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GULF WAR ILLNESSES

Federal Research Strategy Needs Reexamination

Statement of Donna Heivilin, Director of Planning and Reporting, National Security and International Affairs Division

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our evaluation of the federal strategy to research Gulf War illnesses. We reported our findings on this strategy in June 1997 as part of our response to a congressional mandate regarding the government's clinical care and medical research programs relating to illnesses suffered by Gulf War veterans.[1] I will first summarize our findings and provide some background information on the government's research program before giving you the details on our findings.

Results in Brief

In short, we found that

(1) the government was not proactive in researching Gulf War illnesses;

(2) the government's early research emphasized stress as a cause for Gulf War veterans' illnesses and gave other hypotheses, such as multiple chemical sensitivity, little attention;

(3) in contrast, the private sector pursued research on the health effects of low-level exposures to certain chemical warfare agents or industrial chemical compounds;

(4) government research used an epidemiological approach, but little research on treatment was funded; and

(5) most of the ongoing epidemiological research focusing on the prevalence or causes of Gulf War-related illnesses will not provide conclusive answers, particularly in identifying risk factors or potential causes due to formidable methodological and data problems.

Background

U.S. troops were reportedly exposed before, during, and after the Gulf War to a variety of potentially hazardous substances. These substances include decontaminating and protective compounds used without proper safeguards (particularly decontaminating solution 2, or DS2, and chemical agent resistant coating); diesel fuel used as a sand suppressant in and around encampments, fuel oil used to burn human waste; fuel in shower water; and leaded vehicle exhaust used to dry sleeping bags. Other

[1]Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed (GAO/NSIAD-97-163, June 23, 1997).

potential hazards included infectious diseases (most prominently leishmaniasis, a parasitic infection); pyridostigmine bromide and vaccines (to protect against chemical and biological weapons); depleted uranium (contained in certain ammunition and in residues from the use of this ammunition); pesticides and insect repellents, chemical and biological warfare agents; and compounds and particulate matter contained in the extensive smoke from the oil-well fires at the end of the war. Over 100,000 of the approximately 700,000 Gulf War veterans have participated in health examination programs that the Department of Defense (DOD) and the Department of Veterans Affairs (VA) established between 1992 and 1994. Of those veterans examined by DOD and VA, nearly 90 percent have reported a wide array of health complaints and disabling conditions, including fatigue, muscle and joint pain, gastrointestinal complaints, headaches, depression, neurologic and neurocognitive impairments, memory loss, shortness of breath, and sleep disturbances. Some of the veterans fear that they are suffering from chronic disabling conditions because of exposure during the war to substances with known or suspected health effects.

The federal government, primarily through DOD and VA, has sponsored a variety of research on Gulf War veterans' illnesses. DOD's research is one component of a broader agenda coordinated under the aegis of the Persian Gulf Veterans' Coordinating Board (PGVCB), which comprises the Secretaries of the Department of Health and Human Services, VA, and DOD. The details of this agenda are described in the PGVCB publication entitled A Working Plan for Research on Persian Gulf Veterans' Illnesses.[2] This agenda was developed in response to an Institute of Medicine conclusion that the DOD and VA should determine specific research questions that need to be answered and design epidemiologic research to these questions. Accordingly, most of the research sponsored under this agenda is characterized by PGVCB as epidemiological.

The objectives of epidemiologic research are to determine the extent of diseases and illness in the population or subpopulations, the causes of disease and its modes of transmission, the natural history of disease, and the basis for developing preventive strategies or interventions.[3] To conduct such research, investigators must follow a few basic generally accepted principles.

[2]A Working Plan for Research on Persian Gulf Veterans' Illnesses (First Revision), Department of Veterans Affairs, November 1996.

[3]A. M. Lilienfeld and D. E. Lilienfeld, Foundations of Epidemiology (New York: Oxford University Press, 1980).

First, they must specify diagnostic criteria to (1) reliably determine who has the disease or condition being studied and who does not and (2) select appropriate controls (people who do not have the disease or condition).

