



Rand Report Raises Concerns About Anti-Nerve Gas Pill (PB)

On October 19, 1999, the Department of Defense released a report by its contractor, the Rand Corporation, that focuses on pyridostigmine bromide (PB), used during the Gulf War as a pretreatment to protect military personnel from death in the event of an attack with the nerve agent soman,

For background information about PB, see the next article, which is an excerpt of an article that appeared in the January 1995 issue of this newsletter. Also see the article that follows entitled PAC and IOM on PB.

The Rand report considers a wide array of issues regarding the safety and effectiveness of PB. The discussion of safety explores seven hypotheses of how PB might lead to adverse health effects. Each of these hypotheses is investigated to determine if it can be rejected as a possible cause of the unexplained illnesses reported by some Gulf War veterans. The report explained that if sufficient evidence cannot be found to rule out a hypothesis, this does not imply that it is necessarily a causal factor, only that the possibility cannot be dismissed.

The 385-page scientific literature review contained two major conclusions. First, PB cannot be "ruled out" as a possible contributor to the development of unexplained or undiagnosed illness in some Gulf War veterans. Second, uncertainties remain regarding the effectiveness of PB in the protection of humans against nerve agents.

The report notes that most data on the effectiveness of PB in primates comes from studies using higher doses. It is unclear what these results mean for humans taking smaller doses. The authors added that some literature indicates that the use of PB may reduce the effectiveness of post-exposure treatment for some non-soman nerve agents. The extent and importance this reduction would have in humans is unknown

The report concludes that these findings "raise many questions and have important implications relating to the use of PB in military deployments. The authors call for more and prompt research into the effectiveness of PB for humans. Meanwhile, the issue is a complex one, involving trading off uncertain health risks--but risks that cannot with certainty be ruled out--against possibly uncertain gains from the use of PB in the warfare setting."

According to Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, there are 26 scientific studies, peer-reviewed or research projects underway that specifically address the health consequences of PB as a nerve pretreatment. The funding for this research is about \$20 million. These studies include evaluations of the interaction of PB with other chemicals and low-level exposure to nerve agents. Bailey declared that while most of the ongoing studies to date reveal no definitive results to link PB to illnesses seen in Gulf War veterans, we must continue this "very important" research to determine any causal relationship.

She concluded that "our leadership would be very judicious in deciding to use PB in the future. The decision would involve weighing the concerns about possible long-term effects with a threat-risk assessment of how likely it is that soman would be used against our troops."

The PB report is one of five that the Rand Corporation has prepared for DoD's Office of the Special Assistant for Gulf War Illnesses, headed by Bernard Rostker. According to Rostker, the most important of those reports focused on stress, oil well fires, depleted uranium, and now PB. Rostker indicated that this report was "unique because, for the first time, Rand did not reach a conclusion that the issue under study was not likely a cause of Gulf War illness. In this report, they have reached the conclusion that they just don't know..."

The text of the report is available on the internet at <http://www.gulflink.osd.mil>.



Background Information About PB

Some Persian Gulf veterans have expressed concern about the possible long term health consequences of pyridostigmine bromide (PB) which was issued to nearly all U.S. troops in the Persian Gulf as a nerve agent pretreatment drug.

PB has been approved by the Food and Drug Administration as a treatment for patients who have myasthenia gravis, a neuromuscular disease. It has been effectively used for this purpose for over forty years. Myasthenia gravis patients are known to take PB for many years in doses that are many times higher than those administered to troops without long term adverse health effects.

During Operation Desert Shield/Storm (ODS), sufficient safety data in humans and effectiveness data in animals was presented to the FDA for them to concur in the use of pyridostigmine as a pretreatment for nerve agent poisoning; a waiver of informed consent was granted.

ODS military personnel were provided with packets containing twenty-one, thirty milligrams PB tablets to be self-administered orally. The recommended dose of PB is one tablet every three hours to be initiated and stopped by the direction of the commanding officer. Other coalition troops also used PB as a pretreatment for nerve agents. Although it is not known how much PB was taken by individual servicemembers, it is likely that most members took at least one but not more than twenty-one tablets.

