DEFENSE EXHIBITS

ADMITTED

DEPARTMENT OF THE ARMY
ARMY PUBLIC HEALTH CENTER
BUILDING 5158
8252 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MD 21010-5403

15 December 2021

MEMORANDUM FOR GCMCA OF CPT ALEXANDER MCCARTHY, APHC HHC COMMANDER

SUBJECT: Formal Article 138 Complaint, Uniform Code of Military Justice

References: (a) Army Regulation 27-10 *Legal Services Military Justice*
(b) Army Regulation 600-20 *Army Command Policy*
(c) 10 U.S. Code § 1107a *Emergency use products*
(d) 21 U.S Code § 360bbb-3 *Emergency Use of Medical Products*
(e) Nuremberg Code

1. I, 1LT Mark C. Bashaw, currently assigned to the Army Public Health Center as a Preventative Medicine Officer (67C/72B), Aberdeen Proving Ground, Maryland, make this formal complaint pursuant to Article 138 of the Uniform Code of Military Justice (UCMJ) and Army Regulation 27-10 reference (a). On 23 November 2021 through present day, CPT Alexander McCarthy, APHC HHC Commander, committed the following wrongs against me: discriminated based on my firmly held religious beliefs; disregard of established U.S Code/laws; retaliation for an initial Article 138 Inquiry; retaliation based on the questions I have asked APHC leadership/CV19 Task Force, regarding ivermectin, hydroxychloroquine, zinc, vitamin D, vitamin c, quercetin, and the Emergency Use Authorized (EUA) COVID19 vaccine deaths/adverse events (EXHIBIT A).

2. On 21 September 2021, I submitted religious accommodation to CPT McCarthy for all vaccinations due to my firmly held beliefs (EXHIBIT B & EXHIBIT C). My intent was to get an accommodation for all vaccinations even before the 24 August 2021 SECDEF Memo came out, mandating the FDA Approved COVID19 vaccine. Since that time, I found out the FDA Approved COVID19 vaccine labeled "Comirnaty" has not been produced and/or available to DOD Service Members. Currently, the only available COVID19 "vaccinations" are EUA and are subject to 10 U.S.C 1107a and 21 U.S Code § 360bbb-3. These the same laws that govern all Emergency Use Authorized (EUA) products (vaccines, masks, tests).

3. On 23 November 2021, CPT McCarthy ordered me to self-procure and self-administer EUA rapid antigen SARS-CoV-2 tests. This test/screening was to start 30 November 2021 with a negative test/screening results no more than 72 hours prior to accessing my place of duty. On 24 November 2021, I informed CPT McCarthy that this was discriminatory and unlawful. CPT McCarthy then stated in an email "you are more than welcome to disagree with the order. Does this mean that you will likely refuse the weekly COVID testing?" Again, I stated that this order was discriminatory and unlawful (EXHIBIT D).

4. On 26 November, I submitted an Informal Article 138 Inquiry via email to see if CPT McCarthy was aware of the established laws and individual rights (EXHIBIT E). I did not receive a response back regarding the inquiry, and I showed up to my place of duty to accomplish my responsibilities on 30 November 2021. Shortly after showing up to work, you ordered me to attend a counseling at your office later that day. At this time, I was notified that my security clearance was suspended by the Army Public Health Center's Director. I was ordered to turn in

DEFENSE EXHIBIT A for identification
PAGE OFFERED: 209 PAGE ADMITTED: 214
PAGE 1 of 59 PAGES

my security badge. I was informed that I no longer have access to any APHC facilities. CPT McCarthy also informed me that he was going to restrict me from the installation. CPT McCarthy also initiated a flag with the "Adverse Action" box checked on my military personnel record and informed me of Article 92 UCMJ charges (EXHIBIT F). At the end of the counseling, I hand delivered CPT McCarthy an initial Article 138 complaint even though I already satisfied this requirement IAW AR 27-10 on 26 November 2021. I wanted the discrimination against myself and any others under his command to cease and desist. I also provided the EUA laws where it shows that an individual has the absolute right to refuse EUA products (vaccines, masks, and tests), regarding COVID19 (EXHIBIT F). On 6 December 2021, I was singled out again and counseled via DA FORM 4856 for not wearing a COVID19 EUA mask during the 30 November 2021 counseling (EXHIBIT F).

