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001. fax	To: Melanne Verveer re: personal story (1 page)	01/21/2000	b(6)

COLLECTION:
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First Lady's Office
Melanne Verveer
OA/Box Number: 20033

FOLDER TITLE:
Gulf War

2013-0534-S
rc1809

RESTRICTION CODES

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

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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]
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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]

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Send back 5 cc's to me; Gulf War ill

THE WASHINGTON POST

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 uses 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 Illnesses 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 fending 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.

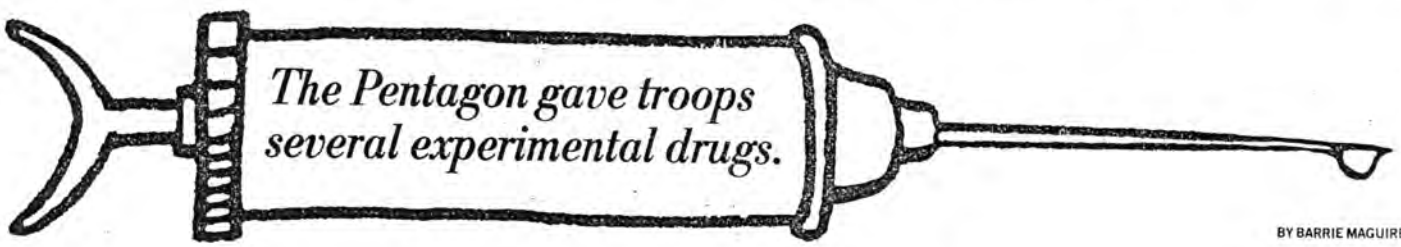
The President's Committee on Gulf War Illnesses was even more critical of the Pentagon's performance with unapproved drugs in the gulf war and Bosnia, saying the Pentagon "currently is incapable" of handling such drugs, and that its poor performance has hampered research into the causes of gulf war illness.

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 editor at Army Times Publishing Co.



BY BARRIE MAGUIRE

Gulf War

file

6174 redo

Gulf War

NATIONAL SECURITY COUNCIL
WASHINGTON, D.C. 20504

October 3, 1997

ACTION

MEMORANDUM FOR SAMUEL R. BERGER
JACK GIBBONS
THURGOOD MARSHALL JR.
MELANNE VERVEER

FROM: PAUL BUSICK PEB

SUBJECT: Current "Snapshot" of Gulf War Illnesses Issue

Sandy asked me for a brutally honest "snapshot" of the Gulf War Illnesses issue using the First Lady's memorandum to the President, dated February 10, 1995, as a basis for identifying what has been accomplished, and what are the continuing problems? I have consulted with two leading Veterans' Service Organizations (VSOs), Capitol Hill staffers, and a look at the draft final PAC report in order to capture their views in the attached paper. I have also included a preliminary discussion of some of our possible next steps. There are two strands to this problem. The first is accountability and DOD's role in investigating events in the desert. The second is the combination of health care and compensation, and what should be done to improve VA's service delivery performance. From my perspective, we need to shift the focus from the first to the second. The VSOs and the PAC agree.

Attached for your comment is a draft information memorandum for the President. This draft has been cleared by selected staff members at the NSC, OSTP, OMB, Cabinet Affairs, and the First Lady's office. When you are comfortable with this draft, I will provide a smooth for initialing by all four principals.

I have included at Tab II a suggested rollout proposal for your consideration.

Concurrence by: David Leavy; Anne Luzzatto; James Seaton; Eric Rubin; Dave Zavada/OMB

RECOMMENDATION

That you review the draft information memorandum to the President at Tab I.

Attachments

Tab I Draft Memo to the President

Tab II Rollout Options Memo

TAB I

INFORMATION

MEMORANDUM FOR THE PRESIDENT

FROM: SAMUEL BERGER
JACK GIBBONS
THURGOOD MARSHALL, JR.
MELANNE VERVEER

SUBJECT: Update on Gulf War Illnesses Problem

The First Lady pointed out in her memorandum, dated February 10, 1995 (Tab I), that Gulf War illnesses (GWI) is a complex and elusive problem that frustrates both the veterans who suffer from debilitating illnesses and government officials working to address their concerns. While significant progress has been made over the past two years, much uncertainty remains. We are continuing our efforts to achieve the GWI strategic objectives established last fall:

- Fully investigate what happened in the Gulf theater (i.e., accountability);
- Ensure research into what makes Gulf War veterans sick is comprehensive and effective;
- Ensure lessons learned are implemented by the agencies;
- Ensure Gulf War veterans receive health care and compensation they deserve; and
- Restore public confidence in government's commitment to veterans.

cc: Vice President
Chief of Staff

The Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC) has completed its final public hearing and is working on its final, "special" report. The report is due October 31 as required by the E.O. We believe the report will provide generally positive assessments of the government's progress in implementing the PAC's earlier recommendations regarding outreach, medical and clinical issues, and coordination. It is likely that the PAC will strongly criticize DOD's investigations of Chemical Warfare (CW)/Biological Warfare (BW) exposures. Finally, the PAC will provide a recommendation for a permanent statutory program that would provide disability compensation and medical benefits for Gulf War veterans similar to the Agent Orange program.

The following is our assessment of progress to date and a brief discussion of the next steps:

Investigations

Almost one year ago in response to White House and PAC concerns, the Department of Defense (DOD) established the Office of the Special Assistant for Gulf War Illnesses (OSAGWI) to conduct a thorough investigation of what happened in theater. OSAGWI is investigating, and making public, reports on a wide range of possible risk factors. As part of this effort, OSAGWI is tracking down specific CW/BW exposure incidents that might have occurred in the Gulf. It has established a case narrative approach that describes what happened and then makes an assessment of the likelihood of exposure to CW/BW agents.

OSAGWI's investigations have come under harsh criticism from the PAC. We expect the final report to say that OSAGWI's

investigative methodology does not allow replication, and that OSAGWI is too slow in completing the investigations. It may state that DOD is biased and should not lead future investigations and recommend we provide publicly accountable outside oversight for the CW/BW investigation process. While we do not agree with all of the PAC criticisms, we have encouraged OSAGWI to address these concerns as forthrightly as possible. OSAGWI has solicited feedback from the Veterans' Service Organizations (VSOs) and received generally favorable comments on its case evaluation procedures. OSAGWI's investigations have taken longer than expected, but because of the volatility of the problem, we believe that it is important to be as thorough as possible. OSAGWI has completed six case narratives and 13 more should be finished by the end of the year. DOD does not anticipate any more Khamisiyah-size CW incidents.

The PAC made strong recommendations regarding the importance of improved communication related to Gulf War veterans' concerns. DOD and VA have agreed with this emphasis, as do we, and have improved their risk communication programs (basically, a sustained plan to effectively communicate health information to an affected community). At the last public hearing, the PAC noted these improvements and commended DOD/VA's outreach and risk communication efforts. Examples of DOD's efforts include reaching out to the veterans through the internet Web site GulfLINK, publishing a bimonthly newsletter, visiting 12 cities to talk to the vets, routinely briefing the VSOs, Congress, press, and establishing a toll free interactive incident reporting line. The VSOs have also commented favorably on OSAGWI's outreach activities.

With respect to the specific results of the Khamisiyah modeling effort, the PAC is likely to recommend that all troops (about 271,000) within a circle 300 miles from the demolition be notified even if they were not under the low-level plume. Some veterans' advocates, and some risk communications experts, have recommended otherwise. OSAGWI has agreed to review this recommendation carefully in light of modeling currently underway. CIA and OSAGWI have a high degree of confidence in their modeling effort, and the PAC and outside experts have endorsed it. We believe that the veterans who were assigned to units under the low-level plume are the critical people to notify, and DOD is notifying all of them (almost 100,000 troops). Except for one veteran, we have no indication that anyone was exposed to high levels of chemical warfare agents.

The specific investigations undertaken by the Army, DOD and CIA Inspectors General continue. The earliest estimate for completion is October 1997. We have no indication of any significant or potentially controversial new issues surfacing from these investigations. In addition, the Senate Veterans Affairs committee has a special investigating unit. It is funded until March 1998 and plans to hold mid-winter hearings. Thus far, it has primarily focused on VA issues, and its preliminary findings roughly mirror our concerns about health care and compensation. Its review of DOD's efforts has not surfaced any significant criticisms. American legion and VFW representatives have said they are satisfied with DOD's efforts. While they expect the DOD investigative process to be publicly accountable, the VSOs hope to shift the focus to research, health care, and compensation issues.

Research

DOD has generated some controversy by funding research outside of the established interagency process. The PAC is likely to be critical of DOD's funding of Dr. Haley's follow-on research, which was published in the Journal of the American Medical Association (JAMA) where he claimed to have found neurological "deficits" in some Gulf War veterans. In this case, DOD selected parts of a follow-on research proposal designed to test the validity of the results claimed in the JAMA article, and plans to fund them outside of the normal interagency process. DOD will subject the Haley proposal to peer review in order to ensure that the objectives supported by government funds are scientifically sound. (Dr. Haley's initial research was funded by Ross Perot.) Haley briefed the First Lady on it in July, after DOD decided to cooperatively fund some of his follow-on work. A Washington Post reporter is looking into DOD's decision to fund the research.)

A June 1997 GAO report criticized the research program for having too much emphasis on epidemiological studies and suggested more targeted research into the health effects of certain risk factors, including low-level exposures to chemicals and their interactive effects. At the time of the report, VA and DOD, through the Persian Gulf Veterans Coordinating Board (PGVCB), were already implementing an increased effort in the area of chemicals and their interactive effects. The agencies and the PAC remain convinced that the epidemiological studies remain important, and we agree. Even though most of this research will not yield answers for many years, the major epidemiological studies in place to improve our understanding of the causes of GWI appear to be well designed and on track. At the last public hearing, the PAC commended the agencies'

progress in implementing its recommendations, and the adjustment of the research portfolio to place more emphasis on the effects of low-level chemical exposure. Overall, the PGVCB interagency research working group process works well in evaluating and recommending funding for research.

Lessons Learned

Medical surveillance of deployed troops, that is, adequate recordkeeping and pre- and post-deployment medical screening, remains a concern. FDA, GAO, and the PAC have questioned the efficacy of DOD's doctrine for the Bosnian deployment. The specific example cited was DOD's poor recordkeeping of the investigational vaccine for tick-borne encephalitis (TBE) administered to troops in Bosnia. DOD's medical surveillance doctrine and instructions have improved based on the Gulf War experience, but came too late to impact the Bosnian deployments. DOD has acknowledged the TBE problem and is taking corrective action.

The administration of the TBE vaccine also raised the issue of use of investigational products on the troops during military exigencies. HHS/FDA and we agree with the PAC recommendation that FDA should revoke or finalize its Interim Final Rule regarding waiver of informed consent for use of investigational drugs by the end of September 1998.

The low-level exposure estimates resulting from CIA/DOD modeling of the Khamisiyah pit demolition also elevated the issue of low-level chemical warfare agent exposure as a potential battlefield risk. As a result, DOD has now begun to improve its technologies and doctrine relating to detection.

Presidential Review Directive NSTC-5 was issued on April 21, 1997 to instruct the National Science and Technology Council to develop an interagency plan to address the health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. OSTP has been coordinating the interagency working groups; a final report is expected by March 1998.

In sum, while the policy lessons learned from the Gulf War are being adequately addressed, the implementation of these lessons still needs attention.