Common side effects of PB include nausea, vomiting, abdominal cramps, diarrhea, increased salivation, sweating, and muscle cramps. These effects appear within a short time after ingesting the PB tablet and reverse with discontinuation of the medication.

Two expert panels (the National Institutes of Health Technology Assessment Workshop and the Defense Science Board) made up of non-government scientists reviewed the use, safety, metabolism and toxicity of PB by troops in the Gulf War. Both groups concluded that the current scientific studies suggest that PB is an unlikely cause of the unexplained illnesses of Persian Gulf veterans.

PAC and IOM on PB

What did the Presidential Advisory Committee (PAC) on Gulf War Veterans' Illnesses conclude about the risks of PB to Gulf War veterans?

The PAC's Final Report, dated December 1996, includes the following language:

Given the extensive cumulative experience with the use of PB in patients with myasthenia gravis and data collected from military personnel, the Committee concludes it is unlikely that health effects reported today by Gulf War veterans are the result of exposure simply to PB. Ongoing federally funded studies should help the scientific community draw conclusions about the synergistic effects of PB and other risk factors.

What did the National Academy of Sciences' Institute of Medicine (IOM) conclude about the risks of PB to Gulf War veterans?

The IOM report, entitled *Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems*, dated 1996, includes the following sentence:

There have been no documented long-term side effects of PB.

IOM to Hold Dissemination Workshop on Reports on Measuring Health of Gulf War Veterans, National Center for Military Deployment Health Research

On December 16-17, 1999, the National Academy of Sciences' Institute of Medicine (IOM) will sponsor a workshop to identify and discuss important issues related to the implementation of two recent IOM reports. The first report, released in early September 1999, entitled *Gulf War Veterans: Measuring Health*, recommended development and implementation of a longitudinal cohort study to measure the current and changing health status of active duty military, reserve, and national guard units.

The report suggested that such a study could have important implications for understanding not only the health of Gulf War veterans, but also the health of veterans of other conflicts. The report recommended that a scientific and policy-oriented independent advisory board, which would include clinicians, scientists, and veterans, oversee the conduct of the study.

While the results of a number of scientific studies are now available and scientists have reached some conclusions about the possible long-term health consequences of military service in the Gulf War, many areas of uncertainty remain. The IOM report noted that

About the "Review"

The "Gulf War Review" is written by VA's Environmental Agents Service (EAS). The "Review" is published to provide information about the concerns of Gulf War veterans, their families, and others interested in possible long-term health consequences of military service in the Gulf War. The "Review" describes actions by VA and others to respond to these concerns.

The most recent, prior to this, issue of the newsletter is dated September 1999. Additional issues will be prepared when warranted by significant developments. EAS anticipates publication of the "Review" three or four times annually. Four issues were published in 1995 (January, April, August, and December), three in 1996 (March, September, and December), three in 1997 (March, June, and September), and four in 1998 (March, June, October, and December). This issue is the fourth for 1999. Earlier issues were published in March, June, and September 1999. It was completed in early November 1999 and does not include developments that occurred after that time.

Comments or questions concerning the content of the "Review" are encouraged. Suggestions and ideas for future issues of the newsletter should be sent to Donald J. Rosenblum, Deputy Director, Environmental Agents Service (131), VA Central Office, 810 Vermont Avenue, N.W., Washington, DC 20420.

Requests for additional copies of this and/or future issues should also be sent to Mr. Rosenblum. A limited supply of issues released in 1995-99 is available. Please specify the quantity and issue requested. VA facilities should order additional copies from the VA Service and Distribution Center. Each station has a Publications Control Officer (PCO). VA facilities should place any orders through their PCO using the LOG system. Questions about the Registry examination should be directed to the Registry Coordinator or Registry Physician at the nearest VA medical facility. The telephone number can be found in the local telephone directory under the "U.S. Government" listings. Assistance is also available from the toll-free VA Gulf War Helpline: 1-800-749-8387.

no one has yet determined the extent of the problem (the number of veterans with symptoms or illnesses they attribute to Gulf War service) or whether the health status of Gulf War veterans is better, worse, or about the same as veterans who were not deployed to the theater of operations.