5. The testing/screening products that I was ordered to purchase (QuickVue, InteliSwab, or BinaxNOW) are all under EUA for SARS-CoV-2. There are no FDA Approved masks, tests, or vaccinations available for COVID19. According to 10 U.S. Code § 1107a *Emergency use products,* for the administration of emergency use products, "individuals are informed of an option to accept or refuse administration of a product." This option to refuse or accept the COVID19 vaccination, testing, and masks NEVER occurred. The waiver authority for this requirement is the President of the United States, and that waiver needs to be in writing. There currently is no Presidential waiver for the mandatory use of EUA products, regarding COVID19. The EUA Pfizer "vaccine" labeled BioNTech is NOT FDA approved and IS legally distinct from FDA Approved Pfizer vaccine labeled Comirnaty (EXHIBIT G, pg. 9). Also, the EUA Pfizer BioNTech "vaccine" and FDA Approved Pfizer Comirnaty vaccine are NOT interchangeable with one another, according to Federal District Judge Allen Winsor (Doe et al. v. Austin). Importantly, the Nuremberg Code and Federal Law provide that no human being can be forced to participate in medical experiments. Emergency Use allows the FDA to authorize use of an experimental drug in an emergency, therefore, EUA products are experimental. Long term safety and efficacy of these products have NOT been proven. In fact, these current EUA "vaccinations" for COVID19 are DEADLY and DANGEROUS. There have been "19,886 cases where vaccine targets COVID-19 and patient died" and 946,463 adverse events from these EUA experimental COVID19 "vaccines," according to VAERS. As a Preventative Medicine Officer (67C/72B) it is my job to inquire about certain information regarding force health protection. My latest request to the APHC COVID19 Task Force asking if they would be changing their risk communication strategy to include the death and adverse reactions to the CV19 EUA "vaccinations" has gone unanswered since 25 October 2021 (EXHIBIT A).

6. Lastly, I have been serving active duty in the military for 16 years with 10 on those years overseas away from my family. I have never received any sort of punishment and don't have any derogatory information within my military records. However, that all changed on 30 November 2021 after I informed CPT McCarthy that the orders to segregate me based on my firmly held beliefs was blatant discrimination and unlawful. I find it despicable that I was retaliated against in such an egregious manner after I submitted an informal Article 138 complaint IAW AR 27-10. After 16 years of faithful service, my record was destroyed. I will not tolerate soldiers being discriminated against based on race, color, sex, national origin, religion, or sexual orientation. Additionally, discrimination is a form of extremism, according to AR 600-20 chapter 4-12 a1. Secretary Lloyd Austin made it clear during the DOD Extremism Standdown that this type of activity will not be tolerated.

7. I respectfully request the following:

a. Cease and desist all discrimination against me or any other individuals of firmly held religious beliefs and/or strong convictions against SARS-CoV-2 (COVID19) EUA "vaccinations" (mRNA gene therapy experiments), EUA testing products, EUA masks and/or vaccination products in general.

b. Cease and desist the unauthorized distribution of my personal medical information and anyone else's under your command.

c. Rescind the order to conduct COVID19 EUA testing until such a time that there is an available DOD-sourced supply of FDA-approved and licensed COVID19 tests for all personnel who provide informed consent to participate in such testing.

d. Elevate this information to DOD and US Army leadership, military and civilian. That the leadership publishes clarification that there are no FDA approved and licensed COVID19 products (vaccines, masks, and tests) at this time.

e. DOD, DHA, Army MEDCOM, APHC, and Commanders update risk communication strategies for the EUA COVID19 injections to include "Death and other severe adverse side effects" and transparently communicate the message for the widest possible dissemination.

f. Remove the flag on my personnel record.

g. Coordinate with Army Public Health Center's Director to reinstate my Security Clearance.

h. Inform all personnel under your command of the EUA laws.

i. Ensure personnel are aware that FDA Approved Pfizer Comirnaty vaccines and the Pfizer EUA BioNTech "vaccines" are NOT interchangeable.

