28 JUN 1994

Ref: 94-F-0782

Ms. Margaret Davidson
[redacted]

Dear Ms. Davidson:

This responds to your Freedom of Information Act (FOIA) request of March 25, 1994. Our interim response of April 1, 1994, refers.

The Offices of the Under Secretary of Defense (Personnel and Readiness) (OUSD(P&R)) and Assistant Secretary of Defense (Health Affairs) (HA) have provided the enclosed documents as responsive to your request. P&R also located documents that originated with the Departments of Veterans Affairs, Health and Human Services, and Army. Therefore, your request and those documents have been referred to those agencies with the request that they respond directly to you. Additionally, your request has been referred to the Department of the Army for documents responsive to items 5, 8, 9, and 27. For your information those agencies addresses are:

Department of Veterans Affairs
Attn: Director, Records Management Services (723)
810 Vermont Avenue, NW
Washington, DC 20420

Department of Health & Human Services
Director, FOIA/Privacy Division
Room 645F HHH Bldg.
Washington, D.C. 20201

Department of the Army
Chief, Freedom of Information & Privacy Acts Division
HQ USAISC-P (ASQNS-OP-F)
Crystal Square II, Suite 201
1725 Jefferson Davis Highway
Arlington, VA 22202

#639

Ms. Norma St. Claire, Director, Information Resource Management, OUSD(P&R), has denied portions of the enclosed

documents pursuant to 5 USC 552 (b)(6), information that would clearly constitute an unwarranted invasion of the personal privacy of an individual.

You may appeal Ms. St. Claire's decision to deny the information by offering justification to support reversal of the initial denial. Any such appeal should be forwarded within 60 calendar days of the date above to the Office of the Assistant to the Secretary of Defense for Public Affairs, Directorate for Freedom of Information and Security Review, Room 2C757, 1400 Defense Pentagon, Washington, D.C. 20301-1400.

There are no assessable fees for this response in this instance.

Sincerely,

SIGNED

D. J. Blakeslee
Acting Director
Freedom of Information
and Security Review

Enclosures:
As stated

CYT/CURRY:sc:denial(b6):940609:gr✓ pk_____ yl_____ wh_____

940628

USAMRIID

Anthrax Vaccine Dosing Schedule: Desert Shield/Storm

- Two doses two weeks apart
- Third dose at least two weeks after second dose when additional vaccine became available
- Involuntary program

USAMRIID

Anthrax Vaccine Usage/Side Effects: Desert Shield/Storm

- Approximately 150,000 servicemembers were given at least one shot of Anthrax Vaccine between 11 January 1991 and 28 February 1991 (25-30% of total deployed forces)
- Few systemic or allergic reactions reported
- One known hospitalization for a vaccination site infection
- Exact side effect data unknown due to difficulties collecting data in a combat theater. No reason to suspect any difference from known side effect data

USAMRIID

Botulinum Vaccine

- Pentavalent Toxoid of *Clostridium botulinum* Toxin Types A, B, C, D, and E
- Five Serotypes Grown Separately in Static Culture or Fermenter Systems
- Toxin Recovered by Precipitation and Partial Purification
- Inactivated with Formalin to Produce Toxoid
- 5 Monovalent Toxoids then Blended for Final Product
- Alum Used as Adjuvant

USAMRIID

Botulinum Toxoid Vaccine

- IND vaccine that has been widely used for over 20 years
- Alum adsorbed pentavalent toxoid of *Clostridium botulinum* types A, B, C, D, E
- Manufactured by Michigan State Department of Public Health
- Demonstrated safety and efficacy in human and primate studies
  - >3,600 doses given at our institute alone through June 1993

USAMRIID

Botulinum Toxoid Vaccine Side Effects

- Up to 10% of recipients will experience mild discomfort (tenderness, redness, swelling or itching) at the inoculation site for up to 72 hours. The frequency increases towards 10% with subsequent inoculations
- Severe local reactions are rare
- Up to 3% of recipients will experience mild systemic reactions (fever, malaise, headache and myalgia) lasting 48-72 hours
- No long-term sequelae demonstrated

USAMRIID

Botulinum Toxoid Vaccine Dosing Schedule

- Primary immunization consists of three deep subcutaneous injections of vaccine; 0.5 ml for each injection, given at 0, 2, and 12 weeks
- The first booster (0.5 ml) is given 12 months after the first injection of the initial series
- Subsequent boosters (0.5 ml) are given at 1-2 year intervals as serum levels of antitoxin dictate

USAMRIID

Botulinum Toxoid Vaccine Immunogenicity

- Approximately 80% are seropositive 2 weeks after the third dose of the initial series

USAMRIID

Botulinum Toxoid Vaccine Dosing Schedule: Desert Shield/Storm

- Same as recommended by the IND. No abbreviated schedule used
- Voluntary program - to include informed consent even though FDA granted waiver of informed consent due to impracticability of obtaining consent given the situation

USAMRIID

Botulinum Toxoid Vaccine Usage: Desert Shield/Storm

- Approximately 8,000 servicemembers were given at least one shot of Botulinum Toxoid Vaccine between 23 January 1991 and 28 February 1991 (1% of total deployed force)
- Only administered to elements of U.S. Marines 1st Marine Division and U.S. Army VII Corps
- Program had late start due to expected quantities of vaccine not being available on time and lack of appreciation at CENTCOM that the vaccine was an IND product

USAMRIID

Botulinum Toxoid Vaccine Side Effects: Desert Shield/Storm

- No known side effects reported during vaccine administration
- USAMMDA conducted retrospective postcard survey of side effect data among marine contingent that had received vaccine at Camp Pendleton, California in August 1991. Data was collected from 121 individuals. Survey data illustrated on next slide.

USAMRIID

Botulinum Toxoid Vaccine-Retrospective Survey-Side Effects: Desert Shield/Storm

116/121 (95.86%) received two injections

5/121 (4.14%) received one injection

0 received a third injection

88/121 (73%) reported no reaction

15/121 (12%) reported mild local reaction

17/121 (14%) reported pain that limited but did not prevent use of arm

1/121 (1%) reported pain that temporarily limited use of arm but no systemic reaction

118/121 (97.5%) no generalized reactions

3/121 (2.5%) fever, fatigue, muscle aches that did not limit activity

This side effect data closely parallels previous experience

USAMRIID

Biological Warfare Education Efforts in the Persian Gulf

- Walter Reed Army Institute of Research Preventive Medicine Handbook
- Office of the Surgeon General Publication: *Diseases of Importance in the Persian Gulf*
- Classified CENTCOM Messages
  - ◊ Anthrax Vaccination Effort
  - ◊ Botulinum Vaccination Effort
  - ◊ Medical Effects of Biological Warfare

April 20, 1994

USAMRIID

Vaccine Prophylaxis Against Biological Warfare in Operation Desert Storm

Major Lester Caudle, M.D., M.T.M. & H.
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

USAMRIID

Anthrax Vaccine

- Killed Vaccine Consisting of Protective Antigen (PA) of Non-Encapsulated Avirulent Strain of *Bacillus anthracis*
- Vaccine Prepared from Culture Supernatant
- Adsorbed onto an Aluminum Hydroxide Adjuvant

USAMRIID

Anthrax Vaccine

- Fully approved and licensed by the FDA since 1972 and does not require informed consent
- Alum precipitated protective antigen preparation
- Manufactured by Michigan State Department of Public Health
- Demonstrated safety and efficacy in human and primate studies
  - >7,900 doses given at our institute alone through June 1993

USAMRIID

Anthrax Vaccine Side Effects

- Up to 6% of recipients will experience mild discomfort (tenderness, redness, swelling or itching) at the inoculation site for up to 72 hours
- Less than 1% will have more severe local reaction potentially limiting the use of the arm for 1 to 2 days
- Systemic reactions are uncommon
- No long-term sequelae demonstrated

USAMRIID

Anthrax Vaccine Dosing Schedule

- Primary immunization consists of six deep subcutaneous injections of vaccine; 0.5ml per injection
  - Three injections are given at 0, 2, and 4 weeks
  - Three more injections are given at 6, 12, and 18 months after the initial injection
- If immunity is to be maintained, a booster injection of 0.5 ml is given at one year intervals

USAMRIID

Anthrax Vaccine Immunogenicity

- Over 85% with some antibody after 1 dose
- Over 90% seropositive after 3 doses
- Rhesus monkeys with 2 vaccine doses survived large aerosol challenges (>50 LD_{50}'s)

ADMINISTRATION OF BOTULINUM VACCINE

PURPOSE: To provide the necessary information for the safe administration of the botulinum vaccine.

BACKGROUND: A pentavalent toxoid vaccine is available for protection against types A, B, C, D, and E Clostridium botulinum. Although classified as an Investigational New Drug (IND), this product has been administered to several thousand volunteers and occupationally at-risk individuals.

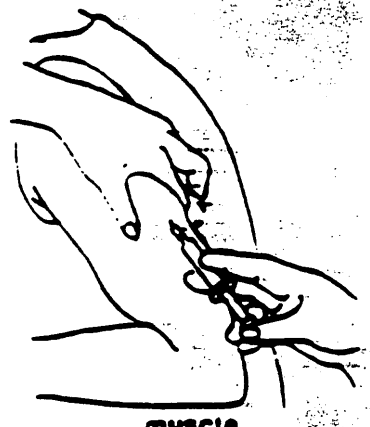
STORAGE: The botulinum vaccine should be kept refrigerated or on wet ice. Freezing or excess heat may inactivate the vaccine.

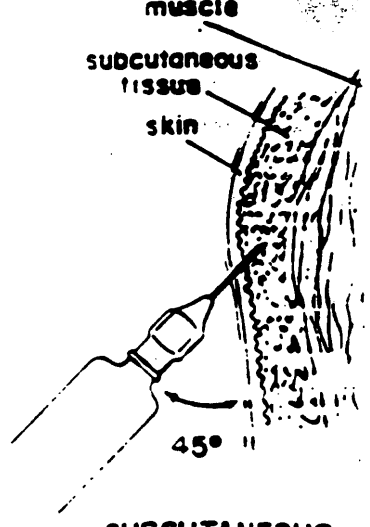
SCHEDULE: Three doses of vaccine are necessary before protective levels of immunity can be expected. The first two doses should be administered two weeks apart; the third dose should be given approximately ten weeks following the second.

SIDE EFFECTS: Reactogenicity is modest, with 2-4% of vaccinees reporting erythema, edema, or induration which peaks at 24-48 hours, then dissipates. The frequency of local reactions increases with each subsequent inoculation; after the second and third doses, 7-10% will have local reactions. Severe local reactions are rare, consisting of more extensive edema or induration. Systemic reactions are reported in up to 3%, consisting of fever, malaise, headache, and myalgia. A few vaccinees will develop small, firm, painless nodules at the injection site which will persist for several weeks.

ADMINISTRATION: The botulinum vaccine should be given as follows:

1. Shake the vaccine bottle immediately before use. Make sure all clumps are gone. Even after thorough shaking botulinum vaccine has a milky texture.
2. Clean the rubber stopper with an alcohol pad.
3. Use the alcohol pad to clean an area of skin on the back-side of the upper arm (see drawing).
4. Draw up 0.5cc of vaccine into the syringe.
5. Using a 25 gauge , 5/8" needle, inject the vaccine subcutaneously at a 45 degree angle into a pinch of skin on the backside of the upper arm (see drawing). This product should be injected deeply; although not recommended for intramuscular inoculation, it is better to inject too deeply than too shallowly.
6. Use separate arms when administering anthrax and botulinum vaccine simultaneously.
7. Warn the patient to expect a burning sensation at the vaccine site approximately 30 seconds after vaccination lasting 1-2 minutes.





SUBCUTANEOUS

BOTULISM

1. Botulism is a life-threatening paralytic illness resulting from the action of neurotoxins elaborated by the gram-positive anaerobic bacillus Clostridium botulinum. These toxins bind at presynaptic sites on cholinergic neurons of the autonomic and peripheral motor nervous systems, preventing release of acetylcholine and interrupting neurotransmission. Under natural conditions, botulism is seen in 3 clinical settings: (1) foodborne botulism, resulting from ingestion of foods containing pre-formed toxin; (2) wound botulism, occurring when C. botulinum organisms contaminate wounds and produce toxin in situ: and (3) infant botulism, a syndrome seen in very young children resulting from in situ toxin production by ingested C. botulinum organisms. In a biowarfare attack, botulinum toxins would be delivered by aerosol to the respiratory tract. The clinical presentation would likely be very similar to that seen with foodborne botulism.

2. Symptoms of botulism may begin as early as 3 hours or as late as several days following exposure to toxin. Initial manifestations include generalized weakness, lassitude, and dizziness. Diminished salivation with extreme dryness of the mouth and throat may cause complaints of sore throat. Urinary retention and ileus may also occur. Motor symptoms generally are present early in disease; cranial nerves are affected first, with blurred vision, diplopia, ptosis, and photophobia. Bulbar nerve dysfunction causes dysarthria, dysphonia, and dysphagia. A progressive, descending weakness and paralysis of the extremities and respiratory muscles soon follows. Development of respiratory failure may be abrupt. Treatment is primarily supportive, with administration of antitoxin indicated for those individuals in whom disease continues to progress (once bound to neurons, toxin cannot be removed; antitoxin is believed to act primarily through neutralization of circulating toxin which has not yet reached the receptor binding site).

3. Primary protection against airborne botulinum toxin involves physical protection from exposure to the respiratory tract and mucous membranes through use of the chemical protective mask. Vaccination with the botulinum toxoid should provide backup protection for those individuals exposed to modest doses of toxin without benefit of physical protection.

CENTOXIN® Patient Enrollment Form

Physician investigator, please complete this form on each patient who receives CENTOXIN.

PATIENT NAME: TODAY'S DATE: / /

PATIENT SSN: - - DATE OF BIRTH: / /

ADMISSION DIAGNOSIS (Please check all that apply)

☐ BURN INJURY ☐ Extremities ☐ Head & neck ☐ Torso ☐ Inhalation

%BODY SURFACE AREA ☐ >50% ☐ 30-50% ☐ 15-30% ☐ <15%

☐ TRAUMATIC INJURY ☐ Extremities ☐ Head & neck ☐ Chest ☐ Abdomen

☐ PENETRATING WOUND ☐ Extremities ☐ Head & neck ☐ Chest ☐ Abdomen

Additional Information:

INCLUSION CRITERIA (Please check all that apply - Patient must meet all five criteria):

☐ Clinical evidence to support a presumptive diagnosis of gram negative sepsis

☐ Temperature>101°F(>38.3°C) or ☐ Temperature<96°F(<35.6°C) or otherwise unexplained hypothermia within 24 hours

☐ Heart rate>90 beats/minute and

☐ Respiratory rate>20 breaths/minute or ☐ Mechanical ventilation

☐ Systolic blood pressure≤90 mm Hg or

☐ Systolic blood pressure drop>40 mm Hg in the presence of an adequate fluid challenge or

☐ Hypoperfusion defined as at least two of the following six criteria:

☐ Unexplained metabolic acidosis defined as a pH ≤ 7.3, a base deficit > 5, or plasma lactate levels greater than normal.

☐ Arterial hypoxia defined as a pO2 ≤ 75 mmHg or a pO2/FIO2 ratio < 250 in patients without overt pulmonary disease as the cause.

☐ Acute renal failure defined as oliguria with a urine output < 30 ml/hr (< 0.5 ml/kg/hr) for at least 1 hour despite acute volume loading or evidence of adequate intravascular volume.

☐ Unexplained coagulation abnormalities (elevated PT or PTT) or unexplained platelet depression (< 100,000 platelets/ml or a decrease of 50% or more of a previously known baseline value).

☐ Sudden deterioration of the patient's baseline mental status.

☐ Elevated cardiac index > 4 L/min/m2 with a low systemic vascular resistance < 880 dyne-sec/m5.

☐ Injuries obtained while a member of a deployed combat force

EXCLUSION CRITERIA (Please check all that apply - Patient must not meet either of the two criteria):

☐ Irreversible disease other than sepsis expected to have a rapidly fatal course

☐ Uncontrolled hemorrhage

BACTERIAL CULTURES COLLECTED PRIOR TO CENTOXIN ADMINISTRATION (Not required for administration)

☐ Blood Culture Date: / / Results:

☐ Blood Culture Date: / / Results:

☐ Urine Culture Date: / / Results:

☐ Other Culture(Site): Date: / / Results:

☐ Other Culture(Site): Date: / / Results:

DATE OF CENTOXIN ADMINISTRATION: / / TIME OF CENTOXIN ADMINISTRATION:

SIDE EFFECTS OF CENTOXIN ADMINISTRATION (Please check all that apply)

☐ Pruritus within 3 hours of administration

☐ Rash within 3 hours of administration

☐ Urticaria within 3 hours of administration

☐ Other within 3 hours of administration (Please explain)

CLINICAL OUTCOMES(To be completed on discharge, transfer, death, or 28 days post infusion):

☐ Discharged alive prior to 28 days post infusion Date: / /

☐ Transferred alive prior to 28 days post infusion Date: / /

☐ Remains hospitalized 28 days post infusion

☐ Died prior to 28 days post infusion Date: / /

NAME OF CARE PROVIDER COMPLETING FORM: Date: / /

Please give completed form to designated Physician Investigator for forwarding to the Principal Investigator.

Copy for Investigator

CENTOXIN® Informed Consent Form

PATIENT NAME: TODAY'S DATE: / /
PATIENT SSN: - - DATE OF BIRTH: / /

DESCRIPTION OF PROJECT: Dr. _____ is conducting a study entitled "Emergency Military Fielding of Centoxin for the Therapy of Gram Negative Bacterial Sepsis, Including Septic Shock" to evaluate a new drug called Centoxin. Centoxin, human protein which is produced in a test tube, can minimize the consequences of some types of bacterial infection which have entered the bloodstream (sepsis). This preparation is experimental; it is not a Food and Drug Administration-approved preparation. I have been asked to participate because my doctor believes that there is a strong possibility that I have developed sepsis.

PROCEDURES: If I agree to participate, I understand the following will happen to me: 1. I will receive an injection of Centoxin into a vein over approximately 15 minutes. 2. During the infusion and for the first 24 hours after the infusion, my temperature, respiratory rate, heart rate, and blood pressure will be taken frequently. I understand that if I participate in this study, I will receive the new drug in addition to rigorous use of all appropriate standard therapy and not as a substitute for a known beneficial treatment.

DISCOMFORTS AND RISKS: I understand there may be risks and discomforts associated with participation in the study. I understand no serious or life threatening adverse reactions attributable to Centoxin were reported among the more than 300 patients who received the product in clinical trials. I understand that side-effects seen when other similar human proteins have been given to people include: fever, chills, skin rashes, itching, swelling, shortness of breath, wheezing, and a drop in blood pressure. In addition, I may develop a side-effect to the drug which has never been reported before and that side-effects may not appear immediately after receiving the drug.

I understand there is no experience to date with the use of Centoxin in pregnant patients and therefore I should not participate if I am, or think I may be, pregnant now or expect to be in the immediate future.

BENEFITS: I understand that it is hoped that Centoxin will decrease the damage resulting from sepsis. I understand, however, that I should not assume that I will directly benefit from participating in this study. I understand that the results of this study may benefit other patients with similar infections.

CONTACTS: Dr. _____ has explained the study to me and answered all of my questions. If I have other questions or research-related problems, I may reach COL Jerald Sadoff, at Division of Communicable Diseases and Immunology, Walter Reed Army Institute of Research, Washington DC 20307-5100, Commercial: 202-576-3755, Autovon: 291-3755. If I have questions about my rights, I may contact the USAMRDC Judge Advocate, Fort Detrick, Frederick, MD 21702-5012, Commercial 301-663-2065, Autovon 343-2065.

CONFIDENTIALITY: I understand that the research records will be kept confidential. I understand that qualified representatives of the U.S. Army Medical Research and Development Command, Centocor, Inc. (the company which manufactures the drug) and the U.S. Food and Drug Administration may review my records. I understand that my name will not be used in any published report of this study.

STATEMENT OF VOLUNTARY PARTICIPATION: I understand that participation in this study is entirely voluntary. I may refuse to participate or withdraw at any time without jeopardizing my medical care. I understand that whether or not I choose to participate in this study, I will receive the standard therapy for my condition. I understand that I am authorized all necessary medical care for injury or illness which is the direct result of my participation in this research study. I understand that I am not giving up any legal rights that otherwise would be available to me.

I have received a copy of this consent form. I agree to participate.

SIGNATURE OF PATIENT: Date: / /

TYPED/PRINTED NAME OF PATIENT:

PERMANENT ADDRESS OF PATIENT:

SIGNATURE OF WITNESS: Date: / /

TYPED/PRINTED NAME OF WITNESS:

SIGNATURE OF CARE PROVIDER OBTAINING CONSENT: Date: / /

SIGNATURE OF PHYSICIAN INVESTIGATOR: Date: / /

This patient is incapable of providing informed consent and the anticipated benefits outweigh the potential risks.

SIGNATURE OF PHYSICIAN INVESTIGATOR: Date: / /

The fact that you are receiving this shot is classified secret and you are not to discuss this shot with anyone.

I have read and understand the information above on the Botulinum toxoid vaccine. I voluntarily submit to the vaccine series.

NAME	RANK	SSN	UNIT	SIGNATURE

INFORMATION ABOUT BOTULINUM VACCINE

You are being given a vaccine called botulinum toxoid because you are considered at risk of exposure to botulism. Botulism can cause serious paralysis or death. It is caused by toxins that interfere with the normal transmission of nerve signals. Botulism can arise from: (a) contaminated food and water, (b) contaminated wounds, or (c) a biological warfare attack. Symptoms of botulism can begin as early as three hours or as late as several days after exposure to the toxin. Symptoms include blurred vision, generalized weakness, difficulty in swallowing and talking. Treatment after exposure is primarily supportive and there is an antitoxin/antidote which may be beneficial. Your primary protection against botulinum toxin is the use of your chemical protective mask and overgarment. Vaccination with botulinum toxoid is expected to provide additional protection for individuals exposed to the toxin. However, no vaccine is 100% effective. No other vaccine is available which can give you this protection.

This is an investigational (not yet licensed) vaccine that has been safely given to over 3,000 laboratory workers and scientists over the past 25 years. It will be administered as a series of three injections under the supervision of qualified medical personnel.

About 92% of people who are vaccinated report no significant side effects beyond the local pain experienced at the time the vaccine is given. However, like other vaccines you have been given, this one may have some side effects. Side effects occur in 4% to 8% of people. When they occur, they are usually at the site of injection and include pain, tenderness, swelling, redness, and/or itching. All these are common symptoms with the typhoid vaccine you have already received. The number of these local reactions tends to increase after the first injection. Rarely an individual may develop a small lump at the injection site which lasts for several days to weeks before going away. Local reactions that can interfere with performance of your duties are very uncommon. Generalized reactions may include fever, tiredness, headache and/or muscle pain and occur in less than 1% of people. Rarely (less than 1 in 1,000 injections) an individual may be unable to perform duties for a day or two. As with any vaccination, a very rare, unexpected, potentially severe, side effect not previously observed could occur. If you are pregnant it is not known if this vaccine will harm your unborn baby. However, most vaccines do not harm an unborn baby when given to the mother.

If a reaction that worries you occurs after you leave the area where the vaccine was given you should report to sick call.

You may be one of a group to receive a postcard in the next few weeks asking for information on your experiences with this vaccine.

LIST OF DRUGS UNDER DISCUSSION BETWEEN FDA AND DoD

1. Pyridostigmine Bromide: This drug was used as prophylaxis against chemical agent attack. The FDA granted an exception for the use of this drug which has had FDA approval for several decades to treat myasthenia gravis.

2. Multi-Shield: Not used; recalled

3. Hepatitis A Vaccine Inactivated: Was under IND testing by the U.S. Army at the time of the Gulf War, but this vaccine was not given to Desert Storm troops.

4. Botulinum Toxoid Vaccine: This vaccine was given to approximately 8,000 troops as prophylaxis against biologic warfare attack. The FDA granted an exception for the use of this vaccine which has IND status.

5. Anthrax Vaccine: This is a FDA approved vaccine which was used in the Gulf.

6. Neupogen: FDA Approved to fight infections *

7. Zoma E-5: Not given to troops.

8. Botulinum Immune Globulin: Not given to our troops but provided to Egypt after the war for an outbreak of botulism.

9. Immune Globulin: Immune serum globulin was used in the Gulf to prevent hepatitis A, as currently recommended.

10. Ribavirin Injection, IV: This drug was sent to the Gulf as a contingency for viral hemorrhagic fever but not used.

11. Ribavirin Capsules: This drug was sent to the Gulf as a contingency for viral hemorrhagic fever but not used.

12. J-5 Monoclonal Antibody (centoxin): Was used for clinical treatment purposes in the Gulf to treat one case of bacterial sepsis.

13. Diazepam Autoinjector: Diazepam was sent to the Gulf to treat acute neurologic chemical warfare exposure. Since there was no CW attach, the diazepam autoinjectors were not used.

14. Atropine Sulfate Inhalation Aerosol: Not used in the Gulf.

15. Field Medical Oxygen Generating and Distribution System: Not used in the Gulf

16. Ohmeda Universal PAC (anesthesia machine): Was used in the

* Telephone conversation 1/30/94 (CDR Hyams)

Gulf. Labeled "For Battlefield Use Only."

17. GENOX Model CT-1 Oxygen/Nitrogen Generating and Distribution system: Was used in the Gulf; a standard USAF item.

18. Powered Ventilator Level I/II: Not used in the Gulf.

19. Life O_2 (oxygen tank and mask): Not used in the Gulf.

HA

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

22 JUL 1991

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (FM&P)
ASSISTANT SECRETARY OF DEFENSE (RA)
ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E)

SUBJECT: Recording of Vaccinations Received in Operation Desert Shield/Desert Storm in the Medical Immunization Record (SF 601)

During the Persian Gulf operation, selected units of the Armed Forces received prophylactic vaccinations of anthrax vaccine or botulinum toxoid vaccine. To ensure operational security, the employment of these vaccines and the selected units immunized were considered classified information. Individuals who were so immunized had this information recorded on various documents, rosters, medical immunization record (SF 601), or International Certificate of Vaccination (PHS 731). For anthrax vaccine, medical personnel may have recorded the information as "Anthrax", "A vaccination", "A-Vacc", "A-Vax" or something similar. For the botulinum toxoid, medical personnel may have recorded the information as "Botulinum", "Bot-Tox", "B vaccination", "B-Vacc", "B-Vax", or something similar.

For continuity of medical records and to ensure the accuracy of medical care, all active duty and reserve units so affected must assure that documentation of vaccination is entered into the Medical Immunization Record SF 601 in the accepted medical format as "Anthrax Vaccine" and "Botulinum Toxoid." This action should be initiated while records and units so affected are still accessible. The Services should ensure that unit rosters or unit immunization logs are retained for purposes of epidemiological tracking. Documentation of these immunizations into the individual's medical record is considered unclassified information; however, the original records and documents used in identifying units and personnel immunized during Operations Desert Shield and Desert Storm are still considered classified information and should be treated appropriately.

I request that the Assistant Secretaries of the Military Departments report to me within six months of issuance of this memorandum the status of actions taken, or upon completion of the above requirement, whichever may occur earliest. Please identify

any difficulties which may be encountered in unit or personnel identification and any decisions taken to preserve available records.

Enrique Mendez, Jr., M.D.

Copies to:
Surgeons General

ADMINISTRATION OF ANTHRAX VACCINE

PURPOSE: To provide the necessary information for the safe administration of the anthrax vaccine.

BACKGROUND: An alum-precipitated, inactivated, anthrax vaccine has been approved and licensed for human use by the Food and Drug Administration since 1972. It has been shown to be safe and effective in protecting occupationally exposed individuals.

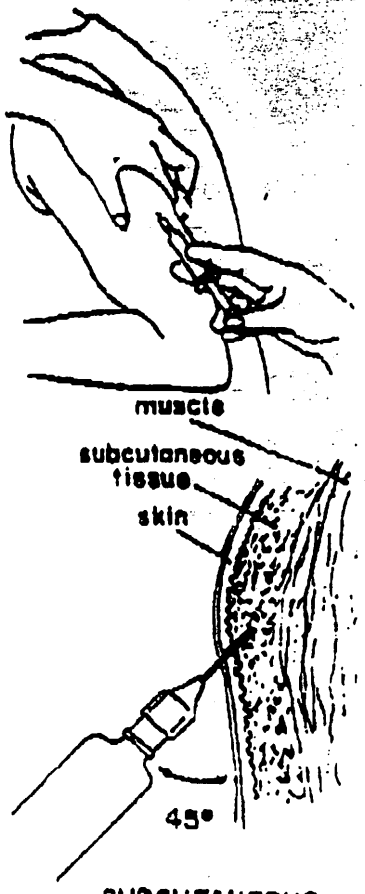
STORAGE: The anthrax vaccine should be kept refrigerated or on wet ice. Freezing or excess heat will inactivate the anthrax vaccine.

SCHEDULE: Two doses of anthrax vaccine should be given two weeks apart. A third dose of anthrax vaccine should be given two or more weeks after the second as additional anthrax vaccine becomes available.

SIDE EFFECTS: Up to 6% of recipients will experience mild discomfort (tenderness, redness, swelling, or itching) at the inoculation site for up to 72 hours. Less than 1% will have more severe local reaction potentially limiting the use of the arm for 1 to 2 days. Mild systemic reactions (muscle aches, fatigue, or fever) are uncommon and severe systemic reaction are rare. A few vaccinees will develop small, firm, painless nodules at the injection site which will persist for several weeks.

ADMINISTRATION: The anthrax vaccine should be given as follows:

1. Shake the vaccine bottle immediately before use. Even after thorough shaking anthrax vaccine has a milky texture.
2. Clean the rubber stopper with an alcohol pad.
3. Use the alcohol pad to clean an area of skin on the back side of the upper arm (see drawing).
4. Draw up 0.5 cc of vaccine into the syringe.
5. Using a 25 gauge, 5/8" needle, administer the vaccine <u>subcutaneously</u> at a 45 degree angle into a pinch of skin on backside of the upper arm (see drawing). Do not give this vaccine intramuscularly.
6. Use separate arms when administering anthrax and botulinum vaccine simultaneously.
7. Warn the patient to expect a burning sensation at the vaccine site approximately 30 seconds after vaccination lasting 1-2 minutes.



SUBCUTANEOUS

ANTHRAX

1. Anthrax is a zoonotic disease caused by a gram positive spore-forming bacteria, Bacillus anthracis. Human cases normally have resulted from contact with anthrax spores that contaminate animal products such as hides, wool, and hair. Under natural conditions, the disease manifests itself in three clinical forms:

a. Cutaneous (malignant pustule): The most common form, normally begins as a painless papule at the site of inoculation. The papule becomes vesicular and then progresses to hemorrhagic necrosis and eschar formation with regional lymphadenopathy. Constitutional symptoms and fever are absent unless dissemination occurs.

b. Gastrointestinal: This uncommon form results from the ingestion of anthrax-contaminated meat from sick animals. The disease course is characterized by abdominal pain, bloody diarrhea, toxemia, shock, and death.

c. Inhalation: This rare form has occurred in the past in unvaccinated textile workers exposed to aerosols containing anthrax spores from contaminated hides or hair/wool. The disease begins after an incubation period varying from 1 to 6 days, presumably dependent on the dose of inhaled spores. It is difficult to diagnose early, as the onset is gradual and non-specific, with fever, malaise, and fatigue, sometimes in association with a nonproductive cough and mild chest discomfort. The initial symptoms are followed in 2 to 3 days by the abrupt development of severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Physical findings may include evidence of pleural effusions, edema of the chest wall, and meningitis. Chest X-ray reveals a dramatically widened mediastinum, often with pleural effusions but typically without infiltrates. Shock and death usually follow within 24 to 36 hours of respiratory distress onset.

2. If this bacterium were used in a biowarfare attack, aerosolized anthrax spores would be released causing the inhalation form of the disease. Preventing exposure of the respiratory tract and mucous membranes (to include the conjunctivae) to infections and/or toxic aerosols through use of a full-face respirator will prevent illness, and should, theoretically, obviate the need for additional measures. However, from a practical standpoint it would be very difficult to wear the chemical protective mask at all times.

3. Primary protection against aerosolized anthrax spores involves physical protection from exposure to the respiratory tract and mucous membranes through use of the chemical protective mask. Immunization with the anthrax vaccine should provide backup protection for those individuals exposed to modest spore doses without benefit of physical protection.