In December 1997, VA and the Department of Defense asked IOM to consider the various questions that had been raised about the health of Gulf War veterans and to determine how best to measure and monitor the health of these veterans. The IOM was asked to 1) identify relevant questions regarding the health status of active-duty troops and Gulf War veterans; 2) identify issues to be considered in the development of study designs and methods that would be used to answer such questions; and 3) develop a research design(s) and methods to respond to such questions.

To accomplish this task, the IOM assembled a committee of experts in outcome analysis, study design, research methods, statistics, epidemiology, health status measurement, military health databases, clinical medicine, and Gulf War veterans' health.

The committee was co-chaired by Dan Blazer II, M.D., Ph.D., M.P.H., and Isabel V. Hoverman, M.D. Dr. Blazer is Dean of Medical Education and Professor of Psychiatry and Community and Family Medicine, Office of the Dean, Duke University Medical Center. Dr. Hoverman is with Austin Internal Medicine Associates, L.L.P., Austin, Texas, and is Clinical Assistant Professor of Medicine, University of Texas Medical Branch, Galveston.

The IOM committee met five times between May 1998 and April 1999. The committee also hosted a workshop, in May 1998, to obtain information on the health concerns of Gulf War veterans and an overview of relevant research.

Recommendations for Measuring Health

The committee concluded that a single study cannot satisfy all the information needs concerning Gulf War veterans' health. The committee recommended that a prospective cohort study of the Gulf War veterans be conducted. Such a study should include appropriate comparison groups.

The committee recommended that this study investigate the following four questions: 1) How healthy are Gulf War veterans? 2) In what ways does the health

of these veterans change over time? 3) Now and in the future, how does the health of Gulf War veterans compare with that of a) the general population; b) persons in the military during the Gulf War but not deployed; c) persons in the military during the Gulf War who were deployed to noncombat areas; and d) persons in the military deployed to other conflicts, such as Bosnia, Somalia? and 4) What individual and environmental characteristics are associated with observed differences in health between Gulf War veterans and comparison groups?

The committee also recommended that multiple studies be initiated through a research portfolio with three components: 1) population studies; 2) health services research studies; and 3) biomedical and clinical investigations.

The committee recommended that a core set of data on health be collected in all studies and include measures of 1) death and duration of life; 2) impairment; 3) functional status; 4) health perceptions; and 5) opportunity (the capacity for health, the ability to withstand stress, and physiological reserve).

The committee recommended that a core set of data on the correlates of health be collected in all studies. These data should include measures of individual and environmental characteristics that are associated with differences in health. Individual characteristics of interest include 1) biology and life course; 2) lifestyle and health behavior; 3) illness behavior; 4) personality and motivation; and 5) values and preferences. Environmental characteristics of interest include 1) social and cultural; 2) economic and political; 3) physical and geographic; and 4) health and social care.

The committee further recommended that the prospective cohort study serve as the foundation for the entire portfolio of activities. The committee recommends that this study incorporate the following features: 1) multiple cohorts, one for each group of interest; 2) multi-stage sampling with initial cluster sampling followed by stratified random sampling within clusters; and 3) random and representative selection of participants within clusters; hypothesis-driven oversampling of specific subgroups; and multiple modes of interviewing, including telephone and in-person interviewing.

The committee also recommended that a pilot study be conducted to determine the feasibility and cost of the prospective cohort study. The pilot study should include

an assessment of the following points: 1) for each of the cohorts, identification of the universe from which the sample is to be drawn, especially the Gulf War veteran sample; 2) willingness of members of each cohort to participate in the baseline study; 3) mode of data collection; and 4) use of incentives to maximize response rates.

Report on National Center for Military Deployment Health Research

A second report, to be released in early November, focuses on recommendations for the implementation of a National Center for Military Deployment Health Research. Recommendations of this report will focus on the structure and functions of such a center, and the appropriate roles for federal departments and agencies, veterans, scientists and other public members in the work of such a center.

The first day of the workshop will focus issues related to the September report. The second day will focus on issues involving the recommendations for implementing the national center. Both days will begin with a short plenary session followed by working groups that will consider a variety of issues related to implementation of the recommendations. At the end of each day, the groups will reconvene to report on their discussions.

The workshop will be held at the Crystal City Marriott in Northern Virginia.

