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# Department of Defense Vaccine Mandate: "Year in Review"







# Overview

- Key Terms
- Roadmap-Key Dates
- Significance of Key

**Dates** 





# **Key Terms**

Emergency Use Authorization (EUA)

**Biologics License Application (BLA)** 

"BLA- Compliant"

**Fully-Licensed** 

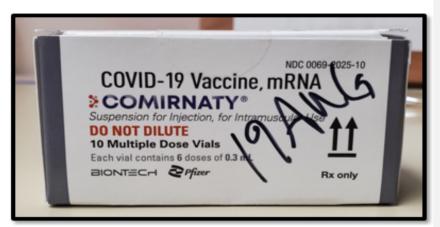
Pfizer-BioNTech "Vaccine"

Comirnaty (BLA125742; License #2229)

\*\*Moderna/Spikevax (BLA125752; License #2256)











# **Key Terms**

Emergency Use Authorization (EUA)

**Biologics License Application (BLA)** 

"BLA- Compliant"

Page 2 - STN BL 125742/0 - Elisa Harkins

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.

Comirnaty (BLA125742; License #2229)

\*\*Moderna/Spikevax (BLA125752; License #2256)



Our STN: BL 125742/0

**BLA APPROVAL** 

August 23, 2021

BioNTech Manufacturing GmbH 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.

Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., (b) (4)

USA, LLC, (b) (4)

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov

Page 2 - STN BL 125742/0 - Elisa Harkins



### Overview

Legal

Maneuvering

Both the Administration and DoD begin their legal maneuvering to mandate an

EUA product

400% Spike in "covid-related" deaths

In the 4-month window immediately after the mandate we lose ~68 SMs due to "covid-related" deaths SMs Sue the DoD

Multiple lawsuits are filed against the DoD to include the Baitand-Switch and RFRA claims

Pre -Mandate Post-Manda<u>te</u> Death-Spike Congress Support

Lawsuits

"COMIRNATYlabeled"

No Fully Licensed Product

Big Pharma signals they DO NOT intend to produce approved COMIRNATY

"Interchangeability" memos

#### Letters to SECDEF

Multiple Congressional inquiries sent to SECDEF.

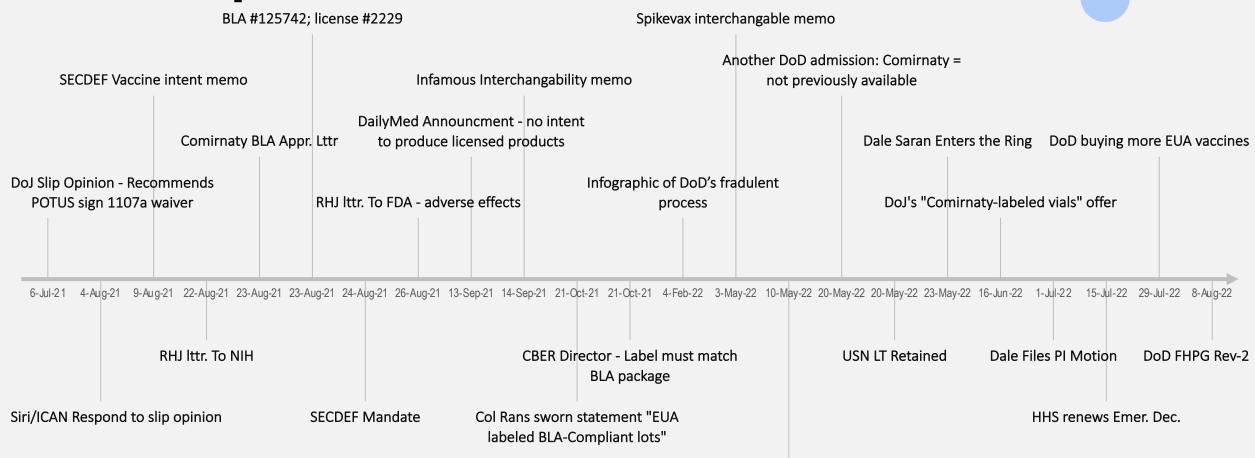
SECDEF ignores all but one.

#### 10 Months Later..

"Comirnaty-Labeled" vials start to appear at certain military installations



# Roadmap



Pentagon briefing; waiting for "gray vials"





# 06 July 2021

## Dawn Johnsen (DoJ) Slip Opinion

- Attempts to Support Mandating EUA-products
  - Numerous Contradictions
  - Section 564 of FD&C ACT
  - Codified as: Title 21 U.S. Code § 360bbb–3
- Waiver: Title 10 U.S. Code § 1107a

#### **Relevant Info:**

- Health and Human Services Secretary (HHS)
   declared Covid-19 an emergency on 31 Jan 2020.
   Renewed every 90 days. Last renewed 15 July
   2022 (2.5 years total)
- Emergency Declaration is legal requirement to utilize EUA products

45 Op. O.L.C. \_\_ (July 6, 2021)

### Significance:

distribution of its Fact Sheet containing the "[i]t is your choice to receive or not receive" language, DOD is required to provide service members with the specified notification unless the President waives the condition pursuant to 10 U.S.C. § 1107a. And because DOD has informed us that it understandably does not want to convey inaccurate or confusing information to service members—that is, telling them that they have the "option" to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

III.

For the reasons set forth above, we conclude that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.

DAWN JOHNSEN

Acting Assistant Attorney General

Office of Legal Counsel



# **04 August 2021**

# Aaron Siri Esq., Response Letter

- "Not only does [your] argument defy common sense..."
- "Your interpretation of Section 564 renders Section 1107a meaningless and nonsensical."

### **Relevant Info:**

- Where is "Accept or Refuse" found?
  - Title 21 U.S. Code § 360bbb–3
  - Title 10 U.S. Code § 1107a
  - DoDI 6200.02
  - Joint Medical Services Regulation (AR 40-562)

Thus, Congress so highly valued the right to individual choice that it allowed only a threat to national security to trump that right, and even then, only with regard to military personnel. As your Slip Opinion admits, this is how members of Congress understood Section 564 and Section 1107a when they were enacted. See Slip Opinion at 16-17. It is also how the DOD understood these sections following their enactment, stating in DOD Instruction 6200.02 § E3.4, adopted February 27, 2008:

In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients **are provided an option** to refuse administration of the product, the President may ... waive **the option** to refuse ... administration of the medical product to members of the armed forces. <sup>15</sup>

Your interpretation of Section 564 renders Section 1107a meaningless and nonsensical. If the military was permitted to create any consequences it deemed appropriate in the event an armed forces member refused an EUA vaccine, it would be unnecessary to create a separate statute and require a written presidential national security finding to remove a requirement that, in your words, "concerns only the provision of information[.]"

for the safe use of unapproved products, and they should be imposed in all cases, except in truly extraordinary circumstances." <a href="https://www.congress.gov/congressional-record/2004/07/14/house-section/article/H5721-3">https://www.congress.gov/congressional-record/2004/07/14/house-section/article/H5721-3</a>

#### 8-3. Refusal options

The FDA may decide that potential recipients of a drug under an EUA should have the option to refuse it. The President may waive this option for military personnel.



# 09 August 2021

# SECDEF "Message to the Force"

- Signals intent to get Covid-19 "vaccines" added to the list of required vaccinations
- "I will seek the President's approval..."
  - Language consistent with federal law and military regulation

#### Relevant Info: (DoDI 6200.02)

E3.4. Request to the President to Waive an Option to Refuse. In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, the President may, pursuant to section 1107a of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces. Such a waiver is allowed if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security. Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse.

Note: Full E3.4 Paragraph which Siri Referenced in "Response Letter"

### Significance:



#### SECRETARY OF DEFENSE 1000 DEFENSE PENTAGON WASHINGTON, DC 20301-1000

AUG 0 9 2021

#### MEMORANDUM FOR ALL DEPARTMENT OF DEFENSE EMPLOYEES

SUBJECT: Message to the Force

As many of you know, President Biden asked me to consider how and when we might add the coronavirus disease 2019 (COVID-19) vaccines to the list of those required for all Service members. So, over the last week, I have consulted closely with the Chairman of the Joint Chiefs of Staff, the Secretaries of the Military Departments, the Service Chiefs, and medical professionals. I appreciate greatly the advice and counsel they provided.

Based on these consultations and on additional discussions with leaders of the White House COVID Task Force, I want you to know that I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Agency (FDA) licensure, whichever comes first.

By way of expectation, public reporting suggests the Pfizer-BioNTech vaccine could achieve full FDA licensure early next month.





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Defense Secretary Lloyd Austin also just got infected with Covid for the second time this year. He is 4x vaccinated/ boosted and wears multiple masks AND a face shield regularly.

Never forget, this is a real picture.



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Significance:



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Based on these consultations and on additional discussions with leaders of the White House COVID Task Force, I want you to know that I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Agency (FDA) licensure, whichever comes first.

By way of expectation, public reporting suggests the Pfizer-BioNTech vaccine could achieve full FDA licensure early next month.

To defend this Nation, we need a healthy and ready force. I strongly encourage all DoD military and civilian personnel — as well as contractor personnel — to get vaccinated now and for military Service members to not wait for the mandate.

All FDA-authorized COVID-19 vaccines are safe and highly effective. They will protect you and your family. They will protect your unit, your ship, and your co-workers. And they will ensure we remain the most lethal and ready force in the world.

Get the shot. Stay healthy. Stay ready.

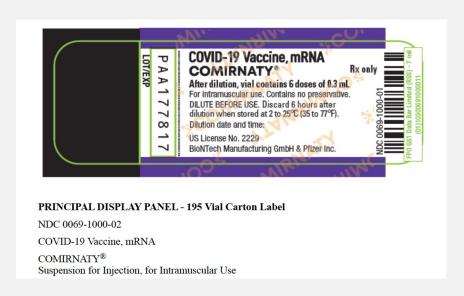
Slay Of Sunt?



# 23 August 2021

### BLA 125742 Approved for a Single Day

- Marketing Start/End Date: 23 Aug 2021
- Why does it matter?
  - Title 42 U.S. Code § 262 Regulation of biological products



#### COMIRNATY

covid-19 vaccine, mrna injection, suspension

#### **Product Information**

Product Type VACCINE Item Code (Source) NDC:0069-1000

Route of Administration INTRAMUSCULAR

#### Active Ingredient/Active Moiety

Ingredient Name Basis of Strength

TOZINAMERAN (UNII: 5085ZFP6SJ) (TOZINAMERAN - UNII: 5085ZFP6SJ) TOZINAMERAN (UNII: 5085ZFP6SJ)

Inactive Ingredients

https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=595377

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These highlights do not include all the information needed to use COMI...nsion for injection, for intramuscular use Initial U.S. Approval: 2021

Ingredient Name Strength 0.4 mg in 2.25 mL ALC-0159 (UNII: PJH39UMU6H) ALC-0315 (UNII: AVX8DX713V) 3.23 mg in 2.25 mL POTASSIUM CHLORIDE (UNII: 660YQ98I10) 0.07 mg in 2.25 mL MONOBASIC POTASSIUM PHOSPHATE (UNII: 4J9FJ0HL51) 0.07 mg in 2.25 mL SODIUM CHLORIDE (UNII: 451W47IQ8X) 2.7 mg in 2.25 mL SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T) 0.49 mg in 2.25 mL SUCROSE (UNII: C151H8M554) 46 mg in 2.25 mL 1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 0431P12M0K) 0.7 mg in 2.25 mL CHOLESTEROL (UNII: 97C5T2UQ7J) 1.4 mg in 2.25 mL WATER (UNII: 059QF0KO0R)

#### **Packaging**

	0 0			
#	f Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:0069-1000-02	195 in 1 CARTON		
1	NDC:0069-1000-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
1	NDC:0069-1000-03	25 in 1 CARTON		
	NDC:0069-1000-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

#### **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
LA	BLA125742	08/23/2021	08/23/2021

13



COMIRNATY covid-19 vaccine, mrna injection, suspensi	on		
Product Information			
Product Type	VACCINE	Item Code (Source)	NDC:0069-1000

INTRAMUSCULAR

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-1000-02	195 in 1 CARTON		
1	NDC:0069-1000-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0069-1000-03	25 in 1 CARTON		
2	NDC:0069-1000-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Route of Administration

### **Marketing Information**

Marketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateBLABLA12574208/23/202108/23/2021

**Labeler -** Pfizer Laboratories Div Pfizer Inc (134489525)

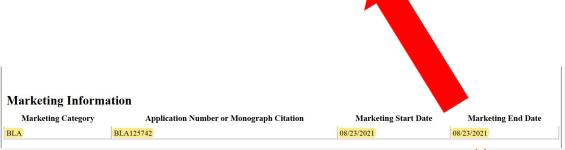
#### PRINCIPAL DISPLAY PANEL - 195 Vial Carton Label

NDC 0069-1000-02

COVID-19 Vaccine, mRNA

COMIRNATY®

Suspension for Injection, for Intramuscular Use





# 24 August 2021

### **SECDEF Mandate**

- "Will only use COVID-19 vaccines that receive full licensure..."
- For example: Comirnaty license #2229

#### **Relevant Info:**

 By the time the "Ink Dried" the original 23 Aug 2021 BLA125742 approval was already expired



#### SECRETARY OF DEFENSE 1000 DEFENSE PENTAGON WASHINGTON, DC 20301-1000

AUG 2 4 2021

# MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP COMMANDERS OF THE COMBATANT COMMANDS DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.



# Quick Detour...

### Today's BLA 125742 looks like this:

- Marketing Start Date: 18 May 2022
  - Note: 3rd change (23 Aug > 22 Dec > 18 May)
- No Marketing end date COVID-19 Vaccine, mRNA
- Same BLA No.
- Same License No.
- Different Formula
- Different National Drug Code (NDC)

#### PRINCIPAL DISPLAY PANEL - 0.3 mL Vial Label

Rx only

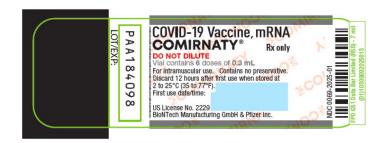
DO NOT DILUTE

Vial contains 6 doses of 0.3 mL

For intramuscular use. Contains no preservative. Discard 12 hours after first use when stored at 2 to 25°C (35 to 77°F). First use date/time:

US License No. 2229

BioNTech Manufacturing GmbH & Pfizer Inc.