Second, the investigators must have valid and reliable methods of collecting data on the past exposure(s) of those in the study and possible factors that may have caused the symptoms. The need for accurate, dose-specific exposure information is particularly critical when low-level or intermittent exposure to drugs, chemicals, or air pollutants is possible. It is important not only to assess the presence or absence of exposure but also to characterize the intensity and duration of exposure. To the extent that the actual exposure of individuals is misclassified, it is difficult to detect any effects of the exposure. Another means of linking environmental factors to disease is to determine whether or not evidence shows that as the exposure increases, the risk of disease also increases. However, this dose-response pattern can be detected only if the degree of exposure among different groups can be determined.

Finally, in addition to specific case definition and dose-specific exposure information with known accuracy, it is important that a sufficient number of persons be studied to have a reasonable likelihood of detecting any relationship between exposures and disease. To the extent that this relationship is subtle or obscured in particular investigations by "loose" case definition (that is, a case definition that is too broad and encompasses different types of illnesses) or problems in measuring exposure, larger samples would be required. For example, the Institute of Medicine noted that "very large groups must be studied in order to identify the small risks associated with low levels of exposure, whereas a relatively small study may be able to detect the effect of heavy or sustained exposure to a toxic substance. In this way, a study's precision or statistical power is also linked to the extent of the exposure and the accuracy of its measurement. Inaccurate assessment of exposure can obscure the existence of such a trend and thus make it less likely that a true risk will be identified."[4] Similarly, if an exposure had an effect only on a particular birth defect for example, this effect might be missed by studying all birth defects as a group.

[4]Veterans and Agent Orange: Update 1996 (Washington, D.C.: Institute of Medicine, 1996), pp. 99-100.

Government Was Not Proactive in Researching Causes of Gulf War Veterans' Illnesses

Although Gulf War veterans' health problems began surfacing in the early 1990s, the vast majority of research was not initiated until 1994 or later. And much of that research responded to legislative requirements or external reviewers' recommendations. As noted by external reviewers, since federal research goals and objectives were not identified until 1995, after most research activities had been initiated, the research reflects a rationalization of ongoing activity rather than a research management strategy.

The government's 3-year delay complicated the researchers' tasks and limited the amount of completed research available. Of the 91 studies receiving federal funding, over 70 had not been completed at the time of our review. The results of some studies will not be available until after 2000.

By the time research was accelerated and broadened, opportunities had been missed to collect critical data that researchers cannot accurately reconstruct. Even efforts to measure the chemical content of the oil-fire smoke, begun only 2 months after the fires began burning, were initiated after most troops had left the affected areas and the climatological dynamics were different. Consequently, researchers had to use statistical models of the behavior of smoke plumes in order to infer the ground-level exposures experienced by the large numbers of troops who had departed by the time they began collecting data. Even if such models could accurately explain the behavior of the smoke plumes, they had not been validated as measures of individual exposure, and their accuracy for this purpose could not be presumed. Similar and even more serious problems were caused in the measurement of other exposures by the failure to collect data promptly and maintain adequate records.[5]

The delay in starting research has also hindered accurate reporting of exposures by Gulf War veterans. At the time of our review, 6 years after the war ended, questionnaires were being distributed requesting information from veterans on their exposures to certain agents during the war.

[5]See Defense Health Care: Medical Surveillance Has Improved Since the Gulf War, but Results in Bosnia Are Mixed (GAO/NSIAD-97-136, May 13, 1997) and Institute of Medicine, Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems, p. 5 (Washington, D.C.: National Academy Press), 1996.

Initial Government Research Emphasized Stress; Other Hypotheses Were Not Pursued Until Later

Early federal research appeared to emphasize risks associated with psychological factors such as stress. To support this emphasis, DOD pointed out that the psychological state of mind can influence physical well-being. DOD also pointed to a recent argument that from the American Civil War onward (and perhaps even earlier), a small number of veterans have reacted to the stress of war by suffering symptoms similar to those reported by some Gulf War veterans.[6]

Of the 19 studies initiated before 1994, roughly half focused on exposures to stress or the potential for posttraumatic stress disorder (PTSD) among returning troops.[7] As late as December 1996, the Presidential Advisory Committee noted that "stress is the risk factor funded for the greatest fraction of total - 32 studies (30 percent)."[8]

While research on exposures to stress received early emphasis, other hypotheses have received scant support. In its Final Report, the Institute of Medicine discusses the evidence for a number of disease hypotheses, including multiple chemical sensitivity, fibromyalgia, and organophosphate-induced delayed neuropathy. However, the federal research program has supported only one study of the relationship between symptoms reported by veterans and fibromyalgia. In addition, prior to October 1996, only one of the studies initiated in response to Gulf War veterans' illnesses focused on the health effects of potential exposures to chemical warfare agents.[9] While multiple studies of the role of stress in the veterans' illnesses have been supported with federal research dollars, other hypotheses have been pursued largely outside the federal research program.