ADMINISTRATION OF BOTULINUM VACCINE

PURPOSE: To provide the necessary information for the safe administration of the botulinum vaccine.

BACKGROUND: A pentavalent toxoid vaccine is available for protection against types A, B, C, D, and E *Clostridium botulinum*. Although classified as an Investigational New Drug (IND), this product has been administered to several thousand volunteers and occupationally at-risk individuals.

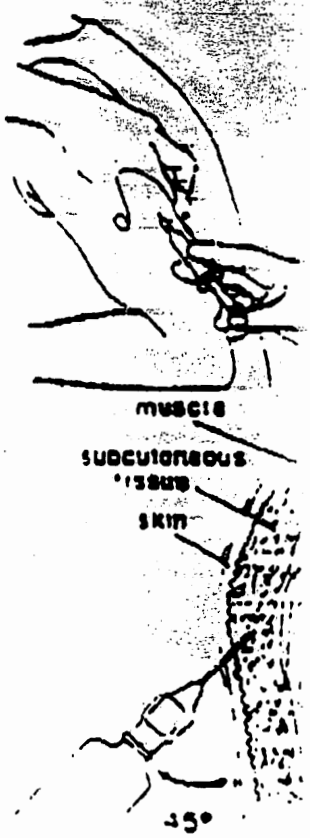
STORAGE: The botulinum vaccine should be kept refrigerated or on wet ice. Freezing or excess heat may inactivate the vaccine.

SCHEDULE: Three doses of vaccine are necessary before protective levels of immunity can be expected. The first two doses should be administered two weeks apart; the third dose should be given approximately ten weeks following the second.

SIDE EFFECTS: Reactogenicity is modest, with 2-4% of vaccinees reporting erythema, edema, or induration which peaks at 24-48 hours, then dissipates. The frequency of local reactions increases with each subsequent inoculation; after the second and third doses, 7-10% will have local reactions. Severe local reactions are rare, consisting of more extensive edema or induration. Systemic reactions are reported in up to 3%, consisting of fever, malaise, headache, and myalgia. A few vaccinees will develop small, firm, painless nodules at the injection site which will persist for several weeks.

ADMINISTRATION: The botulinum vaccine should be given as follows:

1. Shake the vaccine bottle immediately before use. Make sure all clumps are gone. Even after thorough shaking botulinum vaccine has a milky texture.
2. Clean the rubber stopper with an alcohol pad.
3. Use the alcohol pad to clean an area of skin on the back side of the upper arm (see drawing).
4. Draw up 0.5cc of vaccine into the syringe.
5. Using a 25 gauge , 5/8" needle, inject the vaccine <u>subcutaneously</u> at a 45 degree angle into a pinch of skin on the backside of the upper arm (see drawing). This product should be injected <u>deeply</u>; although not recommended for intramuscular inoculation, it is better to inject too deeply than too shallowly.
6. Use separate arms when administering anthrax and botulinum vaccine simultaneously.
7. Warn the patient to expect a burning sensation at the vaccine site approximately 30 seconds after vaccination lasting 1-2 minutes.



SUBCUTANEOU

BOTULISM

1. Botulism is a life-threatening paralytic illness resulting from the action of neurotoxins elaborated by the gram-positive anaerobic bacillus Clostridium botulinum. These toxins bind at presynaptic sites on cholinergic neurons of the autonomic and peripheral motor nervous systems, preventing release of acetylcholine and interrupting neurotransmission. Under natural conditions, botulism is seen in 3 clinical settings: (1) foodborne botulism, resulting from ingestion of foods containing pre-formed toxin; (2) wound botulism, occurring when C. botulinum organisms contaminate wounds and produce toxin in situ; and (3) infant botulism, a syndrome seen in very young children resulting from in situ toxin production by ingested C. botulinum organisms. In a biowarfare attack, botulinum toxins would be delivered by aerosol to the respiratory tract. The clinical presentation would likely be very similar to that seen with foodborne botulism.

2. Symptoms of botulism may begin as early as 3 hours or as late as several days following exposure to toxin. Initial manifestations include generalized weakness, lassitude, and dizziness. Diminished salivation with extreme dryness of the mouth and throat may cause complaints of sore throat. Urinary retention and ileus may also occur. Motor symptoms generally are present early in disease; cranial nerves are affected first with blurred vision, diplopia, ptosis, and photophobia. Bulbar nerve dysfunction causes dysarthria, dysphonia, and dysphagia. A progressive, descending weakness and paralysis of the extremities and respiratory muscles soon follows. Development of respiratory failure may be abrupt. Treatment is primarily supportive, with administration of antitoxin indicated for those individuals in whom disease continues to progress (once bound to neurons, toxin cannot be removed; antitoxin is believed to act primarily through neutralization of circulating toxin which has not yet reached the receptor binding site).

3. Primary protection against airborne botulinum toxin involves physical protection from exposure to the respiratory tract and mucous membranes through use of the chemical protective mask. Vaccination with the botulinum toxoid should provide backup protection for those individuals exposed to modest doses of toxin without benefit of physical protection.

DEFENSE ISSUES

Vol. 9 No. 2

Changes in Military Health Care

Remarks by Edwin Dorn, assistant secretary of defense for personnel and readiness, at the Reserve Officers Association of the United States, Health Services Advisory Committee luncheon, Washington, Jan. 24, 1994.

... Today, when we examine military health care, we need to keep two Clinton administration priorities in mind: national health care reform and maintaining readiness during downsizing.

As reserve officers, you have a unique perspective on both of those priorities. As individual citizens, you will enjoy the benefits of national health care reform. As reserve health professionals, you are a critical element in our determination not to compromise medical readiness during downsizing. There is no doubt that we will continue to rely more heavily on our reserve components.

As the assistant secretary of defense for personnel and readiness, military health care is one of my most important responsibilities.

Let me outline the improvements we plan to make in military health care, keeping those two Clinton administration priorities in mind.

In terms of military health care, there are two "givens": We will provide service members the health benefit, and we will maintain medical readiness.

The department's leaders know that health care is one of the most important considerations for service members and their families. We have the responsibility to keep our service members healthy and fit. We want service members to enjoy peace of mind in knowing that we will care for their families as well. Ensuring the health of our armed forces and their families is a special trust — one which is essential to a force that must be prepared to deploy at a moment's notice.

Military medicine is an important part of the president's reform initiative. I was in the Pentagon only a week when I came face to face with the reality that military medicine is a high-profile "personnel" issue as well as a mission-essential "readiness" issue.

President [Bill] Clinton has recognized the importance of both protecting readiness and providing the health benefit. His national health care legislation ensures that military health care will be preserved. In fact, the president's plan does not affect the structure of care provided to active duty members or reservists.

I want to outline for you how the Department of Defense is seizing this opportunity to improve military medicine. We have drawn from the national design for reform and put together a health care plan that will support medical readiness and strengthen health care commitments for all of our beneficiaries. Our plan has three key features: readiness, security and choice.

Readiness

Early on in this administration, President Clinton made a strong commitment to maintaining the unique readiness requirements of the military health care system. The need to retain these medical capabilities is why we will reform military medicine separate from, but in harmony with, the national plan.

Health care access and eligibility for our active duty personnel, including activated reservists and guardsmen, will not change. Since these personnel continue to be our first priority, we will also ensure that they benefit as the national system improves.

We must have an infrastructure of health care capability ready to support the force. This infrastructure exists in our military hospitals and clinics. It is there that our medical personnel gain and maintain their professional skills which keep them ready to support our service members. We must preserve this capability and ensure continued support of National Guard and Reserve training and readiness.

When our medical personnel are called to deploy, we must have the system flexibility to continue caring for family members, including the families of activated reservists and guardsmen.

The reserve health care professionals are a critical element of our medical readiness. Reserve support, both at home and in theater, was superb and greatly appreciated during the Persian Gulf war.

As Secretary [of Defense Les] Aspin mentioned in his remarks this morning, more than 100,000 reservists served in the gulf, making up 20 percent of our total forces there. Over 200,000 reservists were called up for the conflict. Of that number, over 46,000 were reserve health professionals, whose support was invaluable both in the gulf and in our stateside hospitals.

One of the major issues we will be facing as we restructure our forces will be the level of reserve structure required to maintain our medical readiness.

With the health care reform plan

The comprehensive benefit under military health plans will maintain or enhance the scope of services that eligible beneficiaries receive today.

we have designed, we will be able to keep our medical capability and incorporate flexibility. Very importantly, this plan has been briefed to, and supported by, the Joint Chiefs of Staff as meeting their requirements for medical force readiness.

Security

No matter how you describe it, there are serious problems with this country's health care system. Many Americans have lost their insurance, don't have insurance or are locked into a job to keep their insurance. Just last year, 2 million Americans lost their health care coverage permanently. Every month, 2 million more Americans lose their insurance for some period of time. The U.S. ranks 19th in the world in combating fatal heart disease among adults, 20th in infant mortality, 16th in life expectancy.

What kind of security is that? We can do better. We must do better. Let me share with you one example of the economic insecurity that threatens Americans under our current health care system. I was part of a group of senior defense officials that visited Mare Island, Calif., a community affected by base closure. One of the biggest concerns the people in that community have is the prospect of losing their health care coverage. Under the president's plan they would be able to focus on looking for productive employment — not worrying about losing health care coverage and potentially losing their savings if they become ill.

National health care reform will give Americans peace of mind and the flexibility they need to more easily contribute to our economy. Tomorrow night, President Clinton will address the nation in his State of the Union speech. Health care reform will be the centerpiece of the speech.

In keeping with the president's principle that individuals have access to a comprehensive package of benefits, we will provide that same security of a defined, comprehensive and low-cost benefit to our beneficiaries.

With reform, the department will create TRICARE military health plans. These joint service plans will offer beneficiaries a consistent benefit, regardless of where they may live. This will be possible through contractual arrangements with other federal and civilian health care providers to supplement the care we can provide through our system. All eligible beneficiaries who enroll will have timely access to the care they need.

The comprehensive benefit under military health plans will maintain or enhance the scope of services that eligible beneficiaries receive today.

Choice

The president's national reform also gives us the opportunity to offer our retirees and family members choice in selecting their health plan: the military health plan or a civilian health plan.

Those family members and retirees who choose not to join the military plan will have a selection of no less than two other choices. They may join a civilian fee-for-service plan, which will give them a wide choice of civilian physicians, though at levels of cost-sharing higher than under the military plan.

Or they may join a civilian managed care plan and get health care through a health maintenance organization or through a network of preferred providers. This would entail a more restricted choice of providers, but with lower out-of-pocket costs than under a fee-for-service plan.

In addition, family members or retirees — including, of course, retired reservists — who are age 65 or older would have two basic choices under the proposed health care reform: use Medicare or join a TRICARE military health plan.

Those who choose Medicare would receive enhanced coverage for outpatient prescription drugs, as proposed by the president under the national reform package. They also would have expanded options to join managed care health plans. Those who choose a military health plan would be able to join for a modest annual fee. Cost-sharing levels would be lower than under Medicare, and DoD would receive fixed, per person payments from Medicare to fund these beneficiaries' care.

Positive Changes

Of course, to come up with all of these positive changes, the Defense Department has been conducting an ongoing, comprehensive study of our health care programs. We are primarily looking at the wartime and readiness needs of the health care system — as well as the role the reserve components play in helping us meet those needs, and then we are relating those needs to peacetime structure. That is, we are focusing on both maintaining medical readiness as we downsize the Defense Department and providing health care more efficiently during peacetime.

The study is ongoing, so we don't have all of the results yet. We are looking at several alternatives to find the most cost-effective way of providing the health benefit. Let me assure you that we remain determined not to diminish the benefit.

Preliminary results from our survey of active duty members and retirees — including retired reservists — suggest that overall satisfaction with current health care benefits is high. And by working with national health care reform and maintaining readiness, we can make this good system even better and follow the National Performance Review recommendation that we maximize the efficiency of our health care operations.

Still, there are several unresolved issues when we focus on how we are going to preserve both readiness and the quality of care during the downsizing. Since we are not reducing medical support as quickly as we are reducing the rest

of the force, there are problems of allocation and misallocation. How will the reserves fit into the current planning scenario of two major regional conflicts? Will we come to rely more on the health professionals in the reserve components? Tomorrow morning, Assistant Secretary [of Defense for Reserve Affairs Deborah R.] Lee will speak at your congressional breakfast. She will explain more fully our plans for the National Guard and Reserve forces.

With the closure of the Uniformed Services University of the Health Sciences, as recommended in the vice president's National Performance Review, how will we produce and/or attract doctors to military service? Where will we find our senior, experienced medical personnel? Perhaps, as I mentioned, we will rely more on our seasoned reservists.

Persian Gulf Syndrome

Let me digress just one moment to expand on our experience in the Gulf War. Many of you have heard about Rep. Sonny Montgomery's recent hearings in Mississippi on the Desert Storm syndrome. Let me tell you what we are doing.

On Friday morning, we announced the formation of the Persian Gulf Veterans Coordinating Board to examine the elusive Persian Gulf syndrome that affects many of our veterans.

Secretary Aspin, Secretary of Veterans Affairs Jesse Brown and Secretary of Health and Human Services Donna Shalala established the coordinating board for three reasons: first, to ensure that our different agencies share a common understanding of the problem that needs to be addressed — the unexplained illnesses affecting some of our Persian Gulf veterans; second, to ensure the most effective and the broadest possible allocation of resources to focus on the problem; and third, to ensure the systematic, timely dissemination of information among our agencies on matters related to the unexplained illnesses.

The problem, of course, is that a number of Persian Gulf veterans have complained of illnesses whose causes we have not been able to diagnose. Let me put that problem in perspective: More than 650,000 U.S. military personnel served in the gulf; of those 650,000, thousands have been treated for readily diagnosable injuries or illnesses resulting from their service. A few Persian Gulf veterans have been treated for unusual problems. For example, about 30 veterans have been diagnosed with Leishmaniasis, a parasitic disease. And about 35 have been treated for injuries caused by shrapnel from depleted uranium. We have arranged to do multiyear medical follow-ups on those who retain depleted uranium shrapnel, to see whether there are long-term effects.

Our departments are committed to providing the best care for those who served this nation during the Persian Gulf conflict.

Finally, DoD and VA physicians have seen several hundred gulf veterans who have complained about a combination of symptoms: general fatigue, allergy-like problems, gastrointestinal disturbance, muscle and joint pains, memory loss and headaches. To date, we have not been able to find the cause of these problems. This is the so-called "mystery illness" or "Persian Gulf syndrome."

Three-Pronged Approach

Our three agencies have agreed to approach those illnesses in the following ways:

First, we are caring for the sick. DoD and VA are treating Persian Gulf veterans without requiring proof that their illnesses are related to their gulf service. Now, this was never a major problem as regards DoD's treatment of active duty personnel. However, new legislation was needed so that VA could treat veterans for medical conditions that might be related to their Persian Gulf service. The legislation was passed during the last session of Congress and signed by President Clinton on Dec. 20.

Second, DoD and VA are working closely together to fashion disability and compensation rules for people suffering from these undiagnosed illnesses. By combining our efforts, we hope to speed the process.

Third, our three departments are aggressively pursuing the causes of the illnesses. We have undertaken more than 20 studies that will look at every plausible cause — from parasitic diseases to environmental pollutants to chemical agents.

The mention of chemical agents is a good example of the benefits of interagency coordination. When our military commanders first learned that Czech chemical units had reported detecting traces of a chemical agent on Jan. 19, 1991, the immediate reaction was to discount the report on two grounds: First, the reported detections were not substantiated by any other independent source; and second, the amounts of chemical agent detected were viewed as too small to cause a health risk.

Partly because of our discussions with our VA colleagues and with members of Congress, we have decided to take a new look at the Jan. 19 incident and at other reported detections. We have asked an independent panel of experts to review all the reports of chemical detections. That panel also will review the medical and scientific information available on the possible health effects of low levels of chemical agents.

It is important to stress that this is only part of the substantial effort that DoD, VA and HHS have undertaken. We want to consider all possible causes of the illnesses, including the possible effects of the Kuwaiti oil fires and of the wide range of industrial contaminants to which our Persian Gulf veterans may have been exposed.

Our departments are committed to providing the best care for those who served this nation during the Persian Gulf conflict. The Interagency Coordinating Board will help us do that more effectively.

There is still much developmental work to be done in each of the participating federal agencies.

Thank you for allowing me that digression. I think it is important for you to know exactly what we are doing to resolve this issue. The Clinton administration — the Defense Department and the assistant secretary of defense for personnel and readiness in particular — have made a firm commitment to actively dealing with Persian Gulf syndrome. It is absolutely crucial that we treat our people fairly. That includes both keeping the troops healthy so that they can fight and following through on that commitment by ensuring their well-being during peacetime.

I am enthusiastic about the possibilities for improving military health care; yet I know that the path toward reform will not be easy. There is still much developmental work to be done in each of the participating federal agencies.

As reserve officers and health professionals, you have a unique perspective on both the national health care reform plan and our plan for maintaining medical readiness during downsizing.

You and your dependents will directly benefit from national health care reform. You also play an important, active role in ensuring the services' health care readiness. This dual perspective gives you special credibility and puts you in a unique position to offer suggestions to the Defense Department, and to me, as we work in tandem with national health care reform to improve military health care.

In conclusion, I am convinced that under the Clinton reform program, we can maintain medical readiness and improve DoD's health care system to meet tomorrow's challenges. The result will be better health care for all of our beneficiaries.

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JANUARY 27, 1994

Persian Gulf Veterans Coordinating Board

Research

DoD Research Activities

Review of the Health Consequences of Service During the Persian Gulf War.
Action: National Academy of Sciences (NAS) - Medical Follow-up Agency
Purpose: As directed by P.L. 102-585, the NAS will review existing scientific, medical and other information on the health consequences of military service in the Persian Gulf theater of operations during the Persian Gulf War.
Coordinations: DoD, VA and HHS.

Cooperative DoD/VA Research.
Action: DoD and VA Medical Scientists.
Purpose: Support for partial funding of research on the health consequences of exposure to environmental hazards during the Persian Gulf War. Some of this research will take place at VA Medical Centers.
Coordination: DoD, VA and HHS.

Leishmania Research.
Action: US Army Medical Research and Development Command.
Purpose: Develop a blood assay for leishmania.
Coordinations: DoD, VA and HHS.

Epidemiologic Assessment of Suspected Outbreak of an Unknown Disease Among Veterans of ODS at the Request of the 123d Army Reserve Command, FT. Benjamin Harrison, Indiana.
Action: US Army Medical Research and Development Command.
Purpose: Conducted medical examinations and in-depth surveys of 79 soldiers with symptoms or concerns potentially linked to service in ODS.
Coordinations: DoD, VA and HHS.

Stress-Related Survey of Soldiers Deployed in ODS.
Action: US Army Medical Research and Development Command.
Purpose: To identify correlations between post ODS symptoms and occupational and environmental stresses. These questionnaires were completed by active duty and reserve Army, Navy and Air Force personnel in Hawaii and Pennsylvania. Data analysis is in progress.
Coordinations: DoD, VA and HHS.

Retrospective Studies Involving Military Use of Pyridostigmine as a Pretreatment for Nerve Agent Poisoning.

Action: US Army Medical Research and Development Command.
Purpose: Obtain safety data for pending New Drug Application to FDA.
Coordinations: DoD, FDA and VA

Retrospective Survey of Troops Who Received Clostridium Botulinum Toxoid in the Gulf War.

Action: US Army Medical Research and Development Command.
Purpose: To conduct a retrospective survey of troops who received clostridium botulinum toxoid in the Gulf War after troops returned to the US.
Coordinations: DoD, VA and HHS.

Environmental Toxicology Studies.

Action: Armed Forces Institute of Pathology and Army Environmental Hygiene Agency.
Purpose: To conduct a series of studies in environmental and toxicologic pathology relating to exposures during the Persian Gulf War.
Coordinations: DoD, VA and HHS.

Monitoring Gulf War Veterans With Imbedded Depleted Uranium Fragments.

Action: Armed Forces Radiobiology Research Institute.
Purpose: Conduct clinical follow-up of ODS patients with known or suspected imbedded depleted uranium fragments and assess health risks from imbedded depleted uranium fragments.
Coordinations: DoD, VA and HHS.

Working Group to Establish a Working "Case Definition" for Post-ODS/DS Unexplained Illness.

Action: Walter Reed Army Medical Center.
Purpose: Review and analyze medical records of ODS/DS veterans with unexplained symptoms to establish a working "case definition" for post-ODS/DS unexplained illness.
Coordinations: DoD, VA and HHS.

Persian Gulf Veterans Coordinating Board

Research

VA Research Activities

Children of PG Veterans in Mississippi.
Action: VAMC Jackson.
Purpose: An examination of children born to Persian Gulf veterans for evidence of possible genetically determined health effects related to their parents' service.
Coordinations: VA, DoD and HHS.

Review of the Health Consequences of Service During the Persian Gulf War.
Action: National Academy of Sciences (NAS) - Medical Follow-up Agency
Purpose: As directed by P.L. 102-585, the NAS will review existing scientific, medical and other information on the health consequences of military service in the Persian Gulf theater of operations during the Persian Gulf War.
Coordinations: VA, DoD and HHS.

Pilot Program to Investigate Medical and Psychological Effects of Exposure to Toxic Hazards.
Action: VAMC Birmingham.
Purpose: Conduct pilot program to investigate medical and psychological effects of exposure to toxic hazards. Results of examinations provided to about 11,000 veterans on VA's PG Registry are also being reviewed to determine if these individuals should be called back for testing.
Coordinations: VA, DoD and HHS.

Examining Neuropsychological-Psychological Profiles of Veterans Returning from the Persian Gulf Theater.
Action: VAMC Boston.
Purpose: Conduct a small-scale pilot program examining neuropsychological-psychological profiles of veterans returning from the Persian Gulf Theater.
Coordinations: VA, DoD and HHS.

Environmental Hazards Research Centers.
Action: Three VAMCs (to be determined)
Purpose: A request for proposals to establish up to three, VA-based, research centers for the study of the medical consequences of exposure to environmental and toxic hazards, initially focused on the problems cited by personnel in the PG conflict.
Coordinations: VA, DoD and HHS.

Persian Gulf Interagency Research Coordinating Council.

Action: VA, DoD and HHS.

Purpose: VA, DoD and HHS, make up the newly formed Persian Gulf Interagency Research Coordinating Council. The council, established by the Persian Gulf War Veterans' Health Status Act, will coordinate all research activities undertaken or funded by the Executive Branch of the Federal Government on the health consequences of military service in the Persian Gulf theater of operations during the Persian Gulf War. As an initial step, the council members agreed to organize a conference of experts from within and outside the federal agencies, with a goal of reaching a consensus definition of "Persian Gulf Syndrome."

Coordinations: VA, DoD and HHS.

Persian Gulf Advisory Committee:

Action: VA.

Purpose: A 16 member panel composed of experts in environmental and occupational medicine and related fields from both government and the private sector and representatives from veterans service organizations chartered to address issues related to the diagnosis, treatment and research of PG related health conditions.

Coordinations: VA, DoD and HHS.

Investigation of the Relation Between the Experience of ODS and Post-War Adjustment.

Action: VAMC Clarksburg.

Purpose: Assess difficulties in post-war adjustment among ODS soldiers.

Coordinations: VA, DoD and HHS.

Early Intervention with Appalachian Marine Reservists in ODS.

Action: VAMC Mountain Home, TN.

Purpose: To provide an early intervention debriefing to Marine reservists about the stresses of deployment and combat. Follow-up contacts and tests indicated a high degree of PTSD.

Coordinations: VA, DoD and HHS.

Desert Storm Reunion Survey.

Action: VAMC Boston.

Purpose: Study a broad range of combat and non-combat experiences associated with deployment during ODS. The study will delineate and quantify those experiences and determine their impact on subsequent patterns of adjustment.

Coordinations: VA, DoD and HHS.

Psychological Assessment of Operation Desert Storm Returnees.

Action: VAMC New Orleans.

Purpose: Conduct comprehensive psychological assessments and debriefings of troops mobilized in ODS.

Coordinations: VA, DoD and HHS.

Operation Desert Storm Follow-Up Survey.

Action: VAMC Salt Lake City.

Purpose: A survey designed to elicit VA medical center employees perceptions of ODS activation, deployment, and reintegration experiences.

Coordinations: VA, DoD and HHS.

Psychological Adjustment in ODS Veterans.

Action: VAMC Gainesville.

Purpose: A study of 542 National Guard and Reserve members was conducted with one group being actively involved in ODS and a Control group. Psychological tests were given to determine if differences existed between the service veterans and the control group in terms of overall mental health.

Coordinations: VA, DOD and HHS

Persian Gulf Veterans Coordinating Board

Clinical

DoD Clinical Activities

Persian Gulf Environmental Monitoring Study
Action: U.S. Army Environmental Hygiene Agency
Purpose: To characterize the concentration of environmental pollutants that DoD personnel were exposed to during their stay in the Gulf region.
Coordinations: EPA, VA, CDC, NOAA, NCI, OSHA

Persian Gulf War Industrial Hygiene Evaluation
Action: U.S. Army Environmental Hygiene Agency
Purpose: To monitor and characterize occupational exposures of DoD personnel who had potential high risk exposure to oil fire emissions.
Coordination: Unknown

Persian Gulf War Biologic Surveillance Study
Action: U.S. Army Environmental Hygiene Agency
Purpose: To refine the results obtained from the health risk assessment study.
Coordination: Unknown

Persian Gulf Health Risk Assessment
Action: U.S. Army Environmental Hygiene Agency
Purpose: To assess the health risk from environmental exposures in the Persian Gulf using EPA guidance for Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites.
Coordination: EPA,

Illness and Injury Among U.S. Marines during ODS
Action: U.S. Navy Surgeon General
Purpose: To provide information on the magnitude and severity of acute health problems possibly related to the air pollution from the oil fires.
Coordination: none

DoD Persian Gulf War Personnel Registry
Action: U.S. Army and Joint Environmental Support Group
Purpose: To establish a listing of individuals who were deployed to the Persian Gulf during Operation Desert Storm.
Coordination: VA, USAEHA

Persian Gulf Veterans Coordinating Board

Clinical

VA Clinical Activities

Persian Gulf Registry.
Action: VACO.
Purpose: Establish a special record (mandated by P.L. 102-585) listing certain individuals who served in the PGW. Registry listings total over 127,000. About 11,000 Registry health exams have been completed.
Coordination: VA, DoD and HHS.

Persian Gulf Referral Centers.
Action: VAMCs - D.C., West L.A., and Houston.
Purpose: Establish three centers at VA medical centers to handle cases of unusual symptoms in PG veterans whose evaluation at a local VA medical center has evaded diagnosis. Fifty-three veterans have been treated and discharged.
Coordinations: VA, DoD and HHS.

Family Support Program.
Action: VA.
Purpose: Provide marriage or family counseling for PG veterans their spouses and children Over sixty three thousand veterans have been reached through outreach activities, with 12,608 receiving individual, group, or marriage and family counseling.
Coordinations: VA, DoD and HHS.

Readjustment Counseling Service.
Action: VAMCs.
Purpose: To ease Gulf theater veterans transition to civilian life and gain assistance in such areas as benefit questions, substance abuse, marriage counseling, employment, and PTSD. About 40,000 Gulf theater veterans have been seen to date.
Coordinations: VA, DoD and HHS

Combat Unit Tracking Data Base
Action: U.S. Army and Joint Environmental Support Group
Purpose: To establish a listing of units deployed to the Persian Gulf and their geographic locations during Operation Desert Storm.
Coordination: VA, USAEHA

Environmental Hazard Exposure Model
Action: U.S. Army Environmental Hygiene Agency
Purpose: To provide information on estimated pollution levels on numerous dates and locations throughout the Desert Storm Theater of Operations.
Coordination: VA, NOAA

Leishmaniasis - Clinical Evaluation
Action: Walter Reed AMC
Purpose: To evaluate individuals who were manifesting symptoms compatible with parasitic infection by Leishmania species.
Coordination: WRAIR, CDC

Illness Cluster Investigation - 123rd ARCOM
Action: Army Medical Department
Purpose: To investigate an outbreak of illnesses among members of the 123rd Army Reserve Command in Indiana
Coordination: unknown

Persian Gulf Environmental Industrial Exposures
Action: U.S. Army Environmental Hygiene Agency and the U.S. Navy
Purpose: To attempt to characterize the potential industrial sources for environmental hazards in the Persian Gulf region.
Coordination: unknown

Illness Cluster Investigation - 24th Naval Reserve CB
Action: Navy Environmental Preventive Medicine Unit - 2
Purpose: To investigate an outbreak of illnesses among members of the 24th Naval Reserve Construction Battalion in Georgia and North Carolina
Coordination: USAEHA, DIA

Persian Gulf Veterans Coordinating Board

Disabilities & Benefits

DoD Compensation Activities

Compensation for Service Members with the Persian Gulf War Syndrome.

Action: OASD(HA) and OASD(P&R).

Purpose: DoD is staffing policy guidance which provides compensation for service members with the Persian Gulf War Syndrome. This provides policy for the Physical Evaluation Boards to rate those service members who are no longer fit for duty and may have the residual effects of this Syndrome.

Coordinations: DoD

Persian Gulf Veterans Coordinating Board

Disabilities & Benefits

DoD Compensation Activities

Compensation for Service Members with the Persian Gulf War Syndrome.

Action: OASD(HA) and OASD(P&R).

Purpose: DoD is staffing policy guidance which provides compensation for service members with the Persian Gulf War Syndrome. This provides policy for the Physical Evaluation Boards to rate those service members who are no longer fit for duty and may have the residual effects of this Syndrome.

Coordinations: DoD

Persian Gulf Veterans Coordinating Board

Disabilities & Benefits

VA Compensation Activities

Regional Office Centralized Claims Processing.

Action: VA Louisville, KY, Regional Office Centralized Claims Processing.

Purpose: Centralization of disability compensation claims processing at VA's Louisville office to allow rating specialists to develop expertise in rating the issues concerned and make it easier to VBA to identify common health problems which might appear among PG veterans.

Coordinations: VA.

Persian Gulf Veterans Coordinating Board

Disabilities & Benefits

VA Compensation Activities

Regional Office Centralized Claims Processing.

Action: VA Louisville, KY, Regional Office Centralized Claims Processing.

Purpose: Centralization of disability compensation claims processing at VA's Louisville office to allow rating specialists to develop expertise in rating the issues concerned and make it easier to VBA to identify common health problems which might appear among PG veterans.

Coordinations: VA.

-PROJECT NUMBER.....1 R03 MH51013-01 FY 93

IRG/INTRAMURAL UNIT..SRCM

AWARD AMOUNT..... $52,317

INVESTIGATOR NAME/ADDRESS
SUTKER, PATRICIA B
VA MEDICAL CENTER
1601 PERDIDO ST/116B
NEW ORLEANS, LA 70146

PERFORMING ORGANIZATION: U.S. DEPT/VET AFFAIRS MED CTR-NW ORLEANS

TITLE PSYCHOLOGICAL OUTCOMES TO HURRICANE--RISK FACTOR MODEL

ABSTRACT:

This research project investigates the mental health impact that occurred subsequent to hurricane natural disaster exposure in young adult Operation Desert Storm (ODS) war zone veteran returnees for whom a pre-hurricane comprehensive date set has been collected. The information available includes data descriptive of personal resources and characteristic, ODS war zone experiences and other historical information, and the psychological outcome variables of negative affect states such as anxiety, depression, and anger, symptoms specific to post-traumatic stress disorder (PTSD), somatic complaints, and alcohol and drug use patterns prior to and subsequent to ODS exposure. It is proposed to collect data specific to response to Hurricane Andrew among a total of 400 ODS troops, 300 of whom were subjected to the marked trauma of war zone stress approximately one year prior to hurricane impact. The primary purposes of this research are 1) to describe psychological functioning subsequent to Hurricane Andrew exposure among ODS returnees who were exposed to war zone duty compared to ODS troops who were mobilized to action but not deployed to the war zone prior to this natural disaster; and 2) to explore the contribution of specific person and environment factors that may set individuals at greater risk for development of acute and persistent negative mental health consequences of disaster, specifically, factors of prior war zone trauma, hurricane disaster and its salient aspects, as well as personal history characteristic and resources and characteristics of post-disaster environment/events. Therefore, the research is directed toward study of the role of prior traumatization experiences such as military combat and psychological responses to such trauma as factors provoking accentuation of negative mental health sequelae or re-traumatization responses given subsequent stressors and trauma. A related objective is to explore characteristics of persons or environments that serve to protect against negative psychological outcomes and enhance adaptive responding to calamity.