8. The point of contact for this request is the undersigned at [redacted] or [redacted].

[redacted]

MARK C. BASHAW
1LT, MS

Encls
EXHIBIT A – Affidavit of Fact (External Attachement)
EXHIBIT B – Religious Accommodation e-mail submission
EXHIBIT C – Religious Accommodation
EXHIBIT D – E-mail regarding discriminatory and unlawful order
EXHIBIT E – Article 138 UCMJ Initial Inquiry
EXHIBIT F – DA FORM 4856 masks/tests; Hand Delivered Article 138; EUA Laws
EXHIBIT G – FDA Fact Sheet

DISTRIBUTION:
GCMCA

SUBJECT: Formal Article 138 Complaint, Uniform Code of Military Justice

Reply Reply All Forward

EXHIBIT B

RE: Religious exemption Counseling (UNCLASSIFIED)

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)

To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)

Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)

Attachments: 1LT Mark Bashaw Religious ~1.pdf (170 KB)

Tuesday, September 21, 2021 9:34 AM

- You forwarded this message on 9/29/2021 11:23 AM.

CLASSIFICATION: UNCLASSIFIED

Alex, attached is my religious accommodation request. Please let me know if you need anything else at this time. Thank you!

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: [redacted]

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Sent: Wednesday, September 15, 2021 12:02 PM
To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA) <alexander.p.mccarthy.mil@mail.mil>
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) <phillip.r.tally.mil@mail.mil>
Subject: RE: Religious exemption Counseling (UNCLASSIFIED)

Roger, standing by.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436

EXHIBIT C

DEPARTMENT OF THE ARMY
ARMY PUBLIC HEALTH CENTER
BUILDING 5158
8252 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MD 21010-5403

21 September 2021

MEMORANDUM FOR: Immediate Commander, Army Public Health Center

SUBJECT: Request for Religious Accommodation – 1LT MARK C. BASHAW, Army Public Health Center

1. I request a religious accommodation to not be required to receive a vaccination for COVID-19, or any other military mandated vaccinations and/or immunizations in accordance with the standards provided in Army Regulation 40-562 (Immunizations And Chemoprophylaxis For The Prevention of Infectious Diseases), 10 Jul 2013; and in accordance with the standards provided in Army Directive 2018-19 (Approval, Disapproval, and Elevation of Requests for Religious Accommodation), 8 Nov 2018.

2. This request is based on my personal belief in Christ Jesus my personal Lord and Savior. I cannot receive a COVID-19 vaccine because to do so would violate my sincerely held religious beliefs. Man was created by God, in his image, for God's Joy and Glory. The immune system that God created is nothing short of an amazingly divine feature of Man. "Surely God is my salvation; I will trust and not be afraid. The Lord, the Lord himself, is my strength and my defense; he has become my salvation" Isaiah 12:2. Glory to God. God Bless and Much Love.

3. The point of contact for this request is the undersigned at [redacted] or [redacted]

[redacted]

MARK C. BASHAW
1LT, MS
Entomologist

Reply Reply All Forward

RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) EXHIBIT D

To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)

Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA); Mcnemee, Richard B Jr LTC USARMY MEDCOM APHC (USA)

Wednesday, November 24, 2021 10:25 AM

- You forwarded this message on 11/24/2021 10:30 AM.

