

APPENDIX I

JANUARY 30, 1998

LETTER FROM DR. BERNARD ROSTKER TO HON. ARLEN SPECTER



SPECIAL ASSISTANT
FOR
GULF WAR ILLNESSES

OFFICE OF THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

JAN 30 1998

Honorable Arlen Specter
Chairman, Committee on
Veterans' Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This is an interim response to your recent letter to the Deputy Secretary of Defense requesting information on a variety of medical products. The attached tables identify medical products including vaccines, antitoxins, immune globulins, and pharmaceuticals that were fielded or administered during Operations Desert Shield/Desert Storm to protect against the listed exposures and provides the information available on each product as requested.

In response to your question on quality control measures for perishable medical supplies, the Department procedures follow quality control guidelines in accordance with federal laws, DoD policy, and accepted standards of practice as defined by the Joint Commission on Accreditation of Healthcare Organizations, the American Society of Hospital Pharmacists, and the American Pharmaceutical Association. Each drug is stored in accordance with the package label as directed by the manufacturer and required under applicable Food and Drug Administration rules and regulations. Temperatures are monitored at all points on a routine basis including receipt, storage, and administration. Any time a perishable medical item, including vaccines, leaves a documented cold chain, the item is not returned but destroyed if not used.

We are requesting that the Service Surgeon Generals, ASD (Health Affairs) and the Defense Logistics Agency provide any documentation they have concerning known problems with quality control measures. We anticipate that our response will be provided to you within the next thirty days.

Should you have any questions, please contact me or Mr. Kelly Sharbel (703-695-2503) from the Office of the Assistant Secretary of Defense (Legislative Affairs). A similar letter has been sent to Senator John D. Rockefeller IV, the Ranking Member.

Sincerely,

Bernard Rostker

Enclosure

| DISEASE/AGENT/ EXPOSURE | PRODUCT NAME | CURRENT MANUFACTURER | PRODUCTION FACILITY ¹ | LICENSE STATUS | # DOSES FIELDED | # DOSES ADMINISTERED | |
|----------------------------|--------------|---|---|-------------------|--------------------|-------------------------|---|
| Anthrax | Vaccine | Anthrax Vaccine | Michigan Department of Public Health | Lansing Michigan | FDA Approved | 310,680 ² | Approx. 150,000 individuals vaccinated |
| | Treatment | Ciprofloxacin ³ | Bayer (Miles) | Pittsburgh, PA | FDA Approved | 370,250 ² | See footnote 2 |
| Plague | Vaccine | Plague Vaccine | Miles Inc, Cutter Biological | Elkhart, IN | FDA Approved | 302,240 ^{2,4} | See footnote 9 |
| | Treatment | Doxycycline ³ | Pfizer | Parippany, NJ | FDA Approved | 6,681,300 ² | See footnote 2 |
| Cholera | Vaccine | Cholera Vaccine | Wyeth-Ayerst | Philadelphia, PA | FDA Approved | 143,960 ^{2,4} | See footnote 9 |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Shigella | Vaccine | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Meningitis | Vaccine | Meningococcal Polysaccharide Vaccine | Connaught Laboratories | Swiftwater, PA | FDA Approved | 547,800 ² | See footnote 9 |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Hepatitis A | Vaccine | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable | |

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2. The number of doses fielded does not equate to the number of doses administered. The number of doses fielded were obtained through a search of the Defense Personnel Support Center archived logistic records for Operations Desert Shield/Desert Storm and reflects the amount of product ordered and sent through supply channels. In most cases, only review of each individual's medical treatment record would provide the actual number of doses administered. Few records were maintained by individuals when products were self-administered.
3. Although listed as a specific treatment, these antibiotics were indicated and prescribed for a variety of infectious diseases.
4. Although listed as being requisitioned for Operations Desert Shield/Desert Storm, these products were not recommended for routine use.
5. IG supplies were depleted during DS/DS and DoD negotiated with Sclavo, an Italian based vaccine manufacturer, to acquire IG from them. The product was tested and OK'd by the FDA, but never licensed by FDA for use in the US. Sclavo IG went to the Army supply depot in Germany, but was never shipped to the Gulf. None was administered to US troops, but instead the product was donated to other countries on behalf of the State Department.
6. For protection against chemical warfare agents, personnel were provided training, protective masks and clothing, and electronic early warning detection units. Mobile medical teams in theater provided instruction in the medical defense against chemical warfare agents. Selected individuals and units at risk were provided nerve agent antidote depending on the threat.
7. This list is not all-inclusive. U.S. service members received booster doses of routine immunizations IAW current DoD guidelines. Routine vaccines include typhoid, meningococcus, influenza, Yellow Fever, tetanus-diphtheria, and influenza. Additional immunizations are given for deployment to high-risk areas, to alert forces, as required by the host country, or as directed by the surgeons general. Vaccines include plague, cholera, rabies, and Japanese Encephalitis.
8. Total doses supplied from all manufacturers.
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|---------------------------------|------------------------------------|-------------------------|-------------------------------------|-------------------|--|-------------------------|
| Prophylaxis | Immune Serum Globulin ⁵ | Armour Pharmaceuticals | Collegeville, PA | FDA Approved | 918,390 ⁹ | See footnote 9 |
| Treatment | Medical Care as Required | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Smallpox | | | | | | |
| Vaccine | Smallpox Vaccine | Wyeth-Ayerst | Philadelphia, PA | FDA Approved | 600 | See footnote 9 |
| Prophylaxis | Vaccinia Immune Globulin | Baxter Healthcare Corp | Glendale, CA | FDA Approved | Not fielded | None used during DS/DS |
| Treatment | Medical Care as Required | Not Applicable. | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Viral Hemorrhagic Fevers | | | | | | |
| Vaccine | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Treatment | Ribavirin injection/capsules | ICN Pharmaceuticals | Covina, CA | IND #16666 | 2,400 vials/176 bottles of capsules | None used during DS/DS |
| | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Human Immunodeficiency Virus | | | | | | |
| Vaccine | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Other Retroviruses | | | | | | |
| Vaccine | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