Health Care and Compensation

In the past, the medical and clinical issues have focused on making sure the veterans were eligible for the care they needed and deserved rather than the quality of the care itself. The VA has an aggressive Continuing Medical Education (CME) program to address the quality of care specifically tailored to Gulf War veterans. We note the importance of the CME program, and the PAC has encouraged VA to measure the effectiveness of this training.

The veterans now identify follow-up care by the VA as a weakness. It is our opinion, shared by the PAC, that VA needs to improve their processes for managing individual patient care and measuring their progress. HR 2206 (which we will support), addresses the issue, as will the PAC report. The frustrating part of the GWI problem is that there still is no answer for what is making these veterans sick. Research is proceeding, but there are no medical answers. While the Congress, press, and

"fringe" veterans' groups focus public attention on chemical warfare agent exposure, the vast majority of veterans are primarily concerned about health care and compensation issues.

We have not conducted a comprehensive review of the compensation adjudication process, but are aware of veterans' concerns that the system is not responsive. The initiative you approved last February to increase the window for VA disability compensation eligibility from two to ten years was an important move in support of the veterans' concerns. Our discussions with Hill staffers and VSOs lead us to believe the compensation claim process still needs improvement.

The final recommendation expected from the PAC is a proposal for a permanent statutory program that provides health care benefits and compensation for Gulf War veterans. We have seen the draft recommendation, which is similar to the Agent Orange legislation. VA believes that the proposal is acceptable, and the VSOs and Hill veterans' committees are supportive. OMB's initial review of the program indicates that the recommended approach uses a weak scientific standard to determine service-connected disability that may result in public criticism as well as significant future costs. OMB, VA, and NSC/GWI will develop a policy recommendation in time for the report rollout.

Commitment

Over the past year, the agencies have carried out your direction to "leave no stone unturned" in answering the questions about what happened in the Gulf. The PAC believes that previous DOD denials of the possibility of exposures and delays in making any serious attempt to investigate the possibilities created a

climate of public distrust DOD cannot overcome. Despite the expected PAC criticism of OSAGWI's investigative process, our discussions with mainstream veterans' groups lead us to believe we are turning the corner and restoring confidence in DOD's commitment to the veterans. As we move beyond the investigation phase and place more emphasis on research, health care, and compensation in our communications, the VSOs and we believe that measurable success in this regard can be achieved.

Inadequate time has been spent on the health care and compensation objective because of the high-press visibility resulting from the focus on exposure, DOD's past mistakes, and the delay inherent in coordinating interagency press messages. The PAC's oversight efforts have been important in prompting DOD and CIA to pay attention to exposure issues, gain credibility for their commitment, and dispel any concern of a cover up. Now, however, the PAC's continued focus on exposure contributes to the press spotlight on that aspect rather than on health care and compensation. We will need follow-on oversight, but will want to establish one solely focused on the investigations aspect.

Next Steps

The PAC will go out of business following submission of its report (due to you through the Secretaries of DOD, HHS, and VA by October 31, 1997.) We are developing a rollout plan, which will not include a public event to accept the PAC report. We suggest a brief private event with you and the First Lady to accept the report. That would be followed by a First Lady lunch/meeting with the PAC Chair and Secretaries Gober and Shalala to highlight the First Ladies' role in the issue and

emphasize the importance of the health care aspects of the problem. We would take photos of each and release them with a prepared statement from you describing the meetings. As the remaining DOD case narratives are released, we will continue to emphasize the health care and compensation issues, and use an interagency process to implement our strategic communications plan.

The PAC is expected to say that DOD is biased, and should not lead further investigations of chemical agent exposure. However, at least two mainstream veterans' organizations are satisfied with DOD's efforts, and want them to continue. We feel DOD's approach to the investigations and lessons learned has been deliberate and open. We will continue independent oversight, but envision a smaller, more tightly focused oversight group to monitor DOD's remaining chemical warfare agent investigations. Senator Rudman and Admiral Zumwalt have already agreed to serve on such a panel if asked. The mainstream VSOs will support this. Our rollout plan will include VSO OP/EDS and letters to you supporting this approach.

The interagency research program is working; we will need patience to allow science to answer many of the questions about GWI. The primary focus of the government's efforts needs to shift from the circumstances of possible exposures to various risk factors, to ensuring research outcomes on health effects are efficiently translated into improved health care for our veterans. As we move from investigations of events in the Gulf to health care issues, we will also need to examine the compensation process more closely, including the processing of claims for Gulf War veterans to ensure that the system in place meets the intent of the law.

With respect to the statutory program for compensation and benefits for Gulf War veterans recommended by the PAC, we are working closely with OMB and VA to evaluate both the policy and cost implications of the proposed program and determine specific recommendations. We will have a determination in time for the PAC report delivery to you.

To accomplish our objective of reassuring the veterans and the public of our commitment, and emphasize the human side of the problem, we believe the First Lady's involvement in carefully selected events supportive of the veterans and their families may be helpful over the next few months. At this point, we envision no requirement for you to undertake any direct public role in this process.

Attachment
Tab I First Lady's memo, dtd Feb 10, '95

TAB I

TAB II

Sandy

TAB I

I know I had asked you to look for this - it's the last thing I got from HRC on Gulf War - I finally found it — I kept a copy but you should put this w/ your Gulf War stuff.

27 AUG 1997

Paul B —

8/26

POTUS just sent me the original memo, to them from FLOTUS. I would like to send him back a 2-4 page current snapshot, based on this original memo: what is better? what is worse? what are continuing problems? what has been accomplished?

Brutally honest. This memo will go to POTUS and FLOTUS. Good opportunity for stock-taking. But it must be factually defensible. Thanks.

@

THE PRESIDENT HAS SEEN
8-17-97

THE WHITE HOUSE

WASHINGTON

February 10, 1995

MEMORANDUM FOR THE PRESIDENT

FROM: THE FIRST LADY

You asked me to look into the issue of Gulf War illnesses as a result of the letters the White House has been receiving, as well as the concerns directly raised with you by citizens. Many Gulf War veterans, it seems, have been left with the terrible impression that their country has forgotten them. I wanted to let you know what I have learned in the last several weeks, as I have been consulting with key government officials, Gulf War veterans and their families, and outside advocates. What I have found is that this remains a complex and elusive problem, frustrating both to those who suffer from debilitating illnesses and to the government officials working to address their problems.

Background Information:

There were 697,000 U.S. troops that served in the Persian Gulf War in 1990-91. Many had flu-like symptoms when they were there and after they came home, but it wasn't until more than a year later that concerns were raised about chronic illnesses by hundreds, and then thousands of PGW veterans, some of whom are still on active duty. Of particular concern are a variety of unexplained symptoms that do not fit any neat diagnosis.

Symptoms of the undiagnosed or "mystery illnesses" are varied, including chronic fatigue, memory loss, rashes, difficulty with sleeping, gastrointestinal disorders, allergies, respiratory problems, recurrent infections, headaches, joint pain, nasal discharge, tumors, and unusual bleeding.

Nobody knows what has caused these symptoms and it is likely that there are several causes, some of which may interact with each other. For example, if exposure to a chemical agent lowered a soldier's immune response, he or she would be more susceptible to infectious agents. The list of possible causes includes exposures to: toxic by-products from oil fires or tent heaters; depleted uranium; unapproved vaccinations and anti-nerve gas compound (pyridostigmine); infectious agents (leishmaniasis, malaria, brucellosis, giardiasis); chemical and biological

warfare; pesticides; microwaves; and special paints and solvents. An alternative explanation is post-traumatic stress disorder or stress.

What is particularly unusual is the growing number of reports of spouses and children who also appear to be ill with similar symptoms, as well as reported miscarriages and birth defects. Thus far, no well designed studies have been conducted to determine whether Gulf War veterans are more likely to have family members with these problems than other veterans. However, the VA and CDC have examined this issue with the limited data that are currently available, and they believe that there is no evidence to support these complaints.

VA and DOD Registries

PL 102-585 directed VA to establish a Persian Gulf War Veterans' Health Registry that could easily be cross-referenced with a Department of Defense (DoD) registry that had been previously established under the National Defense Authorization Act for FY 1992-1993. The purpose of the Registries was to gather information about individuals that would be useful in determining whether certain exposures or experiences (especially oil fires) resulted in certain illnesses.

Unfortunately, according to a report issued on September 30, 1993 by the Office of Technology Assessment (OTA), the VA and DoD registries are not well coordinated. Additionally, OTA indicated that the registries cannot be used to determine cause-and-effect relationships between illnesses and exposures. Because the registries were constructed with emphasis on oil fire exposure, the registries are much less useful for examining other potential exposures. Similarly, the medical testing performed through the VA Registry were not relevant to the diagnosis of disorders that have now been associated with the mystery illnesses (i.e., immune dysfunction, neurologic disease, chemical sensitivities).

Of the 697,000 U.S. troops serving in the Persian Gulf war, more than 537,500 are now veterans. Approximately 40,000 veterans are currently enrolled in the VA Registry, and 85% of them are sick. Of those studied thus far, 17% complain of fatigue, 17% have rashes, 14% have unusual headaches, 14% have muscle or joint pain, and 11% have loss of memory, and 8% have shortness of breath. It is unknown how many of these have undiagnosed illnesses.

NIH Workshop on Persian Gulf War Illnesses

In April 1994, several Federal agencies co-sponsored a workshop at NIH, where a panel of experts listened to testimony from Government experts, veterans, and scientists.

They issued a report that concluded that Gulf War veterans were suffering from undiagnosed illnesses of unknown origins, but

that there was no single entity that could be reasonably called "Gulf War Syndrome." They recommended that more research be done.

Recent Reports

In June 1994, the Task Force on Persian Gulf War Health Effects of the Defense Science Board, chaired by Dr. Joshua Lederberg, issued its report on the possible exposure of US troops to chemical or biological weapons or other hazardous agents. The report concluded that there was no evidence that US troops were exposed to chemical or biological weapons, and that "the overall health experience of US troops in Operation Desert Storm was favorable beyond previous military precedent." The report also recommended "substantial improvements" in medical assessments of US troops before and after deployment, to enable DOD and VA to better assess the health effects of military service.

Although some of its findings received wide support, the report was criticized by veterans and Congress because some of its information was based on DoD reports that were not considered credible. For example the report stated that less than one tenth of one percent of the Gulf War troops have reported undiagnosed illnesses. Although the exact number is unknown, this number is considered by many to be unrealistically low and contributed to the perception of the report as a "DOD cover-up." Dr. Lederberg is a very well respected Nobel Laureate, but his selection was criticized because he has financial ties to DOD.

PL 102-585 also required VA and DoD to contract with the Institute of Medicine's Medical Follow-up Agency (MFUA) to review existing scientific, medical, and other information on the health consequences of military service in the Persian Gulf theater of operations.

The Institute of Medicine issued an interim report in January 1995. They concluded that research was needed to determine the prevalence and likely causes of Gulf War illnesses. They criticized the VA and DOD research that was underway as not adequately peer reviewed and concluded that the quality of the data was questionable.

The Senate Veterans Affairs Committee, chaired by Sen. Jay Rockefeller, issued a staff report in December 1994 that concluded that investigational drugs and vaccines were inappropriately distributed to US troops during the Persian Gulf War. Prior to the war, DOD obtained permission from FDA to use pills (pyridostigmine) in a way that was not proven safe or effective and a botulism vaccine that was not proven safe or effective. The report concluded that U.S. troops were not adequately informed of the possible risks of the drugs or

vaccines (as required by law), and that the vaccines and drugs were used in such a way that they probably would not have provided adequate protection against biological or chemical weapons.