CLASSIFICATION: UNCLASSIFIED

This is blatant discrimination based on my firmly held religious beliefs. These are unlawful orders.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA) <alexander.p.mccarthy.mil@mail.mil>
Sent: Wednesday, November 24, 2021 10:22 AM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) <phillip.r.tally.mil@mail.mil>; Mcnemee, Richard B Jr LTC USARMY MEDCOM APHC (USA) <richard.b.mcnemee.mil@mail.mil>
Subject: RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
You are more than welcome to disagree with the order. Does this mean that you will likely refuse the weekly COVID testing?

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

EXHIBIT E

From: [redacted]
To:
Cc:
Subject: Informal Article 138 Inquiry (UNCLASSIFIED)
Date: Friday, November 26, 2021 1:18:00 PM
Importance: High

CLASSIFICATION: UNCLASSIFIED

CPT McCarthy, I am considering filing an Article 138 Complaint. Per AR 27-10 I am required to submit an informal inquiry first. Please consider this as my informal inquiry in an attempt to resolve my complaints.

To clarify, are you requiring me to:
Self-test on a 2 times per week basis utilizing EUA test products?

Will you provide the "informed consent" required by law?

Are you aware that the law provides me the absolute right to refuse use of an EUA Product?

Please explain whether your order for me and others to be vaccinated is your order or merely an order you are yourself conveying.

Please explain whether your order for me to test frequently to return to work is your order or one that you are merely conveying.

Please provide any documentation that you base your order(s) on or you claim you are merely conveying.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: [redacted]
Email: [redacted]

CLASSIFICATION: UNCLASSIFIED

EXHIBIT F

DEVELOPMENTAL COUNSELING FORM

For use of this form, see ATP 6-22.1; the proponent agency is TRADOC.

DATA REQUIRED BY THE PRIVACY ACT OF 1974

AUTHORITY:	5 USC 301, Departmental Regulations; 10 USC 3013, Secretary of the Army.
PRINCIPAL PURPOSE:	To assist leaders in conducting and recording counseling data pertaining to subordinates.
ROUTINE USES:	The DoD Blanket Routine Uses set forth at the beginning of the Army's compilation of systems or records notices also apply to this system.
DISCLOSURE:	Disclosure is voluntary.

PART I - ADMINISTRATIVE DATA

Name *(Last, First, MI)*	Rank/Grade	Date of Counseling
BASHAW, MARK	1LT/O-2	30NOV2021

Organization	Name and Title of Counselor
HHC, APHC	CPT Alexander McCarthy, Commander

PART II - BACKGROUND INFORMATION

Purpose of Counseling: *(Leader states the reason for the counseling, e.g. Performance/Professional or Event-Oriented counseling, and includes the leader's facts and observations prior to the counseling.)*

On 30 November 2021, you knowingly and willfully disobeyed two lawful orders from CPT McCarthy, HHC, APHC Commander. Specifically, you were ordered to do the following and did not comply:

Provide proof of a negative COVID-19 test before coming into your place of duty on 30 NOV 2021 or alternatively reporting to BLDG 1930 between 0730-0830 on 30 NOV 2021 to have a COVID-19 test administered. You failed to provide proof of a negative COVID-19 test and failed to report to BLDG 1930 as ordered.

You were ordered to leave your office on 30 NOV 2021 after your refusal to provide proof of a negative COVID-19 test. You refused the order and remained in your office.

Both of these instances constitute violations of Article 92, UCMJ- Failure to Obey an Order in that you were issued lawful orders by your Commander, you had knowledge of the orders, you had a duty to obey the orders, and you failed to obey the orders.

PART III - SUMMARY OF COUNSELING

Complete this section during or immediately subsequent to counseling.

Key Points of Discussion:

The purpose of this counseling is to document your disobeying direct orders and violating Article 92 of the Uniform Code of Military Justice.

On 29 November 2021, you were ordered to take a COVID-19 test prior to coming into the office. This is in accordance with HQDA EXORD 225-21.