Although veterans raised concerns about potential chemical exposures soon after the war, the federal research plan was not modified to include an investigation of these concerns until 1996, when DOD acknowledged potential exposures to chemical agents at Khamisiyah, Iraq. The failure to

[6]K.C. Hyams et al., "War Syndromes and Their Evaluation: From Civil War to the Persian Gulf War," Annals of Internal Medicine, vol. 125 (1996), pp. 398-405.

[7]An additional 3 of the 19 studies did not provide information about veterans' illnesses but were instead building databases or methods to be used in later studies. Notably, according to PGVCB, none of these three studies had been completed as of June 1997.

[8]Presidential Advisory Committee on Gulf War Veterans' Illnesses, Final Report, p. 34 (Washington D.C.:GPO), December 1996.

[9]This study of the impacts of sulfur mustard agent is a collaborative effort between the Portland VA Medical Center and the Oregon Health Sciences University. The principal investigator for the study pointed out that the possibility of chemical warfare exposure seemed plausible even in 1994 when he sought initial funding for this research.

fund such research cannot be traced to an absence of investigator-initiated submissions. According to DOD officials, three recently funded proposals on low-level chemical exposure had previously been rejected.[10]

Private Sector Pursued Variety of Hypotheses

A substantial body of research suggests that low-level exposures to chemical warfare agents or chemically related compounds, such as certain pesticides, are associated with delayed or long-term health effects. For example, abundant evidence from animal experiments, studies of accidental human exposures, and epidemiologic studies of humans shows that low-level exposures to certain organophosphorus compounds, including sarin nerve agents to which our troops may have been exposed, can cause delayed, chronic neurotoxic effects. This syndrome is characterized by clinical signs and symptoms manifested 4 to 21 days after exposure to organophosphate compounds. The symptoms of delayed neurotoxicity can take at least two forms: (1) a single large dose may cause nerve damage with paralysis and later spastic movement and (2) repetitive low doses may damage the brain, causing impaired concentration and memory, depression, fatigue, and irritability. These delayed symptoms may be permanent.

As early as the 1950s, studies demonstrated that repeated oral and subcutaneous exposures to neurotoxic organophosphates produced delayed neurotoxic effects in rats and mice. In addition, German personnel who were exposed to nerve agents during World War II displayed signs and symptoms of neurological problems even 5 to 10 years after their last exposure. Long-term abnormal neurological and psychiatric symptoms as well as disturbed brain wave patterns have also been seen in workers exposed to sarin in sarin manufacturing plants.[11] The same abnormal brain wave disturbances were produced experimentally in primates by exposing them to low doses of sarin.[12]

[10]The three previously unfunded proposals address central nervous system targets for organophosphates, development of a DNA-based method for assessing exposures to mustard agent, and work on the pharmacokinetics of the nerve agent VX.

[11]F. H. Duffy et al., "Long-Term Effects of an Organophosphate Upon the Human Electroencephalogram," Toxicology and Applied Pharmacology, vol. 47 (1979), pp. 161-176, and F.R. Sidell,"Soman and Sarin: Clinical Manifestations and Treatment of Accidental Poisoning by Organophosphates," Clinical Toxicology, vol. 7 (1979), pp. 1-17.

[12]J. L. Burchfield et al., "Persistent Effect of Sarin and Diodrin Upon the Primate Electroencephalogram," Toxicology and Applied Pharmacology, vol. 35 (1976), pp. 365-379.