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SOURCE: CRISP FORMAT F FY 93 LAST UPDATE 11-19-93

11-17-93 03:11PM FROM IMMED. OFFICE ASB P002

PROJECT NUMBER.....1 Z01 AI00102-18 FY 92
RG/INTRAMURAL UNIT..LPD
WARD AMOUNT..... $0

INVESTIGATOR NAME/ADDRESS
NEVA, F A
NIAID, NIH

ERFORMING ORGANIZATION:
ITLE PATHOGENESIS OF DISEASE CAUSED BY INFECTION WITH INTRACELLULAR PARASITES

BSTRACT:

This project continues to focus upon the different clinical forms of leishmanial infections in humans, the cell-mediated immune responses to leishmanial antigens, and characteristics of the causative parasites.

Six parasitologically proven cases of cutaneous leishmaniasis were diagnosed and treated at the NIH Clinical Center during the past year. Many additional patients referred to the NIH by local military services (Walter Reed Army Medical Center and National Medical Center) were evaluated by cell-mediated immunologic studies and leishmanin skin tests for evidence of past or present leishmanial infection. Many of these cases were leukophoresed to obtain lymphocytes for research purposes. Leishmania tropica, a species that traditionally has been associated with cutaneous leishmaniasis, has been isolated from bone marrow of five Desert Storm operation veterans, and from the lymph node of at least two additional cases. The clinical picture in many of these cases is atypical, and immunologic tests suggest that many additional systemic leishmanial infections have occurred.

Semi-quantitative PCR techniques were employed for detection of mRNA of various cytokines in bone marrow specimens from patients with visceral leishmaniasis (Kala-azar) in the Sudan. Relatively high levels of mRNA for IL-10 appear to be present in active cases, with a marked decrease in levels after treatment. These findings may help explain the antigen-specific anergy that occurs with this disease.

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SOURCE: CRISP FORMAT F FY 93 LAST UPDATE 11-19-93

12-17-93 03:11PM FROM IMMED. OFFICE ASH TO

-PROJECT NUMBER.....Z01 CP05177-11 FY 92

IRG/INTRAMURAL UNIT..CCTP

AWARD AMOUNT..... $0

INVESTIGATOR NAME/ADDRESS
POIRIER, M C
NCI, NIH

PERFORMING ORGANIZATION:

TITLE USE OF IMMUNOLOGICAL TECHNIQUES TO STUDY THE INTERACTION OF CARCINOGENS WITH DNA

ABSTRACT:

Antibodies specific for carcinogen-DNA adducts have been used to quantify DNA modification in biological samples substituted with polycyclic aromatic hydrocarbons (PAH), aromatic amines and cisplatin by quantitative immunoassays, immunohistochemistry, immunoaffinity chromatography (IAC), atomic absorbance spectrometry (AAS) and P-32-postlabeling. Studies are being conducted to measure PAH-DNA adducts in blood cell DNA of coke oven workers, aluminum plant workers, subjects ingesting charbroiled beef and Army personnel exposed to oil well fires in Kuwait, using the benzo[a]pyrene-DNA enzyme-linked immunosorbent assay (ELISA) and the 6-fold more sensitive dissociation-enhanced lanthanide fluoroimmunoassay (DELFIA). Aromatic amine-DNA adducts are being concentrated from human lung DNA by IAC and quantified by P-32-postlabeling. The extent of cisplatin-DNA adduct formation in nucleated blood cell DNA of cancer patients (measured by cisplatin-DNA ELISA) has been positively correlated with disease response in ovarian cancer patients receiving platinum chemotherapy. This association is being further investigated in blood samples from previously-untreated ovarian cancer patients, all given the same protocol. Platinum-DNA adducts have been measured in placenta and blood cell DNA from a woman given cisplatin and carboplatin for ovarian cancer during pregnancy. This human exposure was modeled in the patas monkey, and adducts were measurable in both maternal and fetal tissues. Blood cell platinum-DNA adducts have been correlated with dose by both ELISA and AAS in samples from testicular cancer patients during 3 cycles of platinum-drug chemotherapy. An antiserum specific for the anti-AIDS drug, 3'-azido-2',3'-dideoxy-thymidine (AZT), has been used to establish an RIA and immunohistochemical localization for AZT incorporated into the DNA of human HL 60, hamster Chinese hamster ovary (CHO) and mouse NIH 3T3 cell lines. Incorporation of AZT into DNA by radiolabeling correlated well with that determined by RIA. The highest concentrations of AZT incorporated into CHO cell chromosomal DNA colocalized with regions of DNA in Z conformation.

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SOURCE: CRISP FORMAT F FY 92 LAST UPDATE 10-09-93

12-17-93 03:11PM FROM IMMED. OFFICE ASH TO 917036976691 P.04

JECT NUMBER.....1 Z01 AI00102-18 FY 92
INTRAMURAL UNIT..LPD
RD AMOUNT..... $0

INVESTIGATOR NAME/ADDRESS
NEVA, F A
NIAID, NIH

FORMING ORGANIZATION:
LE PATHOGENESIS OF DISEASE CAUSED BY INFECTION WITH INTRACELLULAR PARASITES

TRACT:

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OURCE: CRISP FORMAT F FY 92 LAST UPDATE 10-09-93

-PROJECT NUMBER.....1 R03 MH48979-01 FY 91

IRG/INTRAMURAL UNIT..SRCM

AWARD AMOUNT..... $50,000

INVESTIGATOR NAME/ADDRESS
LEVAV, ITZHAK
COLUMBIA UNIVERSITY
100 HAVEN AVE TOWER 3-19H
NEW YORK, NY 10032

PERFORMING ORGANIZATION: FALK INSTITUTE FOR MH & BEHAV STUDIES

TITLE ISRAELI REACTIONS TO MISSILE ATTACKS DURING THE GULF WAR

ABSTRACT:

DESCRIPTION (Adapted from applicant's abstract): The recent bombing of the civilian population during the Persian Gulf War offers an important research opportunity in the context of ongoing epidemiological research that has been conducting in Israel since early 1983. This is the chance to study the immediate effects of a life-threatening experience, and to plan subsequent monitoring of long term effects on a sample of 669 young, Israel-born adults on whom detailed antecedent baseline data have been collected. These data consist of a greater variety of social, psychological and psychiatric variables than have even been obtained before on a general population sample prior to a crisis of war or natural disaster.

Specific aims are to assess the nature of the objective threat (e.g., residence in targeted Tel Aviv versus relatively safe Jerusalem), how the threat was defined subjectively, how the threat was reacted to (e.g., symptoms of PTSD and other evidence of psychological distress), and how these reactions were influenced by the objective threat, its subjective definition, and previously measured antecedent factors such as baseline distress and PTSD symptoms, baseline psychiatric diagnoses (especially RDC depression, anxiety disorder, substance use disorders, and antisocial personality), personality characteristics, and demographic characteristics.

These questions will be answered by reinterviewing the above 669 persons to secure the relevant data by telephone for the majority and face to face for persons with no phones. These interviews will start on March 20, which is 3 weeks after the bombing threat ended. Both logistic regression and multiple regression will be included in the data analytic methods.

The longer term goal is to conduct a more extensive and intensive follow-up of a variety of subsamples from the entire screened and diagnosed sample of 4,914 persons from whom the above 669 cases and controls were drawn for intensive study. This longer term follow-up would occur in 1993, ten years after the initial epidemiological field work began. Taken together, the on-going epidemiological research and the proposed study of the immediate effects of the war threat would provide an unprecedented opportunity to investigate how past social, psychological and psychiatric factors affect responses to a life-threatening experience and how such responses, in turn,

CONTINUED ON NEXT PAGE

-PROJECT NUMBER.....1 R03 MH48979-01 (Continued)
are related to the future course and development of psychiatric disorders.

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SOURCE: CRISP FORMAT F FY 91 LAST UPDATE 09-30-93

12-17-93 03:11PM FROM IMMED. OFFICE ASH TO 917036976691 P007

PROJECT NUMBER.....1 Z01 AI00342-10 FY 91

RG/INTRAMURAL UNIT..LID

WARD AMOUNT..... $0

INVESTIGATOR NAME/ADDRESS
KAPIKIAN, A Z
NIAID, NIH

PERFORMING ORGANIZATION:

TITLE STUDIES OF GASTROENTERITIS VIRUSES BY ELECTRON MICROSCOPY

ABSTRACT:

The electron microscope is an integral component of a laboratory engaged in the study of gastroenteritis viruses. Two major groups of gastroenteritis viruses--the 27nm Norwalk virus and the 70nm human rotaviruses--were discovered at NIH and in Australia, respectively, (as well as the hepatitis A virus at NIH, in collaboration with the Hepatitis Section) by the use of electron microscope techniques. Indeed, in this era of tissue culture virology, these agents were discovered without the use of an in vitro tissue culture system, because they could not be grown from clinical specimens in cell culture. The term, "direct virology," is apt to describe this method of examining viruses from clinical specimens by electron microscopy.

Although second and third generation tests have been developed for the detection of the Norwalk group of viruses and the rotaviruses, the electron microscope is still an indispensable tool for the study of these gastroenteritis viruses. It is also the most rapid diagnostic method for detection of rotavirus from a clinical specimen and is the only method available for detecting infection with certain 27nm or similiar small round virus-like particles from individuals with viruses associated with epidemic nonbacterial gastroenteritis. In addition, it is the only method that is capable of detecting all known gastroenteritis viruses (e.g., group A or non-group A rotavirus, Norwalk-like viruses, adenoviruses, astroviruses, caliciviruses) by examination of a single stool specimen. This became especially apparent when stools from Desert Storm troops who developed acute gastroenteritis needed to be evaluated for the presence of viral agents. It also is important for: (i) providing direct visualization of virus particles from density gradients (to establish their morphologic appearance, e.g., single or double capsid, integrity of capsid structure, and to determine presence or absence of particles or their quantitation); (ii) providing direct visualization of particles from unusual clinical specimens to determine their identity, if feasible; (iii) attempting to visualize the site of activity of antibodies such as monoclonal antibodies or recombinant virus induced antibodies; and (iv) serologic studies performed by immune electron microscopy to determine the antigenic relationships of fastidious gastroenteritis agents that cannot be propagated in cell culture such as the human group C rotaviruses, and

CONTINUED ON NEXT PAGE

ROJECT NUMBER.....1 Z01 AI00342-10 (Continued)
he Norwalk group of agents. However, its most important and creative
ole is in its application to the detection of new, heretofore unknown,
gents of acute infectious gastroenteritis and other diseases as well.

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SOURCE: CRISP FORMAT F FY 91 LAST UPDATE 09-30-93

12-1-93 03:11PM FROM IMMED. OFFICE ASH TO 917036976691 P009

12-11-93 09:... ASM IMMED. OFFICE ASH TO 917036976691 P010

OJECT NUMBER.....1 R01 MH51208-01 FY 93

/INTRAMURAL UNIT..VTS

RD AMOUNT..... $110,689

INVESTIGATOR NAME/ADDRESS
DOHRENWEND, BRUCE P
NY STATE PSYCHIATRIC INST
722 W 168TH ST BOX 8
NEW YORK, NY 10032

FORMING ORGANIZATION: COLUMBIA UNIVERSITY NEW YORK

LE ISRAELI REACTIONS TO SCUD ATTACKS DURING THE GULF WAR

TRACT:

e bombing of the Israeli civilian population during the Persian Gulf War ffered a unique and important research opportunity to study effects of a ife-threatening experience on a sample of Israel-born adults on whom we ve detailed pre-war baseline data. These pre-war data were collected in case/control study of life events and other possible risk factors for sychiatric disorders, especially schizophrenia, major depression, ntisocial personality and substance use, including alcoholism.

nder a small grant from the NINH RAPID program, we took the first step to eize this opportunity. We collected post-war data that included not only ssessments of psychological distress and symptoms of PTSD, but also xtensive measures of the stress process. The respondents were 650 people rom our original sample. The interviewing began on March 20, 1991, 3 eeks after the bombing threat ended, and continued for the following ear.

he RAPID grant provided funds for data collection only. The present pplication is for funds to analyze the data. Our aims in these analyses re to: 1) examine the relationship between objective threat (e.g., esidence in targeted and bombed areas) and distress (e.g., demoralization nd symptoms of PTSD); 2) test whether the relationships among stress, ocial situations, personal disposition, and psychopathology in our aseline study of more usual stressors are replicated in a situation of abnormal life threatening stress and, 3) address with prospective analyses questions raised but unresolved with the retrospective data from the baseline case/control study.

Our longer term goal is to conduct further follow-up interviews that will be informed by the results of analyses proposed here. This longer term follow-up would involve clinical diagnoses by psychiatrists as in the original baseline study. This would enable us to investigate not only how past social, psychological and psychiatric factors affect immediate responses to a life-threatening experience, but also how such responses, in turn, are related to the future course and development of psychiatric disorders.

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SOURCE: CRISP FORMAT F FY 93 LAST UPDATE 11-19-93

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ARNOLD L. PUNARO STAFF DIRECTOR
RICHARD L REYNARD STAFF DIRECTOR FOR THE MINORITY

United States Senate

COMMITTEE ON ARMED SERVICES
WASHINGTON, DC 20510-6050

March 16, 1994

The Honorable Sam Nunn
Chairman
Committee on Armed Services
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

I am enclosing a full report of our investigation of the issues related to the possible presence of chemical and biological weapons agents in the theater of operations during Desert Storm and the possible connection between service in the Persian Gulf and the unexplained illness affecting thousands of veterans. This report includes:

Tab A: Interim report of European trip to investigate the Persian Gulf War Syndrome.

Tab B: Report of Middle East trip to continue the investigation into the Persian Gulf War Syndrome.

Tab C: Conclusions and Recommendations.

Tab D: Floor Statement regarding the our investigation of the Persian Gulf Syndrome on behalf of the Committee on Armed Services.

Iraq entered the conflict with a demonstrated chemical weapons capability -- having used chemical weapons indiscriminately during the Iran-Iraq War, not only against the Iranians, but also against the Iraqi Kurds. Iraq was also suspected of developing a biological weapons capability, most likely antrax and botulism. As the coalition formed to fight Iraq's aggression, Suddam Hussein made inflamatory statements implying that he was willing to use these weapons to defeat the coalition by inflicting mass casualties.

With this knowledge and Saddam Hussein's threatening statements, the coalition forces strongly believed that Iraq would use chemical and bioligical weapons should there be a war. An array of defensive measures were adopted including an air campaign against all known chemcial and biolgical weapons sites intended to

G-series nerve gas was found by a Czech chemical detection unit attached to Saudi troops in the area of Hafar-Al-Batin on January 19, 1991. Mustard agent was found in a 20X200 centimeter patch in the desert north of King Khalid Military City on January 24, 1991. A report of these detections was forwarded to the Department of Defense by the Czech government.

This announcement by the Czech News Agency led to a series of meetings with Department of Defense officials, including Undersecretary of Defense John Deutch. While Department of Defense officials maintained that they had no evidence of any chemical weapons attacks by Iraq during the Gulf War, the Department of Defense could not confirm or deny the presence of chemical warfare agents at low levels in the theater of operations.

It was in response to these events that you authorized my travel to the Czech Republic, the United Kingdom and France during the period of November 28 through Decemeber 5, 1993 and to Saudi Arabia, Syria, Egypt, Israel and Morrocco from January 3 to January 15, 1994. I was accompanied by Dr. Edwin Dorn, then Assistant Secretary of Defense for Personnel and Readiness, on the first leg of this investigation. Major General Ronald Blanck, Commander of Walter Reed Army Medical Center, traveled with me on both legs of this journey.

In preparation for the trips, I, and members of my personal staff and the Committee on Armed Services staff received a briefing by Depatment of Defense officals. Upon our return, I tasked my personal staff and the SASC staff to meet again with Department of Defense officials in an attempt to answer questions and inconsistencies which arose as a result of information learned from these trips.

The following report provides details of my contacts with high-level representatives of the Coalition forces, several inexcapable conclusions, and a floor statement addressing this issue.

Sincerely,

Richard

Richard Shelby

SAM NUNN GEORGIA CHAIRMAN

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ARNOLD L PUNARO STAFF DIRECTOR
RICHARD L REYNARD STAFF DIRECTOR FOR THE MINORITY

United States Senate

COMMITTEE ON ARMED SERVICES
WASHINGTON, DC 20510-6050

MEMORANDUM TO SENATOR NUNN AND SENATOR THURMOND

FROM: SENATOR SHELBY

CC: SENATOR COATS

SUBJECT: REPORT ON TRIP TO INVESTIGATE "PERSIAN GULF SYNDROME"

The following is a report on my trip to investigate issues related to the possible presence of chemical/biological weapons agents in the theater of operations during the Persian Gulf War, and any possible connection between service in the Persian Gulf War and the illness among U.S. veterans referred to as the Persian Gulf Syndrome. The trip included visits to Prague, Czech Republic; London, England; and Paris, France.

Members of the Codel included two members of my personal staff, who serve as S.Res.' to the SASC (Terry Lynch and Tom Young) and four members of the SASC staff with responsibilities in the area of manpower, personnel and chemical/biological defense (Charles Abell, Monica Chavez, P.T. Henry, and Frank Norton).

Additionally, the Codel included representatives from DOD (Assistant Secretary of Defense (Personnel and Readiness) Ed Dorn, Major General Ron Blanck, Commander, Walter Reed Army Medical Center and Colonel John Speigel, military assistant to ASD Dorn).

Although the trip was productive, our investigation is incomplete. I believe a trip to the Middle East to meet with our coalition allies stationed in the areas in question is necessary to resolve key questions about the possible presence of chemical agents in the theater of operations and the possible causes of the Persian Gulf Syndrome.

The following is a summary of what the Codel learned during its trip.

Rhein Main Airport, West Germany

Enroute to Prague, the Codel had a layover in Frankfurt, West Germany during which the Codel met with the Deputy Chief of Staff for Operations (DCSOPS) and representatives from the Headquarters of the US Army Europe (USAREUR), and received a briefing on the military and civilian draw down in Europe. During the briefing, the USAREUR representatives provided their

included chemical, medical, and other support personnel. The Czech chemical unit was under contract to the Saudi government to provide chemical weapons/agent detection to the Saudi government during the Persian Gulf War.

- On January 19, 1991, Czech chemical units, that were working with 4th and 20th Saudi brigades and were separated by approximately 20 kilometers, made three nearly simultaneous detections of a low concentration of G-series nerve agent in the air. The Czechs consider the three nearly simultaneous detections to be "one" event. The Czechs indicated that the detections took place in the late afternoon and that the event lasted approximately 40 minutes. The Czechs determined that, at ground level at the time of the event, the wind was blowing from the northwest. The Department of Defense had previously advised the Committee that the prevailing winds were blowing northeastward.

- The Czechs took air samples from two of the three locations, and verified the contents of the air samples in their mobile laboratory to contain G-series nerve agent. The Czechs were not able to distinguish between sarin or soman. LTC Smehlik indicated, however, that they had excluded V-series agents. These air samples were sent back to then Czechoslovakia, and are no longer available, as they have been used up. An air sample from the third location was not taken for the purpose of verification because the Czech chemical unit was moving at the time of the alarm.

NOTE: In the U.S., G-series nerve agents Sarin and Tabun are considered to be nonpersistent, evaporating at the same rate as water. VX, a persistent nerve agent, evaporates much more slowly, and spills of liquid VX can persist for a long time under average weather conditions.

- Captain Ferus, a leader of one of the Czech chemical units, informed us that on January 24, 1991, he was summoned by Saudi officials to an area 10 kilometers north of KKMC. His unit was accompanied to the area by Saudi soldiers, where he was asked to check the area for chemical agents. His unit detected mustard agent in the sand. No sample was taken because the presence of mustard agent was confirmed on the spot using a portable laboratory kit.

- LTC Smehlik informed the Codel that he had recently learned that there had been another detection of mustard agent in the air near the Engineer School in KKMC 2-3 days prior to the detection on January 24. LTC Smehlik indicated that an air sample was taken, verified by the mobile laboratory, and forwarded to Czechoslovakia. This sequence of events was confirmed for the Codel by the Czech warrant officer who reported the actual detection.

presence of any chemical weapons, nerve or mustard agents, in the Persian Gulf. They spent a considerable amount of effort attempting to find plausible means of discrediting the Czech reports.

- The British government does not recognize the possibility of any connection between service in the Persian Gulf and any illness that cannot be explained by conventional medical diagnosis. The British have about 30 veterans from the Persian Gulf with medical problems. These medical conditions are not considered peculiar to their service in the Persian Gulf. British citizens have, however, set up a Persian Gulf Families Hot Line, located in Glouchester, England, that serves as a clearing house for those who believe they have illnesses related to their service in the Persian Gulf. I met with Mr. Raymond Donn, a solicitor from Manchester, England, who is in the process of filing a class action suit against the British government to obtain compensation for these veterans. Mr. Donn informed me that there could be as many as 500 sick British veterans.

- The British government does not recognize Multiple Chemical Toxicity/Sensitivity as a valid concept. Additionally, the representatives with whom the Codel met believe the Persian Gulf Syndrome is the result of American veterans attempting to increase their medical and disability benefits. The Codel was advised that the United States did not have to invent a new environmental disease to explain the symptoms being experienced by American veterans.

Paris, France

While in Paris, the Codel met with Lieutenant Colonel Gerrard Emile Ferrand, a French Army infantry officer who served in the Persian Gulf. The French had about 12,000 personnel in the Gulf.

- Colonel Ferrand informed the Codel that the French had detected nerve and mustard agent at a Logistics Facility approximately 26 or 27 kilometers south of KKMC on the evening of January 24th or January 25th. He indicated that the wind at ground level had been from the north--from Iraq. French chemical alarms were activated at two locations approximately 100 meters apart. Colonel Ferrand, who arrived at the location about 30 minutes after the initial alarm, indicated that litmus badges on the protective suits worn by French troops registered the presence of mustard agent. They contacted a Czech chemical unit and asked it to conduct tests to verify presence of the chemical agents. The Czech chemical unit arrived about 2 hours later, confirmed the presence of a mustard agent and a nerve agent--either Soman or Tabun--and decontaminated the area.

- Colonel Ferrand also noted that, about 2 or 3 days later

were made.

Recommendation

1. In order to complete the investigation of possible presence of chemical/biological agents in the Persian Gulf and the possible causes of the Persian Gulf Syndrome, it is necessary for me to visit with members of the allied coalition and meet with the appropriate representatives of their foreign and defense ministries. Coalition allies stationed in the area in question includes Morocco, Syria, Egypt, and Saudi Arabia. Additionally, it would be useful to meet with appropriate defense and intelligence community representatives from Israel regarding any information they might have about the possible use of chemical weapons. I believe it would be in the Committee's interest for me to travel to the Middle East for this purpose during the first two weeks of January 1994.

2. Prior to my travelling to the Middle East, the Department of Defense should provide maps to the Committee showing the locations of battalion-level and above units during the period from January 17, 1991, through February 1, 1991. Additionally, the Department of Defense should provide maps showing the dates, times, and locations of all bombings of chemical production or storage facilities and ammunition storage areas.

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RICHARD L REYNARD STAFF DIRECTOR FOR THE MINORITY

United States Senate

COMMITTEE ON ARMED SERVICES
WASHINGTON, DC 20510-6050

February 28, 1994

MEMORANDUM SENATOR NUNN AND SENATOR THURMOND

FROM: SENATOR SHELBY

CC: SENATOR COATS

SUBJECT: REPORT ON TRIP TO MIDDLE EAST TO CONTINUE THE INVESTIGATION INTO THE PERSIAN GULF SYNDROME

Upon the completion of my trip in December to Czechoslovakia, the United Kingdom and France to investigate issues related to the possible presence of chemical/biological weapons agents in the theater of operations during the Persian Gulf War, and any possible connection between service in the Persian Gulf War and the illness among U.S. veterans referred to as the Persian Gulf Syndrome, I informed you that I believed the investigation would not be complete without meeting with other coalition allies stationed in the theater of operations. On January 3-15, I travelled to Riyadh, King Khalid Military City, and Jubail, Saudi Arabia; Damascus, Syria; Cairo, Egypt; Tel Aviv and Jerusalem, Israel; and Rabat, Morocco to continue my investigation into this matter.

Members of the Codel included two members of my personal staff who serve as S.Res.' to the SASC (Terry Lynch and Tom Young), four members of the SASC staff with responsibilities in the areas of manpower, personnel and chemical/biological defense (Charles Abell, Monica Chavez, P.T. Henry and Frank Norton), and a representative from the Department of Defense (Major General Ron Blanck, Commander, Walter Reed Army Medical Center).

I believe the investigation of this issue has been productive and is complete, to the extent that the Congress can conclude the investigation. This report summarizes our meetings and discussions in the Middle East and North Africa with coalition allies on the possible presence of chemical agents in the theater of operations and the possible causes of the Persian Gulf Syndrome.

Riyadh and Jubail, Saudi Arabia

On January 4 - 6, we visited Riyadh, King Khalid Military City (KKMC) and Jubail, Saudi Arabia and met with several high

missiles, the Chinese military had no liaison in the theater of operation during the Persian Gulf War.

General Mohammed Saleh al Hammad, Chief of Staff, Minister of Defense Education, had very little to offer regarding the subject of the Codel's inquiry. He expressed confidence in the reliability of the Czech and French detections. When asked about from where the nerve agent and mustard agent could have come, he stated that he had no idea. He speculated, however, that they could have come from either friendly or aggressor forces. He also speculated that perhaps the U.S. military brought it.

King Khalid Military City (KKMC)

On January 6, the Codel flew to King Khalid Military City, where mustard agent had been detected in two locations. The Codel met with Major General Al Alhami, Northern Area Commander, who commanded KKMC during the Persian Gulf War.

- General Al Alhami indicated that, during the war, he received no evidence of any detections of chemical agents nor of any medical problems that could be viewed as "unusual." He indicated that, every time the Iraqis fired SCUDs, all troops donned MOPP chemical protective gear (MOPP gear includes a full body suit and mask with hood). Additionally, he had no recollection of the French reporting their detection of mustard agent to the KKMC Headquarters.

- He has no knowledge of the Saudis, U.S. or Syrians, or any other Coalition forces, having chemical agents/weapons with their forces during the Persian Gulf War.

Jubail Industrial Center

Also on January 6, the Codel travelled to the Jubail Industrial Center to discuss the possibility of industrial chemical releases during the Persian Gulf War. The Codel met with Mr. Terry Velanzano of the Jubail Planning Group and a number of officials from the various civilian industrial concerns located at Jubail. Most of those with whom the Codel met were present at Jubail during the War.

- The industrialists advised the Codel that there were no instances in which industrial chemicals were released either intentionally or unintentionally during the periods of time when coalition forces were located in the Jubail region. They specifically denied the intentional release of chemicals from pressurized systems in response to warnings of SCUD attacks.

- The industrialists also advised the Codel that there were no and are no instances of medical ailments among the Jubail work force and their families that could be construed as "unusual" or in any way linked to chemical agents during the War.

Cairo, Egypt

On January 9, the Codel traveled to Cairo, Egypt. While in Cairo, the Codel received a country team briefing from U.S. Embassy personnel. Senator Shelby met with President Mubarak.

On January 10, the Codel met with Lieutenant General Salah Halaby, Chief of Staff, Egyptian Armed Forces, and his staff. General Halaby advised the Codel that Egypt had its own chemical defense unit, which was very good, but he had no recollection that they had detected any chemical agents during the Persian Gulf War.

- General Halaby indicated that Egypt's chemical defense equipment is from Eastern Europe and from the West, and that their detection equipment is more sophisticated than the Czech equipment. The Egyptians use an American chemical agent alarm (the M-1) and a Russian chemical agent detector (the bulb and probe). The Egyptians also use chemical agent detection strips. He further indicated that the Egyptian chemical defense unit took air samples every day and night to check for changes.

- He suggested that the chemicals detected were not chemical warfare agents, but industrial chemicals or substances used in the construction and structure of the A-10 aircraft. (An A-10 crashed near KKMC during the time frame when the KKMC detections were made). He did not believe the aircraft carried chemical weapons or chemical agents.

- General Halaby and his staff commented that Egypt has no chemical weapons, only chemical defense equipment (protective gear). He said that, although Egyptian troops conduct chemical defense training, they do not use chemical simulants in their training other than tear gas. General Halaby was not aware of the Syrians having had chemical agents/weapons in the theater. He was certain that no Iraqi aircraft or artillery (which could have been used to deliver chemical agents) had crossed the border.

- He asked whether the illnesses suffered by the U.S. troops resulted from their exposure to depleted uranium.

- The Egyptian troops were located approximately 6 miles north of the French troops in KKMC. At one point, General Halaby said they were not aware of the detection of chemical agent by the Czech chemical defense unit, but later in the interview, he acknowledged that they were aware of the detections but did not verify any chemical agents or equipment. General Halaby commented that he knew that chemical agent alarms could be tripped off by cigarette smoke. He suggested that the French and Czech detections could have been false alarms because the atmosphere was so full of petrochemical smoke.

motorized infantry unit from the Western Sahara to the vicinity a petrochemical facility north of Jubail about 50 kilometers from the Kuwait border.

In Rabat, the Codel met with Colonel Major Mohamed Beuboumaudi, Inspector, Military Health Services. He indicated that no Moroccan military personnel saw any chemical weapons or equipment. He mentioned that, on one occasion, his troops went to check the location in which an artillery shell exploded for chemical agent. There were no indications of any chemical agents present.

- The Moroccan troops did not experience any illnesses symptomatic of exposure to chemical agents. Additionally, he pointed out that Moroccan troops were acclimated to service in the desert. The inference here being the possible psychological or environmental origin of the Persian Gulf Syndrome.

- With regard to the origin of Moroccan military chemical defense equipment, he indicated that they used chemical detection badges and gas masks provided by the Saudi military. He noted that Morocco was a signatory of the Chemical Weapons Convention (CC).

- In response to questions regarding the presence of chemical agents or weapons in the theater of operations, and knowledge as to whether coalition allies possessed chemical weapons or agents, Colonel Major Beudoumaudi provided negative responses. He indicated that he was not aware of Moroccan troops participating in chemical defense training with simulants during the Persian Gulf War.

The Codel also met with deputy minister of foreign affairs, who reiterated the comments made by Colonel Major Beudoumaudi regarding the Morocco military personnel's not being aware of the presence of chemical weapons/agent in the theater of operations and not having any knowledge of other coalition allies in possession of chemical weapons/agent in the theater of operation.

CONCLUSIONS AND RECOMMENDATIONS

Mr. President, I have been deeply involved in this issue for nearly two years. After numerous Congressional hearings, after many meetings with official of the Department of Defense and Department of Veterans officials and after two trips abroad I have come to the following conclusions regarding the possible presence of chemical/biological weapons agents in the theater of operations during the Persian Gulf War, and possible connection between service in the Persian Gulf War and the illness among U.S. veterans referred to as the Persian Gulf Syndrome

Chemical agents were present in the theater of operations during the Persian Gulf War. These chemical agents were accurately verified by the Czech Chemical Units and reported to CENTCOM Headquarters.

On this vital issue I have no doubt. Czech and French forces detected both nerve gas and mustard agent at low levels during the early days of Desert Storm. In each instance these chemical agents were verified by Czech equipment. The Codel had the opportunity to view this equipment and received a demonstration. Department of Defense officials have informed us that the Czech detection equipment, which is more sensitive than U.S. equipment, is more than adequate and that Czech personnel are well trained.

The origin of these chemical agents cannot be determined.

Although I have also concluded that we may never be able to determine the origin of these chemical agents there are serveral plausible scenarios. I believe that we can rule out Iraqi Scud or Frog missiles. We can also rule out Iraqi artillery -- the distance from the Iraqi border is too far. The presence of low-level chemical weapons agents could have resulted from U.S. or coalition forces bombing either Iraqi chemical weapons facilities or caches of Iraqi weapons on the Saudi border. Hafar-Al-Batin is approximately 100 miles from the Saudi/Iraqi border. A cloud of nerve agent, dissipating in intensity, could possibly have traveled under the correct climate conditions to Hafar-Al-Batin. There is also the possibility of an accident involving chemical agents among coalition forces. Finally, it has been offered that these detections, especially those in Hafar-Al-Batin and the detection of the mustard agent on the ground north of KKMC, were the result of Saudi Officials attempting to determine the abilities of the Czechs who they had engaged to assist Saudi troops in chemical detections.

