Legal Authorities to Refuse an Emergency Use Authorized Product

Legal Basis to Accept or Refuse any Emergency Use Authorized Product

1. The Secretary of Health and Human Services (HHS) makes an emergency declaration regarding an existing or potential threat. This declaration clearly articulates liability protection for involved parties (i.e. the government and product manufacturers). (42 USC 247(d)-6(d)).
2. The emergency declaration is published in the Federal Register. (42 USC 247(d)-6(d))
3. HHS Secretary can grant emergency use authorization (EUA) for products that do not have approval from the Food and Drug Administration (FDA). (21 USC 360-bbb-3)
4. Any EUA products must be published in Federal Register. (21 USC 360-bbb-3h)
5. The right to accept or refuse an EUA product (and to be informed of this right) is a **required condition** for ALL unapproved products. Products include all drugs, devices, or biological products (i.e. vaccines, masks, test kits, etc.). (21 USC 360-bbb-3e(1)a)
6. Military members can have this right waived in writing by the President only via a written waiver. The U.S. President has not issued a written waiver to date and there are no approved (licensed) masks, test kits, or shots on the current US market. (10 USC 1107a)
7. If the President of the United States issues a written waiver, the Secretary of Defense must submit to the chairman and ranking minority member of each congressional defense committee a notification of the waiver, together with the written determination of the President, and the Secretary's justification for the request or requirement for the member to receive the drug covered by the waiver. (10 USC 1107, 21 USC 355 / 21 USC 321 – all-encompassing definition of a "drug" in the context of 10 USC 1107)
8. An individual's informed consent is required to administer any EUA product because an EUA product is considered experimental. (21 CFR Part 50)

Vaccines - Specific Arguments

- Provides regulations for biological products, to include biologics licensing, interchangeability, biosimilar, and labeling. (42 USC 262)
    - The term BLA-compliant [biological product] is never legally defined. This term, legally, does not exist.
    - Labeling requirements. Must have:
        - Proper name of the product (e.g. Comirnaty/Spikevax)
        - Name, address and applicable license number (e.g HHS License Number 2229/2256)
        - Expiration date of the product
    - Explicitly states "no person shall falsely label any package or container of any biological product or alter any label or mark on the package so as to falsify the label or the mark."
    - Interchangeability requirements are outlined. Paragraph 9 describes the requirement to have a list of each biological product in electronic, searchable format. Interchangeable products are listed in the FDA Purple Book with a reference product (e.g. Comirnaty/Spikevax).
    - Biosimilar product requirements and applications are outlined.

Medical Devices - Specific Arguments for masks, test kits, etc.

- Legal definition of a medical device. (21 USC 321)
- Requirements for medical devices. (21 CFR 800)

Step by Step Breakdown
of the
Legal Basis to Accept or Refuse any Emergency Use Authorized Product

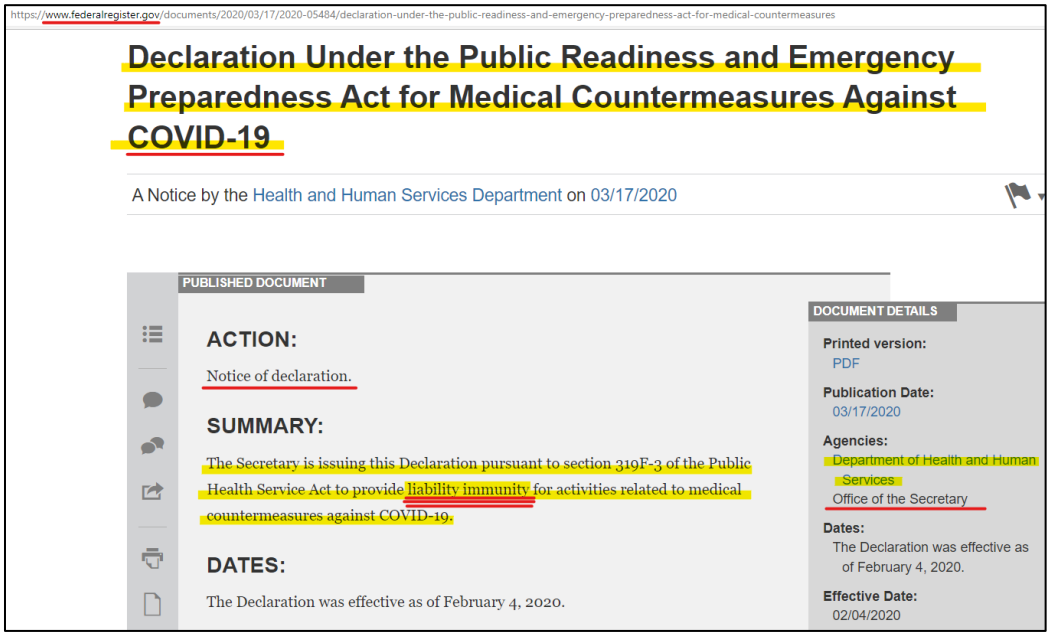
1. The Secretary of Health and Human Services (HHS) makes an emergency declaration regarding an existing or potential threat. This declaration clearly articulates liability protection for involved parties (i.e. the government and product manufacturers). (42 USC 247(d)-6(d)).

Source Documents:

a. 42 USC 247(d)-6(d): 42 USC 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures (house.gov)
b. 21 USC 321(h)(1): 21 USC 321: Definitions; generally (house.gov)
c. 42 USC 262: 42 USC 262: Regulation of biological products (house.gov)
d. 21 USC 360bbb-3: 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
e. Federal Register :: Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

Breakdown:

The Secretary of Health and Human Services (HHS) makes an emergency declaration regarding an existing or potential health threat. The Secretary of HHS has statutory authority to make public health emergency declarations through the PREP Act, codified in 42 USC 247d-6d. The emergency declarations must be posted in the Federal Register.


https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

A Notice by the Health and Human Services Department on 03/17/2020

PUBLISHED DOCUMENT

ACTION:

Notice of declaration.

SUMMARY:

The Secretary is issuing this Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

DATES:

The Declaration was effective as of February 4, 2020.

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
03/17/2020

Agencies:
Department of Health and Human Services
Office of the Secretary

Dates:
The Declaration was effective as of February 4, 2020.

Effective Date:
02/04/2020

This declaration clearly articulates liability protection for involved parties (i.e. the government and product manufacturers):

§247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term "loss" means any type of loss, including-

(i) death;
(ii) physical, mental, or emotional injury, illness, disability, or condition;
(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

Individuals who are being administered a "covered countermeasure" assume all health and liability risks, to include death. Per 42 USC 247(d)-6(d), a "covered countermeasure" includes products under emergency use authorization (EUA) such as vaccines, test kits, and masks designed to counter COVID-19 (the qualified pandemic).

(i) Definitions

In this section:

(1) Covered countermeasure

The term "covered countermeasure" means-

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));
(B) a security countermeasure (as defined in section 247d–6b(c)(1)(B) of this title);
(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b]; or
(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

A drug is defined in 21 USC 321(g)(1).

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia,[1] official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

42 U.S.C. Sec 262 defines biological products (below). Shots are a type of biological product and biological products can become an EUA product.

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

A [medical] device is defined in 21 USC 321 (h)(1). Test kits and masks are devices.

(h)(1) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

Per 42 USC 247(d)-6(d), liability protections are extended to "covered persons":

(2) Covered person

The term "covered person", when used with respect to the administration or use of a covered countermeasure, means-

(A) the United States; or

(B) a person or entity that is-

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

Covered persons include anyone acting in their official capacity in the U.S. government, such as the FDA, CDC, HHS, Congress, and DOD. Covered persons also include Pfizer, Moderna, and other manufacturers. Physicians, nurses, technicians, and pharmacists who prescribe, administer, or dispense the product are also covered persons.

Of note, corporate entities who require vaccination **<u>are *not* covered</u>** persons.

State and local governments are covered by the term "Program planner," which is defined in 42 USC 247(d)-6(d):

(6) Program planner

The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

2. The HHS publishes all emergency declaration and any amendments to the Federal Register for public record. (42 USC 247(d)-6(d)). The FDA/HHS also post all EUA products additions/revocations as notices in the Federal Register.

Source Documents:

a. 42 USC 247(d)-6(d): 42 USC 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures (house.gov)
b. Federal Register: https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures
c. HHS ASPR Page w/C19 Emergency Declaration Amendments: Public Readiness and Emergency Preparedness Act (hhs.gov)
a. Federal Register Combined Notice List for EUA Product Notices (Required by 21 U.S.C. 360bbb-3 (h)) and COVID-19 Declaration Amendments (required by 42 U.S.C. 247d-6d) – Federal Register :: Document Search Results for 'Covid 19 Emergency Use Authorization'

Breakdown:

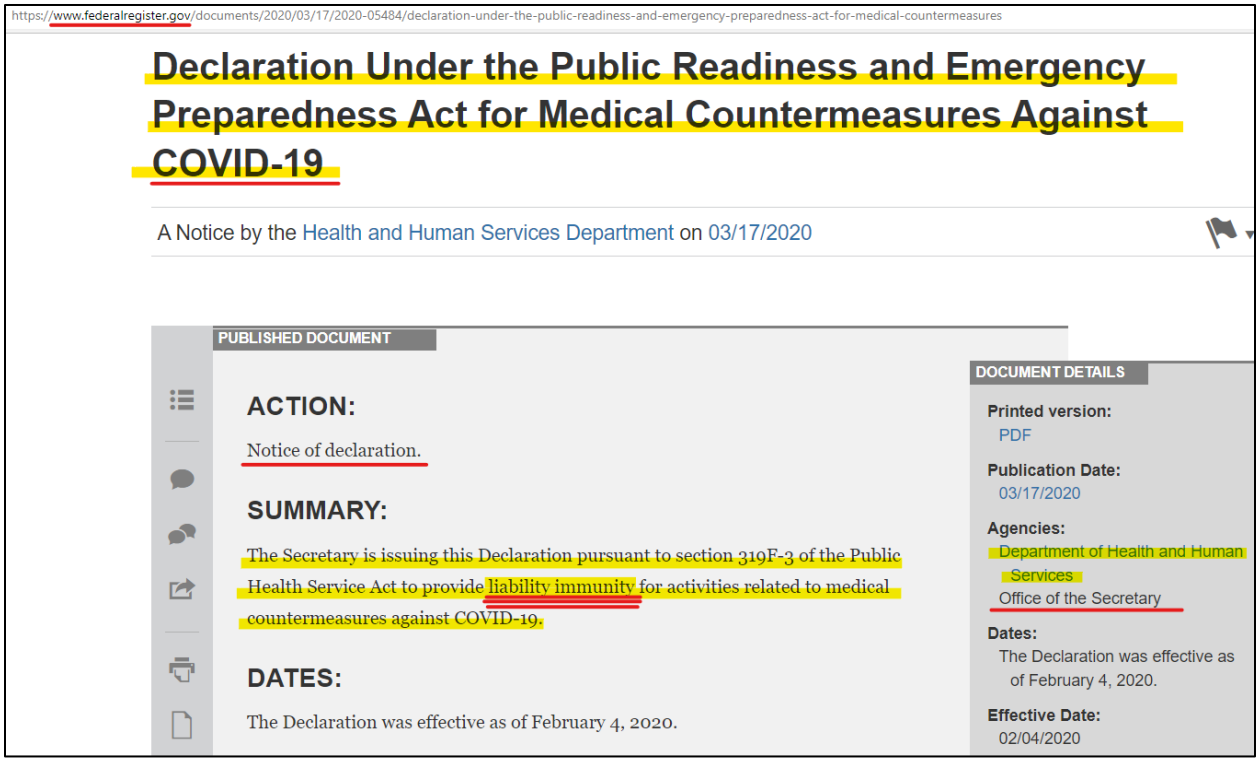
42 USC 247(d)-6(d) states:

(b) Declaration by Secretary

(1) Authority to issue declaration

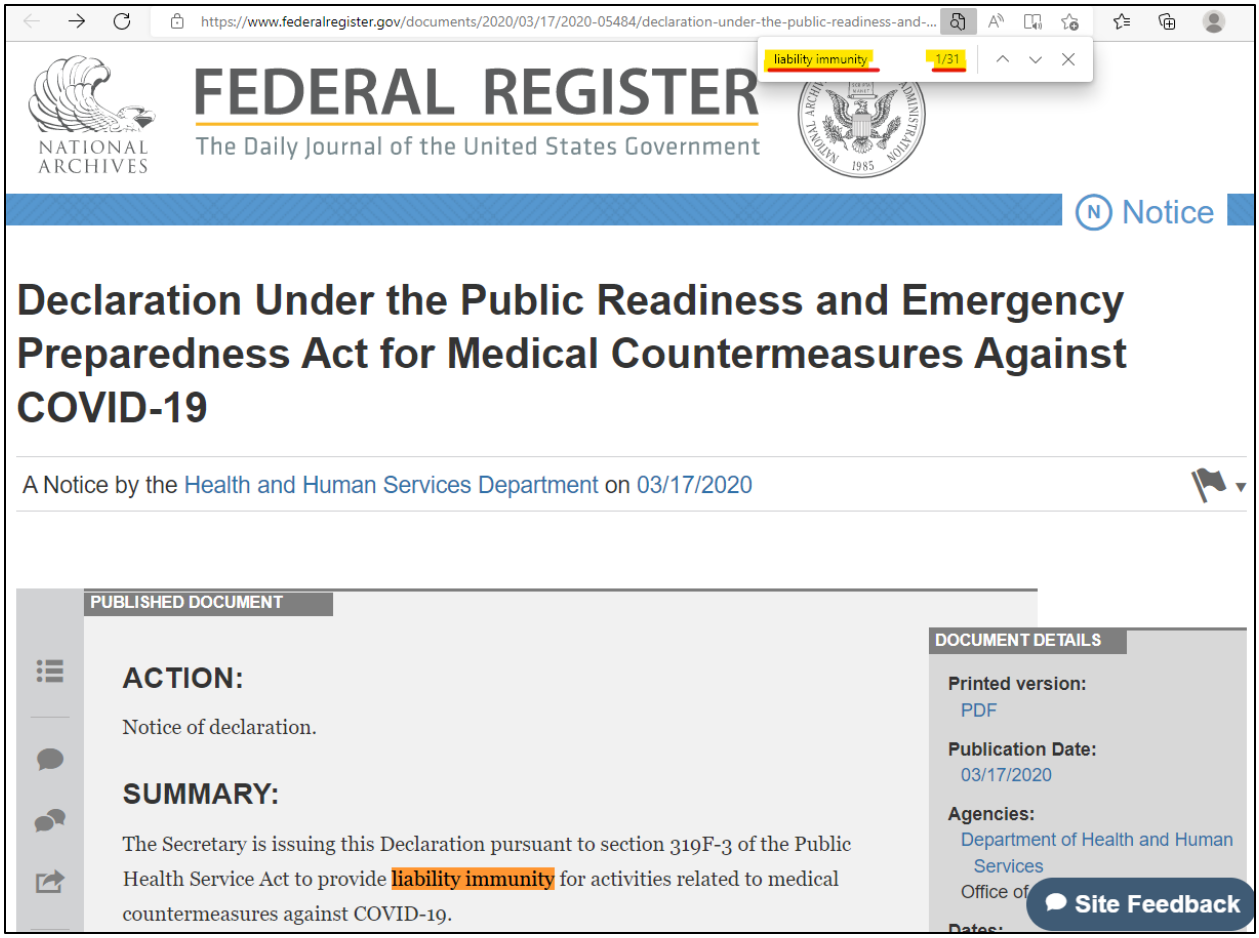
Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

The original COVID-19 emergency declaration posted in the Federal Register on 17 March 2020:



Note that the emergency declaration notifies the American people of the specific emergency and provides liability immunity for activities related to medical countermeasures against COVID-19.

The term “Liability immunity” is **used 31** times in the original emergency declaration:



"42 U.S.C. 247d-6d" is referenced 16 times in the emergency declaration:

It is worth noting that for countermeasures (products) and covered persons to have liability immunity under 42 USC 247d-6d, unapproved products have to be under EUA. For products to be EUA, the HHS Secretary has to declare an emergency. For the HHS Secretary to declare a public health emergency, there needs to be "a disease or other health condition or other threat to health constitutes a public

health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency." **FDA licensure removes liability immunity under Title 42 USC, 247d-6d for a licensed product and all covered persons.**

3. HHS Secretary can grant emergency use authorization (EUA) for products that do not have FDA-approval. (21 USC 360-bbb-3)

Source Document:

b. 21 USC § 360bbb-3: 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
c. Federal Register EUA Notices: Federal Register :: Document Search Results for 'Covid 19 Emergency Use Authorization'
d. FDA Webpage for Covered Countermeasures/EUA Products-Letters by Product Type: Emergency Use Authorization | FDA

Breakdown:

Emergency use authorization is defined in 21 USC § 360bbb-3:

§360bbb–3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that-

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an "unapproved product"); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) Relation to other uses

An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] referred to in paragraph (2)(A).

