that had been exposed to subclinical amounts of OP pesticides. Current scientific evidence suggests that

1 subclinical exposure to OP CW nerve agents does not result in long-term neurophysiological and
2 neurological health effects (NRC 1982 and 1985). Ongoing research at the Boston Environmental
3 Hazards Research Center is investigating the possibility of such effects in Gulf War veterans.

4 As described in the previous section on the health effects of pesticides, severe OP agent
5 poisoning can cause long-term neuropsychological effects, although such effects are not expected in
6 cases of subclinical exposure. Ongoing research at the Boston and Portland Environmental Hazards
7 Research Centers will investigate the possibility of such effects in Gulf War veterans.

8 **Long-term health effects of high-level exposure to mustard agents.** Based on epidemiologic research,
9 humans exposed to mustard agent are at increased risk for lung cancer (NRC 1993; ATSDR 9/92).
10 Several other reviews of human exposure to mustard agent during World War I and other wars also
11 indicate veterans exposed to mustard agents during the Gulf War could experience other respiratory
12 problems as well (NRC 1993; ATSDR 9/92).

13 During World War II (WWII), more than 60,000 U.S. service members were used as human
14 test subjects and exposed to mustard agents, including at least 4,000 individuals exposed to high
15 concentrations of these agents (NRC 1993). A review by the Institute of Medicine (IOM) concluded
16 that several specific chronic diseases are causally associated with mustard agent exposure. These
17 include various respiratory cancers, skin cancer, chronic skin ulceration and scar formation, chronic
18 respiratory disease including asthma, chronic bronchitis, emphysema, chronic eye diseases, and
19 various psychological disorders including PTSD. IOM also found suggestive evidence (weaker than

the associations for the conditions just mentioned) that exposure to mustard agent was associated with leukemia and reproductive dysfunction (NRC 1993).

What do we conclude about the risks of CW agents to Gulf War veterans? Current scientific literature indicates that when exposure to OP CW agents results in immediate and severe poisoning, long-term, subtle neuropsychologic and neurophysiologic effects could occur. Available scientific evidence does not indicate that such long-term effects occur in humans following subclinical exposure levels, but the amount of data from either human or animal research on subclinical exposures is minimal. Long-term effects in humans exposed to mustard agents include an elevated risk of lung cancer beginning decades after exposure. The Committee concludes it is unlikely the health effects reported by Gulf War veterans today are the result of exposure to OP or mustard CW agents during the Gulf War. Ongoing or planned federally-funded studies focused specifically on subclinical exposures and delayed neurotoxicity of CW agents should eliminate any uncertainty from this conclusion and/or identify new directions for research.

Biological Warfare Agents

The U.S. military prepared for the possibility that Iraq might use two BW agents—anthrax and botulinum toxin—against U.S. service members during the Gulf War. After the war, new data revealed Iraq had also weaponized aflatoxin. The Committee evaluated the potential health effects of these three BW agents on the long-term health of Gulf War veterans.

1 **Anthrax.** Anthrax is a bacterial disease most often found in cattle and sheep. Human infection can
2 occur by contact with infected animals or by inhalation of spores from infected animal products (e.g.,
3 as hides or wool). Left untreated the disease usually is fatal. After exposure, the anthrax bacteria
4 travel to the intestines and other areas where they cause severe tissue damage. Initial symptoms
5 include nonspecific malaise, low grade fever, and non-productive cough. Initially, anthrax can be
6 difficult to diagnose because symptoms, although severe, are not specific (Johnson-Wineger 1995).
7 As the disease progresses, symptoms include high fever, labored breathing, choking cough, and
8 vomiting; death usually occurs within 4 days (OTA 1993). Terminal symptoms include abrupt onset
9 of shortness of breath, harsh breathing, skin turning blue, excessively rapid heartbeat, and rapid
10 progression to shock and death. Cases of pulmonary anthrax caused by inhalation of aerosolized
11 spores (which would be the case in a military use) are almost invariably fatal if not treated
12 immediately with antibiotics. Exposure to small numbers of infecting spores can increase the
13 incubation time of the disease from a few days to several weeks, but if infection occurs, the disease
14 progresses toward death in the same manner as for high level exposure (OTA 1993, Johnson-Wineger
15 1995). No long-term effects have been reported in persons successfully treated for anthrax.

16 **Botulinum toxin.** Botulinum toxin is a group of related, highly poisonous protein agents isolated from
17 fermentation of the bacterium *Clostridium botulinum*, which naturally occurs in soil and can grow in
18 many meats and vegetables. Botulinum toxin is fast-acting, usually producing symptoms within 18
19 to 36 hours after ingestion. Death occurs in 80 percent of an exposed population after 1 to 3 days
20 (OTA). Botulinum toxin blocks neuromuscular conduction by binding to receptor sites on motor

nerve terminals and by inhibiting the release of acetylcholine. Symptoms at high exposure levels can include respiratory distress and respiratory paralysis, which may persist for 6 to 8 months (Klaassen). Disability progresses from difficulty in walking and swallowing and impaired vision and speech to convulsions. Ultimately, symptoms include paralysis of the respiratory muscles, suffocation, and death—all within a few hours or days, depending on the amount of toxin ingested (OTA 1993). In cases of accidental exposure in the general population, the fatality rate is 35 to 65 percent and is fatal in 3 to 10 days (Klaassen). Botulism antitoxin can be effective if administered within days of exposure (OTA 1993). The Committee found no scientific literature suggesting adverse long-term health effects from low-level exposure to botulinum toxin.

In fact, botulinum toxin has conventional medical therapeutic uses. Botox[®] is an FDA-approved, purified, type A botulinum toxin, and injecting it into the muscle of patients causes a localized, temporary denervation and muscle paralysis. Such an effect is therapeutically useful for treating a number of conditions, including blepharospasm (an involuntary recurrent spasm of both eyelids) and for use in certain types of eye surgery. Studies on thousands of adults treated with Botox[®] have shown only mild side effects—e.g., a diffuse skin rash lasting several days—as a result of the localized muscle paralysis effects of the toxin. The only long-term effect reported is a slight reduction in the effectiveness of BT vaccine due to a person's natural immune responses.

Aflatoxin. Aflatoxin is a naturally occurring toxic metabolite from certain fungi that sometimes occur on grains, peanuts, and other foods stored under certain conditions (Klaassen). Aflatoxin ingestion can result in immediate, toxic effects in many different species, and death results from acute liver

1 toxicity (Chemical Carcinogens; Klaassen). Aflatoxicosis in humans has been reported following
2 ingestion of aflatoxin contaminated food, and symptoms include vomiting, abdominal pain, pulmonary
3 edema, gastrointestinal hemorrhage, convulsions, coma, and death (Chemical Carcinogens). Several
4 epidemiologic studies suggest aflatoxin causes liver cancer in humans. The only documented health
5 effect that could be expected from low-level exposure to aflatoxin would be an increased prevalence of
6 liver cancer years to decades after exposure.

7 **What do we conclude about the risks of BW agents to Gulf War veterans?** In cases where an individual
8 survives exposure to anthrax or botulinum toxin, no known, long-term health consequences exist.
9 Aflatoxin, however, is a liver carcinogen, and increased rates of liver cancer could result decades
10 following low-level exposure. The Committee concludes it is unlikely the health effects reported
11 today by Gulf War veterans are the result of BW agent exposure.

12 **Anthrax and Botulinum Toxoid Vaccines**

13 Before U.S. troops deployed to the Gulf region, they received a standard series of inoculations against
14 infectious diseases—e.g., cholera, typhoid, tetanus, diphtheria, polio, and measles—that might be
15 given to any U.S. citizen traveling to these regions. After arriving in the Gulf War region, some U.S.
16 service members received two additional vaccines for protection against the BW agents anthrax and
17 botulinum toxin.