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|---|----------------------------------|--------------------------------------|--|--------------------------|--------------------------|---|
| Botulism Vaccine Treatment | Pentavalent Botulinum Toxoid | Michigan Department of Public Health | Lansing Michigan | IND #BB 161 ⁴ | 137,850 ² | Approx. 8,000 individuals vaccinated |
| | Botulism Antitoxin | Connaught Laboratories | Swiftwater, PA | FDA Approved | 120 Vials ² | None used during DS/DS |
| | Botulism Antitoxin (Heptavalent) | University of Minnesota | Minneapolis, Minnesota | IND #3703 | 1,768 Vials ² | None used during DS/DS |
| | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Enterotoxigenic Escherichia Coli (ETEC) | Vaccine | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable |
| Chemical Warfare Agents ⁶ Vaccines Prophylaxis | No Product Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| | Pyridostigmine Bromide (PB) | Duphar Roche | Amsterdam, Netherlands United Kingdom | IND #23509 ⁴ | 5,328,710 ² | Command directed. Estimates are that up to 250,000 personnel took at least some PB ² . |

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|---|--|--|--|---|--|--|--|
| Treatment | Pralidoxime Chloride | Survival Technology Inc. | Rockville, MD | FDA Approved | 422,964 ² | Self administered ² | |
| | Atropine Sulfate | Survival Technology Inc. | Rockville, MD | FDA Approved | 759,306 ² | Self administered ² | |
| | Diazepam | Duphar | Amsterdam, Netherlands | FDA Approved | Not available | Self administered ² | |
| | M291 Skin Decontaminating Kit Medical Care as Required | PACO (Rohm & Haas) Not applicable | New Jersey Not applicable | FDA Approved Not applicable | Individual Issue Not applicable | Not applicable Not applicable | |
| Other Diseases or Exposures ⁷ | | | | | | | |
| Rabies | Vaccine | Rabies Vaccine | Pasteur Merieux | Lyon, France | FDA Approved | 4,153 ² | See footnote 9 |
| | Treatment | Rabies Immune Globulin Medical Care as Required | Miles Inc. Not applicable | Elkhart, IN Not applicable | FDA Approved Not applicable | 25,778 ² Not applicable | See footnote 9 Not applicable |
| Yellow Fever | Vaccine | Yellow Fever Vaccine | Connaught Laboratories | Swiftwater, PA | FDA Approved | 109,600 ² | See footnote 9 |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Tetanus | Vaccine | TetanusDiphtheria(Td) | Connaught Laboratories Lederle Laboratories Wyeth-Ayerst | Swiftwater, PA Pearl River, NY Philadelphia, PA | FDA Approved FDA Approved FDA Approved | 384,690 ⁸ | See footnote 9 |
| | Treatment | Tetanus Toxoid Human Tetanus Immune Globulin Medical Care as Required | Lederle Laboratories Miles Biologicals Not applicable | Pearl River, NY West Haven, CT Not applicable | FDA Approved FDA Approved Not applicable | Not fielded Not fielded Not applicable | Not fielded Not fielded Not applicable |

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| Typhoid | Vaccine | Typhoid Vaccine | Connaught Laboratories | Swiftwater, PA | FDA Approved | 609,700 ² | See footnote 9 |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Malaria | Vaccine | No Vaccine Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| | Prophylaxis | Chloroquine Phosphate Primaquine Phosphate | Sanofi Winthrop Sanofi Winthrop | New York, NY New York, NY | FDA Approved FDA Approved | 4,390,500 ² Not available | See footnote 2 Not applicable |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Dengue Fever | Vaccine | No Vaccine Fielded | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| | Treatment | Medical Care as Required (See Viral Hemorrhagic Fevers above) | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Hepatitis B | Vaccine | Hepatitis B Vaccine | Merck & Co. SmithKline Beecham | West Point, PA Philadelphia, PA | FDA Approved FDA Approved | 10,044 ^{2,8} | See footnote 9 |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| Influenza | Vaccine | Influenza Vaccine | Connaught Laboratories | Swiftwater, PA | FDA Approved | 168,360 ² | See footnote 9 |
| | Treatment | Medical Care as Required ⁷ | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

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|----------------------------|--------------|---------------------------------------|-------------------------------------|-------------------|--------------------|-------------------------|------------------|
| Septicemia | Vaccine | Centoxin (J-5 Monoclonal Antibody) | Centocor, Inc. | Malvern, PA | ND #BB2283 | Not available | Used in one case |
| | Treatment | Medical Care as Required | Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

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