Similarly, it was only after my contact with our allies revealed that they had, in fact, reported various chemical detections to the Central Command Headquarters, that the Department acknowledged evidence of this reporting in the operational logs.

On page 45 of the history of the 2nd Marine division in Operation Desert Shield and Desert Storm, which was published by Marine Corps' History and Museum Division, there is a detailed incident in which Marines of the 2nd Marine Division detected mustard agent. I am at a loss to explain how an offical Marine Corps publication can document such an event and the Department of Defense could deny any evidence regarding chemical weapons agents in the theater of operations.

Persian Gulf medical records of members of the 24th Naval Reserve Battalion are missing from their files.

This passivity on the part of the Department when combined with rather obvious attempts to dissuade the Committee from the need for further investigation typifies the Department's attitude toward the Committee on this matter.

MINISTRY OF DEFENCE
WHITEHALL LONDON SW1A 2HB
Telephone 071-21 82111 23

OFFICE OF THE SECRETARY OF STATE
93 AUG -4 PM 2:27

SECRETARY OF STATE

MO 6/17/15/1M

27 July 1993

Dear Congressman Kennedy,

The Prime Minister has asked me to reply to your letter of 1 July 1993 about the health of servicemen who served in the Gulf during the campaign to force Saddam Hussein out of Kuwait.

We do, of course, place great importance on the health and well being of our Service personnel and we have been monitoring reports of "Desert Storm Syndrome" ever since allegations first emerged of cases of unexplained illness suffered by US Gulf War veterans. We are concerned at any possibility that there might have been unforeseen dangers to our personnel during service in the region. Ministry of Defence staff are liaising closely on the issue with their counterparts in the US Department of Defense, and are sharing available data and assessments.

We are keen to establish whether an identifiable syndrome, or at least illnesses attributable to Gulf service, actually exist. I have to say, however, that to date there is no clinical evidence to support the claims that have been made in the British media that sizeable numbers of UK personnel are also suffering from mystery illnesses following service in the Gulf. The statistics we have indicate that there has been no overall increase among serving

Congressman Joseph P Kennedy II

90694

12

British Service personnel in the incidence of the type of wide-ranging and diverse symptoms which are attributed to the syndrome. The UK Armed Forces Medical Services are not aware of any individual cases of illness among those UK personnel who served in the Gulf where the symptoms cannot be explained by conventional diagnoses. Nor have recognised Service Welfare Organisations, who have contact with ex-service personnel, reported any such cases to my Department.

In an attempt to elicit more hard evidence on these reported cases, the Minister of State for the Armed Forces, Jeremy Hanley, recently appeared on a BBC TV programme dealing with the so-called Desert Storm Syndrome and the alleged connection with use of Depleted Uranium ammunition. He appealed to those service and ex-service personnel who believed they were suffering from unexplained illnesses as a result of service in the Gulf to contact him personally. He has made the same invitation to all Members of Parliament who may have constituents in similar situations.

To date only one serving member (whose case is being investigated) and seven ex-serving members of the Armed Forces claiming to have unexplained health problems related to Gulf service have come forward. The Armed Forces Medical Services have made contact with all these people and investigations into their illnesses are proceeding.

We have no organisation fully equivalent to the Veterans Administration, and health care of former service personnel is the responsibility of doctors in our National Health Service (NHS). But if these individuals and their doctors request it, we would certainly arrange for their cases also to be evaluated by Armed Forces medical experts, and such patients have been encouraged to ask their NHS doctors to refer them to us. So far, however, there have been no such referrals.

Nevertheless, we are keeping an open mind on this issue, and my Department is continuing to monitor all the available evidence. Royal Navy, Army and Royal Air Force medical officers have been instructed to watch for, and to report, any cases of illness among serving personnel which are unexplained and match those of the alleged Syndrome. We are also maintaining our close liaison with authorities in your Department of Defense; and with the French MOD, who also say they have no evidence of unexplained illnesses among any of their service personnel who served in the Gulf.

I can assure you that we will continue to liaise closely with our American colleagues on this matter. I am copying this letter to Les Aspin, and to Jesse Brown.

Yours sincerely,

Malcolm Rifkind

OFFICE OF THE BRITISH DEFENCE STAFF
WASHINGTON
BRITISH EMBASSY
3100 MASSACHUSETTS AVENUE NW
WASHINGTON DC 20008

Hon Les Aspin
Secretary of Defense
Room 3E 880
The Pentagon
Washington DC

DOD + VA

JEB

First position

Dear Mr. President, December 20, 1993

I am a Desert Storm Veteran with cancer. "Desert Storm Syndrome" is very real and in some cases has proven very deadly. In the three years since Operation Desert Storm the Department of Veterans Affairs has compiled a database of less than 20,000 veterans to research Desert Storm Syndrome. With over 500,000 soldiers involved in the war this database called the Desert Storm Registry is by no means a true representation of the widespread effects of Desert Storm Syndrome. Veterans have not been informed of the need to register and active duty military are not even eligible. Those who are on the database were never told what symptoms to report or informed about what to watch for in the future. Many of the common symptoms are so slight that no one would recognize them as an ailment caused by Desert Storm Syndrome (i.e. small skin bumps or unusual fatigue). My point being that the Desert Storm Registry is not capable of doing what it was designed to do.

I receive calls daily from veterans, soldiers and their families who are suffering terrible medical problems related to Desert Storm Syndrome. This is due to the fact that they have seen my name recently in the news. They have no one else to call for answers to their questions about what is going on. This situation must be changed now! It is inexcusable for our soldiers and their families to suffer as the government stands by with only red tape and bureaucracy.

The first and foremost step to properly evaluate the effects of Desert Storm Syndrome is to compile an accurate database of all soldiers and dependents with this illness. I believe I have a plan that can accomplish this in a timely manner at an extremely low cost. At the same time the small number of personnel required to compile this database could man phone lines to answer questions about Desert Storm Syndrome. The database could be used by the Department of Veterans Affairs as a tool to begin unlocking the mysteries behind this illness. At the same time the Department of Defense could use the database to determine what units were affected and where they were on the battlefield. This database could easily be compiled in less than three months by two people with the proper authority and contacts in the V.A. and D.O.D.

All that needs to be done is to create a position for a liaison between the V.A. and D.O.D. specifically to evaluate Desert Storm Syndrome. This liaison would both gather and exchange information between these two agencies and other veterans organizations such as The American Legion, Veterans of Foreign Wars, and Operation Desert Storm Association. The liaison would first need to compile a list of typical symptoms from the Department of Veterans Affairs. Then a simple one or two page questionnaire could be sent out through all chains of command to current soldiers. Soldiers who have retired since the war could be contacted through direct mail or various veterans organizations. This would cover greater than 90% of all soldiers who served in the war. Any soldiers, veterans, or dependents who are experiencing symptoms of Desert Storm Syndrome

would be requested to fill out their name, SSN, and a quick symptoms by the numbers type of chart. The questionnaires could then be put into a computer database to eliminate duplicate entries and sort the information. This would be a fast, accurate and very cost effective way to begin to properly evaluate Desert Storm Syndrome.

I would enthusiastically welcome the opportunity to be this liaison and work on this project full time. I have a good working knowledge of the D.O.D. and V.A. In addition I also have many contacts in veterans organizations through my own networking. I am willing to relocate anywhere in the country if necessary but would prefer to work with the V.A. at their Los Angeles center dedicated to Desert Storm Syndrome. I have a computer that is more than capable of the task at hand and am willing to work out of my home if necessary. The ideal situation would be a small office with one secretary that has computer skills.

If the Government is not willing to take on this task I will do what I can on my own. If someone else is going to fulfill this role then please put them in contact with me. I believe my ideas to be sound and I am more than willing to help in any way possible. In any case this is something that must be done!

This will only be the first step in a three year old problem of investigating Desert Storm Syndrome. The next step will be to get the information into the medical community and try to help them unlock this mystery. If we do not act on this now more people will continue to die and others are being infected every day. Please act on this to help the people who continue to suffer and before we re-visit another chapter of Agent Orange.

Sincerely,

[redacted]

USA
Persian Gulf
Disease

[redacted]

President Bill Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C.

Dear Mr. President

I became aware of the issue that a Persian Gulf War veteran, William Kay, was diagnosed as suffering from chemical biological warfare exposure. According to an article from the Los Angeles Times on October 29, William Kay had experienced shortness of breath, excessive fatigue, intermittent diarrhea, night sweats, memory problems, and joint pains since the Gulf war.

The October 29 article says that Senator Richard C. Shelby held hearings in July in which two war veterans from Alabama said that their units were hit with chemical weapons during the war.

Recently, I have heard on the news that the Pentagon is making no comments on the situation. Is this because it is true that veterans were attacked with chemical weapons, or is it because you have no clue as to what they are talking about? I would greatly appreciate a response or any information regarding this topic of chemical weapons being used during the Persian Gulf War.

Sincerely yours

[redacted]

President Bill Clinton
Whitehouse
Washington, D. C.

DOD

VA medical problem

[redacted]

18 Nov 1993

Dear Mr. President,

Sir, I am writing in regards to the thousands of Saudi veterans who are currently suffering from what is being called Saudi Syndrome/Chemical/Biological Exposure. For your information there are literally thousands of us out here who are dying from rare forms of cancer and other problems related to our service in our armed forces in Saudi Arabia in support of what our country believed to be a worthwhile venture into someone elses business.

Mr. President, we need your help! I have never written a letter to anyone in a position as yours. I wish you would come out with a statement and join our cause as we are in dire need of immediate assistance in this matter. The DOD can stand back and say it's "inconclusive" all day (Les Aspen), but dead people, soldiers of our armed forces is proof enough for me and thousands of others that the DOD is harboring a COVER-UP. Mr. President, might I suggest that you get a meeting scheduled with key personnel of the DOD and members of the Congress and Senate (Mac Collins, Richard Shelby, Lane Evans, Don Riegle, Joseph Kennedy, etc). I hope you will join our cause and come out with a statement for our cause and not be middle of the road. I feel this would save a lot of time, money and embarrassment for many people on the hill in the long run.

Mr. President, I have personally spent hundreds of hours and several thousand dollars of my own money to gather information that I have passed on to the afore mentioned Congressmen and Senators and helping out as much as possible. This, however, has not slowed the death toll down or comforted any spouse, mother or brother of a veteran that has died since returning home. This has not just restricted itself to service members but, although inconclusive as it may be, but has been the cause of death of other family members to include wives, children and relatives who have contact with contaminated service members. As the death toll rises daily we still cannot get the help we so desperately need. We need some Executive help if it is available, namely YOURS!

Mr. President, I'm not a finger pointer or a back slapper but I feel that certain members of the DOD are to blame for a COVER-UP that is far bigger than just a few veterans dying. Enough justification, for myself and thousands of others, has already been brought forth as evidence that chemical, as well as biological, agents have been used against us. I feel they are covering up information on how and where Sadam Hussein acquired these chemicals and technology to deliver it ALIVE. I feel the past regime in the White House had knowledge as well as a hand in assisting Hussein in acquiring chemicals and technology to deliver it. I feel the top ranking generals in authority during the war who have so conveniently retired knew what was happening and did not pass on to the lower echelons the true facts. I would have felt better knowing the truth from the beginning than being lied to and have to watch my friends around me dying from what is being called unknown causes, cancer or war related illnesses.

Mr. President, the magnitude of this whole thing, from what I know, could be a devastating blow to our country, but at present it's only painful and disgusting to those of us who are dying a slow death and suffering daily. Mr. President, some of us have already given our all for our country, why can't our country in turn treat us like we so deserve to be treated. We have proven on several occasions the us of chemical and biological warfare was used during the operation. I now feel it's the DOD's time to prove it didn't happen instead of saying it's inconclusive. What a JOKE! I know we will come out the victor in this as I have given my all and don't plan on stopping anytime soon unless the problem is "TOTALLY" resolved to the satisfaction of every contaminated Saudi veteran nationwide.

Mr. President, your immediate attention is requested to help us in our plight to put the responsibility for our problems in the hands of the DOD for medical and financial assistance. Why should a veteran, when due to no fault of his own, be forced into bankruptcy because he cannot work or his medical expenses have reached astronomical proportions? If we can help everyone around the world why can't we help our own, the ones who have helped make our country what it is today.

Thanks for your time and patience, hoping to hear from you in the near future regarding this matter.

I am sincerely,

[redacted]

11 November 1993

Facsimile Page 1 of 1

[redacted]

To: Congressman Harris Fawell

[redacted]

Dear Congressman,

I have been left absolutely dumbfounded by Les Aspin's denials regarding the harm caused by chemical agents to our servicepeople during the Persian Gulf War. First, he gets our troops slaughtered in Somalia. Now he plays cloak and dagger with "mysteries" in order to avoid acknowledging the truth!

In the 1960's the Government denied harm caused by nuclear tests to our servicepeople during the nuclear tests in the Pacific. Twenty years later legislation is passed to care for the tens of thousands of people effected by these tests.

In the 1970's the government denies harm caused by Agent Orange to our servicepeople during military action in Vietnam. Twenty years later legislation is passed to care for, again, the tens of thousands of people effected by that action.

Now, we have one of the left-over cowards from that era aligned with incompetents in our defense "leadership" who not only squanders the lives of our people in uniform but then denies them the recognition and help they need.

What in the world is going on here? Just how much is a service-person supposed to put up with in the name of God, Country, and Mom's apple pie?

Has Les Aspin ever considered that he is now a case study of the Peter Principle?

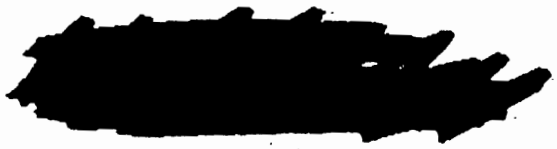
When is Jane Fonda going to be appointed Secretary of Defense?

GAWD help us!

Kind regards

[redacted]

24 DEC 1993

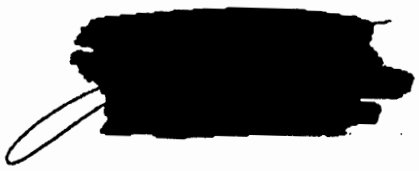


Congressman Barbara Vucanovich
6900 Westcliff Dr.
Las Vegas, NV 89128

Dear Congressman Vucanovich,

First let me begin with I was born and raised in Las Vegas and currently call Las Vegas my home. It is time that I receive some answers pertaining to Operation Desert Storm/Shield, and I hope you can help get me the answers that I need. Yesterday I read that the French Military detected traces of mustard and nerve agents on either Jan. 24 and 25. 1991. the chemicals were detected approximately 15 miles south of King Khalid Military City in Saudi Arabia on a rainy night when the wind was blowing from the direction of Iraq. I do not know if I can reveal my exact location and what my unit did. But I can say that I was serving with a Military Police Company which went deep into Iraq. I currently have several problems such as problems sleeping aches in my joints, a growth on my left arm, problems with my back, unexplained headaches, and other problems. I would like to know what the United States Government is doing about these problems that myself and numerous veterans are having. I know the VA is working on the problems although slow at least they are making some progress. I will probably be separated from the Military within a couple of months from severe back pain that I blame partially on Operation Desert Storm/Shield. I would appreciate any answers or help you could provide me in these trying times.

Sincerely,



P.S.
Please don't let
The veterans go
unnoticed like
Vietnam.

NEWS RELEASE

OFFICE OF ASSISTANT SECRETARY OF DEFENSE
(PUBLIC AFFAIRS)
WASHINGTON, D.C. 20301
PLEASE NOTE DATE

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IMMEDIATE RELEASE November 10, 1993

NO HEALTH LINKAGE FOUND IN CHEMICAL AGENT DETECTION

Secretary of Defense Les Aspin said today a preliminary review has found no linkage between small amounts of chemical weapon agents reported early in Operation Desert Storm and continuing health problems suffered by some Gulf war veterans.

At the same time, the Department announced it was forming a panel of outside experts to further examine the issue. The panel will be headed by Nobel Laureate Joshua Lederberg of The Rockefeller University in New York, and will include Professor George Whitesides, Mallinckrodt Professor of Chemistry at Harvard University.

"I want our Desert Storm veterans to know that I personally take these health problems stemming from the war very, very seriously and the whole department takes these problems very, very seriously," Aspin said.

The chemical agent detections were reported by Czechoslovakian chemical warfare detachments deployed with Saudi Arabian forces. The detections occurred within Saudi Arabia in the opening days of Operation Desert Storm.

A U.S. team of experts was dispatched last month to Prague and assessed the training, equipment, technical competence and measurement procedures employed by the Czech personnel. The U.S. team concluded the Czechs did detect agents.

However, there is no way now to independently confirm the detections.

"We have no independent verification of the detections so we cannot confirm them, but we do not rule out the possibility," said Under Secretary for Acquisition John Deutch, a professor of chemistry on leave from a leading university. Deutch has direct responsibility for reviewing the issue.

-MORE-

The Czech units reported two detections of airborne nerve agent (sarin) in very low concentrations about 40 minutes apart on January 19, 1991, northeast of Hafar Al Batin, and detected a small patch of liquid mustard agent near King Kahlid Military City on January 24, 1991.

Acting for the Defense Department, the Army conducted an examination of the Czech reports, and of the possible health effects on U.S. forces of the presence of such chemical weapon agents. The findings of that examination were released today.

The Army's report said no symptoms were recorded among personnel in the area, and could find "no reasonable linkage" between chemical agents in the low concentrations reported by the Czechs and persistent health problems experienced by some Gulf War veterans.

The report said it was unlikely the source of the agent was Iraqi offensive action. It also ruled out the possibility that allied bombing of Iraqi chemical facilities could have caused the detections. For the agent to reach the detection points from that cause, the initial release would have been so large as to cause considerable casualties along the way. No such casualties were present around chemical facilities bombed by allied forces.

The Department has said there was no verifiable use of chemical weapons during the war. That remains true. For example, the Czech procedures did not fully comply with international protocols designed to verify chemical use. But renewed interest in the Czech reports prompted the visit to Prague by Defense Department experts in October of this year to learn what more they could about the Czech detections.

As far as health effects were concerned, the Army review assumed that chemical agents were present in the concentrations detected by the Czechs and asked what the possible impact would have been. The study found "no reasonable linkage" between the reported agents and the illnesses reported by Gulf war veterans.

"This report is a first step. We're creating this outside panel to double check our findings to make sure we haven't overlooked anything," Deutch said.

The Saudi Arabian government has pledged its cooperation in the effort.

-END-

Senator Richard Shelby

NEWS RELEASE

For More Information Contact: Laura Cox (202) 224-6518

FOR RELEASE FOLLOWING FLOOR STATEMENT
March 17, 1994

SENATOR SHELBY REVEALS HIS CONCLUSIONS ON THE PRESENCE OF CHEMICAL AGENTS IN THE GULF WAR

WASHINGTON, D.C. --- U.S. Sen. Richard C. Shelby (D-Ala.), chairman of the Force Requirements and Personnel Subcommittee of the Senate Armed Services Committee, released his conclusions today regarding the presence of chemical and biological weapons agents in the theater of operations during Desert Storm and the possible connection between service in the Persian Gulf and the unexplained illness affecting thousands of veterans.

Sen. Shelby said his investigation into this issue has led him to the following conclusions:

- "I have no doubt that chemical agents were present in the theater of operations during the Persian Gulf War," Sen. Shelby said. "These chemical agents were accurately verified by the Czech Chemical Units and reported to Central Command Headquarters. During my investigation, Department of Defense officials informed me that the Czech chemical detection equipment is more than adequate and that Czech personnel are well trained."

- "We may never be able to determine the origin of these chemical agents," Sen. Shelby said. "I believe we can rule out Iraqi Scud or Frog missiles, as well as Iraqi artillery because the distance from the Iraqi border is too far. The presence of low-level chemicals could have resulted from U.S. or coalition forces bombing either Iraqi chemical weapons facilities or caches of Iraqi weapons on the Saudi border. It is feasible that a cloud of nerve agent, dissipating in intensity, could have traveled under the correct climate conditions. There is also the possibility of an accident involving chemical agents among coalition forces. Finally, it is possible that the detections were the result of Saudi officials attempting to determine the abilities of the Czechs whom they had engaged to assist in chemical detections."

11:35

-more-

509 Hart Building, Washington, D.C. 20510

11:36 "While a direct connection between the existence of low-levels of chemical agents in the theater of operations and the Persian Gulf Syndrome cannot be established based on the information available at this time, such a connection can not and should not be discounted," Sen. Shelby said.

11:37 "The Department of Defense has proven reluctant to pursue or, in certain instances, to provide the information necessary to prove or disprove allegations about the presence of chemical agents in the theater of operations during the Persian Gulf War," Sen. Shelby said. "I have not determined the reason for this apparent aversion to full disclosure; however, the committee staff working on this issue was constantly challenged by the Department's evasiveness, inconsistency and reluctance to work together toward a common goal."

- "Finally, Persian Gulf medical records for members of the 24th Naval Reserve Battalion are inexplicably missing from their files," Sen. Shelby said.

Sen. Shelby released his conclusions in a letter and full report to Sen. Sam Nunn, chairman of the Senate Armed Services Committee, as well as in a statement on the Senate floor. His involvement in this issue has spanned two years and has included numerous congressional hearings, meetings with Department of Defense and Department of Veterans officials, and two investigative trips abroad.

Copies of the full report and floor statement are available in Sen. Shebly's press office.

Mystery illness gains a name, not a cure

By Vago Muradian
and Soraya S. Nelson
Times staff writers

WASHINGTON — The government is about to give the Persian Gulf mystery illness a new name but is still searching for its cause and cure.

The new name of the mystery illness, and proposed methods by which it will be diagnosed, must still be reviewed by officials responsible for dealing with the health concerns of Persian Gulf war veterans, officials said.

The veterans have reported symptoms including chronic fatigue, joint aches, rashes and intestinal illnesses that cannot be diagnosed using conventional tests.

Dr. Jay Sanford, the former president of the Uniformed Services University of the Health Sciences, proposed the methods for diagnosing the illness with the help of doctors from Tufts University in Medford, Mass., and Massachussetts General Hospital in Boston, said Army Maj. Gen. (Dr.) Ronald R. Blanck, commander of Walter Reed Army Medical Center here.

Sanford was expected to make his recommendations Jan. 27, Blanck said.

In an interview Jan. 26, Blanck said he had promised Rep. Steve Buyer, D-Ind. that he would rename the illness, which the media have dubbed Persian Gulf Syndrome or "mystery illness."

Buyer, an Army reservist, served in the Gulf and revealed his ailments at a hearing last year. Buyer's health has since improved, Blanck said.

The Walter Reed commander said he had asked Sanford to develop a diagnosis for the mystery illness that is similar in approach to what doctors at the federal Centers for Disease Control and Prevention developed for Chronic Fatigue Syndrome several years ago, Blanck said.

That illness mirrors many of the symptoms Desert Storm veterans are experiencing, Blanck said.

Because Chronic Fatigue Syndrome, like the Persian Gulf mystery illness, does not show up on routine tests, the criteria used to diagnose the Persian Gulf illness instead will rely on such factors as how severe the patient's symptoms are and how long they have existed, Blanck said.

Veterans displeased

But the government's efforts so far have not impressed ailing veterans and lawmakers, judging from a Jan. 21 congressional hearing called by House Veterans' Affairs Committee Chairman G.V. "Sonny" Montgomery in Meridian, Miss.

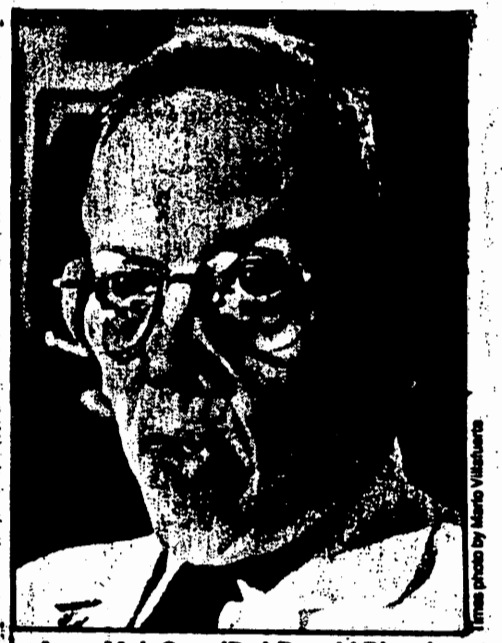
Officials from the departments of defense and veterans affairs must move more quickly to find what is causing the unexplained ailments affecting thousands of service members and their families nationwide, said lawmakers at the hearing.

"The farther we get [from the war], the harder it will be to determine what caused it," Rep. Mike Parker, D-Miss. "Nobody is talking to the people who are hurting out there."

Only now, almost three years after the war's end, is the government gradually mobilizing to respond to veterans' complaints, Parker said.

But state and federal officials attending the Meridian hearing said that families themselves have been slow to report their illnesses or release medical records to the state health department and VA hospitals.

This area of southeastern Mississippi is of particular interest to congressional and government officials, because 13 of 16 children born to parents who served with one Mississippi National Guard unit have serious health problems. Veterans Affairs officials are investigating statewide claims that 37 of 55 children born to Gulf war veterans suffer such problems.



Times photo by Mario Villafuerte

Army Maj. Gen. (Dr.) Ronald Blanck

"We are young people trapped in the bodies of elderly people," said Olivia Fowler, whose husband, Frederick, is a National Guard sergeant. Frederick Fowler served with the former 624th Quartermaster Petroleum Supply Company.

The Fowlers' 21-month-old son was born with a rare urinary tract disorder that makes it difficult for him to urinate, she said. He has undergone several operations and is expected to have medical problems for the foreseeable future.

Ammie West tells a similar story. "My husband and his unit never saw any combat, but provided the ways and means for the ones who did," she said. "Nor did they see the silent enemy that seemed to infiltrate the 624th and many, many more of the Gulf war soldiers. West said her 2-year-old daughter is suffering from respiratory ailments she and her husband believe are related to his service.

"This enemy was so silent that its war cry was not heard until it screamed its attack on our innocent children," West said.

Why isn't more being done?

The congressmen said they want the Pentagon and Department of Veterans Affairs to try harder to talk to veterans about their concerns and keep them better apprised of what's being done to define and treat their symptoms.

They also asked why the government was not working more closely with civilian doctors and specialists who reportedly have succeeded in treating certain aspects of the syndrome.

Blanck insisted the federal government was helping, but that research takes time. He added that a federal grant of $1.2 million will be given to a New Orleans physician whose treatment of ailing veterans has shown promising results. The grant will finance research and treatment for veterans.

Despite the efforts of national and local medical authorities, "we need to learn from this for the future," said Larry Woodard, the director of veterans' benefits at the VA Medical Center in Jackson, Miss.

But the statements of government medical experts did not allay the fears of many veterans and their wives, like National Guard Sgt. Howard H. Turner, 24, and his 22-year-old wife, Shelley. The Turners have decided not to have children until the defects and their cause can be explained.

"We do not want to go through with something now that we may live to regret later," Howard Turner said.

Chemical risks were known during Gulf war

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Chemical risks were known during Gulf war

Saudis told U.S. officials

By Soraya S. Nelson
Times staff writer

WASHINGTON — Contrary to earlier Pentagon statements, top U.S. military leaders were told during Operation Desert Storm that chemical warfare agents had been detected in areas occupied by allied forces, according to a senator just back from the Middle East.

Saudi Arabian officials told Sen. Sen. Richard C. Shelby, D-Ala., that they passed on information about the chemical exposures to U.S. military leaders, according to a Shelby aide.

The Pentagon for months has asserted that it had no records that chemical agents were detected during the war. But at a Jan. 21 press conference, Assistant Defense Secretary for Personnel and Readiness Edwin Dorn said the department had known of one Czech detection of the nerve agent Sarin before press reports on the multiple detections first surfaced.

In addition, U.S. Central Command officials were aware of and followed up on all reported detections when they occurred, said Army Col. Frank Cox, special assistant for chemical matters in the office of the assistant secretary of defense for atomic energy. None of these detections could be confirmed by U.S. units, he added.

All of the reports, along with the possible effects of chemical agents on veterans' health, are being evaluated by an outside panel of experts, Dorn said.

More complaints

The purpose of Shelby's trip was to investigate the growing number of complaints from Persian Gulf veterans about unexplained ailments they attribute to their service during the war.

But the source of nerve and mustard gas agents detected in January 1991 by the French and Czechs remains a mystery, said a congressional aide who accompanied Shelby on the 10-day trip to Saudi Arabia, Syria, Egypt, Morocco and Israel, ending Jan. 15.

The governments of those countries denied having or using any chemical weapons during the Persian Gulf war, said the aide, who asked not to be identified. The Pentagon has denied its bombings of Iraqi targets inadvertently released any chemical agents. And there is no concrete evidence that the Iraqis launched any chemical or biological weapons at allied troops.

"I don't think it's weakened our belief that chemical [agents] were detected," the aide said. "We just have been unable to find the source."

To get more information, Shelby intends to ask the Department of Defense to look through records of the U.S. Central Command, to see if CENTCOM officials logged detections of chemical agents, the aide said.

Defense officials could not be reached for comment. Shelby, in Alabama, also could not be reached for comment, a spokeswoman for his office said.

In November, Shelby went on a fact-finding mission to France, Great Britain and the Czech Republic. During that trip, the Czechs reported making five detections of chemical or nerve agents and the French, two.

"I don't think there were as many new developments as last time," the aide said. "I don't know if we expected them, but we had to go to talk to everybody."

Shelby and his staff have been preparing a report on his findings for the Senate Armed Services Committee, of which he is a member. They expected to complete the report by the end of January.

Exposure a factor

An increasing number of lawmakers say they think exposure to chemical warfare agents plays a part in the unexplained ailments of Desert Storm veterans.

Those symptoms, collectively labeled Persian Gulf Syndrome, include fevers, aching joints, skin rashes, short-term memory loss and chronic fatigue.

Defense officials now acknowledge the Czechs detected chemical agents, but until the recent press conference, insisted that the amounts detected are not tied to Persian Gulf Syndrome.

But Department of Veterans Affairs Secretary Jesse Brown is not so sure. "That is their contention. That is not our contention," Brown said at a Jan. 19 press co ference. He said scientists, r Pentagon officials, need to det mine if the agents detected linked to veterans' illnesses.

"We do not go into this with predrawn conclusion that peo could not have been hurt as a sult of the low concentrations chemical and biological agents. We're going to let the science us exactly whether or not t could have been hurt."

The VA Medical Center in mingham, Ala., is setting u program to evaluate nerve other physical damage to veter who believe they were harmed exposure to chemical and biol cal agents during the Persian War, Brown added.

Meanwhile, the department defense, veterans affairs health and human services said they will form an interage coordinating board to deal veterans' concerns related to Persian Gulf war. The boa goal is to ensure that the agencies work together m closely on defining Persian Syndrome, its treatment compensation.

4/25/94

e Times

VE SICK?

Gulf war leaves a legacy of mystery illness and broken faith

More than three years have passed since allied troops rolled over Iraqi President Saddam Hussein's Republican Guards and liberated Kuwait City. But for thousands of veterans of the Persian Gulf War, the battle rages on.

They are sick. In some cases, their wives or husbands are sick. They have fathered and mothered sick babies. Many are getting sicker. Some have died.

Others are in hiding. Sick and weak, they remain on active duty, afraid that coming forward would result in a career-ending medical discharge.

Increasingly, the sick feel betrayed by the government they served. Many now see the government as the enemy.

Top government officials insist they have an unwavering commitment to helping the ailing veterans. However, the vets say the only thing the government seems committed to is defending itself, and proving the ailments are *not* linked to exposure to chemicals, biological agents or other toxins.

"You get treated like a crook, and the only thing I did was serve my country," says Chuck Weatherman, a former Marine lance corporal from North Carolina who received a medical discharge for a shrapnel wound and now suffers the same unexplained symptoms as thousands of his war comrades.

See SICK next page

Pg 12

WHY ARE

WHY ARE WE SICK? - VETS SEEK ANSWERS

SICK from preceding page

Some have diagnosable diseases such as prostate cancer and illnesses caused by insect-borne parasites.