(4) Definitions

For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].
(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).
(C) The term "product" means a drug, device, or biological product.
(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).
(E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

To receive EUA status, 21 USC § 360bbb-3 identifies the following statutory requirements:

(c) Criteria for issuance of authorization

The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes-

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that-
(A) the product may be effective in diagnosing, treating, or preventing-
(i) such disease or condition; or
(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

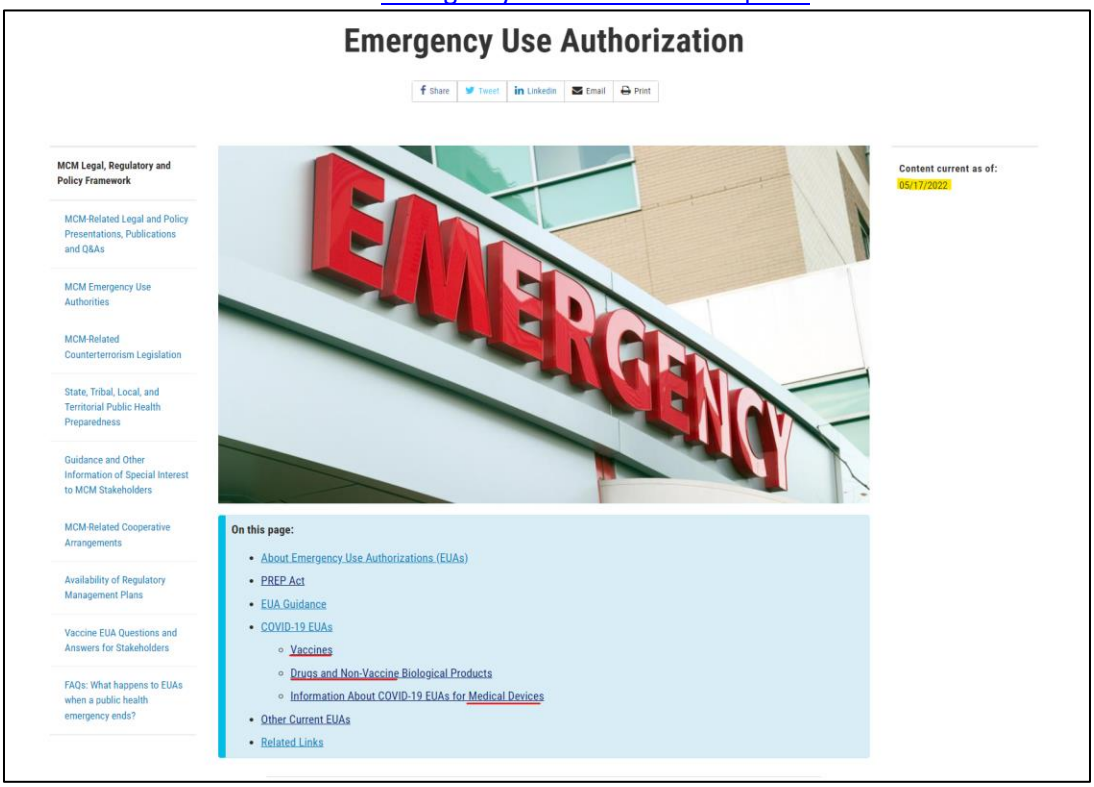
(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;
(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and
(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

There are **NO** FDA approved, licensed, or cleared vaccines, test kits, or masks available in the US market, so all unapproved products remain under liability protections from 42 USC 247d-6d with an EUA label.

If there was an FDA approved product (vaccine, test kit, or mask), the remaining authorized products would not be authorized for use or sale per 21 USC § 360bbb-3(c)(3), highlighted above.

Emergency Use Authorization | FDA



4. Any EUA products must be published in Federal Register. (21 USC 360bbb-3(h))

Source Documents:

f. 21 USC § 360bbb-3(h): 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
a. 42 USC 247(d)-6(d): 42 USC 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures (house.gov)
b. COVID-19 PREP Act Declarations: Public Readiness and Emergency Preparedness Act (hhs.gov)
c. HHS ASPR Page w/C19 Emergency Declaration Amendments (linked to Federal Register Postings): Public Readiness and Emergency Preparedness Act (hhs.gov)
d. Federal Register EUA Notices: Federal Register :: Document Search Results for 'Covid 19 Emergency Use Authorization'

Breakdown:

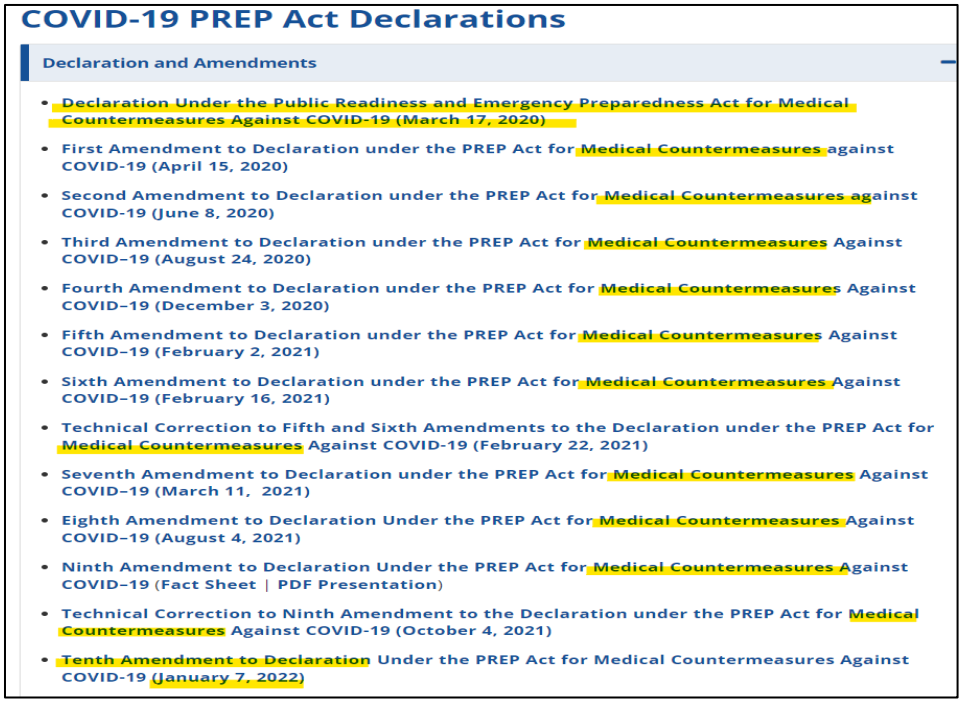
21 USC § 360bbb-3(h) states:

> **(h) Publication; confidential information**
>
> **(1) Publication**
>
> The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 355(i) [1] 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application). The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.

This means the emergency declaration, as well as a notice of all products the HHS Secretary is granting emergency use authorization and why the HHS Secretary is granting those authorizations, **must be published** in the **Federal Register**. As a reminder, when products are authorized for emergency use, they (as well as all relevant covered persons) automatically receive liability immunity in accordance with 42 USC § 427d-6d.

A review of the COVID-19 Public Readiness and Emergency Preparedness (PREP) Act declaration and amendments on the HHS ASPR page (each link is to the federal register posting) show each instance/amendment when the Secretary of HHS granted liability protections to covered countermeasures/persons and/or each instance the FDA through the HHS posted updates to EUA products.

Public Readiness and Emergency Preparedness Act (hhs.gov)



COVID-19 PREP Act Declarations

Declaration and Amendments

- Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (March 17, 2020)
- First Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (April 15, 2020)
- Second Amendment to Declaration under the PREP Act for Medical Countermeasures against COVID-19 (June 8, 2020)
- Third Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (August 24, 2020)
- Fourth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (December 3, 2020)
- Fifth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (February 2, 2021)
- Sixth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (February 16, 2021)
- Technical Correction to Fifth and Sixth Amendments to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (February 22, 2021)
- Seventh Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID–19 (March 11, 2021)
- Eighth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (August 4, 2021)
- Ninth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID–19 (Fact Sheet | PDF Presentation)
- Technical Correction to Ninth Amendment to the Declaration under the PREP Act for Medical Countermeasures Against COVID-19 (October 4, 2021)
- Tenth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 (January 7, 2022)

Federal Register :: Document Search Results for 'Covid 19 Emergency Use Authorization'

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

*5. The right to accept or refuse an EUA product (and to be informed of this right) is a **required condition** for **ALL** unapproved products. Products include all drugs, devices, or biological products (i.e. vaccines, masks, tests, etc.). (21 USC 360-bbb-3e(1)a)*

Source Documents:

a. 21 USC 360-bbb-3e: 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
b. Definition of "shall": https://www.merriam-webster.com/dictionary/shall
c. 21 USC 321 – 21 USC 321: Definitions; generally (house.gov)
d. 10 USC 1107 - 10 USC 1107: Notice of use of an investigational new drug or a drug unapproved for its applied use (house.gov)
e. 10 USC 1107a - 10 USC 1107a: Emergency use products (house.gov)
f. Section 564(e)(1)(A)(ii)(III) – 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov) [***Section 564 is the original section within the Food, Drug and Cosmetic Act-FDCA and passed into law, becoming codified in 21 USC § 360bbb.]
g. 21 USC § 360bbb-3(e)(1)(A)(ii)(III21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
h. Doe v. Rumsfeld, 341 F. Supp. 2d 1 – CourtListener.com
i. *United States v. Members of the Armed Services*, Dale Saran, Chapter 7: Congress Acts: 10 USC 1107.

Breakdown:

*The right to accept or refuse an EUA product is a **required condition** of an unapproved product.*

Required conditions for emergency use of an unapproved product, to include the option to accept or refuse administration of an unapproved product, are identified in 21 USC 360-bbb-3 e(1)a:

(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed-

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed-

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

The two most important parts of the above screenshot are underlined in RED. This is where government legal representatives have misrepresented key words in the past. A failure to notice this error can undermine the defense, resulting in a fundamental misunderstanding regarding the option to refuse an EUA product.

"Unapproved product" refers to all unapproved products (biological products, drugs, medical devices).

Subsection (b)(1) refers to the HHS Secretary's emergency declaration.

"Shall" is defined by Merriam-Webster as "used in laws, regulations, or directives to express what is mandatory."

"…including the following:" indicates the list after the colon represents the minimum requirements. The law does not leave much room to interpret. **The secretary can add to these required conditions, but these at the most minimum are the required conditions because as an individual, YOU BEAR ALL THE SHORT/LONG TERM MEDICAL AND LIABILITY RISK!**

Thus, the right to accept or refuse an EUA product is a required condition of an unapproved product. This includes vaccines, test kits, masks, remdesivir, and any other unapproved product.

When an individual substitutes the red underlined portion of subsection (e), it changes the meaning of this subsection. In 1LT Mark Bashaw's court martial, the prosecution attorney acted as though he was reading subsection (e)(1)(A) verbatim. However, instead of reading the red underlined words, he replaced "required" with "various". And instead of stating "including the following", he said "there is a list below that the Secretary of Health and Human Services MAY include." Subsequently, he argued that subsection (e) states the HHS Secretary can determine what unapproved products under emergency use come with the option to accept or refuse.

Since this seems to be the lynchpin for the government's case, it is worth taking an extra minute to consider the alternative. Reference the "Frequently Referenced Arguments and Counterpoints" section for a more in-depth discussion and review.

6. Military members can have this right waived in writing by the President only. (10 USC 1107a)

Source Documents:

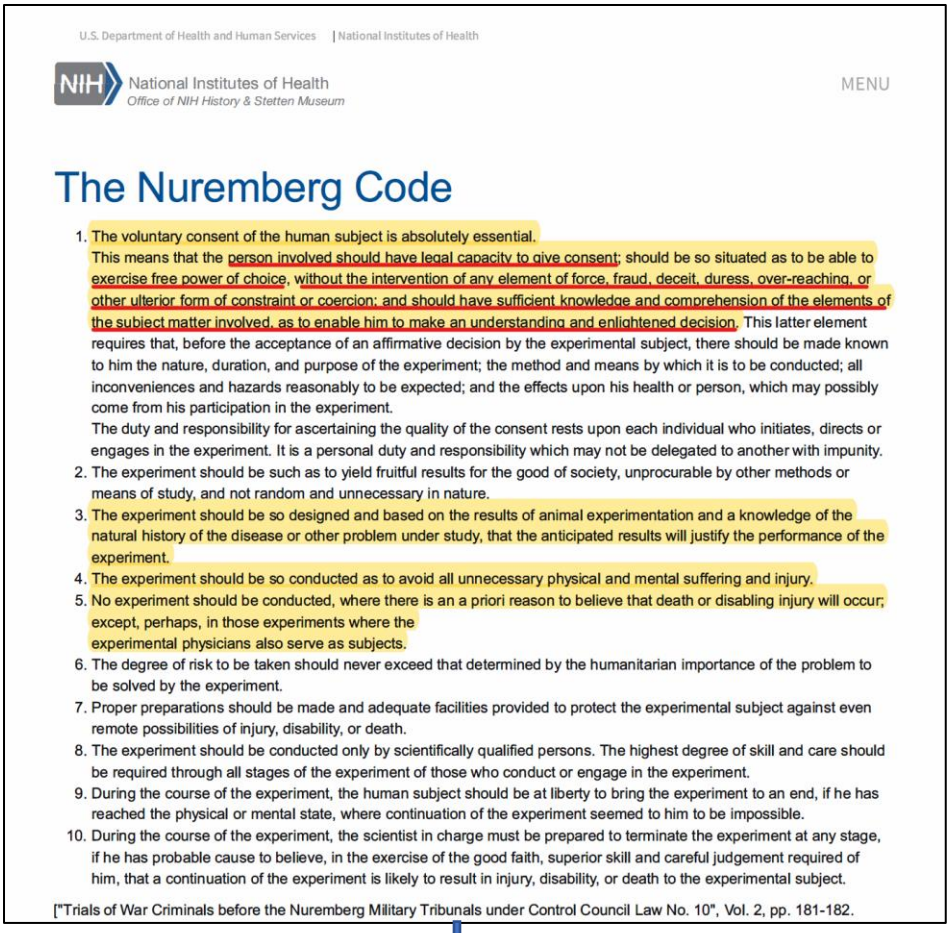
a. 10 USC 1107a - 10 USC 1107a: Emergency use products (house.gov)
g. 21 USC 360bbb-3(e)(1)(A)(II)(III) – 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
b. Nuremburg Code: Nuremberg Code - history - Office of NIH History and Stetten Museum

Breakdown:

The legal intent for all individuals to have the right to accept or refuse administration of an EUA product is clearly stated in 10 USC 1107a. Only in the case of the armed forces can the right to be informed of that stipulation be waived. And only the U.S. President can waive this right. If the President determines the right to inform members they have a right to accept or refuse a product is not in the interests of national security, this determination must be made in writing.

10 USC 1107a and 21 USC 360bbb-3(e)(1)(A)(II)(iii) state Service members NEVER LOSE the right to refuse, only to be informed if the President waives this required condition in writing. 21 USC 360bbb-3 (e) (1) (A) (II) (iii) also states Americans MUST be INFORMED of the RIGHT to Accept/Refuse.

IMPORTANT POINT: **Service members and AMERICANS never lose the right to legally refuse an EUA product!** The 10 USC 1107a written Presidential waiver requirement **ONLY waives the required condition** that Service Members **must** be informed of the right to accept/refuse. Nowhere in 10 USC 1107a or 21 USC 360bbb-3(e)(1)(A)(II)(iii) does it EVER state members of the armed forces lose the inherent right to accept or refuse. This is a direct result of U.S. Federal Laws codifying the major principles in the Nuremburg Code.