On 30 Nov 2021 you ignored the orders and went to your office in BLDG 5800. CPT McCarthy then directed you to be tested or go home to telework. You did not comply and remained at your office.

You have now disobeyed 2 direct lawful orders. To be preemptively screened for COVID-19 and to telework until further notice.

You were also afforded the opportunity to get a different COVID test prior to reporting to work.

IAW AR 380-67, Personnel Security Program, para 8-2 and 8-3, the APHC Director is suspending your security clearance.

I am giving you another opportunity to comply with the order to get a COVID-19 test at BLDG E-1930. If you still refuse to be tested, then I as the Commander, will restrict your access to all APHC buildings and initiate restrictions to APG installation.

Prior to making your decision, please consider speaking with the APG Chaplain. The APG Chaplain's number is 410-278-4333. If you need the assistance of Trial Defense Services, you can contact the office at Ft. Meade.

I am counseling you for the conduct noted above. Continued conduct of this nature may result in initiation of a bar to reenlistment, administrative action to include your separation from the service, and/or punitive action under the UCMJ. If this conduct continues, action may be initiated to involuntarily separate you from the service under AR 635-200. If you are involuntarily separated, you could receive an Honorable, General Under Honorable Conditions, or Other Than Honorable discharge. If you receive an Honorable Discharge, you will be qualified for most benefits resulting from your military service. If you receive a General Under Honorable Conditions Discharge or an Other Than Honorable Discharge, you may be disqualified from reenlisting in the service for some period and you may be ineligible for many, if not all, veterans benefits to include but not limited to the Montgomery G.I. Bill and post-9/11 G.I. Bill. If you receive a General Under Honorable Conditions or Other Than Honorable Discharge, you may face difficulty obtaining civilian employment as employers may have low regard for less than Honorable discharges.

OTHER INSTRUCTIONS

This form will be destroyed upon: reassignment *(other than rehabilitative transfers)*, separation at ETS, or upon retirement. For separation requirements and notification of loss of benefits/consequences see local directives and AR 635-200.

Plan of Action *(Outlines actions that the subordinate will do after the counseling session to reach the agreed upon goal(s). The actions must be specific enough to modify or maintain the subordinate's behavior and include a specified time line for implementation and assessment (Part IV below)*

1. LT Bashaw will take a COVID-19 Test in accordance with HQDA EXORD 225-21 to prove a negative result.

2. If LT Bashaw refuses the above order, I will consider that LT Bashaw be flagged and potentially charged under Article 92 of the UCMJ.

Session Closing: *(The leader summarizes the key points of the session and checks if the subordinate understands the plan of action. The subordinate agrees/disagrees and provides remarks if appropriate.)*

Individual counseled: ☐ I agree ☐ disagree with the information above.

Individual counseled remarks:

Signature of Individual Counseled: _____ Date: _____

Leader Responsibilities: *(Leader's responsibilities in implementing the plan of action.)*

APHC Badge was confiscated from LT Bashaw and SM refused to sign counseling statement.

Signature of Counselor: MCCARTHY.ALEXANDER.P[redacted] Digitally signed by MCCARTHY.ALEXANDER.[redacted] Date: 2021.11.30 16:20:35 -05'00' Date: 20211130

PART IV - ASSESSMENT OF THE PLAN OF ACTION

Assessment: *(Did the plan of action achieve the desired results? This section is completed by both the leader and the individual counseled and provides useful information for follow-up counseling.)*

Counselor: _____ Individual Counseled: _____ Date of Assessment: _____

Note: Both the counselor and the individual counseled should retain a record of the counseling.