PRINCIPAL DISPLAY PANEL - 10 Vial Carton

NDC 0069-2025-10

#### **COMIRNATY**

covid-19 vaccine, mma injection, suspension

#### **Product Information**

**Route of Administration** 

**Product Type** VACCINE Item Code (Source) NDC:0069-2025

**INTRAMUSCULAR** 

#### Active Ingredient/Active Moiety

**Ingredient Name Basis of Strength** Strength TOZINAMERAN (UNII: 5085ZFP6SJ) (TOZINAMERAN - UNII:5085ZFP6SJ) TOZINAMERAN 0.225 mg in 2.25 mL

#### Inactive Ingredient

Ingredient Name	Strength
2-(MPEG 2000)-N,N-DITETRADECYLACETAMIDE (UNII: PJH39UMU6H)	0.41 mg in 2.25 mL
((4-HYDROXYBUTYL)AZANEDIYL)BIS(HEXANE-6,1-DIYL)BIS(2-HEXYLDECANOATE) (UNII: AVX8DX713V)	3.22 mg in 2.25 mL
SUCROSE (UNII: C151H8M554)	231.8 mg in 2.25 mL
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 043IPI2M0K)	0.7 mg in 2.25 n
CHOLESTEROL (UNII: 97C5T2UQ7J)	1.4 mg in 2.25 n
WATER (UNII: 059QF0KO0R)	
TROMETHAMINE (UNII: 023C2WHX2V)	0.45 mg in 2.25 mL
TROMETHAMINE HYDROCHLORIDE (UNII: 383V75M34E)	2.97 mg in 2.25 mL

kaging		
Item Code	Package Description	

Date 1 NDC:0069-2025-10 10 in 1 CARTON 1 NDC:0069-2.25 mL in 1 VIAL, GLASS; Type 0: Not a 2025-01 Combination Product

Marketing Start

2 NDC:0069-25 in 1 CARTON 2025-25

2 NDC:0069-2.25 mL in 1 VIAL, GLASS; Type 0: Not a 2025-01 Combination Product

#### **Marketing Information**

Marketing **Application Number or Monograph** Marketing Start Marketing End Citation Category Date BLA125742 05/18/2022

Marketing End



# Qı

### Toda

#### COMIRNATY

covid-19 vaccine, mrna injection, suspension

**Product Information** 

Product Type VACCINE Item Code (Source) NDC:0069-1000

Route of Administration INTRAMUSCULAR

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
TOZINAMERAN (UNII: 5085ZFP6SJ) (TOZINAMERAN - UNII: 5085ZFP6SJ) TOZINAMERAN (UNII: 5085ZFP6SJ) TOZINAMERAN (UNII

Inactive Ingredients

https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=595377

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ALC-0315 (UNII: AVX8DX713V)	3.23 mg in 2.25 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	0.07 mg in 2.25 mL
MONODASIC DOTASSHIM DUOSDUATE (LINII: ALOCIOUI 51)	0.07 mg in 2.25 mI

These highlights do not include all the information needed to use COMI...nsion for injection, for intramuscular use Initial U.S. Approval: 2021

 POTASSIUM CHLORIDE (UNII: 660YQ98110)
 0.07 mg in 2.25 mL

 MONOBASIC POTASSIUM PHOSPHATE (UNII: 4J9FJOHL51)
 0.07 mg in 2.25 mL

 SODIUM CHLORIDE (UNII: 451W47IQ8X)
 2.7 mg in 2.25 mL

 SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 9425516E2T)
 0.49 mg in 2.25 mL

 SUCROSE (UNII: C151H8M554)
 46 mg in 2.25 mL

 1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE (UNII: 043IPI2M0K)
 0.7 mg in 2.25 mL

 CHOLESTEROL (UNII: 97C5T2UQ7I)
 1.4 mg in 2.25 mL

Diff WATER (UNII: 059QF0KOOR)

Packaging

#### 

#### **Marketing Information**

Marketing Category Application Number or Monograph Citation Marketing Start Date

BLA BLA125742 08/23/2021 08/23/2021

#### **COMIRNATY**

covid-19 vaccine, mma injection, suspension

#### **Product Information**

Product Type VACCINE Item Code (Source) NDC:0069-2025

Route of Administration INTRAMUSCULAR

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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TROMETHAMINE HYDROCHLORIDE (UNII: 383V75M34E)	2.97 mg in 2.25 mL

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0069- 2025-10	10 in 1 CARTON		
	NDC:0069- 2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0069- 2025-25	25 in 1 CARTON		
	NDC:0069- 2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

#### **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
BLA	BLA125742	05/18/2022	

option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

III.

For the reasons set forth above, we conclude that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.

Based on these consultations and on additional discussions with leaders of the White House COVID Task Force, I want you to know that I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Agency (FDA) licensure, whichever comes first.

By way of expectation, public reporting suggests the Pfizer-BioNTech vaccine could achieve full FDA licensure early next month.



E3.4. Request to the President to Waive an Option to Refuse. In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients are provided an option to refuse administration of the product, the President may, pursuant to section 1107a of Reference (e), waive the option to refuse for administration of the medical product to members of the armed forces. Such a waiver is allowed if the President determines, in writing, that providing to members of the armed forces an option to refuse is not in the interests of national security. Only the Secretary of Defense may ask the President to grant a waiver of an option to refuse.

Let's Review...

Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.







# 26 Aug – 1 Sep 2021

### The Navy Saga (Part 1)

- 26 Aug U.S Fleet Forces
- 30 Aug SECNAV
- 31 Aug Chief of Naval Operations (CNO)
- 1 Sept Pacific Fleet

#### **Relevant Info:**

- Top USN Officials fire off Policy memos in Rapid succession
- ALL memos echo SECDEF Guidance "only fully-licensed vaccines will be utilized for the mandate"

#### CLASSIFICATION: UNCLASSIFIED//

#### Generated by OIX GATEWAY NORFOLK VA. Only authorized users may reply.

----OFFICIAL INFORMATION DISPATCH FOLLOWS----

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BT
INCLAS

ALNAV 062/21

MSGID/GENADM

SUBJ/2021-202 POLICY//

REF/A/DOC/SEC AMPN/REF A IS MANDATING CON DEFENSE SERVI

RMKS/1. Prot readiness is of you who ha ensure the he shipmates, ar

2. Coronavia Department of execution. I Respiratory S causes COVID-

3. Vaccinati widespread me last year, mi vaccines in a vaccines has Administratic additional co effective to Considering t Members, vacc received full requirement RMKS/1. Background. Disease modeling forecasts that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19 will continue to spread throughout the remainder

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This NAVAD

2. Policy NAVADMIN, COVID-19 t Food and D voluntary Authorizat Emergency

the Navy.

2.a. Navy service me the Indivi for the pu 2.b. Full

paragraph under FDA applicable establishm Navy servi after comp or two wee 19 vaccine be address

2.c. Coor coordinate along with population

2.d. COVI the most e Look for Classification Marking in Message Body

REF D IS FRAGO 4 TO CONSOLIDATED USINDOPACOM FORCE HEALTH PROTECTION GUIDANCE (FHP) GUIDANCE- BASELINE SUPPLEMENT ISO USINDOPACOM EXORD P-963 RESPONSE TO 2019 COVID-19//

REF E IS ALNAV 062/21, 2021-2022 DEPARTMENTOF THE NAVY MANDATORY COVID-19 VACCINATION POLICY.

RMIKS/THIS IS A COMMANDER, U.S. PACIFIC FLEET (CPF) EXECUTION ORDER (EXORD) DIRECTING COMMANDER, U.S. THIRD FLEET (C3F) AND COMMANDER, U.S. SEVENTH FLEET (C7F) TO ENSURE ALL OPERATIONAL UNITS AND SHORE COMMANDS AGGRESSIVELY AND EFFICIENTLY EXECUTE MANDATORY VACCINATION OF ALL MILITARY PERSONNEL ASSIGNED TO CPF.

// GENTEX/SITUATION//

1. (U) GENERAL. THE SARS-COV-2 VACCINE HAS BEEN ORDERED AS A
MANDATORY VACCINE BY THE OFFICE OF THE SECRETARY OF DEFENSE (OSD)
AND CHIEF OF NAVAL OPERATIONS AS OUTLINED IN REFS A AND B. THIS

AND CHIEF OF NAVAL OPERATIONS AS OUTLINED IN REFS A AND B. THIS ORDER IS APPLICABLE TO ALL MILITARY PERSONNEL ASSIGNED TO CPF AND ITS SUBORDINATE UNITS AND COMMANDS.

GENTEXT/MISSION//

2. (U) MISSION. ADMINISTER VACCINE TO ALL UNVACCINATED ACTIVE DUTY AND ACTIVATED RESERVE COMPONENT MILITARY PERSONNEL IN CPF IOT MAINTAIN FORCE HEALTH PROTECTION, UNIT READINESS, AND MISSION ASSIRBANCE.

GENTEXT/EXECUTION//

3.A. (U) COMMANDERS INTENT.

3.A.1. (U) PURPOSE. MAINTAINING FORCE HEALTH PROTECTION IN ORDER TO ACHIEVE MISSION ASSURANCE REMAINS OUR HIGHEST PRIORITY. A SOUND COVID VACCINATION PLAN EXECUTED WITH PRECISION AND SPEED WILL ENSURE OUR FORCES ARE COVID-19 RESILIENT AND DEPLOYMENT READY.

3.A.2. (U) METHOD:

3.A.2.Á. (U) NUMBERED FLEET AND TYPE COMMANDERS WILL COORDINATE EFFORTS WITH THE RESPECTIVE NAVAL MEDICAL FORCES REGION AND LOCAL MILITARY THEATMENT FACILITIES (MTF) FOR DISTRIBUTION AND SYNCHRONIZED EXECUTION OF VACCINATION.

3.A.2.B. (U) THE PRIORITY IS SHOTS IN ARMS AND GETTING OPERATIONAL UNITS VACCINATED, DO NOT LIMIT OR DELAY VACCINATION COMPLETION FOR UNAVAILABLE UNITS OR FOR VACCINATION PREFERENCE.

3.A.2.C. (U) FIRST SHOT WILL BE ADMINISTERED REGARDLESS OF AVAILABILITY OF SECOND DOSE.

3.A.2.D. (U) FOOD AND DRUG ADMINISTRATION (FDA)-LICENSED COVID-19
VACCINE WILL BE USED FOR VACCINATION. IF IMMEDIATELY AVAILABLE AT
THE TIME AND LOCATION OF VACCINATION, MILITARY PERSONNEL MAY
VOLUNTEER TO RECEIVE A VACCINE UNDER AN FDA EMERGENCY USE
AUTHORIZATION (EUA).

3.A.2.E. (U) UNVACCINATED RESERVE COMPONENT (RC) CURRENTLY ON ORDERS WILL RECEIVE A VACCINATION WITHIN 14 DAYS, OR BEFORE THE END OF THEIR ORDERS, WHICHEVER OCCURS FIRST. RC NOT ON ORDERS/NOT IN A

DUTY STATUS WILL FOLLOW REF B AND CNIFC GUIDANCE.
3.A.2.F. (U) SERVICE MEMBERS ARE CONSIDERED FULLY VACCINATED TWO
WEEKS AFTER COMPLETING THE SECOND DOSE OF A TWO-DOSE COVID-19
VACCINE OR TWO WEEKS AFTER RECEIVING A SINGLE DOSE OF A ONE-DOSE
COVID-19 VACCINE.



# 3 Sept - 8 Sep 2021

### The Navy Saga (Part 2)

- 3 Sept USN/SG "Interchangeable" memo
  - RADM B.L. Gillingham
- 4 Sept Concerned USMC Generals seek Comirnaty
  - (Email between 2-Star and 3-Star)
- 8 Sept Asst. Secretary of the Navy (ASN)



#### DEPARTMENT OF THE NAVY BUREAU OF MEDICINE AND SURGERY 7700 ARLINGTON BOULEVARD FALLS CHURCH VA 22042

IN REPLY REFER TO 6300 Ser M00/21M00035 3 Sep 21

MEMORANDUM FOR COMMANDER, NAVAL MEDICAL FORCES ATLANTIC COMMANDER, NAVAL MEDICAL FORCES PACIFIC COMMANDER, NAVAL MEDICAL FORCES SUPPORT COMMAND

Subj: INTERCHANGABILITY OF FOOD AND DRUG ADMINISTRATION-APPROVED PFIZER-BIONTECH VACCINE COMIRNATY® AND FOOD AND DRUG ADMINISTRATION-AUTHORIZED PFIZER-BIONTECH VACCINE UNDER EMERGENCY USE AUTHORIZATION

ef: (a) Comirnaty® Biologics License Application

- (b) Emergency Use Authorization for Pfizer-BioNTech COVID-19 vaccine of 23 Aug 2021
- 1. <u>Purpose</u>. Address the interchangeability of the Food and Drug Administration (FDA)-approved Comirnaty® and FDA-authorized Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) vaccine.
- 2. <u>Background</u>. On 23 August 2021, the FDA approved the Biologics License Application submitted by Pfizer-BioNTech for individuals 16 years of age and older, reference (a). On the same day the FDA revised the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine for individuals 12-15 years of age and for a third dose in immunocompromised individuals, reference (b).
- 3. The FDA-approved vaccine, and the vaccine used under the EUA, have the same formulation, and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Navy medical providers can use Pfizer-BioNTech doses previously distributed under the EUA to administer mandatory vaccinations.

B. L. GILLINGHAM

Copy to: COMPACFLT COMUSFLTFORCOM OPNAV (N3N5) HQMC HS



# 3 Sept - 8 Sep 2021

### The Navy Saga (Part 2)

- 3 Sept USN/SG "Interchangeable" memo
  - RADM B.L. Gillingham
- 4 Sept Concerned USMC Generals seek Comirnaty
  - (Email between 2-Star and 3-Star)
- 8 Sept Asst. Secretary of the Navy (ASN)

Sir, Good morning. Yesterday we offered completely voluntary vaccinations for the flu and COVID going into the 96. A Capt asked to see the vial and stated "this is not the approved vaccination"...he was right! You have got to be Wanted to share amongst the Team some lessons we learned Friday about the COVID vaccination as we soon enter mandatory vaccinations. Background: The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine; the military doses are labelled **BioNTech** Pfizer used all BioNTech data in its submission for FDA approval...but called it Comirnaty (koe-mir'-na-tee). It is molecularly exactly the same. SECDEF's press release states: On Aug. 23, the FDA gave full approval to the Comirnaty vaccine — previously known as the Pfizer-BioNTech vaccine — for individuals 16 years of age and older. Why they would change the name (for marketing) is beyond me. The confusion that was generated Friday comes in part from the Pfizer Information Fact Sheet, 23 August (www.cvdvaccine.com <a href="http://www.cvdvaccine.com">http://www.cvdvaccine.com</a>). A footnote in that Fact Sheet states that: "The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness." Throughout this document, the two brand names are mentioned interchangeably when describing formulation, ingredients, side effects, and how the product is administered. The MARADMIN states: "3.b. COVID-19 vaccines that have received Food and Drug Administration (FDA) licensure are mandated for all DoD service members by ref (b). FDA Licensed vaccine(s) are the only vaccine(s) that can be mandated for DoD personnel at this time." As currently written/directed, the vials should be labelled Comirnaty when it comes time for mandatory vaccinations.

Bottom line: BioNTech and Comirnaty are molecularly the same. Technically, Comirnaty is the only one approved for mandatory vaccinations (right now). Just wanted you all to have the background our great COS flushed out Friday.

Hope you have a GREAT Weekend!

Very Respectfully

Homey



# 3 Sept - 8 Sep 2021

### The Navy Saga (Part 2)

- 3 Sept USN/SG "Interchangeable" memo
  - RADM B.L. Gillingham
- 4 Sept Concerned USMC Generals seek Comirnaty
  - (Email between 2-Star and 3-Star)
- 8 Sept Asst. Secretary of the Navy (ASN)



#### THE ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS) 1000 NAVY PENTAGON WASHINGTON, D.C. 20350-1000

SEP 0 8 2021

#### MEMORANDUM FOR ASSISTANT SECRETARIES OF THE NAVY CHIEF OF NAVAL OPERATIONS COMMANDANT OF THE MARINE CORPS GENERAL COUNSEL OF THE NAVY

SUBJECT: Use of Pfizer-BioNTech Vaccine for Mandatory Vaccination

- Reference: (a) Secretary of Defense memorandum, dtd 24 Aug 2021
  - (b) ALNAV 062/21, Department of Navy Mandatory COVID-19 Vaccination Policy
  - (c) Comirnaty® Biologics License Application Approval, dtd 23 Aug 2021
  - (d) Bureau of Medicine and Surgery Memorandum, Ser M00/21M00035, dtd 3 Sep 2021

This memorandum clarifies that mandatory COVID-19 vaccinations under references (a) and (b) can utilize the Pfizer-BioNTech and Comirnaty® vaccines because the two vaccines are the same formulation and are interchangeable.