But many more, like Weatherman, suffer from problems defying diagnosis. The symptoms include fatigue, joint and muscle aches, intermittent diarrhea, respiratory problems, memory loss, rashes and bleeding gums. Some report that sex has become difficult, because their partners complain of "burning semen" that makes it painful.

'Battlefield injuries'

The sick insist that they, just as someone shot in battle, are suffering from battlefield injuries. They will not be satisfied until the government concedes its responsibility to treat them as such and to compensate them for their losses.

"Call us a generation of crybabies if you want, but we watched what happened to Vietnam veterans, and that is not going to happen to us," vows former Army Reserve Spec. Brian Martin of Niles, Mich., a sick soldier who was a driver in an airborne combat engineers unit.

As their health deteriorates, they feel trampled by a foot-dragging bureaucracy. Some even insist that a top-level conspiracy, not mere indifference, is to blame.

Alleged motivations, all unconfirmed, range from a desire to keep veterans' claims costs from skyrocketing to secret policies that forbid acknowledgment of chemical and biological warfare exposure until a certain number of troops fall ill.

They say their health is deteriorating while the government has been slow to act.

Among their complaints:

■ It took two years after the war for the Department of Veterans Affairs and military medical officials to say that the unexplained ailments may have had a physical cause unrelated to stress.

■ It took pressure from Congress to make the VA and the military under then-President Bush begin to track the sick veterans in Operation Desert Storm registries.

■ Not until last year did VA hospitals treat Desert Storm veterans without first making them prove that their illnesses are service related. Even now, only a handful of those with unexplained ailments have been granted disability ratings.

■ Not until late January, apparently after prodding from the Clinton White House, did the Pentagon, VA and Department of Health and Human Services form a task force to coordinate government efforts on the sicknesses.

■ It took until February just to give the phenomenon a name — gulf war syndrome.

Top government officials flatly deny there is any effort to sweep these veterans and their problems under the rug.

"Everyone is making a really sincere effort to understand what is going on," said Edwin Dorn, deputy secretary of defense for personnel and readiness.

"Anybody who has called a doctor and not come away with clear answers is frustrated," Dorn said. "That frustration gets compounded when it's hinted that maybe the doctor or somebody has an answer they are not giving you."

The veterans say they have waited long enough. After more than two years, the search for a cause seems to have turned up nothing concrete. The government does not even know how many are sick, in part because it has yet to define the illness.

Burning questions: Did the Kuwait oil fires contribute to the mystery illnesses of some gulf war vets? Some environmental scientists and VA doctors have drawn the conclusion that an allergy-like reaction to such pollutants could be a cause.

Theories about a cause come and go. First the symptoms were blamed on battlefield stress, a claim that nearly all of the sick reject and that does not account for so many of the stricken being in support units away from the fighting.

Then some environmental scientists and VA doctors began suspecting an allergy-like reaction to common chemicals and pollution, such as the smoke from oil-well fires.

Now a government task force is preparing to issue a report, due this summer, that is expected to blame "chronic fatigue syndrome," an illness with no known cause or cure that afflicts thousands of Americans. Like gulf war syndrome, chronic fatigue is characterized by a persistent feeling of exhaustion and listlessness.

Still others, including Dr. Stephen Joseph, the Pentagon's new health chief, suspect that veterans were infected by something indigenous to the Middle East — something to which the local population is immune.

Suspicious victims

Those explanations do not wash for many of the veterans, however. Although without proof, an increasing number are convinced that they were exposed to chemical and biological warfare agents. Some believe that, contrary to official U.S. government statements, Saddam did use chemical or biological weapons during the war.

Others speculate that allied planes bombed manufacturing or storage sites for chemical or biological weapons during the war, inadvertently releasing the agents.

No matter the cause, what bothers the sick vets most is that they cannot get the government to officially recognize them as casualties of the war.

"It's a wound from combat," said former Army 1st Lt. Troy Albuck, a sick veteran who was an Airborne Ranger infantry officer. "It's so painfully obvious to me."

But defense and service officials say they lack the evidence needed to come to the same conclusion.

"Every time we got a report, we tried to follow it up and see to it that folks got evaluated," said Army Maj. Gen. (Dr.) Ronald Blanck, commander of Walter Reed Army Medical Center in Washington. He and others maintain that many of the reported causes and cures being put forth by civilian doctors and scientists are medically controversial and need to be thoroughly reviewed.

Those reviews mean more delays. And each delay makes the sick veterans and their allies more suspicious.

Veterans' advocates want more. What is needed, says retired Army Lt. Col. Richard Christian, an American Legion lobbyist and a member of the interagency task force, is an all-encompassing study outside the government tracking 15,000 Desert Storm veterans and comparing their health with that of 15,000 service members who stayed in the United States.

The government plans nothing so extensive. Studies are on a far smaller scale. For example, Blanck got the go-ahead in April to choose at least 10 sick vets and, for the first time, run the same comprehensiv tests on each of them.

Flaws in the system

Although the government now is treatin all sick veterans who come forward, vete ans say the mystery disease has revealed serious flaws in the government's safe net for war casualties.

One of the most troubling flaws is th VA's system of assigning veteran's disab ity ratings. Although thousands of vetera have been left unable to work, few get t disability rating required to receive milita or veterans' disability payments. Becau the government does not know why th are sick, it has refused to give them ratin for service-connected disabilities.

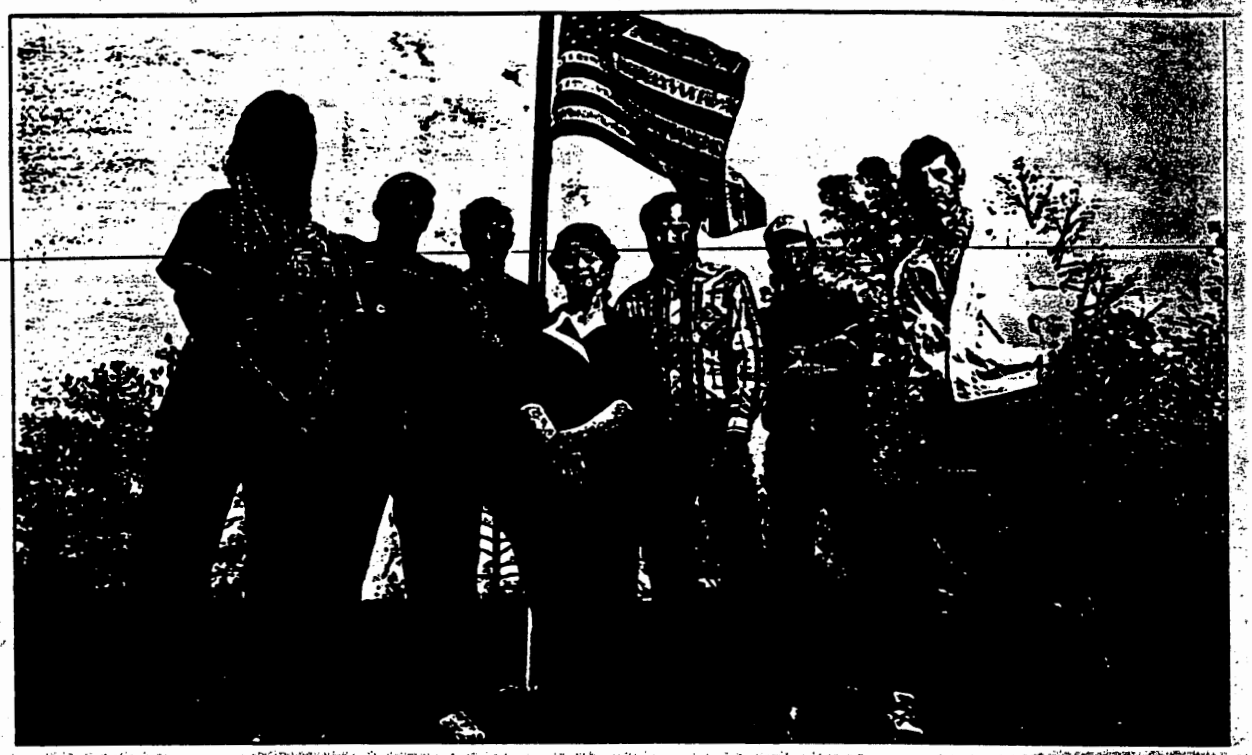
Government officials and veterans ag there is a compelling reason to see that cause and cure are found and that vetera who cannot be cured are compensated. order to fight effectively, troops need know they and their families will be tak care of if they are hurt or killed.

With that in mind, Joseph has orde all service members returning from Sor lia to undergo rigid physical exams, inc ing taking and storing blood samples fr everyone who served so that better e dence will be available if something i gulf war syndrome surfaces again.

But for Albuck and the hundreds oth that is all coming too late. They want to recognized, treated and made better.

"DoD owes us what they owe every dier," said Albuck. "And that is to treat wounded."

The Forgotten Wounded



Family affair: Some Seabees of Naval Mobil Construction Battalion 24 and their wives gather at the home of Nick Roberts in Phenix City, Ala. They are from left: Pixie Roberts, Larry Kay, Gary Linder, Phyllis Butler, Roy Butler, Roy Morrow and Nick Roberts.

Former Marine sergeant Todd See, a machine gunner, recalls days when "it was raining black" from the oil-well fires. "I immediately had trouble with my lungs," he says now. Given a medical discharge in September 1992 for "severe asthma," See also suffers from recurring bronchitis, rashes, bloody noses, sores, severe headaches and fatigue.

Air Force MSgt. Chuck Rehome, a 23-year veteran, remembers sirens warning of chemical attacks — all of which were considered false alarms. Now suffering from fatigue, sore joints, headaches, rashes, and liver problems, he is scared.

"I thought I was in good health," he says. "It's scary. You don't want to let it get to the Agent Orange level, wait 20 years and let it creep up on you."

These veterans and thousands like them did not suffer bloody wounds in battle. Rather, they are the victims of gulf war syndrome — an illness that strikes with no apparent cause. Among the sick are Marines and soldiers who fought on the front lines; sailors and airmen who served in Saudi Arabia, away from the fracas; mechanics, cooks, truck drivers, reservists, active troops . . . and their families.

No one knows how many of them there are. The services say fewer than 300 active-duty personnel are sick. But interviews with dozens of soldiers, sailors, airmen and Marines show that many are afraid to come forward for fear of being forced out with medical discharges.

The Department of Veterans Affairs also has a registry. And even though many of the sick are so disillusioned they are not even sure they will bother to register, the VA's statistics so far suggest the number of sick could be far higher.

VA Secretary Jesse Brown, himself a disabled veteran, says his department's Desert Storm Registry offers grave reason for concern: Gulf war veterans, sick or not, were asked to sign up. And so far, about 5.8 percent appear to be sick. If that number were extended over all Persian Gulf war vets, the sick would total close to 30,000. And that would not include husbands, wives or children with similar symptoms.

One 24-year-old Marine reservist has not put his name on the VA's registry for fear it might hurt his chances of getting a police job. Doctors already have removed two tumors from his head, and he continues to have acne-like rashes on his back that he says are like large, painful cysts. A new lump is growing in his mouth, one he has not told his doctor about.

And while this young man runs and lifts weights daily, his friends and family are concerned. "He likes to play the tough guy," says his father.

Nationwide, other tough guys are trying to come to grips with what is cutting them down. These are their stories.

Sick wives wonder if anyone cares

Kimberly Martin is 25 years old and should be looking to nothing but a bright future.

But her husband, Brian, was an Army Reserve specialist during the Persian Gulf War. And while he was there, something happened to him that changed the Martins' lives forever.

Unfortunately, no one knows exactly what that was.

Brian Martin has been diagnosed with multiple-chemical sensitivity and other health problems, like hundreds, perhaps thousands of gulf war vets. Among his symptoms, Martin hears a ringing in his ears and has lower back problems.

But Brian Martin is not the only one who is sick. Kimberly Martin is now suffering from gynecological problems and a mysterious thinning of her skull.

"My insides are shot," she says.

The Martins of Niles, Mich., are not alone. She is one of at least 50 wives who say their husbands' illnesses have somehow infected them as well.

The sick wives report having gynecological problems including severe recurrin yeast infections and abnormal menstru periods. In many of these women, doctor have found abnormal lumps or growths or their uteruses or ovaries. Several have ha partial hysterectomies. Many report th sex with their husbands has become painf because of "burning semen" that leave rashes on the exposed skin of bot partners.

Many children, too, are sick, and the su fering parents blame the mysterious ai ments they have had since the end of th gulf war for their plights.

About a thousand miles away from th Martins, in Laurel, Miss., another family suffering: Army National Guard Sgt. Olivi Fowler; her husband, Frederick, a 31-year old staff sergeant; and their second-chil 2-year-old Frederick Jr. Frederick Jr. wa born with a rare disorder that makes it di ficult to urinate. He has undergone sever operations and may need more as he get older.

of the Persian Gulf war

Frederick is one of 16 children born to parents who served in the National Guard's 624th Quartermaster Petroleum Supply Company during the gulf war; 14 of them now are suffering from medical problems ranging from chronic respiratory illness to urinary tract disorders. Their parents are convinced the problems are rooted in something they contracted while fighting for their country.

"I think the government knows a lot more than they are letting on, and I think it was irresponsible of them to let us come home and have children without telling us," said Olivia Fowler, who retired from the Guard in February.

She still suffers from debilitating headaches and, like her husband, has mysterious rashes on her feet.

So bad have things become, in fact, that some Operation Desert Storm vets are delaying having children for fear that their children, too, might become sick.

Sgt. Richard Mays, 25, who served in the gulf as a Marine, is now a member of the Army National Guard's 728th Transportation Company in Quitman, Miss.

Although he suffers no symptoms and since the war has fathered a child, 2-year-old Richard James Jr., he and his wife, Cynthia, 18, are "very concerned about what's going on. She is afraid to have kids, and so am I."

Falling through the cracks

Most of the sick wives say they feel helpless. Family finances are being stretched to the breaking point, and the resulting strain on their marriages is almost too much to bear.

"There is no help for women and children who are having problems," Kimberly Martin said.

For many, sex with their husbands has become painful, if not impossible. They describe how their husbands' semen "burns," "itches" or is "stronger" than before. Often, it causes red welts on both husband and wife, they say.

"Today, most of us do not know what it feels like to be intimate or close anymore," said Penny Larrisey of Chalfont, Pa. Her husband, Robert, a former technical sergeant with the Air Force Reserve's 913th Tactical Airlift Group in Willow Grove, Pa., is suffering from fatigue, memory loss and severe rashes.

"We have our own diseases we never had before," Penny Larrisey said.

Defense officials are not convinced that there is a connection between these women's illnesses and their husbands' service in the Persian Gulf. They report that there has been no increase in the rate of miscarriages in the families of service members who went to Desert Storm. In fact, their rate is lower than among the military as a whole, they say.

Army officials report that, as of late January, only one active-duty spouse and three children have been identified as having gulf war syndrome. There is some hope that the government's position on this is changing, however.

Inspired by testimony before Congress, a National Academy of Sciences panel is going to include family members in its study of the mystery illnesses, officials said. Similarly, defense and service health officials say they, too, plan to expand the Pentagon registry of sick active-duty veterans to include sick family members.

The registry will be linked to the Persian Gulf Registry run by the Department of Veterans Affairs.

But, for now, ailing spouses must rely on their own funds, donations or government aid for medical answers and financial help.

Kimberly Martin and others believe they contracted their husbands' illnesses through sex, a claim government officials deny. But Martin does not buy their argument.

Rumors on post

Indeed, says Kelli Albuck of Barrington, Ill., a victim of the gulf war syndrome, Army posts were awash in rumors about soldiers bringing back an illness that could be sexually transmitted long before mystery ailments began to surface.

Albuck's husband, Troy, was a first lieutenant and gulf war vet but was forced to leave the Army on a medical discharge. He has suffered from painful lesions on his skin, diarrhea and fatigue.

The Albucks and their son, Alexander, who was born in January 1993, are ill, while their daughter, Shelby — conceived and born before the war — is healthy. Alexander, now 15 months, has been sick since birth. He suffers from severe respiratory illness and had to have part of one lung removed.

In the past three years, Kelli Albuck, 25, has had two miscarriages. She also suffers chronic pelvic infections, constant fatigue, joint pain and blurred vision.

Alexander was born two months prematurely and with the same red welts his parents developed shortly after Troy Albuck's return from the Persian Gulf. So expensive were the treatments needed to save Alexander's life that the infant used up the $500,000 lifetime maximum of his private health insurance within the first three months of his life.

Says Kimberly Martin: "They are saying it is not sexually transmittable right now, but they don't know that, because they have not taken one of us wives to run tests on us. They say they cannot find anything in veterans that could possibly be connected to sexual transmission. But why not test us?"

Mounting medical expenses and the deteriorating health of these families also is leaving some unable to work. The Albucks, Martins and others depend on government aid, donations, and friends and families to pay the rent and put food on the table.

"If [Troy] could go back on active duty, it would make our life so much easier," Kelli Albuck said. "At least we'd have access to military health care. We don't want to be public aid junkies, but right now, we don't have a choice."

— Soraya S. Nelson, Vago Muradian and Gidget Fuentes

Photo courtesy of Kimberly Martin

Incidental victims: Desert Storm veterans, their spouses and their children are dealing with the mystery illness they say came from something the vets were exposed to in the gulf. Right, Kimberly Martin, wife of Brian Martin, an Army Reserve specialist during the gulf war, is now suffering from gynecological problems and a mysterious thinning of her skull. Below, Mississippi Army National Guard vets Sgt. Olivia Fowler and her husband, Frederick, are both sick, and their youngest son, Frederick Jr., right, was born with a rare urinary tract disorder.

Photo by Frank Scott

Photo by Mark Wilkerson

Feeling the effects: Kelli Albuck, wife of Army 1st Lt. Troy Albuck, a gulf war veteran, has had two miscarriages since her husband returned from the gulf.

In silence and fear

Sick and suffering, untold numbers of active-duty veterans of the Persian Gulf war are in hiding.

They are convinced that they have gulf war syndrome. They know they need help, and desperately want it. But they are afraid to come forward, fearing that to do so will end their careers.

Although the military encourages them to step forward and get treatment, the sick service members are afraid and reluctant. They say they have seen too many comrades forced out with medical discharges after officially saying they were sick.

"Many of the wounded are hiding. They have seen others be eliminated from the service for admitting they are (sick.) ... and now conceal their symptoms to avoid being thrown out," former Army 1st Lt. Troy Albuck told a National Academy of Sciences panel at a recent hearing.

"These guys do not want medical [discharge] board," said one sick veteran. "We are getting the shaft."

So they remain silent and are not part of the official sick count. Their illnesses go undiagnosed and untreated.

Many grow ever weaker, until they no longer pass physical fitness tests. Then they are discharged.

What medical help they do get comes from private doctors. But that route is costly. Unlike reservists or Guard members, active-duty personnel cannot seek civilian care at government expense.

And because they are full-time service members, they do not have civilian medical insurance.

Those who do come forward are tracked by the services' medical departments as part of a government effort to develop a registry to keep tabs on veterans for future treatment and benefits.

But fewer than 300 active-duty members have done so. As of March 15, a registry of active-duty sick listed 175 in the Army, 40 in the Navy, 17 in the Marine Corps and 44 in the Air Force.

Ridiculously low?

Sick service members and some Department of Veterans Affairs counselors say that number is ridiculously low.

One active-duty soldier who came forward fears he will be discharged. His intermittent symptoms include severe diarrhea, chronic fatigue, stomach cramps, night sweats and aches and pains throughout his body. He is sick at irregular intervals.

The 26-year-old staff sergeant vows to remain in the Army. Like most sick active-duty people interviewed, he asked that his name, unit and duty station not be used.

"I got sick right after I drove through an ammunition dump that we had blown up," he said. "A great, great number of people went through there." He says others got sick, but he has lost track of them.

After becoming ill in early 1991, he complained to U.S. military doctors in Saudi Arabia and several months later in Europe, but he found them unhelpful. Last August, fearing that he was giving the military the ammunition it needed to drum him out, he just stopped complaining.

"I see no reason to go in to see military doctors," he said. "What are they going to do for me?"

To make sure he passes his fitness tests, he works out despite his pain. "I've seen the Army kick people out for less. I'll keep going ... and hope for the best," he said.

A Marine nuclear, biological and chemical officer who served in the Persian Gulf said he and others think money, not good medicine, is controlling the action.

"The Department of Defense would do the medical discharge, so we're no longer their budgetary charge," he said, pointing out that sick veterans become the VA's responsibility.

Military officials disagree and say the troops should come forward because they have treatable illnesses.

No reprisals

Defense and service officials say the sick troops should not fear reprisals.

VA Secretary Jesse Brown and then-Defense Secretary Les Aspin pledged in an Oct. 27 letter to Congress that commanders would not penalize service members who come forward.

It is intolerable that "there is a concern that commanders would just not be sympathetic," said Pentagon personnel chief Edwin Dorn.

"These were men and women who two years earlier were entrusted to make life-and-death decisions ... and, damn it, we are not trusting them to tell us if they are sick or not.

"We might not know exactly what is wrong, but if a veteran says, 'I'm not feeling good,' we ought to trust that judgment," Dorn said.

Those statements ring hollow to those who are sick.

"I have already been told I will be separated," said a 22-year-old sergeant on medical hold pending discharge from the Army. "This is why people who are active are afraid to say anything."

His administrative troubles started after he went to military doctors for help, and he was placed on the Army's registry of sick veterans. "I had planned on staying in a few years ... but after I came forward, I was forced out," he said.

At least one Desert Storm veteran is holding out hope that he will fully recover. CWO3 Joseph Threat, the nuclear, biological and chemical officer with Regimental Combat Team 7 at Twentynine Palms, Calif., said his health has improved "85 percent" since feeling he was "near death" 18 months ago.

He was diagnosed with the parasitic staphylococcus, which results in boils, and was put on limited duty in January 1993.

Threat, 40, who has been on a health-food diet with the help of a physician, got off limited duty March 7 and is still regaining his strength. He recommends other veterans "try to hang tough, even though whatever it is happening to us, it's weird."

Other veterans have not been as fortunate. They have become so sick that they have been discharged.

One is former Army SFC Carol Picou, 32, a nurse who spent five months in the desert with the 41st Combat Support Hospital. Before the ground war, she was stationed in northwestern Saudi Arabia, but when the battle started her unit moved near Basra, Iraq.

"I loved my military career and wanted to see retirement as the first female sergeant major of the Army, and I can't see that now," said Picou, who now lives in Univeral City, Texas.

Picou was medically discharged in April 1992 after 15 years' service. She suffers from memory loss, fatigue, impaired balance, aching joints and diarrhea, she said. She also may have a brain tumor and may need a hysterectomy.

Her memory loss is so bad that her 7-year-old son, Pierce, has to leave her notes reminding her to pick him up after school.

"It is a shame. All I know is I wasn't like this at all before I went," Picou said.

— *Vago Muradian*

Times photo by Mario Villafuerte

Discharged: Former Army sergeant first class Carol Picou, left, talks with a friend at her home in Texas. She was medically discharged after 15 years of service after gulf war syndrome symptons made her too ill to work.

Unwitting victims

Operation Desert Storm may be over, but for the men and women of the Mississippi Army National Guard, the war is still claiming new victims: their children.

Of 54 children born since the end of the war to veterans around rural Waynesboro, Miss., 37 have had serious, often-chronic health problems. In one unit — the 365th Maintenance Company, which was the 624th Quartermaster Petroleum Supply Company during the war — 14 of the 16 children born to veterans since the war's end have medical problems ranging from chronic respiratory illness to urinary disorders.

Staff Sgt. Frederick Fowler and his wife, former Sgt. Olivia Fowler, both served with the 624th in the gulf and both are sick. The couple had one healthy child, Christopher, now age seven, before the war. Their second child, Frederick Jr., now age two, was born with a urinary disorder and has undergone several operations and may need more.

Dozens of 624th soldiers also are ill. But while confounded health authorities search for clues in this medical whodunit, Mississippi veterans like Sgt. Howard Turner, 24, and his 22-year-old wife, Shelley, are waiting for answers. They won't have children until they believe this case is closed.

—*Vago Muradian*

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Theories abound, but answers do not

What is causing the mysterious illness that is striking countless Persian Gulf veterans and their families?

Is it chronic fatigue syndrome? A sensitivity to common chemicals and pollutants? A chemical or biological agent? Was it smoke from oil-well fires? An indigenous parasite?

Government and civilian researchers are investigating the question, but so far there are no answers. All that is certain is that scores of gulf veterans have taken ill, and no one knows precisely why.

Two theories are favored: Military researchers favor chronic fatigue syndrome, an illness that has no known cause or cure, is relatively common in the civilian world, and is believed by some to be stress related. Doctors at the Department of Veterans Affairs, meanwhile, look to multiple-chemical sensitivity, an allergy-like reaction to common chemicals and pollution. The chemical theory could explain why troops exposed to different toxins in different areas have the same symptoms.

Increasingly, however, sick veterans are rejecting both theories. Despite government denials and a lack of proof, they are sure they were exposed — either on purpose or accidentally — to chemical or biological warfare agents.

To bolster their theories they note:

■ Chemical-warfare detectors were silent during Operation Desert Shield, but went off repeatedly once the fighting began. Military officials say the alarms malfunctioned.

■ The allies bombed chemical and biological warfare plants during the war. Given the routine trade winds, the toxins would have moved toward the allied troops. Satellite weather maps at the time show clouds of smoke from the allied bombings drifting south. The government denies this possibility.

■ Scores of dead animals were found on the battlefield without visible injuries and without insects swarming on them. Several military nuclear, biological and chemical officers and troops say dead animals and vegetation are signs that biological or chemical agents had been in the area.

Tests done on some of the carcasses at the Army's Biological Research Development Laboratory at Fort Detrick, Md., showed the animals were killed by bacteria common to Southwest Asia, Army medical officials say.

■ Many troops experienced odd smells and tastes during Scud- and Frog-missile attacks. The government says no missiles carried biological or chemical agents.

■ Biological agents act slowly and could have been carried home on clothes and transferred to family members.

So far, no one has been able to offer any evidence that service members brought biological agents home. Some veterans say that is because the government refuses to do the tests necessary to find it.

"Did the Iraqis use biological weapons? I don't know, but enough people are sick, making it safe to say that something peculiar happened there," said retired Army Maj. Gen. Vincent Falter, President Reagan's deputy assistant defense secretary for atomic energy.

Jerrold Post, director of the political psychology program at George Washington University, said a chemical or biological attack by Saddam would "not be inconsistent with my mental picture of him."

Sen. Richard Shelby, D-Ala., spent two years investigating reports of chemical agents on the battlefield. In a March 17 report, Shelby noted that chemical agents were detected at least five times in Saudi Arabia by French and Czech troops in January 1991. But, he said, there is not enough evidence to link illnesses to those agents.

Meanwhile new attention appears to be centered on a theory that some unidentified infection is responsible.

Dr. Stephen Joseph, assistant secretary of defense for health affairs, likes that theory. He says history is replete with cases of large populations from one part of the world going to distant lands and either coming home sick or bringing disease to the native population.

But, Joseph concedes, he may be attracted to the theory because infectious disease is his area of specialty.

"I think it is something," Joseph said. "With enough study, the cause should be found."

Digging for causes

The question of what causes gulf war syndrome has generated many answers since the war with Iraq. Ten prevalent theories have emerged — none proved but all with arguments on both sides. Those theories and their pros and cons:

Theory	Arguments for	Arguments against
STRESS	Military researchers say stress is the only common link they have found between many of those suffering from unexplained illness.	Few veterans believe that stress is at the root of their illness, even though they feel stressed as a result of being sick.
SMOKE AND "BLACK RAIN" FROM OIL-WELL FIRES	This was the first culprit government researchers pinpointed, given the amount of smoke inhaled and oily rains that bathed people, camps and equipment for weeks on end. Compounds released from burned fuel can cause cancer.	The theory has been largely discredited: An Army study found that the fires burned so hot that anything toxic was eliminated. Also, Red Adair Co. of Houston, which was brought in to extinguish the fires, said none of its employees are sick.
OTHER ENVIRONMENTAL HAZARDS	Troops were exposed to leaded fuel, toxic paints, uncontrolled burning of waste and pesticides, all within their encampments. All of these are identified as health risks in the United States.	These health risks existed to one extent or another in past wars, and yet no group of veterans from past wars is known to have had the syndrome.
VACCINES AND NERVE AGENT ANTIDOTES	Some of the inoculations and antidotes given to service members to protect them from expected chemical, nerve and biological agent attacks had never been given to such large numbers of people before. As with allergies, only a small percentage of the people who received them would have had immune-system reactions and become ill.	Not everyone who is sick received the inoculations and antidotes being blamed for illness in veterans.
PARASITES AND BACTERIA	This was the first war fought by a large American contingent in Southwest Asia, where parasites, bacteria and other disease-inducing organisms not found in the United States reside. Organisms could have affected troops in ways not usually seen in the local population. For example, there have been three dozen cases of parasite-induced leishmaniasis diagnosed, half a dozen of them treated successfully by an experimental antibiotic.	Many of those afflicted with gulf war syndrome do not have abnormal test results, military and VA doctors say. Such infections tend to show up on tests, whether as elevated white-blood-cell counts or other indicators that a person is fighting an infection.
DEPLETED URANIUM	Roughly two dozen veterans have shrapnel containing depleted uranium, which emits radiation in their bodies. They are being checked periodically by the Army and VA. Other veterans say they breathed depleted uranium from tank rounds and armor in the dust of vehicles and tanks they cleaned.	The Army says the amount of depleted uranium was too low to be the source of illness in these veterans. Lengthy and unprotected suntanning yields more radioactive exposure than what the veterans were exposed to. Also, not all veterans who are sick were exposed to depleted uranium.
CHEMICAL WARFARE AGENTS	Some service members reported burning eyes, being overcome by fumes and experiencing an almond taste in the air, all consistent with chemical exposure. Chemical warfare agents could explain large numbers of dead animals reported. No studies have been done on the long-term effects of low-level exposure to chemical agents.	There has been no evidence of attack and only small amounts of chemical agents detected by Czechs or individual U.S. units. No immediate adverse reactions were seen. Dead animals examined by Army researchers were found to have died from an infection native to that region.
BIOLOGICAL WARFARE AGENTS	Some veterans are turning to the possibility of biological warfare. It could not have been detected by chemical detectors and would explain why spouses and children are getting sick, as the agents could have been carried back on clothing or other personal items. Saddam Hussein was known to have been developing the weapons.	Army researchers say there was no evidence of attack. If there had been such an attack, an immediate reaction among troops should have been evident, researchers say.
CHRONIC FATIGUE SYNDROME	The main argument for this theory is that the existing definition for the syndrome — little understood itself — matches many of the symptoms of the sick veterans.	What is known about chronic fatigue syndrome does not explain why spouses are sick or the presence of rashes and some other symptoms.
MULTIPLE CHEMICAL SENSITIVITY	Some veterans have been diagnosed with multiple chemical sensitivity. Those afflicted suffer damage to their immune systems and are abnormally sensitive to household and industrial chemicals and pollution. Exposure to solvents, jet fuel, oil-well fire smoke and a host of other pollutants could have triggered the problem.	Multiple chemical sensitivity is an environmental disease and does not explain why spouses and children are getting sick.

ATPCO

People like former Air Force sergeant Paul E. Perrone of Methuen, Mass., hope so. Perrone, 29, spent seven months with the 4409th Security Police Squadron in Riyadh, Saudi Arabia. Since May 1991, he's been plagued by headaches, fatigue, dizziness and ear infections.

He breaks out in hives after eating some foods that never bothered him before. "I used to eat hot dogs by the dozen when I was a kid," he said. "Now I can't eat any."

Doctors blame multiple chemical sensitivity. But Perrone strongly suspects the cause were either the shots he and his comrades were given to guard against hepatitis and anthrax or, perhaps, anti-nerve agent pills.

"It doesn't matter where you were. People were assigned all over, and they've got the same things," he said. "It has to be something the military was using."

— Vago Muradian and [illegible]

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Sickness reveals broken safety net

It wasn't supposed to be like this.

Six hundred thousand Americans, not a draftee among them, went off to war. Not only did they win the war they were sent to fight, but they allowed their fellow citizens to throw off the albatross of the Vietnam War. Victory was healing.

Now, the victims of the gulf war syndrome are asking when they will be healed.