U.S. Department of Health and Human Services | National Institutes of Health

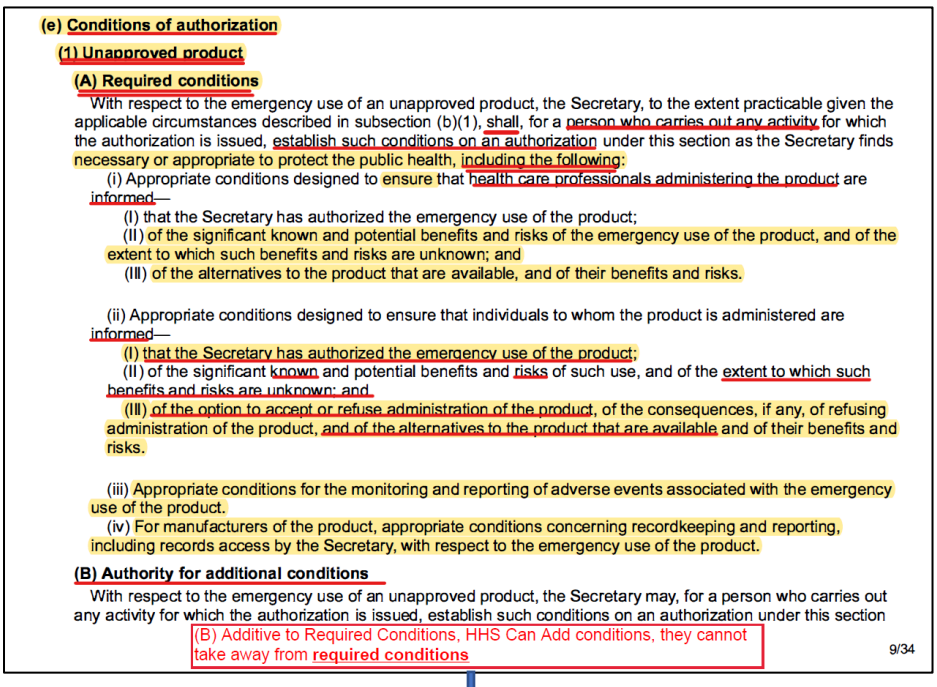
NIH National Institutes of Health
Office of NIH History & Stetten Museum

MENU

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.
The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182.



(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) Authority for additional conditions

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section

(B) Additive to Required Conditions, HHS Can Add conditions, they cannot take away from **required conditions**

9/34

§1107a. Emergency use products

Products (biological products-shots, devices-test kits/masks/PPE, and drugs-pills/injectables

(a) WAIVER BY THE PRESIDENT.-(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act 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. The Written POTUS waiver ONLY waives the required condition that Service Members MUST be informed. Pay attention to the legal definition. **We NEVER LOSE the RIGHT to REFUSE, only to be informed if POTUS Waives this required condition in writing 21 USC 360bbb-3 (e) (1) (A) (ii) (iii) also states Americans MUST be INFORMED of the RIGHT to Accept/Refuse. BLUF: Service members and AMERICANS never lose our right to refuse legally!**

(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.

(b) PROVISION OF INFORMATION.-If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(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.

Americans, to include members of the armed forces, never lose their right to refuse legally!

Many medical providers have directly violated this requirement by **not informing patients of their rights**. It is important to keep in mind that failure to inform someone of these rights does not change the EUA status of the product or liability afforded that EUA product. The individual also retains the inherent right to refuse.

7. If the President of the United States decides to issue a Waiver in writing, the Secretary of Defense must submit to the chairman and ranking minority member of each congressional defense committee a notification of the waiver, together with the written determination of the President, and the Secretary's justification for the request or requirement for the member to receive the drug covered by the waiver. (10 USC 1107)

Source Documents:

a. 10 USC 1107 - 10 USC 1107: Notice of use of an investigational new drug or a drug unapproved for its applied use (house.gov)
b. 21 USC 355: 21 USC 355: New drugs (house.gov)
c. 21 USC 321 - 21 USC 321: Definitions; generally (house.gov)
d. Executive Order 13-139: 99-26078.pdf (govinfo.gov) and Federal Register :: Improving Health Protection of Military Personnel Participating in Particular Military Operations

Breakdown:

10 USC 1107 articulates what actions would need to take place in the event a Presidential waiver was written for an investigational new drugs or drugs unapproved for its applied use on military members:

> (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.
>
> (2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which prior consent for administration of a particular drug is required by reason of a determination by the Secretary of Health and Human Services that such drug is subject to the investigational new drug requirements of section 505(i) of the Federal Food, Drug, and Cosmetic Act.
>
> (3) The Secretary of Defense may request the President to waive the prior consent requirement with respect to 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. With respect to any such administration-
>
> (A) the Secretary may not delegate to any other official the authority to request the President to waive the prior consent requirement for the Department of Defense; and
>
> (B) if the President grants the requested waiver, the Secretary shall submit to the chairman and ranking minority member of each congressional defense committee a notification of the waiver, together with the written determination of the President under paragraph (1) and the Secretary's justification for the request or requirement under subsection (a) for the member to receive the drug covered by the waiver.

A Presidential waiver of consent for military members requires:

1. The Secretary of Defense requests the President to waive the prior consent requirement. This cannot be delegated.
2. The President determines obtaining consent is not in the interests of national security and grants a waiver in writing. This cannot be delegated.
3. The Secretary of Defense submits the following to the chairman and ranking minority member of each congressional defense committee:
    a. A notification of the waiver
    b. The written determination of the President
    c. The Secretary of Defense's justification for the request or requirement
4. Though 10 USC 1107 does not explicitly state the requirement to submit written requests to the federal register as it does for EUA products (21 USC 360bbb-3(h)), the fact that a waiver must be in writing means it must be a public document/record. An Executive Order from 1998, EO

13139, required the Secretary of Defense to post any Presidential approved waiver to the Federal Register.

The 21 USC 355(i)(4) states:

> (4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 282 of title 42.

The term “drug” is defined in 21 USC 321:

> (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia,[1] official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.
>
> (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

The term “drug” includes articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals (i.e. vaccines, test kits, masks, etc.).

8. An individual's informed consent is required to administer any EUA product. (21 CFR Part 50)

Source Documents:

a. 21 USC 360bbb-3: 21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov)
b. 21 CFR Part 50 - eCFR :: 21 CFR Part 50 -- Protection of Human Subjects

Breakdown:

21 CFR Part 50 outlines the legal requirements for government agencies to comply with **informed consent and human subjects**.

21 CFR Part 50.25 provides the administrative law (rules) for ALL agencies to follow when providing informed consent.

Quick Summary of Statutory Laws (Passed by the Legislature, codified in the United States Codes 1-50) and Code of Federal Regulations (Agency Rules and Implementation Policies).

-The Federal Laws (United States Code) provide the over-arching framework and delegated authorities, whereas the Code of Federal Regulations (CFR) describe how agencies will use their delegated authority to execute their granted authorities.

21 CFR Part 50.25: eCFR :: 21 CFR Part 50 -- Protection of Human Subjects

§ 50.25 Elements of informed consent.

(a) ***Basic elements of informed consent.*** In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) ***Additional elements of informed consent.*** When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

(d) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

(e) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

[46 FR 8951, Jan. 27, 1981, as amended at 76 FR 270, Jan. 4, 2011]

§ 50.27 Documentation of informed consent.

(a) Except as provided in § 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

(b) Except as provided in § 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A *short form* written consent document stating that the elements of informed consent required by § 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

eCFR :: 21 CFR Part 50 -- Protection of Human Subjects

Frequently Referenced Arguments and Counterpoints

1. Availability of FDA-Approved COVID-19 Vaccines

2. Comirnaty and Spikevax are just marketing names. They're the same as Pfizer-BioNTech and Moderna.

3. The products are interchangeable.

4. The HHS Secretary did not require informed consent for this product.

5. The vaccines are safe.

6. Anyone that experiences an adverse event from the vaccines can sue.

7. Could a covered person ever be sued?

1. Availability of FDA-Approved COVID-19 Vaccines

The Centers for Disease Control and Prevention (CDC) website states the products approved under a Biologics License Application (BLA), Comirnaty and Spikevax, are not available in the United States. Reference the CDC's website at: [IIS COVID-19 Vaccine Related Code | CDC]

Here is a screenshot of the CDC website:

The following vaccines and associated tradenames have been approved by the FDA under BLA License. They are listed separately because while they may represent the same formulations as the EUA authorized and labeled products listed above, the NDCs listed with the new BLA licensed tradenames in the FDA BLA approval or the FDA Structured Product Labels (SPL) are not currently being produced by the manufacturers while EUA product is available.

Manufacturer	FDA Authorization (BLA, EUA, Pre-EUA)	Sale Proprietary Name	Product Description	Unit of Sale NDC10 (UOS)	UoS Package	Unit of Use NDC10 (UOU)	UoU Presentation	
Pfizer-BioNTech	BLA-licensed for ages 16+	COMIRNATY	30 mcg/0.3 mL for adult 16+ (original formula)	0069-1000-02	CARTON, 195 MULTI-DOSE VIALS	0069-1000-01	VIAL, 2 mL, MULTI-DOSE VIAL	COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels: "Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and
				00069-1000-03	CARTON, 25 MULTI-DOSE VIALS			
Pfizer-BioNTech	BLA-licensed for ages 16+	COMIRNATY	30 mcg/0.3 mL for adult 16+ (Same as EUA tris sucrose formula)	0069-2025-10	CARTON, 10 MULTI-DOSE VIALS	0069-2025-01	VIAL, 2 mL, MULTI-DOSE VIAL	

If you scroll all the way down the link, it states when the page was last reviewed (date at time of drafting was May 17, 2022). BLA-licensed Pfizer and Moderna products are unavailable.

It is worth noting that Comirnaty was considered FDA-approved on 23 August 2021. Spikevax was considered FDA-approved on 31 January 2022. The vaccines and associated tradenames that have been approved by the FDA under BLA license are **NOT** currently being produced by the manufacturers. As a result, the vaccine manufacturers, the government, healthcare workers, etc. are still covered persons and have full liability protection in the event an individual experiences an adverse event.

A Freedom of Information Act (FOIA) response dated 20 April 2022 from the Defense Health Agency (DHA) confirming there are no search results for any COMIRNATY order or requisition in the DoD:

DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

April 20, 2022

[redacted]

DHA Initial Case No: 21-00359 (Other category) Requester's Tracking No 256601:

Dear [redacted]:

Thank you for your Freedom of Information Act (FOIA) request received by the Defense Health Agency (DHA) on September 13, 2022. This correspondence serves as a final response to your request.

A review of your request shows that you are seeking:

[How many COVID19 Vaccines under the name COMIRNATY (not under the name Pfizer BioNTech COVID-19 Vaccine) the DoD ordered, received, has on stock, has available, administered to service members, by service branches (Army, Navy, Marine Corps, Air Force, and Coast Guard) and when. How many COVID19 Vaccines under the name COMIRNATY (not under the name Pfizer BioNTech COVID-19 Vaccine) is scheduled to receive in the future by service branches.]

After conducting a search, it was determined that the DHA does not have records in response to your request. Although this does not constitute a denial because no records were found or withheld, you may appeal to the appellate authority if you are not satisfied with this response.

Your appeal must be written and postmarked within 90 calendar days of the date of this

DHA has not ordered Comirnaty because despite being FDA-approved for almost a year, Pfizer is not manufacturing the FDA-approved vaccines. The available COVID-19 vaccines are EUA.

2. Comirnaty and Spikevax are just marketing names. They're the same as Pfizer-BioNTech and Moderna.

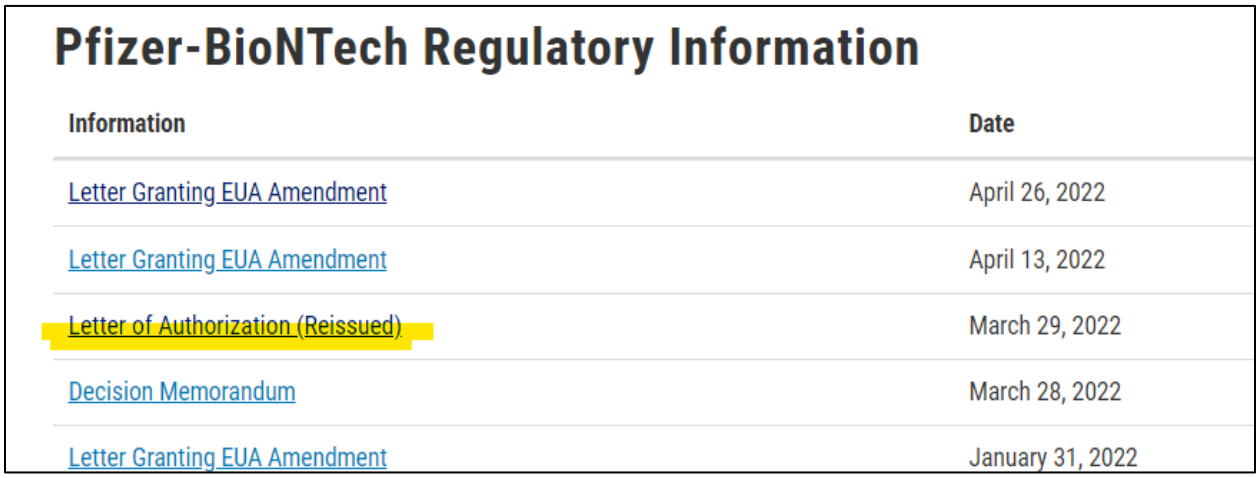
The COVID-19 vaccine EUA letters from the FDA clearly articulate the difference between the two products. These letters can be found on the FDA website. Pertinent FDA documents relating to both the EUA and FDA-approved COVID-19 vaccines can be found at:

Comirnaty and Pfizer-BioNTech: Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA

Spikevax and Moderna: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine

Johnson & Johnson: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

Upon opening one of the above links, scroll down and you will locate the regulatory documents. The Pfizer-BioNTech page, for example, looks like this:

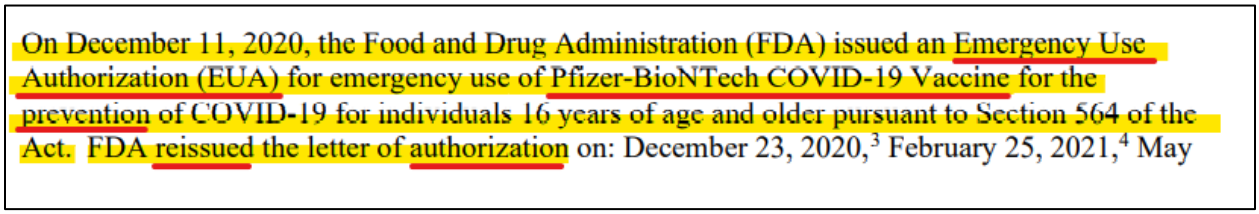


Pfizer-BioNTech Regulatory Information

Information	Date
Letter Granting EUA Amendment	April 26, 2022
Letter Granting EUA Amendment	April 13, 2022
Letter of Authorization (Reissued)	March 29, 2022
Decision Memorandum	March 28, 2022
Letter Granting EUA Amendment	January 31, 2022

To view the Letter of Authorization, click on the associated hyperlink (Pfizer-BioNTech COVID-19 Vaccine EUA LOA reissued March 29 2022 (fda.gov)). Unlike the Factsheet, this EUA Letter is the binding agreement between Pfizer-BioNTech and the FDA to give Emergency Use Authorization for the Pfizer-BioNTech COVID-19 Vaccine. As of this writing, the most recently reissued EUA letter was reissued on March 29, 2022. Subsequent reissuances will also include the verbiage below because the FDA is required by law to ensure certain statements are included in every EUA letter.

This is the Pfizer-BioNTech Letter of Authorization from the FDA, pages 1-3:



On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7] On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA)[8] and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA).[9] Subsequently, FDA reissued the letter of authorization on September 22, 2021,[10]

October 20, 2021,[11] October 29, 2021,[12] November 19, 2021,[13] December 9, 2021,[14] December 16, 2021,[15] and January 3, 2022.[16]

On March 29, 2022, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is reissuing the January 3, 2022 letter of authorization in its entirety with revisions incorporated to authorize the administration of a second booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech

Although the FDA approved Comirnaty, the FDA-approved vaccines are not being produced. As a result, the FDA has reissued in its entirety the Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine - over half a year after the administrative approval of Comirnaty.

Pfizer-BioNTech Letter of Authorization from the FDA, page 13:

The Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) that uses PBS buffer have the same formulation. Additionally, the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer and COMIRNATY (COVID-19 Vaccine, mRNA) that uses Tris buffer have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness. Accordingly, under this EUA, the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) that uses PBS buffer can be used interchangeably, and the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer and COMIRNATY (COVID-19 Vaccine, mRNA) that uses Tris buffer can be used interchangeably, as described above, without presenting any safety or effectiveness concerns. As described below under *Product Description*, the formulations that

The EUA Pfizer-BioNTech COVID-19 vaccine and Comirnaty are **legally distinct**.

Pfizer-BioNTech Letter of Authorization from the FDA, page 21:

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use either in individuals 12 years of age and older, or in individuals 5 through 11 years of age, as appropriate; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

The Pfizer-BioNTech COVID-19 vaccine must be clearly labeled and shall state the product has not been approved or licensed by the FDA… because the Pfizer-BioNTech COVID-19 vaccine is EUA.