Delayed, chronic neurotoxic effects were also seen in animal experiments after the administration of organophosphates.[13] These effects include difficulty in walking and paralysis. In recent experiments, animals given a low dosage of the nerve agent sarin for 10 days showed no signs of immediate illness but developed delayed chronic neurotoxicity after 2 weeks.[14]

It has been suggested that the ill-defined symptoms experienced by Gulf War veterans may be due in part to organophosphate-induced delayed neuropathy.[15] This hypothesis was tested in a privately supported epidemiological study of Gulf War veterans.[16] In addition to clarifying the patterns among veterans' symptoms by use of statistical factor analysis, this study concluded that vague symptoms of the ill veterans are associated with objective brain and nerve damage compatible with the known chronic effects of exposures to low levels of organophosphates.[17] It further linked the veterans' illnesses to exposure to combinations of chemicals, including nerve agents, pesticides in flea collars; DEET and highly concentrated insect repellents; and pyridostigmine bromide tablets.

Finally, research that we reviewed also indicates that agents like pyridostigmine bromide, which some Gulf War veterans took to protect themselves against the immediate, life-threatening effects of nerve agents, may alter the metabolism of organophosphates in ways that activate their

[13]M. B. Abou-Donia, "Organophosphorus Ester-induced Delayed Neurotoxicity," Annual Review of Pharmacology Toxicology, vol. 21 (1981), pp. 511-548, and M. K. Johnson, "The Target for Initiation of Delayed Neurotoxicity by Organophosphorus Esters: Biochemical Studies and Neurotoxicological Applications," Review of Biochemistry and Toxicology, vol. 4 (1982), pp. 141-212.

[14]K. Husain et al., "Assessing Delayed Neurotoxicity in Rodents after Nerve Gas Exposure," Defense Science Journal, vol. 44 (1994), pp. 161-164; K. Husain et al., "Delayed Neurotoxic Effects of Sarin in Mice After Repeated Inhalation Exposure," Journal of Applied Toxicology, vol. 13 (1993), pp. 143-145; and K. Husain et al., "A Comparative Study of Delayed Neurotoxicity in Hens Following Repeated Administration of Organophosphorus Compounds," Indian Journal of Physiology and Pharmacology, vol. 39 (1995), pp. 47-50.

[15]R. W. Haley et al., "Preliminary Findings of Studies on the Gulf War Syndrome," Presentations to the Intergovernmental Coordinating Board for the Gulf War Illnesses and the Staff of the Presidential Advisory Committee on Gulf War Veterans' Illnesses," September 16, 1995, and R. W. Haley, "Organophosphate-Induced Delayed Neurotoxicity," Internal Medicine Grand Rounds, University of Texas Southwestern Medical Center, Dallas, Texas, October 10, 1996.

[16]This research, conducted at the University of Texas Southwestern Medical Center, has been supported in part by funding from the Perot Foundation.

[17]R. W. Haley et al., "Is There a Gulf War Syndrome? Searching for Syndromes by Factor Analysis of Symptoms," Journal of American Medical Association, vol. 277 (1997), pp. 215-222; R. W. Haley et al., "Evaluation of Neurologic Function in Gulf War Veterans: A Blinded Case-Control Study," Journal of American Medical Association, vol. 277 (1997), pp. 223-230; and R. W. Haley et al., "Self-reported Exposure to Neurotoxic Chemical Combinations in the Gulf War: A Cross-sectional Epidemiologic Study," Journal of American Medical Association, vol. 277 (1997), pp. 231-237.

delayed, chronic effects on the brain.[18] Moreover, exposure to combinations of organophosphates and related chemicals like pyridostigmine or DEET has been shown in animal studies to be far more likely to cause morbidity and mortality than any of the chemicals acting alone.[19]

Despite the fact that in 1994, Congress directed DOD and VA to research treatments for ailing Gulf War veterans, such research has largely not taken place. While 61 of the 91 federally sponsored studies (67 percent) were classified as epidemiological by the PGVCB, only three of the studies had focused primarily on identification and improvement of treatments for these illnesses.

Formidable Methodological Problems Have Hampered Research

Our review indicated that most of the epidemiological studies have been hampered by data problems and methodological limitations and consequently may not provide conclusive answers in response to their stated objectives, particularly in identifying risk factors or potential causes.