18 **Anthrax vaccine.** In 1971, FDA licensed anthrax vaccine to protect civilian workers against possible
19 infection by anthrax bacteria. Since 1967 and before the Gulf War, more than 20,000 inoculations had
20 been routinely administered to at-risk populations, including laboratory personnel who work with the

bacteria that causes anthrax, persons in industries that work with animal hides and wool (which can be a source of anthrax infection), and veterinarians who come in contact with anthrax-infected animals.

Although long-term safety surveillance is not generally part of the FDA vaccine licensing process, the law requires that U.S. health care providers and manufacturers report serious adverse reactions for all licensed vaccines (FDA regs). FDA has not received data that raise concerns about the safety of the anthrax vaccine.

Historical data for short-term health effects of the anthrax vaccine indicate up to six percent of recipients experience mild discomfort, including tenderness, redness, swelling or itching at the inoculation site for up to 72 hours. Fewer than one percent experience a more severe local reaction that potentially limits the use of the arm for 1 to 2 days. Systemic reactions, e.g., fever, malaise, are uncommon (about 0.1 percent) (Johnson-Winegar 1996 and 1995).

According to DOD, medical monitoring and surveillance conducted during the Gulf War found the expected short-term side effects of anthrax vaccines occurring at approximately the historical rates (Eitzen). A single hospitalization for a vaccination site infection was reported. DOD points out that precise information about all possible short-term side effects is unknown, however, because of difficulties in collecting such data during and after the Gulf War.

Botulinum toxoid vaccine. Botulinum toxoid (BT) vaccine has been used for more than 25 years to protect industry and laboratory workers from occupational exposure to the extremely poisonous botulinum toxins. All civilian vaccinations have been administered under an investigational new drug

1 (IND) application sponsored by CDC. For both civilian and military use, BT vaccine remains in
2 “investigational” status—i.e., not yet licensed by FDA.

3 Since 1970, as part the IND evaluation, FDA has reviewed information from CDC about the
4 cumulative safety record for BT vaccine. Records of more than 10,000 administered vaccine doses
5 (including approximately 2,200 in the five years before the Gulf War) indicate that treated individuals
6 experience only local side effects often associated with many types of vaccinations. These effects,
7 primarily at the injection site, include local pain, tenderness, swelling, redness, and itching. Systemic
8 reactions such as temporary fever, tiredness, headache, or muscle pain also can occur. Rarely,
9 reactions include soreness of the arm sufficient to leave individuals unable to perform duties for a day
10 or two or development of a lump at the injection site that generally resolves within several weeks.
11 Such adverse reactions also are observed with other licensed toxoid vaccines, such as diphtheria and
12 tetanus toxoids (Eitzen; J-W 1996).

13 The U.S. Army examined the frequency of side effects of BT vaccinations seen in some U.S.
14 service members. In one report of 237 Gulf War veterans who had received BT vaccine, 2.5 percent
15 had systemic reactions. This rate parallels that recorded by the U.S. Army and CDC prior to the Gulf
16 War (Langford).

17 **Precautions against contaminants.** The Committee examined the hypothesis that Gulf War veterans’
18 illnesses could be the result of contamination of anthrax vaccine lots by *Mycoplasma incognitus*
19 (Nicholson). Discussions with staff of FDA, Walter Reed Army Medical Center, U.S. Army Medical
20 Research and Material Command, academic experts, and the manufacturer of the vaccines indicate that

Mycoplasma could not survive in the anthrax and BT vaccines (Lewis 1996a; Lo; FDA fact sheet; Myers).

Mycoplasma is difficult to grow, and the culture media used to produce Anthrax and BT vaccines do not contain serum, an essential ingredient for *Mycoplasma* growth. In addition, the vaccines are preserved and/or processed with other products that create a hostile environment for *Mycoplasma*, including:

- formaldehyde (Anthrax and BT vaccines),
- benzethonium chloride (Anthrax vaccine only),
- isotonic saline solution (BT vaccine only), and
- Thimerosal (BT vaccine only).

The Committee concludes it is unlikely that *Mycoplasma* organisms contaminated anthrax vaccine or BT vaccine.

Health effects of multiple vaccines. The human immune system has evolved the capability to deal with thousands of foreign substances, to sort them out, and to regulate immune response. Humans live among a vast population of hostile microorganisms, and vaccinations—even multiple, contemporaneous vaccinations—are a small part of total immune stimulation. Individual vaccines can cause adverse effects, but several studies of the effects of giving multiple vaccinations at one time have found no adverse effects associated with the practice. Research on this issue continues, but based on

1 available evidence, the Committee believes it is unlikely that multiple vaccines are responsible for
2 illnesses reported today by Gulf War veterans (Russell, Pitman 1995 and 1996).

3 **What do we conclude about the risks of vaccines to Gulf War veterans?** The Committee concludes it is
4 unlikely that health effects reported by Gulf War veterans result from the BT or anthrax vaccines, used
5 alone or in combination.

6 **Pyridostigmine Bromide**

7 PB is a pretreatment drug used to protect against the CW nerve agent soman. By itself PB is not
8 protective against CW nerve agent poisoning. Used as a pretreatment, however, PB can enhance the
9 antidote effects of the standard atropine and 2-PAM treatments used by the U.S. military for nerve
10 agent poisoning (MSDS 12/90).

11 Since 1955, FDA has approved PB for use by persons suffering from myasthenia gravis. No
12 long-term health problems thought to be associated with PB have been reported for persons with
13 myasthenia gravis who regularly take PB over many years or decades (Penn; Sander/MG Foundation
14 Medical Board). DOD filed a New Drug Application in May 1996, but PB currently has the status of
15 an IND for nerve gas pretreatment use.

16 According to FDA, its conclusion that PB was safe for use by U.S. service members during the
17 Gulf War was based largely on the extensive cumulative experience with this drug in patients with
18 myasthenia gravis. Typically these patients are treated with PB doses of up to 1,500 mg per day for
19 many years, compared to the prescribed dose of 90 mg per day for a maximum of seven days use

1 during the Gulf War. Reported side effects of PB include increased salivation, increased tearing,
2 urinary urgency and frequency, nausea, vomiting, muscle weakness, abdominal cramps and diarrhea
3 (MG Foundation Phys. Man.). These effects disappear when individuals stop taking PB.

4 Data from one DOD retrospective study on 30 medical support officers of the 18th Airborne
5 Corps reveal a similar range of short-term health effects from PB. The 18th Airborne Corps instructed
6 1,650 soldiers (6.5 percent women) to take PB tablets at the onset of Operation Desert Storm in
7 January 1991. Half those surveyed reported gastrointestinal symptoms, 5 to 30 percent reported
8 increased urinary urgency and frequency, and fewer than 5 percent reported headaches and tingling of
9 extremities. The need for a medical visit was reported by less than 0.1 percent, and the decision to
10 discontinue use based on medical advice was reported by less than 0.1 percent. As with myasthenia
11 patients, DOD reported that side effects ceased when PB use was discontinued (Keeler 1991). Other
12 retrospective studies found similar results (DOD/USA, Clawson).

13 A survey of 213 Israeli soldiers asked about possible symptoms of PB and their severity. The
14 most frequent health complaints reported were generally mild and nonspecific, including dry mouth,
15 general malaise, fatigue, and weakness, which appeared about 1.6 hours after taking the medication
16 and recurred after each intake. For this group the typical side effects associated with PB, such as
17 nausea, abdominal pain, frequent urination and runny nose, were infrequent (Sharabi).