The Senate report expressed strong concern that the pyridostigmine, which was intended to protect against chemical weapons, may have caused adverse reactions in some individuals, or may have enhanced the toxic effects of insecticides or other chemicals that were widely used in the Gulf.

Sen. Donald Riegle, Jr. issued two reports claiming that allied troops were exposed to chemical warfare, resulting from scud missile attacks or U.S. military bombing of Iraq's chemical warfare plants at a time when down-winds were unfavorable.

My meetings with DOD, VA and HHS

In January, I met with key officials from the DoD, VA, and HHS to discuss how best the Administration can respond to the concerns that have been raised. The agencies have been very engaged in addressing this issue. They are trying to improve medical evaluations and services for Gulf War veterans, conduct research that will enable them to better understand the causes of the illnesses, and provide compensation to veterans who are disabled. I received assurances that the departments are moving quickly to implement legislative provisions that you signed into law in October and November.

However, in the course of these meetings, I also learned that some of the research that the law requires to be conducted by independent researchers (such as university scientists) under grants from DoD was mistakenly being conducted by DoD. Deputy Secretary John Deutch assured me that this could be corrected, and suggested that he might ask NIH to assist DoD with a peer review system for these grants. I raised this issue with Dr. Phil Lee, the Assistant Secretary of Health at HHS, who agreed that PHS has much more expertise with peer review of grants than DOD.

Agency officials report that they are doing their best under difficult circumstances and feel besieged by Congress and the media. They claim that anecdotes, while compelling, do not constitute scientific evidence, and that Congress and the media are taking these anecdotes too seriously. In contrast, well respected scientists have testified before Congress that these "anecdotes" should be considered case studies, and point out that they may well be the first sign of significant health problems that will become obvious when research is finally conducted.

Meeting with Veterans' Service Organization Representatives

I also have had meetings with officials from the American Legion and the Veterans of Foreign Wars. Both of these meetings have been extremely helpful in helping me understand how the veterans view our Administration's role in helping Gulf War veterans. For example, I met with Steve Robertson, who is Legislative Director of the American Legion, and is himself a Gulf War veteran with multiple undiagnosed illnesses. One of his concerns was the DoD and VA view that stress was the main cause of these symptoms. He made it clear that he had experienced extreme stress in previous deployments (he gave the example of the possibility that he would have to "push the button" to launch nuclear weapons at the Soviet Union) and made it clear that his Persian Gulf experience was not at all stressful in comparison. He recited a long list of potential toxic exposures that were common in the Gulf; for example, pesticides that were sprayed everywhere, including on cooking utensils. He is very concerned that the combination of these exposures could have been much more toxic than any would have been individually. The Executive Director of the Legion, John Sommer, was clearly supportive of Steve's views.

In talking to the Commander of the Veterans of Foreign Wars (Gunner Kent) and their staff, I was assured that the VFW appreciates the legislative efforts that you and the VA have made to provide medical care and compensation to Gulf War veterans. He praised this Administration's quick response, especially compared to the "15 years it took to get anything for Agent Orange." However, the VFW has conducted a survey of more than 2,000 Gulf War veterans, which found that most have undiagnosed illnesses that are not being successfully treated. (This is not a random sample, but it is worrisome nevertheless.) The VFW does not blame the VA, but they do believe that the DOD is not providing VA with the information it needs to help determine the causes of these illnesses.

Veterans and Their Family Members

I have received many letters from Gulf War veterans and their spouses, and have had the opportunity to speak to some of these individuals on the telephone as well. They express great frustration with VA and DOD, and they clearly feel that the government has not done enough to address this health problem and that the government has not taken their concerns seriously enough. The specter of the government cover-up of the dangers of Agent Orange for Vietnam veterans is frequently mentioned.

One recurring theme is that doctors at the individual VA facilities minimize the seriousness of the patients' symptoms, are not particularly well informed about Gulf War illnesses, and sometimes even ignore the law that requires VA to provide free medical care to these veterans. For example, the President of the Gulf War Veterans of Massachusetts wrote on February 9, 1995:

"Veterans are bitter, and many of the ones I speak to have concluded that they are never going to get any help from the VA system. Why? First, despite the laws which have been passed, and despite Secretary Brown's convictions, Gulf veterans are still frequently refused service in VA hospitals. The VA claims system is a disaster...(my own claim was lost for over a year, and 30 months have passed since I initially filed it.) One of the biggest problems which I have been trying to work with on a local basis is simple ignorance of the situation by many of the VA physicians who are treating us. During my Persian Gulf Registry exam in January 1994, the doctor who examined me had never heard of depleted uranium and did not believe me when I told him of the exposure."

I have also heard from veterans who have cancer or who report that an usually high number of young Gulf War veterans have died of cancers or heart conditions. There is great fear that these fatal diseases were caused by service in the Gulf. Many veterans believe that the VA and DOD have not provided full and accurate information about deaths and diagnoses, and some staff from the agencies concur (off the record) with that assessment. I don't think that anyone knows whether there is statistical evidence of an abnormally high number of cancers or heart disease among Gulf War veterans, but it seems to me the thing to do is make sure that kind of information is available to the public, and properly analyzed by CDC. According to reports I have heard, several FOIA requests for such information have gone unanswered, or have been answered with information that is perceived to be inaccurate.

Lack of Effective Treatment

One of the major problems is that many of the undiagnosed illnesses do not respond to treatment. For example, some veterans complain of having diarrhea for 3 years, rashes that come and go but do not respond to treatment, or sensitivities to chemicals that make it impossible to go to gas stations or sit in hospital waiting rooms. Women who are married to Gulf War veterans report constant vaginal infections and pain related to sexual intercourse; neither the cause nor an effective treatment has been determined. VA does not provide medical care to spouses, so many of these women do not have access to medical tests or treatment. This is especially true if the veteran is too ill to work. This lack of health care makes it especially difficult to determine whether these illnesses are unusual or whether the major problem is lack of appropriate medical care.

In cases where VA and DOD medical facilities have been unable to effectively treat Gulf War veterans, many veterans have sought care in the private sector. Some Gulf War veterans have complained that the VA and DOD facilities are too conservative in their treatments. The countervailing point of view is that

private sector doctors are taking advantage of the desperation of Gulf War veterans, by selling useless or even dangerous diagnostic tests or treatment.

My staff has called scientists from across the country to learn more about the controversial treatments that Gulf War veterans are receiving in the private sector. Thus far, the experts suggest that there are no good diagnostic tools for determining chemical exposures to the brain, and that such diagnostic tools as SPECT scan and brain mapping have limited usefulness. One of the veterans who is very ill is currently going to a private facility for plasma pharesis at a cost of $15,000/month. Several experts have claimed that such a painful, dangerous, and expensive treatment would be difficult to justify except on an experimental basis. So, thus far the academic experts have made statements that are consistent with VA decisions not to use those tests and treatment. However, the usefulness of treatments that have been devised for multiple chemical sensitivity and other controversial diagnoses are more debatable.

Compensation

Veterans who have disabilities that are associated with military service are entitled to monthly benefits from the VA. The maximum benefit is approximately $23,000/year for a veteran who is considered 100% disabled.

As of ____ 1994 there were approximately ____ claims filed by PGW veterans or their survivors for general VA benefits. Approximately 10% were from veterans claiming disabilities from exposure to environmental hazards, but very few of those claims were granted. This is partly a function of the lack of diagnosis for these symptoms, and partly because it is more difficult to prove that an illness is service-connected if it is not reported until after a person leaves the military (battle wounds are obviously much easier to prove when filing a claim).

Thanks to the law that you signed in November (PL 103-), veterans whose illnesses are not diagnosed will, for the first time, be eligible to receive compensation if they can prove that they are disabled as a result of military service. The first compensation checks resulting from this law should be distributed in March. However, proving disability may still be difficult, and it will be essential to monitor this program to make sure that veterans receive the compensation that they deserve.

Working as a Team With VA, DOD and HHS

Among the VA, DOD, and HHS officials and the Gulf War veterans there is wide agreement that more targeted and coordinated research is needed. The Defense Reauthorization and the Veterans' Persian Gulf War Benefits Act that you signed in October and November include some important new research efforts, including research on the possibility that the veterans's health problems are transmissible to spouses and offspring. It is important that these efforts go forward expeditiously.

The agency officials expressed their desire to work together to ensure that the needs of Gulf War veterans are met. We agreed that we must convey to the American people that the Administration recognizes that there are serious questions that need to be resolved, and we are committed to working to address them. For example, Dr. Kizer, the VA Under Secretary for Health, admitted that some VA facilities are doing a better job than others, and indicated his strong commitment to improving that situation, so that all veterans receive the care they deserve. He also is planning a major new effort to examine whether birth defects and reproductive problems are unusually prevalent among Gulf War veterans.

As you said when you asked me to follow up on this issue, we must do our very best to guarantee that the concerns of our veterans who served our nation so nobly in the Gulf are addressed properly and honestly, with the compassion their cases merit. This must be our collective guiding principle.

I suggested to Secretary Perry and Secretary Brown that together we visit appropriate sites, such as hospitals or research centers, to demonstrate the concern of this Administration and our commitment to working together to get answers and provide assistance to those who are suffering health problems from their service during the Gulf War. My first such visit, at the VA Medical Center in Washington, DC, is scheduled for February 14.

I believe that the agencies involved are making great efforts to improve the research and services for Gulf War veterans, but that the statements made by Department officials are often perceived as defensive and less than candid. This may be partly because many of the career employees who are providing information to Department officials are themselves responsible for previous decisions. It is human nature to be reluctant to admit that mistakes might have been made; however, these mistakes were made during the previous Administrations, and we should be willing to admit that they occurred and that we must and will do better in the future. Given the enormous publicity and the increased concerns that the veterans are expressing about the

adequacy of the Administration response, I believe it is essential to be more open and let veterans and the American people know that we are not satisfied with the status quo.

I believe we can move ahead to immediately reassure the veterans and the public by moving quickly on some new initiatives, and making those initiatives public. We need to let the American people know that we are just as concerned as they are about the veterans whose illnesses are not responding to treatment. And of course, we need to move as quickly as possible to make progress on these issues.

I suggest that we consider two very public announcements in the coming weeks:

A. DoD Press Conference:

1. The message needs to be that DoD is concerned that the safety of the long-term use of pyridostigmine, alone and in combination with stress, pesticides, and other toxic chemicals, was not adequately studied under the Reagan/Bush Administration prior to the Persian Gulf War. That is why new research is now underway. DoD can announce that research is underway, and that most of it will be peer reviewed, independent research. This will have implications for future soldiers, in addition to Gulf War veterans who are ill. Of course, any future use of these agents will be reviewed in light of the results. Dr. Steven Joseph could be in charge of this effort.

2. Announce that DoD has developed new policies to make sure that all service members are adequately warned about any potential side effects from any vaccines, drugs, pesticides, decontamination agents, and other toxic chemicals that they will come in contact with. Dr. Susan Bailey is the person in charge of this effort.

3. I believe that DOD should announce that they have withdrawn a request for a permanent waiver of informed consent for the use of experimental drugs. [They may still request such waivers on a case by case basis]. This could be done by Executive Order, or Secretary Perry could make the decision.

