

UNCLASSIFIED

Medical Products for Supporting Military Readiness

Vaccines & Drugs
(Go Book)



December 1999

U.S. Army Medical Research and Materiel Command

Protect, Project, Sustain

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DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

14 DEC 1999

Office of the Commanding General

The U.S. Army Medical Research and Materiel Command (USAMRMC) is responsible for solving medical problems and providing the solutions to the Armed Forces. In keeping with the goals of the USAMRMC to protect, project, and sustain our forces, this third edition of the "GO Book" provides information to facilitate planning and to assist Commanders in Chief (CINCs) in their preparations for operational readiness, international assistance missions, and warfighting. The information contained is current and timely for planning purposes.

The book begins with a map of regional CINC areas of responsibility followed by summary charts of the Diseases of Operational Importance during deployment and pre-deployment in these geographical areas. The introductory list of diseases was provided by the Armed Forces Medical Intelligence Center.

The book provides a list of products recommended for intervention when exposed to infectious disease, chemical, and biological threats. Most products listed are licensed or approved by the Food and Drug Administration. Several, however, are investigational products and special conditions apply for their use. A copy of the recent Presidential Executive Order 13139 is included as an Appendix and it outlines the required process for using investigational products.

While not a compendium of all medical products available for treatment in the supply system, the products listed emphasize protection of soldiers from exposure or morbidity to infectious diseases, and chemical and biological threats. Each product has an information paper that describes the status of the product and includes a point of contact (POC) for reference. Additionally, a list of DOD reference research laboratories is included for your information.

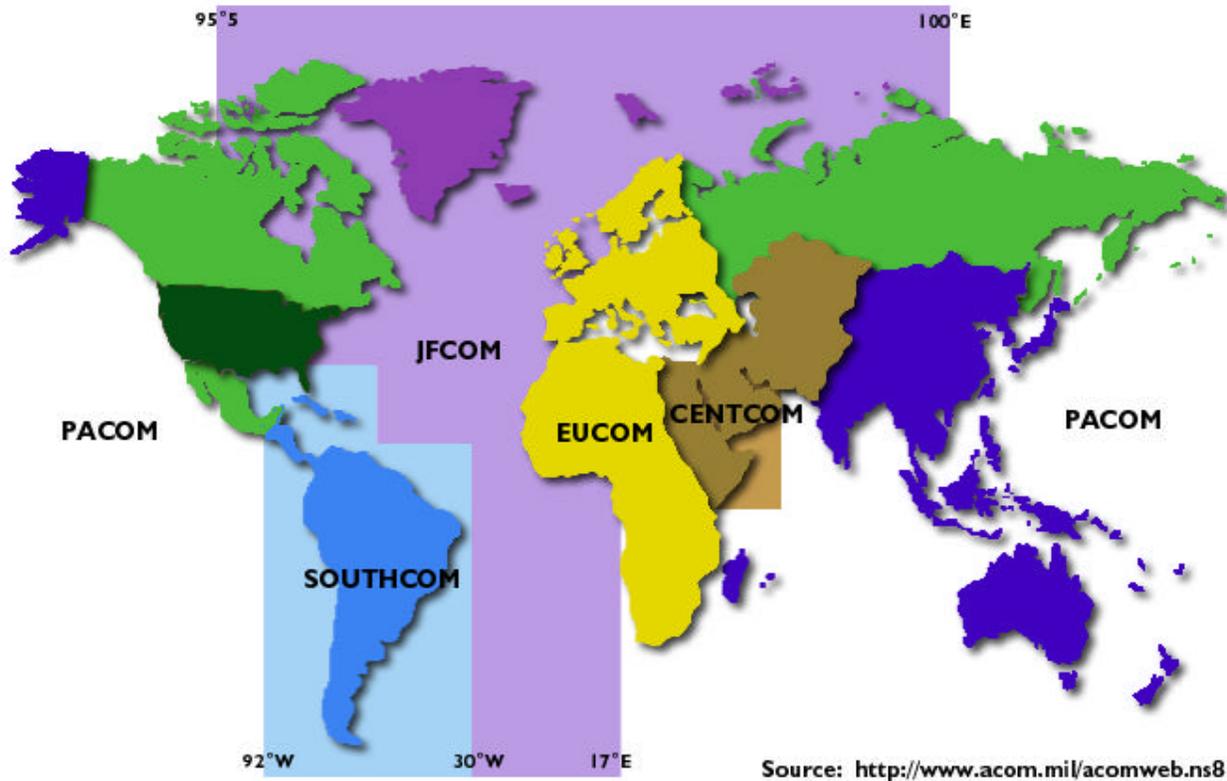
Thank you for the opportunity to provide this valuable resource. My POC for acquiring copies of this book is the Secretary of the General Staff, Headquarters, USAMRMC, Fort Detrick, Maryland, at 301-619-7111 or DSN 343-7111.

John S. Parker
Major General, Medical Corps
Commander

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CINC Areas of Responsibility



Diseases of Operational Importance, During Deployment*

	Regional CINC			
	USSOUTHCOM	USEUCOM	USCENTCOM	USPACOM
<i>Food- or Water-borne Diseases</i>				
Bacterial/Protozoal/Viral Diarrheal	X	X	X	X
Cholera	X	X	X	X
Hepatitis A	X	X	X	X
Hepatitis E	X	X	X	X
Typhoid Fever/Paratyphoid Fever	X	X	X	X
<i>Respiratory-borne Diseases</i>				
Acute Bacterial/Viral Diseases	X	X	X	X
Meningococcal Meningitis	X	X	X	X
Tuberculosis	X	X	X	X
<i>Sexually Transmitted and/or Blood-borne Diseases</i>				
Gonorrhea/Chlamydia/others	X	X	X	X
HIV/AIDS	X	X	X	X
Hepatitis B	X	X	X	X
Hepatitis C	X	X	X	X
Hepatitis D	X	X	X	X
<i>Vector-borne Diseases</i>				
California group Encephalitides		X	X	X
Chikungunya		X	X	X
Crimean-Congo Hemorrhagic Fever		X	X	X
Dengue Fever	X	X	X	X
Japanese Encephalitis			X	X
Leishmaniasis, Cutaneous	X	X	X	X
Leishmaniasis, Visceral	X	X	X	X
Lyme	?	X	X	X
Malaria	X	X	X	X
Mayaro	X			
Omsk Fever				X
Oropouche	X			
Plague	X	X	X	X
Rift Valley Fever		X	X	
Sandfly Fever	X	X	X	X
Sindbis		X	X	X
Spotted Fever Group, Rickettsiosis	X	X	X	X
Tick-borne Encephalitis		X	X	X
Trypanosomiasis	X	X	X	
Typhus, Epidemic (louse-borne)	X	X	X	X
Typhus, Murine (flea-borne)	X	X	X	X
Typhus, Scrub			X	X

Diseases of Operational Importance, During Deployment* - cont.

	Regional CINC			
	USSOUTHCOM	USEUCOM	USCENTCOM	USPACOM
<i>Vector-borne Diseases – cont.</i>				
Venezuelan Equine Encephalitis	X			
West Nile Fever		X	X	X
Yellow Fever	X	X	X	
<i>Animal Associated Diseases</i>				
Anthrax	X	X	X	X
Brucellosis	X	X	X	X
Hantavirus Pulmonary Syndrome	X			
Hantavirus Renal Syndrome		X	X	X
Leptospirosis	X	X	X	X
Q-fever	X	X	X	X
Rabies	X	X	X	X
Tularemia		X	X	X
<i>Other Endemic Diseases</i>				
Schistosomiasis	X	X	X	X

? = serology only

* = From Armed Forces Medical Information Center

Note: Some other disease-causing agents of special concern include Botulinum toxins, Smallpox virus, chemical nerve agents and chemical vesicants.

Diseases of Operational Importance, Pre-Deployment

<i>Respiratory-borne Diseases</i>	
Adenovirus Pneumonia	Basic Training Centers
Diphtheria	Basic Training Centers
Influenza	Annual Requirement All Posts
Measles	Basic Training Centers
Meningococcal Meningitis	Basic Training Centers
Mumps	Basic Training Centers
Pneumococcal Pneumonia	As indicated
Rubella	Basic Training Centers
Streptococcal Group A	Basic Training Centers
Varicella	As indicated
<i>Other Diseases</i>	
Polio	Basic Training Centers
Tetanus	Basic Training Centers

Product Listing

Disease	Product	NSN	Info Page #
Adenovirus	Adenovirus Vaccine, Type 4, Live, Oral	6505011052313	A-1
	Adenovirus Vaccine, Type 7, Live, Oral	6505011052314	A-2
Anthrax (Bacillus anthracis)	Anthrax Vaccine, Adsorbed	N/A	B-1
Botulism	Botulinum Toxoid Vaccine, Pentavalent	N/A	B-3
Cholera	Cholera Vaccine	6505001601500	A-5
Crimean-Congo Hemorrhagic Fever (CCHF)	Ribavirin	N/A	A-34
Hantavirus Hemorrhagic Fever with Renal Syndrome (HFRS)	Ribavirin	N/A	A-34
Hepatitis A	Hepatitis A Vaccine, Inactivated	6505014320376	A-8
	Immune Globulin, Human U.S.P.	6505001536276	A-13
Hepatitis B	Hepatitis B Vaccine (Recombinant)	6505012663780	A-10
Influenza	Influenza Virus Vaccine 10 Dose Vial	6505014604731	A-14
	Influenza Virus Vaccine 1 ml Needle Unit	6505014604740	A-14
	Influenza Virus Vaccine 0.5 ml Needle Unit	6505014604746	A-14
Japanese Encephalitis	Japanese Encephalitis Vaccine, Inactivated, 3 Dose	6505013806465	A-15
	Japanese Encephalitis Vaccine, Inactivated, 10 Dose	6505013561194	A-15
Leishmaniasis	AmBisome	N/A	A-3
	Pentostam (WR 229, 870)	N/A	A-26
Lyme Disease	Lyme Disease Vaccine (Recombinant OspA) (10s)	6505014626643	A-17
	Lyme Disease Vaccine (Recombinant OspA) (5s)	6505014626648	A-17
Malaria	Chloroquine Phosphate	6505001176450	A-4
	Doxycycline Hyclate	6505010954175	A-6
		6505011534335	A-6
	Halofantrine HCl (Halfan®)	6505013671331	A-7
	Mefloquine HCl	6505013151275	A-23
	Primaquine Phosphate	6505013482465	A-30
Measles	Measles Virus Vaccine, Live Attenuated	6505010380794	A-18
& Rubella	Measles & Rubella Vaccine, Live (M-R-Vax)	6505010988004	A-19
& Mumps & Rubella	Measles, Mumps & Rubella Vaccine, Live	6505001656519	A-21
Meningococcal Disease	Meningococcal Vaccine (A/C/Y/W-135)	6505011313436	A-24
Mumps	Mumps Virus Vaccine, Live	6505010376792	A-25
Nerve Agents	Diazepam, Convulsant Antidote for Nerve Agent (CANA)	6505012740951	C-2
	Atropine, Aerosolized (Medical Aerosolized Nerve Agent Antidote [MANAA])		C-1
	Nerve Agent Antidote Kit (Mark I)/Pralidoxime Cl	6505011253248	C-3
Nerve Agents (Liquid), Vesicants	Skin Decontamination Kit (M291)	6850012761905	C-5
Nerve Agents (Soman, Tabun)	Nerve Agent Pretreatment Pyridostigmine (NAPP)	6505011787903	C-4

Product Listing – cont.

Disease	Product	NSN	Info Page #
Plague	Plague Vaccine	6505009351128	B-5
Pneumococcal Disease	Pneumococcal Vaccine	6505010920391	A-27
Polio	Poliovirus Vaccine, Inactivated, 1 Dose	6505013476834	A-28
	Poliovirus Vaccine, Inactivated, 10 Dose	6505013539866	A-28
	Poliovirus Vaccine, Live, Oral	6505011858848	A-29
Rabies	Rabies Immune Globulin (Human), USP	6505010670807	A-31
	Rabies Vaccine, Human Diploid Cell	6505010916063	A-32
Rift Valley Fever (RVF)	Ribavirin	6505012638166	A-34
Rubella	Rubella Virus Vaccine, Live	6505001450180	A-36
Smallpox	Smallpox Vaccine (Vaccinia)	N/A	B-7
Tetanus	Human Tetanus Immune Globulin	6505013327888	A-12
	Tetanus Toxoid	6505006855189	A-39
& Diphtheria	Tetanus & Diphtheria Toxoid, 5 ml	6505002998296	A-37
	Tetanus & Diphtheria Toxoid, 30 ml	6505008645249	A-37
Tick-Borne Encephalitis (TBE)	Tick-Borne Encephalitis Vaccine, Inactivated	N/A	A-40
Typhoid	Typhoid Vaccine; Live, Oral Ty21a	6505013246964	A-41
	Typhoid Vi Polysaccharide Vaccine	6505013856328	A-42
Varicella	Varicella Vaccine	N/A	A-43
Yellow Fever Virus	Yellow Fever Vaccine	6505001621520	A-44

**DoD Medical Research Laboratories
for Infectious Disease Diagnosis**

		CINC Region
<u>U.S. Army</u>		
Walter Reed Army Institute of Research Silver Spring, MD 301-319-9262	(WRAIR)	CONUS
U.S. Army Research Institute of Infectious Diseases Fort Detrick, MD 301-619-2833	(USAMRIID)	CONUS
Armed Forces Research Institute of Medical Science Bangkok, Thailand 66-2-245-7284	(AFRIMS)	USPACOM
U.S. Army Medical Research Unit – Kenya Nairobi, Kenya 254-2-729-303	(USAMRU-K)	USEUCOM
<u>U.S. Navy</u>		
Naval Medical Research Center Silver Spring, MD 301-319-7401	(NMRC)	CONUS
Naval Medical Research Institute Detachment Lima, Peru 51-1-561-2882 or 2733 or 3043	(NAMRID)	USSOUTHCOM
Naval Medical Research Unit, No. 2 Jakarta, Indonesia 62-21-421-4457	(NAMRU-2)	USPACOM
Naval Medical Research Unit, No. 3 Cairo, Egypt 202-2-841-375	(NAMRU-3)	USCENTCOM
Naval Health Research Center San Diego, CA 619-553-9967	(NHRC)	CONUS

Infectious Disease Products Supporting Readiness

(Go Book)

Licensed Product	Adenovirus Vaccine, Type 4, Live, Oral
Countermeasure to	Acute, febrile respiratory tract infections caused by adenovirus Type 4 infection
Status	FDA licensed
Availability	Unavailable, out of production
Manufacturer	No manufacturer
POC	Research Area Manager, Military Infectious Disease Research Program, 301-619-7567

Product Description	This vaccine contains a selected viable strain of Type 4 adenovirus prepared from tissue cultures of human diploid fibroblast cells (Strain WI 38). The vaccine is formulated as an enteric-coated tablet containing not less than 32,000 tissue-culture infective doses.
Effectiveness	The use of adenovirus vaccines has been shown to achieve dramatic reduction in the occurrence of disease and associated hospital admissions in military environments during basic combat training.
Dose & Administration	Single tablet taken orally without chewing, preferably 2-4 weeks prior to exposure. May be administered simultaneously with the Type 7 vaccine.
Side Effects	Administration of vaccine to several hundred thousand military recipients has been accomplished without evidence of untoward effects.
Shipping/Handling Requirements	Maintain tablets at 2-8°C.
Other Available Countermeasures	Adenovirus Type 7 vaccine (described elsewhere in this <i>Go Book</i>)
Contingency Protocol	N/A
Note	New manufacturer is being sought.

