

# APPENDIX I

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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 <sup>1</sup>	LICENSE STATUS	# DOSES FIELDED	# DOSES ADMINISTERED	
Anthrax	Vaccine	Anthrax Vaccine	Michigan Department of Public Health	Lansing Michigan	FDA Approved	310,680 <sup>2</sup>	Approx. 150,000 individuals vaccinated
	Treatment	Ciprofloxacin <sup>3</sup>	Bayer (Miles)	Pittsburgh, PA	FDA Approved	370,250 <sup>2</sup>	See footnote 2
Plague	Vaccine	Plague Vaccine	Miles Inc, Cutter Biological	Elkhart, IN	FDA Approved	302,240 <sup>2,4</sup>	See footnote 9
	Treatment	Doxycycline <sup>3</sup>	Pfizer	Parippany, NJ	FDA Approved	6,681,300 <sup>2</sup>	See footnote 2
Cholera	Vaccine	Cholera Vaccine	Wyeth-Ayerst	Philadelphia, PA	FDA Approved	143,960 <sup>2,4</sup>	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 <sup>2</sup>	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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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.
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Prophylaxis	Immune Serum Globulin <sup>5</sup>	Armour Pharmaceuticals	Collegeville, PA	FDA Approved	918,390 <sup>9</sup>	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 <sup>4</sup>	137,850 <sup>2</sup>	Approx. 8,000 individuals vaccinated
	Botulism Antitoxin	Connaught Laboratories	Swiftwater, PA	FDA Approved	120 Vials <sup>2</sup>	None used during DS/DS
	Botulism Antitoxin (Heptavalent)	University of Minnesota	Minneapolis, Minnesota	IND #3703	1,768 Vials <sup>2</sup>	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 <sup>6</sup> 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 <sup>4</sup>	5,328,710 <sup>2</sup>	Command directed. Estimates are that up to 250,000 personnel took at least some PB <sup>2</sup> .

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Treatment	Pralidoxime Chloride	Survival Technology Inc.	Rockville, MD	FDA Approved	422,964 <sup>2</sup>	Self administered <sup>2</sup>	
	Atropine Sulfate	Survival Technology Inc.	Rockville, MD	FDA Approved	759,306 <sup>2</sup>	Self administered <sup>2</sup>	
	Diazepam	Duphar	Amsterdam, Netherlands	FDA Approved	Not available	Self administered <sup>2</sup>	
	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	
<b>Other Diseases or Exposures <sup>7</sup></b>							
Rabies	Vaccine	Rabies Vaccine	Pasteur Merieux	Lyon, France	FDA Approved	4,153 <sup>2</sup>	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 <sup>2</sup> Not applicable	See footnote 9 Not applicable
Yellow Fever	Vaccine	Yellow Fever Vaccine	Connaught Laboratories	Swiftwater, PA	FDA Approved	109,600 <sup>2</sup>	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 <sup>8</sup>	See footnote 9
	Treatment	Tetanus Toxoid	Lederle Laboratories	Pearl River, NY	FDA Approved	Not fielded	Not fielded
		Human Tetanus Immune Globulin Medical Care as Required	Miles Biologicals Not applicable	West Haven, CT Not applicable	FDA Approved Not applicable	Not fielded Not applicable	Not fielded Not applicable

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Typhoid	Vaccine	Typhoid Vaccine	Connaught Laboratories	Swiftwater, PA	FDA Approved	609,700 <sup>2</sup>	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 <sup>2</sup> 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 <sup>2,8</sup>	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 <sup>2</sup>	See footnote 9
	Treatment	Medical Care as Required <sup>7</sup>	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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