18 DOD recently completed a study begun in November 1994 that looked at differential
19 tolerances to PB between women and men (RWG/AR, Lasseter and Garg 1996). Ninety subjects,
20 equally divided by gender and in three weight classes, took 30 mg of PB every 8 hours for 21 days

(plus one dose). PB was found to be safe and well-tolerated. All side effects were mild and resolved with no intervention. Headaches, dizziness, nausea, rash, and hair loss were reported in both drug and placebo groups. Diarrhea and abdominal pain were reported in the PB group only (four study participants). Overall, the occurrence of adverse effects did not differ between active and placebo subjects, nor were differences observed among gender or weight groups. Results from a one-year follow up, indicated no long-term effects except possibly a skin rash that resolved with treatment (Lewis 1996).

DOD continues to seek FDA approval to use PB for the protection of U.S. troops against CW agents. To support this approval process, DOD has (since 1984) sponsored various research efforts to gather information on the effects of PB pretreatment on healthy individuals. To date, DOD reports no serious or long-term reactions from this research.

Genetic predisposition to PB sensitivity. Some scientists suggest that persons who are genetically unable to produce the plasma enzyme butyryl cholinesterase (BuChE) could be more sensitive to PB's known side effects, and at least one apparent case has been reported (Lowenstein-Lichtenstein 1995). The estimated frequency in the general population of persons unable to produce BuChE is about 0.03 percent. Exposure to PB (or similar compounds) could cause immediate and marked health effects in these individuals. Based on studies of PB-related compounds in BuChE deficient individuals, however, symptoms vanish when exposure to PB is removed. Limited population genetic data indicate that about four percent of all people have slightly reduced ability to produce functional

1 cases of malaria and one case of West Nile fever, a mosquito-borne viral illness. No rickettsial
2 illnesses and no cases of other arthropod-borne viral illnesses were identified.

3 Viscerotropic leishmaniasis (VL) and cutaneous leishmaniasis (CL) are the only endemic
4 infectious diseases demonstrated to cause chronic morbidity among a number of Gulf War service
5 members. These diseases are transmitted through the bites of sand flies; person-to-person infection
6 does not occur. Thirty-two cases of leishmaniasis were diagnosed among U.S. troops, including 12
7 cases of VL and 20 cases of CL (Magill 1996; CCEP 1996). CL causes a characteristic ulcerative or
8 nodular skin rash that can persist for more than a year without treatment. And, while VL can be
9 difficult to confirm, it is not considered to be a cause of widespread illness in Gulf War veterans. All
10 veterans diagnosed with VL, except one, have experienced the signs characteristic of the disease,
11 including high fever, lymphadenopathy, hepatomegaly, and/or splenomegaly (Hyams 1995; Magill
12 1993; PGVCB 1995).

13 It is unlikely that veterans in the Registry or CCEP who have unexplained illnesses are
14 suffering from VL. The incidence of VL during the Gulf War and the five years since has been low
15 (12 of 697,000), and other sandfly-borne infectious diseases in the troops have been absent (Hyams
16 1995; CCEP 1995). Additionally, individuals with unexplained illnesses also lack signs and symptoms
17 characteristic of VL. VL can sometimes occur following a prolonged incubation period (more than 18
18 to 24 months); there is also a risk of activation of latent infections in immunosuppressed persons
19 (Gasser 1991; Hyams 1995; Magill 1993). To date, DOD and VA report that delayed onset of VL has
20 not occurred.

1 From August 1990 through July 1991, the U.S. Army deployed approximately 347,000
2 individuals to the Gulf region. Based on information from U.S. Army field hospitals, the only
3 infectious diseases that caused 30 or more each of approximately 14,000 admissions were pneumonia,
4 intestinal infections, inflammation of the testes and/or epididymus, chicken pox, and kidney infections
5 (Writer 1996).

6 **What do we conclude about the risks of infectious diseases to Gulf War veterans?** Based on a review
7 of the rates and types of the diseases diagnosed during and after the Gulf War, the Committee
8 concludes it is unlikely that infectious diseases endemic to the Gulf region are responsible for long-
9 term health effects in Gulf War veterans, except in a small, known number of individuals.

10 **Depleted Uranium**

11 Uranium is a naturally occurring, chemically toxic, and radioactive element made up of a mixture of
12 isotopes. Relative to other radionuclides, uranium is only slightly radioactive because of its low
13 specific activity (ATSDR 12/90). When the uranium isotope used for nuclear reactors and weapons is
14 extracted from natural uranium, DU is the byproduct.

15 DU is nearly twice as dense as lead—a property used to improve the performance of both
16 armor and armor penetrating munitions. During the Gulf War, some U.S. tanks and U.S. aircraft fired
17 DU munitions, which produced shrapnel and an aerosolized dust on impact with armor or on ignition
18 in accidental munitions fires. DU retains natural uranium's toxicological properties and approximately
19 half its radiological activity (AEPI). Most of DU's radiation cannot penetrate skin, and DU poses
20 little threat to human health while it is external to the body (ATSDR 12/90).

1 Because it is slightly radioactive, uranium is considered to be a potential carcinogen—albeit
2 with a small cancer risk relative to other radionuclides (ATSDR). Taken together, human and animal
3 studies do not indicate that natural uranium causes cancer in humans. Epidemiologic studies of
4 uranium miners experiencing extremely high, lifetime, occupational exposures to uranium show an
5 increase in mortality due to lung cancer, but such cancers are thought to be caused by miners’
6 concurrent exposures to radioactive radon gas and its decay products, tobacco smoke, silica and other
7 dusts, or exhaust fumes from diesel engines (Voelz 1996, BEIR IV). Animal studies conclude that
8 exposure to uranium for long periods of time does not result in increased incidence of cancer, except
9 in the case of one study. This study found prolonged (more than five years) inhalation of high levels of
10 uranium dioxide led to lung neoplasms in dogs (Leach 1970 and 1973).

11 The chemical toxicity of uranium as a heavy metal is well characterized. In fact, the kidney is
12 the most sensitive organ affected by exposure to uranium and is the critical target organ for risk
13 assessment. For this reason, uranium exposure is regulated based on its chemical toxicity and not its
14 radiological properties (McGuire). Even so, more than 50 years of occupational health data from
15 uranium miners reveal little epidemiologic evidence of excess kidney disease among workers exposed
16 for years or decades (Voelz 1992).

17 The health risks of internalized uranium or DU particles depend on dose, exposure pathway,
18 and solubility of the ingested particle. Ingestion of insoluble uranium compounds poses little health
19 hazard because they pass rapidly through the body and are eliminated in the feces. However, animal
20 studies have shown that ingestion of large doses of relatively soluble uranium compounds are

1 associated with kidney toxicity (Layton and Armstrong; ATSDR). Inhaled uranium particles that are
2 nonrespirable are cleared from the respiratory tract and either expelled from the body (cough) or
3 swallowed and passed to the GI tract. Respirable and relatively soluble particles are cleared to blood
4 and can affect kidney toxicity (Bohning, L&A). Less soluble particles can remain in the lung longer
5 and in theory could pose a radiological hazard. The U.S. Army has conducted tests to characterize
6 aerosols associated with DU munitions impacts with armor and with accidental DU munitions fire; it
7 concluded a service member's risk exceeds civilian safety standards only when he or she is inside a
8 vehicle when it is penetrated by DU munitions (Daxon, IOM). The adequacy of the research
9 supporting this conclusion has been questioned by some reviewers (Shelton, AEPI).

10 No studies of long-term human health effects of uranium metal implanted in tissues exist.
11 Nevertheless, toxic effects are likely to be similar to the kidney toxicity observed from inhaled or
12 ingested uranium. To date, VA has reported no kidney toxicity among soldiers wounded by DU
13 fragments in friendly fire episodes (Keogh). VA currently monitors the health of approximately 30
14 veterans suspected of retaining embedded DU fragments, and the U.S. Army Medical Research and
15 Materiel Command is funding animal studies to investigate the health hazards associated with short-
16 and long-term exposure to DU metal fragments (RWG/AR 1995).