Licensed Product	Adenovirus Vaccine, Type 7, Live, Oral
Countermeasure to	Acute, febrile respiratory tract infections caused by Adenovirus Type 7 infection
Status	FDA licensed
Availability	Unavailable, out of production
Manufacturer	No manufacturer
POC	Research Area Manager, Military Infectious Disease Research Program, 301-619-7567

Product Description	This vaccine contains a selected viable strain of Type 7 adenovirus prepared from tissue cultures of human diploid fibroblast cells (Strain WI 38). The vaccine is formulated as an enteric -coated tablet containing not less than 32,000 tissue-culture infective doses.
Effectiveness	The use of adenovirus vaccines has been shown to achieve dramatic reduction in the occurrence of disease and associated hospital admissions in military environments during basic combat training.
Dose & Administration	Single tablet taken orally without chewing, preferably 2-4 weeks prior to exposure. May be administered simultaneously with the Type 4 vaccine.
Side Effects	Administration of vaccine to several hundred thousand military recipients has been accomplished without evidence of untoward effects.
Shipping/Handling Requirements	Maintain tablets at 2-8°C.
Other Available Countermeasures	Adenovirus Type 4 vaccine (described elsewhere in this <i>Go Book</i>)
Contingency Protocol	N/A
Note	New manufacturer is being sought.

Licensed Product	AmBisome
Countermeasure to	Leishmaniasis, visceral
Status	FDA approved
Availability	Available
Manufacturer	Fujisawa Healthcare, Inc., Parkway North Center, 3 Parkway North, Deerfield, IL 60015-2548, 847-317-8800
POC	Prime Vendor

Product Description	AmBisome is a sterile, non-pyrogenic, lyophilized product for intravenous infusion. Each vial contains 50 mg of Amphotericin B, USP, intercalated into a liposomal membrane.
Effectiveness	AmBisome is approved for the treatment of visceral leishmaniasis. In controlled studies of its efficacy, cure rates >98% were achieved.
Dose & Administration	The drug is administered intravenously using controlled infusion device over a period of approximately 120 minutes. The dosage recommended for visceral leishmaniasis is 3 mg/kg/day on days 1-5 and days 14 and 21. Higher doses for longer periods may be required for immunocompromised patients. Contents of the vial <u>must</u> be reconstituted with sterile water. Do Not Use Saline.
Side Effects	In a study of patients given AmBisome (343) or Amphotericin B (344), the incidence of infusion-related cardiorespiratory events (hypotension, tachycardia, hypertension, dyspnea, hyperventilation, and hypoxia) ranged from 0.3% to 5.2% in the former treatment group compared with 0.6% to 12.5% in the latter. AmBisome also had a lower incidence of chills, renal, hepatic, and serum electrolyte effects. Serum electrolytes, alkaline phosphatase, and creatinine should be monitored during administration of the drug.
Shipping/Handling Requirements	AmBisome for injection is available as single 50 mg vials or in packs of 10 individual vials with a prepackaged disposable 5 µ filter.
Other Available Countermeasures	Since visceral leishmaniasis is acquired by the bites of sand flies, insect control measures will reduce the risk of infection.
Contingency Protocol	N/A

Licensed Product	Chloroquine Phosphate
Countermeasure to	Malaria
Status	FDA approved
Availability	Available
Manufacturer	Sanofi Winthrop Pharmaceuticals, 90 Park Avenue, New York, NY 10016, 800-446-6267
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	An antimalarial drug for <i>Plasmodium vivax</i> , <i>P. malariae</i> , <i>P. ovale</i> , and <i>P. falciparum</i> infections available as 500 mg (=300 mg base) tablets for oral administration.
Effectiveness	Chloroquine phosphate is indicated for suppressive treatment and for acute attacks of malaria due to <i>P. vivax</i> , <i>P. malariae</i> , <i>P. ovale</i> , and susceptible strains of <i>P. falciparum</i> . It does not prevent relapses in patients with <i>P. vivax</i> and <i>P. malariae</i> infections, and must be followed with primaquine to effect radical cure of these diseases. Because of the increasing frequency of parasite resistance to chloroquine, the drug is considered most useful for prophylaxis in Mexico, Central America and limited areas of the Middle East.
Dose & Administration	For suppression: one 500 mg tablet taken orally once a week beginning 2 weeks prior to departure to endemic areas and continued for 8 additional weeks upon return. For treatment: an initial dose of two 500 mg tablets followed by an additional 500 mg tablet after 6-8 hours, and a single dose of one 500 mg tablet on each of two consecutive days for a total of five tablets in 3 days.
Side Effects	The most frequently observed side effects include gastrointestinal reactions such as anorexia, nausea, vomiting, diarrhea, and abdominal cramps. Mild and transient headache, tinnitus, and nerve type deafness have been reported. Ocular reactions including blurred vision, and difficulty in focusing or accommodation may also occur. Long-term or high-dosage therapy may result in irreversible retinal damage. This product should be administered with caution to patients having G-6-PD (glucose-6-phosphate dehydrogenase) deficiency.
Shipping/Handling Requirements	Available in bottles of 25 tablets.
Other Available Countermeasures	Other antimalarial drugs and vaccines are either FDA approved or in various stages of advanced development.
Contingency Protocol	N/A

RDA Product	Cholera Vaccine
Countermeasure to	Cholera
Status	FDA licensed
Availability	Available, but not recommended
Manufacturer	Wyeth-Ayerst, P.O. Box 8299, Philadelphia, PA 19101, 610-688-4400
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Sterile suspension of equal parts of phenol-killed Ogawa and Inaba serotypes of <i>Vibrio cholerae</i> .
Effectiveness	This cholera vaccine does not prevent transmission of infection, and is not recommended by the World Health Organization, or the DoD.
Dose & Administration	The primary immunizing course consists of two doses administered 7-30 days apart. Vaccine may be administered subcutaneously, intramuscularly or intradermally. For persons over 10 years, individual doses (for both primary series and boosters) are 0.5 ml for either subcutaneous or intramuscular routes. Subsequent single booster doses should be given every 6 months to those entering endemic areas.
Side Effects	Typical local injection site reactions may occur and persist for a few days. Other fairly common reactions include malaise, headache, and mild-to-moderate temperatures that persist for 1-2 days.
Shipping/Handling Requirements	Store between 35-46°F, do not freeze.
Other Available Countermeasures	Treatment: Rehydration orally if possible; tetracycline 2 gms per day in divided doses Prevention: Cholera vaccine, whole cell with B subunit.
Contingency Protocol	N/A

Approved Product	Doxycycline Hyclate
Countermeasure to	Malaria
Status	FDA approved
Availability	Available
Manufacturer	Pfizer, Inc. Consumer Health Care, 235 E. 42nd Street, New York, NY 10017-5755, 212-573-5656
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	An antimalarial primarily for prevention of <i>P. falciparum</i> infections available as 100 mg tablets for oral administration. Supplied in 50 and 500 tablet bottles.
Effectiveness	Doxycycline is indicated for the prophylaxis of malaria due to <i>Plasmodium falciparum</i> ; it is less effective against <i>P. vivax</i> infections. It is effective against the asexual, erythrocytic forms of <i>P. falciparum</i> , but not the exoerythrocytic gametocytes.
Dose & Administration	For prophylaxis: one 100 mg tablet taken orally daily beginning 1-2 days prior to departure to endemic areas, throughout the stay in the area, and continued for 4 weeks upon return. Regimen should not continue for longer than 4 months.
Side Effects	The most frequently observed side effects include nausea and epigastric distress; less frequent are incidents of diarrhea and vomiting. Stomach and esophageal ulceration has been reported. The frequency and severity of gastrointestinal side effects may be reduced by taking doxycycline with meals. Absorption of this drug is impaired by antacids containing aluminum, calcium, magnesium, iron, or bismuth subsalicylate.
Shipping/Handling Requirements	Store below 30°C (86°F); store in dry place in light-resistant containers.
Other Available Countermeasures	Other antimalarial drugs and vaccines are either FDA approved or in various stages of advanced development.
Contingency Protocol	N/A

Approved Product	Halofantrine HCl (Halfan®)
Countermeasure to	Falciparum and Vivax Malaria
Status	FDA approved for treatment only
Availability	Available in the UK – not yet marketed in the U.S.
Manufacturer	SmithKline Beecham Pharmaceuticals, New Horizons Court, Brentford, Middlesex TW 8 9EP, UK
POC	Director, U.S. Army Medical Materiel Development Activity Fort Detrick, MD 21702, 301-619-7643

Product Description	A phenanthrenemethanol discovered and developed by WRAIR, and subsequently co-developed by SmithKline Beecham, Halfan® 250 mg tablets are indicated for the treatment of adults who can tolerate oral medication and who have mild to moderate malaria caused by <i>P. falciparum</i> and <i>P. vivax</i> .
Effectiveness	Halofantrine HCl is effective against chloroquine-sensitive and chloroquine-resistant <i>P. falciparum</i> . It is also effective against <i>P. vivax</i> and some strains of <i>P. falciparum</i> which are multi-drug resistant. There may be cross-resistance to mefloquine in certain endemic areas.
Dose & Administration	For Treatment: Halfan® 500 mg (2 x 250 mg tablets) every 6 hours for 3 doses (total first course dose 1,500 mg). This course of therapy should be repeated 7 days after the first course. Should be taken on an empty stomach (i.e., no food 2 hours before or 2 hours after each dose).
Side Effects	Generally well-tolerated. May cause gastrointestinal symptoms, including diarrhea. In doses higher than normal or when taken with food containing fat can cause prolongation of QT interval. Prior treatment with mefloquine increases the likelihood of QT interval prolongation. Can lead to torsade-de-pointes in individuals with congenital prolonged QT syndrome.
Shipping/Handling Requirements	Available in blister packs containing 6 tablets each.
Other Available Countermeasures	Other antimalarial drugs are either FDA approved or in various stages of advanced development.
Contingency Protocol	N/A

Licensed Product	Hepatitis A Vaccine, Inactivated
Countermeasure to	Hepatitis A virus
Status	FDA licensed
Availability	Available
Manufacturer	SmithKline Beecham Pharmaceuticals, P.O. Box 7929, Philadelphia, PA 19101, 215-751-4000 Merck & Co. Inc., P.O. Box 4, West Point, PA 19486-0004 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Both the SmithKline Beecham and Merck vaccines are formalin-inactivated Hepatitis A virus suspensions in aluminum hydroxide (alum) ready for intramuscular injection. Virus particles are derived from human diploid cell cultures.
Effectiveness	SmithKline Beecham Vaccine: In clinical studies of over 400 adults, 96% of subjects developed antibody within 1 month of a single 1.0 ml dose (80%-98% developed antibody within 15 days). 100% of 269 vaccines produced protective antibodies (within 1 month) after a booster dose was given 6 months after the primary injection. Based on data from clinical trials in 19,000 Thai children, the protective efficacy was determined to be 94%. Merck Vaccine: 95% of adults, 18 years of age developed serum antibody within 4 weeks after a single 1.0 ml dose. Serum antibody was detected in 100% of 1,152 adults following a booster dose at 6 months. Based on a clinical trial in 1,037 U.S. children, the protective efficacy was determined to be 100% after a single dose.
Dose & Administration	SmithKline Beecham Vaccine: Primary immunization is a single 1.0 ml dose administered in a deltoid region followed by a 1.0 ml booster dose at 6-12 months. Merck Vaccine: Primary immunization is a single 1.0 ml intramuscular dose followed by a 1.0 ml booster dose 6 months later. Either product may be given simultaneously with human immune globulin injected in a different site in order to obtain immediate protection. Serum antibody levels to the vaccine may be somewhat lower than when vaccine is given alone; however, protection from disease has not been shown to be decreased.
Side Effects	SmithKline Beecham Vaccine: The most frequent side effects in adults were injection-site pain (56%) and headache (14%). Most events were considered mild and did not last for more than 24 hours. Merck Vaccine: Injection-site tenderness (52.6%), pain (51.1%), and headache (16.1%) are the most common complaints seen in adults. Complaints are generally mild and transient.

Shipping/Handling Requirements	Store between 2-8°C; do not freeze. Both products are supplied in single dose vials or prefilled disposable syringes.
Other Available Countermeasures	Immune globulin is available for induction of passive immunity.
Contingency Protocol	N/A

Licensed Product	Hepatitis B Vaccine (Recombinant)
Countermeasure to	Hepatitis B virus
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372 SmithKline Beecham Pharmaceuticals, P.O. Box 7929, Philadelphia, PA 19101, 215-751-4000
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Both the Merck and the SmithKline Beecham vaccines are non-infectious subunit vaccines derived from Hepatitis B surface antigen (HBsAg) produced in yeast cells.
Effectiveness	Merck Vaccine: For 1,213 adults receiving a 3 dose regimen, vaccination produced protective antibodies in 96%. SmithKline Beecham Vaccine: Following vaccination with the recommended 3 dose regimen, protection was observed in 79% at 6 months and 96% after the seventh month in healthy adults and adolescents.
Dose & Administration	Merck Vaccine: The recommended dose regimen is 3 doses administered IM in the deltoid muscle at day 0, 1 month and 6 months. The recommended dose varies with age: for persons <20 yrs, administer three 0.5 ml doses. For persons >20 yrs, administer three 1.0 ml doses. SmithKline Beecham Vaccine: Recommended: 1.0 ml administered IM into deltoid muscle at day 0, 1 month, and 6 months. An alternative regimen (3 doses) for travelers to high risk areas is also recommended, consisting of doses at 0, 1 month, and 2 months. Though no efficacy data are available for exposed persons, it is recommended that they receive Hepatitis B immune globulin (0.06 ml IM) as soon as possible, followed by recommended 3 dose Hepatitis B vaccination initiated within 7 days.
Side Effects	Merck Vaccine: Side effects occurring after <1% of injections: fatigue, weakness, headache, fever >100°F, as well as injection site reactions (i.e., pain, redness, swelling). SmithKline Beecham Vaccine: Side effects recorded from 1% -10% of injections: fever (>100°F), headache, dizziness, as well as injection site reactions (pain, swelling, etc).
Shipping/Handling Requirements	Vaccine requires no reconstitution; store at 36-46°F.

**Other Available
Countermeasures**

Hepatitis B immune globulin for infants whose mothers are carriers of Hepatitis B virus.