On 23 August 2021, the U.S. Food and Drug Administration (FDA), per reference (c). approved the first COVID-19 vaccine, Pfizer-BioNTech, for the prevention of COVID-19 in individuals 16 years of age and older, and announced that the vaccine will be marketed as Comirnaty®. Since December 11, 2020, the Pfizer-BioNTech vaccine has been available under an Emergency Use Authorization (EUA) for individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. These two vaccines have the same formulation. The FDA's press announcement is available online at https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

On 24 August 2021, the Secretary of Defense mandated COVID-19 vaccinations for service members on active duty or in the Ready Reserve, using only COVID-19 vaccines that receive full FDA licensure in accordance with FDA-approved labeling and guidance. Per the FDA's guidance, the Pfizer-BioNTech vaccine distributed under the EUA and the licensed Comirnaty® vaccine have the same formulation and are interchangeable. Navy medical providers can use Pfizer-BioNTech doses previously distributed under the EUA to administer mandatory vaccinations. The Surgeon General has provided amplifying guidance at reference (d).

Maintaining the readiness of our force is everyone's responsibility. Vaccinations continue to be the most effective tool available to prevent the spread of COVID-19.

> Robe. S. Hogue Robert D. Hogue Acting





# THE ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS) 1000 NAVY PENTAGON WASHINGTON, D.C. 20350-1000

SEP 0 8 2021

# 3 Sept - 8 Sep 20

## The Navy Saga (Part 2)

- 3 Sept USN/SG "Interchangeable" men
  - RADM B.L. Gillingham
- 4 Sept Concerned USMC Generals seek Comirnaty
  - (Email between 2-Star and 3-Star)
- 8 Sept Asst. Secretary of the Navy (ASN

#### **Relevant Info:**

- Same USN/SG who stated:
- "Absent a Presidential Waiver, I cannot make a COVID vaccine either mandatory or a readiness requirement. The choice [to receive EUA] is yours.
- What Changed?



From: Gillingham, Bruce L RADM USN SURGEON GENERAL (USA)

To: USN NCR BUMED FCH VA DDL NMED-ALL-01; USN NCR BUMED FCH VA DDL NMED-ALL-03; USN NCR BUMED FCH VA DDL NMED-ALL-03
Cc: Shaffer, Gayle D RADM USN BUMED FCH VA (USA); 'james.hancock@usmc.mil'; Riggs, Mary C RADM USN DHA J-9 (USA); Freedman, Rick
RDML USN DCNO N4 (USA); USN NCR BUMED FCH VA List BUMED - SG Staff; Via, Darin K RDML USN NAVMED EAST PORS VA (USA); Swap, Anne
M RADM USN DHA (USA); Kuehner, Cynthia Ann RDML USN NAVMEDEDTRNCMDSATTX (USA); Weber, Timothy Harding (Tim) RDML USN NAVMED
WEST SAN CA (USA); Roberts, Michael J MCPO USN BUMED FCH VA (USA); Malanoski, Michael P SES USN (USA)

**Subject:** We Are At War-Are You Protecting Your Community? (UNCLASSIFIED)

#### CLASSIFICATION: UNCLASSIFIED

Sent: Friday, February 26, 2021 4:56 PM

Esteemed Shipmates:

This message is for our entire Navy Medicine team, especially those who have concerns about receiving COVID-19 vaccinations. As your Surgeon General, my first concern is your safety. I would never allow you to go into a combat zone without flak and Kevlar. By the same token, I am concerned that Navy Medicine personnel are electing to serve on the front lines of the war against COVID every day without the single best protection we have: the SARS-CoV-2 vaccine. The vaccine is our "biological body armor," a safe, highly effective defense against a virus which can cause serious long term disability, even in those minimally symptomatic and, in over 500,000 cases so far, death. Tragically, we have lost seven active duty sailors, (four in the last month) and 53 Department of the Navy civilians thus far. Fortunately, our scientific panel, world class experts in their fields, assure me that the benefits of the vaccine far, far, outweigh possible side effects.

I recognize that receiving a COVID vaccine is voluntary. Absent a presidential waiver, I cannot make a COVID vaccine either mandatory or a readiness requirement. The choice is yours, and I ask that you make the best choice for your own health and, importantly, for those around you. Frankly, many have asked "what's in it for me" noting that even if they get the vaccine they will not see an immediate relaxation of our current public health restrictions. As the adage "a journey of a thousand miles starts with a single step" reminds us, all of us have a small but very important role to play by getting vaccinated. It is estimated that 75% or more of us need to be vaccinated if we are to achieve the community immunity that will allow that return to normalcy. We are each a part of several communities: those of our families, friends, co-workers and the neighborhoods in which we live. Communities depend upon shared, coordinated actions to thrive and reach their "common" vision of happiness. This sometimes requires compromise and sacrifice. The COVID pandemic is one of those times. Please consider the impact of not getting vaccinated on your community. Ignore biased social media, examine the science and reach out to a trusted medical provider to address your reservations. We are truly in this together.



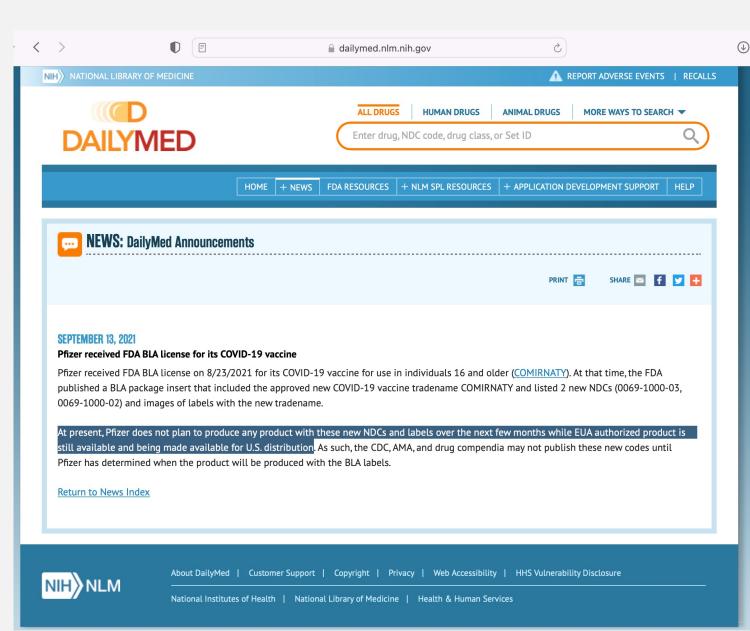
# 13 Sept 2021

# NIH DailyMed Announcement

No Intent to produce Fully-licensed products IAW
 23 Aug 2021 BLA125742

#### **Relevant Info:**

 This is the same day I am ordered to receive fully licensed "vaccine"



**13** 

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No Inter 23 Aug :

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# MEMORANDUM FOR MAJ DAVID BECKERMAN

FROM:

SUBJECT: Order to Receive Mandatory COVID-19 Vaccine

Secretary of Defense, Mandatory Coronavirus Disease 2019 Vaccination of References: (a) Department of Defense Service Members (24 August 2021)

(b) Secretary of the Air Force, Mandatory Coronavirus Disease 2019 Vaccination of

Department of the Air Force Military Members (3 September 2021)

Commander, 17th Training Wing, Mandatory COVID-19 Vaccination of Military Members (10 September 2021)

(d) AFI 48-110\_IP, Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases (16 February 2018)

- 1. On 24 Aug 21, the Secretary of Defense issued a mandate for all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, to receive the COVID-19 vaccine (Reference (a)). Subsequently, on 3 Sep 21, the Secretary of the Air Force issued a directive for the Department of the Air Force ordering all Airmen and Guardians to receive the COVID-19 vaccine with additional implementation guidance of the Secretary of Defense's order (Reference (b)).
- 2. Mandatory vaccination will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA).
- 3. As of 10 September 2021, the local medical facility did not have record of your COVID-19 vaccination. As a result, and in accordance with the above paragraph, I am ordering you to receive an initial dose of a COVID-19 vaccine with full licensure approval from the FDA on 14 September 2021. You must provide proof to the First Sergeant that you have complied with this order by 1630 on 17 September 2021. Additionally, you are ordered to receive the second dose of the same vaccine AND provide proof to the First Sergeant by 19 October 2021.

13

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No Inter 23 Aug

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This fully

- 4. The Pfizer COVID-19 vaccine is not the only option available for complying with paragraph 3 of this 4. The Pfizer COVID-19 vaccine is a state of the two-shot Moderna COVID-19 vaccine or the single order. Alternatively, you may choose to receive the Manager to shot J&J COVID-19 vaccine. If you choose to receive the Moderna series vaccine, you must comply with the two deadlines listed in paragraph 3. If you choose to receive the J&J vaccine, you must comply with the two deadlines listed in paragraphs of completed vaccination status NLT 1630 on 15 September 2021. It is YOUR responsibility to pay attention to these timelines. A request (to me) for good cause for an extension to this order must be received in writing before the ordered due date.
- 5. If you have concerns about the COVID-19 vaccine, you have access to free advice and counseling through any of the installation agencies listed below. The completion dates listed above should provide a reasonable amount of time in which to coordinate with these agencies.

a. Medical Concerns - you can contact the Operational Medical Element at

- b. Legal Implications the Area Defense Counsel (ADC) can be reached at
- c. Religious Objections the Chaplain's Office can be reached at
- 6. Failure to comply with this lawful order may result in administrative and/or punitive action under Article 92, Uniform Code of Military Justice.

USAF

Commander

2 Attachments:

- 1. Vaccine Information Fact Sheet for Recipients and Caregivers About Comirnaty (COVID-19 Vaccine, mRNA) and Pfizer-Biontech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
- 2. Department of the Air Force Mandatory COVID-19 Vaccine Frequently Asked Questions

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- 2. I understand a request for an extension to this order must be in writing, prior to the due dates, and can only be approved by the Commander.
- 3. I acknowledge that if I will be on leave or TDY on 14 September 2021, and do not otherwise provide proof of an exemption or fully vaccinated status by the deadlines above, that I must arrange for an extension to the above deadlines prior to departing for leave or TDY.

4. IDO/DO NOT (circle one) intend to request a religious accommodation or medical exemption.

DAVID BECKERMAN, MAJ, USAF

2d Ind to

MEMORANDUM FOR MAJ DAVID BECKERMAN

On or before 17 September 2021, the member:

- a. \_\_\_\_\_ provided proof of receiving an initial dose of a Pfizer or Moderna COVID-19 vaccination series;
  - b. \_\_\_\_\_ provided proof of receiving a J&J COVID-19 vaccination;
  - c. \_\_\_\_ submitted a completed religious accommodation request;
  - d. \_\_\_\_ provided proof of an approved military medical exemption;
  - arranged for an extension until \_\_\_\_\_\_\_ to comply with this order; or
- f. \_\_\_\_ did not provide sufficient proof of any of the above and must comply with this order or risk adverse consequences

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# 14 Sept 2021

### **ASD/HA Terry Adirim Memo**

- "DoD healthcare Providers"
- "Will use both... [EUA]...and Comirnaty...interchangeably"

#### **Relevant Info:**

- Recall: ASN 8 September "interchangeability" memo
- Today Terry Sings a different tune..

#### ASSISTANT SECRETARY OF DEFENSE



#### 1200 DEFENSE PENTAGON WASHINGTON, DC 20301-1200

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS

ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS

ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the Comirnaty vaccine, made by Pfizer-BioNTech, as a two-dose series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the Comirnaty vaccine. Per FDA guidance, these two vaccines are "interchangeable" and DoD health care providers should "use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine."

Consistent with FDA guidance, <u>DoD health care providers</u> will use both the Pfizer-BioNTech COVID-19 vaccine and the Comirnaty COVID-19 vaccine interchangeably for the purpose of vaccinating Service members in accordance with Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021.

My point of contact for this guidance is Colonel Michael J. Berecz, who may be reached at (703) 681-8463 or michael.j.berecz.mil@mail.mil.

ADIRIM.TERR Digitally signed by ADIRIM.TERRY.A.152384 Y.A.152384712 7127 Date: 2021.09.14 11:02:05 -04'00'

Terry Adirim, M.D., M.P.H., M.B.A. Acting

cc:

Surgeon General of the Army Surgeon General of the Navy Surgeon General of the Air Force Joint Staff Surgeon



Replying to @ShrimeMark and @Rosenlaw

It's regrettable because they knew going in vaccines are required to enter the military and to go to college anywhere. A shame that a safe and effective vaccine has been enmeshed in disinformation and politics. And to your point, in the military, you have to follow lawful orders

4:34 AM · May 16, 2022 · Twitter for iPhone

SEPTEMBER 14, 2021

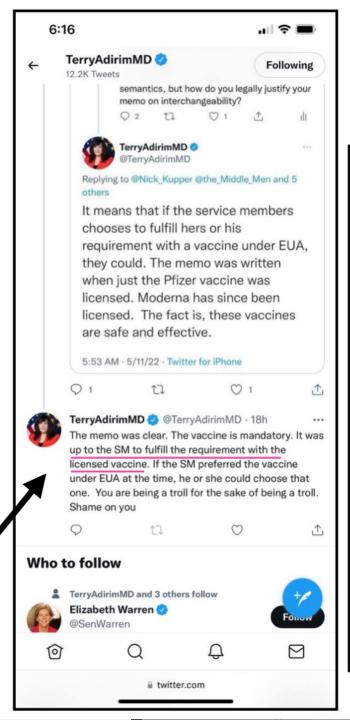
FRAGO 5 TO HQDA EXORD 225-21 COVID-19 STEADY STATE OPERATIONS

3.D.8.A

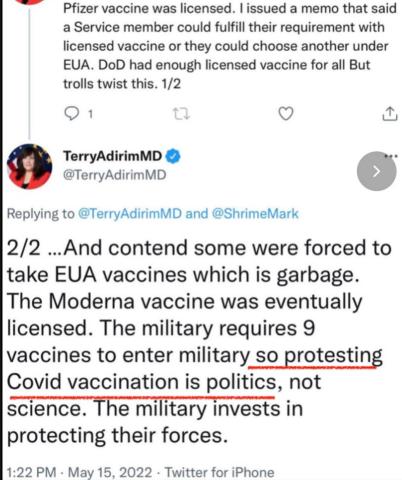
WHILE THE ONLY MANDATORY VACCINE IS THE PFIZER/COMIRNATY COVID-19 VACCINE

3.D.8.B.1

COMMANDERS WILL ENSURE SUFFICIENT DOSES OF DEPARTMENT OF DEFENSE APPROVED VACCINES ARE ON HAND AND AVAILABLE FOR THEIR UNIT



# Adirim Tweets



DoD made COVID vaccination mandatory once the



Replying to @Shrime!

It's regrettabl
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A shame that
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4:34 AM · May 16, 20

SEPTEMBER 14, 202

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3.D.8.A WHILE THE ONLY MA PFIZER/COMIRNATY

3.D.8.B.1
COMMANDERS WILL E
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ARE ON HAND AND A



Replying to @ShrimeMark @JanineG385 and @TwitterSupport

We do. This is related to a memo I issued advising Service members they could fulfill their vaccine requirement with the licensed vaccine or if they choose, with those under EUA. This person is an anti-vaxxer spreading disinformation.

lawful orders 3:38 PM · Jun 1, 2022 · Twitter for iPhone



Replying to @ShrimeMark and @pwhickey

I don't know the current status of this issue. When the BLA was issued, that is true. We made sure there were doses of the Comirnaty at immunization sites for those people who insisted on the version with the right label.

9:02 AM · Jul 7, 2022 · Twitter Web App



Replying to @ShrimeMark and @pwhickey

When the Pfizer BLA was first issued, it was done under the brand name Comirnaty. It was the same formulation as the pre BLA doses. So in reality, doesn't matter but as a technical point, the military was mandating Comirnaty.