Note: Section 564 of the FD&C Act became 21 USC § 360bbb-3 when it was codified in law. These references discuss authorization for medical products for use in emergencies. It also discusses the right to accept or refuse and EUA product.

Pfizer-BioNTech Letter of Authorization from the FDA, page 22:

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine for this population.

The distinction between Comirnaty, the FDA approved / BLA licensed product, and the Pfizer-BioNTech COVID-19 vaccine is reiterated. The Pfizer-BioNTech COVID-19 vaccine is AUTHORIZED for emergency use (aka EUA).

3. The products are interchangeable.

The legal basis for interchangeability is outlined in 42 USC § 262 (42 USC 262: Regulation of biological products (house.gov)):

§262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—
(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and
(B) each package of the biological product is plainly marked with—
(i) the proper name of the biological product contained in the package;
(ii) the name, address, and applicable license number of the manufacturer of the biological product; and
(iii) the expiration date of the biological product.

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

Biological product labels are required to be plainly marked. If a product's label says "For use under an Emergency Use Authorization," it means it is not FDA approved. It means the product is not BLA compliant. The product is only authorized for emergency use (EUA) and as a result, comes with liability protection for the manufacturer, healthcare workers, the government, and other covered persons.

Biological products include vaccines, test kits, masks, etc. and must be properly labeled.

(i) "Biological product" defined

In this section:
(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—
(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.
(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(o), 505(p), and 505–1 of such Act [21 U.S.C. 355(o), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

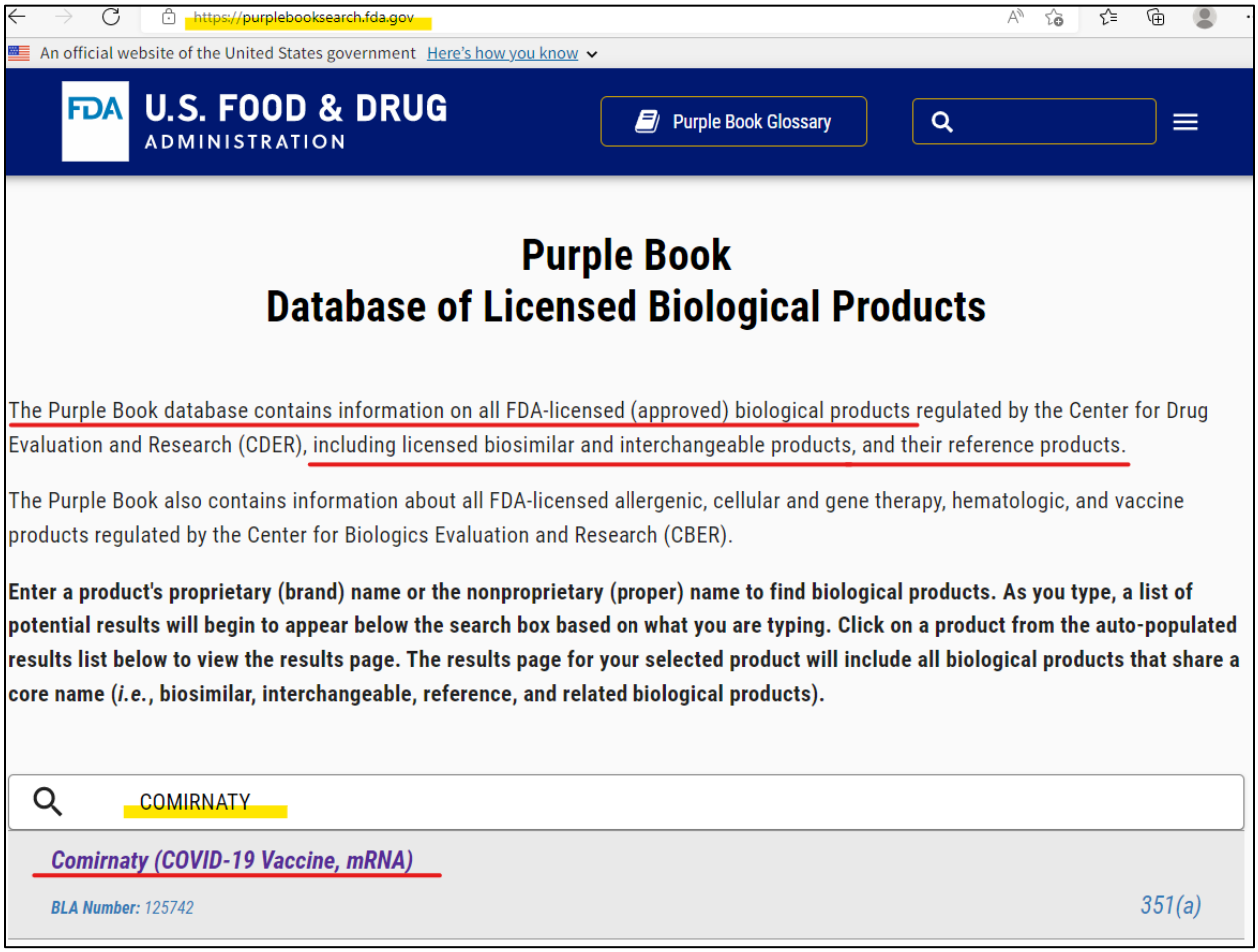
(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

For something to be "interchangeable" with another product:

- Paperwork must be submitted requesting interchangeability
- Must be biosimilar and expected to produce the same results as the reference product.
- Must meet certain safety standards, to include no increased risk if the product is administered more than once to someone.
- The HHS Secretary must determine the biological product is interchangeable with a reference product. The reference product must be licensed.

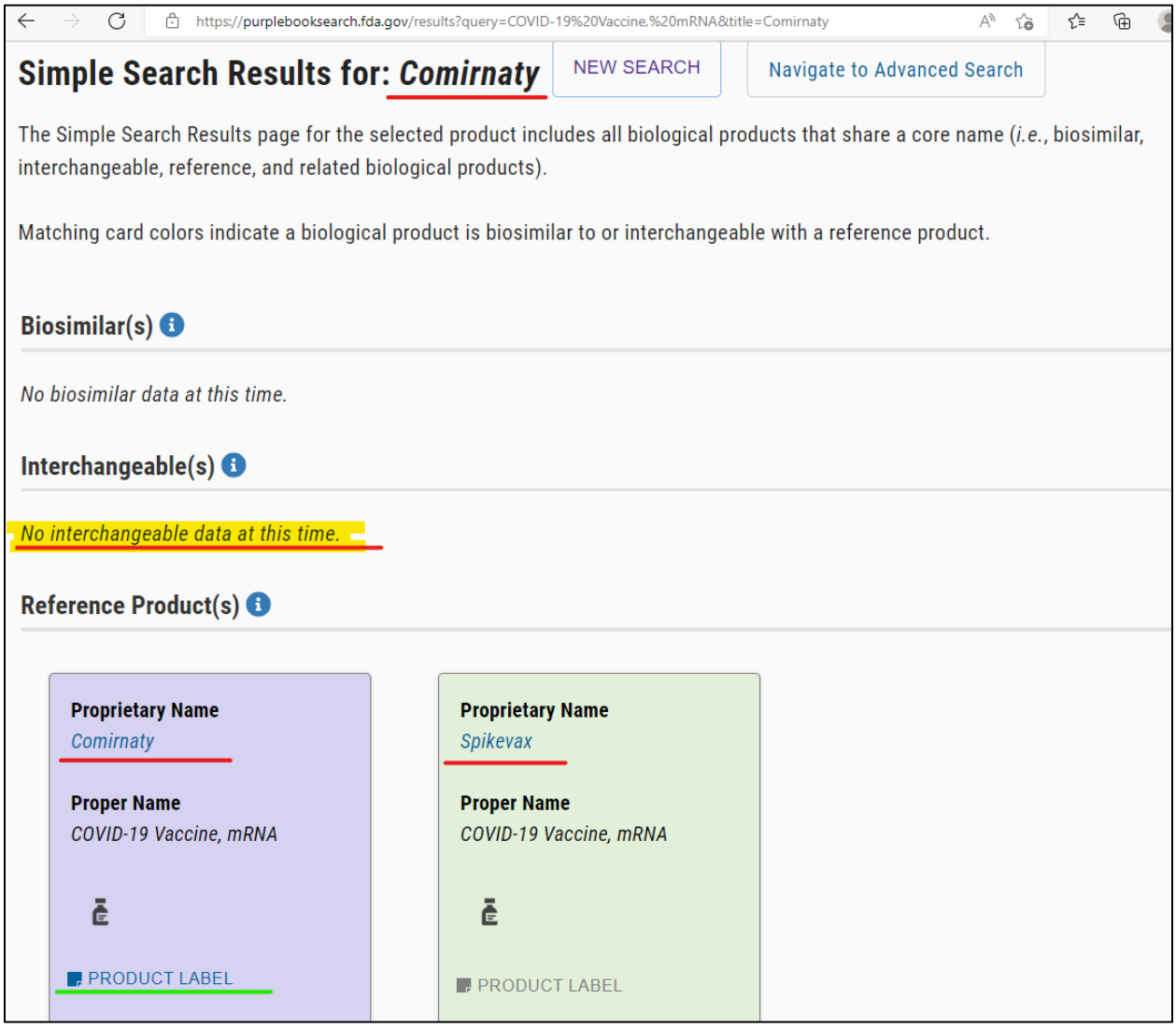
When a biological product is determined to be interchangeable with a reference product, Title 42 Section 262 requires those products to be listed in a publicly searchable, electronic database: The FDA Purple Book (FDA Purplebook).

The FDA Purple Book website:



To obtain information about a specific biological product, to include licensed biosimilar and interchangeable products, search for the product. A search of "Comirnaty" returns a purple link for Comirnaty (COVID-19 Vaccine, mRNA). FDA Purplebook

Clicking the purple link for Comirnaty (COVID-19 Vaccine, mRNA) results in:



The FDA Purple Book is very clear. The FDA has not identified any biological products that are biosimilar or interchangeable with Comirnaty. In fact, there are no interchangeable products for either Comirnaty or Spikevax.

The FDA Purple Book site also has pictures of the product label.

The following is the label for a Comirnaty COVID-19 vaccine:

This is the approved "Properly Labeled" Comirnaty Label. BLUF: If a vial has this label, it is using the approved label. **These labels are not in the US market as of May 2022.**

COMIRNATY- covid-19 vaccine, mrna injection, suspension

Image 1 of 3 VIEW ENLARGEMENT +

NIH NLM

https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty

This is the legally licensed Biological **Product Label** IAW 42 U.S.C. § 262

The minimum legal requirements for a legally licensed product are the following (Highlighted or Underlined in RED):

§262. Regulation of biological products

(a) Biologics license

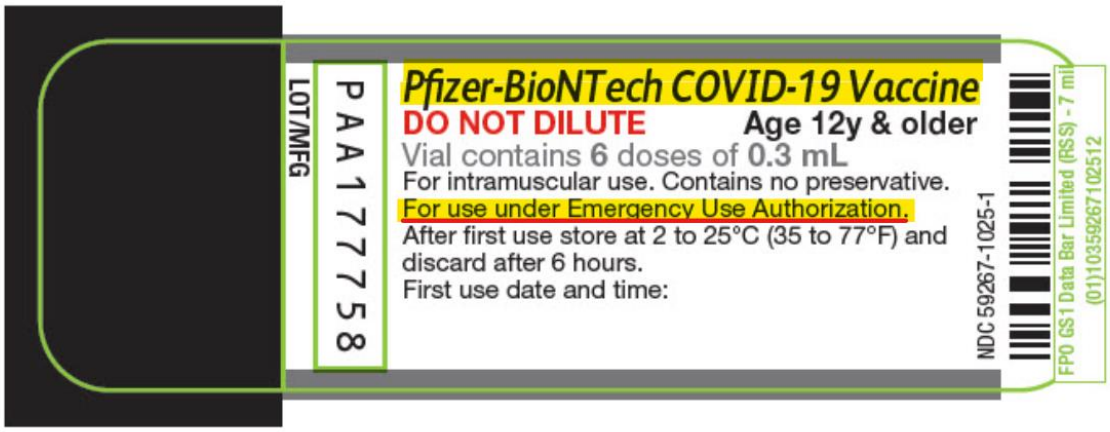
(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—
(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and
(B) each package of the biological product is plainly marked with—
(i) the proper name of the biological product contained in the package;
(ii) the name, address, and applicable license number of the manufacturer of the biological product; and
(iii) the expiration date of the biological product.

Consider the requirements for something to be "interchangeable" with another product. How can anyone know if the Pfizer-BioNTech COVID-19 vaccine produces the same clinical results as the reference product, Comirnaty, in any given patient or if there is greater risk associated with multiple uses of the product if Comirnaty doesn't exist and therefore, clinical studies comparing the two products cannot be performed?

This impossibility is further exposed in the Comirnaty approval letter (August 23, 2021 Approval Letter - Comirnaty (fda.gov)).

This is the Pfizer-BioNTech mRNA Covid19 Vaccine under EUA (and still the only Pfizer shot in the market):

PFIZER-BIONTECH COVID-19 VACCINE (bnt162b2) injection, suspension



VIEW ENLARGEMENT +

NIH NLM

The label indicates Pfizer-BioNTech COVID-19 mRNA Vaccine "For use under Emergency Use Authorization." The Pfizer-BioNTech COVID-19 mRNA Vaccine is the only Pfizer-BioNTech COVID-19 vaccine available to Americans. It is "Legally Distinct" from the Comirnaty vaccine, as per Page 13 (PDF Page 14) of the Re-Issued EUA Letter below. These EUA labeled products remain under EUA as evidenced by the accompanying FDA Issued EUA Letter as of 29 March 2022.

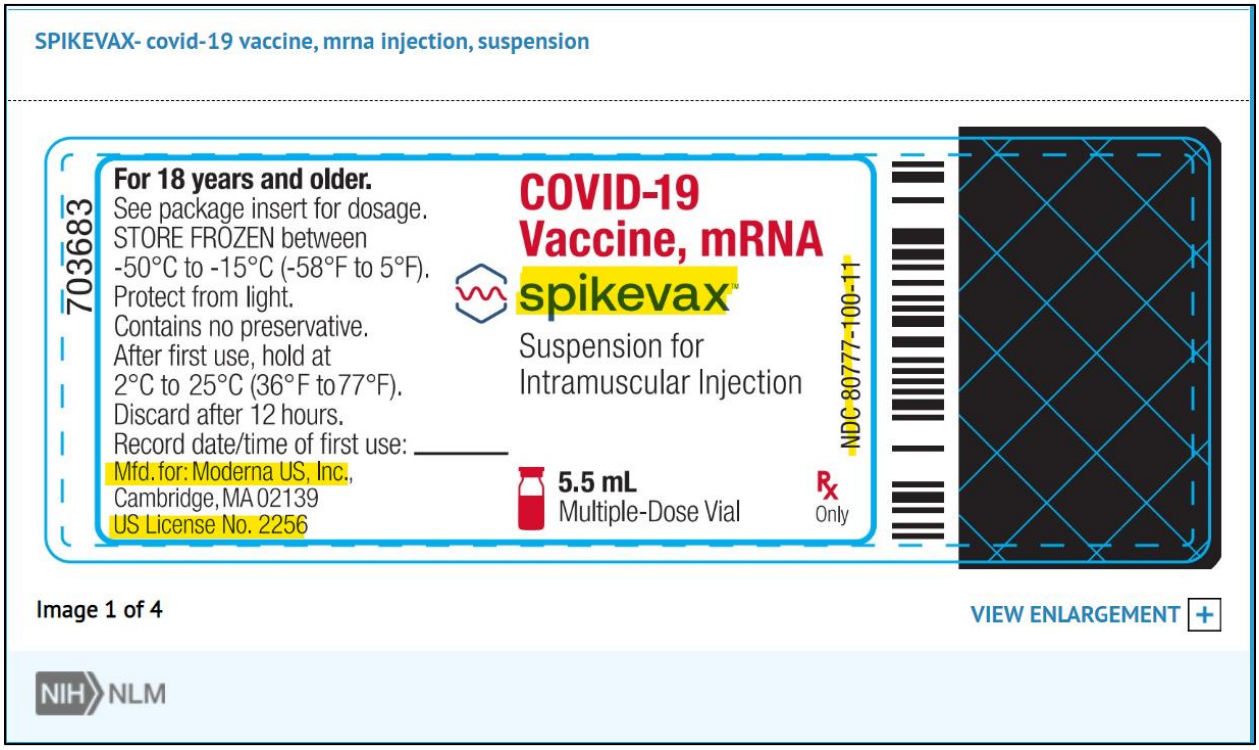
§262. Regulation of biological products

(a) Biologics license

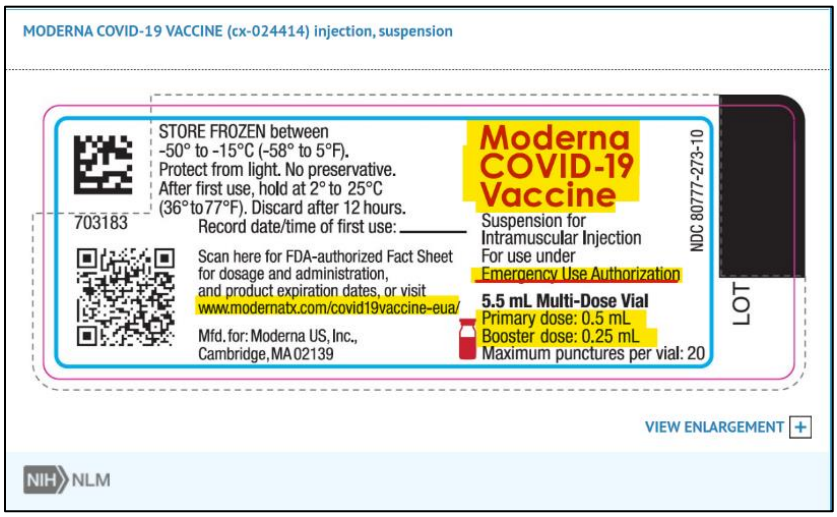
(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—
(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and
(B) each package of the biological product is plainly marked with—
(i) the proper name of the biological product contained in the package;
(ii) the name, address, and applicable license number of the manufacturer of the biological product; and
(iii) the expiration date of the biological product.