17 **What do we conclude about the risks of DU to Gulf War veterans?** The Committee concludes it is
18 unlikely that health effects reported by Gulf War veterans today are the result of exposure to DU
19 during the Gulf War. Since uranium is a potential carcinogen, it is possible that exposure to DU

during the Gulf War could lead to a slight increase in the risk for lung cancer after decades following the end of the war.

Oil-well Fire Smoke

At the end of the Gulf War, more than 600 Kuwait oil wells and several pools of spilled oil were left burning after being ignited by retreating Iraqi troops. Huge, dramatic plumes of billowing smoke from these fires rose high into the atmosphere. Occasionally the smoke remained low to the ground, in some cases enveloping U.S. military personnel.

Some chemicals contained in oil-well fire smoke, such as benzene and PAHs, are human carcinogens. As described earlier in this chapter, the amounts of these pollutants in the air were low. Hence, their contribution to excess cancer risk would be expected to be small and increased rates of cancers likely would not result. The U.S. Army used EPA's standardized methodology to estimate cancer and noncancer risks from the oil-well fire smoke (USAEHA 1994). It concluded "the potential for significant long-term adverse health effects for the exposed DOD troop or civilian employee populations is minimal." Risks from cancers were estimated not to exceed two excess cancers per one million people exposed, a value well within EPA's acceptable range.

Noncancer risks from smoke exposure were calculated as Hazard Indices (HI). When the HI exceeds 1.0, there can be concern about potential noncarcinogenic health effects. In Saudi Arabia, the HI ranged from 0.6 to 2.0, while in Kuwait it ranged from 2.0 to 5.0. Most of this noncancer risk was contributed by inhalation of volatile organic compounds, particularly benzene. The U.S. Army concluded that risk of noncarcinogenic health effects among the U.S. service members was low since

1 HIs are based on EPA toxicity values that are set far below levels thought to cause health effects and
2 that also account for sensitive subpopulations such as children and the elderly. A congressional Office
3 of Technology Assessment analysis of the U.S. Army's risk assessment methods and findings
4 concluded "the risks to health from exposure to the smoke and the background air contaminants in the
5 Persian Gulf are likely to be extremely small" (OTA, 1994).

6 Oil-well fire smoke appears not to have caused observable changes in lung tissue. Researchers
7 at the Armed Forces Institute of Pathology found no significant differences in lung tissue in autopsies
8 of 33 U.S. service members who died after the start of the oil well fires (Mullick 1996).

9 Information has been gathered from 110 firefighters working for private companies examined
10 before and after each firefighting tour of duty. Individuals were deployed for 28-day periods, working
11 daily at the well heads without breathing protection equipment. Most were over 30 years old and had
12 10 or more years experience fighting similar well fires, many of them in Kuwait and elsewhere in
13 Southwest Asia. No cases of illnesses resembling those reported by Gulf War veterans were reported,
14 nor have such complaints been observed among thousands of oil-well firefighters who have spent years
15 experiencing similar exposures (Friedman 1994 and 1996).

16 Known immediate health effects from inhaling large amounts of smoke and particulates are
17 primarily respiratory, including coughing, wheezing, increased airway resistance, and respiratory
18 infections. Toxic gases that can be found in oil-well fire smoke—such as hydrogen sulfide and sulfur
19 dioxide—can cause eye and nose irritation, decreased pulmonary function, and increased airway
20 reactivity (Utell and Frampton, 1992; Naval Medical Research Institute, 1991). Nevertheless, these

toxic gases were not detected at high levels during the fires (WMO 1992; EPA 1991; Husain 1995; DHHS 1991). High levels of airborne particulates, which sometimes occurred in the Gulf region, are associated with increased rates of asthma and can exacerbate other chronic respiratory conditions. With chronic (months or years) exposure to particulates, there is increased risk of some loss in lung function or chronic bronchitis, especially in cigarette smokers.

What do we conclude about the risks of oil-well fires to Gulf War veterans? Based on research on human and animal health effects of exposure to air pollutants, the Committee concludes it is unlikely exposure to oil-well fire smoke is responsible for symptoms reported today by Gulf War veterans.

Petroleum Products

Diesel, kerosene, gasoline, jet fuel, and other petroleum based fuels were widely used during the Gulf War for dust suppression, waste incineration, and for fueling vehicles, stoves, heaters and generators. U.S. service members in certain jobs were occupationally exposed to petroleum fuel vapors and combustion products, such as toluene, xylene, benzene, ethyl benzene, carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants. Additionally, in some areas near the Kuwait oil well fires, unburned crude oil drizzled down, covering the ground and troops below (Stevens et al., 1993).

Petroleum fuels are a complex mixture of aliphatic hydrocarbons and aromatic hydrocarbons such as benzene and PAHs. These fuels also commonly contain various additives, like lead. When burned, petroleum fuels produce a variety of potentially hazardous combustion products. High-level,

1 short-term exposures to fuel solvents can cause immediate effects. In most cases, however, complete
2 recovery occurs when the exposure ceases (USDHHS 1993; Baker 1988).

3 U.S. service members could have been exposed to petroleum fuels by inhalation, ingesting
4 contaminated water or dusts, and skin contact. Inhalation exposure could depress the central nervous
5 system (CNS). Symptoms include short-term effects ranging from fatigue, headache, nausea, blurred
6 vision, and dizziness, to convulsions, paralysis, and loss of consciousness depending on the dose
7 (Naval Medical Research Institute, 1991; USDHHS 9/93). Again, exposure to high, nonlethal levels
8 usually is followed by complete recovery (Klaassen 1996; Porter 1990; USDHHS, Sept. 1993),
9 although rare cases of permanent brain damage after massive exposure have been reported (USDHHS
10 Sept. 1993).

11 Prolonged breathing of diesel fuel vapors can damage kidneys or lower blood clotting ability
12 (USDHHS, 1995a). Studies of workers occupationally exposed to certain hydrocarbon solvents in
13 petroleum fuels suggest that long-term high-dose exposure over 12 to 14 years can lead to neurotoxic
14 effects (Klaassen 1996, USDHHS 1995b). For example, psychomotor disturbances, visual memory
15 and perception, and visuomotor learning ability were significantly affected in exposed gasoline-pump
16 workers compared to matched controls, particularly workers exposed for more than a year (Kumar
17 1988). Some studies suggest there are neurotoxic effects from long-term exposure, including
18 decrements in memory, cognitive functioning, and sometimes neuromotor functions (Klaassen, 1996).
19 Other researchers, however, have challenged the existence of what is sometimes referred to as

1 “chronic toxic encephalopathy,” and uncertainty exists about CNS effects from long-term, low-level
2 exposures to solvents (Gerr and Letz 1992).

3 Benzene makes up about one percent of U.S. gasoline and up to five percent of European
4 formulations. It is a known human carcinogen that is associated with certain types of leukemia.
5 Nevertheless, more than 55 published epidemiologic studies of workers exposed occupationally to
6 hydrocarbons such as gasoline generally do not replicate the carcinogenic effects reported for
7 experimental animals (DHHS, Sept 1993; McLaughlin, 1993). Recent studies of refinery workers also
8 do not reveal a clear association between gasoline production and leukemia (DHHS Sept 1993,
9 Honda, 1995). Still, based on the limited evidence from animal studies and the presence of benzene in
10 gasoline, the International Agency for Research on Cancer (IARC) concluded that gasoline is possibly
11 carcinogenic to humans. It is not known if other petroleum products cause cancer in humans. IARC
12 believes there are insufficient data to assess whether light fuel oils or light diesel fuels cause cancer in
13 humans. However, IARC has determined that occupational exposure to fuel oils during petroleum
14 refining is probably carcinogenic to humans (DHHS 1995a).