National Health Survey of Gulf War Era Veterans and Their Families

The National Health Survey of Gulf War Era Veterans and Their Families is a large VA supported research study to determine how deployment to the Gulf has affected veterans' health. The health of one thousand Gulf War era veterans who were deployed to the Gulf, their spouses, and their children will be compared to the health of one thousand Gulf War era veterans who were not deployed to the Gulf, their spouses, and their children. Over 800 veterans and their families have been examined so far. Participants are randomly selected from a group of about 20,000 deployed and non-deployed veterans who previously participated in a mail and telephone survey of veterans' health.

Examinations are being performed at sixteen VA medical centers throughout the United States. Each

Registry Health Examinations Top 77,000

More than 77,000 Gulf War veterans have now completed the Gulf War Veterans Registry Health examination initiated by the Department of Veterans Affairs (VA) in August 1992.

All Gulf War veterans, with or without health problems, are invited to participate in the voluntary medical examination program offered at VA medical centers nationwide. A complete medical history, physical examination, and interview are performed and documented in the veteran's medical record. Each participating veteran is given the following baseline laboratory studies: 1) Chest x-ray (if medically appropriate); 2) complete blood count; 3) SMA-6, SMA-12, or equivalent blood chemistries and enzymes studies, and 4) urinalysis.

The Registry Physician (or designee) discusses with each individual participant the result of his or her physical examination, completed diagnostic studies, and laboratory results that are available when the physical examination is complete. The interview is conducted in such a way as to encourage the veteran to discuss any health concerns, as well as concerns expressed by family members. A description of the discussion and a copy of the personalized follow-up letter sent to each participant to further describe the veteran's condition, are included in the veteran's permanent health record.

The results of each examination are also summarized on a code sheet and combined with records of other veterans at the VA Automation Center in Austin, Texas, to assist researchers in developing scientific studies. To date, the most common problems among registry participants are 1) loss of memory and other general symptoms; 2) headache; 3) fatigue; 4) skin rash; and 5) muscle, joint pain.

Gulf War veterans who wish to participate in this examination program should contact the nearest VA medical center for an appointment.

III Spouses/Children Encouraged to Participate in Health Examination Program; Examinations May End in December

VA officials are encouraging and welcoming the spouses and children of Gulf War veterans to participate in an examination program designed to identify their

adult participant receives a thorough physical, neurological, and psychological examination, and routine laboratory tests. Female participants are offered a gynecological examination. In addition, tests to determine how well nerves and lungs are functioning are performed on veteran participants, Pediatricians, usually from a cooperating university medical center, examine children. The examination of a veteran and family typically requires a couple of days. VA pays the travel, hotel, and meal costs of each participant, and also compensates veterans and their families for their time.

Individuals who are selected to participate will receive a packet of information by mail that will explain the study in more detail and requests return of an enclosed "Letter of Intent" to participate. Individuals who do not receive this packet of information have not been selected to participate in this phase of the study. Letters of Intent are sent to a coordinating center and then to the assigned participating VA medical center. Study personnel will then contact the participants to schedule the examination.

Veterans who were not deployed to the Gulf who are invited to participate commonly ask, "Why do you want to examine me?" To completely understand the effects of the Gulf War experience, the health of veterans who were deployed and their families must be compared to the health of veterans who were not deployed and their families. If veterans who were not deployed and their families do not participate, researchers will not be able to determine if Gulf War-deployed veterans have more or less illnesses than other veterans.

Veterans who were not deployed also commonly ask, "Why should I participate? This will take a lot of time and will be inconvenient for both me and my family." The most direct benefit to everyone who participates is that they will receive a comprehensive examination that may detect an early phase of an illness that can then be treated before it causes permanent damage. The study has found illnesses such as high blood pressure, diabetes, high cholesterol, and anemia. With written approval, medical information will be sent to the participants' physician for follow-up and treatment. In addition, those who participate will have the satisfaction of knowing that they have contributed to the understanding of how the Gulf War has affected veterans' health.

problems and suggest possible areas for researchers. The health examination program for certain spouses and children of Gulf War veterans, established by the Department of Veterans Affairs (VA) in April 1996, has provided valuable health status information to participants. Last year, with the enactment of Public Law 105-368, this program was expanded and extended through December 31, 1999. It is unclear now whether the program will be extended again.