So far, the sick insist, the government they served has been unable or unwilling to live up to the military's oft-repeated pledge: "We take care of our own."

The sick veterans charge the government has treated them as second-class citizens, and that the huge bureaucracies they deal with have been slow to react and stubborn to change.

They see a pattern of indifference, incompetence, or both.

No plan in place

When the first pockets of sick veterans, most of them reservists, started to surface in 1992, no one in the Pentagon or the Department of Veterans Affairs had a plan for dealing with them.

No one put in place a uniform system of examining them, gathering data, comparing test results or coordinating treatment. Some veterans received comprehensive tests. Others were given cursory exams.

When the first study revealed no common physical cause, military officials speculated that most of those who were sick were probably ill because of stress.

The diagnosis infuriated many veterans and was one of the first sources of the distrust that now runs so deep.

"The stress that I am under is from the syndrome. We are all tired of being ill and sick; [the government] says that this is all stress related, but the war was not that stressful," said former Army Sgt. 1st Class Carol Picou, who served as a nurse during the war and since has been discharged for numerous medical problems.

As the numbers complaining of similar symptoms mounted, and after members of Congress started asking why their constituents were sick, military health officials changed their tone, if not their story. They were not ruling out anything, they said.

But the change in the official line did not always make it to the field.

Last December, around the time top Pentagon officials were explicitly assuring Congress that they were searching hard for physical causes for the illness, a Navy Bureau of Medicine message was still following earlier conclusions that stress is the source of symptoms in "many, if not most of the affected veterans."

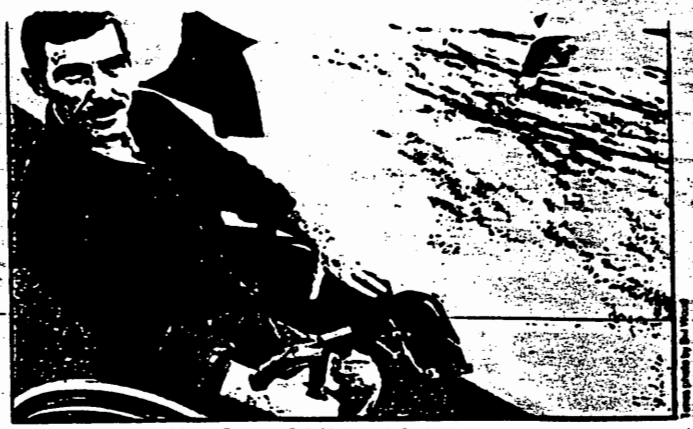
The message went on: "Although some patients resist accepting this explanation, many patients have symptoms which are classically associated with stress, depression, and/or chronic fatigue syndrome."

Even getting the treatment afforded to other casualties of war has been difficult, in part because of the mysterious nature of the illness.

Treating sick veterans is not the purview of the Department of Defense. It falls to the Department of Veteran's Affairs. But while the VA is a worldwide leader in treating people for conventional war injuries — burns, limb replacement and even stress — it isn't set up to treat unidentified illnesses.

The laws governing the VA and the agency's own regulations made it impossible for the department to react quickly. For veterans to be eligible for treatment, they must prove that their illness is service-connected. But how can they meet that test if no one knows why they are sick?

It took two years for Congress and the VA to change those rules and allow all veterans who think they suffer gulf war syndrome to be treated at VA hospitals.



'I've lost everything:' Army Reserve Col. Herbert J. Smith's illness has left him wheelchair bound. He now rents out the building that once housed his lucrative veterinary practice.

But even so, the VA seems to have missed a simple opportunity to get a better handle on the scope of the problem. Ordered by Congress to start keeping a registry of sick gulf war veterans, the VA is not routinely signing up those who come in for treatment. Only those who ask to be included are registered.

Former Marine lance corporal Chuck Westherman's treatment at the hands of the VA has so embittered him that he refuses to put his name on the VA's registry.

The 23-year-old from Waynesville, N.C., was medically discharged with a 10 percent disability rating for a shrapnel wound to his neck. But Westherman said he's too ill to hold a regular job because of gulf war syndrome that has left him with bleeding gums, severe headaches, dizzy spells, respiratory problems and pains in his legs, knees and hips.

He said he has been to several VA doctors but feels they're not willing to find out what's making him sick.

"They're in no hurry to help us," said the former machinegunner with Lima Co., 3d Battalion, 9th Marine Regiment in Saudi Arabia. "It's a waste of time."

The disability link

Getting treatment is only part of the VA equation. Sick veterans whose war wounds do not heal are supposed to be eligible for disability compensation. But again, there has to be some proof that the disability was caused by their military service. So far, only a relative handful of gulf war syndrome victims have qualified.

One who has not is Army Reserve Col. Herbert J. Smith, of Ijamsville, Md.

Smith, whose deteriorating health has left him wheelchair-bound, now rents out the building that once housed his lucrative veterinary practice.

At age 54, he says he should be at the peak of his career. Instead, "I live off my wife now. I've lost everything."

While top government officials are reluctant to criticize past efforts, they say more must be done to find a cause and to give the sick the care they deserve.

"That future veteran could be my son or my daughter," VA Secretary Jesse Brown said. "I don't want to place them at risk be-

See SEARCH next page

Distrust rages as Seabees charge cover-up

COLUMBUS, Ga.

While frustration is all-pervasive among gulf war syndrome sufferers, the feeling of outright betrayal may be strongest among members of a Georgia Naval Reserve unit.

They are convinced that something more than indifference or incompetence is at work. The sailors accuse Navy officials of taking medical files from the records of sick veterans in November 1991. They say those records prove that they were exposed to either chemical or biological warfare agents while serving during the Persian Gulf war.

"This is a cover-up ... they are trying to outsmart us from the top," said Construction Electrician First Class Roy Butler of 16th Detachment of the Naval Mobile Construction Battlion-24.

But Navy medical officials, who say they're aware of the complaints of missing records, insist they cannot figure what re-

If the records did exist, they might have been useful, said Navy Capt. (Dr.) S. William Berg, who is in charge of the Navy environmental and preventive medicine unit that surveyed four detachments within the sick Seabee battalion.

A spokesman for the Navy's Bureau of Medicine also denied taking anything out of the Seabees' medical records, or looking at or removing records from personnel files.

The sailors here say the Navy wants to eradicate all records of what happened to them during their six-month tour of duty in the gulf near the Saudi port city of Al Jubayl. Those records, they insist, would show that 28 of the unit's 43 members who went to the gulf are sick.

Butler, 50, was forced in December 1991 to retire after 29 years in the Navy because of his gulf war-related illnesses, he said. He suffers from joint pains, facial numbness, fatigue, memory loss, diarrhea, fevers and

over and over by his comrades.

The sailors' troubles began Jan. 20, 1991, when at about 3 a.m. they were jolted from their bunks by a massive explosion that rocked their quarters. It was an Iraqi Scud missile attack near the Al Jubayl docks.

By the time the attack was over, the sailors had been ordered into the chemical protection gear twice. Almost immediately, sailors began complaining of burning eyes and skin, numb lips and labored breathing.

After the second chemical attack alarm, the men ran to washing stations to clean off the substance, which burned their skin.

But symptoms persisted for about a week, and then fatigue set in, said Nick Roberts, 39, a sailor who served with the 24th in the gulf. "I thought I had the flu, I tried to shrug it off," he said.

In the days after the attack, dozens of sailors reported to sick bay. Doctors gave them aspirin and a couple days off to overcome mild fevers, Roberts said. Records from those

treatments, the sailors say, are missing.

After returning from the war May 5, 1991, Roberts, of Phenix City, Ala., found lumps in his groin. He also grew progressively fatigued, and began having dizzy spells and night sweats, joint aches and other ailments.

"I never could get my test results from the Navy. The lymph glands in my groin [swelled] so bad, I could hardly walk, they were so swollen," Roberts said.

Roberts has been diagnosed with a rare cancer called Non-Hodgkins Lymphoma, which is now in remission after he underwent chemotherapy. Had he believed the VA doctors, he would now be dead, he said.

Builder Second Class Roy Morrow now has a scar where a nonmalignant tumor was removed from his neck. He has lost faith. "Nobody is taking care of us, not the Navy nor the VA. I don't trust their doctors, because they always tell us we're fine."

— *Vago Muradian*

Not another Agent Orange

Vets, supporters fear a repeat of long fight to get their benefits

It's the battle cry of the victims of gulf war syndrome, and the motto of the politicians who have come to support them. "Not another Agent Orange."

It is also a shorthand way of saying that these veterans are determined not to be trapped in the same kind of protracted battle with the government that occurred after the Vietnam War.

During that war, the military sprayed tons of toxic defoliants over Southeast Asia. In the years since, tens of thousands of combat veterans have fallen ill or died of diseases believed linked to their exposure to the herbicides — links the government denied for years.

Many still are fighting with the government to acknowledge their injuries and to get just compensation.

Deja vu

Now it looks as if history is repeating itself. Veterans suffering from the Persian Gulf "mystery" illnesses see frightening similarities between the two cases.

"Look how long it took for action with the guys in Vietnam," said Brett Doggett, a former Marine from Orange, Calif., who served with the 4th Light Armored Infantry Battalion from Camp Pendleton, Calif. He lost a leg to an Iraqi land mine in Kuwait and is ill with the syndrome.

"There were men who died of cancer, and their children were born with birth defects," he said.

Although the frustrations are similar, the controversies over Agent Orange-induced illnesses and gulf war syndrome are quite different, according to Bernard Siegel, chief of staff of the ambulatory clinic at the West Los Angeles Veterans Medical Center.

The culprit in gulf war syndrome remains unknown. With the gulf war, he said, "we do not know of any specific issue." But with Agent Orange, "there was a special chemical involved, which was known to have been used and known in the lab to have severe consequences."

Still, sick Desert Storm veterans see similarities in how their cases and the Agent Orange controversy are being handled:

■ Veterans then and now are becoming ill, with symptoms ranging from rashes to cancer. Their doctors are stumped.

■ Both sets of sick veterans were told initially that their illnesses are a result of post-traumatic stress disorder.

■ Vietnam veterans reported mysterious ailments affecting spouses and children, including miscarriages and birth deformities. Some Desert Storm veterans have reported similar problems with their wives and children. In both cases, veterans complained, and the government was slow to react.

■ Reluctance by active-duty personnel — especially careerists — to report their illnesses hindered investigations of both problems. After Vietnam, "there were guys on active duty who wanted to hang on until they got their 20, simply because it was their life and their job," said retired Army Lt. Col. Richard S. Christian, a Washington lobbyist for the American Legion who served three tours in Vietnam.

Many Desert Storm veterans on active duty said they have not reported being sick for fear of receiving medical discharges.

■ The government responded with a registry and questionnaire after Agent Orange reports began to surface, and it has done the same with Persian Gulf veterans. The government rejected many Vietnam veterans' claims for service-connected illnesses, and some Persian Gulf veterans are fighting to get compensation for illnesses linked to their service in Desert Storm.

— *Gidget Fuentes*

AP/Wide World photo

Spray of Orange: U.S. aircraft sprayed thousands of jungle acres in Vietnam with the defoliant Agent Orange during the 1960s. But the chemical was later determined to be responsible for myriad deaths and illnesses among U.S. veterans.

Broken safety net

SEARCH from preceding page

cause we did not do our job."

Added Dr. Stephen Joseph, the Pentagon's newly installed health chief: "I'm not sure that I would say that our role, as a medical role, should be a greater one, but I believe it does need to be a more activist and aggressive one."

To that end, Joseph points to steps now planned or under way to reach out to the sick and find a cause — and cure:

■ A letter will be sent shortly to all active-duty Desert Storm veterans and their families, reassuring them of the Defense Department's commitment to their health needs and asking them to report problems to military hospitals and clinics.

■ Studies have started or are planned by the Navy into death and illness among Persian Gulf veterans.

■ A study will soon be released by the Army on the effects of oil-well fires on gulf war veterans.

■ A new policy has been established for the monitoring of health of troops returning from Somalia. Joseph says blood samples are being taken and thorough exams are being given to all returning veterans.

■ The department plans to bring in an outside consultant to review its efforts on gulf war syndrome.

But Joseph says there is nothing he can say that by itself will restore broken faith. Action and results are the only answer.

"We are really not going to be able to deal satisfactorily with all the issues," he said, "until we actually know what [the sickness] is."

— *Soraya S. Nelson*

from a mysterious illnesses, you and your family can get medical attention, advice, and financial and emotional support from these organizations:

Military and federal

Military medical facility: Sick families will be entered onto the Persian Gulf Registry by the individual military medical centers and hospitals they go to.

Active-duty personnel can also go to the Department of Veterans Affairs for diagnosis and treatment. But you'll need your medical command to request that for you.

Veteran medical care: The Department of Veterans Affairs is the primary agency for veterans and reservists. Contact any of the 171 VA medical hospitals for referrals and information. The Persian Gulf Registry coordinator or social worker can provide information about getting a physical exam.

For information on compensation benefits and eligibility, call the VA's counseling and information line, (800) 827-1000.

VA family support centers: To help ailing Persian Gulf veterans, the VA has set up 32 family support centers in 26 states. The Persian Gulf Family Support Program provides marriage and family counseling, education, information and referral to other services. Contact your local VA medical facility for locations.

Veterans centers: If you are not near a family support center, you can get assistance from 202 VA Veterans Centers nationwide.

Spouses: Although the VA doesn't provide medical treatment for sick spouses, you can get information and referrals to the local medical community from registry coordinators.

Service organizations

■ The American Legion's Family Support Network provides financial assistance, support and referrals for married and single gulf war veterans and their families. The network is open from 9 a.m. to 4 p.m. Central time ; and you can leave a recorded message anytime. The number is (800) 433-3318.

■ Local posts of the Veterans of Foreign Wars can provide referrals and information. Check your local telephone directory.

Private groups

■ The San Antonio chapter of the Operation Desert Shield/Desert Storm Association is helping active-duty and war veterans and their families. The chapter is providing information and referrals about military and VA medical care, the Persian Gulf registries and emotional support and guidance.

Contact Carol Picou and Anthony J. Picou Jr. at the San Antonio chapter, (210) 658-7870. You can reach them by fax at (210) 658-8022.

■ The Military Family Support Network. Contact Dorothy Brooks in North Carolina, (910) 892-9315.

■ The Persian Gulf Veterans Support Group, formed by a former Marine, Todd Richmond in Iowa City, Iowa, (319) 351-8339.

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Former Marine lance corporal Chuck Weatherman's treatment at the hands of the VA has so embittered him that he refuses to put his name on the VA's registry.

The 23-year-old from Waynesville, N.C., was medically discharged with a 10 percent disability rating for a shrapnel wound to his neck. But Weatherman said he's too ill to hold a regular job because of gulf war syndrome that has left him with bleeding gums, severe headaches, dizzy spells, respiratory problems and pains in his legs, knees and hips.

He said he has been to several VA doctors but feels they're not willing to find out what's making him sick.

"They're in no hurry to help us," said the former machinegunner with Lima Co., 3d Battalion, 9th Marine Regiment in Saudi Arabia. "It's a waste of time."

The disability link

Getting treatment is only part of the VA equation. Sick veterans whose war wounds do not heal are supposed to be eligible for disability compensation. But again, there has to be some proof that the disability was caused by their military service. So far, only a relative handful of gulf war syndrome victims have qualified.

One who has not is Army Reserve Col. Herbert J. Smith, of Ijamsville, Md.

Smith, whose deteriorating health has left him wheelchair-bound, now rents out the building that once housed his lucrative veterinary practice.

At age 54, he says, he should be at the peak of his career. Instead, "I live off my wife now. I've lost everything."

While top government officials are reluctant to criticize past efforts, they say more must be done to find a cause and to give the sick the care they deserve.

"That future veteran could be my son or my daughter," VA Secretary Jesse Brown said. "I don't want to place them at risk be-

See SEARCH next page

Distrust rages as Seabees charge cover-up

COLUMBUS, Ga.

While frustration is all-pervasive among gulf war syndrome sufferers, the feeling of outright betrayal may be strongest among members of a Georgia Naval Reserve unit.

They are convinced that something more than indifference or incompetence is at work. The sailors accuse Navy officials of taking medical files from the records of sick veterans in November 1991. They say those records prove that they were exposed to either chemical or biological warfare agents while serving during the Persian Gulf war.

"This is a cover-up ... they are trying to outsmart us from the top," said Construction Electrician First Class Roy Butler of 16th Detachment of the Naval Mobile Construction Battlion-24.

But Navy medical officials, who say they're aware of the complaints of missing records, insist they cannot figure what re-

If the records did exist, they might have been useful, said Navy Capt. (Dr.) S. William Berg, who is in charge of the Navy environmental and preventive medicine unit that surveyed four detachments within the sick Seabee battalion.

A spokesman for the Navy's Bureau of Medicine also denied taking anything out of the Seabees' medical records, or looking at or removing records from personnel files.

The sailors here say the Navy wants to eradicate all records of what happened to them during their six-month tour of duty in the gulf near the Saudi port city of Al Jubayl. Those records, they insist, would show that 28 of the unit's 43 members who went to the gulf are sick.

Butler, 50, was forced in December 1991 to retire after 29 years in the Navy because of his gulf war-related illnesses, he said. He suffers from joint pains, facial numbness, fatigue, memory loss, diarrhea, fevers and

over and over by his comrades.

The sailors' troubles began Jan. 20, 1991, when at about 3 a.m. they were jolted from their bunks by a massive explosion that rocked their quarters. It was an Iraqi Scud missile attack near the Al Jubayl docks.

By the time the attack was over, the sailors had been ordered into the chemical protection gear twice. Almost immediately, sailors began complaining of burning eyes and skin, numb lips and labored breathing.

After the second chemical attack alarm, the men ran to washing stations to clean off the substance, which burned their skin.

But symptoms persisted for about a week, and then fatigue set in, said Nick Roberts, 39, a sailor who served with the 24th in the gulf. "I thought I had the flu, I tried to shrug it off," he said.

In the days after the attack, dozens of sailors reported to sick bay. Doctors gave them aspirin and a couple days off to overcome mild fevers, Roberts said. Records from those

treatments, the sailors say, are missing.

After returning from the war May 5, 1991, Roberts, of Phenix City, Ala., found lumps in his groin. He also grew progressively fatigued, and began having dizzy spells and night sweats, joint aches and other ailments.

"I never could get my test results from the Navy. The lymph glands in my groin [swelled] so bad, I could hardly walk, they were so swollen," Roberts said.

Roberts has been diagnosed with a rare cancer called Non-Hodgkins Lymphoma, which is now in remission after he underwent chemotherapy. Had he believed the VA doctors, he would now be dead, he said.

Builder Second Class Roy Morrow now has a scar where a nonmalignant tumor was removed from his neck. He has lost faith. "Nobody is taking care of us, not the Navy nor the VA. I don't trust their doctors, because they always tell us we're fine."

— *Vago Muradian*

21

Not another Agent Orange

Vets, supporters fear a repeat of long fight to get their benefits

It's the battle cry of the victims of gulf war syndrome, and the motto of the politicians who have come to support them. "Not another Agent Orange."

It is also a shorthand way of saying that these veterans are determined not to be trapped in the same kind of protracted battle with the government that occurred after the Vietnam War.

During that war, the military sprayed tons of toxic defoliants over Southeast Asia. In the years since, tens of thousands of combat veterans have fallen ill or died of diseases believed linked to their exposure to the herbicides — links the government denied for years.

Many still are fighting with the government to acknowledge their injuries and to get just compensation.

Deja vu

Now it looks as if history is repeating itself. Veterans suffering from the Persian Gulf "mystery" illnesses see frightening similarities between the two cases.

"Look how long it took for action with the guys in Vietnam," said Brett Doggett, a former Marine from Orange, Calif., who served with the 4th Light Armored Infantry Battalion from Camp Pendleton, Calif. He lost a leg to an Iraqi land mine in Kuwait and is ill with the syndrome.

"There were men who died of cancer, and their children were born with birth defects," he said.

Although the frustrations are similar, the controversies over Agent Orange-induced illnesses and gulf war syndrome are quite different, according to Bernard Siegel, chief of staff of the ambulatory clinic at the West Los Angeles Veterans Medical Center.

The culprit in gulf war syndrome remains unknown. With the gulf war, he said, "we do not know of any specific issue." But with Agent Orange, "there was a special chemical involved, which was known to have been used and known in the lab to have severe consequences."

Still, sick Desert Storm veterans see similarities in how their cases and the Agent Orange controversy are being handled:

■ Veterans then and now are becoming ill, with symptoms ranging from rashes to cancer. Their doctors are stumped.

■ Both sets of sick veterans were told initially that their illnesses are a result of post-traumatic stress disorder.

■ Vietnam veterans reported mysterious ailments affecting spouses and children, including miscarriages and birth deformities. Some Desert Storm veterans have reported similar problems with their wives and children. In both cases, veterans complained, and the government was slow to react.

■ Reluctance by active-duty personnel — especially careerists — to report their illnesses hindered investigations of both problems. After Vietnam, "there were guys on active duty who wanted to hang on until they got their 20, simply because it was their life and their job," said retired Army Lt. Col. Richard S. Christian, a Washington lobbyist for the American Legion who served three tours in Vietnam.

Many Desert Storm veterans on active duty said they have not reported being sick for fear of receiving medical discharges.

■ The government responded with a registry and questionnaire after Agent Orange reports began to surface, and it has done the same with Persian Gulf veterans. The government rejected many Vietnam veterans' claims for service-connected illnesses, and some Persian Gulf veterans are fighting to get compensation for illnesses linked to their service in Desert Storm.

— Gidget Fuentes

AP/Wide World photo

Spray of Orange: U.S. aircraft sprayed thousands of jungle acres in Vietnam with the defoliant Agent Orange during the 1960s. But the chemical was later determined to be responsible for myriad deaths and illnesses among U.S. veterans.

from a mysterious illnesses, you and your family can get medical attention, advice, and financial and emotional support from these organizations:

Military and federal

Military medical facility: Sick families will be entered onto the Persian Gulf Registry by the individual military medical centers and hospitals they go to.

Active-duty personnel can also go to the Department of Veterans Affairs for diagnosis and treatment. But you'll need your medical command to request that for you.

Veteran medical care: The Department of Veterans Affairs is the primary agency for veterans and reservists. Contact any of the 171 VA medical hospitals for referrals and information. The Persian Gulf Registry coordinator or social worker can provide information about getting a physical exam.

For information on compensation benefits and eligibility, call the VA's counseling and information line, (800) 827-1000.

VA family support centers: To help ailing Persian Gulf veterans, the VA has set up 32 family support centers in 26 states. The Persian Gulf Family Support Program provides marriage and family counseling, education, information and referral to other services. Contact your local VA medical facility for locations.

Veterans centers: If you are not near a family support center, you can get assistance from 202 VA Veterans Centers nationwide.

Spouses: Although the VA doesn't provide medical treatment for sick spouses, you can get information and referrals to the local medical community from registry coordinators.

Service organizations

■ The American Legion's Family Support Network provides financial assistance, support and referrals for married and single gulf war veterans and their families. The network is open from 9 a.m. to 4 p.m. Central time, and you can leave a recorded message anytime. The number is (800) 433-3318.

■ Local posts of the Veterans of Foreign Wars can provide referrals and information. Check your local telephone directory.

Private groups

■ The San Antonio chapter of the Operation Desert Shield/Desert Storm Association is helping active-duty and war veterans and their families. The chapter is providing information and referrals about military and VA medical care, the Persian Gulf registries and emotional support and guidance.

Contact Carol Picou and Anthony J. Picou Jr. at the San Antonio chapter, (210) 658-7870. You can reach them by fax at (210) 658-8022.

■ The Military Family Support Network. Contact Dorothy Brooks in North Carolina, (910) 892-9315.

■ The Persian Gulf Veterans Support Group, formed by a former Marine, Todd Richmond in Iowa City, Iowa, (319) 351-8339.

Broken safety net

SEARCH from preceding page

cause we did not do our job."

Added Dr. Stephen Joseph, the Pentagon's newly installed health chief: "I'm not sure that I would say that our role, as a medical role, should be a greater one, but I believe it does need to be a more activist and aggressive one."

To that end, Joseph points to steps now planned or under way to reach out to the sick and find a cause — and cure:

■ A letter will be sent shortly to all active-duty Desert Storm veterans and their families, reassuring them of the Defense Department's commitment to their health needs and asking them to report problems to military hospitals and clinics.

■ Studies have started or are planned by the Navy into death and illness among Persian Gulf veterans.

■ A study will soon be released by the Army on the effects of oil-well fires on gulf war veterans.

■ A new policy has been established for the monitoring of health of troops returning from Somalia. Joseph says blood samples are being taken and thorough exams are being given to all returning veterans.

■ The department plans to bring in an outside consultant to review its efforts on gulf war syndrome.

But Joseph says there is nothing he can say that by itself will restore broken faith. Action and results are the only answer.

"We are really not going to be able to deal satisfactorily with all the issues," he said, "until we actually know what [the sickness] is."

— Sorayo S. Nelson

Ribavirin Post Exposure Prophylaxis of Crimean Congo Hemorrhagic Fever: Treatment Experience Form

Patient Information Name _____ SSN _____ Unit _____ Medical facility _____ Job _____	***High risk exposure*** High risk exposure to CCHF date ____/____/____ Exposure case diagnosis based on clinical [ ] IgM [ ] IgG [ ] Antigen [ ] virus isolation [ ] (check all applicable)
	Prophylaxis Information Initiated Prophylaxis date ____/____/____ Prophylaxis initiated <48 Hrs [ ] ≥ 48 hr [ ] after exposure [ ] < 48 hrs (PO 400 mg QID for 1 day; PO 400 mg TID for 6 days) [ ] (IV 33 mg/kg, then 16 mg/kg Q8H X3 doses; PO 400 mg TID for 6 days)
Information on treatment care facility Attending physician _____ Facility _____	***Ribavirin treatment Information*** Full Ribavirin regimen Administered [yes] [no] If Ribavirin Therapy discontinued Explain: _____ Were adverse reaction (except anemia) attributed to Ribavirin [yes] [no] Explain _____
	Patient outcome Patient Outcome at 30 days: Free of signs of CCHF [ ] clinical disease [ ] If Diagnosis CCHF: based on clinical [ ] IgM [ ] IgG [ ] Antigen [ ] visus isolation [ ] (check all applicable)

Record laboratory evidence of CCHF/RVF Infection

Viral IgM Day 0	CCHF [+] [-] [?]	Viral IgG Day 0	CCHF [+] [-] [?]	Viral Antigen D 0	CCHF [+] [-] [?]
Viral IgM Day 14	CCHF [+] [-] [?]	Viral IgG Day 14	CCHF [+] [-] [?]	Viral Antigen D 14	CCHF [+] [-] [?]
Viral IgM Day 30	CCHF [+] [-] [?]	Viral IgG Day 30	CCHF [+] [-] [?]		

Anemia

Day	Hct
0	
7	
14	
30	

Administer adverse reactions questionaire on day 14 and record symptoms that occur at least 1 time

CNS Systems		GI Symptoms		Musculoskeletal	
Headache	[None] [Mild] [Moderate] [Severe]	Metallic taste	[None] [Mild] [Moderate] [Severe]	Myalgia	[None] [Mild] [Moderate] [Severe]
Agitation	[None] [Mild] [Moderate] [Severe]	Dry mouth	[None] [Mild] [Moderate] [Severe]	Arthralgia	[None] [Mild] [Moderate] [Severe]
Irritability	[None] [Mild] [Moderate] [Severe]	Anorexia	[None] [Mild] [Moderate] [Severe]	Back pain	[None] [Mild] [Moderate] [Severe]
Mood lability	[None] [Mild] [Moderate] [Severe]	Increased appetite	[None] [Mild] [Moderate] [Severe]	Hand weakness	[None] [Mild] [Moderate] [Severe]
Confusion	[None] [Mild] [Moderate] [Severe]	Nausia	[None] [Mild] [Moderate] [Severe]	Ataxia	[None] [Mild] [Moderate] [Severe]
Insomnia	[None] [Mild] [Moderate] [Severe]	Vomiting	[None] [Mild] [Moderate] [Severe]	Miscellaneous	
Poor Concentration	[None] [Mild] [Moderate] [Severe]	Diarrhea	[None] [Mild] [Moderate] [Severe]	Fataque	[None] [Mild] [Moderate] [Severe]
Forgetful	[None] [Mild] [Moderate] [Severe]	Loose Stools	[None] [Mild] [Moderate] [Severe]	Fever	[None] [Mild] [Moderate] [Severe]
Depression	[None] [Mild] [Moderate] [Severe]	Constipation	[None] [Mild] [Moderate] [Severe]	Night sweats	[None] [Mild] [Moderate] [Severe]
Dizziness	[None] [Mild] [Moderate] [Severe]	Flatulence	[None] [Mild] [Moderate] [Severe]	Chills	[None] [Mild] [Moderate] [Severe]
Nightmares	[None] [Mild] [Moderate] [Severe]	Abdominal cramps	[None] [Mild] [Moderate] [Severe]	Cold sensitive	[None] [Mild] [Moderate] [Severe]
Dementia	[None] [Mild] [Moderate] [Severe]	Rectal burning	[None] [Mild] [Moderate] [Severe]	swollen tongue	[None] [Mild] [Moderate] [Severe]
Miscellaneous	[None] [Mild] [Moderate] [Severe]	rectal urgency	[None] [Mild] [Moderate] [Severe]	slow healing	[None] [Mild] [Moderate] [Severe]
Cardovascular		rectal pain	[None] [Mild] [Moderate] [Severe]	Paresthesia	[None] [Mild] [Moderate] [Severe]
Palpitations	[None] [Mild] [Moderate] [Severe]	GU Symptoms		Bleeding gums	[None] [Mild] [Moderate] [Severe]
Chest pain	[None] [Mild] [Moderate] [Severe]	Urinary frequency	[None] [Mild] [Moderate] [Severe]		
Respiratory		Dysuria	[None] [Mild] [Moderate] [Severe]		
DOE	[None] [Mild] [Moderate] [Severe]	Decreased libido	[None] [Mild] [Moderate] [Severe]		
Rhinitis	[None] [Mild] [Moderate] [Severe]	Dark urine	[None] [Mild] [Moderate] [Severe]		

Comments

_____

Physician certification _____ date _____

Protocol IND 16,666 Amendment 007

Forward to SGRD-UIV-S; Chief, Department of Antiviral Studies, Virology Division, USAMRIID, Ft Detrick, MD 21702-5011, USA

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38, the proponent agency is OTSG

PRIVACY ACT OF 1974

uthority:	10 USC 3013, 44 USC 3101, and 10 USC 1071-1087
rinciple Purpose:	To document voluntary participation in the clinical investigation and Research Program SSN and home address used for identification and locating purposes
outine Uses:	The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study, implementation of medical programs, adjudication of claims, and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.
isclosure:	The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicated that you health may be adversely affected. Failure to provide information may preclude your voluntary participation in this investigation study

PART A(1) - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for njury or disease which is the proximate result of their participation in such studies.

I, _____, SSN _____-_____-_____, having ull capacity and having attained my _____ birthday, do hereby volunteer to participate in: **Emergency Military Fielding for Operation Desert Shield of Ribavirin (Intravenous and Oral) for Post Exposure rophylaxis of High Risk Contacts to Crimean Congo hemorrhagic fever** under the direction of: COL Thomas Monath, MD, C, Virology Division, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), t. Detrick, Frederick, MD 21702-5011 USA conducted at: DOD-affiliated medical treatment facilities ssociated with Operation Desert Shield.

he implications of my voluntary participation; duration and purpose of the research study, the methods and neans by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have een explained to me by

_____

have been given an opportunity to ask questions concerning this investigational study. Any such questions were nswered to my full and complete satisfaction. Should any further questions concerning my rights on study elated injury, I may contact: Command Post Judge Advocate, Ft. Detrick, MD 21702-5011 at Tel: (301) 663-2643, AV 343-2643

understand that I may at any time during the course of this study revoke my consent and withdraw/have the erson I represent withdrawn from the study without further penalty or loss of benefits; however, the person I represent may be required military volunteer) or requested (civilian volunteer) to undergo certain examination if, n the opinion of the attending physician, such examinations are necessary for my/the person I representative's efusal to participate will invoke no penalty or loss of benefits to which I am/the person I represent is otherwise ntitled.