EXHIBIT F

DEPARTMENT OF THE ARMY
ARMY PUBLIC HEALTH CENTER
BUILDING 5158
8252 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MD 21010-5403

30 November 2021

MEMORANDUM FOR CPT ALEXANDER MCCARTHY, HHC COMMANDER, APHC

SUBJECT: Informal Article 138 UCMJ Complaint Redress

1. On 26 November 2021, I, 1LT Mark C. Bashaw, sent you an informal Article 138 UCMJ redress and inquiry, per Army Regulation 27-10. I informed you that FRAGO 10 is an unlawful order. I also informed you that this was blatant discrimination of my firmly held religious beliefs. As of today, you have 12 more days to redress my complaint that was sent electronically via e-mail on 26 November 2021. Also, a reminder to the initial redress was sent again on 29 November 2021. Again, today I am informing you in person of this complaint with SGT Alexis Danenhower as my witness, and I am handing you a printout of the laws that govern emergency use authorized products (links within). Cease and desist all discrimination against me, and any others who might fall into the same situation within your unit. Stop the release of my personal medical information to inviduals outside the authorized chain of command. Stop harassing me with coercive phone calls and isolation meetings in your office.

2. I will continue to carry out the duties that were bestowed upon me by Law. I will continue to honor my Oath of Office to the United States of America. I request redress to my informal Article 138 UCMJ complaint IAW AR 27-10. If a resolution, or a lack of response to my initial complaint goes unsuccessful, I will then press forward with further actions IAW AR 27-10. It is my recommendation that you seek counsel.

3. The point of contact for this request is the undersigned at [redacted]

Encls:
1. EUA Laws

MARK C. BASHAW
1LT, MS

EXHIBIT F

EUA LAWS

The information below lays out the US laws that govern the administration of Emergency Use Authorized (EUA) products for military personnel.

EUA products cannot be mandated for use on military personnel without informing us of the possible benefits or harms of the products and our right to refuse their administration.

21 U.S.C. 360bbb-3 says that individuals who are administered an EUA product must be informed of the "significant known and potential benefits and risks of such use" and "of the option to accept or refuse administration of the product" and "of the alternatives to the product that are available." The intent of this law is that the member has the ability to refuse the EUA product due to any potential harm that may come from administering an EUA product in or on their body.

The FDA has not approved any Covid tests. They have issued EUAs.

Additionally the SECDEF, in his 9 Aug 21 memo, stated; "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 Administration (FDA) licensure."

Based on this memo, since an EUA vaccine would require a presidential waiver, so would an EUA test. 10 U.S.C. 1107a says that the President can waive aspects of the requirements laid out in Title 21, but no such waiver has been signed to date.

The links for the two Titles and the SECDEF's memo are below.

SECDEF Memo: https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF

21 U.S.C. 360bbb-3: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section360bbb-3&num=0&edition=prelim

10 U.S.C. 1107a: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section1107a&num=0&edition=prelim

For Official Use Only

EXHIBIT F

REPORT TO SUSPEND FAVORABLE PERSONNEL ACTIONS (FLAG)

For use of this form, see AR 600-8-2; the proponent agency is DCS, G-1.

SECTION I - ADMINISTRATIVE DATA

1. NAME (Last, First, MI)	2. SSN	3. RANK
BASHAW, MARK CHARLES	[redacted]	1LT

4. ☐ On Active Duty ☐ Not on Active Duty ☐ On ADT

5. ETS/ESA/MRD

6. UNIT ASSIGNED AND ARMY COMMAND
W03HAA USA PUBLIC HEALTH CENTER US ARMY MED COMMAND

7. STATION (Geographical Location)
ABERDEEN PROV GND, MD

8. HR OFFICE CONTROLLING FLAGGING ACTION AND TELEPHONE NUMBER
W4QVAA USAG ABERDEEN PG

9. THIS ACTION IS TO:

☑ Initiate a flag (Sections II and IV Only)

☐ Remove Flag (Sections III and IV Only)

SECTION II - INITIATE A FLAG

10.