Measurement of Exposures Is Problematic

The research program to answer basic questions about the illnesses that afflict Gulf War veterans has at least three major problems in linking exposures to observed illness or symptoms. First, it is extremely difficult to gather information about unplanned exposures (for example, oil-fire smoke and insects) that may have occurred in the Gulf. And DOD has acknowledged that records of planned or intentional exposures (for example, the use of vaccines and pyridostigmine bromide to protect against chemical/biological warfare agents) were inadequate. Second, the veterans were typically exposed to a wide array of agents with commonly accepted health effects, making it difficult to isolate and characterize the effects of individual factors or to study their combined effects. Third, the passage of time following these exposures has made it increasingly

[18]C. N. Pope and S. Padilla, "Potentiation of Organophosphorus Delayed Neurotoxicity," Journal of Toxicology and Environmental Health, vol. 31 (1990), pp. 261-273.

[19]M. B. Abou-Donia et al., "Increased Neurotoxicity Following Concurrent Exposure to Pyridostigmine Bromide, DEET, and Chlorpyrifos," Fundamental of Applied Toxicology, vol. 34 (1996), pp. 201-222 and M. B. Abou-Donia et al., "Neurotoxicity Resulting From Coexposure to Pyridostigmine Bromide, Deet, and Permethrin," Journal of Toxicology and Environmental Health, vol. 48 (1996), pp. 35-56.

difficult to have confidence in any information gathered through retrospective questioning of veterans.[20]

In part, the latter difficulty was created by the delayed release of information about detection of chemical warfare agents during the war as well as the delayed collection of exposure data. Five years passed before DOD acknowledged that American soldiers may have been exposed to chemical warfare agents shortly after the war ended in 1991 (at the Khamisiyah site). Moreover, although chemical detections by Czech forces are regarded as valid by DOD, the origin of the detected chemical agents has not been identified by either DOD or the Central Intelligence Agency (CIA). In the face of denials by DOD officials, several researchers told us that they had considered it pointless to pursue hypotheses that the symptoms may have been associated with exposures to chemical weapons.

When we asked investigators responsible for federally funded epidemiological research how they were collecting data on the various elements to which Gulf veterans may have been exposed, they indicated that they had no means other than self-reports for measuring most of these elements. This reliance on self-reports was not much less for elements such as vaccines, for which the opportunity for record keeping clearly existed.[21]

Two problems are associated with reliance on self-reports for exposure assessments. First, recalled information may be inaccurate or biased after such a long time period; that is, some veterans may not remember that they were exposed to particular factors, while others may not have been exposed but nonetheless inaccurately report that they were. Information also may be biased if, for example, veterans who became sick following the war recalled their exposures earlier, more often, or differently from veterans who had not become sick. Second, there is often no

[20]Large numbers of veterans questioned during their participation in the VA's health registry examination program reported they did not know whether they were exposed to certain agents. "Don't know" responses were greatest for nerve gas (64.9 percent), mustard gas (60.2 percent), depleted uranium (52.5 percent), chemical-agent resistant coating (47.8 percent), microwaves (32.8 percent), paints or solvents (24.9 percent), and pyridostigmine (21.1 percent). To the extent that a response of some kind reflects greater certainty, veterans were more confident in their reports regarding smoke from tent heaters, passive smoking, diesel or other petrochemical fumes, skin exposure to fuel, pesticides in cream or spray form, and burning trash or feces, each of which resulted in fewer than 11 percent of respondents reporting "don't know." While such confidence does not necessarily mean that the reports are accurate, the lack of confidence in responding to questions about some exposures raises questions about studies relying on self-reports to assess these exposures.

[21]Defense Health Care: Medical Surveillance Improved Since Gulf War, but Mixed Results in Bosnia (GAO/NSIAD-97-136).

straightforward way to test the validity of self-reported exposure information, making it impossible to separate bias from actual differences in exposure frequency.

Several investigators were also relying on a model developed by the U.S. Army Environmental Hygiene Agency for assessing exposures to components of oil-fire smoke through the combination of unit location data with information from models of the distribution of oil-fire smoke. However, this model requires the use of unit location as a proxy for exposure, and the validity of this approach is unknown. The Presidential Advisory Committee has noted, "DOD's Persian Gulf Registry of Unit Locations lacks the precision and detail necessary to be an effective tool for the investigation of exposure incidents."