15 Although ingesting small amounts of fuel oils is unlikely to cause significant symptoms,
16 ingesting fuel oils in larger quantities can cause vomiting, diarrhea, swelling of the stomach, stomach
17 cramps, coughing, drowsiness, restlessness, irritability, and unconsciousness (USDHHS 1995a).
18 Ingestion of fuel oils can be accompanied (during vomiting) by aspiration of some of the material into
19 the lungs, which can produce a chemical pneumonitis.

1 Skin exposure to large amounts of oil can physically clog pores and hair follicles,
2 compromising body heat loss. Long-term exposure can cause acne and other skin problems. With
3 high concentration or extended exposure, lighter components of crude oil or other fuel oils can defat
4 the skin, leading to redness and itching or dermatitis (Naval Medical Research Institute, 1991; US
5 DHHS 1995a).

6 Exposure to the normal combustion products of petroleum fuels is also a health concern.
7 Limited epidemiologic evidence indicates daily use of kerosene stoves for cooking or heating does not
8 cause breathing problems for most people (USDHHS, 1995a). If insufficiently vented, however,
9 carbon monoxide generated from fuel oil combustion can build up, causing drowsiness, nausea, and
10 even asphyxiation. Individuals exposed to unvented combustion of fuels containing lead could
11 experience health effects ranging from subtle biochemical changes in blood to severe CNS effects at
12 high doses. Occupational exposure to inorganic lead is associated with subjective signs of
13 neurotoxicity such as forgetfulness, lethargy, and weakness. These neurological signs and symptoms
14 occur at about the same blood lead levels as other overt signs of lead intoxication, such as
15 gastrointestinal complaints like abdominal pain, nausea, and vomiting (DHHS, April 1993).

16 **What do we conclude about the risks of petroleum products to Gulf War veterans?** While certain
17 subsets of Gulf War service members may have experienced increased risks for health effects from
18 their occupational exposures to petroleum products, it is unlikely that health effects reported today by
19 Gulf War veterans are due to exposure to petroleum products during the war.

1 **Psychological and Physiological Stress**

2 Virtually all Gulf War participants were exposed to a wide range of stressors associated with the war.
3 Throughout human history, observers have noted a correlation between the horrors of war and
4 “mysterious” illnesses in soldiers and veterans (Hyams 1996). Only recently, however, have the broad
5 range of symptoms for such illnesses been recognized as serious, physiological effects of stress.

6 During World War I, unexplained illnesses in soldiers were widely interpreted as a form of
7 malingering. It was not until the 1940s, when WWII veterans experienced many of the same
8 symptoms seen in WWI, that Charles Samuel Dyers coined the term “shell shock.” He began to study
9 and write about what actually happened to the minds and bodies of soldiers on and off the battlefield.
10 Physicians began to describe psychosomatic symptoms—physical disorders caused or influenced by a
11 psychological state—as the normal and expected consequences of experiencing fear and fright, and
12 recognized the relationship between intense emotion and bodily changes.

13 During this period, a telling example came to light that illustrated how traumatic experience
14 can lead to a decline in physical health. A group of merchant marines in Norway during WWII were
15 preselected for their excellent physical and mental health. Yet after exposure to extraordinary stress,
16 they showed a sharp decline in their health. Many had symptoms of chronic fatigue, chronic pain,
17 impotence, and irritability.

18 Today, scientists are beginning to unravel the physiological connection between the brain and
19 various other parts of the human body. Recent animal and human studies reveal numerous pathways
20 connecting the brain to the rest of the body, through which psychological stress can be physically

expressed (Chrousos). Animal studies have shown that stress can have measurable effects on the brain, the immune system, and various hormonal responses. Although the human body can adapt to normal stresses, if the stress lasts longer it can be expressed in a variety of physical illness symptoms (McEwen). Some researchers suspect that the inadequate production of stress hormones and stress response occurs in some (not all) humans with chronic fatigue syndrome and PTSD.

Based on this understanding and supported by decades of clinical observations, physicians can link many physical and psychiatric diagnoses as the consequences of stress. This connection is not limited to soldiers only. Experts now know the effects of conventional stressors such as bereavement, family problems, financial and job problems, domestic or other violence can cause significant and long-term physical health effects.

Physicians and scientists also note substantial variability in the human response to stress. One individual's reaction to trauma could be hypertension; in another individual, the reaction to similar trauma might be severe anxiety. A number of medical diagnoses are linked with stress, including somatoform disorders, chronic fatigue syndrome, and fibromyalgia. These conditions share many overlapping features, and each diagnosis depends on meeting specific case definitions. While some physicians consider these illnesses to be primarily psychiatric in origin, significant evidence supports the likelihood of a physiological, stress-related origin.

What do we conclude about the risks of stress to Gulf War veterans? The Committee concludes that stress can contribute to a broad range of physiological and psychological illnesses. Stress is likely to

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file gulf war

NATIONAL SECURITY COUNCIL
WASHINGTON, D.C. 20504

June 6, 1997

MEMORANDUM FOR MELANNE VERVEER

FROM:

PAUL BUSICK *PB*

SUBJECT:

Study Finds No Increase in Birth Defects in
Children of Persian Gulf War Veterans

Given the First Lady's longstanding involvement with veterans health issues and particularly those relating to Gulf War service, I thought both of you might be interested in a synopsis of the recently-released New England Journal of Medicine (NEJM) study on birth defects. As you know, anecdotal information about children of Gulf War veterans born with birth defects has been widely reported, perhaps most memorably in a People magazine feature in January 1995.

Fortunately, recent research appears to provide a reassuring negative finding on at least this disturbing possibility. This new study, which was published yesterday and has been widely reported, compared children born in military hospitals to virtually all active duty military members who served in the Persian Gulf with those of a parallel group of 700,000 service members who were not deployed. The study concludes that analysis of this data reveals "no evidence of an increase in the risk of birth defects among the children of Gulf War veterans."

As with any study, there are limitations, and there remain a great many other questions which the relevant agencies continue to examine. Because the study dealt only with children born at military hospitals, it excludes some high-risk pregnancies and those relating to Reserve and National Guard members, who are typically delivered at civilian hospitals. And because the study was limited to defects immediately identifiable following live births, no information regarding defects in aborted fetuses and stillbirths or defects not apparent at birth was included. As a result, it is probably premature to say that this study rules out definitively a link between service in the Gulf War and an increased risk of birth defects. Several other ongoing studies will help fill in these gaps.

Nonetheless, the study's strengths -- foremost among them its large population size, resulting in a high degree of statistical power -- and the NEJM's reputation justify a fair degree of confidence in its conclusions that there is no evidence of increased risk of birth defects, or of detectable differences in the overall risk of adverse reproductive outcomes generally. Given the mostly even-handed press coverage the study has thus far received, it seems reasonable to hope that this study will help to reassure Persian Gulf veterans and their families about this issue at least.

Of course, the possibility of increased risk of birth defects is merely one question being studied as part of the much larger research program now underway in coordination with DOD, VA, HHS and other agencies. Additional research designed to address other important Persian Gulf-related health concerns in as thorough and credible a manner remains in progress, and we look forward to communicating future results -- whatever they are -- to concerned Persian Gulf veterans and others as soon as they become available.

cc: Kitty Higgins
Jack Gibbons

Attachments

Current news articles
People magazine article

No Birth-Defect Rise Found In Gulf War Soldiers' Babies

By David Brown

Washington Post Staff Writer

Children born to Persian Gulf War veterans do not have an unusual pattern or frequency of birth defects, according to new research.

There is also no relationship between the length of time a soldier spent in the gulf and the risk of having a child with a birth defect, a team of military and civilian scientists has found. Nor were children conceived immediately after a soldier's return to the United States more likely to have abnormalities than children conceived a year later.