8:59 AM · Jul 7, 2022 · Twitter Web App



mandatory once the sued a memo that said heir requirement with choose another under I vaccine for all But

were forced to

0

neMark

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Replying to @pwhickey

I'm being trolled by anti-vaxxers who seventually accuse me of signing a memo promoting lires 9 "illegal" vaccines not licensed, etc. so protesting What I issued was a memo clarifying cs, not that SMs can fulfill their requirement will sts in any FDA authorized vaccine and does NOT require non-licensed COVID vax.

9:46 AM · Jul 6, 2022 · Twitter Web App



Replying to @Shrime!

It's regrettabl in vaccines ar military and to A shame that vaccine has b disinformation point, in the r lawful orders 3:38 PM · Jun 1, 2022 · To

4:34 AM · May 16, 20

SEPTEMBER 14, 202

FRAGO 5 TO HQDA E STATE OPERATIONS

3.D.8.A WHILE THE ONLY MA PFIZER/COMIRNATY

3.D.8.B.1 COMMANDERS WILL E DEPARTMENT OF DEF ARE ON HAND AND A



Replying to @ShrimeMark

We do. This is re issued advising { could fulfill their with the licensed choose, with the person is an anti disinformation.



TerryAdirimMD @TerryAdirimMD

Replying to @ShrimeMark

I don't know the issue. When the is true. We mad of the Comirnaty for those people version with the

9:02 AM · Jul 7, 2022 · Tv



Replying to @ShrimeMark and @pwhickey

I don't know the current status of this issue. When the BLA was issued, that is true. We made sure there were doses of the Comirnaty at immunization sites for those people who insisted on the version with the right label.

9:02 AM · Jul 7, 2022 · Twitter Web App



TerryAdirimMD 🥝 @TerryAdirimMD



Change My Tune Forest Sun

Replying to @GermHunterMD @ShrimeMark and 6 others

Sigh, I wrote a memo of clarification after the Pfizer vaccine's BLA was approved stating a Service member can fulfill their vaccine requirement with any authorized vaccine. We made sure Pfizer was available at all vax sites. But anti-vaxxers have twisted this and trolled me.

4:49 AM · Aug 18, 2022 · Twitter Web App

# -\dirim !weets

vhickey

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vas first issued, it and name same formulation So in reality, a technical point, ating Comirnaty.

imMD · 5m mandatory once the sued a memo that said heir requirement with choose another under vaccine for all But







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were forced to is garbage. i-vaxxers who s eventually memo promoting lires 9 censed, etc. so protesting emo clarifying cs, not ir requirement will<sup>sts</sup> in

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# 20 - 29 Oct 2021

### **Air Force Saga**

- 20 Oct Attempt to Correct the Memo IAW the law
- 21 Oct Col Tanya Rans Declaration (exhibit 14)
- 21 Oct Dr Peter Marks Declaration (exhibit 13)
- 29 Oct "Non-concur" because it subverts our vaccination policy

#### Relevant Info:

- Dr. Peter Marks contradicts Col Tanya Rans in the same day
- Air Force "non-concur" due to requiring "significant remedial action""



**HEALTH AFFAIRS** 

#### OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

#### 1200 DEFENSE PENTAGON WASHINGTON, DC 20301-1200

#### ACTION MEMO

FOR: TERRY ADIRIM, M.D., M.P.H., M.B.A., ACTING ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

FROM: David J. Smith, M.D., Deputy Assistant Secretary of Defense (Health Readiness Policy and Oversight)

SMITH.DAVID. Digitally signed by SMITH.DAVID. 10985460975

J.1085480975 Date: 2021.10.20 08:29

SUBJECT: Mandatory Vaccination of Service Members using the Pfizer-BioNTech/Comirnaty®
Coronavirus Disease 2019 Vaccines

- Request your signature on the Action Memo at NEXT UNDER forwarding the Action Memo to the Under Secretary of Defense for Personnel and Readiness to approve the letters at TAB A that rescinds and replaces Assistant Secretary of Defense for Health Affairs Memorandum, Mandatory Vaccination of Service Members using the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) and Comirnaty® COVID-19 Vaccines, September 14, 2021.
- The memorandum states that the Pfizer-BioNTech COVID-19 vaccine produced under Emergency Use Authorization (EUA) has the same formulation as the Pfizer-BioNTech/Comirnaty® vaccine produced under the Biologics License Application (BLA).
- The memorandum adds a statement that a Service member, after medical counseling, declines administration of the EUA-manufactured Pfizer-BioNTech COVID-19 vaccine but will accept the BLA-manufactured product. The Department of Defense health care providers should engage with their logistics chain to secure and administer the BLA-manufactured Pfizer-BioNTech/Comirnaty® product prior to any punitive action being taken against the Service member.

RECOMMENDATION: Sign the action memo next under.

COORDINATION: TAB B

Attachments: As stated

Prepared by: CATMS2010202125C87X/UPR003415-21

# 20 - 29 Oct 2021

### Air Force Saga

- 20 Oct Attempt to Correct the Memo IAW the law
- 21 Oct Col Tanya Rans Declaration (exhibit 14)
- 21 Oct Dr Peter Marks Declaration (exhibit 13)
- 29 Oct "Non-concur" because it subverts our vaccination policy

#### Relevant Info:

- Dr. Peter Marks contradicts Col Tanya Rans the same day
- Air Force "non-concur" due to requiring "significant remedial action""

### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA

JANE DOE #1, et al.,	)	
	)	
	)	
	)	
Plaintiffs,	)	
	)	
VS.	)	No. 3:21-CV-01221-AW-HTC
	)	
LLOYD AUSTIN, in his official		
capacity as Secretary of Defense,		
et. al,	)	
	)	
Defendants.	)	

#### **DECLARATION OF COLONEL TONYA RANS**

#### I, Colonel Tonya Rans, hereby state and declare as follows:

1. I am currently employed by the U.S. Air Force as the Chief, Immunization Healthcare Division, Defense Health Agency – Public Health Directorate, located in Falls Church, Virginia. I have held the position since June 2017. I am a medical doctor and have been board certified in Allergy/Immunology since 2008 and was a board certified Pediatrician from 2001-2015.

# 20 - 29 Oct 2021

### **Air Force Saga**

- 20 Oct Attempt to Correct the Memo IAW the law
- 21 Oct Col Tanya Rans Declaration (exhibit 14)
- 21 Oct Dr Peter Marks Declaration (exhibit 13)
- 29 Oct "Non-concur" because it subverts our vaccination policy

#### Relevant Info:

- Dr. Peter Marks contradicts Col Tanya Rans the same day
- Air Force "non-concur" due to requiring "significant remedial action""

and older. COVID-19 vaccine effectiveness against severe disease (hospitalization and death) remains high. 10

JA

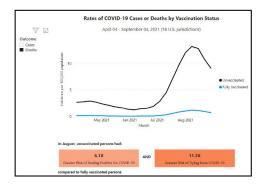
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S11



17. As of October 15, 2021, DoD immunization sites have administered 5.7 million doses of COVID-19 vaccine. As of October 8, 2021, DoD has received a total of 6,470 unique Vaccine Adverse Event Reporting System (VAERS) reports (approximately 11 VAERS reports/10,000 doses administered). Note that the number of VAERS reports/10,000 doses administered for DoD beneficiaries is likely to be lower, as the denominator does not take into account beneficiaries who receive vaccine in the civilian sector.

- 18. As of October 16, 2021, the DoD has in its possession hundreds of thousands of BLA-compliant vaccine doses that are EUA-labeled, and is using them.
- 19. Approach to immunizations within DoD are outlined in DoD Instruction 6205.02, "DoD Immunization Program", June 19, 2019, which states that it is DoD policy that all DoD personnel and other beneficiaries required or eligible

<sup>&</sup>lt;sup>10</sup> Link-Gelles, Ruth. COVID-19 Vaccine Effectiveness in the United States, presented to the Advisory Committee on Immunization Practices, 22 September 2021 https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html.

#### Case 3:21-cv-01211-AW-HTC Document 31-14 Filed 10/21/21 Page 11 of 17

Case 3:21-cv-01211-AW-HTC Document 31-13 Filed 10/21/21 Page 2 of 161

# 20 - 29 Oct 2021

### **Air Force Saga**

- 20 Oct Attempt to Correct the Memo IAW the law
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# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA

JANE DOE #1, et al.	)	
Plaintiffs,	)	
V.	)	Case No. 1:21-cv-01211-AW-HTC
LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, et al.	)	
Defendants.	) ) )	

#### DECLARATION OF PETER MARKS, M.D., Ph.D.

- I, Peter Marks, declare as follows:
- 1. I am the Director of the Center for Biologics Evaluation and Research ("CBER"),

United States Food and Drug Administration ("FDA"), a position I have held since 2016. In this role, I direct the development and implementation of programs and policies for assuring the safety, purity, and potency of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies.

S111 23.html.	.3-2021-07-22
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## 20 - 29 Oct 2021

## **Air Force Saga**

- 20 Oct Attempt to Correct the Memo IAW the law
- 21 Oct Col Tanya Rans Declaration (exhibit 14)
- 21 Oct Dr Peter Marks Declaration (exhibit 13)
- 29 Oct "Non-concur" because it subverts our vaccination policy

#### Relevant Info:

- Dr. Peter Marks contradicts Col Tanya Rather the same day
- Air Force "non-concur" due to requiring "significant remedial action""

Case 3:21-cv-01211-AW-HTC Document 31-13 Filed 10/21/21 Page 6 of 161

10. The determination that FDA made for Comirnaty and Pfizer-BioNTech Covid-19 vaccine should not be confused with the statutory interchangeability determination that FDA may make when reviewing a BLA for a biological product manufactured by one company and comparing it with a biological product manufactured by a different company. Under 42 U.S.C. § 262(k)(4), FDA may determine that a biological product is "interchangeable" with a "reference product." "Reference product" is defined at 42 U.S.C. § 262(i)(4) as a "single biological product licensed under [42 U.S.C. § 262(a)] against which a biological product is evaluated in an application submitted under [42 U.S.C. § 262(k)]." The statutory interchangeability determination requires a licensed reference product and a subsequent applicant seeking licensure. which is not present here. The PHSA interchangeability provision also contains obligations related to exclusivity and exchange of patent information for interchangeable products, which would not make sense for two products produced by a single company. See 42 U.S.C. § 242(k)(6), (l).

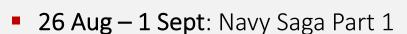
11. While FDA determined Comirnaty and Pfizer-BioNTech Covid-19 vaccine are medically interchangeable, there are legal distinctions between BLA-approved and EUA-authorized products. For example, products approved under BLAs are required to have the labeling that was approved as part of the BLA, whereas products authorized under the EUA would have the EUA labeling, and there may also be differences in manufacturing sites for BLA and EUA vaccine. Both the EUA and BLA processes have required the sponsor to identify specific facilities that will manufacture the vaccine. See Summary Basis for Regulatory Action – Comirnaty, pp. 12-13 (August 23, 2021), available at https://www.fda.gov/media/151733/download.

	DoD ISSUANCE COORDINATION RESPONSE: Issuance Type and Number, "Title"										
20 - 20	CLASS	#	PAGE	PARA	BASIS FOR NON- CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL				
	1	1	1								
Air Force		6	1-2	all		Coordinator Comment and Justification: Significant concerns with the memo statement "Service members who request the BLA-manufactured Pfizer-BioNTech/Comirnaty COVID-19 vaccine for the primary two-dose					
<ul><li>20 Oct – Atte Memo IAW t</li></ul>						series shall be informed of FDA guidance on Pfizer-BioNTech/Comirnaty®'s BLA formulation being the same as the Pfizer-BioNTech COVID-19 vaccine manufactured under (EUA and that FDA and CDC has advised that the two vaccines can be used interchangeably without presenting any safety or					
<ul><li>21 Oct – Col (exhibit 14)</li></ul>						effectiveness concerns. If a Service member, after medical counseling, declines administration of the EUA-manufactured Pfizer-BioNTech COVID-19 vaccine but will accept the BLA-manufactured product, DoD health care providers should engage with their logistics chain to secure and administer					
<ul><li>21 Oct – Dr I (exhibit 13)</li></ul>						the BLA-manufactured Pfizer-BioNTech/Comirnaty® product prior to any punitive action being taken against the Service member."	AFMRA/SG3PM				
<ul><li>29 Oct – "No subverts our</li></ul>						The memo states the vaccines can be used interchangeably; however, this paragraph would suggest DoD considers them different, and as different, cannot carry out punitive action against the Service member until they have the opportunity for a BLA-manufactured vaccine. This subverts our current DAF vaccination mandate and may open up the Air Force for	703-681-9307 usaf.pentagon.af- sg.mbx.team-covid- 19@mail.mil				
Relevant Info:						increased litigation from individuals who have been mandated since 24 August to be vaccinated. If there is no difference that can otherwise be	703-681-9307 usaf.pentagon.af- sg.mbx.team-covid-				
<ul><li>Dr. Peter Ma the same da</li></ul>						communicated, we recommend non-concur with this paragraph as it subverts current policy. We are all operating under the belief that the lot issue is a distinction without a difference from a health/safety/medical/legal perspective. As the services have taken action, possibly include adverse					
<ul><li>Air Force "no "significant r</li></ul>						action, based on a belief that the distinction is one without meaningful difference, OSD retrenchment signifying that the distinction does matter would probably require significant remedial actions.					
						Coordinator Recommended Change: Non-concur as written.  Originator Response: Choose an item.					

## Let's Review...

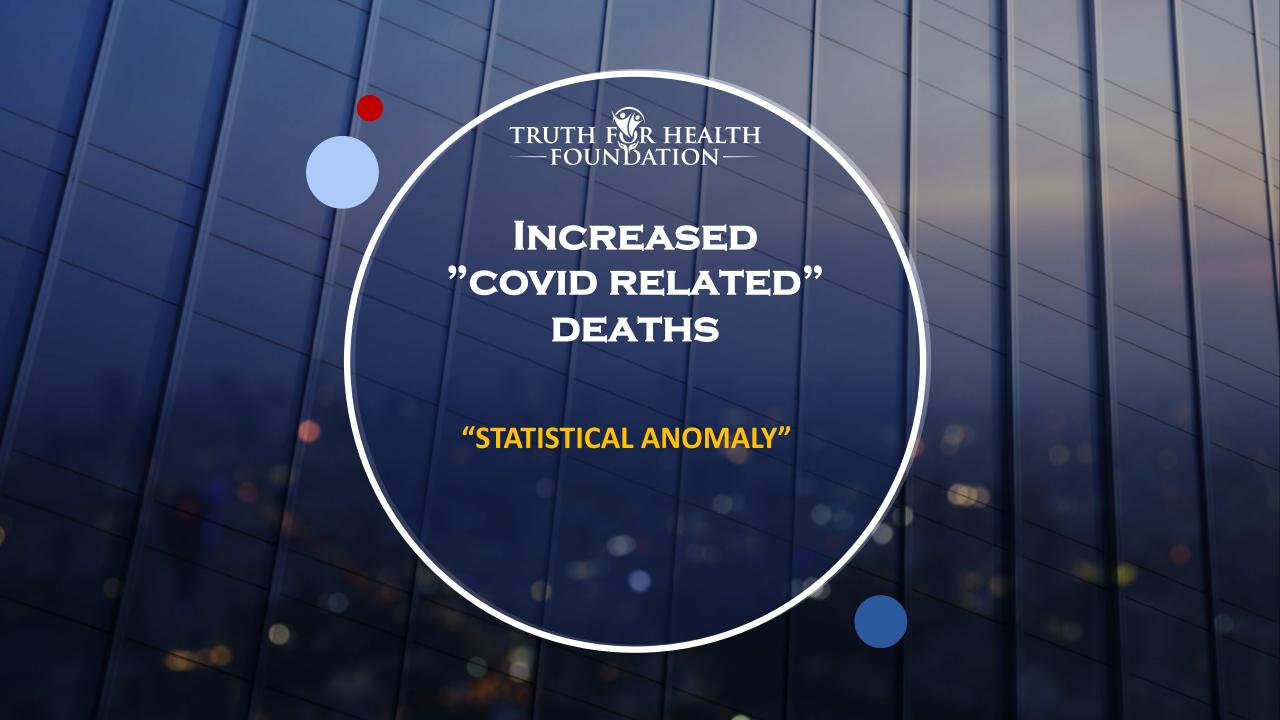


### DoD either *knew in advance* –or – *covered up a mistake*



- All policy/guidance memos state
- Mandatory = Fully-licensed
- Voluntary = EUA
- 3 Sept 8 Sept: Navy Saga Part 2
  - "Same Formula" = Interchangeable
  - What about Title 42 U.S. Code § 262? *Legally Distinct*
- 13 Sept: DailyMed "No Intent" Announcement

- 14 Sept: DoD-wide "Interchangeable" Memo
- 20 Oct: Attempt to Correct the Policy
- 21 Oct: "Overly Confident" Declaration
  - We are using EUA labeled vials that are "BLA-Compliant"
- 29 Oct: "Non-Concur"
  - Subverts current vaccine policy



## Military Times Headlines

Your Military

## Military COVID-19 deaths double in two months

By **Meghann Myers** 

**Sep 24, 2021** 















Fifty-two service members have died of COVID-19 complications to date. None of them were fully vaccinated. (Lance Cpl. Tyler W. Abbott/Marine Corps)

It took more than a year for 26 service members to <u>die of COVID-19</u>, even as the pandemic raged through the country. It took two months for that <u>death toll</u> to double this summer.

