Department of Defense

# DIRECTIVE

NUMBER 6205.3

November 26, 1993

ASD(NS&CP)

SUBJECT: DoD Immunization Program for Biological Warfare Defense

References: (a) Title 10, United States Code
(b) DoD Instruction 6205.2, "Immunization Requirements," October 9, 1986
(c) AR 40-562/NAVMEDCOMINST 6230.3/AFR 161-13/CG COMDTINST M6230.4D, "Immunizations and Chemoprophylaxis," November 7, 1988
(d) DoD Directive 5136.1, "Assistant Secretary of Defense for Health Affairs," December 2, 1992
(e) through (g), see enclosure 1

## 1. PURPOSE

This Directive:

1.1. Establishes policy, assigns responsibilities, and prescribes procedures for members of the Department of Defense against validated biological warfare threats, and prioritization of research, development, testing, acquisition, and stockpiling of biological defense vaccines under reference (a).

1.2. Provides vaccination guidance that focuses exclusively on defense against biological warfare threats and complements immunization requirements for naturally occurring endemic disease threats outlined in references (b) and (c).

1.3. Addresses peacetime and contingency requirements for immunization against biological warfare threats against U.S. personnel.

1.4. Designates the Secretary of the Army as the "DoD Executive Agent" for the DoD Immunization Program for Biological Warfare Defense.

1.5. Provides direction on levels of acquisition and stockpiling of biological defense vaccines and prioritizes research and development efforts in defending against current and emerging biological warfare threats.

## 2. APPLICABILITY AND SCOPE

This Directive applies to:

2.1. The Office of the Secretary of Defense, the Military Departments (including their National Guards), the Chairman of the Joint Chiefs of Staff, the Unified Commands, and the Defense Agencies (hereafter referred to collectively as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

2.2. Essential DoD civilian personnel, and personnel of other Federal Departments, when assigned as part of the U.S. Armed Forces.

## 3. DEFINITIONS

Terms used in this Directive are defined in enclosure 2.

## 4. POLICY

It is DoD policy that:

4.1. For immunization, the following personnel, subject to special exceptions approved by the Chairman of the Joint Chiefs of Staff, should be immunized against validated biological warfare threat agents, for which suitable vaccines are available, in sufficient time to develop immunity before deployment to high-threat areas:

4.1.1. Personnel assigned to high-threat areas.

4.1.2. Personnel predesignated for immediate contingency deployment (crisis response).

4.1.3. Personnel identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area.

4.2. For vaccine research, development, testing, evaluation, acquisition, and stockpiling, efforts for the improvement of existing vaccines and the development of new vaccines against all validated biological warfare threat agents shall be integrated and prioritized. The Department of Defense shall develop a capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threats.

## 5. RESPONSIBILITIES

5.1. The Under Secretary of Defense for Acquisition and Technology shall ensure the coordination and integration of the DoD Immunization Program for Biological Warfare Defense with all acquisition-related elements of the DoD Biological Defense Program.

5.2. The Under Secretary of Defense for Policy shall review all facets of the DoD Immunization Program for Biological Warfare Defense to ensure that it is consistent with DoD policy and is adequately integrated into overall DoD biological defense policies.

5.3. The Assistant Secretary of Defense for Health Affairs shall:

5.3.1. Serve as the advisor to the Secretary of Defense as in DoD Directive 5136.1 (reference (d)) on the DoD Immunization Program for Biological Warfare Defense.

5.3.2. In consultation with the DoD Executive Agent, the Secretaries of the Military Departments, and the Chair of the Armed Forces Epidemiological Board, identify vaccines available to protect against biological threat agents designated by the Chairman of the Joint Chiefs of Staff and recommend appropriate immunization protocols.

5.3.3. Issue instructions to the Military Departments and the other appropriate DoD Components on the immunization of DoD personnel, under the guidelines of this Directive, and monitor and evaluate the implementation of those instructions.

5.4. The Secretary of the Army, as the DoD Executive Agent for the Immunization Program for Biological Warfare Defense, shall:

5.4.1. Besides those responsibilities in the Deputy Secretary of Defense Memorandum and the Joint Service Agreement (references (e) and (f)), do the following to enhance the DoD Immunization Program for Biological Warfare Defense, and report annually through the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to the Secretary of Defense the capability to carryout those policies:

5.4.1.1. Vaccine Research and Development. Priorities developed in coordination with the ASD(HA), the Chairman of the Joint Chiefs of Staff, and the Secretaries of the Military Departments shall include the development of vaccines against validated biological warfare threat agents for which none exist, improvement of vaccines that are unacceptable in the time they take to produce immunity or in the level of immunity they produce or are inadequate because of the number of doses required to achieve immunity, assessment of the effectiveness of vaccines against biological warfare threat agents in their likely modes of use (e.g., aerosols), and development of multivalent vaccines that will produce protective immunity after a single vaccination. Vaccines must be either licensed by the Food and Drug Administration (FDA) or have been designated, under FDA requirements, "for use as investigational new drugs (INDs)," as in 21 CFR 50 (reference (g)).

5.4.1.2. Vaccine Acquisition and Stockpiling

5.4.1.2.1. Develop and maintain a DoD capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threat agents for which suitable vaccines exist.

5.4.1.2.2. On an annual basis, provide information and recommendations, in coordination with the Secretaries of the Military Departments and the Chair of the Armed Forces Epidemiological Board, to the ASD(HA) on vaccines to acquire and appropriate immunization schedules that include reimmunization required to develop and maintain protective immunity. Those recommendations should include, but not be limited to the following:

5.4.1.2.1.1. All relevant data on the effectiveness of each vaccine against the corresponding biological warfare threat agent.