The study, published in today's *New England Journal of Medicine*, addresses one of the more emotional charges made in recent years by some veterans—that wartime hazards were visited on their children in the form of stunted limbs and damaged organs.

"In terms of the question whether there's a general increase in birth defects in Gulf War veterans, I think this answers it definitively," said David N. Cowan, an epidemiologist for the consulting firm SRA Technologies, in Falls Church, who performed the study along with several military physicians.

"It is possible someone had an exposure that resulted in a malformation," he added. "Our study cannot eliminate that possibility. But if that did occur, it had to have been rare, because we did not

detect any overall increase in risk."

The research looked only at the offspring of active-duty military personnel born in military hospitals. Infants of reservists and National Guardsmen—nearly all born in civilian hospitals—were not included. Nevertheless, the scientists believe there is no reason the two groups would have markedly different birth outcomes.

The Gulf War ended Feb. 28, 1991. The researchers used hospital records to determine the health of infants conceived after a soldier's return home and before Oct. 1, 1993. The offspring of 579,000 active-duty servicemen and women who went to the gulf were compared to those of about 700,000 people who were in the military at the same time but did not go to the gulf. Together, the groups produced about 75,000 babies.

Among the infants of Gulf War veterans, the rate of any kind of birth defect (including abnormalities as minor as large birth marks) was 7.45 percent. Among infants of non-deployed soldiers, the rate was 7.59 percent, which, in statistical terms, was no different. For severe defects (such as those of the heart, urinary tract or skeleton), the rate was 1.85 percent in gulf veterans and 1.86 percent in non-deployed soldiers.

When compared to non-deployed female soldiers, female gulf veterans had

a 12 percent greater risk of bearing a child with some sort of defect. However, the researchers believe that difference stems from the fact that a greater number of gulf veterans were single, black or in the Army as opposed to the Navy or Air Force.

All those variables are associated with a slightly increased risk of bearing a child with a defect. When the scientists adjusted for those demographic differences, female gulf veterans' babies had the same rate of birth defects as did those of non-deployed female soldiers.

In major heart defects, women who served in the gulf actually had a 33 percent lower risk of bearing an abnormal child as did female soldiers who served elsewhere. Cowan speculated that difference occurred by chance.

There was no increased risk of birth defects among the children conceived soon after their parents returned from the gulf, as might have been the case if the parents were recently exposed to a mutation-causing chemical. Nor did length of gulf service alter risk.

The director of the American Legion's Gulf War programs, Matt Puglisi, praised the study, but added that he hoped further research would look into the reproductive experience of reservists, and of active-duty soldiers who left the military soon after the war and subsequently had children.

Currently underway are several surveys asking veterans about infertility, miscarriage and other reproductive problems, and a study of birth-defect registries in seven states to see if they contain an unexpected number of children of veterans.

NYT 6/5/97 A14

Study of Gulf Veterans' Babies Called Reassuring

BOSTON, June 4 (AP) — Veterans of the Persian Gulf war face no unusual risk of having babies with birth defects, as some had feared, a large study has found.

The study reviewed the records of more than 75,000 babies born at military hospitals from 1991 through 1993. It found that the number of birth defects among the children of gulf war veterans was identical to that among the babies of military people who were stationed elsewhere. It was also virtually the same as the risk among civilians.

"We think this is reassuring news," said an author of the study, Dr. David N. Cowan, an epidemiolo-

gist at SRA Technologies of Falls Church, Va., a consulting concern.

Many veterans of the war have complained of a variety of unexplained symptoms, including fatigue, diarrhea and problems with memory and sleeping. Some have also said they fear that their experiences in the Persian Gulf left them more likely to have babies with birth defects.

To study this idea, Dr. Cowan and colleagues from the Walter Reed Army Institute of Research looked at all the births at 135 military hospitals. The results are being published on Thursday in *The New England Journal of Medicine*.

The study found that 1.9 percent of

the babies of gulf war veterans had severe birth defects, identical to the percentage among veterans who had not served in the gulf. The veterans' fertility also appeared to be unaffected by their war duty.

Betty Mekdeci, director of the Association of Birth Defect Children in Orlando, Fla., said the study had drawbacks that could have led the researchers to miss an increase in war-related birth defects. For instance, she said, it did not include babies from high-risk pregnancies that were sent to civilian hospitals.

The study "certainly doesn't reassure me," Ms. Mekdeci said.

Defects in gulf veterans' babies disputed

Study, at odds with anecdotal data, criticized

By Judy Foreman
GLOBE STAFF

Despite a rash of anecdotal reports to the contrary, there is no evidence that children of Persian Gulf veterans have had more than their share of birth defects, according to a study being published today in the New England Journal of Medicine.

The finding was met with immediate criticism from a Florida group that studies birth defects among Gulf War veterans.

In the study, researchers from the Walter Reed Army Institute of Research in Washington and elsewhere surveyed more than 75,000 children of Gulf War veterans and other service personnel who were on

active duty during the war.

In one part of the study, they compared medical records of 30,151 children born to male Gulf War veterans with 32,638 children born to veterans who served elsewhere.

They also compared 3,847 children of female Gulf War veterans to 8,825 children of female veterans deployed elsewhere. All the babies were born in military hospitals.

They found no difference in the overall rate of birth defects, but they did find a small but statistically significant — 12 percent — increase in risk for female Gulf veterans. But when differences in marital status, race and ethnicity were considered, the link with Gulf War service disappeared.

David Cowan, lead author of the study and an epidemiologist at SRA Technologies, Inc. in Falls Church, Va. said unmarried pregnant women, as some who served in the Gulf were, have long been known to have

'The children of Gulf War veterans are not more likely to suffer birth defects. Our work suggests that service should not affect family planning or a decision on childbearing.'

DAVID COWAN
Author of study

a higher rate of adverse pregnancy outcomes. He said he did not know specifically if these included birth defects.

Black women, he added, have a somewhat higher risk of having babies with minor birth defects such as extra nipples, extra fingers and skin "tags" — tiny bits of excess skin. While such defects are not life threatening or disfiguring in any major way, he said, they are counted as defects.

The study found no association between severe birth defects and race, ethnicity or Gulf War service, he added.

Overall, the rate of birth defects among all veterans studied was 7.45 percent, and the risk of severe birth defects was 1.85 percent — both rates comparable to those in civilians.

Since the study was based on records of live births only, spontaneous abortions or miscarriages could not be evaluated, the researchers said.

"This study provides strong scientific evidence that the children of

Gulf War veterans are not more likely to suffer birth defects," said Cowan. "Our work suggests that service in the Gulf War should not affect family planning or a veteran's decision on childbearing."

The study also found that the proportion of Gulf War veterans who had children after the war was no different from the rate among other veterans, suggesting that Gulf War service did not impair fertility. It also found that the ratio of male to female babies was roughly the same in both groups.

But Betty Mekdeci, director of the Association of Birth Defect Children in Orlando, took issue with many of the study's findings. The researchers, for instance, did not include 110,000 reservists who went to the war and left out all births in civilian hospitals, she said, adding that many women with high risk pregnancies were referred out of military hospitals.

Cowan disputed that, saying there was no difference in the proportion of pregnancies referred out of the military between women who went to the war and those who didn't.

Mekdeci also said the study looked only at hospital records before babies were discharged and would have missed birth defects that take several years to show up. Her group is particularly worried about what its own informal survey suggests is a four-fold increase in risk of Goldenhar's syndrome, a deformity of the skull and face.

Because many babies' faces are slightly and temporarily pushed out of shape during birth, the syndrome might be missed in hospital discharge records, she said. Cowan said the military is investigating the syndrome among children of veterans.