To be eligible for participation, an individual must (1) be the spouse or child of a veteran who is (a) listed in VA's Gulf War Veterans Health Registry, and (b) suffering from an illness or disorder; (2) be suffering from, or may have suffered from an illness or disorder (including a birth defect, miscarriage, or stillbirth) which cannot be disassociated from the veteran's service in the Southwest Asia theater of operations; and (3) have granted VA permission to include in the Registry relevant medical data from the evaluation. The examinations have been provided at more than thirty locations.

In addition to extending the program, Public Law 105-368 provided for program improvements through "enhanced flexibility," by permitting examinations to be completed under a fee arrangement and providing for VA payment of certain transportation expenses. Due to the complexity involved in contracting for pediatric examinations and the great distance many spouses and children were travelling for examinations, VA now is allowing facilities the option of paying private providers to conduct the examinations. The veteran (or spouse) must still call the toll-free Helpline (1-800-PGW-VETS; 1-800-749-8387) to register for this program and confirm their eligibility. Please note that no payments can be made to private physicians unless the above requirements are met and the spouse or child is officially enrolled in the examination program.

When the veteran is notified of program enrollment by the coordinating facility, he or she may request that the examination be conducted by his or her private physician. Private physicians must agree to fill out all required VA forms to obtain payment. If reimbursement for travel is required, VA will provide payment at the same rate as beneficiary travel for veterans. Reimbursement of travel costs is processed in the same way as payment for the examination; that is, all reimbursements are paid by the VA Denver Payment Processing Center.

Questions about this program should be directed to the Gulf War Veterans Helpline (**1-800-PGW-VETS; 1-800-749-8387**). Individuals wishing to participate in the program should call this toll-free telephone number. No treatment is available for illnesses detected in this program. Authority for the program was initially established in Public Law 103-446. It was extended by Public Law 104-262, and, as noted above, most recently by Public Law 105-368, the Veterans Programs Enhancement Act of 1998, signed by President Clinton on November 11, 1998.

Has Your Address Recently Changed? Are You Receiving More than One Copy of the Review?

If you have recently moved, please use this form to update our mailing list. Send the completed form to the Gulf War Review, Austin Automation Center (200/397A), 1615 Woodward Street, Austin, TX 78772-0001. Thank you.

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If you are receiving more than one copy of the newsletter, please let us know. Write to the address above, please provide your name, address, and social security number.. Thank you.

VA Issues Updated Questions & Answers Brochure, Research Fact Sheet

In September 1999, VA published an eight-page questions-and-answers brochure and a two-page research report on Gulf War veterans' illnesses. These publications were written by officials in the Environmental Agents Service in VA Central Office, with input from experts from several other departments and agencies. The September 1999 publications revise, update, and replace similar publications, dated June 1998.

The revised publications are being widely distributed to VA sites throughout the Nation as well as non-VA locations. Individuals who wish to obtain both or either of these items can contact the nearest VA facility or the Environmental Agents Service (131), VA Central Office, 810 Vermont Avenue, N.W., Washington, DC 20420.

The following questions are included in the brochure: Is there a "Persian Gulf Syndrome" or "Gulf War Syndrome"? What symptoms are Gulf War veterans reporting? What is VA doing to help veterans of Desert Shield and Desert Storm? What is the Gulf War Registry health examination program? How can a veteran participate? What happens to the information gathered in the registry examination program? Can an ill Gulf War veteran get medical treatment at VA for his or her medical problems? Can the spouses and children of Gulf War veterans get free medical examinations? What happens if a veteran has symptoms that cannot be diagnosed by doctors at the local VA medical center? and How can a veteran get referred to one of these special centers?

Additional questions include: What VA research is going on regarding Gulf War veterans' illnesses? What is depleted uranium (DU), and why are Gulf War veterans concerned about exposure to it? What is VA's view on Gulf War veterans' exposure to chemical warfare agents? Is an infectious agent making Gulf War veterans ill? What treatment is effective for the symptoms that some Gulf War veterans are experiencing? Do the children of Gulf War veterans have an increase in birth defects? Can a veteran be compensated for illnesses related to Gulf War service? and How can a Gulf War veteran, family member, or

other interested people keep up-to-date on scientific developments, legislation, and related matters?