**Contingency
Protocol**

N/A

Licensed Product	Human Tetanus Immune Globulin
Countermeasure to	Exotoxin of tetanus organism <i>Clostridium tetani</i>
Status	FDA licensed
Availability	Available
Manufacturer	Bayer Corporation, Pharmaceutical Division, Biologic Products, 400 Morgan Lane, West Haven, CT 06516, 800-468-0894
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Sterile solution of tetanus hyperimmune immunoglobulin pooled from individuals immunized with tetanus toxoid vaccine. The solution is 15%-18% protein, of which 90% is IgG.
Effectiveness	Although multiple studies indicate treatment with doses ranging from 500-8,000 antitoxin units reduces mortality, an optimal total dose has not been determined.
Dose & Administration	Recommended for administration during the initiation of active immunization with tetanus toxoid vaccines: 250 units should be administered by deep IM injection. For wound management treatment, dosing depends on the vaccination status of the individual. For persons known to have completed active tetanus immunization, no immune globulin is required if last immunization was <10 years prior for clean, minor wounds and <5 years prior for other wounds. For all wounds other than clean, minor wounds, if last immunization was >5 years prior, administer 250 units by deep IM injection along with a tetanus/diphtheria toxoid booster.
Side Effects	No major side effects other than soreness at injection site and occasional mild fever.
Shipping/Handling Requirements	Maintain at 2-8°C.
Other Available Countermeasures	See tetanus toxoid and tetanus/diphtheria combination toxoid vaccines.
Contingency Protocol	N/A

Licensed Product	Immune Globulin, Human U.S.P.
Countermeasure to	Hepatitis A
Status	FDA licensed
Availability	Available
Manufacturer	Centeon L.L.C., 1020 First Avenue, King of Prussia, PA 19406-1310, 800-683-1288
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	A sterile solution of immunoglobulin principally IgG, containing approximately 17% protein. Product is intended for intramuscular injection to provide passive immunity to hepatitis A.
Effectiveness	Peak IgG levels are obtained within 2 days of injection, with a plasma half-life in normal individuals of 23 days. Passive immunization with immune globulin attenuates hepatitis A, and its prophylactic value is maximized when given before or soon after exposure.
Dose & Administration	For persons entering endemic areas, the dose depends on the anticipated length of stay. For less than 3 months, 0.02 ml/kg administered IM in the gluteal region is recommended. For greater than 3 months, 0.06 ml/kg is recommended, repeated every 4-6 months. Total doses over 10 ml should be divided and injected in several muscle sites to reduce local pain and discomfort.
Side Effects	Local pain at the injection site, hives and angioedema may occur. Anaphylactic reactions have been noted but are rare.
Shipping/Handling Requirements	Store at 2-8°C (35-46°F). Do not freeze. Do not use past expiration date. Visually inspect for the presence of particulate matter and discoloration. If present, discard.
Other Available Countermeasures	Hepatitis A Vaccine.
Contingency Protocol	N/A

Licensed Product	Influenza Virus Vaccine, Trivalent Types A and B 1999-2000 Formula
Countermeasure to	Selected strains of influenza virus
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE Wyeth-Ayerst, P.O. Box 8299, Philadelphia, PA 19101, 610-688-4400
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	The 1999-2000 formula is a sterile suspension for intramuscular injection containing formaldehyde-inactivated influenza virus harvested from infected chick embryos. It contains 45 micrograms (µg) hemagglutinin per 0.5 ml dose, combining 15 µg each of the following strains: A/Beijing/262/95 (H1N1), A/Sydney/05/97 (H3N2), and B/Beijing/184/93, according to recommendations of the USPHS. Whole virion (Connaught) and split virion (Wyeth-Ayerst) formulations are available. The injectable solution is essentially clear and slightly opalescent in color. It should be noted that influenza vaccines are updated annually to incorporate antigen characteristics of each year's current strains.
Effectiveness	Most vaccinated children and young adults develop high post-vaccination hemagglutinin-inhibition antibody titers that protect against infection by strains similar to those in the vaccine and related variants. The effectiveness of a current year's influenza vaccine in preventing or attenuating illness varies, depending on the similarity between vaccine strains and viruses circulating in the population. When there is a good match, the protective efficacy is typically 70% in young adults.
Dose & Administration	For persons >12 years of age, immunization consists of a single 0.5 ml injection administered IM in the deltoid muscle.
Side Effects	The composition of influenza vaccines rarely causes systemic or febrile reactions. It cannot cause influenza. The most frequent side effect is soreness at the infection site.
Shipping/Handling Requirements	Store between 2-8°C (35-46°F). Do not freeze.
Other Available Countermeasures	Each year, a new formulation of the influenza vaccine is developed.
Contingency Protocol	N/A

Licensed Product	Japanese Encephalitis Vaccine, Inactivated
Countermeasure to	Japanese encephalitis virus
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation for reconstitution consisting of formaldehyde-inactivated Japanese encephalitis virus (Nakayama - NIH strain) derived from infected mouse brains.
Effectiveness	The precise relationship between antibody level and efficacy has not been established. Tests in 43,708 Thai children vaccinated with two 1.0 ml doses of JE vaccine resulted in only 2 cases of JE. Three-dose vaccination is recommended by CDC for full immunogenicity. CDC experience shows neutralizing antibodies in >80% following two doses, falling rapidly after 6 months, for most JE vaccines. Two 3-dose regimens (0, 7 & 14 days vs. 0, 7 & 30 days) were evaluated for immunogenicity in 538 people. All had neutralizing antibodies at 2 and 6 months. Persons given a third dose on day 30 initially showed higher antibody response, but no difference in antibody levels was observed after 12 months. Duration of protection is unknown. Follow-up study in 273 of initial 538 subjects tested the effectiveness of boosting. 252 out of 273 persons were boosted at 1 year - all had antibody 1 year post-booster. Antibody persisted for 2 years in the other 12 persons who did not receive boosters.
Dose & Administration	Three 1.0 ml doses given subcutaneously on days 0, 7, & 30 is recommended (alternate schedule of 0, 7 & 14 days can be used if recommended regimen is impractical due to time constraints). When neither 3-day schedule is possible, two doses given a week apart will produce protective antibodies in about 80%. A single 1.0 ml booster dose may be given subcutaneously after 2 years. Efficacy of additional boosters beyond 2 yrs has not been tested. Vaccinated persons should be monitored for 30 min and have ready access to medical care for 10 days after vaccination. Injectable epinephrine should be immediately available in the event of anaphylactic reactions (severe allergic reaction with shock).
Side Effects	Headache, rash, edema and generalized hives or angioedema may occur usually within 10 days (most within 2 days, some up to 17 days) of vaccination. Side effects are more likely in persons with history of hives. An Army study of 4,034 showed arm soreness (23%), local redness (5%), headache (15%), and fever (6%). In a 3-dose vaccination study in 538 persons, incidence of side effects diminishes for subsequent doses. Less than 1% of side effects were reported as severe. Data from a Navy immunization program of 35,253 persons showed allergic reactions (rash, wheezing) occurring in about 63 per 10,000 persons, none of the reactions were considered life-threatening.

Shipping/Handling Requirements	Reconstituted vaccine should be stored at 35-46°F and used within 8 hours. Inspect for discoloration and presence of particulate matter; if present, do not administer. Reconstituted vaccine is a clear, colorless liquid.
Other Available Countermeasures	Symptomatic and supportive care if sick. Use of skin and clothing insect repellents to prevent infection.
Contingency Protocol	N/A

Licensed Product	Lyme Disease Vaccine (Recombinant OspA)
Countermeasure to	Lyme Disease transmitted by ticks
Status	FDA licensed
Availability	Available
Manufacturer	SmithKline Beecham Pharmaceuticals, P.O. Box 7929, Philadelphia, PA 19101, 215-751-4000
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	A noninfectious recombinant vaccine consisting of lipoprotein OspA, an outer surface protein of <i>Borrelia burgdorferi</i> expressed in <i>E. coli</i> . The vaccine is adsorbed onto aluminum hydroxide.
Effectiveness	In a randomized, double-blind, placebo-controlled trial of 10,936 individuals ranging from 15 to 70 years of age at 31 U.S. sites in endemic areas, the vaccine demonstrated efficacy rates of 78% against definite Lyme disease and 100% against asymptomatic infection after a complete immunization series.
Dose & Administration	Three 0.5 ml intramuscular doses injected at 0, 1, and 12 months. Vaccine is approved for individuals 15 to 70 years of age.
Side Effects	The most common symptoms reported following 3 doses are injection site pain (21.87% recipients), myalgia (4.83%), fever (2.58%), influenza-like symptoms (2.54%), and chills (2.05%). All symptoms were most frequent following the first dose and much less frequent with subsequent doses.
Shipping/Handling Requirements	Packaged in single dose syringes. Store at 2-8°C (36-46°F). Do not freeze. If vaccine is frozen, it should be discarded.
Other Available Countermeasures	Antibiotic treatment following infection.
Contingency Protocol	N/A

Licensed Product	Measles Virus Vaccine, Live Attenuated
Countermeasure to	Measles virus (rubeola)
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation for reconstitution of a more attenuated line of live measles virus derived from Enders' attenuated Edmonston strain.
Effectiveness	Extensive clinical trials indicate that the measles vaccine is highly immunogenic and generally well tolerated. Single injections have been shown to induce measles-inhibiting antibodies in more than 97% of susceptible persons. These antibody levels persist for at least 13 years. Vaccine may provide some protection if given immediately after exposure to natural measles.
Dose & Administration	Administer a single 0.5 ml dose subcutaneously in the outer aspect of upper arm. Revaccination of previously immunized persons entering endemic areas is recommended to prevent import of the virus into the U.S. upon return. Do not give immune globulin concurrently. Simultaneous administration of mumps and rubella vaccines is common. If measles-only vaccine is unavailable, combined measles, mumps, and rubella vaccine can be used regardless of immune status to mumps and rubella. Routine concurrent administration with diphtheria, tetanus, pertussis, or oral poliovirus vaccines is not recommended but is acceptable. Measles vaccine should not be given less than 1 month before or after administration of other virus vaccines. Epinephrine injection should be immediately available in the event of anaphylactic reaction.
Side Effects	Vaccine produces a modified measles reaction. Occasionally, moderate fever (101-103°F) occurs in the first month; higher fever is rare. When present, fever and/or rash (mild) often occur between days 5 and 12. More severe rash and other more severe reactions requiring hospitalization are rare.
Shipping/Handling Requirements	Protect from light. Store refrigerated at 36-46°F. When reconstituted, vaccine is clear yellow. Visually inspect for presence of particulate matter or discoloration. If present, do not use. Discard reconstituted vaccine if not used within 8 hrs.
Other Available Countermeasures	Individual measles vaccine. Combined measles, mumps and/or rubella vaccines.
Contingency Protocol	N/A

Licensed Product	Measles & Rubella Vaccine, Live (M-R-Vax)
Countermeasure to	Measles (rubeola) and rubella (German measles) viruses
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation for reconstitution consists of a combination of live-attenuated measles virus (derived from Enders' attenuated Edmonston strain) and live-attenuated rubella virus (Wistar RA 27/3 strain). The viruses used in this combination are identical to those used in individual measles and rubella vaccines.
Effectiveness	Vaccine is a combination of individual measles and rubella vaccines (M-R). In clinical studies of 237 unimmunized children, a single dose of the M-R vaccine produced protective antibodies to measles and rubella in 95% and 99%, respectively. The rubella strain used in this vaccine more closely mimics natural infection and produces increased and broader profile protective antibody responses than other rubella vaccines.
Dose & Administration	Administer a single 0.5 ml dose subcutaneously in the outer aspect of upper arm. Revaccination of previously immunized persons entering endemic areas is recommended to prevent import of any of the viruses into the U.S. upon return. To avoid unnecessary vaccination, ensure written documentation of vaccination. Do not give with immune globulin. Concurrent administration of diphtheria, tetanus, pertussis, or oral poliovirus vaccines is not recommended but is acceptable. Measles vaccine should not be given less than 1 month before or after administration of other virus vaccines. Epinephrine injection should be immediately available in the event of anaphylactic reaction.
Side Effects	The M-R vaccine produces mild, modified symptoms of the natural illnesses, such as fever, rash, swollen glands. Moderate fever (<103°F) occurs occasionally; higher fever is rare. Arthralgia and transient arthritis, features of natural rubella infections, may occur. Other side effects may include malaise, sore throat, cough, runny nose, headache, dizziness, fever, rash, nausea, vomiting, and diarrhea; mild local reactions such as redness, tenderness, stinging; nerve deafness, blood changes (thrombocytopenia), hemorrhagic lesions in the skin. Other reported side effects include allergic reactions, otitis media, conjunctivitis and polyneuritis. Rare effects may include vasculitis, optic neuritis, and encephalitis.
Shipping/Handling Requirements	Protect from light. Store refrigerated at 36-46°F. When reconstituted, vaccine is clear yellow. Visually inspect for presence of particulate matter or discoloration. If present, do not use. Discard reconstituted vaccine if not used within 8 hrs.

**Other Available
Countermeasures**

Individual licensed vaccines for measles and rubella, and a combination measles/mumps/rubella vaccine are available.

**Contingency
Protocol**

N/A

Licensed Product	Measles, Mumps & Rubella Vaccine, Live
Countermeasure to	Measles (rubeola), mumps, and rubella (German measles) viruses
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation for reconstitution consists of a combination of live, attenuated measles virus (derived from Enders' attenuated Edmonston strain), live mumps virus (Jeryl Lynn - B level strain), and live-attenuated rubella (virus/Wistar RA 27/3 strain). Measles and mumps viruses are grown in chick embryos; rubella virus is grown in human diploid cells.
Effectiveness	Vaccine is a combination of individual measles, mumps and rubella vaccines (MMR). In clinical studies of 279 unimmunized children, a single dose of the MMR vaccine produced protective antibodies to measles, mumps, and rubella in 95%, 96%, and 99%, respectively. The rubella strain used in this vaccine more closely mimics natural infection and produces increased and broader profile protective antibody responses than other rubella vaccines. Protective antibody levels for all three viruses persist up to 11 years without substantial decline.
Dose & Administration	Administer a single 0.5 ml dose subcutaneously in the outer aspect of upper arm. Revaccination of previously immunized persons entering endemic areas is recommended to prevent import of any of the viruses into the U.S. upon return. To avoid subsequent unnecessary vaccination, ensure written documentation of vaccination. Do not give immune globulin concurrently. Routine concurrent administration with diphtheria, tetanus, pertussis, or oral poliovirus vaccines is not recommended but is acceptable. Measles vaccine should not be given less than 1 month before or after administration of other virus vaccines. Epinephrine injection should be immediately available in the event of anaphylactic reaction.
Side Effects	The MMR vaccine produces mild, modified symptoms of the natural illnesses, such as fever, rash, swollen glands. Moderate fever (<103°F) occurs occasionally; higher fever is rare. Joint pain and transient arthritis, features of natural rubella infections, may occur. Other side effects may include malaise, sore throat, cough, runny nose, headache, dizziness, fever, rash, nausea, vomiting, and diarrhea; mild local reactions such as redness, tenderness, stinging; swollen testes, nerve deafness, blood changes (thrombocytopenia), hemorrhagic lesions in the skin. Other reported side effects include otitis media, conjunctivitis, and polyneuritis. Rare effects may include vasculitis, optic neuritis, and encephalitis.
Shipping/Handling Requirements	Protect from light. Store refrigerated at 36-46°F. When reconstituted, vaccine is clear yellow. Visually inspect for presence of particulate matter or discoloration. If present, do not use. Discard reconstituted vaccine if not used within 8 hrs.

**Other Available
Countermeasures**

Individual licensed vaccines for measles and rubella, and a combination measles/rubella vaccine are available.