PART B - TO BE COMPLETED BY INVESTIGATOR

NSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: *(Provide a detailed explanation in ccordance with Appendix C, AR 40-38 or AR 70-25)*1. **Title of Study and location:** Emergency Military Fielding or Operation Desert Shield of Ribavirin (Intravenous and Oral) for Post Exposure Prophylaxis of High Risk Contacts to Crimean Congo hemorrhagic fever. The study will be conducted in DOD affiliated medical reatment facilities supporting Operation Desert Shield. 2. **Principal Clinical Evaluator:** COL Thomas P. Monath, MD, Chief, Virology Division, U.S. Army Medical Research Institute of Infectious Diseases, USAMRIID), Fort Detrick, Frederick, MD 21702-5011 USA. 3. **Purpose of Study:** This protocol is designed to rovide post exposure prophylaxis of soldiers who have had a high risk exposure to Crimean-Congo emorrhagic fever. You have been exposed to a case of Crimean-Congo hemorrhagic fever. Your exposure has een characterized as high risk by the Centers for Disease Control (CDC) guidelines. There is no known ffective treatment for CCHF. However, ribavirin has been used to treat CCHF experimentally in a very small umber of patients (12) in South Africa. The physicians who treated those individuals felt that the drug was of ome benefit. Patients who become ill with CCHF may choose to be treated with a high dose of ribavirin. You ay have been infected, and although you are not ill, the virus may be incubating in your body. This is a very rious disease. Twenty percent of patients who become infected with CCHF will become ill. Of those who ecome ill however 30% will die. This means that 8% of patients who become infected are expected to die. Since ll exposed individuals will not become infected, your risk of dying is expected to be much less than 8%. The earlier antiviral treatment is started, the more effective it is likely to be. Post exposure prophylaxis with a low dose of ribavirin, that is treatment begun before you become ill, may give you the best chance of surviving CCHF and you may not even become ill. You are being asked to volunteer to receive prophylactic ribavirin for 7 days after your last high-risk exposure to prevent you from developing the disease. 4. **Duration of Study:** You will receive drug for 7 days after your last high-risk exposure and be followed for 30 days, both to allow for early detection of clinical disease from CCHF and to evaluate any side effects of treatment; closely for 14 days and again at 30 days for followup. 5. **Procedure to be followed:** You will receive an experimental antiviral drug called ribavirin (trade name Virazole®) that is not approved as either intravenous or oral formulation for the prophylaxis of Crimean-Congo hemorrhagic fever. The Department of Defense has permission from the Food and Drug Administration for use of this drug under special circumstances associated with Operation Desert Shield, but that does not indicate approval for routine use of the drug. If your exposure occurred less than 48 hours before beginning prophylaxis you will receive oral ribavirin at a dose similar to what was well tolerated by over 2,000 patients with HIV or hepatitis. If you have been exposed for over 48 hours you will receive four doses of the drug in your vein, followed by oral drug for a total of seven days after your last high-risk exposure. Laboratory tests to determine if you have been infected will require that about 2 tea spoons of blood be drawn from your arm whether you receive ribavirin or not. If you receive intravenous drug then an intravenous line will be started, but this is a common procedure and the minimal risks involved will be explained. 6. **Risks:** This drug has been give to over 2,000 individuals, mostly with HIV or hepatitis, at similar doses for extended periods of time (greater that 1 month) and the only side effect, or risk, we can anticipate is a fall in the number of red blood cells, but your body should be able to compensate for this. If you are pregnant or a disease of your red blood cell producing organs (dyscrasia) you should know that you are at increased risk of ribavirin side effects and this will be fully explained to you before you make any decision. There are no known increased risks from CCHF due to pregnancy, but very limited experience exists. Ribavirin causes birth defects in animals. Several studies of pregnant animals have shown that ribavirin taken during early pregnancy at doses lower than you will be given caused severe birth defects and/or death of the unborn fetus. Such studies are known to predict similar risks in humans, although no formal studies in pregnant women have ever been done. It is known that at least 11 pregnant women in Mexico have been treated with ribavirin during their first trimester and no effects on their babies were able to be detected. The use of ribavirin in pregnant patients is contraindicated and patients who are or may be pregnant are excluded from participation in this protocol. Under most conditions, where the potential benefit is not clearly established by signs of clinical disease, the potential risk to the fetus outweighs the benefit and ribavirin prophylaxis is not indicated. If you are pregnant you should know that ribavirin therapy begun after onset of early signs of clinical disease is perceived to be efficacious based on limited experience, and in the case of confirmed CCHF with 30% mortality, ribavirin therapy would have a very different risk versus benefit consideration. You will have the opportunity to participate in that study. Ribavirin will remain in your body for several months and because of potential risks to a developing fetus, if you are a female, we ask that you use birth control measures for at least 6 months after hospital discharge. 7. **Benefits:** The potential benefit to you of receiving prophylaxis is that if ribavirin is effective it may keep you from becoming ill, or decrease the amount of time you are ill or need to remain in the hospital, and if you are among the 30% who would have had severe disease it may save your life. 8. **Alternative therapy available:** There are no appropriate alternative courses of treatment. If you do not participate you will be carefully watched for signs of clinical disease, and you will be offered ribavirin treatment if you become ill. 9. **Confidentiality of Medical Records:** All data and medical information obtained, that specifically identifies an individual, will be considered privileged and held in confidence. Individuals will not be identified in public presentations or publications. Complete confidentiality cannot be promised because information bearing on your health may be required to be reported to appropriate medical or command authorities. This information will be entered into your medical records and have the same confidentiality as those records. Representatives of the U.S. Army Medical Research and Development Command and the Food and Drug Administration shall have access to records as required for their official duties.

You will receive a copy of this Volunteer Agreement Affidavit (informed consent form).

do ☐ do not ☐ *(check one and initial)* consent to the inclusion of this form in my outpatient medical treatment record.

Signature of Volunteer	Date	
Permanent Address of Volunteer	Typed Name of Witness	
	Signature of Witness	Date

Copies: 1. Case Report Form, 2. Inpatient Chart, 3. Outpatient Medical Record (if authorized) 4. Patient copy

Protocol IND 16,666 Amendment 007 Revised 29 October 1990

RIBOVIRIN IV & ORAL

18

ADMINISTRATION OF ANTHRAX VACCINE

PURPOSE: To provide the necessary information for the safe administration of the anthrax vaccine.

BACKGROUND: An alum-precipitated, inactivated, anthrax vaccine has been approved and licensed for human use by the Food and Drug Administration since 1972. It has been shown to be safe and effective in protecting occupationally exposed individuals.

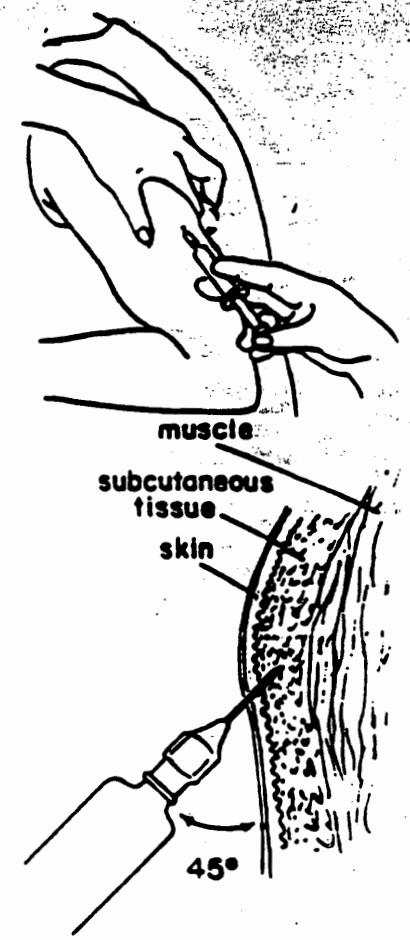
STORAGE: The anthrax vaccine should be kept refrigerated or on wet ice. Freezing or excess heat will inactivate the anthrax vaccine.

SCHEDULE: Two doses of anthrax vaccine should be given two weeks apart. A third dose of anthrax vaccine should be given two or more weeks after the second as additional anthrax vaccine becomes available.

SIDE EFFECTS: Up to 6% of recipients will experience mild discomfort (tenderness, redness, swelling, or itching) at the inoculation site for up to 72 hours. Less than 1% will have more severe local reaction potentially limiting the use of the arm for 1 to 2 days. Mild systemic reactions (muscle aches, fatigue, or fever) are uncommon and severe systemic reaction are rare. A few vaccinees will develop small, firm, painless nodules at the injection site which will persist for several weeks.

ADMINISTRATION: The anthrax vaccine should be given as follows:

1. Shake the vaccine bottle immediately before use. Even after thorough shaking anthrax vaccine has a milky texture.
2. Clean the rubber stopper with an alcohol pad.
3. Use the alcohol pad to clean an area of skin on the back side of the upper arm (see drawing).
4. Draw up 0.5 cc of vaccine into the syringe.
5. Using a 25 gauge, 5/8" needle, administer the vaccine <u>subcutaneously</u> at a 45 degree angle into a pinch of skin on backside of the upper arm (see drawing). Do not give this vaccine intramuscularly.
6. Use separate arms when administering anthrax and botulinum vaccine simultaneously.
7. Warn the patient to expect a burning sensation at the vaccine site approximately 30 seconds after vaccination lasting 1-2 minutes.



SUBCUTANEOUS

ANTHRAX

1. Anthrax is a zoonotic disease caused by a gram positive spore-forming bacteria, Bacillus anthracis. Human cases normally have resulted from contact with anthrax spores that contaminate animal products such as hides, wool, and hair. Under natural conditions, the disease manifests itself in three clinical forms:

a. Cutaneous (malignant pustule): The most common form, normally begins as a painless papule at the site of inoculation. The papule becomes vesicular and then progresses to hemorrhagic necrosis and eschar formation with regional lymphadenopathy. Constitutional symptoms and fever are absent unless dissemination occurs.

b. Gastrointestinal: This uncommon form results from the ingestion of anthrax-contaminated meat from sick animals. The disease course is characterized by abdominal pain, bloody diarrhea, toxemia, shock, and death.

c. Inhalation: This rare form has occurred in the past in unvaccinated textile workers exposed to aerosols containing anthrax spores from contaminated hides or hair/wool. The disease begins after an incubation period varying from 1 to 6 days, presumably dependent on the dose of inhaled spores. It is difficult to diagnose early, as the onset is gradual and non-specific, with fever, malaise, and fatigue, sometimes in association with a nonproductive cough and mild chest discomfort. The initial symptoms are followed in 2 to 3 days by the abrupt development of severe respiratory distress with dyspnea, diaphoresis, stridor, and cyanosis. Physical findings may include evidence of pleural effusions, edema of the chest wall, and meningitis. Chest X-ray reveals a dramatically widened mediastinum, often with pleural effusions but typically without infiltrates. Shock and death usually follow within 24 to 36 hours of respiratory distress onset.

2. If this bacterium were used in a biowarfare attack, aerosolized anthrax spores would be released causing the inhalation form of the disease. Preventing exposure of the respiratory tract and mucous membranes (to include the conjunctivae) to infections and/or toxic aerosols through use of a full-face respirator will prevent illness, and should, theoretically, obviate the need for additional measures. However, from a practical standpoint it would be very difficult to wear the chemical protective mask at all times.

3. Primary protection against aerosolized anthrax spores involves physical protection from exposure to the respiratory tract and mucous membranes through use of the chemical protective mask. Immunization with the anthrax vaccine should provide backup protection for those individuals exposed to modest spore doses without benefit of physical protection.

Postexposure Prophylaxis against Experimental Inhalation Anthrax

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Inhalation anthrax is a rare disease that is almost invariably fatal. This study determined whether a prolonged course of postexposure antibiotics with or without vaccination would protect monkeys exposed to a lethal aerosol dose of *Bacillus anthracis* when the antibiotic was discontinued. Beginning 1 day after exposure, groups of 10 animals were given penicillin, ciprofloxacin, doxycycline, doxycycline plus vaccination, vaccination alone, or saline. Antibiotics were administered for 30 days and then discontinued. Vaccine was given on days 1 and 15. Two animals died of causes other than anthrax and were not included in the statistical analysis. Nine of 10 controls and 8 of 10 animals given only vaccine died. Each antibiotic regimen completely protected animals while on therapy and provided significant long-term protection upon discontinuance of the drug (penicillin, 7 of 10 survived, $P < .02$; ciprofloxacin, 8 of 9 survived, $P < .002$; doxycycline, 9 of 10 survived, $P < .002$; doxycycline plus vaccination, 9 of 9 survived, $P < .0002$). Protection against rechallenge was provided by combining postexposure antibiotic treatment with vaccination.

Anthrax is a zoonotic infection caused by *Bacillus anthracis*. Humans become infected by contact with infected animals or contaminated animal products. Anthrax begins by introduction of the spore through skin, producing cutaneous anthrax; the gastrointestinal tract, causing gastrointestinal anthrax; or the respiratory tract, causing inhalation or mediastinal anthrax. Inhalation anthrax is extremely rare, with ~30 cases reported in this century, most often associated with industrial exposure to spores [1]. The disease has been almost uniformly fatal because of the difficulty in establishing the diagnosis and the rapid progression of the disease. Previous experimental studies demonstrated that treatment with penicillin for 5 or 10 days, beginning 1 day after aerosol exposure of monkeys, was protective during drug therapy, but animals died when the antibiotic was discontinued [2]. Long-term protection was afforded only by combining penicillin therapy with postexposure vaccination. Recent events in the Gulf War heightened the awareness of the possibility that anthrax could be used as a biologic weapon. For this reason, we determined whether a more prolonged course of antibiotic therapy alone or with vaccination, begun after an aerosol exposure, could protect animals from inhalation anthrax.

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The experiments were carried out under the guidance of the Veterinary Medicine Division in compliance with the Animal Welfare Act and other federal statutes and regulations relating to animals and experiments involving animals and adhere to principles stated in the Guide for the Care and Use of Laboratory Animals, National Institutes of Health publication 86-23, 1985. The facilities are fully accredited by the American Association for Accreditation of Laboratory Animal Care.

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Materials and Methods

Bacterial strain preparation, animals, and aerosol exposure. *B. anthracis* Vollum 1B spores were prepared as previously described, except for the omission of centrifugation through Renografin gradients [3]. Spores were diluted in sterile water, heated at 60°C for 45 min, and then kept on ice. Rhesus monkeys (*Macaca mulatta*) of both sexes (5.8–13.0 kg) anesthetized with tiletamine/zolazepam (3 mg/kg; A. H. Robins, Richmond, VA) were exposed in a head-only chamber to an aerosol generated with a Collison nebulizer. The mass median diameter of the particles generated was 1.2 μm as determined by cascade impacter and particle sizer (model 3310; TSI, St. Paul). The concentration of spores in the aerosol was determined during each exposure using an all-glass impinger. The minute respiratory volume was measured on each animal immediately before exposure. In the first challenge experiment, animals were exposed to an inhaled dose of $4.0 \pm 1.6 \times 10^5$ spores (mean ± SD), corresponding to ~8 LD_{50} [2] (unpublished data). Survivors from the first experiment were rechallenged with an inhaled dose of $2.6 \pm 1.4 \times 10^6$ spores (50 LD_{50}).

Experimental groups. Animals were randomly distributed by sex and weight into six groups of 10 animals each. (1) Controls were given saline intramuscularly (im) every 12 h, beginning 1 day after exposure. (2) Procaine penicillin G was given im at a dose of 180,000 units (0.6 mL) every 12 h, beginning 1 day after exposure and continuing for 30 days. Groups 3–5 received drugs by orogastic tube every 12 h, beginning 1 day after exposure and continuing for 30 days: (3) ciprofloxacin, 125 mg (in 5 mL H_2O); (4) doxycycline, 30 mg (6 mL); (5) doxycycline, 30 mg (6

mL), plus vaccination (0.5 mL of human anthrax vaccine [Michigan Department of Public Health, lot FAV001] on days 1 and 15 after aerosol exposure). (6) The vaccination group received 0.5 mL of the human anthrax vaccine on day 1 and, if still alive, on day 15 after aerosol exposure and water by orogastic tube every 12 h, beginning 1 day after exposure and continuing for 30 days.

Animals given ciprofloxacin, doxycycline, or vaccination were anesthetized with tiletamine/zolazepam (3 mg/kg) so medication could be given by orogastic tube. After 30 days of treatment, antibiotics were discontinued. Survivors were rechallenged 131–142 days after the initial exposure together with 5 new saline control monkeys.

Clinical, microbiologic and pathologic studies. Daily blood cultures were obtained from the saline controls and the group given only vaccine until death or for 14 days. In the antibiotic-treated groups, blood was cultured every other day until 80% of the controls died, then twice weekly until day 30, then every other day until ~day 60, and then once a week until rechallenge. Blood from animals not given antibiotics was collected in an Isolator 1.5 (Du Pont, Wilmington, DE) and cultured in 10-fold dilutions in triplicate on trypticase soy agar. Blood from antibiotic-treated animals collected in an Isolator 1.5 was cultured undiluted and at a 1:100 dilution on trypticase soy agar. In addition, 1 mL was cultured in a BACTEC Peds Plus bottle (Becton Dickinson, Towson, MD). Blood obtained before and at various times after challenge was analyzed for IgG antibodies to the anthrax protective antigen by ELISA [4].

Moribund animals were killed by deep anesthesia (tiletamine/zolazepam, 6 mg/kg) and exsanguination. All animals were autopsied. A diagnosis of anthrax was confirmed in all animals by isolating *B. anthracis* from the blood. In some cases, organs were cultured quantitatively. In all deaths in which antemortem blood cultures were negative, cultures were done of blood, spleen, lung, liver, intrathoracic lymph nodes, and brain.

Antibiotic sensitivity testing and serum levels. MICs of the *B. anthracis* Vollum 1B strain were determined in Mueller-Hinton broth dilutions using an inoculum of $2.5–3.0 \times 10^5$/mL in tubes and in a microtiter format. The MIC was 0.08 μg/mL for penicillin, 0.08 μg/mL for ciprofloxacin, and 0.02 μg/mL for doxycycline. The MBC was 0.32 μg/mL for penicillin and 0.08 μg/mL for ciprofloxacin. Peak serum levels were determined for 1 h (ciprofloxacin) or 2 h (penicillin and doxycycline) after a dose. Trough levels were measured 12 h after a dose for all drugs.

Procaine penicillin G, penicillin G potassium used as a reference standard, and doxycycline monohydrate suspension were purchased from Pfizer (New York). Powdered doxycycline hyclate for a reference standard was a gift of Pfizer (Groton, CT). Ciprofloxacin tablets and powdered ciprofloxacin for a reference standard were gifts of Miles Pharmaceuticals (West Haven, CT).

Statistical analysis. The significance of the differences in survival between the experimental and control groups was determined using Fisher's exact test, two-tailed.

Results

Description of disease in controls. Nine of the 10 control animals exposed to an inhaled dose of 8 LD_{50} died 3–8 days after challenge (mean ± SE 5.6 ± 1.1). The animals were ill for 1 to 4 days before death, demonstrating decreased spontaneous activity, weakness, and anorexia. One animal had a single seizure on the day of death and was found on autopsy to have meningitis. Respiratory distress was observed in only 1 animal. Bacteremia at levels of $10–10^5$ cfu/mL was present for a mean of 1.8 ± 0.9 days before death. Terminal bacteremias in 8 of the 9 animals that died varied from 10^4 to 10^9 cfu/mL. The 1 animal with a low terminal bacteremia of 2×10^2 cfu/mL had meningitis with 2×10^7 cfu/g of brain tissue. Five of 9 animals had gross findings of mediastinitis and enlarged hemorrhagic intrathoracic lymphadenitis. Meningitis was present in 5 of 9 animals and was hemorrhagic in 3. The 1 animal that survived never had a positive blood culture.

Antibiotic serum levels. The mean peak and trough serum levels for each of the antibiotics did not vary significantly when measured on days 5, 9, 20, and 30. The peak levels were at least 10 times the MIC for all antibiotics, and the trough levels varied from 1 times the MIC for ciprofloxacin to 1–10 times for penicillin and doxycycline [5].

Effect of postexposure treatment on survival. Survival of the various treatment groups is shown in table 1 and figure 1. Eight of 10 animals treated with vaccination alone died. The time to death and clinical and autopsy findings did not differ from untreated controls. One of the two vaccinated animals that survived had persistently negative blood cultures. The other had positive blood cultures on days 5, 11, and 12 at low levels of 10–20 cfu/mL with negative blood cultures thereafter.

We observed significant protection against death in each of the antibiotic-treated groups. All animals in the penicillin group survived the 30 days of treatment, during which their blood cultures were negative. Three of 10 animals died of anthrax on days 9, 12, and 20 after penicillin was stopped.

One animal given ciprofloxacin died 5 days after exposure from an aspiration pneumonia 24 h after the inadvertent introduction of drug into the trachea. All antemortem blood cultures were negative for anthrax as were postmortem cul-

Table 1. Survival after postexposure treatment of inhalation anthrax.

Treatment	Anthrax deaths	*P* vs. control
Control untreated	9/10	
Vaccine alone	8/10	>.1
Penicillin	3/10	<.02
Ciprofloxacin	1/9*	<.002
Doxycycline	1/10	<.002
Doxycycline + vaccine	0/9†	<.0002

* One animal died 5 days after exposure from aspiration pneumonia, had no evidence of anthrax at autopsy, and was excluded from analysis.

† One animal died 6 days after discontinuing doxycycline with no evidence of anthrax on autopsy. Cause of death remains unknown; the animal was excluded from statistical analysis.

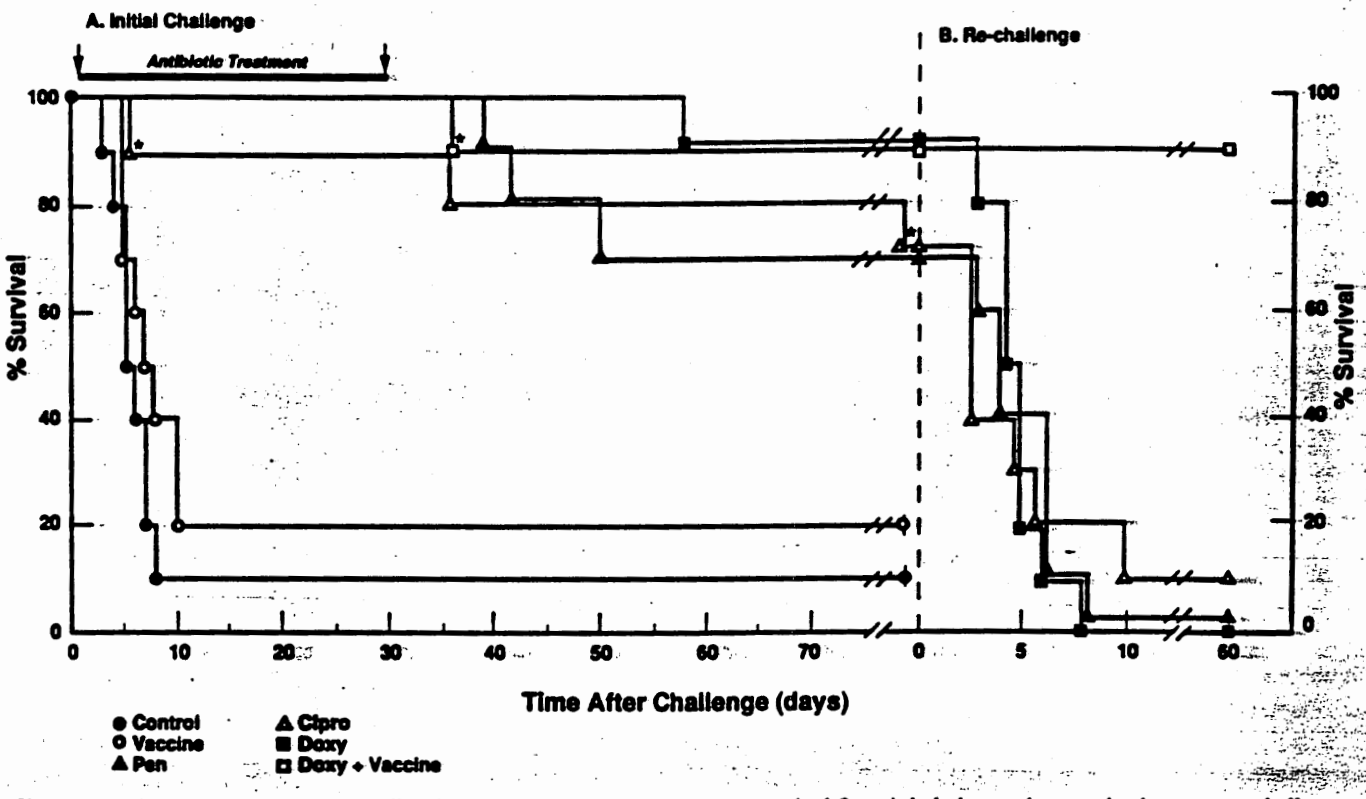

Figure 1. Effect of postexposure antibiotic treatment and vaccination on survival from inhalation anthrax and subsequent rechallenge. A, Groups of 10 animals were exposed to aerosol of anthrax spores on day 0 and were untreated (control), given vaccine only on days 1 and 15, or treated with penicillin (pen), ciprofloxacin (cipro), doxycycline (doxy), or doxy plus vaccination. Antibiotics were given from days 1 to 30. B, Survivors were rechallenged by aerosol on days 131–142 (day 0, B). Percentage survival is plotted against day after initial challenge (A) or rechallenge (B). *, 3 animals that died of causes other than anthrax.

tures of blood, lung, liver, spleen, and brain. Pathologic analysis showed an aspiration pneumonia with no evidence of anthrax in any organ. This animal was eliminated from analysis, as no assessment of the effectiveness of antibiotic treatment on long-term survival was possible. All other ciprofloxacin-treated animals survived the 30 days of treatment with negative blood cultures. One animal died of anthrax 6 days after antibiotic was stopped. Another animal in the ciprofloxacin group died 73 days after antibiotic was discontinued. Autopsy revealed no evidence of anthrax either by culture or histologically. This animal died of urethral obstruction due to rubbery plugs (concretions) in the proximal urethra and bladder and was considered to be a survivor of the anthrax challenge.

In the group treated with doxycycline alone, all animals survived during therapy and had negative blood cultures. One animal died of anthrax 28 days after treatment was stopped.

None of the animals treated with doxycycline plus postexposure vaccination died of anthrax. One animal in this group died 6 days after discontinuance of doxycycline but had no evidence of anthrax on autopsy by either culture or histologically. Mild myocardial degeneration was observed but the exact cause of death could not be determined. The effect of treatment on long-term survival from anthrax could not be evaluated and this animal was eliminated from statistical analysis.

Animals that survived the aerosol challenge were examined for evidence of an immune response 131–142 days after exposure by measuring antibody to the protective antigen component of anthrax toxin. No surviving animals treated with penicillin, ciprofloxacin, or doxycycline alone had an immune response. In contrast, the surviving animals given vaccine in addition to doxycycline all developed a fourfold or greater rise in antibody. The two surviving animals given vaccine alone also developed an antibody response.

Resistance of surviving treated animals to rechallenge. Significant protection against rechallenge of the survivors occurred in the group vaccinated and treated with doxycycline, with 9 of 9 animals surviving (figure 1). These animals remain free of disease 1 year after rechallenge. No significant protection was afforded by antibiotic treatment alone (penicillin, 0/7 survived; ciprofloxacin, 1/7 survived; doxycycline, 0/9 survived).

Discussion

The clinical and pathologic findings we observed after aerosol exposure to anthrax spores are consistent with those

previously reported in nonhuman primate studies [6, 7]. The observations are strikingly similar to those reported in cases of human inhalation anthrax [1, 8], confirming the relevance of this experimental model [2, 6, 7]. The most striking pathologic findings were intrathoracic hemorrhagic lymphadenopathy, mediastinitis, and meningitis.

One control animal survived the initial aerosol challenge and appears not to have become infected, as blood cultures were negative and an immune response never developed.

There were three deaths that were not due to anthrax. One ciprofloxacin-treated animal died of an aspiration pneumonia, 1 animal in the doxycycline plus vaccine group died 6 days after discontinuing the antibiotic and the cause of death could not be established, and 1 animal in the ciprofloxacin group died 73 days after antibiotic was discontinued because of urethral obstruction due to rubbery concretions. The relationship of the latter finding to the crystalluria induced by ciprofloxacin in nonhuman primates [9] is unclear, as the ciprofloxacin had been stopped for >2 months.

Critical to the rational treatment of inhalation anthrax is an understanding of the initial pathogenesis of the disease. Studies by Ross [10] suggest that inhaled spores are phagocytosed by alveolar macrophages and transported to the regional lymph nodes where they germinate to vegetative bacilli. However, some of the inhaled spores do not germinate and remain dormant within the lung for extended periods. Henderson et al. [2] demonstrated that 42 days after inhalation of spores by monkeys, 15%–20% of the initially retained dose of spores was still present in the lung. The significance of this for therapy of anthrax was initially appreciated by Barnes [11], who stated in reference to penicillin that spores may persist in the tissues and germinate after the level in blood falls. The findings by Henderson et al. [2] that animals treated for 5 or 10 days with penicillin died when the antibiotic was discontinued are consistent with this concept.

Our experiments clearly demonstrate that more prolonged antibiotic treatment for 30 days results in statistically significant long-term survival after discontinuance of treatment. Seven of 10 penicillin-, 8 of 9 ciprofloxacin-, and 9 of 10 doxycycline-treated animals survived. This result supports the hypothesis that treatment with antibiotics alone will be successful if the treatment continues until the level of retained persistent spores falls to less than the infectious dose. However, the five anthrax deaths in the antibiotic-treated animals, particularly the animal that died 58 days after exposure, directly support the concept that spores persist for prolonged periods in the host. The present data, taken together with the previous report of treatment failure with a short course of antibiotics [2], suggest that an even more prolonged course of antibiotics might have prevented all deaths from anthrax.

The results also showed that complete, long-term survival, after discontinuance of antibiotics, occurred when postexposure antibiotic treatment was combined with vaccination, confirming previous reports [2, 12]. Survival rate in these animals did not differ statistically from that of animals treated with antibiotics alone.

No animals treated with penicillin, ciprofloxacin, or doxycycline alone developed evidence of an immune response to anthrax. This suggests that antibiotic treatment, begun early after exposure, prevented the infection from fully developing. The only animals that seroconverted after the aerosol challenge were those that had been vaccinated. A serologic response is observed in humans who recover from established clinical anthrax after treatment [4, 13] and in monkeys after vaccination [14] (unpublished data).

Development of an immune response was found to predict resistance to rechallenge. The only animals resistant to a second aerosol challenge were those that had been vaccinated and had seroconverted (figure 1). Animals protected against the initial infection by antibiotic treatment did not develop an effective immune response and were susceptible to reinfection. This agrees with a previous report where animals treated after exposure with antibiotics and hyperimmunization with five doses of vaccine and that survived were protected upon rechallenge [12]. The protection afforded by vaccination before exposure is to be expected, on the basis of prior reports [14, 15] and our experiments (unpublished data).

Thus, these results suggest that therapy for an unimmunized person exposed to an aerosol of anthrax spores should consist of long-term suppressive antibiotics. Vaccination may provide an additional degree of protection against relapse after antibiotic treatment and would protect against a subsequent exposure.