5.4.1.2.1.2. The expected type, frequency, and severity of vaccine-associated adverse reactions.

5.4.2. Serve as the focal point for the submission of information from the Services, as specified by paragraph 5.5., below, and monitor the Services' implementation of the DoD Immunization Program for Biological Warfare Defense.

Recommend appropriate changes and improvements to the Secretary of Defense through the ASD(HA), and the Secretaries of the Military Departments. Report to the Secretary of Defense annually on the Immunization Program for Biological Warfare Defense.

5.4.3. The Executive Agent Acquisition Executive (AE) shall plan, program, and budget for biological defense. The AE shall coordinate directly with the ASD(HA), the Under Secretary of Defense for Policy, the Under Secretary of Defense for Acquisition, the Secretaries of the Departments, and other offices as required to ensure program integration.

5.5. The Secretaries of the Military Departments shall:

5.5.1. Implement, monitor, evaluate, and document the DoD Immunization Program for Biological Warfare Defense in their Department and establish procedures for coordinating and reporting the following information to the Executive Agent:

5.5.1.1. The identification, reporting, and epidemiologic evaluation of vaccine-associated adverse reactions, in accordance with FDA requirements.

5.5.1.2. The collection and forwarding of data required by the Executive Agent needed to meet requirements of the FDA for products that are the INDs.

5.5.2. Transmit the instructions of the ASD(HA) about the immunization program for biological warfare defense to subordinate units.

5.5.3. Program and budget for the required vaccinations for members of their Department and provide the DoD Executive Agent with projected program requirements.

5.6. The Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified Commands; the Chiefs of the Military Services; and the Director, Defense Intelligence Agency (DIA), annually and as required, shall validate and prioritize the biological warfare threats to DoD personnel and forward that list to the DoD Executive Agent through the ASD(HA).

5.7. The Commanders of the Unified Commands, annually and as required, shall provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theaters.

5.8. The Chair of the Armed Forces Epidemiological Board, in consultation with the DoD Executive Agent and the Secretaries of the Military Departments, annually and as required, shall identify to the ASD(HA) vaccines available to protect against validated biological warfare threat agents, and recommend appropriate immunization protocols.

## 6. PROCEDURES

The DoD Immunization Program for Biological Warfare Defense shall be conducted, as follows:

6.1. The Commanders of the Unified Commands, annually and as required, shall provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theater.

6.2. The Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified Commands; the Chiefs of the Military Services; and the Director, DIA, annually, shall validate and prioritize the biological warfare threats to DoD personnel and forward them to the DoD Executive Agent through the ASD(HA).

6.3. Within 30 days of receiving the validated and prioritized biological warfare threat list from the Chairman of the Joint Chiefs of Staff, the DoD Executive Agent shall, in consultation with the Secretaries of the Military Departments and the Chair of the Armed Forces Epidemiology Board, provide recommendations to the ASD(HA) on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents.

6.4. Within 30 days of receiving the coordinated recommendations of the DoD Executive Agent, the ASD(HA) shall direct the Secretaries of the Military Departments to begin immunization of the specified DoD personnel against specific biological warfare threat agents.

6.5. For biological threats for which the only available vaccine is an ND, it shall be administered under 21 CFR 50 and 312 (reference (g)) and the established ND protocol and/or other applicable legal procedures.

## 7. INFORMATION REQUIREMENTS

The annual reporting requirements in section 5., above, have been assigned Report Control Symbol DD-POL(A)1921.

8. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. The Secretaries of the Military Departments shall forward one copy of implementing documents to the Assistant Secretary of Defense for Health Affairs within 120 days.

William J. Perry
Deputy Secretary of Defense

Enclosures - 2

E1. References, continued
E2. Definitions

## E1. ENCLOSURE 1

## REFERENCES, continued

(e) Deputy Secretary of Defense Memorandum, "Biological Warfare Defense Program," August 26, 1991
(f) Joint Service Agreement, "Joint Service Coordination of Chemical Warfare and Chemical-Biological Defense Requirements, Research, Development, and Acquisition," July 5, 1984
(g) Title 21, Code of Federal Regulations, Parts 50, "Informed Consent of Human Subjects," and 312, "Investigational New Drug Application," current edition

## E2. ENCLOSURE 2

## DEFINITIONS

E2.1.1. Biological Warfare Agent. A microorganism or biological toxin intended to cause disease, injury, or death in humans.

E2.1.2. Biological Warfare Threat. A biological materiel planned to be deployed to produce casualties in humans.

E2.1.3. High-Threat Area. A geographic area in the proximity of a nation or nations considered to pose a potential biological threat to DoD personnel by the Chairman of the Joint Chiefs of Staff in consultation with the Commanders in Chief of the Unified Commands and the Director, DIA.

E2.1.4. Immunity. The capacity to resist the effects of exposure to a specific biological agent or toxin.

E2.1.5. Immunization. The process of rendering an individual immune. Immunization refers to "the administration of a vaccine to stimulate the immune system to produce an immune response (active immunization)." That process may require weeks to months and administration of multiple doses of vaccine.

E2.1.6. Programmed Force. The DoD active and Reserve force approved by the Secretary of Defense in the Future Years Defense Program.

E2.1.7. Vaccination. The administration of a vaccine to an individual for inducing immunity.

E2.1.8. Vaccine. A preparation that contains one or more components of a biological agent or toxin, and induces an immune response against that agent when administered to an individual.

E2.1.9. Validated Biological Warfare Threat Agent. A biological warfare agent that is validated as a threat to DoD personnel by the Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified and Specified Commands; the Chiefs of the Military Services; and the Director, DIA.