To date, 52 troops have died from COVID-19 complications. None of them have been <u>fully vaccinated</u>, Maj. Charlie Dietz, Pentagon spokesman, told Military Times on Wednesday.

Your Military

# Three troops die on the same day as military COVID-19 deaths continue to spike

By Meghann Myers 📋 Oct 8, 2021













About 73 percent of troops are at least partially vaccinated against COVID-19. (Maj. Charles An/Army Reserve)

Three <u>troops died of COVID-19</u> on Oct. 3, bringing the total number to 62 as of Wednesday, according to the latest Defense Department update.

COVID-19 deaths among troops have been surging since late July, after zero deaths in June, and generally one or two a month going all the way back to March 2020. Then 14 troops died in August, followed by another 14 in September.

#### Your Military

# 5 more military COVID-19 deaths as active-duty force inches toward 100% vaccination

By Meghann Myers

















Sergeant Major of the Marine Corps Sgt. Maj. Troy E. Black receives the COVID-19 vaccine as part of Operation Warp Speed at Walter Reed National Military Medical Center, Maryland, Dec. 22, 2020. (Lance Cpl. Tyler W. Abbott/Marine Corps)

Military COVID-19 deaths are <u>continuing to trend upward</u>, even as more of the force gets vaccinated. The five most recently reported deaths all came in members of the Army's reserve component, whose organizations are among the least vaccinated in the military.

In the <u>36 deaths reported since August</u>, 19 – or 53 percent – were among Army Reserve and Army National Guard soldiers, though they make up roughly 20 percent of the military overall. Since the pandemic began, they have made up 26 of 67 total deaths, or 39 percent.

Your Military

### **New military COVID-19 deaths come down** slightly as cases drop nationwide

By Meghann Myers

Ct 21, 2021















Col. Joshua Bookout, commander, 3rd Infantry Brigade Combat Team, 25th Infantry Division receives the Pfizer-BioNTech COVID-19 vaccine at the Conroy Bowl on Schofield Barracks, Hawaii on Jan. 14, 2021. (1st Lt. Angelo Mejia/Army)

Three service members died of COVID-19 complications between Oct. 13 and Oct. 20, according to the Pentagon's latest data, bringing the death toll for October so far to 11.

The deaths reflect a continuing trend among troops that began in late July and has since more than doubled the COVID-19 death toll. The latest update, however, shows fewer deaths than in any week since August, along with a decrease in new cases for the second week in a row.

#### Your Military

### October COVID-19 troop deaths stay at record highs

By Meghann Myers

Nov 4, 2021













Army Capt. Alexis Acuna, a critical care nurse, treats a COVID patient Sept. 26 at Kootenai Health Regional Medical Center in Coeur d'Alene, Idaho. An Army medical team has been deployed to the hospital since September to help with a flood of COVID patients that threatened to overwhelm the hospital. (Sgt. Kaden D. Pitt/Army)

Eleven service member deaths so far have been reported as a result of COVID-19 in October, according to Defense Department numbers released Wednesday, a third month in a row where fatalities numbered in the double-digits.

For all of 2020 and up until August 2021, generally only one or two troops died of COVID-19 complications each month, but as the delta variant surged around the country, so did cases in the military. August saw 15 deaths, September saw 14, and deaths dipped slightly in October as vaccine mandate deadlines closed in.

Your Military

### Military COVID-19 deaths on upswing as vaccination deadlines pass

By **Meghann Myers** 

Dec 15, 2021

















Senior Airman Rendall Powell of the 412th Test Wing receives a COVID-19 vaccination shot from Lt. Col. Yvonne Storey at Edwards Air Force Base, California, Aug. 25, 2021. (Katherine Franco/Air Force)

Eighty troops have died of COVID-19 complications, according to the Defense Department's most recent data, including five deaths in November and three so far in December.

November did see a two-week period without deaths, following a spike in deaths that began in late July, resulting in double-digit monthly deaths through October. While that number has come down, the services are still experiencing one of the most deadly periods of the pandemic, after seeing only one or two deaths for most of 2020 and the first half of 2021.

#### Your Military

### No active duty COVID deaths since vaccination deadlines, but reserve deaths continue

By Meghann Myers

Thursday, Jan 20











About 75 percent of National Guard and Reserve troops are at least partially vaccinated against COVID-19. (Senior Airman Neil Mabini/Air National Guard)

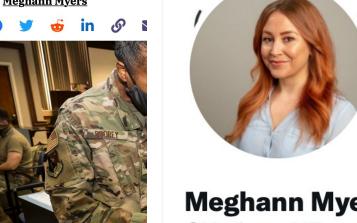
Over 98% of the active duty military is at least partially vaccinated against COVID-19, directly reflected in a sharp drop in active duty deaths since the delta variant surge that began in late fall and lasted into November.

For going on two months, the only deaths have been in the reserve component, where vaccination deadlines stretched to the new year for some of the services, or until the end of June for the Army.

### Military COVID-19 deaths on upswing as vaccination deadlines pass

By Meghann Myers





Meghann Myers 📀 @Meghann\_MT

Pentagon bureau chief @MilitaryTimes. Left my heart in San Francisco. I'm accountable for my retweets. mmyers@militarytimes.com meghannmyers@protonmail.com

Journalist Washington, DC armytimes.com/author/meghann... Joined February 2013

**1,008** Following 10.6K Followers

Followed by Heather S. Mongilio, U.S. Air Force, and 2 others you follow

No active duty COVID deaths since erve deaths

**Following** 

Thursday, Jan 20



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November did see a two-wee

Senior Airman Rendall Powell of

Col. Yvonne Storey at Edwards Air

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8 While that number has come down, the services are still experiencing one of the

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of 2020 and the first half of 2021.

es

For going on two months, the only deaths have been in the reserve component, where vaccination deadlines stretched to the new year for some of the services, or until the end of June for the Army.

Meghann Myers 🔮

Wednesday, July 13

few months now.

The spike in deaths came last fall,

when there was no mandate yet.

It corresponded with spikes all

over the country because of the

delta variant. Out of 95, two were

partially vaccinated and the rest

Hey you wrote a lot of these

articles on covid deaths after the mandate. What are your thoughts

mandate? We've now been steady

In the military times

11:16 🗸

about the spike in deaths post

at 95 covid related deaths for a



### Meghann Myers 🔮

12:35 🗸

### No active du

Your Military



## Meghann Myers 📀

10.6K Followers **1,008** Following

For going on two month where vaccination dead until the end of June fo

## @Meghann\_MT

Pentagon bureau chief @Military accountable for my retweets. mn meghannmyers@protonmail.com

 Journalist 🏻 🏵 Washington, D III Joined February 2013



he

most

Followed by Heather S. Mong





were unvaccinated.

I think you're confused about the deadlines for vaccines. No one was required to be vaccinated on Sept. 13. Further, as I have said multiple times, none of the SMs who died of COVID were fully

vaccinated.

And the fact that you're repeating "gene therapy" just shows how little you care about facts. So I'm not sure why you are reaching out to me.

The fact that we already separated members pre "deadlines" says otherwise. I'm reaching out because you're a journalist. Why are you ignoring the facts?

I 100% was required to be vaccinated by the 13th of September. You saw the order I received no?

## Let me explain...

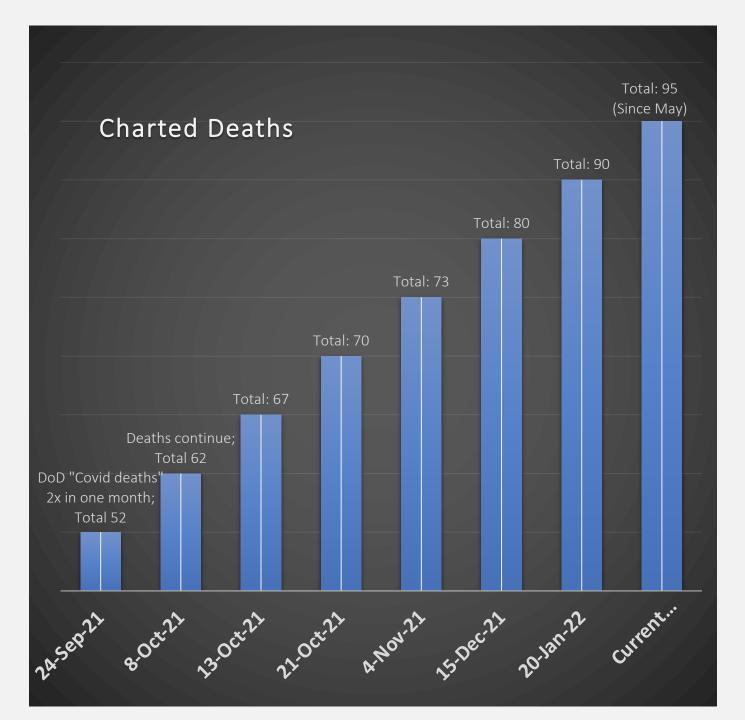
### Pentagon's Official Stance

- All SMs were "unvaccinated"
  - Fully-vaccinated = 14 days after the 2<sup>nd</sup> dose
- Delta Variant

#### **Relevant Info:**

- Pre-Mandate: Avg Death Rate ~ 1 per month
  - Jan 2020 Aug 2021 (20 Months)
- Post Mandate (First 4.5 Months) ADR ~ 4 per week!
  - Statistical Anomaly
- Average age = 45 yrs. Old
  - Youngest; 27 yrs. Old
  - Oldest; 56 yrs. Old
- Total Deaths 95 Since May 2022, unchanged through Omicron.
- ONLY ONE REASONABLE EXPLAINATION...

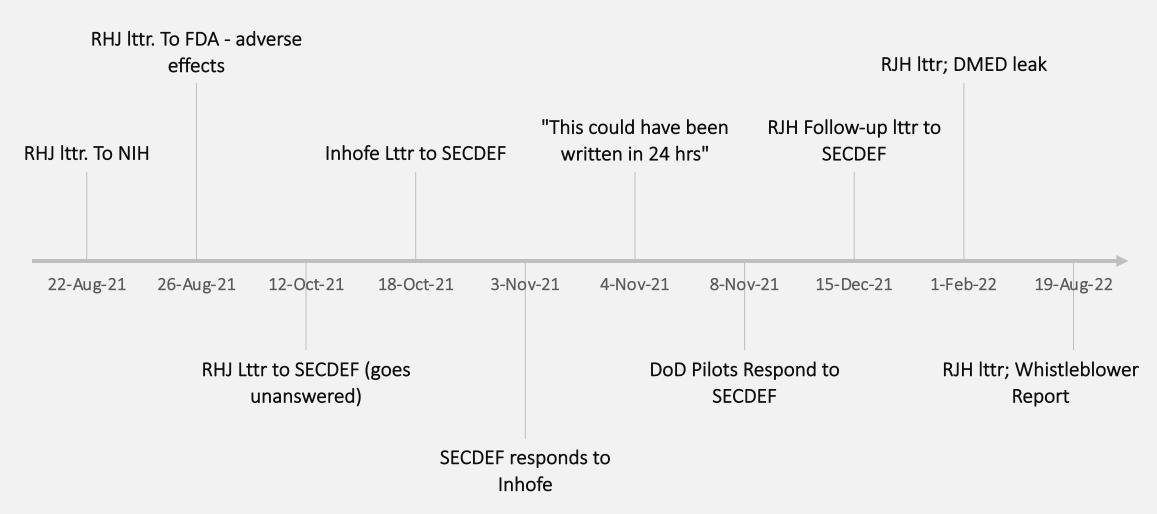








## RoadMap – Congressional Inquiries



## 22 August 2021

## Sen. Ron Johnson to NIH, CDC, FDA

(Two days prior to mandate)

### **Highlights:**

- 4 Vaccine Safety Oversight letters
- Deaths occurred on Day 0, 1, or 2 following [injection]
- 12,000+ Deaths in 8 Months compared to 9000 to all vaccines in 31 years!
- Dismissing Natural Immunity
- Recall: DoD "Death Spike"



As you are well aware, I first raised the issue of vaccine safety signals coming from FDA and Centers for Disease Control and Prevention's (CDC) Vaccine Adverse Event Reporting System (VAERS) in a meeting with National Institutes of Health Director Collins on April 27, 2021. Since then, I have written four oversight letters on the subject of vaccine safety,

August 22, 2021 Page 2

effectiveness, and adverse events.<sup>4</sup> To date, I have received little to no substantive response. This lack of transparency is unacceptable.

As of August 20, 2021, VAERS is reporting 12,791 worldwide deaths associated with the three Covid-19 vaccines available under an FDA Emergency Use Authorization (EUA). Of those deaths, 4,632 occurred on Day 0, 1, or 2 following vaccination. As the CDC and the FDA are quick to point out, VAERS reports do not prove causation. But this number of deaths, particularly with 36.2% occurring within 2 days of vaccination, should raise serious concerns.

It should also be noted that the 12,791 deaths related to Covid-19 vaccines reported on VAERS over the period of 8 months, compares to 8,966 deaths related to all other vaccines reported on VAERS since the inception of VAERS – a period of 31 years. And this does not raise alarm bells within your agencies, or cause you to reconsider assembling an independent safety panel of outside experts?

In addition to deaths, VAERS is also reporting 16,044 permanent disabilities, 51,242 hospitalizations, and 571,831 total adverse events related to the Covid-19 vaccines. I am receiving a growing number of letters from doctors and nurses detailing the vaccine injuries they are witnessing and treating, together with the suppression and censoring of this information they are experiencing.

Your agencies' dismissive attitude toward natural immunity has also been puzzling to say the least, and may increase the chances of vaccine injury in previously infected individuals. In its May 19, 2021 advisory, the FDA specifically discouraged Americans and their physicians from determining the status of their antibody immunity to SARS-CoV-2. It would seem to me that more medical information, not less, is the key to improving health outcomes related to any disease, including Covid-19.

<sup>&</sup>lt;sup>1</sup> Gareth Iacobucci, Covid-19: FDA set to grant full approval to Pfizer vaccine without public discussion of data, THE BMJ (Aug. 20, 2021), available at https://www.bmj.com/content/374/bmj n2086.