**Contingency
Protocol**

N/A

Approved Product	Mefloquine HCl
Countermeasure to	Falciparum and Vivax Malaria
Status	FDA approved
Availability	Available
Manufacturer	Roche Laboratories, Inc., 340 Kingsland Street, Nutley, NJ 07110-1199, 800-526-6367
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	An antimalarial drug for <i>P. falciparum</i> and <i>P. vivax</i> infections available as 250 mg tablets for oral administration.
Effectiveness	Mefloquine HCl provides improved prophylaxis against chloroquine-resistant strains of <i>P. falciparum</i> and <i>P. vivax</i> . However, <i>P. falciparum</i> strains resistant to mefloquine have been reported.
Dose & Administration	For prophylaxis: one 250 mg tablet taken orally once a week, beginning 1 week prior to departure into endemic areas and continued for 4 additional weeks upon return. For treatment: Five 250 mg tablets given as a single oral dose. The drug should not be administered on an empty stomach and should be taken with 8 oz. of water.
Side Effects	The most frequently observed side effect is vomiting, occurring with approximately 3% incidence. Dizziness, syncope, and other effects are reported with less than 1% incidence.
Shipping/Handling Requirements	Store at 15-30°C (59-86°F).
Other Available Countermeasures	Other antimalarial drugs and vaccines are either FDA approved or in various stages of advanced development.
Contingency Protocol	N/A

Licensed Product	Meningococcal Vaccine (A/C/Y/W-135)
Countermeasure to	<i>Neisseria meningitidis</i> , the causative agent of meningitis and meningococemia
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation of the group-specific polysaccharide antigens of <i>N. meningitidis</i> Groups A, C, Y, and W-135.
Effectiveness	This vaccine induces antibodies to the serogroups A, C, Y, & W-135 of <i>N. meningitidis</i> . The serogroup A microbe is the most common cause of epidemics outside the U.S. The group A component has been shown to have a clinical efficacy of 85% -95% and to be of use in controlling epidemics. Similar efficacy has been observed for the group C component in military recruits. Group Y and W-135 components have been demonstrated as safe and efficacious, though clinical protection has not been demonstrated directly. Protective antibody levels are achieved within 10-14 days of a single dose of vaccine. Protection against groups A & C serotypes last for up to 3 years. This vaccine will not prevent group B meningococcal infections.
Dose & Administration	Primary immunization: single 0.5 ml dose administered subcutaneously. Need for revaccination in adults is unknown. Declining antibody levels after 3 years suggest the possible need for revaccination for individuals at high risk.
Side Effects	Adverse reactions are infrequent and usually mild, typically being limited to redness at injection site lasting 1-2 days. As with any vaccine, hypersensitivity reactions are possible. Epinephrine injection should be immediately available in the event of an allergic reaction.
Shipping/Handling Requirements	Freeze-dried and reconstituted vaccine should be stored at 35-46°F. Multidose vials of reconstituted vaccine should be discarded after 5 days; single dose vials are discarded after 1 day. Injection solutions should be visually inspected to ensure the absence of particulate matter or discoloration prior to injection.
Other Available Countermeasures	Parenteral aqueous penicillin; prophylactic rifampin.
Contingency Protocol	N/A

Licensed Product	Mumps Virus Vaccine, Live
Countermeasure to	Mumps virus
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation for reconstitution containing live mumps virus (Jeryl Lynn B level strain) derived from chick embryos.
Effectiveness	Extensive clinical trials have shown the vaccine to be highly immunogenic and well tolerated. A single injection produces mumps neutralizing antibodies in > 97% of children and > 93% of adults for at least 15 years. The close resemblance of vaccine-induced antibody response to that of the natural infection suggests that vaccine protection may be permanent (although this has not been completely established).
Dose & Administration	Single 0.5 ml dose administered subcutaneously into the outer aspect of upper arm. Although not recommended for routine concurrent administration with diphtheria/tetanus/pertussis or oral poliovirus vaccines, these vaccines can be administered concurrently (using separate injection sites) under extenuating circumstances. The mumps vaccine should not be given less than 1 month before or after administration of other virus vaccines. DO NOT administer to persons with any febrile or respiratory illness, and DO NOT administer immune globulin concurrently.
Side Effects	The vaccine produces a modified, non-communicable mumps infection. Occasional adverse effects include mild fever (<103°F), cough, runny nose, diarrhea, swollen lymph nodes. Fever >103°F is rare.
Shipping/Handling Requirements	Protect unconstituted and reconstituted vaccine from light; store at 36-46°F; discard reconstituted vaccine if not used within 8 hrs.
Other Available Countermeasures	This vaccine is also a component of the combined measles/mumps/rubella vaccine. For concurrent vaccination for mumps and measles or rubella, the combination vaccines are available as described elsewhere in this document. If only mumps vaccination is required, but single vaccine is not available, the combination vaccine may be used according to its specific instructions.
Contingency Protocol	N/A

Approved Product	Pentostam (WR229, 870)
Countermeasure to	Visceral and cutaneous leishmaniasis
Status	IND #14150
Availability	May be purchased from the manufacturer
Manufacturer	Burroughs Wellcome & Co., London, England
POC	Director, U.S. Army Medical Materiel Development Activity, Fort Detrick, MD 21702, 301-619-7643

Product Description	Pentostam is a sterile solution of sodium stibogluconate that provides 100 mg equivalent pentavalent antimony per ml.
Effectiveness	Pentostam has traditionally been the drug of choice for treating visceral and cutaneous leishmaniasis. The drug is manufactured in England and marketed throughout the world. Previously, the dosage prescribed for treating cutaneous leishmaniasis was identical to that for treating visceral leishmaniasis, but Army data suggested an approximately 40% failure rate using their dosage. Efficacy is now 90% using high doses for long periods of time.
Dose & Administration	Visceral Leishmaniasis: 20 mg/kg/day IV or IM for 28 days Cutaneous Leishmaniasis: 20 mg/kg/day IV or IM for 20 days
Side Effects	Documented side effects include anorexia in 30%, asymptomatic pancreatitis in >90% and symptomatic pancreatitis in 30%, myalgias/arthralgias in 50%, neutropenia and thrombocytopenia in 1%-5% and EKG changes in 20%. Reactions are not severe as a rule.
Shipping/Handling Requirements	If stored below 25°C and protected from light, shelf-life is 3 years.
Other Available Countermeasures	Leishmanial diseases are transmitted by sand flies; thus, insect control measures and repellents reduce the risk of exposure.
Contingency Protocol	No.

Licensed Product	Pneumococcal Vaccine
Countermeasure to	<i>Streptococcus pneumoniae</i> , causative agent of approximately 25% of serious cases of pneumonia
Status	FDA licensed
Availability	Available
Manufacturer	Lederle Laboratories, American Cyanamid Co., Pearl River, NY 10965, 610-688-4400 (Also supplied by Merck & Co.)
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	A mixture of purified capsular polysaccharide antigens from the 23 most prevalent types of <i>S. pneumoniae</i> in thimerosal preservative.
Effectiveness	More than 90% of adults show at least a twofold rise in type-specific antibodies for all 23 types within 2-3 weeks of immunization. Antibody levels remain elevated for at least 5 years but may fall to pre-immunization levels by 10 years.
Dose & Administration	Vaccine is administered intramuscularly or subcutaneously. Immunization requires a single 0.5 ml dose. Reimmunization should be cautiously considered for only the highest risk situations in persons who received the 23 valent vaccine more than 6 years earlier. Reimmunization should be strongly considered for persons receiving the 14 valent vaccine (a different vaccine) if they are at the highest risk of fatal infection only.
Side Effects	Relatively low incidence of adverse effects has been reported. Observed reactions are typically short-lived and mild. In one study of 32 patients, 72% experienced soreness at injection site up to 3 days post-administration. Mild fever (less than 100°F) and muscle pains usually resolve in 24 hrs. Other side effects including fever over 102°F, rash, arthralgia, arthritis, adenitis, and serious anaphylactoid reactions are rare.
Shipping/Handling Requirements	Store refrigerated at 36-46°F. Do not freeze.
Other Available Countermeasures	In addition to the 23 valent vaccines, lesser valent vaccines (8, 13, and 14) have been used clinically.
Contingency Protocol	N/A

Licensed Product	Poliovirus Vaccine, Inactivated
Countermeasure to	Paralytic poliomyelitis caused by poliovirus infection
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE
POC	Defense Supply Center, Philadelphia ; 215-737-2839, DSN 444-2839

Product Description	A clear, colorless sterile suspension for subcutaneous injection. Contains formaldehyde-inactivated polioviruses (Types 1-3) produced by microcarrier culture. Each 0.5 ml immunizing dose contains 40D, 8D, and 32D antigen units of Type 1, 2, and 3 polioviruses, respectively.
Effectiveness	Studies with infants and children have shown the vaccine to produce high levels of neutralizing antibodies for all three types of poliovirus in >99% of vaccines after two doses. Field studies in Europe with a similar inactivated poliovirus vaccine indicated the persistence of circulating antibodies for at least 10 years.
Dose & Administration	For unvaccinated adults, the recommended primary series is two 0.5 ml s.c. injections at a 1-2 month interval, followed by a booster dose (0.5 ml s.c.) 6-12 months later. If less than 3 months are available, three doses can be given 1 month apart. If less than 1 month is available, a single dose of this product or oral vaccine is recommended. Incompletely vaccinated adults at high-risk should either complete a primary series or receive oral vaccine. Previously vaccinated persons of increased risk may receive a single dose as a booster.
Side Effects	In a U.S. study, there were no significant local or systemic reactions. 7%, 12%, and 4% of children experienced temperatures over 100.6°F after the first, second and third doses, respectively.
Shipping/Handling Requirements	Store between 2-8°C (35-46°F). Do not freeze.
Other Available Countermeasures	A licensed, live-attenuated oral poliovirus vaccine is available from Lederle Laboratories and is described elsewhere in this <i>Go Book</i> .
Contingency Protocol	N/A

Licensed Product	Poliovirus Vaccine, Live, Oral
Countermeasure to	Poliomyelitis caused by poliovirus Types 1, 2, & 3
Status	FDA licensed
Availability	Available
Manufacturer	Lederle Laboratories, American Cyanamid Company, Pearl River, NY 10965
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Mixture of Sabin strain Types 1, 2, and 3 attenuated polioviruses propagated in monkey kidney cell culture.
Effectiveness	When used in the prescribed manner, type-specific neutralizing antibodies to poliovirus Types 1, 2, and 3 will be induced in 95% or more of susceptible persons.
Dose & Administration	Unimmunized persons should receive two doses (0.5 ml each) 6-8 weeks apart (8 weeks preferred). A third dose is given 6-12 months after the second dose. In cases of substantial risk, the third dose can be given 6-8 weeks after the second dose. Previously immunized persons entering endemic areas should be given a supplemental dose (0.5 ml). Oral poliovirus vaccine can be administered simultaneously with tetanus/diphtheria toxoid, pertussis vaccine, and measles-mumps-rubella vaccine. Vaccine should not be administered during the course of any acute illness or when adverse gastrointestinal symptoms are present (vomiting, diarrhea).
Side Effects	Paralytic disease has been observed rarely in persons receiving the vaccine, and in persons who were in close contact with a person receiving the vaccine. The historical incidence in over 274 million administrations is 1 per 2.6 million. The incidence of paralytic disease is slightly higher for persons in contact with an individual undergoing immunization than for persons being immunized.
Shipping/Handling Requirements	Store below 32°F. Must be completely thawed prior to use. May undergo up to 10 freeze-thaw cycles, provided it never exceeds 46°F during thaw, and cumulative thaw time is less than 24 hrs. If thawed beyond 24 hrs, vaccine must be used within 30 days. Normally pink in color, but slight yellowing is acceptable.
Other Available Countermeasures	An inactivated poliovirus vaccine (IPV) is available and efficacious. In unimmunized adults, ACIP recommends primary immunization with IPV rather than oral vaccine.
Contingency Protocol	N/A

Approved Product	Primaquine Phosphate
Countermeasure to	Relapsing forms of malaria
Status	FDA approved
Availability	Available
Manufacturer	Sanofi Winthrop Pharmaceuticals, Inc., 90 Park Avenue, New York, NY 10016, 800-446-6267
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	An antimalarial drug for radical cure of relapsing malaria infections. Available as 26.3 mg (=15 mg base) tablets for oral administration.
Effectiveness	Primaquine phosphate is indicated for radical cure of malaria due to <i>Plasmodium vivax</i> and <i>P. ovale</i> .
Dose & Administration	For treatment: one tablet daily for 14 days, or 3 tablets as a single dose once a week for 8 weeks. Primaquine regimen must overlap at least one dose of chloroquine.
Side Effects	The most frequently observed side effects include abdominal discomfort, nausea, headache, interference with visual accommodation, and pruritus. Methemoglobinemia is common, but rarely necessitates interruption of therapy. Leukopenia and agranulocytosis occur rarely. Should not be given during pregnancy. Caution should be used when treating patients with glucose-6 phosphate dehydrogenase (G-6-PD) deficiency.
Shipping/Handling Requirements	Available in bottles of 100 tablets.
Other Available Countermeasures	Other antimalarial drugs and vaccines are either FDA approved or in various stages of advanced development.
Contingency Protocol	N/A

Licensed Product	Rabies Immune Globulin (Human), USP
Countermeasure to	Rabies
Status	FDA licensed
Availability	Available
Manufacturer	Bayer Corporation, Pharmaceutical Division, 400 Morgan Lane, West Haven, CT 06516, 800-468-0894
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	A sterile solution of antirabies immunoglobulin for intramuscular administration prepared from human plasma.
Effectiveness	Rabies immunoglobulin (human) is extremely effective in preventing rabies in humans when administered immediately after exposure. It can also be used simultaneously with initial vaccination using duck-embryo or human diploid cell derived vaccines. It should not be used in individuals who have previously been vaccinated against rabies and who have confirmed adequate antibody titer against rabies. Such people should receive vaccine only.
Dose & Administration	For treatment: A single dose containing 20 IU/kg (0.133 ml/kg) of body weight intramuscularly, preferably at the time of first vaccine dose, but at a different site. It may be given through the seventh day after first vaccine dose. If anatomically feasible, up to one half the dose should be thoroughly infiltrated in the area around the wound. The remainder of the dose should be administered in the gluteal area.
Side Effects	Soreness at the site of injection and mild temperature elevation may occur. Sensitization to repeated injections may occasionally occur in immunoglobulin deficient patients.
Shipping/Handling Requirements	Provided in 10 ml vials with an average potency of 150 IU/ml. Store refrigerated between 2-8°C (36-46°F). Do not freeze.
Other Available Countermeasures	Antirabies vaccines are available as licensed products.
Contingency Protocol	N/A

Licensed Product	Rabies Vaccine, Human Diploid Cell
Countermeasure to	Rabies virus from bites or non-bite exposure to tissues from infected animals
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried suspension of rabies virus for reconstitution. Virus is harvested from human diploid cells and inactivated chemically.
Effectiveness	<p>Protection: WHO specifies protection at 0.5 IU specific antibody titer, while CDC specifies a 1:5 titer for complete inhibition of the RFFIT test as acceptable. Protection is described in terms of Pre and Post exposure to rabies.</p> <p>Pre: Clinical trials in Europe - 100% of patients receiving 2 doses 1 month apart developed protective antibody titer >10 IU. Clinical trials in U.S. - vaccination gave mean titers of 12.5 IU/ml and 5.1 IU/ml at day 49 and day 90, respectively.</p> <p>Post: 45 persons bitten by rabid animals were vaccinated within hours and up to 14 days after the bites. All were fully protected against rabies.</p> <p>Note - Pre-exposure vaccination does not eliminate need for treatment following exposure.</p>
Dose & Administration	Vaccine should be administered in deltoid muscle. Pre-exposure immunization consists of three 1.0 ml doses on days 0, 7, and 21 or 28. Boosters not required except under extreme circumstances. In high risk situations, serologic tests every 2 years should be conducted. If serology reveals titer below 1:5, boost with a single 1 ml dose. Post-exposure therapy of previously immunized persons consists of two 1.0 ml doses (IM) at day 0 and day 3 post-exposure. No rabies immune globulin (RIG) is necessary. For previously unimmunized persons, ACIP recommends five IM doses (1 ml each) at day 0, 3, 7, 14, & 28 in conjunction with RIG at day 0.
Side Effects	Local reactions (pain, redness, swelling, itching) at injection site and mild systemic reactions (nausea, headache, abdominal pain, muscle aches, dizziness) were noted in 25% & 20% of cases, respectively. "Immune complex-like" reactions, consisting of hives, arthritis, joint pain, nausea and vomiting, fever have occurred in up to 6% of persons receiving boosters (much less frequent in primary immunization). If these reactions occur, test serum for antibody titers to determine whether therapy should be continued. Treatment of allergic reactions with corticosteroids may interfere with development of immunity.

