The Intersection of FDA Regulations and DoW Operations

Rachel K. Hunnicutt, JD, MS

August 4, 2026

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Key Statutes, Orders, and Policies Governing DOW Use of Medical Products

- 10 U.S. Code § 1107, Notice of use of an investigational new drug or a drug unapproved for its applied use
- 10 U.S. Code § 1107a, Emergency use products
- Public Law 115-92
- Executive Order 13139, Improving Health Protection of Military Personnel Participating in Particular Military Operations
- DoDI 6200.02, Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs

10 USC § 1107

(a)NOTICE REQUIRED.—

(1) Whenever the Secretary of Defense requests or requires a member of the armed forces to receive an investigational new drug or a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in subsection (d).

(2) The Secretary shall also ensure that health care providers who administer an investigational new drug or a drug unapproved for its applied use, or who are likely to treat members who receive such a drug, receive the information required to be provided under paragraphs (3) and (4) of subsection (d).

(f)LIMITATION AND WAIVER.—

(1) In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation, the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) may be waived only by the President. The President may grant such a waiver only if the President determines, in writing, that obtaining consent is not in the interests of national security.

10 USC § 1107a – Emergency Use Products

(a) Waiver by the President.

(1) In the case of the administration of a product authorized for emergency use under section 564 of the [FDCA] to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(c) Applicability of Other Provisions.-In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act, subsections (a) through (f) of section 1107 shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

Public Law 115-92

- OSW-led effort to expand the existing Emergency Use Authority at Section 564 of the Federal Food, Drug and Cosmetic Act (FD&C Act) to apply beyond CBRN threats. Enacted 12/12/17.
- Section 1(a)
  - "(B) a **determination by the Secretary of Defense** that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, United States Code, of attack with—

    "(i) a biological, chemical, radiological, or nuclear agent or agents; or

    "(ii) an agent or agents that may cause, or are otherwise associated with, an **imminently life-threatening and specific risk to United States military forces**;"

Public Law 115-92 Cont.

- In addition to expanding emergency use authority, P.L. 115-92, requires enhanced collaboration between FDA and DoW.
  - DoW-FDA MOU 225-19-001 executed 11/2018 implements framework for P.L. 115-92 collaboration.
  - Semi-Annual meetings between DoW and FDA Senior leadership
    - ✓ Semi-annual meetings have participation of the Directors of the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH)
    - ✓ Quarterly meetings with the Director of CBER, with other centers looped in as appropriate per Priority List products, and ASW(HA)
  - DoW agreed to establish Medical Product Priority List.
  - DoW established the Medical Product Acceleration Committee, managed by the Office of the ASW(HA)

Executive Order 13139

- EO 13139 has been incorporated into 10 USC §§ 1107, 1107a (as previously discussed)
- Signed by President Clinton in September 1999, EO 13139 regulates the conditions under which the DoW can administer investigational new drugs and off-label pharmaceuticals to U.S. Service Members.
  - Requires service members to receive written notice and provide informed consent before receiving an investigational new drug.
  - The order stipulates that only the President can waive the requirement for informed consent.

DoDI 6200.02, Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs

- Does not apply to standard U.S. medical practice/not regulated by FDA
- Updates policy and assigns responsibility for complying with 10 USC §§ 1107, 1107a, EO 13139, Title 21 of CFR to force health protection programs regarding emergency use authorized products and investigational new drugs.
  - A "Force Health Protection Program" is defined as "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." E2.2.
- "The DoD Components shall make preferential use of products approved by the FDA for general commercial marketing, when available, to provide the needed medical countermeasure." 4.1.
- Enclosure 3 details requirements and procedures applicable to EUAs (doesn't currently reflect PL 115-92 updates)
- Enclosure 4 details requirements and procedures applicable to IND applications

What Does This Mean to DoW?

- Regardless of whether being in the U.S. or outside the U.S., DoW has limitations on the ability to administer non-FDA approved drugs and biologics
- One of DoW's more powerful tools is the ability to determine a military emergency and seek an emergency declaration from HHS. An emergency declaration needs to be declared before EUA applications can be approved.
- 10 USC § 1107 as currently written restricts DoW's ability to provide foreign-approved medical products to service members in times of need.