Case Definition Is Complicated by Presence of Nonspecific Symptoms

Another major hurdle to the development of a successful research agenda has been the difficulty in classifying symptoms into one or more distinct illnesses. Some veterans complain of gastrointestinal pain, others report musculoskeletal pain or weakness, and still others report emotional or neurological symptoms. As explained previously, development of one or more specific case definition is essential to conducting certain types of epidemiological studies.

The VA collected some data on symptoms beginning in 1992 with the initiation of its registry. However, these efforts to collect information about symptoms and exposures from registry participants were limited and nonspecific. This constrained VA's potential use of the information for improving understanding of the patterns of veterans' complaints. These data limitations were unfortunate, as detailed information about symptoms and exposures might have yielded earlier, more reliable analyses of the nature and causes of veterans' complaints and could have also assisted in developing working case definitions.

We also found that both the federally supported projects and the federal registry programs have generally failed to study the conjunction of multiple symptoms in individual veterans. Articles and briefing documents that we obtained from DOD and VA reported findings that addressed only the incidence of single symptoms and diagnoses. There were two exceptions. First, for an Air National Guard unit in Pennsylvania, the Center for Disease Control and Prevention developed an operational case definition, which was quite similar to the case definition of chronic fatigue

syndrome. Second, the studies conducted by Haley et al. also focused on identifying symptom clusters.

For those ongoing, epidemiological studies that were built on case-control designs, we asked about how a case was defined. The specificity of this definition is important because a vague case definition can lead to considering multiple kinds of illnesses together. When this is done, it is not surprising to find no commonality of experience among the cases. Moreover, the use of specific case definition is particularly critical to achieving meaningful results within this type of research design. At the same time, for the case definition to be relevant, it must fit the symptoms described by an important portion of the group being studied.

Sample Size

Most of the investigators we interviewed took steps to estimate the size of the sample they would require to have a reasonable expectation of detecting the effects of exposures to hazardous substances. However, many other variables were involved in such calculations, for example, the prevalence of exposures, some of which were unknown at the time the studies were planned. Thus, they had to make estimates within somewhat broad parameters.

Although steps were clearly taken to plan for an adequate sample size, some investigators reported difficulty in locating subjects due to factors beyond their control, such as the rate of referrals from VA examination centers or the rate of identification of subjects that fit highly specific case definitions. Moreover, other studies, such as those on specific birth defects, required extremely large samples.

Conclusions

The ongoing epidemiological research cannot provide precise, accurate, and conclusive answers regarding the causes of veterans' illnesses because of researchers' methodological problems as well as the following:

- Researchers have found it extremely difficult to gather information about many key exposures. For example, medical records of the use of pyridostigmine bromide tablets and vaccinations to protect against chemical/biological warfare exposures were inadequate.
- Gulf War veterans were typically exposed to a wide array of agents, making it difficult to isolate and characterize the effects of individual agents or to study their combined effects.

- Most of the epidemiological studies on Gulf War veterans' illnesses have relied only on self-reports for measuring most of the agents to which veterans might have been exposed.
- The information gathered from Gulf War veterans years after the war may be inaccurate or biased. There is often no straightforward way to test the validity of self-reported exposure information, making it impossible to separate bias in recalled information from actual differences in the frequency of exposures. As a result, findings from these studies may be spurious or equivocal.
- Classifying Gulf War veterans' symptoms and identifying their illnesses have been difficult. From the outset, the symptoms reported have been varied and difficult to classify into one or more distinct groups. Moreover, several different diagnoses might provide plausible explanations for some of the specific health complaints. It has thus been difficult to develop one or more working case definitions to describe veterans undiagnosed complaints.

Recommendations

Because of the numbers of veterans who have experienced illnesses that might be related to their service during the Gulf War, we recommended in our report that the Secretary of Defense, with the Secretary of Veterans Affairs, give greater priority to research on effective treatment for ill veterans and on low-level exposures to chemicals and other agents as well as their interactive effects and less priority to further epidemiological studies.

Mr. Chairman, that concludes my prepared remarks. I will be happy to answer any questions you may have.

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