<sup>&</sup>lt;sup>2</sup> *Id*.

<sup>3</sup> Id.

## 26 August 2021

### Sen. Ron Johnson to FDA

(Two days after mandate)

### **Highlights:**

- Short Version: Where is Comirnaty!?
- Questions:
  - Why wasn't Pfizer-BioNTech approved?
  - What does legally distinct mean?
  - Will mandates use Fully-licensed version or is it likely/certain they will be "vaccinated" with EUA?
  - Legal protections for vaccine Injury?



#### United States Senate

WASHINGTON, DC 20510

August 26, 2021

Janet Woodcock, M.D. Acting Commissioner Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993

Dear Acting Commissioner Woodcock

On August 23, 2021, the FDA reissued the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. This vaccine is currently available and used in the United States. At the same time, the FDA announced its approval of the biologics license application submitted by BioNTech Manufacturing GmbH for Comirnaty (COVID-19 Vaccine, mRNA) against COVID-19 for individuals 16 years of age and older. According to the FDA, "there is not sufficient approved vaccine [Comirnaty] available for distribution" in the U.S.3

In the letter that reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine, the FDA stated that Comirnaty and the Pfizer-BioNTech COVID-19 vaccines are "legally distinct with certain differences that do not impact safety or effectiveness." That statement, together with the fact that the FDA issued two distinct letters — one extending the EUA for the vaccine used in the U.S. and the other granting the FDA approval of the Comirnaty vaccine used in Europe and other countries — has caused a great deal of confusion.

As I stated to you in my letter dated August 22, 2021, "I see no need to rush the FDA approval process for any of the three COVID-19 vaccines. Expediting the process appears to only serve the political purpose of imposing and enforcing vaccine mandates." Because the FDA-approved Comimaty vaccine is not generally available in the U.S., but the Pfizer-BioNTech COVID-19 vaccine will continue to be used in the U.S. under a reissued EUA, the FDA seems to be confirming my suspicion.

Acting Commissioner Janet Woodcock Aug. 26, 2021 Page 2

In order to address the confusion created by the FDA's August 23, 2021 letters, I am asking that you expeditiously provide answers to the following questions:

- 1) Why didn't the FDA grant full licensure for the Pfizer-BioNTech vaccine that is in use and available in the U.S.?
- 2) How are the Comirnaty and Pfizer-BioNTech COVID-19 vaccines "legally distinct" and what are the "certain differences"?
- 3) There is no doubt that the FDA's action will lead to more vaccine mandates and increased pressure on those currently choosing not to get vaccinated. Your letter to Pfizer suggests that "there is not sufficient approved vaccine available for distribution." Is there sufficient supply in the U.S. of the Comirnaty vaccine to ensure that those being vaccinated under mandates will be receiving the FDA-approved version? Or is it more likely (or certain) that they will be vaccinated using the vaccine administered under the reissued EUA?
- 4) If there is insufficient supply of Comirnaty vaccines for those succumbing to the coercion of mandates, isn't the FDA de facto endorsing vaccine mandates utilizing EUA vaccines?
- 5) Will individuals who receive either vaccine be afforded the same legal protections if they are injured by the vaccine? If not, why not?

<sup>&</sup>lt;sup>1</sup> Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download.

<sup>&</sup>lt;sup>2</sup> Letter to Amit Patel, BioNTech Manufacturing GmbH, from Mary Malarkey, Director, Office of Compliance and Biologics Quality, U.S. Food and Drug Administration, and Marion Grüber, Director, Office of Vaccines Research and Review, U.S. Food and Drug Administration, Aug. 23, 2021 available at https://www.fda.gov/media/151710/download.

<sup>&</sup>lt;sup>3</sup> Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 5, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download (See footnote 9).

<sup>&</sup>lt;sup>5</sup> Letter from Ron Johnson, U.S. Senator, to Janet Woodcock, Acting Commissioner, U.S. Food and Drug Administration, et al., Aug. 22, 2021.

## 12 October 2021

## Sen. Ron Johnson to POTUS, SECDEF, CJCS

(Forty-nine days after mandate)

### **Highlights:**

- Short Version: Where is Comirnaty x2
- Questions:
  - How many doses administered?
  - How many voluntary vs mandatory?
  - Show me what the Orders look like
  - Show me the guidelines
  - Show me how you implanted the mandate
  - Respond by 26 October 2021
- Recall: Navy Saga (26 Aug 8 Sept)
- Recall: AF Saga (14 Sept 29 Oct)



October 12, 2021 Page 2

[individuals 16 years of age and older] in its entirety at the time of reissuance of this EUA." Absent a sufficient supply of the only approved COVID-19 vaccine, Comirnaty, it is not clear how DoD is complying with Secretary Austin's assertion that mandatory vaccination will only occur with the fully-licensed vaccine.<sup>5</sup>

In order to understand the extent to which DoD service members subject to mandatory COVID-19 vaccination may have not received fully-approved vaccines as prescribed by Secretary Austin's vaccine mandate, I request the following information:

- 1. How many vaccinations have been administered since Secretary Austin's vaccine mandate?
- Please provide the number of voluntary and mandated vaccinations administered to DoD service members using each vaccine by month:
  - a. Moderna EUA;
  - b. Johnson and Johnson (Janssen) EUA;
  - c. Pfizer-BioNTech EUA; and
  - d. Comirnaty FDA approved.
- 3. Please provide all orders issued to DoD personnel regarding DoD's vaccine mandate.
- 4. Please provide all guidelines issued to DoD personnel regarding DoD's vaccine mandate.
- 5. Please provide all documents and communications regarding DoD's vaccine mandate, including but not limited to the development and implementation of the vaccine mandate.

Thank you for your attention to this urgent matter. Please respond no later than October 26, 2021.

Sincerely,

Ron Johnson U.S. Senator

 <sup>&</sup>lt;sup>4</sup> Letter to Amit Patel, BioNTech Manufacturing GmbH, from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 6, Sept. 22, 2021, available at https://www.fda.gov/media/150386/download (See footnote 12).
 <sup>5</sup> Memorandum from Secretary of Defense Lloyd Austin to Senior Pentagon Leadership, et al. (Aug. 24, 2021) (available at https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF).

## **18 October 2021**

### Sen. Inhofe to SECDEF

(Fifty-Five days after mandate)

### **Highlights:**

- Short Version: Let's talk Readiness
- Threats of Separations and some Separations had already begun
- The Gist:
  - DoD Logic: We must vaccinate to remain ready!
  - Also, DoD logic:
  - We must separate SMs to remain ready!
  - Everything is a "readiness issue"
- SEC DEF Responds... (late)



Accordingly, in your role as Secretary of Defense, and in conjunction with the Service Secretaries and Chairman of the Joint Chiefs and the Combatant Commanders, I ask that you provide me the following data and information pertaining to the armed forces, broken down by each Military Service and Combatant Command, and including the Joint Staff:

- The total cost associated with discharging the service members, civilian personnel and
  contractors who fail to comply with the vaccination mandate according to the current
  prescribed deadlines. Additionally, the cost associated with replacing these vacancies with
  new hires and any planning conducted for recruitment or retention strategies to offset
  anticipated discharges, particularly in mission-critical areas.
- The anticipated impacts to mission readiness, i.e. loss in flight training hours, loss in
  aircraft and shipyard repair maintenance hours, etc. if the Department pursues the
  discharging of service members, civilian personnel and contractors who fail to comply with
  the vaccination mandate according to the current specified deadlines.
- The anticipated cost to contractors caused by failure to comply with the vaccination
  mandate and expected requests for equitable adjustment. Additionally, an analysis of the
  long term effects on the defense industrial base, particularly suppliers and subcontractors,
  resulting from loss of key workforce personnel.
- An analysis of the potential impacts to the workforce both uniformed and civilian if the
  Department were to retain those who choose not to receive the COVID vaccination.
  Additionally, an independent Department of Defense analysis of the potential merits of
  earned immunity and an assessment of the risk posed to those immunized with one of the
  FDA approved vaccines.
- The processes for service members, civilian personnel and contractors seeking vaccination
  exemptions and the criteria by which individual cases are being adjudicated. Additionally,
  the process by which an individual may pursue an appeal to the initial ruling.
- An analysis of the of service members, civilian personnel and contractors on track to
  comply with the vaccination mandate deadlines as currently prescribed. Additionally, a
  study to determine the potential risk posed to those vaccinated and unvaccinated should the
  Department forgo discharging those who elect not comply with the mandate.
- A classified briefing for Senate Armed Services Committee members on the anticipated ability of the Department to execute operational plans within a year of the Department's dismissal of unvaccinated personnel, and any tabletop exercises or analysis planned to study such negative operational consequences.

Although the actual costs associated with each of these undertakings is certainly cause for concern, the opportunity cost they have and continue to visit on the force, its readiness, and morale is nothing short of devastating—particularly in light of current threats.

I look forwarding to receiving your written response and your views on these important matters not later than November 1, 2021.

Sincerely,

James M. Inhofe Ranking Member

## 3 November 2021

### SECDEF to Sen. Inhofe

(Two days late)

### **Highlights:**

- Short Version: "Readiness issue –full stop"
  - Parrots: Safe and Effective narrative
- "Nominal attrition;" However to date:
  - Separated 7,000+ Service Members
  - ~70,000 remain unvaccinated
- To Compare
  - Vietnam: ~58,000 Casualties
  - Gulf war: ~ 219 Casualties
  - Afghanistan: ~7000 KIA (20+ years)





#### SECRETARY OF DEFENSE 1000 DEFENSE PENTAGON WASHINGTON, DC 20301-1000

NOV 0 3 2021

The Honorable James N. Inhofe Ranking Member Committee on Armed Services United States Senate Washington, DC 20510

Dear Senator Inhofe,

I sincerely appreciate your concern for the readiness of our troops. And I know you agree with me that our Force must remain healthy and ready to defend the Nation. Vaccination against the coronavirus disease 2019 (COVID-19) helps us achieve that goal. And I believe the overwhelming majority of the Department of Defense (DoD) workforce understands that as well. This is a readiness issue – full stop.

I am proud to report that our efforts to date, and the steady increases in the overall percentages of DoD-affiliated personnel who are vaccinated, confirm that the Department is coming together to finish the job with urgency, professionalism, and compassion.

As you know, mandatory vaccinations are familiar for all our Service members and mission-critical inoculation is almost as old as the U.S. military itself. Department policy requires over a dozen vaccines, and such requirements have been in place in varying forms since 1914. The Food and Drug Administration authorized and approved COVID-19 vaccines have been studied extensively and found to be safe and effective.

In making our decision to require vaccination for Service members, we prudently considered the impacts of the highly transmissible Delta variant, the hospitalizations of our people, and the approximately 12,000 COVID-19 related cases and hundreds of deaths, among Service members, families, and our military community. COVID-19 takes our Service members out of the fight, temporarily or permanently, and jeopardizes our ability to meet mission requirements. If left unchecked, this virus can render an entire unit unfit for mission accomplishment.

It is my assessment – after consulting with senior leaders here – that the Department will incurnominal attrition due to individuals refusing COVID-19 vaccination. To date, over 97 percent of our active duty force has received at least one dose of the COVID-19 vaccine, and more than 87 percent are fully vaccinated. To date, there has not been an exceptional number of exemptions sought. These requests will be adjudicated individually, ensuring each Service member's request is appropriately and fairly addressed.

The Department's civilian and contractor workforces are also critical to the readiness of the Force. President Biden has issued two Executive Orders requiring COVID-19 vaccination for all Federal civilian employees and certain Government contractor personnel, to ensure their health and safety, as well as those with whom they interact. The Department has issued policies to implement these orders, while providing guidance concerning the circumstances when an individual is legally entitled to an exemption for religious or medical reasons. I likewise anticipate that the vast majority of our civilian personnel will choose COVID-19 vaccination. As you know, the Department neither discharges contractor personnel nor processes contractor personnel's exemption requests, as contractor personnel are employed by the party under contract with the Department, and all decisions concerning their employment are up to their employer.

### SECDEF to Sen. Inhofe



SECRETARY OF DEFENSE 1000 DEFENSE PENTAGON WASHINGTON, DC 20301-1000

The Honorable James N. Inhofe Ranking Member Committee on Armed Services United States Senate Washington, DC 20510 NOV 0 3 2021

Again, I am encouraged by the COVID-19 vaccine acceptance rates to date, which confirms traditional military compliance with legal orders. And I firmly believe that the mandatory vaccination policy for COVID-19 protects our military readiness and the safety of our military families.

I have instructed the Under Secretary of Defense for Personnel and Readiness to provide you as much detail as possible in a separate written response, and in a classified brief, in response to your questions on readiness.

COVID-19 vaccination will ensure that we remain the most lethal and ready force in the world.



## 03 November 2021

## Sen. Inhofe Annoyed

- This could have been done in a day
- No reason to be late and then pass the buck

## Vaccine Mandate Delayed for Military Contractors; Inhofe Continues Call to Suspend Mandate for Service Members, DOD Civilians

U.S. Sen. Jim Inhofe (R-Okla.), ranking member of the Senate Armed Services Committee, welcomed news that the administration will delay the vaccine mandate deadline for military contractors:

"By delaying the vaccine mandate deadline for contractors, the Biden administration is finally recognizing what the rest of us already knew – their vaccine mandate hurts national security and must be suspended. The delay came less than 24 hours after their lackluster response to my inquiries which only serves to highlight the disorganization of the administration.

I will continue to fight the mandate, but giving more time for businesses to adapt or challenge it is a major victory. This temporary relief, however, is wholly insufficient because it is not applied to service members and DOD civilians. The need for this suspension only grows each day as the readiness impacts of the mass firings and discharges will have on our military and defense industrial base become clear."

Additionally, yesterday afternoon, Secretary Austin responded to Sen. Inhofe's letter about the impact of the vaccine mandate – but the response lacked any data or specifics. Inhofe stated:

"This letter could have been written in 24 hours — there was no need for it to take two weeks and two days to not answer any of my data-driven inquiries and simply punt my questions to the Undersecretary of Defense for Personnel and Readiness. I expect detailed, specific answers from the Undersecretary no later than November 10."



## 03 November 2021

## Sen. Inhofe Annoyed

- This could have been done in a day
- No reason to be late and then pass the buck

## o8 November 2021

## **Pilots Respond to SECDEF**

- Already a pilot shortage
- Loss in experience & tax-payer \$\$
- 357/600 pilots responded
- Self-Harm Policies



From: Department of Defense Pilots Submitting Religious Accommodation for Vaccination

To: The House and Senate Armed Services Committees

Subject: An Independent Analysis on the Threat to National Security and Readiness Posed by the DoD COVID-19 Vaccine Mandate (Addendum to our 14 October 2021 Memo)

On the 19<sup>th</sup> of October, the Senator James Inhofe requested a report from Secretary Lloyd Austin on the costs and impacts to readiness from the COVID-19 vaccine mandate. On the 3<sup>rd</sup> of November, Secretary Austin replied claiming attrition from the mandate would be "nominal" and that "COVID-19 vaccination will ensure that we remain the most lethal and ready force in the world." We represent more than 600 pilots, the equivalent manning of approximately 12 squadrons, facing potential discharge for their moral, religious, or medical concerns about the COVID-19 vaccines. We strongly, but respectfully, disagree with Secretary Austin's response.

The Department of Defense (DoD) policy to mandate vaccination in the military has, and will continue to have, significant negative repercussions on cost effectiveness, training output, and, most importantly, readiness. If discharge or loss of flying status is the end result for the hundreds of pilots with moral, religious or medical concerns about the vaccine, there will be a noticeable degradation in military effectiveness and national security.

