Exhibit 3

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IN FOCUS

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Defense Health Primer: Military Vaccinations

The Department of Defense (DOD) administers a variety of force health protection (FHP) measures to "promote, protect, improve, conserve, and restore" the health and well-being of servicemembers. These measures include health promotion and education programs, periodic health assessments, preventive therapies, medical countermeasures, and vaccinations. The U.S. military instituted its first vaccination program in 1777 when General George Washington directed the inoculation of the Continental Army to protect personnel from smallpox. Since then, DOD has implemented a variety of enduring or situational FHP measures to protect servicemembers from health threats. Certain vaccines are required for all servicemembers, while others may only be required for those deploying to particular locations. Other vaccines may be available based on public health recommendations or on a voluntary basis.

Since at least the late 1990s, Congress has expressed interest in DOD vaccination policies, specifically those on compulsory vaccinations. Similar interest among certain Members of Congress has arisen as DOD administers the Coronavirus Disease 2019 (COVID-19) vaccine to servicemembers on a voluntary basis. This In Focus describes DOD's military vaccination policies and immunization program, and offers issues for congressional consideration.

DOD Policies on Military Vaccinations

DOD Instruction 6205.02 establishes the DOD Immunization Program. The policy generally directs combatant commands and the military departments (MILDEPs) to identify and define "mandatory immunization requirements" for servicemembers. The *Joint Regulation on Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases* outlines specific vaccination requirements for servicemembers, as well as service-specific procedures for administering such requirements. In general, DOD vaccination requirements follow the recommendations of the U.S. Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP). DOD vaccination requirements fall into one of three categories:

- vaccinations during initial entry or basic training;
- routine adult vaccinations; and
- special risk-based, or occupation-specific vaccinations.

Table 1 lists the mandatory vaccinations required for all servicemembers upon entering initial entry or basic training. In addition to these vaccinations, combatant commands establish further requirements for servicemembers, other DOD personnel, and certain family members, based on specific health threats in a geographic region.

Table 1. Mandatory Vaccinations for All Servicemembers

Adenovirus	Meningococcal
Hepatitis A & B	Poliovirus
Influenza	Tetanus-Diphtheria
Measles/Mumps/Rubella	Varicella

Source: Joint Service Regulation on Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases, October 7, 2013, p. 29.

DOD Immunization Program

The Defense Health Agency (DHA) manages the DOD Immunization Program. Based on the MILDEPs' and combatant commands' vaccination requirements, as well as CDC and ACIP recommendations, DHA coordinates the administration of vaccines to servicemembers and other DOD beneficiaries. Vaccinations are typically available in military treatment facilities, certain military-specific settings (e.g., basic training), or from participating TRICARE providers. DHA is also responsible for relevant medical documentation, patient safety surveillance, and coordination with the Defense Logistics Agency and commercial manufacturers to procure such vaccines. DOD health care providers typically document servicemember vaccinations and any related adverse health events in the electronic health record system (e.g., MHS Genesis), paper medical records, and the respective MILDEPs' medical readiness information system.

Opting Out of a Vaccination

A servicemember may request to opt out of a mandatory vaccination. Upon request by a servicemember, DOD may authorize a temporary or permanent medical or administrative exemption to a required vaccine. DOD health care providers may authorize a *medical exemption* when a servicemember has an underlying health condition or known adverse reaction contraindicated with a certain vaccine. Unit commanders may authorize an *administrative exemption* for a servicemember who is within 180 days from separating or retiring from the military or within 30 days of departing a permanent assignment location. Pursuant to the Religious Freedom Restoration Act (42 U.S.C. §2000bb-1), administrative exemptions for religious reasons may also be granted. DOD policy requires that:

- the unit commander seek input from medical, legal, and chaplain representatives;
- the unit commander counsel the servicemember on potential adverse impact to "deployability, assignment, or international travel"; and
- a military physician counsel the servicemember on the benefits and risks of forgoing a required vaccination.

Unit commanders may revoke a religious exemption "if the individual and/or unit are at imminent risk of exposure to a disease for which an immunization is available." Commanders may also administratively separate, or initiate disciplinary proceedings under the Uniform Code of Military Justice, servicemembers without an authorized exemption, if they are non-compliant with a mandatory vaccination.