Shipping/Handling Requirements	Freeze-dried vaccine is stable if refrigerated between 36-45°F. Do not freeze. Preparation contains no preservatives and must be used immediately after reconstitution. If not administered promptly, discard.
Other Available Countermeasures	Post-exposure treatments have included rabies immune globulin. An inactivated rabies diploid cell vaccine is also produced by SmithKline Beecham.
Contingency Protocol	N/A

RDA Product	Ribavirin
Countermeasure to	Crimean-Congo Hemorrhagic Fever (CCHF), Rift Valley Fever (RVF), Hantavirus Hemorrhagic Fever with Renal Syndrome (HFRS)
Status	BB-IND #16666
Availability	Available
Manufacturer	ICN Pharmaceuticals, 3300 Highland Avenue, Costa Mesa, CA 92629, 800-548-5100
POC	Director, U.S. Army Medical Materiel Development Activity, Fort Detrick, MD 21702, 301-619-7643

Product Description	Ribavirin is a synthetic, water soluble, colorless nucleoside available as an injectable solution for IV administration or in a capsule form for oral administration.
Effectiveness	Efficacy against HFRS was demonstrated in double-blind placebo-controlled human studies in China. IV therapy was associated with a seven-fold decrease in mortality. An open treatment double-blind, placebo-controlled clinical trial is currently being conducted and treats 5-10 cases per year. Most cases are associated with extended field training exercises near the Korean DMZ. Twelve patients with CCHF were treated with ribavirin in South Africa. 3 of 5 patients in whom therapy was initiated late (>5 days post-onset) died, while none of 7 patients treated early died. In another case, 6 of 9 patients with sustained direct blood exposure were treated with ribavirin. 1 of 6 treated had mild CCHF, 5 of 6 did not and all 3 untreated persons had severe CCHF. No clinical trials against RVF have been conducted.
Dose & Administration	Therapy of viral hemorrhagic fevers: initial loading dose of 33 mg/kg (up to 1.28 grams) every 6 hours for the first 4 days, 8 mg/kg (up to 0.64 grams) every 8 hours for subsequent 6 days. IV doses infused over 30-40 minutes. For CCHF prophylaxis initiated <48 hours post-exposure: four 400 mg oral doses on day 1, followed by three 400 mg doses for 7 days following the last exposure. For prophylaxis initiated >48 hours post-exposure: IV loading dose (33 mg/kg up to 2.64 grams) followed after 8 hours by three IV doses (16 mg/kg up to 1.28 grams) every 8 hours on day 1. Thereafter, followed by three 400 mg doses for 7 days following the last exposure.
Side Effects	Ribavirin produces a reversible, dose-dependent anemia that does not require transfusion. Other side effects of ribavirin may include insomnia, irritability, headache, pancreatitis and poor concentration. The incidence of these side effects has not been firmly linked to ribavirin. Ribavirin causes changes in testicles and birth defects in laboratory animals. No such studies have been done in humans.
Shipping/Handling Requirements	Ship at ambient temperature, store IV drug at 2-8°C and oral drug at room temperature.

Other Available Countermeasures

None other than vector avoidance.

Contingency Protocol

Yes. Approved for use in Operation Desert Shield/Storm, Somalia and Korea. Contingency protocol use approved for use in Bosnia and Korea. Approved Military Fielding of Intravenous Ribavirin for the Therapy of Bunyavirus Hemorrhagic Fevers (Crimean Congo hemorrhagic fever, Rift Valley fever, Hantavirus [hemorrhagic fever with renal syndrome]) in DoD Associated Medical Treatment Facilities. Military Fielding of Ribavirin (Intravenous and Oral) for Post Exposure Prophylaxis of High Risk Contacts to Crimean Congo hemorrhagic fever in DoD Associated Medical Treatment Facilities.

Licensed Product	Rubella Virus Vaccine, Live
Countermeasure to	Rubella virus (German measles)
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried preparation for reconstitution containing live-attenuated rubella virus (Wistar RA 27/3 strain) derived from human diploid cells.
Effectiveness	Extensive clinical trials have been conducted with the rubella strain used in this vaccine (28,000 subjects), as well as this particular formulation (11,000). A single injection produces rubella-inhibiting antibodies in more than 97% of susceptible persons. The rubella strain used in this vaccine produces higher and broader profile antibody responses, and stimulates natural infection more closely than strains used in other vaccines. Vaccine-induced antibody levels persist for at least 10 years.
Dose & Administration	Single 0.5 ml dose administered subcutaneously. Although not recommended for routine concurrent administration with diphtheria/tetanus/pertussis or oral poliovirus vaccines, these vaccines can be administered concurrently (using separate injection sites) under extenuating circumstances. However, the rubella vaccine should not be given less than 1 month before or after administration of other virus vaccines. DO NOT administer to persons with any febrile or respiratory illness, and DO NOT administer immune globulin concurrently.
Side Effects	Vaccine produces a modified, non-communicable rubella infection, possibly consisting of rash, sore throat, fever, headache, dizziness, nausea, vomiting, diarrhea, runny nose, mild regional lymphadenopathy, joint pain, and/or transient arthritis. Fever is usually less than and rarely greater than 103°F.
Shipping/Handling Requirements	Protect unconstituted and reconstituted vaccine from light; store at 36-46°F; discard reconstituted vaccine if not used within 8 hours.
Other Available Countermeasures	This vaccine is also a component of combined measles/rubella and measles/mumps/rubella vaccines. For concurrent vaccination for rubella and measles or mumps, the combination vaccines are available as described elsewhere in this document. If only rubella vaccination is required, but single vaccine is not available, combination vaccines may be used according to their specific instructions.
Contingency Protocol	N/A

Licensed Product	Tetanus & Diphtheria Toxoid
Countermeasure to	Exotoxin produced by <i>Clostridium tetani</i> (tetanus) and diphtheria toxin produced by <i>Corynebacterium diphtheriae</i>
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA, Lederle Laboratories, Pearl River, NY, and Wyeth-Ayerst, P.O. Box 8299, Philadelphia, PA 19101, 610-688-4400
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Formaldehyde detoxified tetanus and diphtheria toxins.
Effectiveness	Despite the ubiquitous presence of <i>C. tetani</i> spores, only 90 cases are reported annually in the U.S., testimony to the efficacy of tetanus vaccination. Complete primary immunization with tetanus toxoid typically produces protective levels of antitoxin that persist for at least 10 years. Likewise, the incidence of diphtheria has decreased from 200,000 cases in 1921 (before general use of toxoid vaccine) to only 15 cases reported between 1980-1983 and only one case in 1994. As with tetanus toxoid, diphtheria toxoid produces protective levels of antitoxin for at least 10 years.
Dose & Administration	Most Americans have undergone primary immunization. Vaccine is administered intramuscularly in the deltoid muscle. Primary immunization consists of two 0.5 ml doses 1-2 months apart, followed by a reinforcing dose (0.5 ml) 1 year after the second dose. Previously immunized persons require boosters consisting of a single 0.5 ml dose every 10 years. For wound management or diphtheria exposure, boosters should only be given if the previous booster or primary immunization was more than 5 years prior. If a booster is given sooner than 10 years for wound management or diphtheria exposure, the next booster should be administered only after 10 years. More frequent boosting can increase the incidence and severity of adverse reactions.
Side Effects	Local reactions (redness, soreness) are common and require no therapy. Nodule, sterile abscess formation, or subcutaneous atrophy may occur at injection site. Fever, chills, and myalgias and headache may occur. High fever may occur when boosters are given too frequently. Neurologic complications, including convulsions, encephalopathy, mono- and polyneuropathies, and hypersensitivity reactions including rash, arthralgia, difficulty breathing and shock may be severe but occur rarely.
Shipping/Handling Requirements	Store at 36-46°F, do not freeze. Properly prepared vaccine is a homogenous white suspension. Visually inspect for presence of particulate matter and discoloration; if present, do not administer.

Other Available Countermeasures	Monovalent tetanus toxoid vaccine. Tetanus immune globulin 3,000-6,000 IU, IM. Diphtheria antitoxin 20,000-100,000 units IM after sensitivity testing.
Contingency Protocol	N/A

Licensed Product	Tetanus Toxoid
Countermeasure to	Exotoxin produced by <i>Clostridium tetani</i>
Status	FDA licensed
Availability	Available
Manufacturer	Lederle Laboratories, American Cyanamid Company, Pearl River, NY 10965
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Formaldehyde detoxified tetanus and diphtheria toxins.
Effectiveness	Despite the ubiquitous presence of <i>C. tetani</i> spores, only 90 cases are reported annually in the U.S., testimony to the efficacy of tetanus vaccination. Complete primary immunization with tetanus toxoid typically produces protective levels of antitoxin that persist for at least 10 years.
Dose & Administration	Most Americans have undergone primary immunization. Vaccine is administered intramuscularly in the deltoid muscle. Primary immunization consists of two 0.5 ml doses 1-2 months apart, followed by a reinforcing dose (0.5 ml) 6-12 months after the second dose. Previously immunized persons require boosters consisting of a single 0.5 ml dose every 10 years. For wound management, boosters should only be given if the previous booster or primary immunization was more than 5 years prior. If a booster is given sooner than 10 years for wound management, the next booster should be administered only after 10 years. More frequent boosting can increase the incidence and severity of adverse reactions.
Side Effects	Local reactions (redness, soreness) are common and require no therapy. Nodule, sterile abscess formation, or subcutaneous atrophy may occur at injection site. Fever, chills, and myalgias and headache may occur. High fever may occur when boosters are given too frequently. Neurologic complications, including convulsions, encephalopathy, mono- and polyneuropathies, and hypersensitivity reactions including rash, arthralgia, difficulty breathing and shock may be severe but occur rarely.
Shipping/Handling Requirements	Store at 36-46°F, do not freeze. Properly prepared vaccine is a homogenous white suspension. Visually inspect for presence of particulate matter and discoloration; if present, do not administer. Shake vigorously prior to administration.
Other Available Countermeasures	Tetanus immune globulin 3,000-6,000 IU, IM. A combined tetanus and diphtheria toxoid vaccine, utilizing the same tetanus component, is available.
Contingency Protocol	N/A

RDA Product	Tick-Borne Encephalitis Vaccine, Inactivated
Countermeasure to	Tick-borne encephalitis
Status	An improved vaccine has been produced; IND to be submitted
Availability	Not available until Summer 2000 when IND is filed
Manufacturer	Baxter-Immuno Vertriebs GmbH
POC	Director, U.S. Army Medical Materiel Development Activity, Fort Detrick, MD 21702, 301-619-7643

Product Description	A highly purified, formalin-inactivated virus vaccine. Provided ready-to-use in single dose syringes.
Effectiveness	The previous version of this vaccine was administered as a licensed product in Europe to over 6 million people. It is not yet licensed by FDA for use in the U.S., and thus must be administered under a contingency use protocol as an Investigational New Drug (IND). The vaccine produced antibodies in up to 93% of individuals receiving the first two doses of the three-dose series, and in virtually all persons following the third dose. The vaccine was 80% to 90% effective in preventing disease.
Dose & Administration	An accelerated dose schedule is the only schedule allowed under the contingency protocol. Primary immunization is three 0.5 ml doses intramuscularly at days 0, 7, and 28. A booster dose of 0.5 ml should be administered intramuscularly at 9 months after the first dose, and annually thereafter.
Side Effects	There are no reports of serious adverse reactions having occurred with this product. Up to 25% of recipients have experienced mild swelling, redness, and soreness at the injection site, as well as temporary headache and malaise. Less than one person in 100 has had a fever over 38°C (100.4°F).
Shipping/Handling Requirements	Store between 2-8°C; do not freeze.
Other Available Countermeasures	Supportive care. Use of skin and clothing insect repellents to prevent tick bites. Monitor milk supply; boil pasteurized milk of susceptible animals.
Contingency Protocol	No. However, when a CINC determines there is a disease threat to operational efficiency and a requirement exists for use of this drug without informed consent, a request should be relayed to the J4, JCS who, in turn, will notify the ASD(HA) who, in turn, will notify the SECDEF of the requirement. According to Presidential Executive Order 13139, 30 September 1999, the SECDEF is responsible for preparing the request for waiver of informed consent in accordance with 10 USC 1107(f) and in consultation, and submitting it, with a copy to the Commissioner of the FDA, to the President for a decision.

Licensed Product	Typhoid Vaccine; Live, Oral Ty21a
Countermeasure to	Typhoid fever
Status	FDA licensed
Availability	Available
Manufacturer	Swiss Serum and Vaccine Institute, distributed in the U.S. by Berna Products Corp., 4216 Ponce de Leon Boulevard, Coral Gables, FL 33146, 800-533-5899
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Live, attenuated vaccine for oral administration. Contains 2-6 x 10 ⁹ viable attenuated <i>S. typhi</i> (Strain TY21a) and 6-50 x 10 ⁹ nonviable <i>S. typhi</i> Ty21a. The vaccine is freeze-dried and prepared in capsule form for oral administration.
Effectiveness	Immunization with three doses of vaccine resulted in a 95% decrease in the incidence of typhoid fever during a 3-year field study of >32,000 Egyptian children. In large field trials (Chile), the vaccine efficacy for subjects age 15-44 years was approximately 60%. Efficacy has been shown to persist for up to 5 years.
Dose & Administration	For primary immunization four doses are required: one capsule should be taken orally approximately 1 hour before a meal on days 1, 3, 5 and 7. An optimal booster schedule has not been determined, but for cases of repeated or continuous exposure, the currently suggested booster regimen is to repeat the primary series every 5 years.
Side Effects	In several large field trials, as well as “post-marketing surveillance,” noted side effects were infrequent, transient, and self-limiting. Reported effects included nausea, abdominal cramps, vomiting, and skin rash.
Shipping/Handling Requirements	Store between 2-8°C (35-46°F). Each package shows an expiration date.
Other Available Countermeasures	Typhoid Vi Polysaccharide Vaccine (Connaught). Typhoid Vaccine (Wyeth-Ayerst)
Contingency Protocol	N/A

Licensed Product	Typhoid Vi Polysaccharide Vaccine
Countermeasure to	Typhoid fever
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Sterile solution for intramuscular injection containing the cell surface Vi polysaccharide extracted from <i>Salmonella typhi</i> Ty2 strain. The vaccine appears as a clear, colorless solution. Each 0.5 ml dose contains 25 µg of purified Vi polysaccharide.
Effectiveness	3,454 subjects were vaccinated in Katmandu, Nepal to test the efficacy of this vaccine. The overall protective efficacy was determined to be 74% during 20 months of post-vaccination follow-up. Correlation of vaccine-induced antibody levels with subsequent efficacy, or levels that will provide protection have not been determined. Immunogenicity studies have shown that a single dose produces a fourfold increase in antibody levels in 88% -96% of subjects within 1 month post-vaccination.
Dose & Administration	Primary immunization is a single 0.5 ml IM injection administered in the deltoid region. A booster injection (0.5 ml IM) may be given under conditions of repeated or continuous exposure. Optimal booster schedules have not been determined, but the current recommendation is every 2 years (for persons at high-risk).
Side Effects	Adverse reactions noted in clinical trials in over 10,000 subjects were predominantly minor transient local reactions. Local tenderness and pain were commonly observed while induration and erythema were observed occasionally (approximately 5%). Common systemic reactions in approximately 15% were malaise and headache. Myalgia, nausea, and diarrhea were observed in about 5% of cases, and slight fever (>100°F) was noted in about 1% of subjects.
Shipping/Handling Requirements	Store between 2-8°C (35-46°F), do not freeze.
Other Available Countermeasures	Two licensed typhoid vaccines are available: a killed <i>S. typhi</i> vaccine and a live, attenuated oral <i>S. typhi</i> vaccine. The live, attenuated oral vaccine is described elsewhere in this <i>Go Book</i> . Comparative efficacy studies of this and other typhoid vaccines have not been performed.
Contingency Protocol	N/A