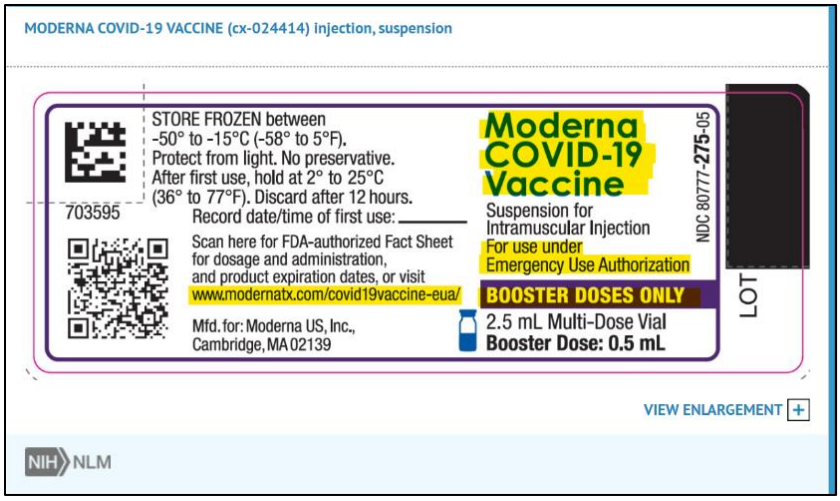
[EUA LABELS ARE Missing ALL THREE 42 USC 262 Required Elements)

Moderna labels have similar discrepancies. This is the legally licensed Biological Product Label in accordance with 42 U.S.C. § 262 (https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Spikevax):



The American people only have access to the Moderna COVID-19 vaccine that is labeled with "Emergency Use Authorization," as depicted below:



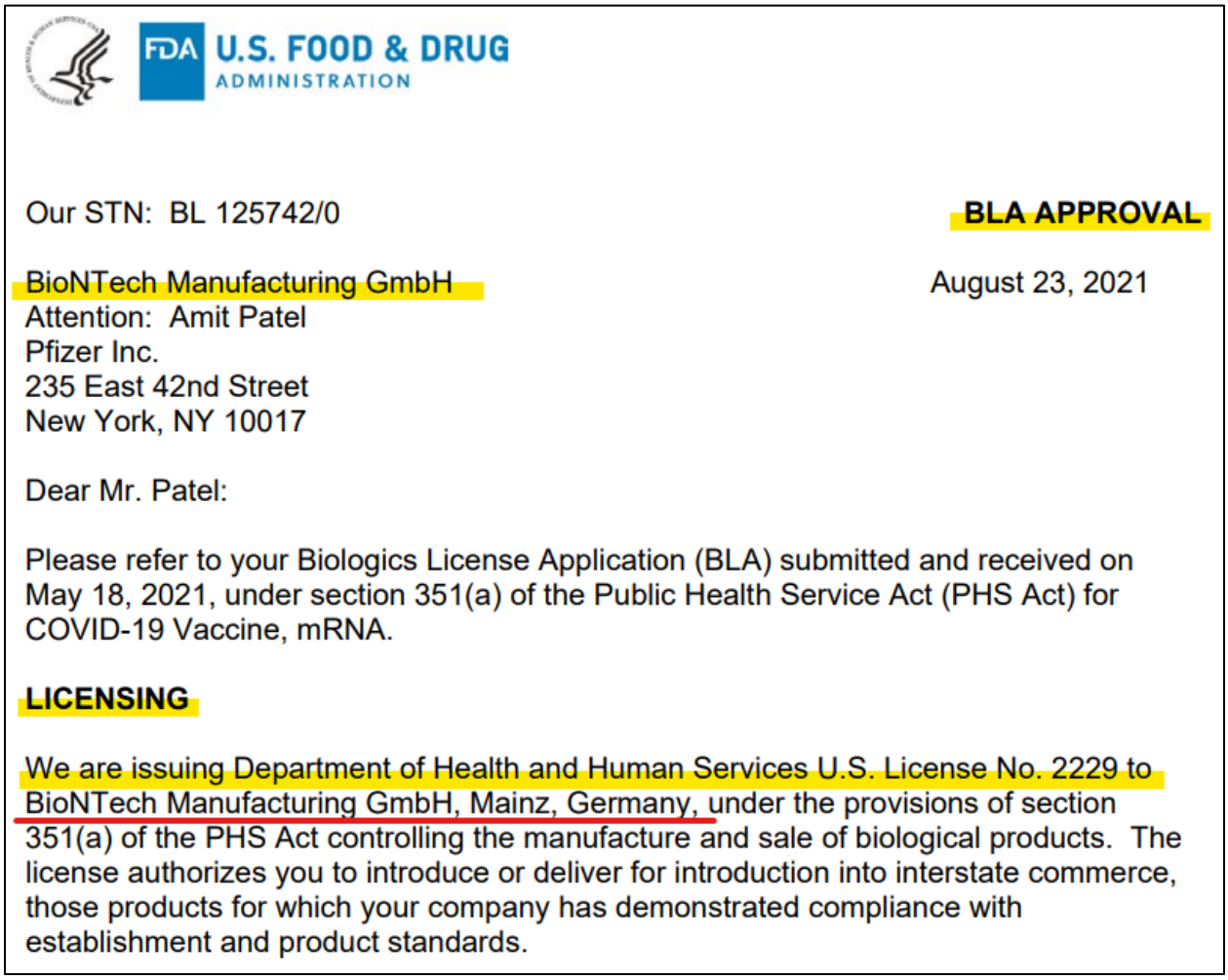


Again, the EUA labels are missing all three 42 USC 262 required elements:

- The proper name of the biological product contained in the package;
- The name, address, and applicable license number of the manufacturer of the biological product; and
- The expiration date of the biological product.

Bottom Line: If you are using this shot/product, you are using an **unapproved** EUA product defined and governed by 21 U.S.C. § 360bbb-3 and with Liability Protections as a Covered Countermeasure under 42 U.S.C. § 247d-6d (Enclosure "Properly Labeled" Spikevax Label. BLUF: If a vial has this label, IT IS NOT LICENSED OR APPROVED AND IS SUBJECT TO ALL LIABILITY PROTECTIONS. THESE LEGALLY CANNOT BE MANDATED BECAUSE THESE ARE EXPERIMENTAL BY LAW.

This is the Comirnaty approval letter:



U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH

August 23, 2021

Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

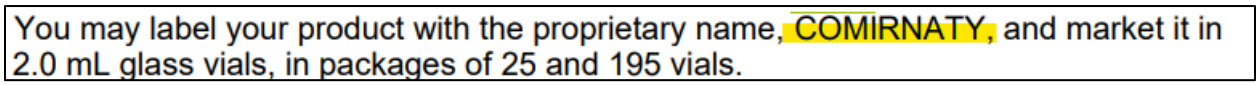
Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Of interest, the FDA license is issued to BioNTech Manufacturing GmbH, not Pfizer.

Comirnaty approval letter, page 2:



You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.

The FDA approval letter specifically discusses the labeling, to include use of the name “Comirnaty.”

Comirnaty approval letter, page 6

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

The clinical studies for the FDA approved Comirnaty vaccine are being performed with the emergency use authorized Pfizer-BioNTech COVID-19 vaccine. The clinical studies will not be complete until the year 2025.

Put in other words, the clinical studies for the reference product are not being performed with the referenced product, the FDA approved Comirnaty vaccine, but rather with the EUA Pfizer-BioNTech COVID-19 vaccine. It is 2022 and we are in the middle of ongoing trials!

The claim that both vaccines can be used "interchangeably… without presenting any safety or effectiveness concerns" is baseless, since Comirnaty, the product that is compared to the EUA product Pfizer-BioNTech, doesn't exist. The products are legally distinct.

4. The HHS Secretary did not require informed consent for this product.

For argument's sake, **if** the option to accept or refuse were determined by the HHS Secretary:

- Why bother having subsection (e)(1)(A) if required conditions do not in fact mean REQUIRED? Subsection (a)(1) already gives the HHS Secretary the authority to give unapproved products (vaccines, test kits, masks, etc) deemed appropriate EUA status for a declared emergency. If the list outlined in subsections (e)(1)(A)(i) and (e)(1)(A)(ii) were optional, subsection (e) would read "optional conditions of authorization"; (e)(1) would read "Selected Unapproved products"; and (e)(1)(A) would read "Various conditions."

- If the word "may" was used (as misrepresented above), there would also have to be an additional subsection within 21 USC 360bbb-3 that delineated the basis for a product to come with the option to accept or refuse. The laws are designed to be specific. For an example, 21 USC 360bbb-3(b)(1) states:

> **(b) Declaration of emergency or threat justifying emergency authorized use**
>
> **(1) In general**
>
> The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of-
>
> (A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;
>
> (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, 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;
>
> (C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or
>
> (D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient to affect national security or the health and security of United States citizens living abroad.

  There is always a basis of something that allows the appropriate authority to do what it "may" do. In 21 USC 360bbb-3(b)(1), the Secretary may make an emergency declaration to justify issuing EUA for a product on the basis of a determination made by the three specific secretaries, or the identification of a material threat. Additionally, there are always "pursuant to section" is always used to articulate the legal authority.

  If the list in 21 USC 360-bbb-3 e(1)a, specifically the option for the individual being administered the EUA product to accept or refuse, is not a required condition for all unapproved products, what is the criteria or basis for an unapproved product under emergency use to come with the option to accept or refuse a product? 21 USC § 360bbb-3 does not list any criteria or basis.

- 10 USC 1107 provides guidance regarding the use of EUA products on members of the armed forces. Throughout this section, the term "drug" is used. To mitigate confusion, this term is defined in 21

USC 321 as:

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia,[1] official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

The term “drug” as used in 10 USC 1107 includes articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. In this context, “drug” includes vaccines, test kits, masks, etc.

10 USC 1107 describes the notice required to use investigational new drugs or drugs unapproved for its applied use on military members:

§1107. Notice of use of an investigational new drug or a drug unapproved for its applied use

(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).

10 USC 1107 subsection (d) states:

(d) CONTENT OF NOTICE.-The notice required under subsection (a)(1) shall include the following:

(1) Clear notice that the drug being administered is an investigational new drug or a drug unapproved for its applied use.

(2) The reasons why the investigational new drug or drug unapproved for its applied use is being administered.

(3) Information regarding the possible side effects of the investigational new drug or drug unapproved for its applied use, including any known side effects possible as a result of the interaction of such drug with other drugs or treatments being administered to the members receiving such drug.

(4) Such other information that, as a condition of authorizing the use of the investigational new drug or drug unapproved for its applied use, the Secretary of Health and Human Services may require to be disclosed.

In addition to the requirement for the Secretary of Defense to notify members when they are receiving an EUA product as well as the Department of Defense must state why it is being administered, as well as possible side effects and other conditions of authorizing the product, the notification must be provided prior to receiving the product and in writing. The Secretary of Defense is required to ensure health care providers receive the information listed above to ensure members are properly notified.

(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).

(b) TIME OF NOTICE.-The notice required to be provided to a member under subsection (a)(1) shall be provided before the investigational new drug or drug unapproved for its applied use is first administered to the member.

(c) FORM OF NOTICE.-The notice required under subsection (a)(1) shall be provided in writing.

Reason for 10 USC 1107 (and 1107a). Congress passed 10 USC 1107 into law via the FY1998 National Defense Authorization Act (October 1997). Congress passed 1107 into law as a direct result of all of the damaging health effects suffered by our Gulf War veterans by being forced to take experimental drugs that ended up making health effects worse once exposed to Sarin gas. Shortly after 10 USC 1107’s passage, the DoD forced a licensed product for an unlicensed use

(investigational new drug) (Anthrax Vaccine-AVA). [See Doe v. Rumsfeld, 341 F. Supp. 2d 1 – CourtListener.com; *United States v. Members of the Armed Services*, Dale Saran, Chapter 7: Congress Acts: 10 USC 1107.]

- 10 USC § 1107a provides further evidence of the legal intent for all individuals to have the right to accept or refuse administration of an EUA product:

> **§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 Federal Food, Drug, and Cosmetic Act 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.

- Section 564 is the original section within the Food, Drug and Cosmetic Act-FDCA and passed into law becoming codified in 21 USC § 360bbb. Section 564(e)(1)(A)(ii)(III) and 21 USC § 360bbb-3(e)(1)(A)(ii)(III) are the same:

> (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.

The government has used this section to assert the right to accept or refuse a product is not a required condition of an EUA product. The claim is that because a fact sheet for a specific product (i.e. test kit, mask, etc.) does not specifically state the right to accept or refuse the product, an individual does not inherently have that right and, therefore, 10 USC § 1107a (the law stating, among other things, that only the President can waive that right, and any waiver must be done in writing) is not a requirement.

Command JAGs, prosecutors, and leaders have misread and misapply the phrase "shall not be construed to apply" as meaning 1107a does not apply for a servicemember (meaning the President does not need to issue a written waiver). The text of 1107a(2) is stating the waiver authority shall not be construed to apply to any other event (public health emergency) or circumstance that is not specifically declared to be a Public Health Emergency made by the Secretary of HHS. In short, if an unapproved product (biological product, device, drug) is granted emergency use authorization by the HHS Secretary (through the FDA) for a declared health emergency, then the 1107 and1107a waiver requirements fully apply to service members.

All unapproved COVID-19 products are unlicensed/unapproved products that are experimental by law. The Presidential waiver requirements within 10 USC 1107a fully applies because there are no licensed products (shots, test kits/masks, drugs) available to date. ALL unapproved products come with REQUIRED CONDITIONS outlined in 21 USC 360-bbb-3e(1)a, one of which is the inherent right to accept or refuse an unapproved product.

Presidential Waiver. At this point, the President issuing a written waiver for an existing COVID-19 product would tacitly admit mandated products are indeed (and always were) under emergency use authorization and reinforce that by law, no one has the right to mandate EUA products. It is important to remember the FDA approval of Pfizer's COVID-19 vaccine is what triggered institutions and organizations throughout the U.S. to require Americans to get COVID-19 vaccines because the

FDA “licensed” a vaccine (the FDA Licensed BioNTech to produce “Cominarty” under license number 2229, none of these labels are in the US market or DoD inventory) to maintain their employment.