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ACUTE PYRIDOSTIGMINE OVERDOSE: A REPORT OF NINE CASES

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ABSTRACT. Pyridostigmine is known as a pre-treatment drug against intoxication with organophosphorus nerve agents. During the Persian Gulf war, we encountered a cluster of nine cases of pyridostigmine self-poisoning, of which three presented with mixed drug poisoning. The clinical and laboratory features of pyridostigmine toxicity are presented. Doses ranged between 390 and 900 mg. Pyridostigmine ingestion resulted in mild to moderate cholinergic symptoms such as abdominal cramps, diarrhea, emesis, nausea, hypersalivation, urinary incontinence, fasciculations, muscle weakness and blurred vision. No central nervous system manifestations were evident. The symptoms developed within several minutes and lasted up to 24 h. All patients underwent gastric emptying followed by administration of activated charcoal. Atropine (1–8 mg) was required in only three patients. Measurement of serum cholinesterase inhibition was found to be a reliable and sensitive diagnostic tool in pyridostigmine poisoning. No clear correlation was found between the extent of cholinesterase inhibition and the incidence or severity of the cholinergic signs. The clinical recovery was faster than the spontaneous recovery of the enzyme. Pyridostigmine intoxication is self-limited and well tolerated by young healthy adults. *Isr J Med Sci* 1991;27:659–663

Keywords: Persian Gulf war; pyridostigmine; intentional overdose

Pyridostigmine bromide, a quaternary carbamate, is a reversible cholinesterase inhibitor. It is currently used for the treatment of myasthenia gravis (1) and for reversing nondepolarizing neuromuscular blockade (2). Pyridostigmine is also being recommended for pre-treatment against intoxication with organophosphorus nerve agents (3). Repeated doses of 30 mg three times daily do not cause any significant side effects (4–6). Chronic treatment with relatively high doses of pyridostigmine given to myasthenic patients (1) may lead to cholinergic toxicity, due to an accumulation of acetylcholine at the muscarinic and the nicotinic receptor sites. Abdominal cramps, diarrhea, excessive salivation, bradycardia, muscle fasciculations and muscle weakness are the most common adverse effects (7). Occasionally, bromide intoxication has also occurred (8). Experimental chronic overdose of pyridostigmine in dogs (10–20 mg/kg) for up to 14 days caused hypersalivation, tremor, diarrhea, emesis, reddened feces, intestinal intussusception and death (9). Carbamate toxicity in humans is well documented (10–16). There is, however, a paucity of specific information regarding the toxic complications of pyridostigmine.

During the Persian Gulf war, we encountered nine cases or pyridostigmine self-poisoning. In this study, we describe the clinical manifestations of pyridostigmine toxicity, the usefulness of serum cholinesterase activity measurement for diagnosis, and the efficacy of supportive and specific therapy.

PATIENTS AND METHODS

We reviewed the medical records of nine patients who were hospitalized with the diagnosis of pyridostigmine overdose during the Gulf war. The Institute of Clinical Pharmacology and Toxicology, which serves as a reference toxicology laboratory,

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was notified and consulted in seven of the nine cases. In a case of pyridostigmine overdose, the initial therapeutic approach includes gastrointestinal decontamination with gastric lavage and administration of 50 g of activated charcoal through a nasogastric tube. Supportive therapy includes replacement of fluid loss and correction of electrolyte imbalance, as well as any other indicated therapeutic measures. In patients with moderate to severe cholinergic symptoms, antidotal treatment with atropine is recommended.

Blood samples were drawn into heparinized tubes and kept at 4°C until analyzed. Serum cholinesterase activity was measured colorimetrically within several hours, according to the method of Ellman et al. (17), using a Progress Autoanalyzer (Kone, Finland). For the measurement of the baseline value, we first decarbamylated the enzyme by dilution of the sample 1:50 with normal saline followed by incubation at 37°C for 24 h. At 50% inhibition of pseudocholinesterase activity, the within-day and the between-day coefficient of variation is 2.0% and 4.5%, respectively.

RESULTS

Nine patients were admitted to emergency rooms within 10–180 min following an acute intentional pyridostigmine overdose. The clinical data are presented in Table 1. Six of the patients were males and the overall age range was 17–19 years. The ingested dose ranged from 390 to 900 mg (13–30 tablets, 30 mg each). Three patients presented with a mixed drug intoxication. The first simultaneously ingested 100 mg oxazepam and 10 g acetaminophen, a second patient ingested 4 g propranolol and the third one self-injected i.m. two automatic atropine injectors (2 mg each).

Clinical manifestations and treatment

All patients underwent gastric emptying followed by administration of activated charcoal. Two patients (nos. 1 and 2) treated within 20 min of ingestion remained asymptomatic. Patient no. 3 developed gastrointestinal symptoms only. Patient no. 4 had a clinical course consisting of abdominal pain, diarrhea, nausea, emesis, hypersalivation, fasciculations, weakness and blurred vision that persisted for 1 day. However, repeated determinations of cholinesterase activity showed an unusual sustained inhibition of the enzyme activity for 4 days (Fig. 1). The patient was confronted with the fact that laboratory findings indicated repeated pyridostigmine ingestion during hospitalization. Recovery of enzyme activity was observed within 30 h of confrontation, suggesting possible cessation of ingestion. Patient 6 had muscle tremor and fasciculations. Patient 5 who had a similar clinical picture, also developed vomiting, hypersalivation and involuntary micturition.

In the three patients with mixed drug ingestion, symptoms were mostly related to the other drugs. Patient no. 7 who ingested oxazepam and acetaminophen appeared drowsy. Patient no. 8 had sinus tachy-

Table 1. Clinical data of nine patients with acute intentional pyridostigmine ingestion and the nadir of serum cholinesterase (ChE) activity

Patient no.	Age/Sex		Dose (mg)	Mixed drugs	Lag period[a]	Clinical features	Serum ChE (% inhibition)	Atropine therapy	LOS[b] (days)
1	18	M	630	None	20	None	33	None	1
2	17	M	630	None	20	None	53	None	1
3	18	F	630	None	60	Emesis, abdominal pain	65	1 mg	1
4	19	F	390	None	90	Emesis, abdominal pain, nausea, diarrhea, hypersalivation, fasciculations, weakness, blurred vision	78	8 mg	5
5	19	F	570	None	10	Emesis, enuresis, hypersalivation, fasciculations	25	None	2
6	19	M	630	None	60	Fasciculations			
7	19	M	630	Oxazepam and acetaminophen	60	Drowsiness	79	None	2
8	18	M	900	Atropine	30	Emesis, tachycardia	[c]	[d]	1
9	19	M	630	Propranolol	90	Cardiac arrest	40	None	4

[a]Time from ingestion to admission.
[b]Length of stay in hospital.
[c]Data not available.
[d]The patient self-injected 4 mg atropine i.m. before admission to hospital.

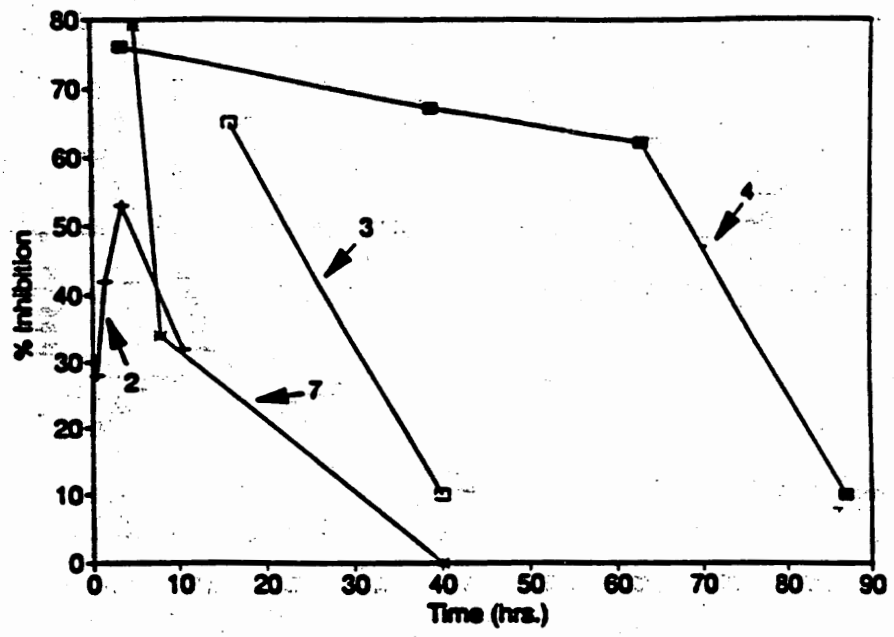

Fig. 1. Serum cholinesterase inhibition profiles in pyridostigmine-intoxicated patients. The arrows indicate patient no.

cardia of 160/min and mydriasis due to self-administration with two 2-mg atropine injectors. Patient no. 9 presented with hypotension bradycardia and eventually developed cardiac arrest, due to ingestion of 4,000 mg propranolol and 630 mg of pyridostigmine. He underwent a successful cardiovascular rescusitation and insertion of a temporary pacemaker. Intravenous atropine (1–8 mg) was administered to three patients (nos. 3, 5 and 8) to counteract muscarinic effects. All patients recovered within several hours to 5 days and were discharged with a referral to further psychiatric care.

Laboratory Assessment

The nadir of serum cholinesterase inhibition in seven patients is shown in Table 1. Values ranged between 25 and 79%. The decrease in cholinesterase activity was transient and returned to normal values within 24–48 h after the ingestion, with the exception of patient no. 4 as described above (Fig. 1). The marked decrease in enzyme activity observed in some patients was associated with mild cholinomimetic signs and symptoms.

DISCUSSION

Pyridostigmine poisoning is uncommon. The unique circumstances in which pyridostigmine was widely distributed as a prophylactic drug against organophosphorus nerve agents carry a significant potential of misuse. All nine patients had ingested pyridostigmine in a suicide attempt.

Pyridostigmine is poorly but rapidly absorbed from the gastrointestinal tract. The bioavailability of the administered dose is only 5–10% (18). Despite the poor bioavailability, enough of the drug was absorbed to cause an inhibition of 25–79% of serum cholinesterase activity. Symptoms developed within 15 min to 2 h and lasted for several hours. This observation is in accord with the pharmacokinetic behavior of pyridostigmine. It has been shown that the T_{max} (the time needed to reach maximal concentration in plasma) is 60–120 min and the elimination half-life time is 3–4 h (19,20). Pyridostigmine is a reversible cholinesterase inhibitor. Accumulation of acetylcholine at the cholinergic synapses results in symptoms and signs of cholinergic hyperactivity. These can be divided into muscarinic, nicotinic and CNS effects.

In the present report, some patients presented with muscarinic signs such as abdominal cramps, diarrhea, nausea, hypersalivation, vomiting and urinary incontinence. Although lacrimation and increased sweating are known symptoms of carbamate poisoning, they were not prominent in our patients. Vomiting and other gastrointestinal effects may have been due to

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systemic cholinergic activity and/or to the local effect of pyridostigmine on the gastrointestinal tract. Among the nicotinic effects we observed only transient fasciculations and muscle weakness. As expected, considering the quaternary ammonium structure of pyridostigmine, no CNS manifestations were exhibited by our patients. CNS toxic effects such as ataxia, confusion, psychosis, respiratory and cardiovascular depression, seizures and coma are related to large doses of some carbamates. Unlike organophosphates, most carbamates, including pyridostigmine, poorly penetrate the blood–brain barrier and usually do not cause any CNS symptoms unless they are present in high concentrations (9).

The treatment of patients with carbamate poisoning consists of general supportive care, with particular emphasis on establishing a free airway, stabilizing the vital signs, gastric decontamination and administration of atropine when indicated. Our patients had mild to moderate symptoms requiring minimal antidotal therapy. Atropine antagonizes the cholinergic effects by blocking the muscarinic receptors. It has little, if any, effect on nicotinic receptors. In adults, an initial i.v. dose of 2 mg atropine repeated every 5–30 min is required to reach atropinization. Our study demonstrated that in a case of moderate pyridostigmine poisoning, one to four doses may suffice.

Pyridostigmine poisoning was diagnosed by medical history, the presence of cholinergic signs, and response to atropine administration. The diagnosis was confirmed by determining serum cholinesterase activity. Most clinicians depend on normal ranges of enzyme activity to evaluate a single post-exposure value. This common approach is misleading when a mild to moderate poisoning is involved. Since a patient's baseline value is usually not available, the interpretation of a single post-exposure value is made difficult by the wide range in normal cholinesterase activity. According to the analytical procedure currently used by us, normal values ranged from 1.5 to 4.3 units/ml. Thus, patients with values at pre-exposure in the upper normal range (e.g., 4.3 units/ml) may have a 60% inhibition of their cholinesterease activity and still have values above the lower limit (e.g., a post-exposure value of 1.5 units/ml).

Coye et al. (21) suggested sequential post-exposure cholinesterase determinations for several days until no further increase in activity is measured. This approach is widely applicable for occupational medicine purposes but has a limited value, if any, in acute toxicological cases. In a study concerning the stability of cholinesterase–pyridostigmine complex conducted by us, we found that dilution of the sample 1:50 with saline followed by incubation at 37°C for 24 h causes a complete decarbamylation of the enzyme (unpublished data). We used this method for determining the baseline value of each individual patient. With this approach we were able to confirm the exposure to pyridostigmine in all our patients. It is noteworthy that plasma cholinesterase levels were reduced by 30–50% before other signs or symptoms were evident (Table I). Pseudocholinesterase inhibition is therefore a reliable and sensitive diagnostic tool in pyridostigmine poisoning. This conclusion is supported by previous clinical studies in which ingestion of therapeutic doses of pyridostigmine produces 20–40% cholinesterease inhibition without any side effects (4–6). No clear correlation was found between the extent of cholinesterase inhibition and the incidence or severity of the cholinergic signs in our patients. On admission, cholinesterase levels were depressed but returned to normal within 1–2 days (Fig. 1). However, the major features of the clinical symptoms resolved within several hours. The clinical recovery is therefore faster than the spontaneous recovery of the enzyme. A similar phenomenon is known in organophosphate poisoning in which the clinical syndrome was proven to be influenced by neuroadaptation processes producing tolerance to the continuing low acetylcholinesterase activity (22,23).

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Brief Report

Pyridostigmine Used as a Nerve Agent Pretreatment Under Wartime Conditions

LTC Jill R. Keeler, AN; COL Charles G. Hurst, MC; COL Michael A. Dunn, MC

Objective.—To determine the adverse effects of pretreatment with pyridostigmine bromide for nerve agent exposure during wartime.

Design.—A retrospective study.

Setting.—Southwest Asia.

Participants.—Personnel who provided medical support to the XVIII Airborne Corps. These medical officers supplied information pertaining to symptoms and composition of 41 650 soldiers who received pyridostigmine at the onset of hostilities of Operation Desert Storm.

Intervention.—Pyridostigmine bromide, 30 mg orally, was self-administered every 8 hours while under the threat of nerve agent attack (for 1 to 7 days).

Main Outcome Measure.—Physiologic changes attributable to pyridostigmine that resulted in need for medical attention, discontinuation of the drug, hospitalization, and/or evacuation from Southwest Asia.

Results.—About half of the population noted physiologic changes that were not incapacitating, such as increased flatus, abdominal cramps, soft stools, and urinary urgency. Approximately 1% of the soldiers believed they had effects that warranted medical attention, but fewer than 0.1% had effects sufficient to discontinue the drug. Nonincapacitating symptoms often occurred; however, military mission performance was not impaired.

Conclusion.—While under the threat of nerve agent attack, pyridostigmine can be administered to virtually all soldiers.

(JAMA, 1991;266:683-686)

DURING Operation Desert Storm there was a credible threat of chemical warfare even though there was never actual use of chemical agents. Intelligence reports indicated that the Iraqi chemical arsenal contained nerve, vesicant, and blood agents. Nerve agents are organophosphorus inhibitors of acetylcholinesterase, such as sarin and tabun. The vesicants are skin-blistering compounds, such as mustards and arsenicals, while blood agents are the cyanides, inhibitors of cytochrome oxidase.

The US Armed Forces' approach to the medical management of actual or anticipated nerve agent injuries employs a regimen that consists of pretreatment with pyridostigmine bromide tablets prior to nerve agent exposure, followed by atropine citrate and pralidoxime chloride by autoinjector intramuscularly on actual exposure.[1] Proper administration of this drug combination provides significantly increased survival after lethal exposures to nerve agents above that provided by atropine and pralidoxime therapy alone.[2]

The recent addition of pyridostigmine to the US therapeutic regimen for nerve agent poisoning was based on efficacy data in animals[3] and safety studies in humans.[4] Operation Desert Storm necessitated the first large-scale human use of pyridostigmine under field conditions prior to anticipated nerve agent attack. The Food and Drug Administration issued an interim rule, effective December 21, 1990, that obtaining informed consent was not feasible for wartime use of pyridostigmine in Operation Desert Storm.[5]

The troops were given pyridostigmine in a blister pack containing twenty-one 30-mg pyridostigmine bromide tablets. The decision to begin, continue, or discontinue pyridostigmine rested with each major unit commander, based on his chemical, medical, and intelligence staff officers' advice. Troops took one to 21 pyridostigmine tablets at the specified regimen of one tablet every 8 hours.

At the prescribed dosage of pyridostigmine, anticipated undesirable effects were a slight increase in flatus, occasional diarrhea, and a decrease in heart rate of about five beats per minute.[6] Cases of nausea, headache, and vivid daydreams have also been reported.[6] Data were collected in Saudi Arabia to determine whether the physiologic responses to pyridostigmine were the same under the conditions of anticipated chemical attack as had been noted under controlled, non-combat-associated conditions.

the US Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, Md.
Reprint requests to Commander, US Army Medical Research Institute of Chemical Defense, ATTN: SGRD-UV-YY/LTC Keeler, Aberdeen Proving Ground, MD 21010-5425.

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Effects of Pyridostigmine Pretreatment*

Effect	Range of Incidence, %
Gastrointestinal symptoms	≥50
Urinary urgency and frequency	5-30
Headaches, rhinorrhea, diaphoresis, tingling of extremities	<5
Need for medical visit	1
Discontinuation on medical advice	<0.1

*Based on reports from medical personnel providing care to 41 650 soldiers (6.5% women) who took pyridostigmine bromide orally at 30 mg every 8 hours for periods of 1 to 7 days. Drug administration resulted in 483 clinic visits, and use of the drug was discontinued in 28 soldiers.

Methods and Results

The XVIII Airborne Corps instructed 41 650 soldiers (6.5% women) to take pyridostigmine tablets at the onset of Operation Desert Storm hostilities in January 1991. The dosage of pyridostigmine, prescribed as one tablet every 8 hours, was variable depending on the order issued by each unit commander; total dosage ranged from one to 21 tablets over 1 to 7 days, with 34 000 soldiers reportedly taking the medication for 6 to 7 days. In all, 234 000 person-days of pyridostigmine administration occurred. Total dosages differed among the six major units of the corps. In some instances, depending on commanders' assessment of the nerve agent threat, the regimen was stopped and restarted repeatedly. Few soldiers admitted to discontinuing pyridostigmine without medical advice. Although it is likely that some individuals discontinued the drug, actual data were not obtainable.

We queried approximately 30 medical officers (physicians and physician's assistants) as to the number of aid station or clinic visits, discontinuations, hospitalizations, and evacuations attributable to pyridostigmine. These officers were in close daily contact with the combat units they served. They included the division surgeons who had responsibility for all medical care, hospitalization, and evacuation of soldiers in this corps. They also provided us with their impressions of the incidence of general physiologic response to pyridostigmine and potential adverse effects.

Effects of pyridostigmine pretreatment experienced by the soldiers are shown in the Table. Regardless of the total dosage or pattern of pyridostigmine administration, gastrointestinal changes, including flatus, loose stools, abdominal cramps, and nausea, were noted by about half the troops. Other reported effects were urinary urgency, headaches, rhinorrhea, diaphoresis, and tingling of the extremities. These effects were considered tolerable. They did not noticeably interfere with performance of the full range of demanding physical and mental tasks required of these soldiers.

Intolerance to pyridostigmine was defined as a perceived need for medical attention. A total of 483 aid station or clinic visits were related to pyridostigmine administration. Specific information as to when symptoms occurred in relation to dosing was not obtained at every visit. The general impression was that the symptoms were experienced within hours after taking the first tablet. In some individuals these symptoms continued as long as pyridostigmine was taken, and in others they abated after 1 or 2 days of use. Gastrointestinal disturbances severe enough to prompt medical attention accounted for 313 of these visits. Another 150 soldiers had frequency or urgency of urination. Five complained of bad dreams, three of worsening of acute bronchitis, and three of headache. Three had slurred speech (one of these also complained of "blurry" vision) but had normal findings on neurological examinations. Rashes occurred in two individuals, one of whom also had edema and urticaria of his hands and feet that responded to diphenhydramine hydrochloride. One soldier complained of vertigo; a soldier with a history of asthma had bronchospasm that was temporally associated with pyridostigmine administration.

An unexpected adverse association was seen in two otherwise normotensive individuals, who experienced acute elevations in blood pressure (180 to 220/110 to 120 mm Hg) and sought medical aid because of bleeding. One individual had epistaxis. The second bled profusely from a shaving nick. He discontinued pyridostigmine for 2 days with resolution of hypertension. When he restarted the drug, not being positive of its association with his symptoms, significant hypertension promptly recurred. He had a normal complete blood cell count, prothrombin time, partial thromboplastin time, platelet count, and bleeding time.

Pyridostigmine therapy was discontinued by the unit physician for 28 soldiers: the three with exacerbated acute bronchitis, the asthmatic, the two with allergic reactions, the two hypertensive patients, and 20 soldiers with intolerable nausea and diarrhea. One physician discontinued his own therapy because of gastrointestinal effects and headaches.

There were no medical evacuations among this corps because of problems with pyridostigmine.

One medical specialist took two pyridostigmine tablets simultaneously in an effort to make up for a missed dose. After realizing he was experiencing a mild cholinergic crisis, he self-administered atropine by autoinjector intramuscularly and reported to his medical treatment facility; he was admitted for observation, and reportedly had no further effects.

Additional information was volunteered by hospital personnel who took pyridostigmine during the third week of January or last week of February 1991. In general, they noted the same gastrointestinal and urinary disturbances described above. Several physicians admitted to discontinuing pyridostigmine because of the unpleasant effects. Two women, with body weights of approximately 45 to 50 kg, recounted that their experience with pyridostigmine included increased salivation, severe abdominal cramps, nausea, diaphoresis, and muscular twitching. Unfortunately, our retrospective study did not provide data relating symptoms to body size or gender, a point worthy of further investigation.

Comment

Soldiers taking pyridostigmine under combat conditions performed at full effectiveness but had a higher incidence of minor intestinal and urinary symptoms than expected. Because of the nerve agent threat, there was no control or placebo-treated population of soldiers not taking pyridostigmine and subject to identical combat stresses. Clearly, the other stress factors present in this combat situation could have contributed to these symptoms; therefore, our data represent a worst-case estimate of effects attributable to pyridostigmine. Our retrospective gathering of anecdotal information from unit medical officers within 10 days of the use of pyridostigmine may have missed minor events; however, the nature of the field medical system provided assurance that all events that required evacuation, referral, or hospitalization were recorded.

Soldiers may not have thought that their symptoms warranted a clinic visit, may have become accustomed to the perceived changes, or may have developed a pharmacologic tolerance to pyridostigmine. Some reported that when pyridostigmine was taken with a meal, gastrointestinal complaints decreased. Practices such as this were implemented by some units to decrease the incidence of symptoms and enhance compliance. Indeed, full compliance with an every-8-hour regimen would be unlikely when soldiers themselves believed the nerve agent threat was low. Based on experience of XVIII Airborne Corps medical personnel, compliance in combat units was well over 99% at the start of hostilities in January 1991. Dur-

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ing this time there was a generally accepted perception of a definite nerve agent threat from chemically armed missiles. Again in February 1991, units entering Iraq and Kuwait at the start of ground combat perceived a real nerve agent threat, and there was virtually complete compliance with pyridostigmine dosing as ordered.

Most soldiers were aware that pyridostigmine altered their normal physiology in some way, but these changes did not interfere with their daily lives. This awareness was shared by medical personnel, including the authors of this report, who took pyridostigmine under field conditions. One percent of this military population had effects from pyridostigmine for which they sought medical advice. Fewer than 0.1% had effects sufficient to warrant discontinuation of the drug.

The most common side effects were related to the gastrointestinal and urinary tracts. These were predictable effects of muscarinic receptor activation. The worsening of symptoms in soldiers with acute bronchitis may have been the result of muscarinic activation of bronchial smooth-muscle receptors. The fact that few cases of asthma were exacerbated or unmasked may be due to this deployment in the desert for about 4 months, so that those with asthmatic reactions had already been medically evacuated from the region.

The two episodes of hypersensitivity were not unexpected. Pyridostigmine is formulated as a bromide salt, and the bromide constituent has been implicated in rashes. The three incidents of slurred speech were unusual. Findings on neurological examinations were normal, and there was not excessive salivation. It is not known if there was oral or peripheral edema.

The bad dreams and equilibrium problems reported may have been stress responses, as they were not expected consequences of pyridostigmine administration. One advantage of pyridostigmine as a pretreatment for nerve agent poisoning is that it does not readily penetrate the blood-brain barrier or interfere with cognitive or psychomotor function.[6,7] Whether these individuals would have a recurrence of such symptoms if challenged with pyridostigmine under peacetime conditions is unknown.

Headaches were an unexpected phenomenon, and while only three soldiers sought medical attention for headaches, conversation with hospital personnel indicated that headaches were not rare occurrences. Two individuals assigned to a field hospital did not seek medical attention for headaches but reported that their blood pressures were moderately elevated during the episodes. The basis for the headaches may be that excess acetylcholine activated vascular receptors to induce vasodilation. This observation deserves further study.

The two episodes of hypertension were unexpected and may have represented a more prevalent phenomenon. The hypertension may have been due to hypersensitive sympathetic ganglionic receptors, subclinical pheochromocytoma, or other unknown mechanisms.

The signs and symptoms of pyridostigmine overdose, as described in military training literature, include abdominal cramps, nausea, diarrhea, pinpoint pupils, and muscular weakness, cramps, and twitching.[1] Abdominal cramps, nausea, and mild diarrhea were all experienced by soldiers receiving the prescribed dosage, as were rhinorrhea, flatulence, urinary urgency, and diaphoresis. Whether these were a consequence of dosage cannot be determined. Muscular weakness, cramps, and twitching were seen only in small women.

The pyridostigmine regimen followed by soldiers under wartime conditions caused a higher incidence of adverse physiologic events than had been reported in earlier peacetime evaluations. It seems possible that the combined stresses of anticipated combat, sleep deprivation, and life in the field may well have affected or modified many of these responses. Based on our observations, we conclude that the pyridostigmine regimen can be administered to virtually all soldiers under wartime conditions without impairment of military performance.

We acknowledge with appreciation the assistance of the XVIII Airborne Corps medical personnel who provided information for this report.

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THE UNDER SECRETARY OF DEFENSE

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ACQUISITION AND TECHNOLOGY

02 MAR 1994

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
UNDER SECRETARY OF DEFENSE (POLICY)
VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF
PRINCIPAL DEPUTY UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND TECHNOLOGY
DEPUTY UNDER SECRETARY OF DEFENSE FOR ADVANCED TECHNOLOGY
DIRECTOR OF TACTICAL WARFARE PROGRAMS
DIRECTOR OF PROGRAMS ANALYSIS AND EVALUATION
DIRECTOR OF ARPA

SUBJECT: Revolution in Military Affairs Project - Formal Authorization of Task Force Activities

In order to better understand and exploit the potential for revolutionary changes in warfare, the Secretary of Defense has authorized the establishment of a Revolution in Military Affairs (RMA) Senior Steering Group, chaired by the USD for Acquisition and Technology. In January, the Steering Group created four task forces to assist its efforts. I ask that you assign personnel who can represent your organization on each task force that has been established to assist the Steering Group.

These task forces will present their recommendations to the Steering Group by mid-September 1994. Three of these task forces will explore the potential for exploiting emerging technologies, as well as new operational and organization concepts, to enable revolutionary changes in theater warfare and smaller-scale operations. A fourth task force will develop specific proposals to foster innovation in technology, doctrine, operational concepts, and organization within DoD.

In addition, an RMA Working Group, chaired by the DASD/SR&R, Strategy, has been established to support the Steering Group's activities and to oversee and assist the task forces. The membership of the Steering Group, the Working Group, and the task forces in composed of representatives from OSD, the Joint Staff, the Services, and selected defense agencies.

I have attached a list of those who are currently working on the RMA Project for your information. In addition, I have attached a paper on the RMA that offers a summary of the concept and the current status of the Steering Group's activities.

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Please have your designees contact David Ochmanek or Matthew Russell, at (703) 697-2467 or DSN 227-2467.

The next meeting of the Senior Steering Group for Policy on Exploiting the Military Technical Revolution will be held on March 7, 1994 from 1000-1200 in the Pentagon, Room 3E947 (USDA&T Conference Room).

John M. Deutch

Attachments
a/s

Exploiting the Revolution in Military Affairs

Background:

There is considerable evidence to suggest that we are in a period of revolutionary change in the ways in which wars are fought and other military operations are conducted. A revolution in military affairs (RMA) (also often described as the "military technological revolution" (MTR)) involves the synergistic incorporation of new technologies in military systems, innovative operational concepts, and organizational adaptation within the armed forces that fundamentally alter the character and conduct of military operations. The combination of these elements can produce dramatic improvements in military effectiveness and combat potential.

There is a broad consensus that the 20th century has witnessed three such revolutions. In the period between 1917 and 1939, internal combustion engines, armored vehicles, improved aircraft designs, and radio and radar were harnessed in new operational concepts and organizational structures to produce the *blitzkrieg*, carrier warfare at sea, and strategic aerial bombardment. A second revolution sparked by the incorporation of modern weapons (including nuclear weapons), jet aircraft, ballistic missiles, and advances in electronics brought fundamental changes in the 1950s and early 1960s.

A third revolution began in the late 1970s and 1980s. This revolution involves the application to theater warfare of cruise missiles, the use of satellites for reconnaissance, communications and global positional information, "stealthy" aircraft, advanced airborne radars, and precision-guided munitions. The revolution arrived operationally, at least in part, during the Gulf War of 1991, where the enormous potential of the integration of weapons systems with information networks began to be realized. A key breakthrough, however, is anticipated when we succeed in fully integrating the information networks we have developed for surveillance, tracking, target acquisition, and battle-damage assessment with our latest generation of weapons systems.

Maintaining America's superiority in military technology and its applications in this environment will require DoD to exploit new technologies, alter dramatically its traditional approach to system development, identify new operational concepts, and promote organizational innovation and adaptation.

Discussion:

In September of 1993, the SecDef directed the establishment of an RMA Senior Steering Group, chaired by the USD for Acquisition and Technology, to coordinate and guide RMA activities within DoD. The Steering Group brings together the policy, technical, and operator communities to promote operational and organizational innovation within DoD to better exploit new advances in technology. The current membership of the Steering Group includes the USD for Acquisition and Technology, the DUSD for Advanced Technology, the Vice Chairman of the Joint Chiefs of Staff, representatives of the Services, the ASD for Strategy, Requirements, and Resources, the ASD for Plans and Policy, the Director of Net Assessment, the Director for Tactical Systems, and the Director for PA&E. The USD for Acquisition and Technology established a Working Group, chaired by SR&R, which is supporting the Steering Group's activities.

At the Steering Group's first meeting in January, the group approved the Working Group's recommendation to create three task forces to explore the potential for exploiting emerging technologies, as well as new operational and organizational concepts, to enable revolutionary changes in theater warfare and smaller-scale operations. The Steering Group also directed the creation of a fourth task force to develop specific proposals on ways to foster innovation in technology, doctrine, operational concepts, and organization within the Department of Defense. Working with the oversight and assistance of the RMA Working Group, the task forces are developing work plans for studies to be conducted by personnel within and outside DoD over the next several months.

RMA Working Group Membership List

Name/Organization	Phone #	Room #
David Ochmanek, DASD OSD(P), SR&R, Strategy Chair, RMA Working Group	7-2467	4C767
Dr. Richard Wishner OSD(A), Advanced Technology	4-0205	3E1045
Steve Head OSD(A), Tactical Systems	7-6445	3E1044
Clark Murdock, DASD OSD(P), Policy Planning	5-2161	4B940
Chris Lamb, Director OSD(P), SO/LIC Chair, RMA Task Force on Smaller Scale Operations	3-5209	2B525
Andy Marshall, Director OSD(P), Net Assessment Chair, RMA Task Force on Innovation	5-1811	3A930
LCOL Tom Smith OSD(P), Net Assessment	7-1312	3A930
LCOL Jim Hardin J-7, Joint Staff	4-9621	1A720
LCOL Steve Cullen J-5, Joint Staff	4-7352	2E949
COL Bill Foster Army Staff Co-Chair, RMA Task Force on Combined Arms/Maneuver Warfare	7-4974	3E533
CDR Joe Sestak Navy Staff Co-Chair, RMA Task Force on Deep Attack	7-2534	4E514

LCDR Russ Keller LT Trey Mitchell Navy Staff	7-2534	4E514
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COL Chuck Miller Air Force Staff Co-Chair, RMA Task Force on Deep Attack	7-3717	4D1083
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Gil Klinger, Director OSD(P), Space & Advanced Technology Strategy	3-6927	1E760