Licensed Product	Varicella Vaccine
Countermeasure to	Chickenpox and Herpes Zoster (Shingles)
Status	FDA licensed
Availability	Available
Manufacturer	Merck & Co., P.O. Box 4, West Point, PA 19486-0004, 800-672-6372
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839
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Product Description	Freeze-dried preparation for reconstitution consisting of a live, attenuated Varicella virus (Oka/Merck strain) purified from cell culture and sucrose, glutamate, and processed gelatin as stabilizers.
Effectiveness	Among 4,142 children who received one dose of vaccine, 2.1%-3.6%/year reported chickenpox compared to the number of expected cases for unvaccinated children of 8.3%-9.1%/year, an approximately 67% reduction in disease rate. Among adults exposed to household cases of chickenpox, the 27% vaccine recipients had breakthrough chickenpox; 71% had <50 lesions. The duration of protection is not known for either age group. Herpes zoster following vaccination occurs in an estimated rate of 18.5-18.8 per 100,000 person years. The long term effect of preventing herpes zoster following exposure to wild strains of Varicella is not known.
Dose & Administration	Children 12 months to 12 years of age should receive a single 0.5 ml dose subcutaneously in the upper arm. Adolescents and adults 13 years and older should receive 0.5 ml in the upper arm and a second dose 4 to 8 weeks later. Do not give Varicella Zoster Immune Globulin concurrently with Varicella vaccine since it will inactivate the live virus in the vaccine.
Side Effects	The most common symptoms in >1,500 adolescents and adults following the first dose are fever >100°F (10.2%) and localized pain, erythema, swelling, induration and itching at the injection site (24.4%). A Varicella-like rash appeared at the injection site in 3% and was generalized (median of 5 lesions) in 5.5%. The same symptoms occurred approximately as frequently in 955 individuals after the second dose.
Shipping/Handling Requirements	Vaccine should be stored at -15°C (+5°F) or colder before use. Unreconstituted vaccine is provided in single dose vials and separate vials of diluent. Vaccine should be used within 30 minutes of reconstitution.
Other Available Countermeasures	Varicella Zoster Immune Globulin
Contingency Protocol	N/A

Licensed Product	Yellow Fever Vaccine
Countermeasure to	Yellow fever virus
Status	FDA licensed
Availability	Available
Manufacturer	Pasteur Mérieux Connaught Laboratories, Swiftwater, PA 18370, 800-VACCINE
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Freeze-dried vaccine for reconstitution is prepared by culturing the 17D strain of yellow fever virus in chick embryos.
Effectiveness	Tests in 18 persons showed production of protective antibodies in all subjects. Immunity develops by the tenth day. WHO recommends revaccination every 10 years.
Dose & Administration	A single 0.5 ml dose administered subcutaneously. Should be administered 1 month apart from other live-virus vaccines, but data indicate the simultaneous administration with the most widely used live vaccines has not resulted in impaired antibody responses or increased side effects. Epinephrine injection should be immediately available in the event of anaphylactic reaction (severe allergic reaction with shock).
Side Effects	Fever or malaise, typically appearing 7-14 days after immunization, has been noted with a frequency of 10%.
Shipping/Handling Requirements	Freeze-dried vaccine must be maintained constantly at 32-41°F. Reconstituted vaccine should be used within 1 hour or discarded. Properly reconstituted, vaccine appears slightly opalescent and light orange.
Other Available Countermeasures	Symptomatic and supportive treatment. Use of skin and clothing insect repellents to prevent infection.
Contingency Protocol	N/A

**Medical Biological Defense
Products Supporting
Readiness**

(Go Book)

Licensed Product	Anthrax Vaccine, Adsorbed
Countermeasure to	Bacillus anthracis
Status	Licensed in U.S. since 1970
Expected Route of Exposure	Via aerosol and cutaneous
Availability	Available
Manufacturer	BioPort Corporation, 3500 Martin Luther King, Jr. Boulevard, Lansing, Michigan 48906, 517-327-1500
POC	Joint Program Office for Biological Defense, Medical Program Manager, 703-756-0467, DSN 289-0467

Product Description	Formalin-inactivated sterile -filtered culture fluid supernatant vaccine comprising the protective antigen (PA) of the organism.
Effectiveness	By Route of Exposure: Protects against dermal exposure in occupational setting. Probably protects against inhalant exposure based on animal studies and occupational experience. Immune Response in Humans: Antibody titers against PA are demonstrated in 85% to 95% after initial three doses, and in 100% after 12-month dose.
Dose & Administration	Primary Immunization Dose/Schedule: 0.5 ml subcutaneous dose/6 dose primary series given at 0, 2, 4 weeks, then 6, 12, and 18 months. Minimum Time/# Doses to Protection: Primate studies indicate that protection is afforded 2 weeks after minimum of two doses (abbreviated series) given approximately 2 weeks apart. Booster Schedule: Yearly after primary six shot series. Preliminary data indicate boosters given after longer intervals (up to 2 years after initial abbreviated series) may be effective.
Side Effects	Primarily local: 5% to 8% will have tenderness, redness, swelling, itching at inoculation site for up to 72 hours; less than 1% will have more severe local reactions; moderate systemic reactions and severe reactions such as anaphylaxis are rare.
Shipping/Handling Requirements	Store at 2-8°C, (must not be frozen).

**Other Available
Countermeasures**

Antibiotic prophylaxis given immediately post-exposure with penicillin, ciprofloxacin or doxycycline may suppress clinical illness. Vaccination is necessary to produce immunity and prevent illness after antibiotic withdrawal. Penicillin or ciprofloxacin may be used to treat symptomatic cases: effectiveness depends on how early treatment is started and the antibiotic sensitivity of the organism. Case-fatality rate is high following onset of pulmonary signs and symptoms.

**Contingency
Protocol**

Not required.

Licensed Product	Botulinum Toxoid Vaccine, Pentavalent
Countermeasure to	Five of the seven neurotoxins (Types A through E) produced by the bacterium <i>Clostridium botulinum</i> .
Status	BB-IND status: Army (#3723) and CDC (#161)
Expected Route of Exposure	Via aerosol
Availability	Available as an IND product
Manufacturer	BioPort Corporation, 3500 Martin Luther King Jr. Boulevard, Lansing, Michigan 48906, 517-327-1500, and Porton Products, Center for Applied Microbiology and Research
POC	Joint Program Office for Biological Defense, Medical Program Manager, 703-756-0467, DSN 289-0467

Product Description	Formalin-inactivated toxoid of botulinum toxins Types A, B, C, D, and E (pentavalent vaccine).
Effectiveness	<p>By Route of Exposure: Preliminary results from primate studies for Botulinum A indicate that the vaccine is effective against inhalation exposure. Human efficacy studies cannot be done ethically. The vaccine probably protects against exposure by inhalation and ingestion although studies are lacking.</p> <p>Immune Response in Humans: Based on the CDC recommendation of 0.25 IU/ml for serotype A, about 83% have adequate antibody titers after the third (12-week) dose; antibody titers then wane before the 1 year booster, after which nearly 100% demonstrate adequate levels of antibody.</p>
Dose & Administration	<p>Primary Immunization Dose/Schedule: 0.5 ml dose given subcutaneously in three dose primary series at 0, 2, and 12 weeks, with a booster injection given at 1 year.</p> <p>Booster Schedule: At 1 year and then every 2 years thereafter.</p>
Side Effects	Some local pain just after injection. Mild local side effects in 2% to 4% such as redness, swelling, or induration which peak at 24-48 hours, and then resolve. Frequency of such local reactions increases to 7% to 10% after second and third doses, and up to 20% with yearly boosters. Systemic reactions such as fever, malaise, headache, and muscle aches lasting 1 to 3 days are reported in up to 3% of recipients. Severe local or systemic reactions, including anaphylaxis, are rare.
Shipping/Handling Requirements	Store at 2-8°C.

**Other Available
Countermeasures**

Several antitoxins which may be available for post-exposure use in individuals exposed to botulinum toxins. A trivalent licensed antitoxin against Types A, B, and E is available from the Centers for Disease Control (CDC); this is an equine product and has a high potential for adverse reactions. A heptavalent antitoxin against Types A through G is available as an investigational (IND) product from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID).

**Contingency
Protocol**

No. However, when a CINC determines there is a BW threat to operational efficiency and a requirement exists for use of this toxoid without informed consent, a request should be relayed to the J4, JCS who, in turn, will notify the ASD(HA) who, in turn, will notify the SECDEF of the requirement. According to Presidential Executive Order 13139, 30 September 1999, the SECDEF is responsible for preparing the request for waiver of informed consent in accordance with 10 USC 1107(f) and in consultation, and submitting it, with a copy to the Commissioner of the FDA, to the President for a decision.

Licensed Product	Plague Vaccine
Countermeasure to	<i>Yersinia pestis</i> , a gram-negative coccobacillus
Status	Licensed
Expected Route of Exposure	Inhalation or possibly via infected vectors (fleas) or secondary transmission
Availability	Limited to remaining stock
Manufacturer	No manufacturer
POC	Defense Supply Center, Philadelphia; 215-737-2839, DSN 444-2839

Product Description	Formalin-killed, whole cell vaccine.
Effectiveness	<p>By Route of Exposure: Experience from Vietnam, where plague is endemic, suggests that the vaccine protects against intradermal exposure.</p> <p>Immune Response in Humans: After three doses most recipients have titers greater than 1:128 against the F1 antigen. Approximately 7% to 8% of recipients do not show any antibody response to the vaccine.</p>
Dose & Administration	<p>Primary Immunization Dose/Schedule: The standard schedule that is recommended is 1.0 ml IM, followed by 0.2 ml IM 1 to 3 months later, and 0.2 ml IM at 3 to 5 months. Preliminary data indicate that a rapid immunization schedule of 0.5 ml IM at 0, 1, and 2 weeks produces similar antibody titers to that observed after the third dose of the standard schedule.</p> <p>Minimum Time/#Doses to Protection: Extrapolations from animal studies indicate that at least three doses will yield protective immune response to intradermal challenge at 4-7 months under the current dose schedule.</p> <p>Booster Schedule: Recipients should receive three additional doses of a 0.2 ml IM booster every 6 months after the primary series, and then 0.2 ml every 1 to 2 years subsequently for continued protection.</p>
Side Effects	<p>8% to 10% of inoculations result in local reactions including redness, swelling, induration, and tenderness. These reactions usually resolve within 48 hours.</p> <p>About 7% to 10% of inoculations result in systemic side effects of malaise, lymph node swelling, and fever. Severe side effects are rare. Systemic side effects tend to increase in frequency after more than five doses of the vaccine have been given to an individual.</p>
Shipping/Handling Requirements	Store at 4°C.

Other Available Countermeasures Post-exposure prophylaxis with either doxycycline or tetracycline has been recommended in known exposures. The current vaccine demonstrates limited efficacy against inhaled bacteria in experimental animals. Based upon animal experiments, ciprofloxacin may also provide protection. Doxycycline and ciprofloxacin resistant strains have been reported. The addition of chloramphenicol or ceftriaxone is recommended for plague meningitis.

Contingency Protocol Not required.

Note A manufacturer is being sought.

Licensed Product	Smallpox Vaccine (Vaccinia)
Countermeasure to	Variola virus (smallpox), a member of the Orthopoxvirus
Status	Licensed, Wyeth-Ayerst Laboratories
Expected Route of Exposure	Inhalation or direct contact
Availability	Available
Manufacturer	Repository at Centers for Disease Control and Prevention, Atlanta, Georgia
POC	Joint Program Office for Biological Defense, Medical Program Manager, 703-756-0467, DSN 289-0467

Product Description	Live, attenuated vaccine.
Effectiveness	By Route of Exposure: Reliable data are surprisingly sparse as to efficacy and durability of protection. Indirect evidence indicates a highly effective vaccine. Immune Response in Humans: >95% of primary vaccines develop neutralizing or hemagglutination inhibition antibody titers greater than or equal to 1:10.
Dose & Administration	Primary Immunization Dose/Schedule: 1 dose by the scarification technique. Minimum Time/# Doses to Protection: 14 days/1 dose. Booster Schedule: Repeat dose every 5-10 years for protection against variola major virus.
Side Effects	Infrequent other than short-lived mild temperature elevation. Occurrences of complications are as follows: Cases/1,000,000 Vaccine Recipients: Accidental autoinoculation: 25.4 primary, 0.8 booster. Generalized vaccinia: 23.4 primary, 1.2 booster. Eczema vaccinatum: 10.4 primary, 0.9 booster. Progressive vaccinia: 0.9 primary, 0.7 booster. Post-vaccinal encephalitis: 2.9 primary, <0.1 booster.
Shipping/Handling Requirements	Maintain at 2-8°C, reconstitute with sterile water. May be used for 3 months after reconstitution if stored below 0°C. Sterilize vials and syringes prior to disposal.
Other Available Countermeasures	Post exposure can be effected with vaccinia immune globulin – 0.6 mg/kg IM or primary vaccination within 3-4 days of exposure yields some protection. Vaccinia immune globulin should be kept available for potential complications arising from vaccination.
Contingency Protocol	Not required.

**Medical Chemical Defense
Products Supporting
Readiness**

**Pretreatments, Antidotes, and
Skin Decontaminants**

(Go Book)

Approved Product	Atropine, Aerosolized (Medical Aerosolized Nerve Agent Antidote [MANAA])
Countermeasure to	Nerve agents, including GA (Tabun), GB (Sarin), GD (Soman), GF and VX
Status	FDA approved
Availability	Available
Manufacturer	Riker/3M Pharmaceuticals, 3M Center, Building 275-3W-01, St. Paul, MN 55133-3275, 800-328-0255
POC	Manager, Medical Chemical Defense Research Program, 301-619-7439

Product Description	MANAA consists of atropine solution in a pressurized canister and an inhaler. MANAA delivers approximately 240 puffs for inhalation, each containing 0.43 mg of atropine sulfate, equivalent to 0.36 mg of atropine.
Effectiveness	MANAA is safe and effective for the indication of nerve agent poisoning. The MANAA is FDA approved.
Dose & Administration	Used by ambulatory nerve agent casualties with respiratory symptoms for supplemental treatment after adequate injectable atropine has been given. It is used under medical supervision, not for self/buddy aid.
Side Effects	Side effects of the inadvertent use of atropine include inhibition of sweating, dilation of pupils, dry mouth, decreased secretions, mild sedation, and increased heart rate. These effects are insignificant in a nerve agent casualty.
Shipping/Handling Requirements	Handled as a compressed medical gas. Store at 59-86°F.
Other Available Countermeasures	Intravenous atropine.
Contingency Protocol	N/A

Approved Product	Diazepam, Convulsant Antidote for Nerve Agent (CANA)
Countermeasure to	Nerve agent GD (Soman)
Status	Fielded, FDA approved
Availability	Available
Manufacturer	Meridian Medical Technologies, 10240 Old Columbia Road, Columbia, MD 21046, 800-638-8093
POC	Manager, Medical Chemical Defense Research Program, 301-619-7439

Product Description	The CANA consists of a single autoinjector containing 10 mg of diazepam. Used to control convulsions and prevent brain and cardiac damage following severe exposure to nerve agents. Used in conjunction with NAPP and Mark I kits.
Effectiveness	CANA is safe and effective for use as an adjunct to control convulsions following severe exposure to nerve agents. CANA is FDA approved.
Dose & Administration	Personnel are issued one CANA. Use for self/buddy aid of nerve agent casualties in accordance with doctrine (FM 8-285, NavMed P-5041, AFM 160-11).
Side Effects	Side effects of the inadvertent use of CANA include drowsiness. These effects are insignificant in a nerve agent casualty.
Shipping/Handling Requirements	Must be passed hand-to-hand or placed in secure storage; accountability necessary.
Other Available Countermeasures	Intravenous diazepam.
Contingency Protocol	N/A

Approved Product	Nerve Agent Antidote Kit (Mark I)/Pralidoxime Cl
Countermeasure to	Nerve agents, including GA (Tabun), GB (Sarin), GD (Soman), GF, and VX
Status	Fielded, FDA approved
Availability	Available
Manufacturer	Meridian Medical Technologies, 10240 Old Columbia Road, Columbia, MD 21046, 800-638-8093
POC	Manager, Medical Chemical Defense Research Program, 301-619-7439