A survey was conducted of 357 pilots who are exercising their Constitutional and statutory rights to request a religious accommodation. They represent a small fraction of DoD pilots seeking the same accommodation. The value of surveyed pilots, including salary, flight hours, and training, totaled to:

- \$7.8 Billion in tax dollars
- 4,842 years of cumulative service
- 14 years of service on average: highly experienced aviators
- 2456 cumulative years of service to retirement<sup>1</sup>
- 677,324 cumulative flight hour experience
- 135,416 combat hours across 1114 deployments

In 2017, former USAF Chief of Staff Goldfein called a shortage of 1500 pilots a "crisis"<sup>2</sup>.

According to the FY21 budget request for the USAF, that shortage has grown to 2100 pilots below what is "required to execute the National Defense Strategy"<sup>3</sup>. This same strategy states: "The size of our force

## 15 December 2021

### Sen. Ron Johnson to SECDEF

### Highlights:

- SECDEF didn't respond to initial 12 Oct Inquiry
- Discharges/separations have begun
- Do you have fully-licensed product (Comirnaty)?
- Are you still ignoring Natural Immunity?
- SECDEF Doesn't Respond



December 15, 2021

The Honorable Lloyd J. Austin III Secretary of Defense U.S. Department of Defense 1000 Defense Pentagon Washington, D.C. 20301

Dear Secretary Austin

On October 12, 2021, I sent you a letter requesting information about your August 24, 2021 memorandum, which instituted a COVID-19 vaccine mandate for all service members. Your memorandum stated that "[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance."2 In light of FDA's statement that "there is not sufficient approved [supply]" of Comirnaty, the only fully-licensed vaccine, I asked you to explain how the Department of Defense (DoD) will comply with the vaccine mandate.<sup>3</sup> To date, you have failed to provide that explanation and respond to my letter.

Despite this lack of clarity, DoD has reportedly begun discharging service members "for not obeying orders to get vaccinated." Reports indicate that on December 13, 2021, the Air Force discharged 27 service members for noncompliance with the DoD's COVID-19 vaccine mandate.<sup>5</sup> An Air Force spokeswoman stated that these 27 individuals were "the first activeduty Air Force Members to be discharged over the Pentagon's vaccination requirements for military members." The discharge classification of these 27 veterans is uncertain, as is their eligibility for veteran benefits.

Secretary Austin December 15, 2021

Despite my and other concerned individuals' attempts to get clarity about your COVID-19 vaccine mandate, you have ignored our requests for information, and instead have allowed DoD to discharge service members for not obeying your ambiguous mandate. I ask that you immediately respond to my October 12, 2021, letter and provide the following information by no later than January 4, 2022:

- 1. Please provide the number of doses of the fully-licensed Comirnaty vaccine that have been given and are available to active-duty military personnel.
- 2. Will DoD provide a vaccination waiver acknowledging natural immunity to active-duty military personnel who have been previously infected with COVID-19? If not, why not?



<sup>1</sup> Letter to Lloyd Austin, Secretary of Defense et al., from Ron Johnson, U.S. Senator, Oct. 12, 2021, https://www.ronjohnson.senate.gov/services/files/1BC1491B-CFAB-4784-9DBB-8DCAC9E30BD9

<sup>&</sup>lt;sup>2</sup> Memorandum from Secretary of Defense Lloyd Austin to Senior Pentagon Leadership, et al. (Aug. 24, 2021) (available at https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORYCORONAVIRUS

DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICEMEMBERS

<sup>&</sup>lt;sup>3</sup> Letter to Amit Patel, BioNTech Manufacturing GmbH, from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 6, Sept. 22, 2021, available at https://www.fda.gov/media/150386/download (See footnote 12). <sup>4</sup> Alex Horton and Timothy Bella, Air Force discharges 27 service members in first apparent dismissals over vaccine refusal, Wash Post, Dec. 14, 2021, available at https://www.washingtonpost.com/nationalsecurity/2021/12/14/air-force-vaccines-discharges/.

<sup>&</sup>lt;sup>7</sup> Id. Allegedly, as many as 40,000 active-duty military personnel have elected not to receive a COVID-19 vaccine. Alex Horton, Vaccine holdouts in U.S. military approach 40,000 even as omicron variant fuels calls for boosters,

## 1 February 2022

# Sen. Ron Johnson to SECDEF DMED LEAK!

- Brief Overview
  - DMED Saga can be its own presentation
  - Matthew Crawford; Rounding The Earth Substack
- DoD Covers up the Data!
- RHJ Presses SECDEF about the dramatic increase of various medical conditions



United States Senate

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFA WASHINGTON, DC 20510-6250

February 1, 2022

The Honorable Lloyd J. Austin III Secretary Department of Defense

Dear Secretary Austin:

On January 24, 2022, I held a roundtable featuring world renowned doctors and medical experts who shared their perspectives on COVID-19 vaccine efficacy and safety and the overall response to the pandemic. At that roundtable, I heard testimony from Thomas Renz, an attorney who is representing three Department of Defense (DoD) whistleblowers, who revealed disturbing information regarding dramatic increases in medical diagnoses among military personnel. The concern is that these increases may be related to the COVID-19 vaccines that our servicemen and women have been mandated to take.

Based on data from the Defense Medical Epidemiology Database (DMED), Renz reported that these whistleblowers found a significant increase in registered diagnoses on DMED for miscarriages, cancer, and many other medical conditions in 2021 compared to a five-year average from 2016-2020.<sup>2</sup> For example, at the roundtable Renz stated that registered diagnoses for neurological issues increased 10 times from a five-year average of 82,000 to 863,000 in 2021.<sup>3</sup> There were also increases in registered diagnoses in 2021 for the following medical conditions:<sup>4</sup>

- Hypertension 2,181% increase
- Diseases of the nervous system 1,048% increase
- · Malignant neoplasms of esophagus 894% increase
- Multiple sclerosis 680% increase
- Malignant neoplasms of digestive organs 624% increase
- Guillain-Barre syndrome 551% increase
- Breast cancer 487% increase
- Demyelinating 487% increase
- Malignant neoplasms of thyroid and other endocrine glands 474% increase

The Honorable Lloyd Austin February 1, 2022 Page 2

- Female infertility 472% increase
- Pulmonary embolism 468% increase
- Migraines 452% increase
- Ovarian dysfunction 437% increase
- Testicular cancer 369% increase
- Tachycardia 302% increase

Renz also informed me that some DMED data showing registered diagnoses of myocarditis had been removed from the database. Following the allegation that DMED data had been doctored, I immediately wrote to you on January 24 requesting that you preserve all records referring, relating, or reported to DMED. I have yet to hear whether you have complied with this request.

<sup>&</sup>lt;sup>1</sup> Press Release, VIDEO RELEASE Sen. Ron Johnson COVID-19: A Second Opinion Panel Garners Over 800,000 Views in 24 Hours, Jan. 25, 2022, https://www.ronjohnson.senate.gov/2022/1/video-release-sen-ron-johnson-covid-19-a-second-opinion-panel-garners-over-800-000-views-in-24-hours.

<sup>&</sup>lt;sup>2</sup> COVID-19: A Second Opinion, Rumble, Jan. 22, 2022, https://rumble.com/vt62y6-covid-19-a-second-opinion.html (at 4;54:35).

<sup>3</sup> Id. at 4:55:23.

<sup>&</sup>lt;sup>4</sup> Data on file with staff

## 1 February 2022

# Sen. Ron Johnson to SECDEF DMED LEAK!

- Brief Overview
  - DMED Saga can be its own presentation
  - Matthew Crawford; Rounding The Earth Substack
- DoD Covers up the Data!
- RHJ Presses SECDEF about the dramatic increase of various medical conditions

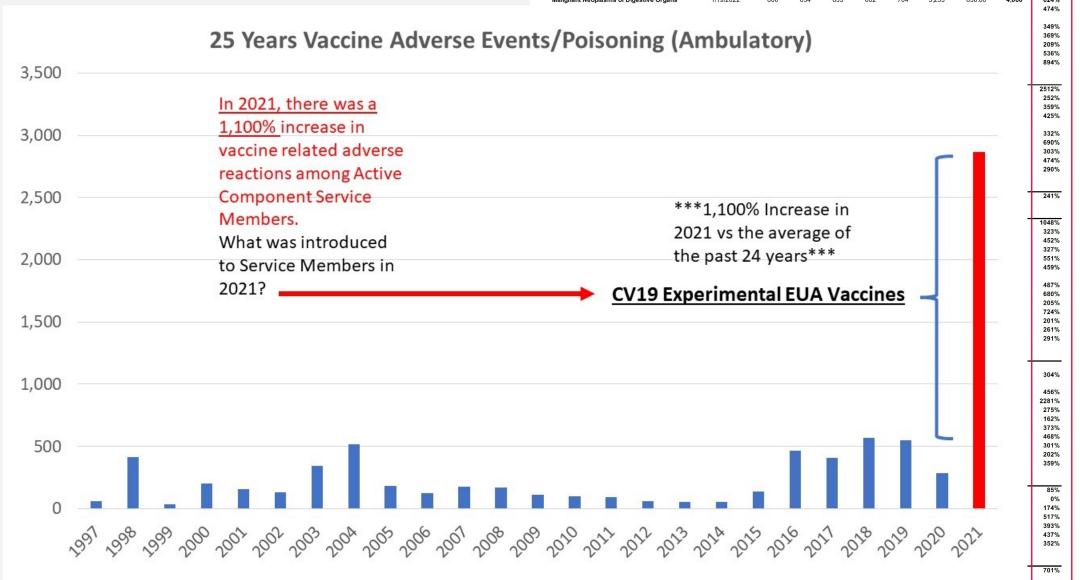
It gets worse...

Diamento en Interna	Ourse Data	V						And Industry		
Diagnosis or Injury	Query Date	rearry rotats					Total	Avj Injuries Per Year	2021 %	Increase
All Diseases & Injuries		2016	2017	2018	2019		2016-2020	2016-2020	(Partial Yr)	202
All Disease & Injuries (Amb)	1/19/2022	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	10,227,779	2,045,555.80	21,512,583	1052
All Disease & Injuries (Hosp)	1/19/2022	43,786	43,338	42,024	43,493	40,052	212,693	42,538.60	54,776	129
Cancer										
Neoplasms (ALL CANCERS)	1/19/2022	41,557	39,139	37,756	38,889	36,050	193,391	38,678.20	114,645	296
Malignant Neoplasms of Digestive Organs	1/19/2022	660	654	633	602	704	3,253	650.60	4,060	624
Malignant Neoplasms of Thyroid & Other	1/19/2022	550	394	369	374	372	2,059	411.80	1,950	474
Endocrine Glands										
Malignant Neuroendocrine tumors	1/19/2022	167	135	98	113	117	630	126.00	440	349
Testicular Cancer (Amb)	1/10/2022	1,156	1,008	866	880	889	4,799	959.80	3,537	369
Ovarian Cancer (Amb)	1/10/2022	121	88	73	82	69	433	86.60	181	209
Breast Cancer (Amb) Malignant Neoplasm of Esophagus	1/10/2022 1/19/2022	934 29	810 36	766 35	792 20	766 26	4,068 146	813.60 29.20	4,357 261	536 894
Mental Health & Metabolic Function	4/40/0000	07.044	00.007	00.445	07.700	07.070	405.455	27 004 00	004 704	0540
Anxiety (Amb)	1/10/2022	37,011	36,667 2.577	36,145	37,762	37,870 2,642	185,455	37,091.00 2.579.40	931,791	2512
Anxiety (Hosp) Suicide	1/10/2022 1/10/2022	2,478 359	496	2,534 530	2,666 570	550	12,897 2,505	501.00	6,496 1,798	252 359
Endocrine Nutritional & Metabolic Diseases (Amb)	1/10/2022	33,140	31,825	30,814	31,504	30,506	157,789	31,557.80	134,053	425
							101,100			
Disorders of Thyroid Gland	1/19/2022	8,078	7,694	7,357	7,289	6,893	37,311	7,462.20	24,769	332
Malasie & Fatigue (Amb)	1/10/2022	3,851	3,842	3,832	3,885	3,735	19,145	3,829.00	26,416	690
Thyroid Dysfunction (Amb)	1/10/2022 1/10/2022	8,074 1,319	7,696	7,357 1.072	7,289	6,891 960	37,307	7,461.40 1,110.80	22,620 5,269	303 474
Diabetes Type 1 (Amb) Disease of Liver (Amb)	1/10/2022	1,319	1,167 2.053	2,063	1,036 2,234	2.322	5,554 10.666	2.133.20	6,187	290
Disease of Liver (Allib)	1/10/2022	1,994	2,055	2,003	2,234	2,322	10,000	2,133.20	0,107	290
Narcolepsy & Cataplexy Narcolepsy & Cataplexy	1/19/2022	995	898	864	830	766	4.353	870.60	2.097	241
	1713/2022	330	030	004	000	700	4,000	070.00	2,037	241
Neuromuscular & Skeletal Systems Diseases of the Nervous System	1/19/2022	82,435	81,998	81,382	85,012	80,786	411,613	82,322.60	863,013	1048
Diseases of the Eye & Adnexa	1/19/2022	88,091	87,712	86,417	91,503	79,529	433,252	86,650.40	280,206	323
Migraine	1/19/2022	15,734	15,714	16,462	17,116	16,331	81,357	16,271.40	73,490	452
Seizures (Amb)	1/10/2022	196	148	130	150	123	747	149.40	489	327
Guillian-Bare Syndrome (Amb)	1/10/2022	66	79	71	85	65	366	73.20	403	551
Acute Transverse Myelitis in Demyelinating Disease of CNS	1/19/2022	46	57	48	35	34	220	44.00	202	459
Demyelinating Diseases of the CNS	1/19/2022	785	737	690	677	648	3,537	707.40	3,444	487
Multiple Sclerosis	1/19/2022	479	391	367	400	385	2,022	404.40	2,750	680
Rhabdomyolysis (Hosp)	1/10/2022	216	209	227	222	198	1,072	214.40	440	205
Rhabdomyolysis (Amb)	1/10/2022	706	696	740	755	669	3,566	713.20	5,162	724
Eye Disorder (Amb)	1/10/2022	6,044	6,013	5,647	6,312	5,623	29,639	5,927.80	11,892	201
Extra Pyramidal (Amb)	1/10/2022	1,509	1,474	1,339	1,371	1,338	7,031	1,406.20	3,669	261
Bell's Palsy (Amb)	1/10/2022	483	462	457	447	450	2,299	459.80	1,338	291
Cardiovascular System										
Diseases of the Blood & Blood-forming Organs & Certain Disorders Involving the Immune	1/19/2022	11,533	11,122	10,851	11,773	11,429	56,708	11,341.60	34,486	304
Mechanism	1/13/2022	11,000	11,122	10,001	11,775	11,423	30,100	11,541.00	34,400	304
Acute Myocardial Infarction (Amb)	1/10/2022	324	370	376	366	372	1,808	361.60	1,650	456
Hypertension (Amb)	1/10/2022	2,308	2,323	2,363	2,392	2,415	11,801	2,360.20	53,846	2281
Acute Myocarditis (Amb)	1/21/2022	84	92	116	159	108	559	111.80	307	275
Acute Pericarditis (Amb)	1/10/2022	535	538	522	531	499	2,625	525.00	850	162
Nontraumatic subarachnoid hemorrhage	1/19/2022	219	139	134	170	196	858	171.60	640	373
Pulmonary Embolism (Amb)	1/19/2022	678	701	668	716	968	3,731	746.20	3,489	468
Tachycardia (Amb)	1/10/2022	845	814	893	903	849	4,304	860.80	2,595	301
Disease of the Arteries (Amb)	1/10/2022	3,164	2,965 848	2,938	3,096	2,860	15,023	3,004.60	6,069	202
Cerebral Infarction (Amb)	1/10/2022	887	848	858	888	887	4,368	873.60	3,136	359
Reproductive System & Birth Spontaneous Abortion (First Occurrence)	1/19/2022	2,668	2,532	2,475	2,608	2,404	12,687	2,537.40	2,164	85
Spontaneous Abortion (First Occurrence) Spontaneous Abortion (All Occurences)	1/19/2022	1,431	1,518	1,493	1,578	1,477	7,497	1,499.40	2,104	85
Spontaneous Aportion (All Occurences) Congenital Malformations (Amb)	1/10/2022	11,710	11,131	1,493	11,081	10,153	54,531	10,906.20	18,951	174
nfertility, Female (Amb)	1/19/2022	2,261	2,262	2,243	2,340	2,262	11,368	2,273.60	11,748	517
nfertility, Male (Amb)	1/19/2022	2,187	2,287	2,037	2,152	1,990	10,653	2,130.60	8,365	393
Ovarian Dysfunction (Amb)	1/19/2022	862	936	908	945	1,022	4,673	934.60	4,086	437
Dysmenorrhea (Amb)	1/10/2022	3,104	3,403	3,481	3,943	3,900	17,831	3,566.20	12,539	352
										l
/accine Adminstration										



## 1 February 2022

Diagnosis or Injury	Query Date	Yearly Totals						Avj Injuries		
							Total	Per Year	2021 %	Increase in
All Diseases & Injuries		2016	2017	2018	2019	2020	2016-2020	2016-2020	(Partial Yr)	2021
All Disease & Injuries (Amb)	1/19/2022	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	10,227,779	2,045,555.80	21,512,583	1052%
All Disease & Injuries (Hosp)	1/19/2022	43,786	43,338	42,024	43,493	40,052	212,693	42,538.60	54,776	129%
Cancer										
Neoplasms (ALL CANCERS)	1/19/2022	41,557	39,139	37,756	38,889	36,050	193,391	38,678.20	114,645	296%
Malignant Neoplasms of Digestive Organs	1/19/2022	660	654	633	602	704	3,253	650.60	4,060	624%





## **Quick Highlight**

# There are currently 34 lawsuits open against DoD

(36 on the list; 2 were dismissed)

- Military Freedom Keepers
- 2 EUA lawsuits\*
  - Coker v. Austin et al.
  - Wilson v. Austin et al.