B. President (and Secretary Brown) Announces:

1. You and/or Secretary Brown could request that the VA Inspector General investigate allegations that some VA facilities are not providing appropriate free medical care to Gulf War veterans as required by law. VA does not have enough investigative staff to do this, and anyway, the IG is preferable because it is independent of VA.

2. The VA PGW Hot Line will compile information about any reported problems regarding access to medical care or compensation, and Secretary Brown will ensure that information will be used by VA to improve those efforts.

3. The lack of mortality statistics has angered some veterans groups. The VA could announce that, in response to requests from veterans groups, the VA will analyze data from PGW veterans who have died, and CDC will work with them to evaluate whether the number of deaths or diagnoses are unusual.

4. The VA will include information about ill spouses and children, including miscarriages and stillbirths, on the PGW Health Registry starting [insert date]. VA is already including information about birth defects. This will help provide information about whether an unusually large number of these problems are occurring. Dr. Ken Kizer has also proposed an even more ambitious surveillance system for reproductive problems among veterans, which he should announce.

5. Announce that the first compensation checks for undiagnosed illnesses will be sent in March.

Blue Ribbon Panel

I also believe that we should consider a new "blue ribbon" panel to examine these issues. This panel should have a broader mandate than the Lederberg panel, and should not include members who have contracts or consulting relationships with DOD or VA, or the chemical industry. In order to have credibility with veterans and the public, we need to make sure that the panel includes scientific experts who have reputations as being consumer-oriented or absolutely objective. The panel should have an adequate staff that enables them to monitor the many activities of these three agencies for at least one year.

We may want to consider "reinventing" the concept of a blue ribbon panel to make it less reliant on the expertise of a large number of extremely busy scientists. Unfortunately, such experts are often perceived as relying too heavily on the information provided by the agencies. Perhaps the focus should be on a small top-notch, independent investigative staff that is advised by a small number of well-respected experts, such as Admiral Zumwaldt, a medical ethicist, and a small number of scientists.

cc: Leon Panetta

TAB II

Draft PAC Special Report Rollout Options

The following outlines a proposed rollout strategy for the PAC's final "Special Report" which is due to the President not later than October 31.

The primary communications strategy is to receive the report in a low-key manner and quickly shift the focus of the debate away from critical investigations toward concrete actions that ensure the health care and compensation for the nation's veterans.

Toward that end, the following is recommended:

- The President and the First Lady would briefly meet privately with the PAC Chair to thank her for their hard work, underscore the Administration's commitment to veteran's health care benefits, and officially receive the report. (Alternatively, the First Lady could do this on behalf of the President.) They/she would be joined by Secretaries Cohen, Gober, and Shalala. We recommend October 30th (or as soon thereafter as possible) as a potential date in order to minimize press coverage. A White House Photo would be taken for release to press.

- The First Lady would host a brief meeting/lunch with the PAC Chair to discuss health care issues. Secretaries Gober and Shalala would be present to underscore health care emphasis. Again, photos taken for release to press.

- The President would release a written statement describing the meeting(s) receiving the report, describe the Administration's effort to date, and announce support for the following PAC recommendations:

    1. Creation of an Agent Orange-like eligibility program for Gulf War veterans.

    2. Continued DOD oversight and the appointment of an oversight board to focus on DOD's remaining investigations.

    3. DOD/VA will continue their risk communications programs. DOD will announce additional "town hall" meetings.

4. VA/DOD will accept the PAC recommendations for improving patient care management and come back in 45 days with a pilot plan for implementation.

5. HHS/FDA will agree with the timetable suggested by the PAC to finalize their investigational drug use rules.

6. Finally, the President will give the agencies 45 days (December 15) to develop programs responsive to the remaining PAC recommendations.

- Work with Veterans' Service Organizations that are supportive of our efforts to release positive statements.

- If necessary, have Secretaries Gober and Shalala do a press briefing.

- Work with the First Lady's staff to develop a public appearance shortly after receipt of the report to begin putting a human face on the issue and again emphasize the health care and compensation aspects of GWI. NSC/GWI is working with the First Lady's office and VA for an appropriate venue site.

19 September 1997

NATIONAL SECURITY COUNCIL

Thurgood Marshall, Jr.
Melanne Verveer

Enclosed is your copy of the draft PAC Special Report. I would appreciate any comments you have by COB Monday, 22 September. I will consolidate comments provided by White House staff and send a consolidated report to the PAC in time for their Wednesday deadline.

Paul

Paul Busick

file

Presidential Advisory Committee on Gulf War Veterans' Illnesses

TO: Paul Busick
Phil Heyl

FR: Robyn Nishimi
Gary Caruso

RE: Review of draft *Special Report*

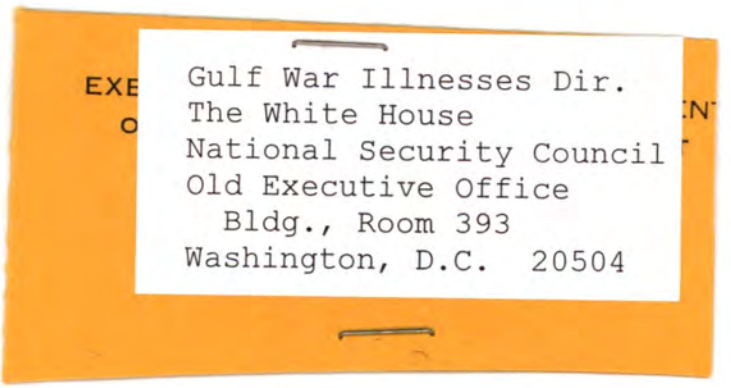
DA: September 18, 1997

Enclosed for your review are two copies of the Advisory Committee's draft *Special Report*. We greatly appreciate your reviewing the document for factual content. As with previous reviews, the drafts have been reproduced on Copisafe® paper. Your copies also have been numbered and otherwise marked. Additionally, since the review period for our previous reports has been the time at which the document was leaked, the enclosed drafts have been redacted for the lead-in paragraph for each Committee recommendation and the recommendation itself.

As previously discussed, we also have transmitted review copies to several individuals and/or units of CIA, DOD, VA, DHHS, and the Coordinating Board. For your information, selected representatives of outside organizations also are participating in the review.

All draft copies and reviews MUST be, *without exception*, returned to the Committee's office no later than 5:30 p.m., Wednesday, September 24, 1997. To facilitate return of the draft copies, a pre-addressed Federal Express label is enclosed. We cannot overemphasize the importance and firmness of the deadline. We appreciate the difficulties associated with the short timeframe, but such a schedule is necessary if the Committee is to deliver the *Special Report* to the President by October 31, 1997.

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


Gulf War Illnesses Dir.
The White House
National Security Council
Old Executive Office
Bldg., Room 393
Washington, D.C. 20504

Presidential Advisory Committee on Gulf War Veterans' Illnesses

White House

DRAFT SPECIAL REPORT — Copy 3

September 18, 1997

Distribution of this draft has been limited to invited external reviewers.

Comments and this copy must be returned by close of business, September 24, to:

Gary Caruso/Robyn Nishimi
Presidential Advisory Committee on Gulf War Veterans Illnesses
1411 K Street, NW #1000
Washington, DC 20005-3404

WORKING DRAFT: DO NOT CITE, QUOTE, REPRODUCE, OR CIRCULATE

SPECIAL REPORT

Caring for veterans is not a partisan issue, it is a national obligation . . . . I pledge to our veterans and to every American, we will not stop until we have done all we can do to care for our Gulf War veterans.

– President Clinton
January 7, 1997

SUMMARY

[TEXT REDACTED]

WORKING DRAFT: DO NOT CITE, QUOTE, REPRODUCE, OR CIRCULATE

INTRODUCTION

On May 26, 1995, President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses to conduct an independent, open, and comprehensive analysis of health concerns related to Gulf War service (appendix A). As mandated, the Committee delivered its *Interim Report* on February 15, 1996 (PACGWVI, 1996a) and its *Final Report* on December 31, 1996 (PACGWVI, 1996b). Appendix B contains the Committee's findings and recommendations from both reports.

On January 7, 1997, President Clinton released the *Final Report* and extended the Committee's tenure. The President's new charge directed the Committee to i) evaluate the government's implementation of our previous recommendations, and ii) oversee the government's ongoing investigations into possible chemical or biological warfare agent exposures during the Gulf War (appendix C). In February 1997, the President also asked the Committee to evaluate the adequacy of the government's response to his concerns about the implications of then recently declassified documents associated with chemical munitions at Khamisiyah (appendix D). We provided a status report of our efforts and addressed the President's additional task in a supplemental letter report, delivered on April 30, 1997 (appendix E).

This *Special Report* responds to the President's request that we assess by October 31, 1997, the government's progress in implementing our earlier recommendations on outreach, medical and clinical issues, research, and coordination. The document also reports our assessment of the government's efforts to investigate possible chemical and

biological warfare (CBW) agent exposures. Finally, based on our oversight activities during the past 10 months, the Committee provides its policy recommendation to address the persistent perception that the government lacks the commitment to resolve issues surrounding the health consequences of service in the Gulf War.

IMPLEMENTATION

Upon receipt of the Committee's *Final Report*, the President requested a response from the Department of Defense (DOD), Department of Health and Human Services (DHHS), and Department of Veterans Affairs (VA) within 60 days. On March 7, 1997, the departments forwarded their implementation plan (Coordinating Board, 1997). This plan has served as the basis for the Committee's evaluation of the government's implementation of our previous recommendations (appendix B), which encompassed five broad areas: outreach, medical clinical issues, research, chemical and biological weapons, and coordination. In this section, we provide our assessment of the current progress of the departments' implementation of the Committee's recommendations related to outreach, medical and clinical issues, research, and coordination. The Committee assesses the government's efforts concerning CW agent incidents later in this report.

The implementation plan described DOD's, VA's, and DHHS's individual, joint, ongoing, or proposed initiatives to address the Committee's recommendations. In that document, the agencies concurred with all recommendations except two, about which they concurred in part. One partial concurrence involved our recommendation for 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." (Coordinating Board, 1997) VA's partial concurrence related to its specific, limited authority under Section 107 of Public Law 103-446. The second instance involved a recommendation pertaining to chemical weapons, which we discuss later in this report.

Outreach

Since the Committee issued its *Final Report*, DOD and VA have expanded and refined their outreach initiatives. In particular, DOD's communication efforts have improved considerably. DOD's Special Assistant for Gulf War Illnesses conducted, and continues to conduct, roundtables with representatives from veteran service organizations (VSOs). He also held a series of open meetings with concerned veterans in 12 cities, and recently announced a new series would be convened. VSOs now are routinely briefed in advance of major announcements. DOD's toll-free incident reporting line was significantly expanded, improved, and standardized, with debriefings by trained interviewers.

Then Secretary of Veterans Affairs Jesse Brown personally stepped up VA's outreach to Gulf War veterans. He conducted public forums in six cities to highlight Gulf War veterans' initiatives and to receive input on VA's undiagnosed illness compensation programs for Gulf War veterans. VA also continued publishing its quarterly *Persian Gulf Review*, public service announcements, and community-based outreach.

Additionally, although the Committee's recommendations on outreach did not specifically encompass the Central Intelligence Agency (CIA), the agency recently has been a prominent participant in DOD's and VA's outreach to Gulf War veterans. Over the past 10 months, CIA also has issued its own reports to veterans and the public. The Committee commends CIA's unprecedented efforts in this regard.