Product Description	The Mark I kit consists of an atropine autoinjector (2 mg), a pralidoxime chloride autoinjector (2-PAM Cl, 600 mg), the plastic clip joining the two injectors, and a foam case.
Effectiveness	The atropine and 2-PAM Cl in the Mark I kit are safe and effective for the indication of nerve agent poisoning. The Mark I is FDA approved.
Dose & Administration	Personnel are issued three Mark I kits. Use for self/buddy aid of nerve agent casualties in accordance with doctrine (FM 8-285).
Side Effects	Side effects of the inadvertent use of atropine include inhibition of sweating, dilation of pupils, dry mouth, decreased secretions, mild sedation, and increased heart rate. Side effects of the inadvertent use of 2-PAM-Cl include dizziness, blurred vision, nausea, and vomiting. These effects are insignificant in a nerve agent casualty.
Shipping/Handling Requirements	Protect from freezing below 32°F. Solutions in both autoinjectors freeze at about 30°F.
Other Available Countermeasures	Intravenous atropine and 2-PAM Cl.
Contingency Protocol	N/A

Approved Product	Nerve Agent Pretreatment Pyridostigmine (NAPP)
Countermeasure to	Soman and/or Tabun
Status	Fielded, IND product, NDA under FDA review
Availability	Contingency stockpiled
Manufacturer	ICN Canada Ltd., 1956 Bourdon Street, St. Laurent, Canada H4M 1U1
POC	Project Manager, Pharmaceuticals Division, U.S. Army Materiel Development Activity, 301-619-2051

Product Description	NAPP consists of twenty-one 30 mg pyridostigmine bromide (PB) tablets in a blister pack contained in a sealed pouch. Can presently only be used under an activated contingency protocol. If CINCs determine that Soman and/or Tabun are threats, they will direct that PB pretreatment be initiated.
Effectiveness	Research in animals, including primates, has demonstrated that PB substantially increases the efficacy of the chemical components of the Mark I kit against Soman and Tabun. Safety has been demonstrated in thousands of myasthenics (an FDA approved indication for PB) over many years at much higher doses, and by the DoD using the 30 mg tablet in clinical trials and during ODS.
Dose & Administration	Tablets will be taken every 8 hours. PB pretreatment requires Mark I and (possibly) CANA treatment for effectiveness in the event of exposure. Personnel are issued 2 blister packs of 21 tablets each.
Side Effects	Increased gastrointestinal activity, increased urination, headaches, runny nose, tingling, difficulty breathing, slurred speech, increased blood pressure. These effects are insignificant in light of the vast enhancement of Mark I kit effectiveness against the nerve agent GD (Soman) offered by NAPP.
Shipping/Handling Requirements	Store refrigerated at 2-8°C. If removed from cold storage, use within 6 months.
Other Available Countermeasures	None.
Contingency Protocol	Yes. When a CINC determines there is a chemical threat of Soman to operational efficiency and a requirement exists for use of this drug without informed consent, a request should be relayed to J4, JCS who, in turn, will notify ASD(HA), who, in turn, will notify the SECDEF of the requirement. According to Presidential Executive Order 13139, 30 September 1999, the SECDEF is responsible for preparing the request for waiver of informed consent in accordance with 10 USC 1107(f) and in consultation, and submitting it, with a copy to the Commissioner of the FDA, to the President for a decision.

Approved Product	Skin Decontamination Kit (M291)
Countermeasure to	Liquid nerve agents including GA (Tabun), GD (Sarin), GD (Soman), GF, and VX and vesicant agents HD (sulfur mustard)
Status	Fielded, FDA approved
Availability	Normal supply channels
Manufacturer	Soldier Biological and Chemical Defense Command, Rock Island, IL 61299-7390, 309-782-0310 or 0374
POC	Manager, Medical Chemical Defense Research Program, 301-619-7439

Product Description	The M291 kit consists of six packets each containing a pad filled with a mixture of activated resins which both absorb and neutralize liquid agents. Used to decontaminate skin exposed to liquid nerve or vesicant agents.
Effectiveness	The M291 kit is safe and effective for the indications of nerve and vesicant agent decontamination from skin. The M291 kit is FDA approved.
Dose & Administration	Use for skin decontamination following percutaneous exposure to nerve or vesicant agents. One resin pad will decontaminate both hands and the face, or an equivalent area of skin.
Side Effects	The reactive and absorptive resins in the M291 kit are nonirritating and nontoxic, even after prolonged contact with skin. Contact with open wounds, eyes, and mouth should be avoided.
Shipping/Handling Requirements	No special shipping/handling requirements.
Other Available Countermeasures	M258A1 Skin Decontamination Kit, 4230-01-101-3984.
Contingency Protocol	N/A

Defense Supply System

(Go Book)

Supply System Stocked Items

The following three charts depict the serums, toxoids and vaccines, antibiotics and miscellaneous pharmaceuticals, and chemical defense materiel stocked and available either in Defense Logistics Agency (DLA) depots, through pharmaceutical prime vendors, or as part of the Services' managed materiel, respectively.

The Defense Supply Center, Philadelphia (DSCP), is the DLA Integrated Materiel Manager (IMM) for medical commodities. As the IMM, it computes stockage requirements based on recurring demands from all the Services. With the advent of pharmaceutical prime vendors in the military health system, most items previously stocked in the depot by DSCP are now managed by prime vendors under contract with DSCP.

Some pharmaceutical items required for U.S. Army readiness are stocked and maintained by the U.S. Army Medical Materiel Agency (USAMMA). Although not identified separately in the charts that follow, these Army Prepositioned Stocks (APS) are specifically computed levels of equipment and supplies needed to deploy and sustain forces worldwide until the industrial base can provide for additional supply requirements. USAMMA, as the Service Item Control Center (SICC), annually computes the Class VIII (medical) requirements based on planning guidance through day 130. Levels are based upon the following factors:

- Replacement of consumable medical items within critical sets, kits, and outfits
- Special programs (Aeromedical Evacuation, Chemical/Biological Defense, Division-Ready Brigade Support, Hospital Expansion)
- Special requirements computations (vaccines, serums, and toxoids)

Vaccines and toxoids are typically administered prior to deployment. Because the planning guidance ends at day 130, no replenishment of vaccines is computed. Therefore, vaccine requirements are calculated based on the dosing regimen times the number of soldiers to be vaccinated times the unit of issue. The requirements are then stratified into 30-day increments.

Current pricing and availability information for Supply System Stocked Items may be obtained from USAMMA at (301) 619-4323 (DSN 343); the Air Force Medical Logistics Office (AFMLO) at (301) 619-4170; and the Naval Medical Logistics Command (NMLC) at (301) 619-3085.

U.S. ARMY MEDICAL MATERIEL AGENCY
In relentless pursuit of MEDICAL READINESS!

LEGEND

AAC: Acquisition Advice Code:

- A - Service/Agency Regulated
- D - Depot Stocked (DLA)
- H - Non-Stocked Items
- I - Direct Ordering
- L - Local Purchase
- R - Restricted
- X - Semi Active No Replacement

Serums, Toxoids, and Vaccines

Generic Nomenclature	Trade Name	Pkg size	NSN	NDC	Manufacturer	Source of Supply*
Adenovirus Vaccine, Type 4, Oral		100s	6505-01-105-2313	00008-0502-FA	Wyeth-Ayerst	A
Adenovirus Vaccine, Type 7, Oral		100s	6505-01-105-2314	00008-0501-FA	Wyeth-Ayerst	A
AmBisome, packs of 10 individual vials		50 mg/vial		0469-3051-30	Fujisawa	L
Anthrax Vaccine Adsorbed 5 ml		EA	6505-01-399-6828	NO NDC	Bioport	A
Cholera Vaccine		20 ml	6505-00-160-1500	00008-0342-01	Wyeth-Ayerst	L
Diphtheria/Tetanus Toxoids/Acellular Pertussis, 10 dose vial	Acel-Imune	5 ml	6505-01-356-1193	00005-1800-31	Lederle Laboratories	L
Diphtheria/Tetanus Toxoids/Acellular Pertussis, 10 dose vial	Acel-Imune	5 ml		54868-3355-00	Phys Total Care	L
Diphtheria/Tetanus Toxoids/Acellular Pertussis, 15 dose vial	Tripedia	7.5 ml	6505-01-362-7431	49281-0288-15	Pasteur Merieux Connaught	L
Diphtheria/Tetanus Toxoids/Acellular Pertussis, 0.5 ml syringe	Infanrix	10s	6505-01-442-6262	58160-0840-11	SmithKline Beecham	L
Diphtheria/Tetanus Toxoids/Acellular Pertussis, 0.5 ml syringe	Tripedia	10s		49281-0288-05	Pasteur Merieux Connaught	L
Diphtheria/Tetanus Toxoids/Acellular Pertussis, 15 dose vial	Certiva	7.5 ml		62448-4012-01	Ross Pharm/ No Amer	L
Diphtheria/Tetanus Toxoids/Pertussis, 15 dose vial		7.5 ml		49281-0280-84	Pasteur Merieux Connaught	L
Diphtheria/Tetanus Toxoids/Pertussis, 15 dose vial	Tri-Immunol	7.5 ml	6505-00-286-5349	00005-1948-33	Lederle Laboratories	L
Globulin Immune, USP (IM), 10 ml	Bay Gam	10 ml	6505-01-458-5599	00026-0635-12	Bayer Corporation	L
Globulin Immune, USP (IM), 10 ml		10 ml	6505-00-153-8278	00192-0615-12	Gamastan	X
Globulin Immune, USP (IM), 5 ml	IG Gamma	5 ml	6505-01-330-3807		Sclavo Inc.	L
Hepatitis B Virus Vaccine, 10 mg/ml, 3 ml		3 ml	6505-01-266-3780	00006-4773-00	Merck & Co.	L
Influenza Trivalent Vaccine 10 doses		10s	6505-01-460-4731	49281-0366-15	Pasteur Merieux Connaught	A
Influenza Trivalent Vaccine 10 doses		10s	6505-01-460-4731	00008-0982-01	Wyeth-Ayerst	A
Influenza Trivalent Vaccine syringe unit, 0.5 ml, 10s		10s	6505-01-460-4746	49281-0366-11	Pasteur Merieux Connaught	A
Influenza Trivalent Vaccine syringe unit, 0.5 ml, 10s		10s	6505-01-460-4740	00008-0982-02	Wyeth-Ayerst	A
Japanese Encephalitis, 10 Dose	Je-Vax	EA	6505-01-356-1194	49281-0680-20	Pasteur Merieux Connaught	L
Japanese Encephalitis, 3 Dose	Je-Vax	PG	6505-01-380-6465	49281-0680-30	Pasteur Merieux Connaught	L
Lyme Vaccine 0.3 mg/0.5 ml single dose vials, 10s	Lymerix	10s	6505-01-462-6643	58160-0845-11	SmithKline Beecham	L
Lyme Vaccine 0.3 mg/0.5 ml syringes, 5s	Lymerix	5s	6505-01-462-6648	58160-0845-35	SmithKline Beecham	L
Measles & Rubella Virus Vaccine	MR VAX II	50s	6505-01-098-8005	00006-4679-00	Merck & Co.	L
Measles & Rubella Virus Vaccine, 10 Dose	MR VAX II	10s	6505-01-352-9530	00006-4678-00	Merck & Co.	L
Measles & Rubella Virus Vaccine, Single Dose	MR VAX II	50s	6505-01-098-8004	00006-4677-00	Merck & Co.	L

* See Legend, page D-1

Serums, Toxoids, and Vaccines – cont.

Generic Nomenclature	Trade Name	Pkg size	NSN	NDC	Manufacturer	Source of Supply*
Measles & Rubella Virus Vaccine, Single Dose Vial	MR VAX II	EA		00006-4751-00	Merck & Co.	L
Measles Virus Vaccine, Live, Attenuated 10s	Attenuvax	10s	6505-01-038-0794	00006-4589-00	Merck & Co.	L
Measles Virus Vaccine, Live, Attenuated single dose vials	Attenuvax	EA	6505-01-222-6467	00006-4709-00	Merck & Co.	L
Measles, Mumps & Rubella	MMR II	EA		54569-3066-00	Allscripts	L
Measles, Mumps & Rubella	MMR II	10s		54569-1588-00	Allscripts	L
Measles, Mumps & Rubella	MMR II	EA		54868-0980-00	Phys Total Care	L
Measles, Mumps & Rubella	MMR II	EA		00006-4749-00	Merck & Co.	L
Measles, Mumps & Rubella	MMR II	10s	6505-00-165-6519	00006-4681-00	Merck & Co.	L
Meningococcal Vaccine, 10 dose vial	Menomune	EA	6505-01-461-1546	49281-0489-91	Pasteur Merieux Connaught	L
Meningococcal Vaccine, 10 dose vial		10s	6505-01-286-5312			L
Meningococcal Vaccine, single dose vial	Menomune	EA	6505-01-425-7573	49281-0489-01	Pasteur Merieux Connaught	L
Mumps Virus Vaccine, single dose vial	Mumpsvox	10s	6505-01-037-6792	00006-4584-00	Merck & Co.	H
Plague Vaccine		20 ml	6505-00-935-1128	22840-0600-02	Greer Labs	D
Plague Vaccine		Bulk Stock	6505-00-138-1025			R
Pneumococcal Vaccine, 0.5 ml syringe	Pnu-Imune 23	5s	6505-01-229-7694	00005-2309-33	Lederle Laboratories	I
Pneumococcal Vaccine, 0.5 ml vial	Pneumovax 23	5s		54569-2720-00	Allscripts	L
Pneumococcal Vaccine, 0.5 ml vial	Pneumovax 23	10s		00006-4943-00	Merck & Co.	L
Pneumococcal Vaccine, 2.5 ml vial	Pneumovax 23	EA		00403-1697-18	Compumed	L
Pneumococcal Vaccine, 2.5 ml vial	Pneumovax 23	EA		54569-1412-00	Allscripts	L
Pneumococcal Vaccine, 2.5 ml vial	Pneumovax 23	EA	6505-01-092-0391	00006-4739-00	Merck & Co.	L
Pneumococcal Vaccine, 2.5 ml vial	Pnu-Imune 23	EA	6505-01-189-2979	00005-2309-31	Lederle Laboratories	L
Poliovirus Vaccine Syringe	IPOL	10s	6505-01-353-9866			L
Poliovirus Vaccine, 1 Dose Syringe	IPOL	EA	6505-01-347-6834	49281-0860-51	Pasteur Merieux Connaught	L
Poliovirus Vaccine, 5 ml vial	IPOL	EA		49281-0860-10	Pasteur Merieux Connaught	L
Poliovirus Vaccine, Live Oral single dosettes	Orimune	10s		0005-2084-08	Lederle Laboratories	L
Poliovirus Vaccine, Live Oral single dosettes	Orimune	50s	6505-01-185-8848	00005-2084-12	Lederle Laboratories	L
Q-Fever Vaccine	Q-Vax					R

* See Legend, page D-1

Serums, Toxoids, and Vaccines – cont.