Mekdeci said she was "not satisfied at all" with the study's findings.

AN ENEMY WITHIN

Gulf War vets face a medical mystery: the birth defects threatening many of their children



◀ U.S. troops were prepared, but experts say Iraq used no biological or chemical weapons.

"The doctors are amazed at what he can do with his hands," says Connie Hanson of son Jayce (nuzzling her, below, and at right).



HIS, IN HIS WAY, A MARVEL—living proof of human adaptability and spirit. Two-year-old Jayce Hanson has no arms, yet he carries books and toys, balancing them against his body with tiny hands attached by joints to his shoulders. His legs are so bent and twisted that he cannot walk, but he can shimmy on his rump, back and forth along the floor, almost as fast as

most children move on their feet.

Jayce has been diagnosed with a genetic disorder known as TAR syndrome. Typically passed down by both parents, TAR stands for thrombocytopenia (a reduction in the number of platelet cells in the blood) and the absence of radius, or bone, in the arms or legs. Jayce has one of the more severe forms of this rare condition and a hole in his heart. Jayce's sister Amy, 4, had been born without the disorder.



But when Jayce was born so profoundly handicapped, surprised physicians asked his mother whether she had been exposed to any chemicals. "I said, 'No,'" recalls Connie Hanson, 30, a tall Virginian with a gentle kind of grace, "but my husband was—in the Gulf War.'"

Jayce's father, Paul, 31, an Army sergeant now based at Fort Bragg, N.C., was a combat engineer stationed along the Kuwaiti border with Iraq. Now he shares a common bond with dozens of other par-



ents who served in the Gulf War. Though the parents themselves have shown no symptoms of what has come to be known as Gulf War syndrome, they have had children with profound afflictions and nearly surrealistic deformities. So far no one has been able to prove—or disprove—whether the war was somehow to blame. But activists suspect that oil-fire fumes or experimental drugs like pyridostigmine bromide (a nerve-gas antidote known as PB, which was given

to soldiers) might have caused genetic mutations in soldiers' reproductive systems that may cause birth defects.

Like many of his counterparts, Paul Hanson has shown no GW symptoms—none of the inexplicable diarrhea, chronic fatigue, headaches, joint pain, rashes, memory loss or tremors. Moreover he and his wife are reluctant to blame his tour for Jayce's defects—at least before all the facts are in.

"I want Jayce to look back and be very

happy that his daddy served in Desert Storm," Connie says. Still, she concedes, "I would just like more research to be done, for the sake of future wars and for Jayce. So he knows whether he could have a child or not." Beyond that, she says with stoic resolve, "the government can't give him back his arms and legs. You just have to deal with it."

Other parents, though, feel certain that the Gulf War somehow left their children deformed. One-year-old Aman-

da Miedona of Chicago Ridge, Ill., suffers from microcephaly. Her head, which measures about 12 1/4 inches in circumference, is about one-third smaller than normal. "I can palm it," says her father, Troy, 24. "It's like holding a softball."

For her mother, Amanda's birth was a shock. "I thought, 'My God, is she ugly!'" recalls Michele Miedona, 22. "I kept calling her Troll Baby. She had so much black hair, and it just stuck straight up. Her eyes were on top of her head. Now that her head has rounded out and grown, she has beautiful features."

According to Dr. Peter Huttenlocher, a pediatric neurologist at the University of Chicago Medical Center who examined Amanda, her defect is a consequence of Seckel syndrome—a rare recessive genetic disorder that, if carried by both parents, commonly results in dwarfism or retardation. The Miedonas will undergo genetic tests to determine if they could be carriers. But Michele and Troy have other ideas about Amanda's condition. "There is no doubt that it was caused by the Gulf War," says Troy, now a chemical-company production operator.

Miedona served in the gulf as a helicopter crew chief and took PB pills, as well as a variety of injections, none of which fazed him at the time. "We did what we had to do," he says. But from the time he returned to the U.S. in February 1992, Miedona found himself ill almost constantly. "I vomited a couple of times a day for six months," he says. "I gained and lost 20 pounds in two days." Though he no longer vomits, his weight still fluctuates wildly, and he is still plagued with constant nausea.

In September 1992, eight months after his return, he and Michele married, and by the following May, Michele was pregnant. It was after a second ultrasound that her obstetrician told her about Amanda's small head, adding that only a chromosome-mapping test could determine whether the child would survive beyond birth. "My face turned beet-red, and my heart was beating louder than the doctor's talking," Michele remembers. "I was beyond crying."

Preparing for the worst, Troy suggested registering Amanda as a potential organ donor. But when the chromosome mapping showed no irregularity, Michele says, "I told the doctor, 'I don't want her organs promised to anyone because I think she is going to live.'"

And she did. But if Dr. Huttenlocher



"We are making her the happiest baby we can," says Michele Miedona (with husband Troy and Amanda, above). Adds Troy (below, in Iraq in 1991): "I've been sick, and I have a baby who is deformed—that's enough to convince me it was caused by the Gulf War."



COURTESY MIEDONA FAMILY

has it right, Amanda's future is fraught with obstacles. The doctor has predicted that she will be hyperactive, slow in learning and in developing motor skills and that she might grow to be only three or four feet tall. Undaunted, the Miedonas have worked strenuously, with some early success, to help develop her dexterity. "We are attached to her in all meanings of the word," says Michele.

Adding to the Miedonas' concern is a recent blizzard of conflicting reports on GWS. A Pentagon study led by Nobel laureate geneticist Joshua Lederberg found "no scientific or medical evidence" that U.S. servicemen and women were exposed to any Iraqi chemical or biological agents in the Persian Gulf. And Dr. Gareth Green of Harvard University, who chaired a National Institutes of Health panel on the Persian



Gulf War's effect on soldiers' health, concurs. "We didn't find data to support any direct connection between the veterans' wartime experience and health effects on them and their children," he says, but the panel recommended that additional studies be conducted into the various afflictions. Moreover, Dr. Robert Roswell, head of the Persian Gulf Veterans Coordinating Board, says that the 3.3 percent incidence of birth defects among 29,000 vets surveyed is similar to those found in the general population.

But a report issued last month by the U.S. Senate Committee on Veterans' Affairs, then chaired by Sen. Jay Rockefeller (D-W.Va.), counters that experimental drugs—chiefly PB tablets and vaccines—were given to soldiers with no caveats about side effects. Such medications, the report asserted, might well have depressed immune systems and wrought genetic havoc.

Among the 150 veterans who were interviewed by the Rockefeller committee was Steve Miller, 35, a U.S. Army nurse at Fort Sam Houston, Texas. Miller's son Cedrick is a victim of Goldenhar syndrome, a rare and sometimes fatal disorder. Cedrick also has an extra chromosome. As a result, he was born hydrocephalic, with excess cerebrospinal fluid pressing dangerously on his brain. His spine was abnormally

curved, and his left ear and eye were missing. The left side of his jaw was smaller than the right, and he had only partial use of his thumbs. Also, Cedrick's heart was on the wrong side of his body—and his trachea and esophagus were attached to each other, which would have caused severe eating and breathing problems if the condition had been left uncorrected. "I wasn't sure if I should hope Cedrick lived or mercifully died," says his mother, Bianca, 25.

Both Miller and his wife have normal chromosomes—and have, in addition to Cedrick, a perfectly normal daughter, Larissa, now almost 5. Neither Steve



Steve Miller (above, with healthy daughter Larissa, 4, and with Cedrick and wife Bianca, left) doubts the government will admit that Gulf War hazards might have affected veterans' children. "It took years for them to say that Agent Orange causes cancer," he says.

nor Bianca used drugs nor had they routinely been exposed to toxic chemicals—with one exception. While serving as a medic in the Gulf War, Miller had taken a number of PB tablets. “The Army did not tell the troops that they were experimental,” he says of the drugs. He believes the military had an obligation to do so. “I accept that I can get shot,” he says. “I enlisted. But Cedrick and Bianca didn’t.”