Authority to Waive Informed Consent

DOD Instruction 6205.02 directs the "preferential use of immunizations approved by the U.S. Food and Drug Administration" (FDA); however, non-FDA approved drugs, biologics (e.g., vaccines), or medical products may be administered for FHP purposes. DOD may administer an "investigational new drug" or "drug unapproved for its applied use" to servicemembers after obtaining *prior consent* (also referred to as *informed consent*). Under 21 U.S.C. §355(i)(4) and related regulations, the informed consent process typically requires human subjects to agree to the receipt of drug, biologic, or medical product upon a disclosure that the product in question is not yet FDA approved and that the receipt of such product is voluntary.

In certain instances, DOD may request a waiver to statutory and regulatory informed consent requirements in order make an investigational drug, biologic, or medical product mandatory for servicemembers participating "in a particular military operation." Section 1107 of Title 10, U.S. Code:

- authorizes the Secretary of Defense to request a waiver;
- assigns approval authority to the President of the United States; and
- if a waiver is approved, directs a congressional notification process.

If a waiver of informed consent is approved, the statute also requires DOD, prior to administering the investigational product, to notify servicemembers that a non-FDA approved product is being administered, the reasoning for such use, information on known side effects, and other information that the "Secretary of Health and Human Services may require to be disclosed." For products subject to emergency use authority (EUA), as is the case for several COVID-19 vaccines, Section 1107a of Title 10, U.S. Code grants the President the authority to waive certain EUA conditions "designed to ensure that individuals are informed of an option to accept or refuse administration" of the product.

A waiver of informed consent does not abrogate the *Feres* doctrine. If a servicemember is harmed from an administered drug, biologic, or medical product, *Feres* generally prohibits active duty servicemembers from filing medical malpractice lawsuits against the United States. However, servicemembers may seek alternative recourse through a DOD administrative process, the National Vaccine Injury Compensation Program, the Countermeasures Injury Compensation Program, or disability compensation administered by the Department of Veterans Affairs.

Issues for Congress

The following lines of inquiry may assist Congress in obtaining further clarification on the administration of compulsory vaccinations and may support congressional oversight of the DOD Immunization Program.

Program Administration

- Are the MILDEPs receiving adequate support from DHA to meet their medical readiness requirements?
- How do DOD and CDC share pertinent health information documented in the Vaccine Adverse Event Reporting System?
- What health communication strategies are used to educate or solicit feedback from servicemembers on DOD's vaccination or other FHP requirements?

Military Readiness

- Does DOD have adequate authorities and processes in place to protect the health and well-being of servicemembers and other DOD personnel conducting the full range of military operations?
- What were the lessons learned from the Anthrax Vaccine Immunization Program and how were those lessons used to improve the DOD Immunization Program?

COVID-19 Vaccinations

- What is DOD's long-term strategy to mitigate risks from COVID-19 and of future pandemics?
- Will DOD's COVID-19 mitigation strategy require compulsory vaccination of servicemembers? Is DOD considering requesting a waiver of informed consent for the COVID-19 vaccine?

Relevant Statutes and Policies

10 U.S.C. §1107 – Notice of use of an investigational new drug or a drug unapproved for its applied use

10 U.S.C. §1107a – Emergency use products

21 U.S.C. §355 – New drugs

DOD Directive 6200.04 – *Force Health Protection (FHP)*

DOD Instruction 6200.02 – *Application of Food and Drug Administration Rules to Department of Defense Force Health Protection Programs*

DOD Instruction 6205.02 – *DoD Immunization Program*

Joint Service Regulation on Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

CRS Products

CRS In Focus IF10530, *Defense Primer: Military Health System*, by Bryce H. P. Mendez

CRS Report R46745, *State and Federal Authority to Mandate COVID-19 Vaccination*, by Wen W. Shen

CRS In Focus IF11102, *Military Medical Malpractice and the Feres Doctrine*, by Bryce H. P. Mendez and Kevin M. Lewis

CRS Legal Sidebar LSB10584, *Compensation Programs for Potential COVID-19 Vaccine Injuries*, by Kevin J. Hickey and Erin H. Ward

CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*, by Agata Bodie

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