Generic Nomenclature	Trade Name	Pkg size	NSN	NDC	Manufacturer	Source of Supply*
Rabies Immune Globulin, 150 u/ml	Bay Rab	10 ml	6505-01-067-0807	00026-0618-10	Bayer Corporation	L
Rabies Immune Globulin, 150 u/ml	Bay Rab	2 ml	6505-01-145-5223	00026-0618-02	Bayer Corporation	L
Rabies Vaccine, Human Diploid, 2.5 iu/ml inj syringe		EA	6505-01-284-2949	49281-0251-20	SmithKline Beecham	L
Rabies Vaccine, Human Diploid, 2.5 iu/ml, vial		EA	6505-01-091-6063	49281-0250-10	Pasteur Merieux Connaught	L
Rubella Virus Vaccine, 50 Dose	Meruvax II	pg	6505-01-222-6468	00006-4675-00		L
Rubella Virus Vaccine, Single Dose Vial	Meruvax II	10s	6505-00-145-0180	00006-4673-00		L
Tetanus & Diphtheria Toxoid (Adult)		5 ml		00005-1875-31	Lederle Laboratories	L
Tetanus & Diphtheria Toxoid (Adult)		5 ml		49281-0271-83	Pasteur Merieux Connaught	L
Tetanus & Diphtheria Toxoid (Adult)		5 ml	6505-00-299-8296	00008-0341-02	Medeva	L
Tetanus Immune Globulin, 250 u. syringe	Bay Tet	10s	6505-01-332-7888	00026-0634-70	Bayer Corporation	L
Tetanus Toxoid, Adsorbed		5 ml	6505-00-685-5189	00008-0339-03	American Home Products	L
Typhoid Vaccine Live, Oral, 4 dose strip		4/pg	6505-01-324-6964	58337-0003-01	Serna	D
Typhoid Vaccine, 1 billion org/ml, 20 dose vial		5 ml		00008-0343-01	Wyeth-Ayerst	L
Typhoid Vaccine, 1 billion org/ml, 20 dose vial		10 ml	6505-01-225-9301	00008-0343-02	Wyeth-Ayerst	L
Typhoid Vaccine, 20 dose vial	Triphim	10 ml	6505-01-385-6328	49281-0790-20	Pasteur Merieux Connaught	D
Vaccinia Immune Globulin		5 ml vial	6505-01-053-2600		Baxter	D
Varicella Vaccine, Single Dose Vial	Varivax	10s	6505-01-413-1331	00006-4827-00	Merck & Co.	L
Varicella Vaccine, Single Dose Vial	Varivax	EA		00006-4826-00	Merck & Co.	L
Yellow Fever Vaccine, 1 dose		EA		49281-0915-01	Pasteur Merieux Connaught	L
Yellow Fever Vaccine, 20 doses		10 ml	6505-00-162-1520	49281-0915-20	Pasteur Merieux Connaught	D
Yellow Fever Vaccine, 5 doses		2.5 ml	6505-01-203-6289	49281-0915-05	Pasteur Merieux Connaught	L

* See Legend, page D-1

Antibiotics and Miscellaneous Pharmaceuticals

Generic Nomenclature	Trade Name	Pkg size	NSN	NDC	Manufacturer	Source of Supply*
Chloroquine Hydrochloride Injection; 50 mg/ml, 5 ml Amp		5s	6505-01-078-3717	00024-0074-01	Sanofi Winthrop Pharmaceuticals	L
Chloroquine Phosphate Tablets 250 mg		100s		00223-0691-01	Consolidated Midland	L
Chloroquine Phosphate Tablets 250 mg		1000s	6505-00-582-1639	00223-0691-02	Consolidated Midland	L
Chloroquine Phosphate Tablets 250 mg		50s		00115-2790-06	Global Pharm	L
Chloroquine Phosphate Tablets 250 mg		100s		00115-2790-01	Global Pharm	L
Chloroquine Phosphate Tablets 500 mg	Aralen Phosphate	500s	6505-00-117-6450		Sterling-Winthrop Res. Inst.	D
Chloroquine Phosphate Tablets 500 mg		100s	6505-00-113-9295			D
Chloroquine Phosphate Tablets 500 mg		25s	6505-01-267-9662	00024-0084-01	Sanofi Winthrop Pharmaceuticals	L
Ciprofloxacin 250 mg Tablets unit dose	Cipro	100s	6505-01-372-2383	00026-8512-48	Bayer Corporation	L
Ciprofloxacin 400 mg/40 ml Vial	Cipro	10s		00026-8564-64	Bayer Corporation	L
Ciprofloxacin 500 mg Tablets unit dose	Cipro	100s	6505-01-273-8650	00026-8513-48	Bayer Corporation	L
Doxycycline 100 mg Injection vials		5s	6505-01-108-4828	00469-1300-30	Lyphomed	L
Doxycycline Hyclate Capsules 100 mg		BT 500s	6505-00-009-5063	00143-3142-05	West Ward	L
Doxycycline Hyclate Tablets 100 mg		BT 50s	6505-01-095-4175	00364-2063-50	Schein	L
Doxycycline Hyclate Tablets 100 mg		BT 50s	6505-01-095-4175	00536-0340-06	Rugby Group Inc	L
Doxycycline Hyclate Tablets 100 mg		BT 500s	6505-01-153-4335	00364-2063-05	Schein	L
Doxycycline Hyclate Tablets 100 mg		BT 500s	6505-01-153-4335	00536-0340-05	Rugby Group Inc	L
Halofantrine Hydrochloride Tablets, 250 mg		BT 60s	6505-01-450-9048	00007-4195-18	SmithKline Beecham	L
Mefloquine HCl Tablets 250 mg, Unit Dose		25s	6505-01-315-1275	00004-0172-02	Roche Labs	L
Primaquine Phosphate Tablets 26.3 mg		BT 100s	6505-01-348-2465	00024-1596-01	Sanofi Winthrop Pharmaceuticals	L
Quinidine Gluconate Inj, 80 mg/ml, 10 ml vial		EA	6505-00-864-6298	00002-1407-01	Lilly	L
Ribavirin Injection, 100 mg/ml, 10 ml vial		EA	6505-01-263-8166			R

* See Legend, page D-1

Chemical Defense Materiel

Generic Nomenclature	Trade Name	Pkg size	NSN	NDC	Manufacturer	Source of Supply*
Antidote Treatment Nerve Agent	MARK I Kit	EA	6505-01-174-9919		Meridian Medical Technologies	D
Antidote Treatment Nerve Agent/Autoinjector Dual-chamber; 2 mg/0.7 ml Atropine & 600 mg/2 ml Pralidoxime Chloride	Dual Chamber Autoinjector	EA	6505-01-302-7427	Not Available	Meridian Medical Technologies	D
Atropine Inj 0.7 ml, Autoinjector		EA	6505-00-926-9083	11704-0101-01	Meridian Medical Technologies	D
Atropine Sulfate Inhaler, 0.36 mg Atropine per actuation, 240 actuations/cannister		6s	6505-01-332-1281		3-M	D
Cyanide Antidote Treatment Kit		1 kt	6505-01-143-4641	11098-0507-01	Akorn	L
Cyanide Antidote Treatment Kit		1 kt		00418-4030-01	Pasadena Research	I
Cyanide Antidote Treatment Kit		1 kt		61147-8601-00	Apotex	I
Diazepam 10 mg/2 ml Ampules	Valium	10s	6505-00-375-8955	00641-1408-33	Elkins-Sinn	L
Diazepam 10 mg/2 ml Ampules	Valium	10s	6505-00-375-8955	00140-1931-06	Roche Labs	L
Diazepam 10 mg/2 ml Autoinjector	CANA	EA	6505-01-274-0951		Meridian Medical Technologies	D
Diazepam 10 mg/2 ml Syringe	Valium	10s	6505-00-137-5891	00140-1933-06	Roche Labs	L
Pralidoxime Chl Inj 2 ml Autoinjector	2-Pam Chloride	EA	6505-01-125-3248	11704-0251-01	Meridian Medical Technologies	D
Pyridostigmine Bro Tablets, 30 mg Tablets 21 Tablets/pg	PB Tablets (PBT)	10s	6505-01-178-7903		ICN Pharmaceuticals	D
Sodium Nitrite Inj 10 ml amp		2s		60267-0079-10	Hope	L
Sodium Nitrite Inj 30 mg/ml, 10 ml amp		PG/5 ea	6505-01-206-6009		Pharma Serve	X
Sodium Thiosulfate 20s		PG/20 ea	6505-01-334-8781			L
Sodium Thiosulfate 5s		PG/5 ea	6505-01-206-6010			L

* See Legend, page D-1

Appendix

(Go Book)

Presidential Documents

Title 3—

Executive Order 13139 of September 30, 1999

The President

Improving Health Protection of Military Personnel Participating in Particular Military Operations

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 1107 of title 10, United States Code, and in order to provide the best health protection to military personnel participating in particular military operations, it is hereby ordered as follows:

Section 1. Policy. Military personnel deployed in particular military operations could potentially be exposed to a range of chemical, biological, and radiological weapons as well as diseases endemic to an area of operations. It is the policy of the United States Government to provide our military personnel with safe and effective vaccines, antidotes, and treatments that will negate or minimize the effects of these health threats.

Sec. 2. Administration of Investigational New Drugs to Members of the Armed Forces.

(a) The Secretary of Defense (Secretary) shall collect intelligence on potential health threats that might be encountered in an area of operations. The Secretary shall work together with the Secretary of Health and Human Services to ensure appropriate countermeasures are developed. When the Secretary considers an investigational new drug or a drug unapproved for its intended use (investigational drug) to represent the most appropriate countermeasure, it shall be studied through scientifically based research and development protocols to determine whether it is safe and effective for its intended use.

(b) It is the expectation that the United States Government will administer products approved for their intended use by the Food and Drug Administration (FDA). However, in the event that the Secretary considers a product to represent the most appropriate countermeasure for diseases endemic to the area of operations or to protect against possible chemical, biological, or radiological weapons, but the product has not yet been approved by the FDA for its intended use, the product may, under certain circumstances and strict controls, be administered to provide potential protection for the health and well-being of deployed military personnel in order to ensure the success of the military operation. The provisions of 21 CFR Part 312 contain the FDA requirements for investigational new drugs.

Sec. 3. Informed Consent Requirements and Waiver Provisions.

(a) Before administering an investigational drug to members of the Armed Forces, the Department of Defense (DoD) must obtain informed consent from each individual unless the Secretary can justify to the President a need for a waiver of informed consent in accordance with 10 U.S.C. 1107(f). Waivers of informed consent will be granted only when absolutely necessary.

(b) In accordance with 10 U.S.C. 1107(f), the President may waive the informed consent requirement for the administration of an investigational drug to a member of the Armed Forces in connection with the member's participation in a particular military operation, upon a written determination by the President that obtaining consent:

- (1) is not feasible;
- (2) is contrary to the best interests of the member; or
- (3) is not in the interests of national security.

(c) In making a determination to waive the informed consent requirement on a ground described in subsection (b)(1) or (b)(2) of this section, the President is required by law to apply the standards and criteria set forth in the relevant FDA regulations, 21 CFR 50.23(d). In determining a waiver based on subsection (b)(3) of this section, the President will also consider the standards and criteria of the relevant FDA regulations.

(d) The Secretary may request that the President waive the informed consent requirement with respect to the administration of an investigational drug. The Secretary may not delegate the authority to make this waiver request. At a minimum, the waiver request shall contain:

(1) A full description of the threat, including the potential for exposure. If the threat is a chemical, biological, or radiological weapon, the waiver request shall contain an analysis of the probability the weapon will be used, the method or methods of delivery, and the likely magnitude of its affect on an exposed individual.

(2) Documentation that the Secretary has complied with 21 CFR 50.23(d). This documentation shall include:

(A) A statement that certifies and a written justification that documents that each of the criteria and standards set forth in 21 CFR 50.23(d) has been met; or

(B) If the Secretary finds it highly impracticable to certify that the criteria and standards set forth in 21 CFR 50.23(d) have been fully met because doing so would significantly impair the Secretary's ability to carry out the particular military mission, a written justification that documents which criteria and standards have or have not been met, explains the reasons for failing to meet any of the criteria and standards, and provides additional justification why a waiver should be granted solely in the interests of national security.

(3) Any additional information pertinent to the Secretary's determination, including the minutes of the Institutional Review Board's (IRB) deliberations and the IRB members' voting record.

(e) The Secretary shall develop the waiver request in consultation with the FDA.

(f) The Secretary shall submit the waiver request to the President and provide a copy to the Commissioner of the FDA (Commissioner).

(g) The Commissioner shall expeditiously review the waiver request and certify to the Assistant to the President for National Security Affairs (APNSA) and the Assistant to the President for Science and Technology (APST) whether the standards and criteria of the relevant FDA regulations have been adequately addressed and whether the investigational new drug protocol may proceed subject to a decision by the President on the informed consent waiver request. FDA shall base its decision on, and the certification shall include an analysis describing, the extent and strength of the evidence on the safety and effectiveness of the investigational new drug in relation to the medical risk that could be encountered during the military operation.

(h) The APNSA and APST will prepare a joint advisory opinion as to whether the waiver of informed consent should be granted and will forward it, along with the waiver request and the FDA certification to the President.

(i) The President will approve or deny the waiver request and will provide written notification of the decision to the Secretary and the Commissioner.

Sec. 4. Required Action After Waiver is Issued. (a) Following a Presidential waiver under 10 U.S.C. 1107(f), the DoD offices responsible for implementing the waiver, DoD's Office of the Inspector General, and the FDA, consistent with its regulatory role, will conduct an ongoing review and monitoring to assess adherence to the standards and criteria under 21 CFR 50.23(d) and this order. The responsible DoD offices shall also adhere to any periodic reporting requirements specified by the President at the time of the waiver approval. The Secretary shall submit the findings to the President and provide a copy to the Commissioner.

(b) The Secretary shall, as soon as practicable, make the congressional notifications required by 10 U.S.C. 1107(f)(2)(B).

(c) The Secretary shall, as soon as practicable and consistent with classification requirements, issue a public notice in the *Federal Register* describing each waiver of informed consent determination and a summary of the most updated scientific information on the products used, as well as other information the President determines is appropriate.

(d) The waiver will expire at the end of 1 year (or an alternative time period not to exceed 1 year, specified by the President at the time of approval), or when the Secretary informs the President that the particular military operation creating the need for the use of the investigational drug has ended, whichever is earlier. The President may revoke the waiver based on changed circumstances or for any other reason. If the Secretary seeks to renew a waiver prior to its expiration, the Secretary must submit to the President an updated request, specifically identifying any new information available relevant to the standards and criteria under 21 CFR 50.23(d). To request to renew a waiver, the Secretary must satisfy the criteria for a waiver as described in section 3 of this order.

(e) The Secretary shall notify the President and the Commissioner if the threat countered by the investigational drug changes significantly or if significant new information on the investigational drug is received.

Sec. 5. Training for Military Personnel. (a) The DoD shall provide ongoing training and health risk communication on the requirements of using an investigational drug in support of a military operation to all military personnel, including those in leadership positions, during chemical and biological warfare defense training and other training, as appropriate. This ongoing training and health risk communication shall include general information about 10 U.S.C. 1107 and 21 CFR 50.23(d).

(b) If the President grants a waiver under 10 U.S.C. 1107(f), the DoD shall provide training to all military personnel conducting the waiver protocol and health risk communication to all military personnel receiving the specific investigational drug to be administered prior to its use.

(c) The Secretary shall submit the training and health risk communication plans as part of the investigational new drug protocol submission to the FDA and the reviewing IRB. Training and health risk communication shall include at a minimum:

- (1) The basis for any determination by the President that informed consent is not or may not be feasible;
- (2) The means for tracking use and adverse effects of the investigational drug;
- (3) The benefits and risks of using the investigational drug; and
- (4) A statement that the investigational drug is not approved (or not approved for the intended use).

(d) The DoD shall keep operational commanders informed of the overall requirements of successful protocol execution and their role, with the support of medical personnel, in ensuring successful execution of the protocol.

Sec. 6. Scope. (a) This order applies to the consideration and Presidential approval of a waiver of informed consent under 10 U.S.C. 1107 and does not apply to other FDA regulations.

(b) This order is intended only to improve the internal management of the Federal Government. Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

William Clinton

THE WHITE HOUSE,
September 30, 1999.

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