The March 1997 implementation plan directed the Persian Gulf Veterans Coordinating Board's (Coordinating Board) Clinical Working Group to develop a comprehensive risk communication plan. Both government and nongovernment risk communication experts were to be engaged to assist in the development and implementation of this effort. The targeted completion was May 1, 1997. In April 1997, the Clinical Working Group convened a 1-day workshop of risk communication experts from the private and governmental sectors. For example, participants included recognized experts from the U.S. Public Health Service who have dealt with similar risk communication situations surrounding toxic waste sites or occupational exposures. A follow-up meeting on risk communication planning and training was held for DOD and VA staff directly involved in matters related to Gulf War veterans' illnesses. To ensure consistency of information provided to Gulf War veterans on the three government World Wide Web sites, the Clinical Working Group also is coordinating the development of plain language fact sheets on: depleted uranium, illnesses of Gulf War veterans, the Persian Gulf Veterans Coordinating Board, medical care programs, case series registries, research, and pyridostigmine bromide. Fact sheets on ten additional topics are planned (Parker, 1997a).

Finally, the deployment of U.S. forces to Bosnia has offered an opportunity to test new approaches to predeployment and in-theater risk communication. Deployed troops have received individual briefings and have been provided with specific pamphlets on the infectious and environmental health threats of the region, and on the appropriate medical countermeasures and how to access needed care. Environmental and occupational health

experts have done extensive air, soil, and other monitoring, and have communicated results to troops (Parker, 1997a; Resta/DeFraites, 1996).

[TEXT REDACTED]

Medical and Clinical Issues

In our *Final Report*, the Committee noted with approval the government's plans for implementing our *Interim Report* recommendations concerning provision of care, particularly follow-up care, for ill Gulf War veterans. DOD and VA continue to operate their clinical evaluation programs and access to these programs appears to be satisfactory. The Committee continued, however, to receive input from veterans and their families that indicates follow-up care in both programs, but particularly with VA, remains problematic. Staffing problems contributed to this situation. In their implementation plan, both DOD and VA indicated they were actively reviewing staffing to fully accommodate the needs of the ill veterans.

Related to staffing and improving follow-up care, VA has testified to the Committee about its effort to implement a case management system at its medical facilities. Under the plan, each patient would be assigned a primary care provider who delivers care or arranges indicated specialty consultations. The Committee endorses this activity, which has great potential for addressing many of the current difficulties that some Gulf War veterans report they encounter when seeking follow-up care.

VA and DOD continue to recognize the critical need to keep their care providers apprised of the latest scientific developments related to Gulf War illnesses. In June 1997, VA sponsored a third continuing education conference on the health consequences of Gulf War service involving VA, DOD, and DHHS health care professionals.

Finally, while not directly related to our recommendations, the Committee is pleased to note VA extended from two years to ten years the window for applying for VA disability compensation for undiagnosed illnesses; efforts are underway to review the records of veterans who previously had been denied compensation; VA's policy for providing medical care to Gulf War veterans had been broader and remains in place.[1]

[TEXT REDACTED]

Medical surveillance. The Committee's earlier reports stressed the importance of improving the government's efforts to collect medical assessment data related to future troop deployments. Adequate pre- and post-deployment screening of individuals is critical to determine medical eligibility to deploy and to serve as baseline information for monitoring health effects associated with a deployment. DOD is finalizing a directive on medical surveillance policy for deployments that specifies a uniform concept for health screening (Trump, 1997). Additionally, the directive requires:

- Service members will be physically and mentally fit to carry out their missions;
- Medical and personnel data systems will be designed and integrated in order to maintain, assess, and protect the physical and mental health of service members;

[1] Currently, "any military individual who served on active duty in the U.S. Armed Forces under any authority; and served in the Persian Gulf theater during the Persian Gulf War; and served a minimum of two years or the period for which they were called to active duty; and were discharged under other than dishonorable conditions, have basic eligibility for medical care within the VA system." Additionally, Gulf War veterans receive "priority care" – i.e., VA must treat a veteran's illness, despite a lack of any indication it resulted from Gulf War service, unless the examining physician determines the illness clearly derived from a cause unrelated to service in the Gulf War.

- The data systems shall be in effect throughout any period of military service, but specifically during deployments;
- Service members will be made aware of any significant health threats and corresponding preventive countermeasures (unit and individual), and commanders are to ensure medical support and training for countermeasures is provided;
- Medical surveillance pre-, during and post-deployment will encompass: monitoring environmental, occupational, and epidemiologic threats and stressors; assessing disease and non-battle injuries, stress-induced casualties, and combat casualties, including those caused by chemical, biological, and nuclear weapons; assessing and reinforcing the use and effectiveness of command-directed and personal countermeasures; and the delivery of optimal medical care during, and after, deployment;
- Operational commanders will be kept informed before, during, and after deployment of the health of the force, health threats, stressors and risk, and available countermeasures.
- A serum repository will be maintained for clinical diagnosis and appropriate epidemiologic studies; and
- Joint technologies, practices, and procedures will be used to ensure consistency among the services (DOD, 1997c).

In addition to involving uniformed service personnel, these surveillance activities will include DOD civilian and contractor personnel when appropriate. DOD expects to publish the directive in September 1997.

We approve of the basic thrust of the policy directive. In testimony before this Committee, however, DOD has acknowledged the pretest of these surveillance procedures in Operation Joint Endeavor, the Bosnian peacekeeping mission, has been problematic. In May 1997, the U.S. General Accounting Office (GAO) also identified problems related to medical surveillance in Bosnia, which DOD did not dispute. Special difficulties were the newness of the policy and the failure to incorporate the elements of medical surveillance into operational doctrine. (GAO also briefly noted DOD deficiencies with respect to

medical recordkeeping, including for the investigational tick-borne encephalitis (TBE) vaccine; the Committee discusses this matter later in this document.) (GAO, 1997)

[TEXT REDACTED]

Use of investigational products. During the Gulf War, DOD used two investigational products as prophylactic measures against chemical and biological warfare agents: pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine. Although already used in the United States, these two products were investigational for the anticipated use in the Gulf War. Under normal circumstances, each could not have been administered without the informed consent of the individuals who received them. In December 1990, the Food and Drug Administration (FDA) issued an Interim Final Rule that permitted DOD to use investigational products without informed consent during military exigencies; FDA granted waivers of informed consent for BT vaccine and PB shortly thereafter. Under the waiver, DOD stipulated it would adhere to specific FDA requirements as a matter of policy, as well as comply with other federal regulations not related to informed consent that govern the use of investigational products.

The Committee's concern the past 2 years has been two-fold: the interim status of FDA's actions related to the rule and DOD's medical recordkeeping in-theater, which we found needed whole scale improvement.

Status of the Interim Final Rule. The Committee's *Interim Report* and *Final Report* did not comment on the merits of FDA's regulation permitting a waiver of informed consent for

investigational products used during specific military circumstances. Rather, we focused on those actions related to the Interim Final Rule we believed FDA should address for the future. Specifically, the Committee recommended that FDA solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. We called attention to four areas that FDA specifically should revisit: 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 DOD; and additional procedures to enhance understanding, oversight, and accountability.

Over the past 18 months, FDA had professed on multiple occasions to the President and the Committee that it was moving forward to address the interim status of the policy governing waiver of informed consent for investigational products during military emergencies. The Committee has been frustrated by the inordinate amount of time that passed with no obvious progress by FDA toward finalizing or eliminating the Interim Final Rule. In July 1997 testimony before this Committee, FDA identified, for the first time in 7 years, specific steps and an approximate timeframe to address this issue. In July 1997, FDA also published in the *Federal Register* "Accessibility to New Drugs for Use in Military and Civilian Exigencies When Traditional Human Efficacy Studies are Not Feasible; Determination Under the Interim Final Rule that Informed Consent is not Feasible for Military Exigencies; Request for Comments" (62 FR 40996). Further in July 1997, FDA sent DOD a letter of deficiency that details DOD's failure to carry out its legal

and ethical obligations for the use of investigational products during the Gulf War. In addition to documenting deficiencies related to the use of BT vaccine and PB during the Gulf War, FDA also enumerated DOD's violations of federal regulations for its use of the investigational TBE vaccine in Bosnia. (We elaborate on this matter in the next section.)

[TEXT REDACTED]

Medical recordkeeping and investigational products during deployments. During combat or peacekeeping missions, U.S. troops need and deserve access to state-of-the art drugs and biologics designed to protect against disease or chemical or biological warfare agents; some of these products could have investigational status. In some cases a drug or biologic could be FDA-approved for one use, but not another. For example, FDA has approved PB for use in treating the disease myasthenia gravis, which is routinely administered at doses up to 17-fold greater than suggested for the short-term, pretreatment against chemical warfare (CW) agents—a use of PB that FDA has not approved. Investigational products also can be approved and routinely used elsewhere, but may not be used on U.S. troops unless FDA-approved. TBE vaccine is an example of this situation.

DOD acknowledged it did not comply with the letter or spirit of its agreement with FDA for use of BT vaccine or PB during the Gulf War. DOD concurred with our recommendations to improve medical recordkeeping in-theater—generally, as well as specifically for investigational products. Moreover, the Committee noted the special importance it placed on improvements in this area by finding "the issue of accurate medical and vaccination records is central to the concerns of many ill veterans, and the

absence of records has been suggested by some as evidence that the government is engaging in a cover-up of its own predeployment practices." (PACGWI, 1996a)

DOD has stated to several parties on multiple occasions that it had learned from its experience in the Gulf War, had improved its medical recordkeeping and investigational product policies, and had implemented new procedures and safeguards in the Bosnian deployment (DOD September 1996/November 1996 testimony). In fact, DOD's performance in Bosnia with the investigational TBE vaccine has been an abysmal failure. DOD's failure, however, is unrelated to a waiver of informed consent, which it did not seek for TBE vaccine in Bosnia.

As determined by FDA, DOD's use of TBE vaccine during Operation Joint Endeavor has violated federal regulations pertaining to investigational products on several accounts, including: recordkeeping failures; failure to monitor fully the study's progress; failure to ensure the protocol was followed so that safety and efficacy can be assessed; promotion of safety and efficacy for the investigational product; and failure to obtain Institutional Review Board approval of informed consent documents. FDA also expressed uncertainty about whether Army recordkeeping requirements governing documentation in service members' permanent records accurately reflected TBE immunizations had been violated. FDA concluded the deviations "do not give us confidence that DOD is at present capable of carrying out its obligations [under an investigational new drug (IND) application] for drugs and biologics that are intended to provide potential protection to deployed military personnel" (Friedman, 1997).

DOD and the Office of the Army Surgeon General, which is responsible for the TBE vaccine IND, again acknowledged problems with legal and ethical execution of the IND during deployment. In July 1997, DOD announced the formation of a committee, to be co-chaired by the Assistant Secretary of Defense (Health Affairs) and the Army Surgeon General, to address future work with investigational products. DOD stated its initiative will include other government agencies and civilian experts (Parker, 1997b).

We are less sanguine than FDA about DOD's capabilities with respect to evaluating investigational products during deployments. The Committee concludes DOD currently is incapable in this area; it's actions with TBE vaccine leave no room for any other interpretation. The Committee recognizes deployments present unique barriers to evaluating investigational products, but these obstacles are not insurmountable. Moreover, Bosnia is a peacekeeping situation, not a war. As with medical surveillance, if lessons from the Gulf War could not be implemented in Bosnia, the Committee wonders about the possibility of success during future conflicts. Moreover, we are concerned about related issues that the evaluation of investigational products raises in both deployment and nondeployment settings—such as the concept versus practice of obtaining informed consent from U.S. service members.