5. The vaccines are safe.

For vaccines, the FDA Letters of Authorization require all serious adverse events to be reported in the Vaccine Adverse Event Reporting System (VAERS) by both the vaccine company (i.e. Pfizer) and vaccination providers administering the vaccine (FDA LOA link):

This is the paragraph in the FDA Letter of Authorization to Pfizer, Inc. requiring VAERS reports:

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

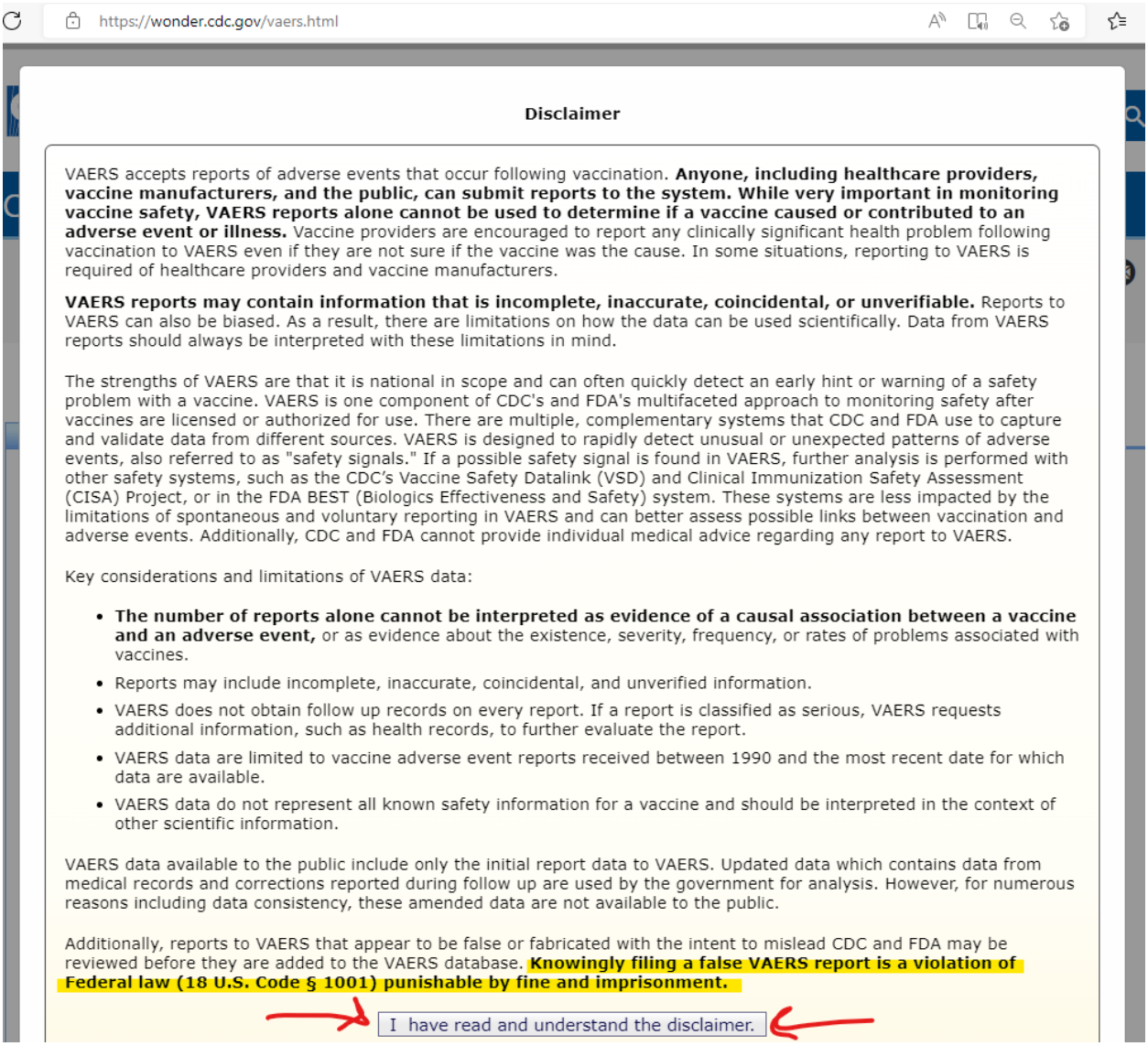
These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

paragraph in the FDA Letter of Authorization to vaccination providers administering the vaccine requiring VAERS reports:

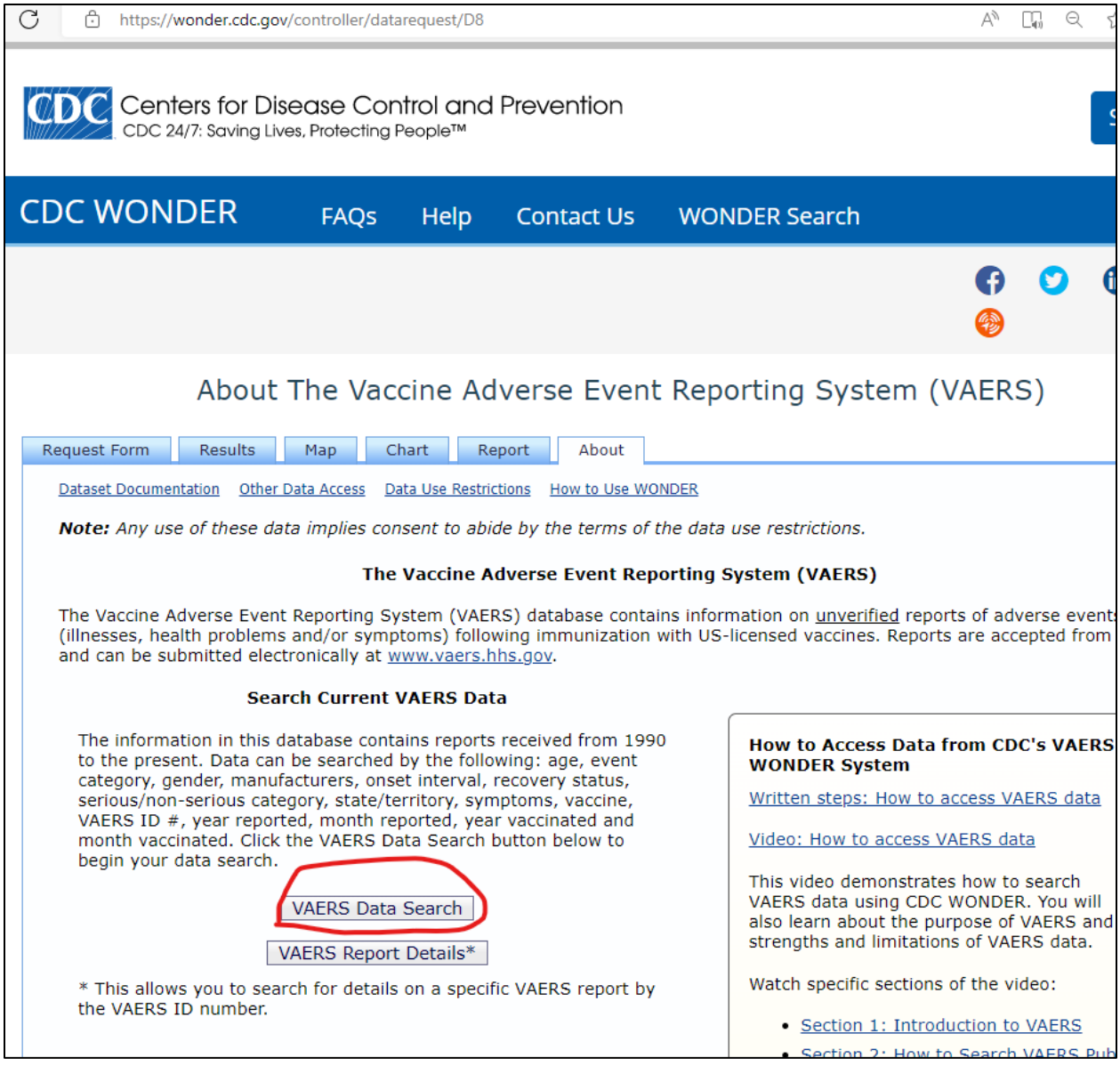
T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

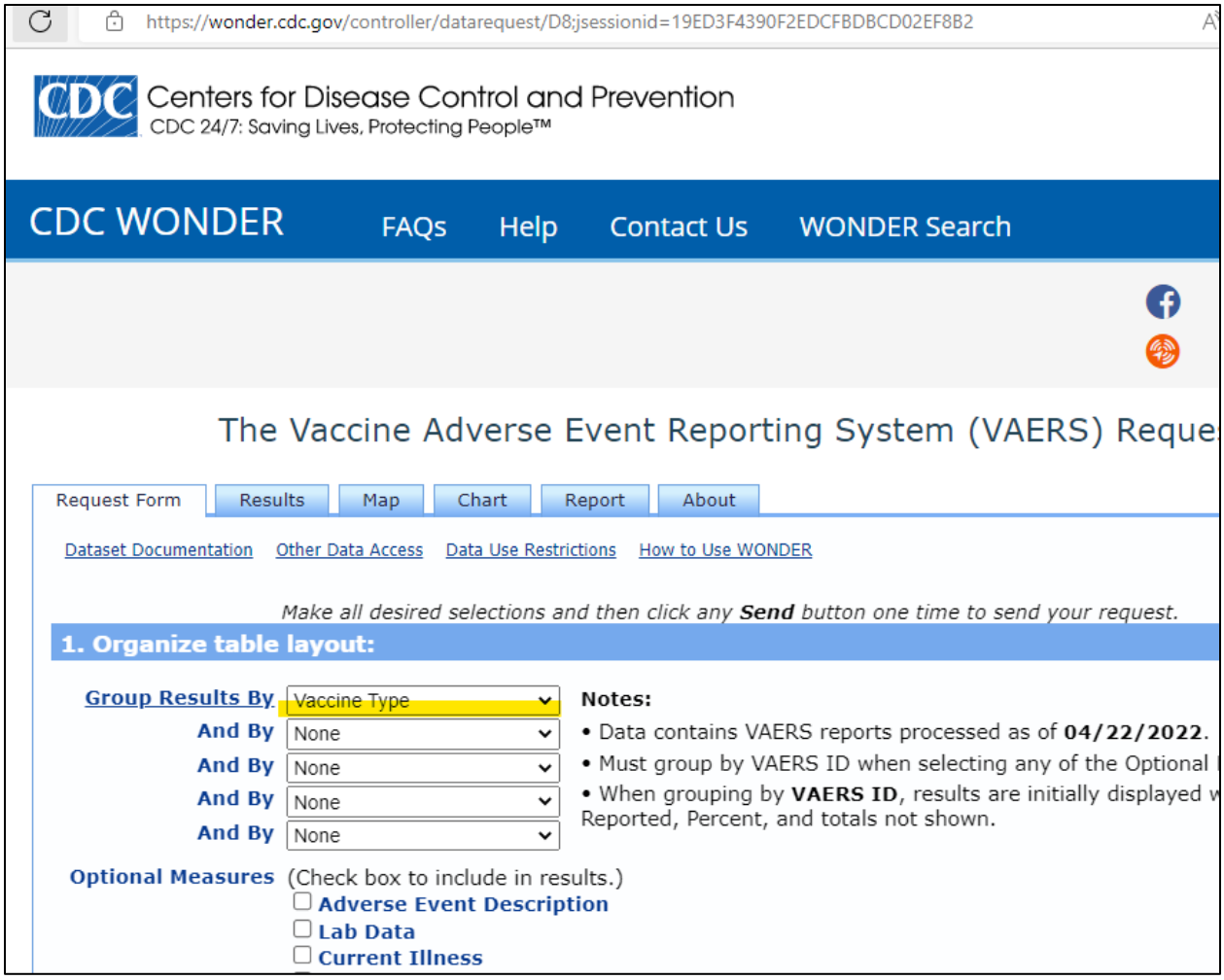
The Vaccine Adverse Event Reporting System (VAERS) can be accessed at [The Vaccine Adverse Event Reporting System (VAERS) Request (cdc.gov)]:



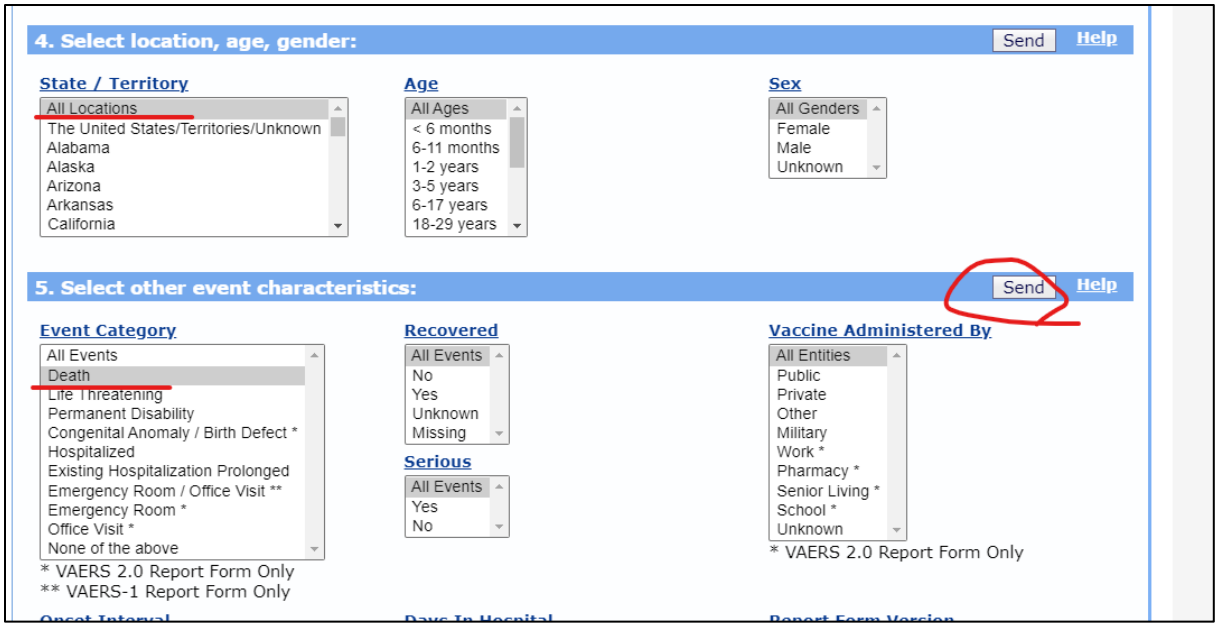
To access the VAERS database, click on the "I have read and understand the disclaimer" button. Note that false VAERS reports are punishable by fine and imprisonment.



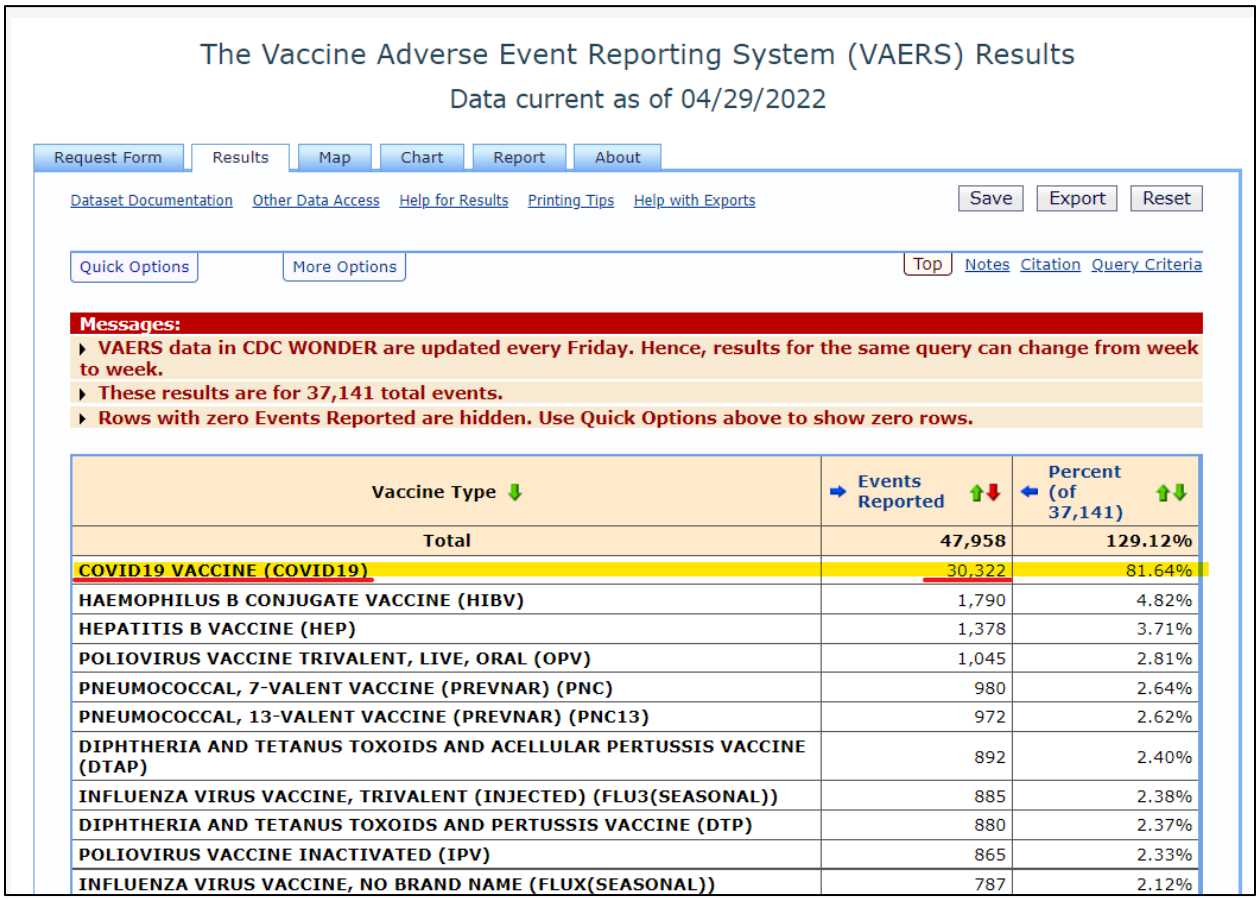
Click on VAERS Data Search.



