THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 24 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Use of Force Health Protection Prescription Products

A requirement of the Federal Food, Drug and Cosmetic Act (21 USC 353(b)(1)) is that certain drugs, vaccines and other medical products, because of the need for medical involvement to assure safe and effective use, may only be used under a physician's prescription. This memorandum establishes policy to comply with this statutory requirement in the context of prescription products used for force health protection. This policy establishes three primary requirements: prescription, issuance in accordance with established medical criteria, and record keeping.

Prescription Requirement

All Force Health Protection Prescription Products (FHPPP) shall be issued under a prescription. A blanket prescription may be issued by a physician serving as the Assistant Secretary of Defense (Health Affairs) (applicable to any or all components of the Department of Defense (DoD)), the Surgeon General of the Army, Navy, or Air Force (applicable to personnel in or under the command or authority of the Army, Navy, or Air Force, respectively), or the Command Surgeon of a Combatant Command (applicable to persons within a Combatant Commander's area of responsibility). A blanket prescription shall describe:

- The categories of military personnel and other individuals who are required and/or eligible to receive an FHPPP;
- The exclusion criteria for identifying individuals who for medical reasons are not required and/or eligible to receive an FHPPP;
- Appropriate dosing information, including start and stop dates or events;
- Any applicable storage, shipment, and maintenance requirements; and
- Any other appropriate requirements or guidance pertaining to proper medical use of the product.

Issuance of Prescription Product

All FHPPP shall be provided or issued by qualified personnel who have been instructed on the exclusion criteria and other medical guidance applicable to the product. These personnel

shall conduct necessary medical screening and issue FHPPP consistent with such criteria and guidance.

The administration or issuance for self-administration of all FHPPP shall be preceded and/or accompanied by appropriate education to ensure that recipients are aware of the exclusion criteria, dosing information, potential side effects and recommended responses, sources for additional information, and any other information appropriate for the proper use of the product.

Although the inclusive list of FHPPP may vary between areas of responsibility based on differing threats, examples of such products include atropine/2-Pam chloride auto-injectors, certain antimicrobials including antimalarials, and pyridostigmine bromide.

Record Keeping

The provision or issuance of FHPPP shall be documented in medical records of the personnel or individuals receiving the FHPPP.

Additional Requirements

Health care providers shall record serious adverse events in medical records and shall report serious adverse reactions to the Adverse Events Reporting System of the Department of Health and Human Services using the Food and Drug Administration MEDWATCH or Vaccine Adverse Event Reporting System procedures and forms.

DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000, applies to the use of investigational new drugs for force health protection.

Definition

In this memorandum, the term "force health protection" means an organized program of healthcare preventive or therapeutic treatment, or preparations for such treatment, designed to meet the actual, anticipated, or potential needs of a group of military personnel in relation to military missions.

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Deputy Director for Medical Readiness, Joint Staff