[TEXT REDACTED]

Research

In the *Interim Report*, the Committee found that the major epidemiological studies undertaken by DOD, VA, and DHHS were well-designed and appropriate. We noted, however, there appeared to be an inadequate response to external peer review, less than adequate regard for the importance of allocating scarce research dollars to the best designed studies, and inattention to the need to communicate effectively with veteran participants. The Committee's recommendations focused on better management of the research portfolio. For the *Final Report*, we concluded the government had been largely responsive to the recommendations of the Committee's *Interim Report*, but problems still remained in two areas: the use of public advisory panels for epidemiologic studies and the utility of the Persian Gulf Registry of Unit Locations. We offered new recommendations on these issues.

Since January 1997, the government has made commendable progress in implementing the Committee's recommendations pertaining to research. We note the most recent round of competition for new research proposals were solicited in three specific groups: i) the feasibility of epidemiological studies involving human subjects, including those thought to be near Khamisiyah, Iraq, in early March 1991 and animal studies to assess possible long-term or delayed clinical effects of low-level or subclinical exposures to CW agents; ii) potential health consequences of exposure to multiple risk factors; and iii) studies of historical war syndromes and physiological manifestations of stress.

Currently, DOD is in final negotiations for the awards, which will be announced in early October 1997. Under the competition for this pool of research funds, approximately

$2.8 million will be awarded for research on low-level health effects of CW agents and approximately $10 million for research on multiple interactions of risk factors used and/or encountered in the Gulf War. An insufficient number of meritorious proposals addressed the solicitation (approximately $4.5 million available) for research on historical war syndromes and stress-related sequalae, and the Research Working Group currently is assessing how to address this situation. All awards were subjected to competition and peer review, then selected for funding based on merit scoring.

The Committee particularly commends the government for its new initiatives targeted to health effects of low-level exposure to CW agents. As noted in the *Final Report*, "the amount of data from either human or animal research on low-level exposures [to CW agents] is minimal," but we believe the planned research may address any uncertainties and inconclusiveness identified in our December 1996 report. We hope this research can clarify the conundrums surrounding Gulf War veterans' illnesses.

With respect to the portfolio of federally funded research on Gulf War veterans' illnesses, we conclude the government is adequately and appropriately responding to our recommendations. Nevertheless, while the Committee approves of the government's targeted solicitation and the process used to make the awards, we have grave reservations about a significant degradation in the government's overall funding mechanism for research related to Gulf War veterans' illnesses. We note with serious concern that since our *Final Report* a substantial amount of money, $6.5 million, has been awarded without

undergoing external competition and peer review. It is immaterial to us that these funds did not come from the allocation set aside for the most recent solicitations and awards.

[TEXT REDACTED]

The Committee is not inflexible on this matter. We acknowledge benefit can accrue from small-scale, short-term funding on a sole source basis for pilot projects or to address narrow scientific questions—e.g., DOD's recent funding of $100,000 for technical issues related to a *Mycoplasma* test. Any protocols still should be peer reviewed prior to funding. Overall, such funding should be rare, limited in the amount of funds released, and not subject to renewal without competition.

Coordination

The Committee's *Final Report* noted the many positive efforts of the Coordinating Board's Disabilities and Benefits, Clinical, and Research Working Groups to address issues specific Gulf War veterans. Additionally, the Coordinating Board intends to establish a fourth working group, the Deployment Working Group. We identified, however, a need for a more forward looking initiative to coordinate post-conflict health concerns following other military engagements.

In April 1997, a Presidential Review Directive instructed the interagency National Science and Technology Council to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts or peacekeeping missions. The President's Committee of Advisors on Science and

Technology and other nongovernmental experts will review the report, which is scheduled for delivery in April 1998.

The Committee concludes the government is addressing the recommendation concerning coordination.

OVERSIGHT OF CHEMICAL AND BIOLOGICAL WEAPONS INVESTIGATIONS

In addition to assessing the departments' implementation of the Committee's recommendations, the President's Executive Order directed the Committee to continue our oversight and evaluation of the government's investigations related to possible CBW agent exposure incidents during the Gulf War. In the February 1997, the President also specifically asked the Committee to address the adequacy of the government's response to his concerns about the implications of then recently declassified documents associated with chemical munitions at Khamisiyah. The April 30, 1997, supplemental letter report contains the Committee's analysis of that task.

This section reports the Committee's views and recommendations based on our oversight of DOD and CIA's investigatory efforts and on the Committee's own inquiries. For this *Special Report*, we have opted to emphasize three broad aspects of the many facets that surround the government's ongoing work related to CW agent investigations: the technologies, the doctrine, and the investigation process. We do not elaborate on issues related to biological warfare agents in this document; appendix B reiterates our assessment of these matters.

Over the past ten months, the Committee primarily used individual case investigations as a means to identify in this *Special Report* the macro issues that decisionmakers should attend to because of their importance for current and future policy. By adopting this approach, it should not be inferred the Committee considered the individual investigations unnecessary. In fact, these investigations were critical to shape the Committee's recommendations on what we view should be the government's next steps to fulfill its commitment to Gulf War veterans.

The Technologies

As the Committee's *Interim Report* discussed, the United States deployed several types of CW agent detectors. M8A1 automatic chemical agent alarms served as the primary U.S. early warning system. Fox reconnaissance vehicles with MM-1 mass spectrometers were deployed, and M256A1 chemical agent detector kits and hand-held chemical agent monitors also were used. Each service member had access to M8 or M9 paper, which are sensitive to liquid chemical agents. Finally, M272 kits were available to detect the presence of chemical agents in water.

Despite the array of technologies available to U.S. troops during the Gulf War, the *Interim Report* also noted all CW agent detectors and warning systems deployed were set to detect nerve agent concentrations that would cause acute symptoms or death, not subclinical concentrations. Nor could M8A1 alarms—troops' primary warning system—detect mustard agent at any concentration. Even at this early juncture, we expressed concern that "battlefield detectors could not measure the types of low-level exposure that

DOD regulations guard against in non-battlefield situations." Hence, the Committee recommended in the *Interim Report* that DOD devote more attention to developing the capability to monitor subclinical exposures to CW agents. Yet as we noted in the *Final Report*, "DOD has not accepted or implemented the Committee's recommendation to develop and implement low-level CW agent monitoring."

The Committee's recent oversight activities have served to underscore the fact that developing appropriate CW agent detection technologies is an imperative. During the Committee's review of individual case investigations, which involve various technologies, new problems with CW agent detectors have been opened to public scrutiny—particularly for the Fox vehicle. Additionally, while our *Interim Report* noted deficiencies in the M8A1 alarms, we observe here that M8A1 alarms were so nonspecific that some units actually were ordered to ignore or disable them.

First, and of over-arching concern for all detectors: Not only were CW agent detectors used during the Gulf War *set* to detect only immediately toxic, incapacitating, or lethal concentrations of agent, but even if circumstances indicated the need for low-level detection capability, the detectors available to U.S. troops *lacked the capacity* to be adjusted for such a purpose. Second, there is a significant and real possibility that the Fox vehicle technology used by U.S. forces would have overlooked a chemical weapons attack during the actual, contaminated battlefield conditions in the Kuwaiti Theater of Operations (KTO)—including detection of CW agent concentration where the earliest health effects

first appear.[2] (DOD training and doctrine, discussed in the following section, exacerbated this situation.)

[TEXT REDACTED]

The Doctrine

The Committee's oversight and investigation of possible CW agent incidents not only revealed technological deficiencies, but also raised questions about the aspects of military doctrine during the Gulf War that related to chemical and biological weapons. Testimony, interviews, and written submissions from DOD and service members whose primary responsibility involved CW agent-related matters were particularly useful to our deliberations.

The Committee realizes that the problems with CW agent-related doctrine for the Gulf War has implications for future force protection and should be reviewed. We do not diminish the importance of identifying lessons from the Gulf War to improve CW agent-related doctrine for future deployments. Of primary importance to the Committee's charge, however, was the direct, adverse impact that doctrine, or lack thereof, has had on the ability of veterans and the public to receive a full and valid accounting of possible CW agent exposure incidents. In this section, we emphasize three areas of particular concern

[2] The Fox vehicle contains a variety of sophisticated chemical detectors. The Committee's analysis on matters related to the Fox vehicle centers on its MM-1 mobile mass spectrometer. The MM-1 operates in two modes: alarm and full spectrum. Following an alarm for a CW agent, the MM-1 can be manually switched to the full spectrum. In theory, the full spectrum mode should provide a more accurate and comprehensive analysis of the compound. In fact, the full spectrum option used during the Gulf War would have analyzed and reported *only* on the compound present in the highest concentration. Hence, under polluted and contaminated battlefield conditions, significant levels of CW agent—subclinical or even first health effects—could have been present and alarmed, but would have been ignored by the Fox vehicle's MM-1 mass spectrometer in the follow-up full spectrum mode if the concentration of another interfering compound, for example oil-well fire smoke, was higher than the amount of CW agent that had triggered the alarm. The full spectrum analysis in such a case would report on the chemical composition of the oil-well fire smoke and miss reporting entirely the presence of the CW agent.

to us, but it should not be inferred these represent the universe of concerns about Gulf War doctrine governing CW agent incidents.

In-theater documentation and records management. Reporting of and recordkeeping for possible detections of chemical or biological weapons were not systematic or standardized during the Gulf War, making the reconstruction of events from operations logs and/or intelligence a challenge. The Committee recognizes the difficulty of imposing burdensome reporting requirements in the face of rapidly shifting combat priorities. Our principal concern centers on the lack of doctrine on the retention of CBW agent-related Gulf War records once they were created. For example, doctrine did not require that the services keep Fox vehicle MM-1 mass spectrometer tapes, which were detector-generated written records of possible CW agent detections. That such information now appears unrecoverable significantly hampers current investigations into possible CW agent detections and contributes to perceptions that the government destroyed or misplaced documents to avoid accountability.

Fox vehicle operation, detection, and confirmation. The Fox vehicle's mobile MM-1 mass spectrometer was widely used and highly regarded by the U.S. military during the Gulf War. When operated in the alarm mode, it could simultaneously monitor for the presence of several chemical compounds, including CW agents. As just noted, the Fox vehicle's technological capability is less than ideal. During our review of case investigations, we also identify deficiencies in the doctrine pertaining to Fox vehicles.

Dogma required that following an alarm for CW agent(s), the Fox vehicle's full spectrum capability should be engaged. Using the full spectrum mode, however, required that U.S. military personnel stop the Fox vehicle and return to the site where the MM-1 alarmed in order to perform the full spectrum analysis, which is a 20-minute process. Fox vehicle personnel recognized the danger stopping in the midst of battle would pose to themselves and their fellow service members, and so they did not stop. As a consequence, full spectrum analyses rarely were performed during the Gulf War. Moreover, doctrine is clear that unless a full spectrum analysis is conducted, a post incident evaluation should disregard the detection for lack of confirmation (Vigus, 1997; Stern 1997). We disagree with such a dismissal. In the midst of combat (e.g., during the Marine minefield breaching), such a series of events was impossible to follow. Doctrine was incompatible with battlefield use of and analyses from Fox vehicle detectors.