\* Denotes = Personal Familiarity

Current lawsuits that have been filed challenging the DoD's policy mandating COVID-19 vaccines for Service members, civilian employees, and contractors:





## 1 July 2022

## Dale Saran Esq.,

Files Motion for Preliminary Injunction

- Many Robust Legal Arguments
  - One stands out specifically (for this presentation)
- DoD Consent Order to NOT do what they are doing now.. 17 years ago (i.e. Anthrax)

Case 4:22-cv-00438-ALM Document 9 Filed 07/01/22 Page 33 of 41 PageID #: 607

Doe v. Rumsfeld may not be binding precedent on this Court, but it is a binding determination on these same Defendants on the same issue and, therefore, these Defendants are estopped from re-litigating the issue against the Plaintiffs. These two Defendants have already had a full and fair opportunity to litigate the same exact issue in the first instance when the statute was just passed and the doctrines of judicial estoppel and issue preclusion both prohibit these Defendants from now claiming the exact opposite in fundamentally the same litigation against an identical class of plaintiffs.<sup>51</sup>

The Doe v. Rumsfeld series of decisions is, therefore, directly relevant on multiple levels: (1) it has obvious factual relevance because it involved injunctive relief by servicememembers against a mandatory vaccination program; (2) it was the first vaccine ever granted EUA status by the FDA; (3) both the Defendants FDA and DoD took public, official positions exact contrary on the same legal issue in the instant case – whether or not servicemembers could refuse an EUA product without penalty – and is therefore relevant to whether or not the agency has abused its discretion record; (4) both Supreme Court and 5th Circuit precedent direct the courts to consider the "reliance interests" that attended a prior policy; and (5) both Defendants were part of a consent order and took record positions 17 years ago to NOT do what they are now doing - violating the informed consent rights of military servicemembers - in keeping with their long history of abrogating the rights of members of the Armed Forces and using them as human guinea pigs.

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<sup>&</sup>lt;sup>51</sup> See, generally, New Hampshire v. Maine, 532 U.S. 742 (2001).



## 20 May 2022

### DoJ to the Courts...

"...as of today's date"

### **Relevant Info:**

- What was DoD using before 20 May?
- Only at select military installations
- Recall: Lack of answers to Congressional Inquiries



These Interrogatories are undisputedly relevant and proportional to the needs of the case, and Plaintiffs have never argued otherwise. Fed. R. Civ. P. 26(b)(1); Ex. 8 at 3-5. Plaintiffs have placed FDA-approved vaccines squarely at issue in this case. Defendants are entitled to know which Plaintiffs would—or would not—take the FDA-approved vaccines, as the answer to that question would determine which Plaintiffs have (or lack) standing to challenge the FDA approval as well as the DoD's vaccination requirement as purportedly violating their informed consent rights. See TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2205 (2021) ("[U]nder Article III, an

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injury in law is not an injury in fact."). These interrogatories also entail virtually no burden to answer, and the information they seek is obtainable solely from Plaintiffs. There is no basis for Plaintiffs to withhold responsive answers. *See Gober*, 197 F.R.D. at 521 (resisting party must show lack of relevance or undue burden).

Plaintiffs' speculation objection is unfounded. Ex. 8 at 3-5. While they may believe that FDA-approved vaccines are "not available," the Comirnaty-labeled vaccine is in fact available for DoD to order as of today's date. Nor does a responsive answer require any speculation: Plaintiffs are the only ones who can determine, yes or no, whether they would take Comirnaty or Spikevax. See also Fed. R. Civ. P. 33(a)(2) (noting that an interrogatory is not objectionable merely because it asks for an opinion). And Plaintiffs are the ones who have asserted challenges to the DoD vaccination requirement, notwithstanding the pendency of certain of their religious accommodation requests and appeals; they cannot use those pending requests both as a sword (in nevertheless moving forward with their claims) and as a shield (in resisting discovery intended to probe their standing to bring such claims). The Court

## ~16 June 2022

### "The Offer"

"Comirnaty-labeled"

- Whistleblower Lt Col Jon Cheek's Analogy:
  - "I wouldn't go to the restaurant and order a Coke-labeled soda, I'd just order a coke!

Now, here's the DoJ offer:

Defendants now have over 35,000 doses of Comirnaty-labeled vaccine. While it is the Defendants' position that all EUA-authorized Pfizer-BioNTech doses for adults are interchangeable for the purposes of the military's vaccination requirement, in order to address Plaintiffs' assertions they were unable to obtain a Comirnaty or BLA-manufactured dose, I wanted to confirm that any of the Plaintiffs who are still required to receive the COVID-19 vaccine to satisfy the military's requirement may receive a shot from a Comirnaty-labeled vial. If any of the Plaintiffs wish to do so, please prepare a memorandum addressed to the individual's commanding officer committing to taking a shot from a Comirnaty-labeled vial. Please provide the memorandum to me and I will ensure the request is appropriately transmitted. Should any Plaintiff confirm in writing that they will take a Comirnaty-labeled dose, Defendants can ensure that Plaintiff will be administered one of those doses. If no Plaintiff is interested, please let us know that as well. As I previously mentioned, this is not intended as an offer of compromise and we anticipate informing the Court of the offer and any response.

Okay – there's the DoJ's offer. Now let me tell you why I recommend that you categorically reject it.

First, notice how curiously it's worded. You're not being offered "Comirnaty" – you're being offered one of 35,000 doses of "Comirnaty-labeled vaccine." Huh. And notice how consistently that term is applied throughout – "Comirnaty labelled vial" appears twice, along with "Comirnaty-labeled dose." Second, I know that there are already a lot of questions about the provenance of any shots the DoD and all this email offer does is raise more questions, particularly since the DoD has been making claims in litigation about "BLA compliant" doses, which has no meaning and has already been rejected in Coker v. Austin. Without belaboring this whole offer, taking this shot would be a complete compromise of our – your – litigation position. But there's the offer – and let's handle responses by exception. Meaning: unless I hear from you specifically asking to accept the DoJ's offer, I will presume that the answer is "No, thank you." (I don't want or need my inbox swamped by "hell no's" or other similar responses or emojis, but you can make your feelings known to some of your "reps" who will get me the word). We've got more folks coming on board soon. We have a right to amend by a certain date and we'll do so in order to add all of the folks who heard late and wanted to get on board. A lot happening over the next week, so likely no update until late next week. In the meantime... Take care, try to have a daily gratitude practice, be kind to yourself and each other, and... make sure you get your docs uploaded to Knack. Fortitudine.

Posted to TheAbjectLesson.com Dale Saran's Blog



## 16 June 2022

## **Policy Change**

- For EUA Vaccines
  - "They have the option to accept or refuse...
- Recall 29 Oct 2021 Coord Memo:
  - "Non-concur"
  - "Subverts our policy"
  - "Creates significant remedial action"



#### ATTACHMENT 2

#### **PROCEDURES**

#### 1. COVID-19 VACCINE INFORMATION

- a. Implementation of an FDA-approved, fully licensed, Biologics License Application (BLA) or Emergency Use Authorization (EUA) COVID-19 vaccine is a critical component of the United States' strategy and international efforts to reduce COVID-19-related illnesses, hospitalizations, and deaths.
- b. DoD beneficiaries and other individuals eligible to receive vaccines from DoD will be offered COVID-19 immunization in accordance with recommendations from the U.S. Centers for Disease Control and Prevention (CDC), its Advisory Committee on Immunization Practices (ACIP), FDA, and DoD guidance.
  - (1) Deviation from FDA guidance or CDC recommendations will be published in policy.
- (2) In accordance with current CDC recommendations, persons are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine.
- (3) Those with a medical history and/or serologic evidence of COVID-19 infection without also having received a complete primary series of COVID-19 vaccine are not considered fully vaccinated.
- c. Personnel will comply with the terms of the FDA Fact Sheets and other regulatory requirements for licensed or EUA vaccines. All individuals seeking immunization will be provided the appropriate FDA Fact Sheet for vaccine recipients or Vaccine Information Statements (VIS), as applicable.
- d. Use of vaccine products for force health protection under EUA will be executed in accordance with References (f) through (h). For EUA vaccines, per FDA guidance in Reference (h), vaccine recipients must be made aware of all of the following:
  - (1) FDA has authorized emergency use of the product.
- (2) The significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown.
- (3) They have the option to accept or refuse the EUA product and are free from any consequences of refusing administration of the product.
- (4) Any available alternatives to the product and of the risks and benefits of available alternatives, and of any other information or condition required by the EUA.

## 18 August 2022

## Sen. Ron Johnson to SECDEF, CDC, FDA

"Comirnaty-labeled" Vials; Whistleblowers

### **Highlights:**

- The Specific lot numbers in DoD's possession are found on Pfizer's EUA Master List
- It is known that these suspected vials did not come from the approved manufacturing location
- Among other discrepancies



August 18, 2022 Page 3

Comirnaty" to be manufactured at the "Pfizer Manufacturing Belgium NV, Purrs, Belgium facility." Any Comirnaty vaccine lots that are manufactured outside of the FDA-approved manufacturing locations and distributed to U.S citizens raises significant legal and health-related concerns.

In addition to the lack of clarity relating to the manufacturing location of vaccine lot FW1331, another DoD whistleblower raised questions about whether this specific vaccine lot is mislabeled as "Comirnaty." 1Lt. Mark Bashaw, who is a commissioned officer in the U.S. Army, found that the lot number contained on these "Comirnaty" vials—FW1331—matched a lot number on a CDC database listing Emergency Use Authorization (EUA) vaccine lots. <sup>12</sup>

According to CDC, this database, which is called the COVID-19 Vaccine Lot Number and Expiration Date Report, "contain[s] all lots for COVID-19 vaccines made available under [EUA] for distribution in the United States." 13 Lt. Bashaw disclosed to my office that he downloaded this database and found that it included vaccine lot FW1331. 14 DoD, FDA, and CDC must provide a thorough explanation for why a vaccine lot with the "Comirnaty" label would be listed on a database that is meant to display vaccine lots associated with the EUA.

Lt. Coppin, 1Lt. Bashaw, and the additional seven DoD whistleblowers who brought this information to my attention have exercised their right to talk to Congress. Any retaliatory actions taken against these individuals will not be tolerated and will be investigated immediately. DoD, FDA, and CDC owe our service members complete transparency regarding the COVID-19 vaccines that the Biden administration has forced upon them. With this in mind, I request that you provide the following information:

- 1. Was vaccine lot FW1331 manufactured at the Pfizer facility located in Belgium? If not, why not?
- 2. Why is vaccine lot FW1331, which is labeled "Comirnaty," listed on a CDC database ("COVID-19 Vaccine Lot Number and Expiration Date Report") for EUA vaccine lots?
- 3. Was vaccine lot FW1331 created under the EUA? If so, why is it labeled "Comirnaty"?
- 4. Please identify the vaccine lot numbers, in addition to FW1331, that are labeled "Comirnaty" and have been distributed to U.S. military bases *and* are also listed on CDC's "COVID-19 Vaccine Lot Number and Expiration Date Report."

<sup>14</sup> Mark Bashaw disclosure (on file).
<sup>13</sup> COVID-19 Vaccine Lot Number and Expiration Date Report, Centers for Disease Control and Prevention. https://vaccinecodeset.cdc.gov/LotNumber.

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<sup>&</sup>lt;sup>11</sup> Letter from Jerry Weir, Food and Drug Administration, to Amit Patel, Pfizer Inc., Dec. 16, 2021, https://www.fda.gov/media/154939/download.

<sup>&</sup>lt;sup>12</sup> Mark Bashaw disclosure (on file).

<sup>14</sup> Mark Bashaw disclosure (on file).





KEY TAKE HOME POINTS

EUA Products cannot be mandated for military

OR civilians

ALL COVID SHOTS ARE EUA

# TRUTH FOR HEALTH —FOUNDATION—

QR Code for the Petition



We need Congress to Act!

18. Like you, we swore an oath to support and defend the Constitution against all enemies, foreign and domestic. Despite spending our careers focused on foreign enemies, it appears the greatest current threat to our Constitution, to the rule of law, and to U.S. military readiness comes from within. On behalf of service members who share our concerns, as well as the citizens we stand in harm's way to protect, we request that you promptly investigate these matters and hold accountable those found to have acted unlawfully. Please end illegal EUA mandates and all related fraudulent activity to ensure that our military can once again be counted on to uphold the rule of law in support of our Constitution.

Executed on 15 August, 2022.

John S. McAfee Colonel, USAF

Jon C. Cheek Lt. Colonel, US Army Olivia K. Degenkolb Commander, USN

Robert A. Green Jr. Commander, USN David I. Beckerman Major, USAF Patrick D. Wier

Joshua P. Hoppe Capt, USMC Chad R. Coppin LT, USCG Mark C. Bashaw 1LT, US Army



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## CHECK OUT OUR <u>WEBSITE</u> RESOURCES! www.TruthForHealth.org

- Citizens Vaccine Injury Reporting System™ (CVIRS)™
- VACCINE INJURY Treatment Guide
- Medical Freedom Legal Defense Program
- **COVID Early Home Treatment Guide**
- FACT SHEETS: Monkey Pox, Marburg Hemorrhagic Fevers...& MORE
- Faith Over Fear: Roadmap to Recovery weekly virtual seminars
- Parents Forum: Protect Our Children weekly virtual seminars
- 5G Radiation and Your Health many resources, including DIA Report from 1976 (now unclassified)
- Health and Resilience: Chlorine Dioxide NASA"s "Universal Antidote"
- DSIAC Presentation: Radiofrequency Directed Energy Weapons & Effects



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