Change “Group Results By” to “Vaccine Type.” Then scroll down to #4 and 5. Change them to “All Locations” for #4 and whatever specific adverse event you are looking for in #5. This example searches for “Death.” Click on “Send” to view the search results.



A search on 29 April 2022 produced the following results:



The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 04/29/2022

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports | Save | Export | Reset

Quick Options | More Options | Top | Notes | Citation | Query Criteria

Messages:

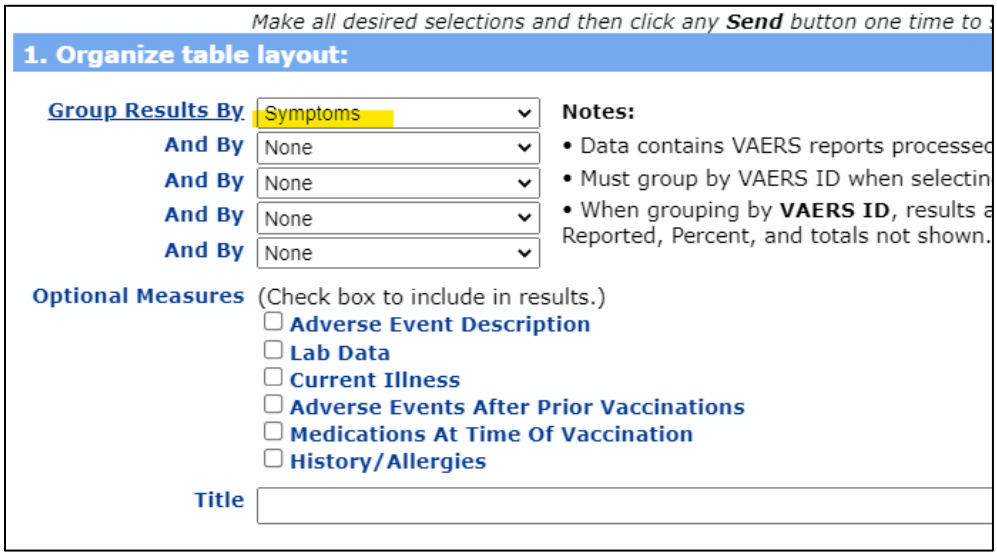
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 37,141 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

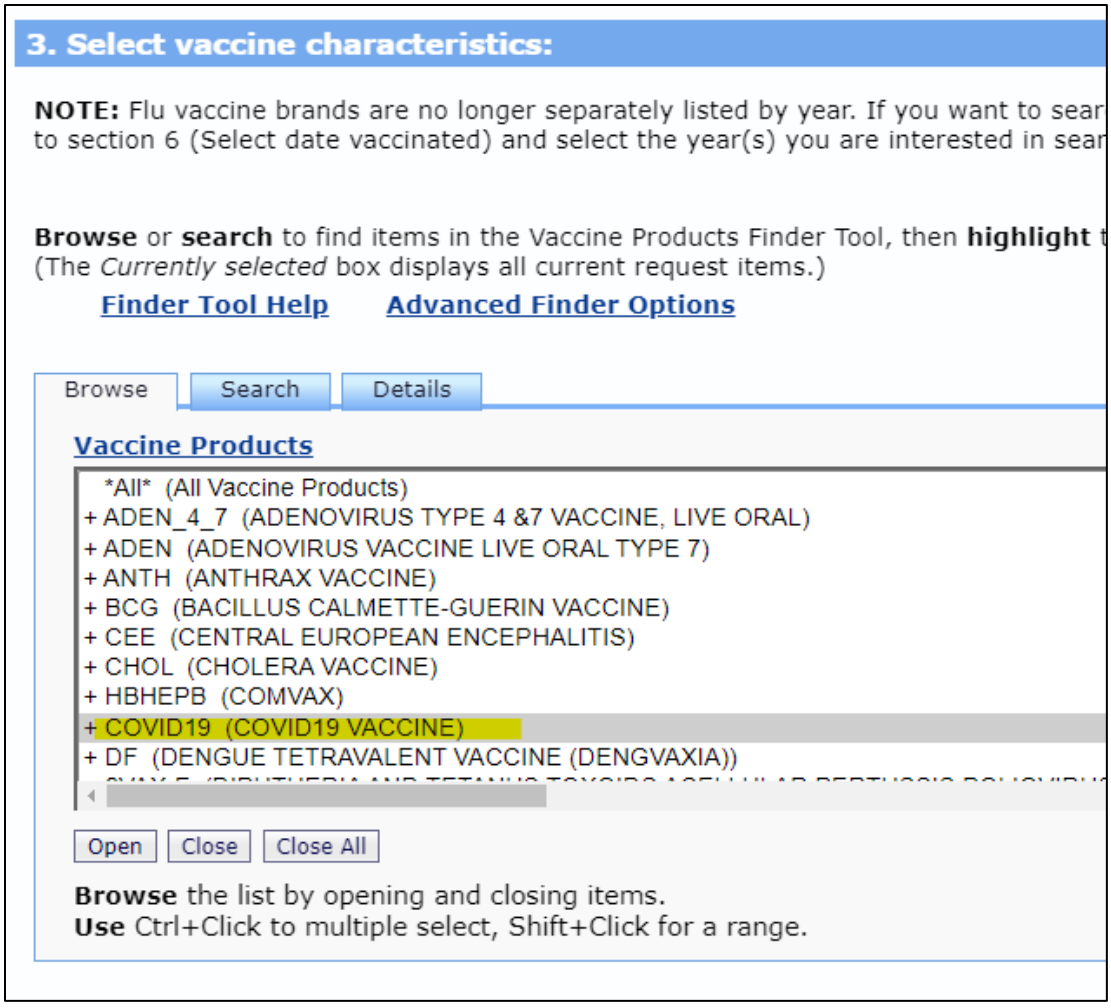
Vaccine Type	Events Reported	Percent (of 37,141)
Total	47,958	129.12%
COVID19 VACCINE (COVID19)	30,322	81.64%
HAEMOPHILUS B CONJUGATE VACCINE (HIBV)	1,790	4.82%
HEPATITIS B VACCINE (HEP)	1,378	3.71%
POLIOVIRUS VACCINE TRIVALENT, LIVE, ORAL (OPV)	1,045	2.81%
PNEUMOCOCCAL, 7-VALENT VACCINE (PREVNAR) (PNC)	980	2.64%
PNEUMOCOCCAL, 13-VALENT VACCINE (PREVNAR) (PNC13)	972	2.62%
DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE (DTAP)	892	2.40%
INFLUENZA VIRUS VACCINE, TRIVALENT (INJECTED) (FLU3(SEASONAL))	885	2.38%
DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE (DTP)	880	2.37%
POLIOVIRUS VACCINE INACTIVATED (IPV)	865	2.33%
INFLUENZA VIRUS VACCINE, NO BRAND NAME (FLUX(SEASONAL))	787	2.12%

One convenient way to sort the table is to click on the arrow next to “Events Reported.” It is clear the damage caused by the COVID-19 vaccines is unprecedented. The COVID-19 vaccines have significantly more reported deaths than all other 94 vaccines **combined** over a period of 30 years.

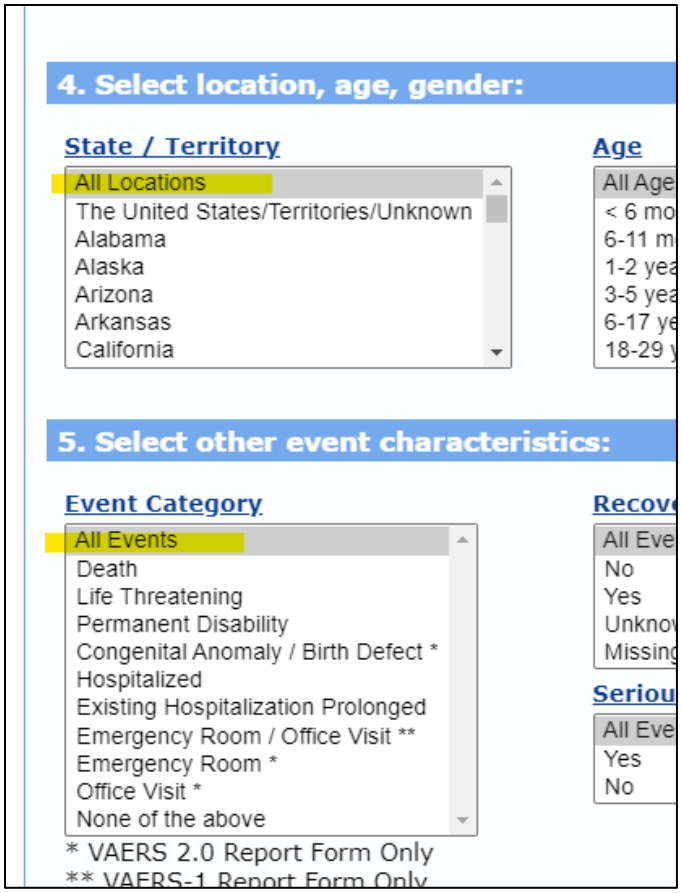
Despite the unprecedented injury, 42 USC § 427d-6d provides liability immunity for all covered persons (including the vaccine manufacturer, government, and medical community).

To see how many adverse events the COVID-19 vaccines have caused, change “Group Results By” to “Symptoms,” then scroll down to #3:

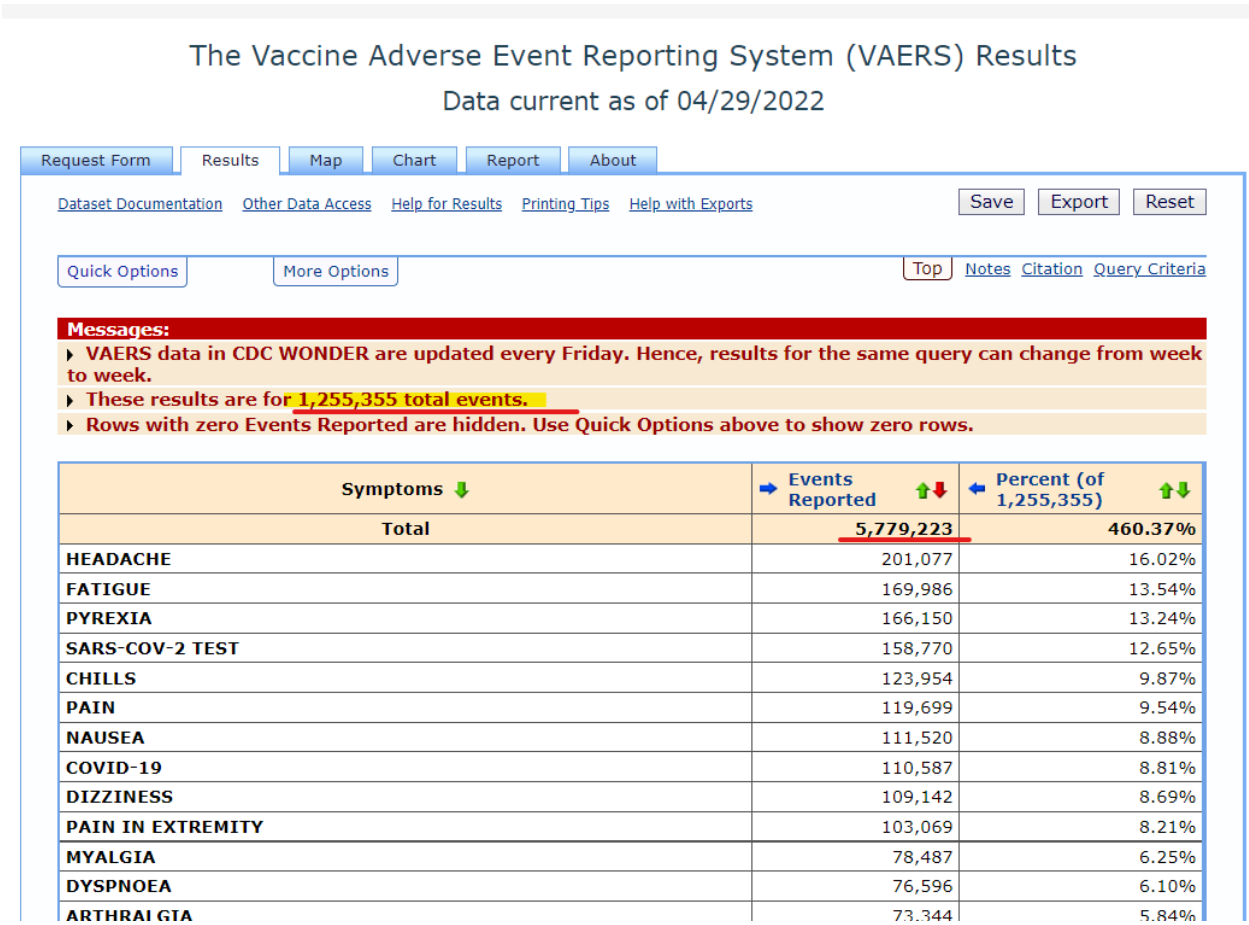




Select "+ COVID19 (COVID19 VACCINE)," then scroll down to #4 and set "All Locations." Set #5 to "All Events," then click "Send."



Again, a convenient way to sort the table is to click on the arrow next to “Events Reported.” Once again, it is clear the damage caused by the COVID-19 vaccines is significant.



The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 04/29/2022

Request Form | Results | Map | Chart | Report | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports

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Messages:

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 1,255,355 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Symptoms	Events Reported	Percent (of 1,255,355)
Total	**5,779,223**	**460.37%**
HEADACHE	201,077	16.02%
FATIGUE	169,986	13.54%
PYREXIA	166,150	13.24%
SARS-COV-2 TEST	158,770	12.65%
CHILLS	123,954	9.87%
PAIN	119,699	9.54%
NAUSEA	111,520	8.88%
COVID-19	110,587	8.81%
DIZZINESS	109,142	8.69%
PAIN IN EXTREMITY	103,069	8.21%
MYALGIA	78,487	6.25%
DYSPNOEA	76,596	6.10%
ARTHRALGIA	73,344	5.84%

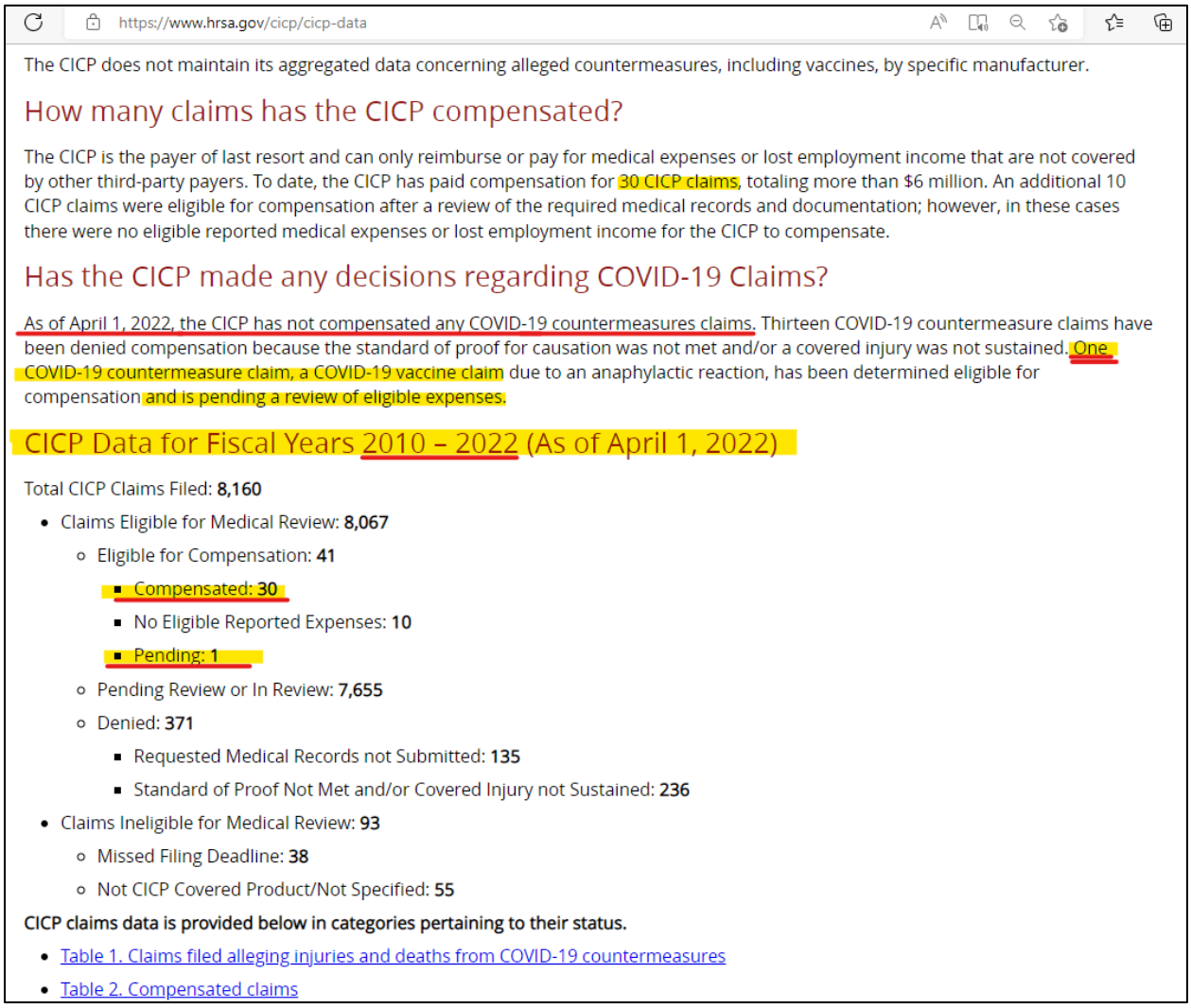
As of 29 April 2022, 1,255,355 individuals had reported 5,779,223 different adverse events.