Cedrick, now 3 and only 20 lbs., has made remarkable progress. Surgery freed his windpipe and a shunt was inserted in his brain to drain excess fluid into his lower body. On the bleaker side, he has had enormous difficulty keeping down his food. It took Bianca a year and a half to get him to swallow a tablespoon of yogurt, and as an infant he needed to take most of his meals through a feeding tube. Cedrick will need at least five more corrective operations. Understandably, the Millers believe that the government should compensate parents for the care of GWS children—though the government has not conceded that such children exist. “If someone had sat down with us when Cedrick was born and said, ‘We are really sorry about what happened, and the government wants to correct it,’” Steve says, “we would have been perfectly happy. But it has been flat denials all the way.”

For the veterans and their families, perhaps the most frightening aspect of what has happened to them and their children is not knowing *why* it has happened. “They need answers now,” says Betty Mekdeci, founder and director of the Association of Birth Defect Children in Orlando, whose organization is surveying affected Gulf War families for defects their kids have in common. “They have to know whether it is safe for them to have more children.”

A similar conviction roused Melanie Ayers of Fort Bragg to activism. Her 5-month-old son, Michael, was dark-haired, like her husband, Glenn, and, though sickly, appeared otherwise normal. But one November night at around 3:00 a.m., his handsome features contorted as he awoke with a cry. Though his legs and arms were cold, the rest of his body was soaked in sweat. Minutes later, in his parents’ car on the way to the hospital, he died.

Michael’s killer, an autopsy showed, was an undiagnosed heart deformity, which had caused the mitral valve to



GARY BOHN/ONYX



MICHELLE PELLETIER/ONYX

swell to 10 times normal size. The boy was one of 14 children of Gulf War veterans—10 of them at Fort Bragg—who have died in infancy of various causes.

“The government keeps talking about how ‘mysterious’ this is—and it’s a load of rubbish,” says British-born Melanie, 29. “If this were E. coli or something, this place would be a federal disaster area. But we now have 14 dead babies—and what are they doing?”

Poised and articulate, the homemaker is now a zealous crusader. As one of the leaders of an informal “Gulf War babies” information network, she has spent hours fielding phone calls and letters from veterans and their families. Most have agonizing stories to tell: of the stillborn baby whose stomach and esophagus were not connected; of a girl born with red and yellow lesions

◀ “There was nothing we could pin down,” said Joshua Lederberg, who sought a cause for the syndrome.

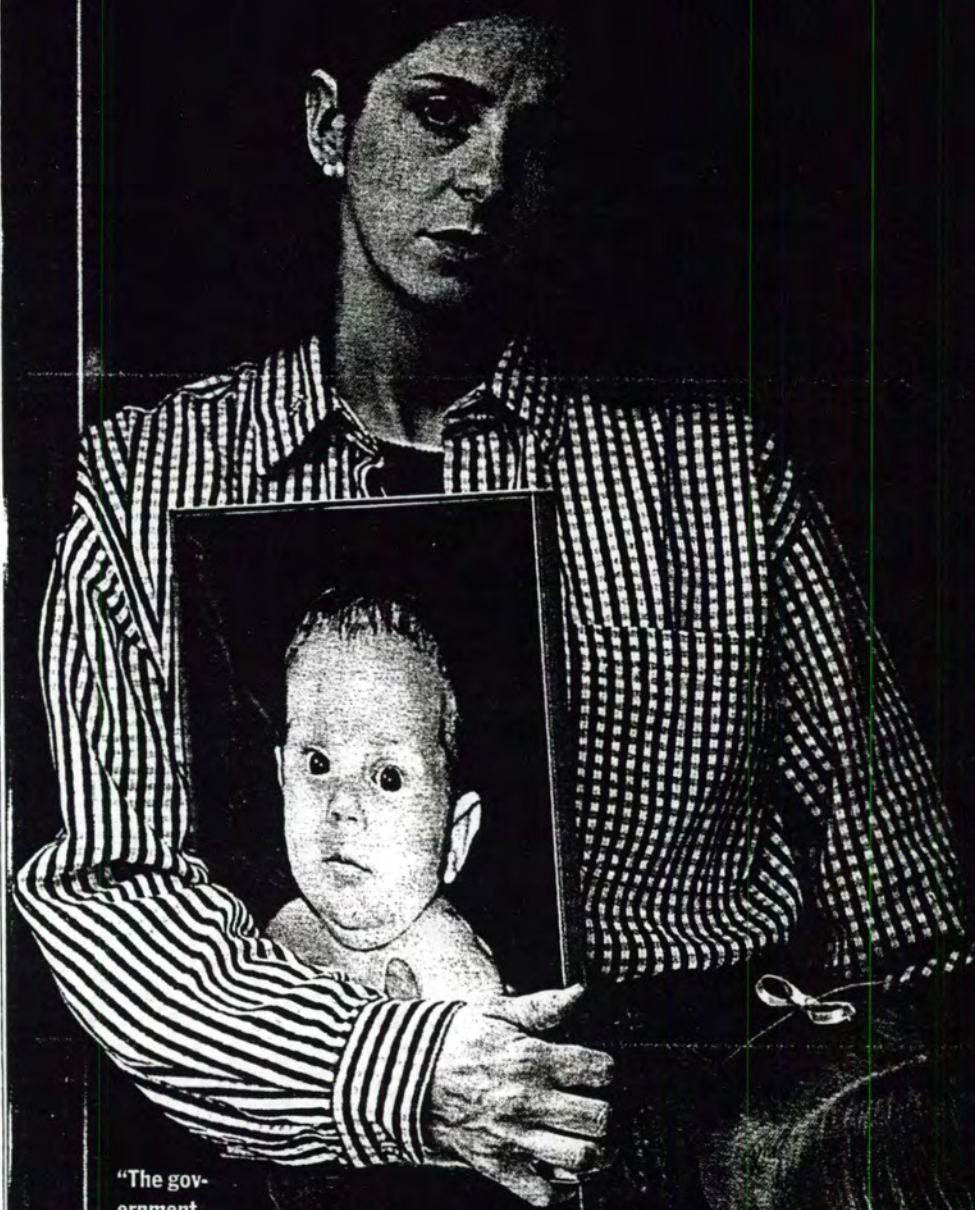
▲ A number of experimental drugs and vaccines were administered to U.S. soldiers, both by pill and injection.

covering her body; and of little Matthew Sullivan, 10 months old, who died in his crib of primary liver cancer, a disease more often associated with aging alcoholics. “All these kids had in common,” Ayers says, “was a daddy who went to the gulf.”

Glenn Ayers, 33, an Army major now stationed at Fort Bragg, was a battery commander who received a 10-week dosage of PB pills. Though he has displayed none of the common GWS symptoms, his wife suspects he may be harboring toxins in his body. “The obvious thing is to test my husband for exposure to radiation and chemicals,” says Melanie. “If there’s something wrong because of the war, don’t you think we should know? And if it’s genetic, there’s even more reason to know, before we try having more children.” Married in 1987 after meeting in Korea, where Glenn was stationed and Melanie was touring with a British dance company, the Ayerses have one surviving child, Rachel, 3, who is not untouched by the grief around her. “She and her friends play dolls—but all the ‘babies’ die,” Melanie says sadly. “They think that’s what babies do.”

■ RICHARD JEROME

■ GIOVANNA BREU in San Antonio and Chicago Heights and KATE McKENNA in Washington and Fort Bragg



"The government would rather ignore us," says Melanie Ayers (with husband Glenn, daughter Rachel and a photo of son Michael).