Low-level exposure to chemical warfare agents. Existing military doctrine only addresses exposure to debilitating or lethal doses of nerve or mustard agents. Notable in its absence is doctrine specific to low-level exposures—i.e., exposures not leading to first health effects but above DOD's general population limit standard.

[TEXT REDACTED]

The Investigations

In the *Final Report*, the Committee recommended ". . . further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD. Openness in oversight activities—including public

access to information and veteran participation—public notice of meetings, opportunity for public comment, and regular reporting are essential. . . ." In one of two instances (see also implementation), DOD partially concurred with this recommendation. DOD's response accepted oversight, but it indicated, "the expertise and knowledge to investigate, analyze and to understand what happened resides in the Pentagon."

DOD has expanded significantly the resources it is devoting to Gulf War veterans' illnesses. As noted earlier, the Committee recognizes the considerable improvement DOD has made in outreach to Gulf War veterans, particularly veterans' service organizations; this section addresses the investigatory process per se. We first discuss one significant, but more focused, matter that had been unaddressed in the *Final Report*: exposure modeling for the demolition of CW agent rockets at the Khamisiyah pit area. We then report the broader evaluation of our oversight efforts during the past 10 months, focusing on DOD's efforts; as noted in our *Final Report*, CIA has been responsive to the Committee's concerns.

In assessing the government's performance with respect to investigating CW agent detections, the Committee's standard in this *Special Report* was our earlier finding that DOD's efforts were unlikely to provide credible answers to veterans' and the public's questions. In other words, the Committee based its new recommendations on the question: Is the current DOD initiative perceived as credible?

Exposure modeling of Khamisiyah pit demolition. The Committee has expressed on multiple occasions our displeasure with the time it took to complete modeling for the pit area. We are pleased that in July 1997 CIA and DOD completed modeling for the March 10, 1991, demolition at the Khamisiyah pit (CIA/DOD, 1997). The Committee also is convinced that the fact the modeling was completed demonstrates the value of oversight through public meetings. We commend CIA's and DOD's efforts, but believe the scope of DOD's notification efforts should be expanded. Currently, DOD has targeted individuals identified as being under the exposure plume.[3]

[TEXT REDACTED]

Bias in fact finding and analysis. DOD's current investigatory approach and reporting of specific incidents through case narratives has been less superficial than the many earlier attempts that purported to address the possibility of presence or release of CBW agents during the Gulf War. Nevertheless, we note that during the past 10 months, DOD has failed to thoroughly and promptly investigate all detections by the most reliable chemical agent detectors the United States fielded during the Gulf War—Fox vehicle MM-1 spectrometers and M256 kits—as we recommended. Moreover, the Committee already has documented in the preceding sections how the deficiencies in technology and doctrine already had biased DOD against viewing any detection as credible.

[3] Beginning in August 1996, DOD began notifying approximately 20,000 individuals they could have been exposed to low levels of CW agent. Based on the July 1997 modeling, 10,075 of these troops have been identified as being outside the area of the plume. DOD also intends to notify these individuals of their change in status.

DOD posits it is gathering all the facts, about which individuals might then disagree on interpretation. DOD emphasizes one function of its case narratives is to seek additional information. On face value, the Committee could conclude we have no disagreement with either message. For the past 10 months, however, it has been our observation that many individual analysts who follow elements of a case on a day-to-day basis do so without bias; we commend their efforts. At some point, however, the evaluation succumbs to an institutional culture and pervasive inclination to reimpose DOD's longstanding position that there is no evidence that CW agents were present in southern Iraq—except Khamisyah (acknowledged June 1996) and Ukhaydir (acknowledged July 1997). We note bias is not limited to analyses, but also can extend to fact finding; lack of due diligence means only certain facts come to light. We briefly highlight three specific examples to illustrate our concerns about bias:

- DOD's predisposition to downplay information that contradicts existing views on CW agents and the Gulf War;
- DOD's failure to present balancing, but conflicting, statements by its own CW detection experts; and
- DOD's failure to pursue, acknowledge, or account for facts identified and analyzed by MITRE Corp., under a contract to the Assistant to the Secretary of Defense (Intelligence Oversight) (ATSD(IO)).[4]

[4] We focus on the ATSD(IO)'s effort because i) MITRE's work is an independent analysis of intelligence related to CW agents, and ii) the process and product had progressed further than those of DOD's Inspector General, CIA's Inspector General, and the Army Inspector General (appendix E).

First, until the Committee's existence, DOD maintained categorically there was no credible or verifiable evidence that CW agents were used or present in the KTO. In June 1996, following revelations about the Khamisiyah munitions depot, DOD began to qualify this statement to "none other than at Khamisiyah." In July 1997, DOD acknowledged as many as 6,000 mustard shells had been present at Ukhaydir, requiring DOD to further qualify its statements. This latter acknowledgment came only after the United Nations Special Commission called attention to Ukhaydir and CIA pursued the analysis at the Committee's request. Early efforts by DOD staff had been to dismiss or to attempt to minimize the situation to Committee staff and others as being limited to a handful of shells; exposure modeling is underway for two events of Coalition bomb destruction of more than 200mustard shells at Ukhaydir (Walpole, 1997).[5] Time after time over the past 10 months, the Committee has battled with DOD about its fact finding and interpretations related to possible CW agent incidents—an approach we believe serves to exacerbate the department's credibility problems.

The second example centers on DOD's recently released case narrative for the Marine Corps minefield breaching (DOD, 1997b). Part of DOD's assessment involved reporting on the judgment its technical experts rendered as to whether conclusions could be drawn from Fox vehicle detection tapes—in this example, tapes available for and associated with an alarm reported on February 24, 1991, by the 2d Marine Division. In its narrative, DOD

[5] In September 1997, CIA testified before the Committee on one preliminary Ukhaydir modeling plume at the general population limit. Based on troop locations provided by DOD, the data indicate U.S. troops were not under the plume for mustard rounds bombed on February 13-14, 1991. The current footprint extends approximately 125 km, and DOD reports the closest U.S. forces were approximately 300 km from Ukhaydir. Modeling for agent release by mustard shells hit by Coalition air strikes on January 20, 1991, is pending. Additional modeling by DOD to account for weather variability for both events is expected by November 1997.

quotes the U.S. Army Chemical and Biological Defense Command (CBDCOM), as follows: "Because of the presence of high concentrations of interferents and the short time span between these responses, we conclude that the presence of the three chemical warfare compounds is highly unlikely."(Fahlsing, 1997) Yet DOD failed to acknowledge in the narrative that its own expert went on in the next sentence to conclude: "On the other hand, we cannot with great certainty conclude that they were not present."(Fahlsing, 1997)

Finally—and highly damaging to DOD's credibility from our perspective—was how the Office of the Special Assistant to the Secretary of Defense for Gulf War Illnesses (OSAGWI) failed to pursue, acknowledge, or account for facts that were directly relevant to its Marine Corps breaching case narrative. MITRE Corp., under DOD contract for a broader in-depth analysis on Khamisiyah and other potential Khamisiyah-like events, had reported information pertinent to Marine Corps activities, including the breaching, during the Gulf War. The Committee's view, based on its review of both MITRE's and OSAGWI's work, is that DOD's case narrative failed to acknowledge or account for facts uncovered by MITRE— even though OSAGWI had the document for nearly 2 months prior to releasing its narrative; OSAGWI maintains it incorporated MITRE's work, "as appropriate" (Rostker, 1997b). OSAGWI considers the draft MITRE report, which has yet to be released and contains some highly classified information, of poor quality and not to be taken seriously. We disagree. Committee staff have reviewed several draft versions of MITRE's work: MITRE's full report represents an impressive, high-quality investigation

and analysis. Moreover, the Office of the ATSD(IO) is to be commended for its role in identifying the approach, as well as executing and overseeing the MITRE contract; its efforts to ensure MITRE's access to the necessary intelligence; and its unbiased assistance and cooperation in facilitation of the Committee's work.

[TEXT REDACTED]

The Committee believes strong consideration should be given to an investigative effort that takes advantage of the database developed by MITRE Corp. for the ATSD(IO) and that builds on the existing expertise and analyses. A non-governmental entity, such as MITRE Corp., could be retained for the purposes of expanding analyses to additional matters other than Khamisiyah, but it should report to an entity outside DOD. Regardless of the specific entity leading future investigations, such an effort should review and analyze intelligence pertaining to: biological warfare agents; reported incidents involving the U.S. Marine Corps; and Coalition bombing and demolition activities at sites identified as having the highest probability of presenting a Khamisiyah-like scenario, including but not limited to Ukhaydir, Al Jazair, Rumaylah Ammo Storage Facility 1, and Ash Shuaybah. We do not intend this list to be exhaustive. Rather, the Committee takes note of these priority areas as additions to the *Final Report's* recommendation that stressed the importance of investigating all reports of positive detections from M256 kits and Fox vehicles.

We emphatically emphasize that our recommendation that an entity other than DOD (e.g., the President's Foreign Intelligence Advisory Board or the National Academy of

Sciences) perform oversight is not intended to reflect negatively on the ATSD(IO)'s exemplary handling of its tasks. The Committee's view, however, is that prudence dictates any opportunity that could be perceived as a conflict of interest should be avoided when possible.

Finally, we realize one factor contributing to the timeliness and success of the ATSD(IO)'s approach to the task he was assigned was his instruction that MITRE produce a thorough report without a priori addressing classification issues of source material. Yet the Committee's recognition that the strength of MITRE's work depended heavily on highly classified information does not undermine our view about the paramount importance of a publicly accessible oversight process. Our view that openness is essential for any evaluation of the government's continuing investigations on possible CBW agent exposures cannot be overstated. We are firmly convinced that much of what has been revealed about CBW agents and the Gulf War would have remained concealed without the pressure of public accountability.

Objective standards. The *Final Report* criticized DOD for first failing to articulate any objective criteria for assessing possible CW agent detections and then for adopting a military standard that requires a valid detection and physical symptoms of poisoning. In response to this criticism, DOD stated in March 1997 it would rely on a "best evidence" rule to establish "preponderance of the evidence" as the standard of proof. In our April 1997 supplemental letter report, the Committee noted that for matters involving the

presence or release of CW agents during the Gulf War, adherence to courtroom standards of evidence was inappropriate.

Following the release of the Committee's supplemental letter report, DOD announced it was employing a "common sense" approach—i.e., DOD has abandoned an objective standard (albeit one with a high threshold) in favor of a subjective decisionmaking process (Rostker, 1997a). The Committee disapproves strongly of this approach. In response to our repeated requests for clarification on what constitutes "common sense," and whose "common sense" serves as the determinant, DOD further articulated its standard for assessment is: "Do the facts available lead a reasonable person to conclude that CW agents were or were not present?" (DOD, 1997a).

[TEXT REDACTED]

CREDIBILITY AND COMMITMENT

Public distrust of government and large institutions has been on the rise since the mid-1970s. Such skepticism is not, of course, limited to issues raised by Gulf War health issues, but this spreading atmosphere of suspicion has fueled speculation about cover-ups and conspiracies surrounding governmental actions related to Gulf War veterans' illnesses—especially with respect to CW agent matters. Addressing the systemic nature of increased public misgivings about government falls beyond our scope. The Committee's oversight of investigations of possible CW agent exposures leads us, however, to believe the government must reinforce and renew its commitment to Gulf War veterans in order to begin erasing the perception of governmental inattention to them.