The research report describes major research initiatives (including two new major studies), the roles of the Persian Gulf Veterans Coordinating Board and the National Academy of Sciences' Institute of Medicine, VA environmental hazards research centers, two large-scale Gulf War-related studies undertaken by VA Environmental Epidemiology Service, and important research findings to date.



HELPLINE Update

In 1995, the Veterans Health Administration and the Veterans Benefits Administration, the two largest agencies in the Department of Veterans Affairs (VA), jointly established the VA Gulf War Information Helpline Center at the St. Louis VA Regional Office. The Helpline provides substantive information and service referral to Gulf War veterans and their families. The toll-free telephone number for the Helpline is **1-800-PGW-VETS** or **1-800-749-8387**.

The April 1995 issue of this newsletter includes an article about the establishment of the Helpline.

Ms. Cheryl Everett is an original member of the Helpline contract team who staff the Helpline. During the past four years, she has answered many of the more than 400,000 calls the Helpline has received. Recently, a troubled New York-area veteran called the Helpline, announcing that he had a gun and planned to kill himself. Ms. Everett kept him on the phone while alerting VA Regional Office personnel of the situation.

Ms. Everett convinced the veteran to accept help from a VA physician and a counselor who arrived at the scene. Ms. Everett's experience, coupled with her compassion and self-control, defused a potentially deadly situation.

Mr. Mike Scheibel, Helpline supervisor, coordinated efforts with the staff of the motel where he was staying, the VA Regional Office in New York, New York Vet Center counselors, and local law enforcement personnel.

Ms. Everett, Mr. Scheibel, and their colleagues in St. Louis are truly making a difference in the lives of Gulf War veterans - one veteran at a time.

Where to Get Help

Active duty military personnel with questions or concerns about their service in the Persian Gulf region - contact your commanding officer or call the Department of Defense (DOD) Gulf War Veterans' Hotline (**1-800-796-9699**) for an examination.

Gulf War veterans with concerns about their health - contact the nearest VA medical center. The telephone number can be found in the local telephone directory under Department of Veterans Affairs in the "U.S. Government" listings. A Gulf War Registry examination will be offered. Treatment will be provided to eligible veterans. The VA Gulf War Information Helpline can also provide the latest information and assistance. The toll-free telephone number is **1-800-PGW-VETS (1-800-749-8387)**.

Gulf War veterans in need of marital/family counseling - contact the nearest VA medical center or VA vet center. For additional information, call the Gulf War Information Helpline at **1-800-PGW-VETS (1-800-749-8387)**.

Gulf War veterans seeking disability compensation for illnesses incurred in or aggravated by military service - contact a Veterans Benefits Counselor at the nearest VA regional office or health care facility at **1-800-827-1000**, or call the VA Gulf War Information Helpline at **1-800-PGW-VETS (1-800-749-8387)**.

Gulf War veterans seeking participation for their spouses or children in the VA-funded health examination program for spouses and children - call

the VA Gulf War Information Helpline at **1-800-PGW-VETS (1-800-749-8387)**.

Veterans interested in the alternative self-funded examination for spouses or children - contact the Gulf War Registry Coordinator at the nearest VA medical center for forms and information.

Gulf War veterans interested in learning about the wide range of benefit programs administered by VA - contact a Veterans Benefits Counselor at the nearest VA regional office or health care facility at **1-800-827-1000** or call the VA Gulf War Information Helpline at **1-800-PGW-VETS (1-800-749-8387)**.

Anyone with first-hand information about "incidents" that occurred in the Southwest Asia theater of operations during the Gulf War that may be related to health problems experienced by military personnel who served in the War - call the DoD "Incidents" Hotline at **1-800-472-6719**.

For additional information about VA's program initiatives, see VA's Gulf War veterans' illnesses home page at **<http://www.va.gov/gulf.htm>**.

Gulf War veterans who encounter difficulties at a VA medical facility can contact the "**patient advocate**" at that facility for assistance in resolving the problem.

Representatives of veterans service organizations, including the American Legion, Veterans of Foreign Wars of the United States, Disabled American Veterans, etc., may also be very helpful to Gulf War veterans, especially veterans who are seeking disability compensation.

Gulf War Review



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