Studies have been performed, which indicate VAERS injury reports are underreported. Despite widespread media discussion regarding the accuracy of VAERS, there has been no study to date indicating VAERS injuries are overreported. Stated another way, all scientific reviews of the VAERS database have shown the actual number of injuries sustained are at least as large as the data shown, and often significantly higher.

6. Anyone that experiences an adverse event from the vaccines can sue.

It is true that Americans have the right file a lawsuit if they are injured by the vaccine. However, given the covered persons status (liability immunity) afforded to EUA products under 42 USC § 427d-6d, lawsuits must be filed through the Countermeasures Injury Compensation Program (CICP).

To determine the likelihood of getting compensated, reference the U.S. government's Health Resources and Services Administration website, Countermeasures Injury Compensation Program (CICP) Data | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov):



https://www.hrsa.gov/cicp/cicp-data

The CICP does not maintain its aggregated data concerning alleged countermeasures, including vaccines, by specific manufacturer.

How many claims has the CICP compensated?

The CICP is the payer of last resort and can only reimburse or pay for medical expenses or lost employment income that are not covered by other third-party payers. To date, the CICP has paid compensation for 30 CICP claims, totaling more than $6 million. An additional 10 CICP claims were eligible for compensation after a review of the required medical records and documentation; however, in these cases there were no eligible reported medical expenses or lost employment income for the CICP to compensate.

Has the CICP made any decisions regarding COVID-19 Claims?

As of April 1, 2022, the CICP has not compensated any COVID-19 countermeasures claims. Thirteen COVID-19 countermeasure claims have been denied compensation because the standard of proof for causation was not met and/or a covered injury was not sustained. One COVID-19 countermeasure claim, a COVID-19 vaccine claim due to an anaphylactic reaction, has been determined eligible for compensation and is pending a review of eligible expenses.

CICP Data for Fiscal Years 2010 – 2022 (As of April 1, 2022)

Total CICP Claims Filed: **8,160**

- Claims Eligible for Medical Review: **8,067**
  - Eligible for Compensation: **41**
    - Compensated: **30**
    - No Eligible Reported Expenses: **10**
    - Pending: **1**
  - Pending Review or In Review: **7,655**
  - Denied: **371**
    - Requested Medical Records not Submitted: **135**
    - Standard of Proof Not Met and/or Covered Injury not Sustained: **236**
- Claims Ineligible for Medical Review: **93**
  - Missed Filing Deadline: **38**
  - Not CICP Covered Product/Not Specified: **55**

CICP claims data is provided below in categories pertaining to their status.

- Table 1. Claims filed alleging injuries and deaths from COVID-19 countermeasures
- Table 2. Compensated claims

Over a period of almost 12 years, 8,160 Countermeasures Injury Compensation Program (CICP) claims were filed. Of those, only 30 CICP claims have been compensated, resulting in $6 million paid out. Despite over 1.25 million individuals that reported adverse events due to COVID-19 vaccines, the injured have not been compensated to date and only one COVID-19 CICP claim is pending. It is worth noting there is a separate program for FDA-approved vaccine injuries-- the Vaccine Injury Compensation Program (VICP), which has an annual budget of several billion dollars for compensation payouts.

The following chart shows the difference between filing a claim for CICP and VICP [Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP) | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)]():

Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)

Program Categories	CICP	VICP
Program Authorization	Public Readiness and Emergency Preparedness Act (PREP Act) (42 U.S.C. §§ 247d-6d, 247d-6e)	National Childhood Vaccine Injury Act of 1986, as amended (42 U.S.C. § 300aa-10, et seq.)
Payment of Legal Fees and Costs	Attorneys' fees and costs are not paid by the program.	Attorneys' fees and costs may be available if certain requirements are met (petition filed in good faith and on a reasonable basis)
Persons who can file Requests/ Petitions	Types of Eligible Requesters	Who Can File a Petition?
Process for Filing a Request/Petition	File the Request Form and documentation with the Secretary of HHS.	File petition and documentation with the U.S. Court of Federal Claims and the Secretary of HHS.
Process for Resolving Requests/ Petitions	Administrative Process	Judicial Process
Covered Injury Determinations	HHS makes decision. Criteria to Demonstrate that a Covered Injury Occurred	Special Masters (or judges) of U.S. of Court of Federal Claims make decision. Criteria to be Found Eligible to Receive Compensation
Appeal Rights	One step administrative reconsideration possible. No judicial appeal permitted.	Judicial appeal by either party to higher courts possible.
Program Funding	Appropriated Funds	Vaccine Injury Compensation Trust Fund funded through excise taxes on covered vaccines. Congress annually appropriates funding from the Trust Fund to the Health Resources and Services Administration (HRSA), Department of Justice, and U.S. Court of Federal Claims to pay their expenses to administer the VICP and to HRSA to compensate VICP claims.

All COVID-19 products have liability immunity protection under 42 USC § 247d-6d. As a result, all COVID-19 products fall under the CICP (i.e. vaccines, tests, masks, etc.). To initiate a claim, a vaccine injured person is required to pay for attorney fees and costs since those fees and costs. The CICP request/petition is filed with the HHS Secretary, the same individual who authorized emergency use of the products. The HHS Secretary also makes the determination regarding legitimacy of a claim and is also the appeal authority. There is also no judicial process.

VICP exists because under the National Childhood Vaccine Injury Act of 1986, which protects vaccine manufacturers from being sued for damages.

Injuries from other emergency use products are also adjudicated through CICP [Countermeasures Injury Compensation Program (CICP) Data | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)](). The following chart shows multiple requests/petitions for COVID-19 tests:

COVID-19 Medications	Death	11
COVID-19 Medications / Intubation	Death	1
COVID-19 Medications / Remdesivir	Death	1
COVID-19 Test	Death	2
COVID-19 Test	Perforated Ethmoidal Artery	1
COVID-19 Test	Punctured Brain / CSF	1
COVID-19 Test / Heparin / Supplemental Oxygen / Ultrasound (Duplex)	Brain Injury / Quadriplegia	1
COVID-19 Test / Oxygen	Death	1
COVID-19 Vaccine	Abdominal and Chest Pain / High Blood Pressure	1
COVID-19 Vaccine	Abdominal Pain	3
COVID-19 Vaccine	Abdominal Pain / Body Aches / Chills / Diarrhea / Headaches / Nausea / Vomiting	1

Individuals have filed requests/petitions for COVID-19 tests and masks. If the products were FDA approved and individuals were harmed, they would be able to sue the manufacturers. It is because of the liability immunity protection afforded under 42 USC § 247d-6d that 21 USC § 360bbb-3 subsection (e) was codified in law and requires the option to accept or refuse administration of ALL products under emergency use authorization.

7. Could a covered person ever be sued?

There is one situation where covered persons do not have liability immunity. 42 USC § 427d-6d, Willful Misconduct Elements, states the following:

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

What is the definition of "willful misconduct"? In subsection (c), it states the following:

(c) Definition of willful misconduct

(1) Definition

(A) In general

Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is taken-

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(3) Proof of willful misconduct

In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

To date, there has not been a plaintiff that was harmed from being administered unapproved products authorized for emergency use for any emergency declaration that has been able to prove willful misconduct of covered persons due to use of covered countermeasures. As a result, it is even more critical for the individual to protect their option to accept or refuse. It is also critical that people document correspondence with those trying to coerce individuals to take EUA products and educate them on the illegal nature of their actions.

21 USC § 360bbb-3(h) states:

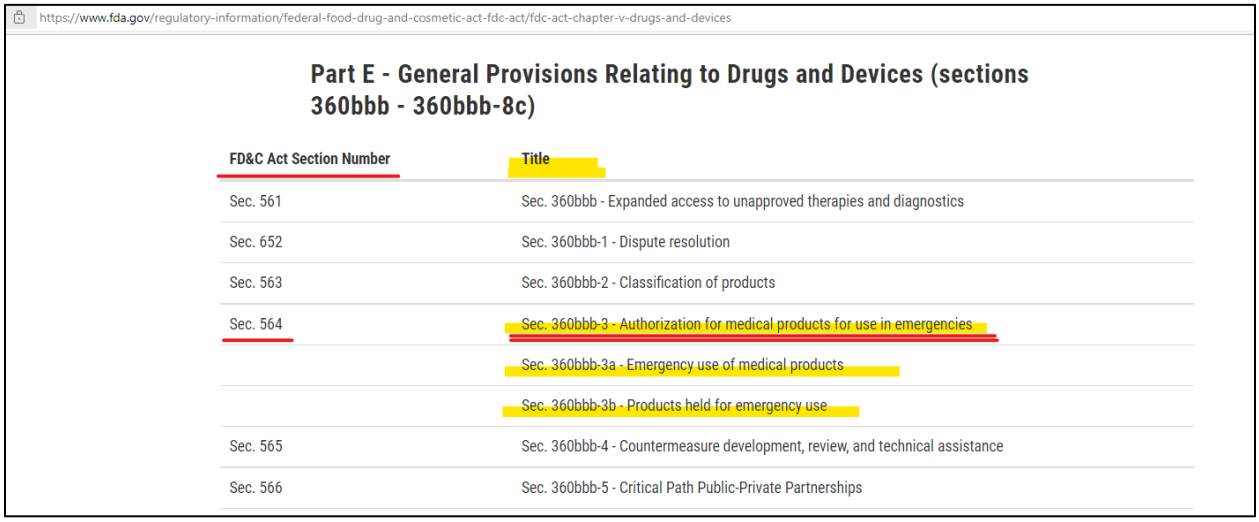
(h) Publication; confidential information

(1) Publication

The Secretary shall promptly publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application under section 355(i) [1] 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application). The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.

The HHS Secretary has the authority to declare an emergency and give unapproved products emergency use authorization. In doing so, the HHS Secretary must publicly announce, by publishing in the Federal Register, an explanation of why they are giving the product (vaccines, test kits, masks, etc.) the emergency authorization, and therefore giving those products and covered persons liability immunity. Given those requirements, how could it not be a required condition to inform American citizens of the product's unapproved status, and by extension, that the product (a covered countermeasure) is being administered by a covered person that has liability immunity?

The legal basis for the right to accept or refuse an EUA product is referenced in each FDA Letter of Authorization. For instance, each issuance / reissuance for the Pfizer-BioNTech COVID-19 vaccine makes numerous references to 21 USC § 360bbb-3 and Section 564 of the FDA&C Act, which codifies the option to accept or refuse (specifically, 21 USC § 360bbb-3 subsection (e)). Of note, Section 564 of the FD&C Act became 21 USC § 360bbb-3 when it was codified in law (FD&C Act Chapter V: Drugs and Devices | FDA):


https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-v-drugs-and-devices

Part E - General Provisions Relating to Drugs and Devices (sections 360bbb - 360bbb-8c)

FD&C Act Section Number	Title
Sec. 561	Sec. 360bbb - Expanded access to unapproved therapies and diagnostics
Sec. 652	Sec. 360bbb-1 - Dispute resolution
Sec. 563	Sec. 360bbb-2 - Classification of products
Sec. 564	Sec. 360bbb-3 - Authorization for medical products for use in emergencies
	Sec. 360bbb-3a - Emergency use of medical products
	Sec. 360bbb-3b - Products held for emergency use
Sec. 565	Sec. 360bbb-4 - Countermeasure development, review, and technical assistance
Sec. 566	Sec. 360bbb-5 - Critical Path Public-Private Partnerships

Here is an example of the Pfizer-BioNTech COVID-19 Vaccine Factsheet (not a binding agreement unlike the reissued EUA letter which we covered earlier) the language states “Under the EUA, it is your choice to receive or not receive the vaccine.” (VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND OLDER (fda.gov)):

WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

Although that specific language is not used in every fact sheet, 21 USC § 360bbb-3 and Section 564 of the FDA&C Act codifies the option to accept or refuse. ALL EUA products come with the option to accept or refuse.

References

42 USC 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures (house.gov) This is the key law that provides manufacturers, governments, distributors, healthcare workers, and other identified covered persons the liability immunity protections...this law alone provides the moral hazard and incentives to keep products under EUA and to direct people to take EUA shots because they are "interchangeable." This portion of Title 42 also provides the Secretary of Health and Human Services the statutory authority to declare Public Health Emergencies.

42 USC 262: Regulation of biological products (house.gov) - Legal requirements for Biological Product [shot] licensing and interchangeability. There is no LEGAL definition of a "BLA Compliant" Biological product.

21 USC 360bbb-3: Authorization for medical products for use in emergencies (house.gov) – The right to accept or refuse EUA products.

21 USC 321: Definitions; generally (house.gov) – Definitions.

eCFR :: 21 CFR Part 50 -- Protection of Human Subjects - [21 Code of Federal Regulations - Legal requirements for government agencies to comply with **informed consent and human subjects**]

10 USC 1107a: Emergency use products (house.gov) – Discusses EUA products as they relate to the armed forces.

10 USC 1107: Notice of use of an investigational new drug or a drug unapproved for its applied use (house.gov) - Notification requirements in the event the President waives the requirement for service members to be notified of the right to refuse an EUA product.

Federal Register :: Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability – The Federal Register is the federal repository of documents, published daily, which includes proposed federal rules, proposed rules, notices, and executive orders and other presidential documents.

Public Readiness and Emergency Preparedness Act (hhs.gov) - Contains links to ALL COVID 19 Emergency Declaration Amendments.

IIS COVID-19 Vaccine Related Code | CDC (COVID19 EUA/BLA Shots in Market, Rollup of Legal Status/availability

Nuremberg Code - history - Office of NIH History and Stetten Museum

FDA EUA Letters (Includes EUA letters for all COVID-19 products):

- Emergency Use Authorization | FDA – Master Page - FDA Webpage for Covered Countermeasures/EUA Products-Letters by Product Type

- Emergency Use Authorization | FDA - Biologic Products, such as vaccines

- Emergency Use Authorization | FDA – Drugs, such as remdesivir and ivermectin
- Emergency Use Authorization | FDA - Medical Devices, such as tests and masks
- In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 | FDA - Test kits

- Spikevax and Moderna COVID-19 Vaccine | FDA
- Comirnaty and Pfizer-BioNTech COVID-19 Vaccine | FDA

Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP) | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov) - All EUA products authorized for COVID-19 are considered "covered countermeasures." This means they have liability protection and the only recourse is through the Countermeasure Injury Compensation Program (CICP)....all products under EUA are covered under the CICP since they are unapproved products under EUA.

FDA Purplebook- This links to the Spikevax and Comirnaty page, which indicates there are no biosimilar/interchangeable products available.