In the *Final Report*, the Committee reported that, for the most part, the government has largely acted in good faith and improved its handling of Gulf War veterans' health concerns in comparison to the post-Vietnam War era. We took strong exception, however, with DOD's inquiries into possible chemical and biological warfare agent incidents. We noted DOD's denials, delays, and actions had strained public trust and that, understandably, an atmosphere of government mistrust surrounded every aspect of Gulf War veterans' illnesses. The Committee emphasized that full public accountability would be essential in trying to restore public confidence in the government's, not just DOD's, commitment to Gulf War veterans.

Ten months after making this assessment, the government's credibility in addressing the health concerns of Gulf War veterans continues to be challenged. To be sure, room for improvement exists. The government's efforts have yielded important, new knowledge—but, still, progress is gradual. Unfortunately, however, such progress now often is viewed skeptically, at best. There remains a widespread and deeply held view that the government is failing to adequately address the health concerns of Gulf War veterans. In fact, the Committee perceives public mistrust about the government's handling of Gulf War veterans' illnesses not only has endured, but has expanded since the *Final Report*. This persistent atmosphere of distrust ill serves the Nation.

[TEXT REDACTED]

We recognize our charge is not to advise Congress; our recommendation centers on urging the Executive Branch to work with Congress. We hope a partnership among all concerned parties can implement this recommendation. The Committee notes, however, that the burden of action rests ultimately with Congress to address this recommendation via legislation.

The legacy of the Gulf War should not be the perception that the government cannot be trusted to candidly address legitimate concerns that veterans have raised—and often have been borne out—about their experiences during Operations Desert Shield/Desert Storm. Rather, the legacy should be a recognition by all Americans that the government acknowledges and honors its obligation to care for the men and women who served in the Gulf War. The Committee has appreciated the opportunity to serve Gulf War veterans, their families, and President Clinton.

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APPENDIXES

A. Executive Order 12961; charter
B. Findings and recommendations: *Interim Report*
   Findings and recommendations: *Final Report*
C. Executive Order 13034; charter
D. February 26, 1997, memorandum from the President
E. April 30, 1997, supplemental letter report
F. Advisory Committee Members
G. Advisory Committee Staff
H. Advisory Committee Meetings

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The American Legion

For God and Country

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June 5, 1997

Melanne Verveer
Chief of Staff
Office of the First Lady
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Ms. Verveer:

I am the director of The American Legion's programs for Gulf War veterans. The American Legion is the nation's largest veterans service organization with three million members, 45,000 of whom are Gulf War veterans.

We have been grateful for the First Lady's interest and concern for the thousands of veterans who suffer from Gulf War Illnesses (GWI), and for the children of Gulf War veterans who suffer from birth defects. We are aware of the First Lady's role in creating the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC), and we have acknowledged the PAC's positive impact on the federal government's approach to GWI. There are two aspects of GWI that the PAC has not had an impact on, however, and they are: medical treatment provided to Gulf War veterans by the federal government; and an open dialogue between federal agencies and the veterans community.

The PAC failed to adequately assess the effectiveness of the medical treatment offered to Gulf War veterans who suffer from poor health. This failure has prevented the federal government from conducting such an assessment itself. The outcome is that Gulf War veterans are not having their illnesses treated effectively, and they are therefore left feeling ill.

The federal agencies responsible for GWI were criticized by the veterans community for failing to inform its leadership about upcoming announcements concerning completed scientific findings. This failure had been adequately addressed late last year, most notably with the appointment of a Special Assistant for Gulf War Illnesses at the Department of Defense. Recently, however, federal agencies have made a concerted effort in withholding important information from the veterans community in order to affect the media coverage of particular announcements. These efforts have consequently undermined the fledgling period of trust that was developing.

I would appreciate the opportunity to discuss these concerns at your earliest convenience. I hope to offer a view of recent events and government programs that will assist the First Lady in remaining Gulf War veterans' most effective advocate. I look forward to your reply.

Sincerely,

MATTHEW L. PUGLISI
Assistant Director
Gulf War Programs

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The Worst Gulf War Ailment

By now there is little doubt that the Pentagon has botched beyond repair its investigation into whether inadvertent exposure to Iraqi chemical weapons might have caused illness among veterans of the Persian Gulf war. That does not mean that chemical weapons will necessarily prove to be a significant cause of the illnesses reported by tens of thousands of gulf war veterans. But it does mean that the Pentagon has lost credibility as an impartial judge of the evidence. There is little choice now but to put a more neutral agency in charge of the inquiry, as a Presidential panel is about to recommend. If the Pentagon is left in control, nobody will believe the verdict.

For five years after the 1991 war, the Pentagon adamantly denied that American troops had been exposed to chemical agents during the conflict. But as a series of investigative reports by a Times reporter, Philip Shenon, unearthed evidence to the contrary, that line gradually crumbled. It became clear that American combat engineers had blown up an Iraqi weapons depot that contained chemical weapons, making it likely that dangerous vapors had escaped. Official estimates of the number of American troops who might conceivably have been exposed rose steadily — from 150 to 5,000 to 15,000 to 20,000 or more. That last estimate is the number of troops within some 30 miles of one weapons depot from which chemical vapors might have been released.

The number of troops who might theoretically have been exposed could rise even higher if other releases, caused by demolition or allied bombing during the war, are established. Two former analysts with the Central Intelligence Agency contend that tens of thousands of Americans may have been exposed in as many as 60 separate incidents. Czech chemical detection troops registered nerve-gas alarms during the war in reports that the Pentagon concedes are credible.

But whether chemical releases caused much of the illness reported by gulf war veterans is uncertain. Some 80,000 of the 700,000 American troops who served in the gulf have requested special medical examinations to determine whether they were made sick by their service. They report a wide range of ailments, including chronic fatigue, aching joints and muscles, digestive problems, skin rashes and memory loss. But scientific panels gathered by the National Institutes of Health, the Defense Science Board and the Institute of Medicine of the National Academy of Sciences have found no unusual pattern of illness among the gulf war veterans as compared with soldiers serving elsewhere, and no clear link between the symptoms reported and chemical exposures.

The conventional scientific view, based on the scant studies available, is that unless a chemical weapon causes acute symptoms at the time of initial exposure, it is unlikely to cause health problems years later. Few of the gulf war veterans who are now sick reported typical chemical weapons symptoms at the time.

The latest group to pass judgment is a special White House panel set up to monitor the investigation after veterans complained about Pentagon stonewalling. As reported yesterday by Mr. Shenon, the Presidential Advisory Committee on Gulf War Veterans' Illnesses is considering a draft report that is sharply critical of the Pentagon's superficial investigation. Although the report finds it unlikely that the health effects reported by gulf war veterans were caused by chemical agents, the draft is being revised to make it clear that clusters of soldiers near demolition sites might have been sickened by exposure. The panel calls for an intensified inquiry under more independent investigators. That is the only way to restore credibility to this bungled enterprise.

Special Care for Special Education

Reforming New York State's special-education system will require dedication from both state and local officials — as well as an effort to reassure parents who fear a return to the days when disabled children were shunted into corners and ignored.

There are signs of hope. An important initiative is due soon from New York City's Schools Chancellor, Rudy Crew, who runs the largest system in the state. Meanwhile, State Education Commissioner Richard Mills proposes to increase state aid and target it better. His ideas deserve support from the Legislature and the Pataki administration.

Mr. Mills's special-education initiative is part of a broader reform and spending package that calls for a $300 million increase in state education aid, with the additional money focused on helping students reach the higher standards that the State Board of Regents put in place last year. The proposal would create a statewide reading program targeted broadly at young children from pre-kindergarten to fourth grade and particularly at the 20 percent of the state's third graders who cannot read at grade level. The funds will flow mainly to poorer schools that have the largest numbers of children with reading difficulties. To address overcrowding, Mr. Mills would spend $5 billion over the next five years to upgrade dilapidated schools.

These spending provisions are important. Many children with disabilities who benefit from special education in expensive, segregated classes are supposed to be returned to the educational mainstream under Federal law. But these children will surely fall by the wayside if the conventional schools are overcrowded or short of adequate support services.

Meanwhile, spending on special education itself is racing out of control, partly because of a dramatic expansion in enrollment. Special education now costs $3.6 billion statewide and consumes a quarter of the education budget. Students classified as learning disabled have increased by 55 percent, from 132,000 in 1983 to 204,000 today.

Mr. Mills's proposal would address this problem as well, mainly by clamping down on the incentives that mainstream schools now have to send children to special ed even though they may not need it. His idea is to change the funding formula. Currently, school systems get about $4,000 for each child sent from the mainstream into special education. Rather than reward schools for isolating the children, Mr. Mills would give each school district a fixed sum, based on the statewide average of children with disabilities, currently about 11 percent. This would discourage unnecessary referrals while controlling costs.

Such a plan would mean making distinctions between students with "severe" disabilities and students with "minor" ones. While special-ed advocates generally applaud Mr. Mills's ideas, they correctly warn that such distinctions should be drawn with care. Many bright children with speech or learning problems are in as much danger of failing and dropping out as children with more visible problems. On balance, however, the overall proposal represents an important step forward for New York State's special-education system.

Will the MCI Merger Help Consumers?

The proposed $20 billion takeover of MCI by British Telecommunications, the largest foreign takeover of an American company, has the potential to create a powerful rival to AT&T, Nynex and other American phone companies — a big plus for consumers. Yet if improperly handled by regulatory authorities, the merged company could do the opposite, squelching competition. The best outcome would have the merger go through, but only if British authorities impose regulatory protections.

MCI is the upstart company that over the past 20 years has wrestled 20 percent of American long-distance business from AT&T. British Telecom, owned by the British Government until 1984, controls 90 percent of domestic phone traffic in Britain. The merged company will become a formidable competitor, generating more than $40 billion in sales and employing about 180,000 people.

But a merger without conditions could do customers harm. British Telecom, like regional phone companies in the United States, controls the wires and switches through which almost all phone calls to British homes and businesses must pass. Carriers that want to provide local service must, in effect, rent British Telecom's wires. The question is at what price — since, left to its own devices, British Telecom would jack up the price to AT&T, thus blocking AT&T's entry.

The United States Federal Communications Commission cleverly solved a similar regulatory problem this summer. Under the 1996 telecommunications law, the commission issued rules that would enable AT&T, MCI and other carriers to compete for local phone customers by using facilities now owned by Nynex and the other regional monopolists. Those rules, now partially held up by a court challenge, would require the local carriers to rent wires and other facilities at a price that covers the costs that an efficient company would incur to provide the same facilities. In other words, local carriers would not be allowed to pass along the cost of wasteful expenditures they make as a regulated utility insulated from competition. The F.C.C. rules would also require that potential rivals be able to provide equivalent service to that furnished by the regional phone companies. For example, Nynex customers who wanted to switch to AT&T would not have to dial additional digits to complete a call.

As yet, similar protections do not exist under British rules. Until they do, a merged British Telecom-MCI could block entry by other carriers. Not only would AT&T or Sprint be unable to compete for British customers, they might also be put at a competitive disadvantage against MCI in American markets if the merged company used its regulation-protected profit in Britain to subsidize entry into United States markets.

An obvious solution would be for American regulators to insist that Britain adopt guidelines similar to those of the F.C.C. There is reason to be optimistic. British regulators are committed to deregulation. American carriers, like U S West and Nynex, already serve British customers, and domestic and international fares have plummeted in Britain since it privatized British Telecom in 1984. The challenge now is to prevent entrenched monopolists from interrupting the deregulatory progress.