☑ A FLAG IS INITIATED, EFFECTIVE 20211130 FOR THE FOLLOWING REASON:

NON-TRANSFERABLE

☑ ADVERSE-ACTION (A)

☐ INVOLUNTARY SEPARATION/DISCHARGE-FIELD INITIATED (B)

☐ REFERRED OER, AER, OR RELIEF FOR CAUSE NCOER (D)

☐ SECURITY VIOLATION/LOSS OF SECURITY CLEARANCE (E)

☐ HQDA DELAY OF PROMOTION/COMMAND ACTION (F)

☐ COMMANDER'S INVESTIGATION (L)

☐ LAW ENFORCEMENT INVESTIGATION (M)

☐ NOT RECOMM/AUTO PROM-PV2,PFC OR SPC (P)

☐ ADMIN NON-DEPLOYABLE RETENTION POLICY FOR NON-DEPLYABLE SLDR (R)

☐ NOT RECOMMENDED FOR AUTOMATIC PROMOTION TO 1LT/CW2 (T)

☐ DRUG ABUSE ADVERSE ACTION (U)

☐ ALCOHOL ABUSE ADVERSE ACTION (V)

☐ HQDA INITIATED INVOLUNTARY SEPARATION/DISCHARGE (W)

☐ OTHER (X), Reason: ___

TRANSFERABLE

☐ PUNISHMENT PHASE(ADVERSE ACTION) (H)
Date Punishment Complete: ___

☐ LACK OF CERTIFICATION- AMEDD BR (I)

☐ PHYSICAL FITNESS TEST FAILURE (PFT FAILURE) (J)

☐ ARMY BODY COMPOSITION PROGRAM (K)

☐ NON-COMPLIANCE WITH 10 USC 10206 (N)

☐ JAG ADVOCATES, LEGAL ADMIN, PARALEGALS LACK OF LICENSE/CERT (O)

☐ LAUTENBERG AMENDMENT (Q)

☐ NO APPROVED FAMILY CARE PLAN (S)

SECTION III - REMOVE A FLAG

11.

☐ A FLAG (CODE: ___) IS REMOVED, EFFECTIVE _____ FOR THE FOLLOWING REASON:

☐ FINAL-FAVORABLE REPORT (C)

☐ FINAL-UNFAVORABLE REPORT (D)

☐ FINAL-OTHER REPORT (E)

☐ DELETE-ERRONEOUS FLAG (Z)

SECTION IV - AUTHENTICATION

DISTRIBUTION
1 - Unit Commander
1 - S-1/MPD
1 - Soldier
1 - Commander, gaining unit (transfer flag only)
1 - HRC (only if Soldier is on a HQDA selection list)

NAME, RANK, TITLE, AND ORGANIZATION	SIGNATURE	DATE
Alexander McCarthy, Commander, HHC, APHC	MCCARTHY.ALEXANDER.P.1[redacted] Digitally signed by MCCARTHY.ALEXANDER.P[redacted] Date: 2021.12.01 08:29:45 -05'00'	

DA FORM 268, MAY 2016 PREVIOUS EDITIONS ARE OBSOLETE APD LC v1.00ES

Privacy Act Data in Accordance With Privacy Act of 1974
Dispose of this Properly

EXHIBIT F

DEVELOPMENTAL COUNSELING FORM

For use of this form, see ATP 6-22.1; the proponent agency is TRADOC.

DATA REQUIRED BY THE PRIVACY ACT OF 1974

AUTHORITY:	5 USC 301, Departmental Regulations; 10 USC 3013, Secretary of the Army.
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ROUTINE USES:	The DoD Blanket Routine Uses set forth at the beginning of the Army's compilation of systems or records notices also apply to this system.
DISCLOSURE:	Disclosure is voluntary.

PART I - ADMINISTRATIVE DATA

Name *(Last, First, MI)*	Rank/Grade	Date of Counseling
BASHAW, MARK	1LT/O-2	03DEC2021

Organization	Name and Title of Counselor
HHC, APHC	CPT Alexander McCarthy, Commander

PART II - BACKGROUND INFORMATION

Purpose of Counseling: *(Leader states the reason for the counseling, e.g. Performance/Professional or Event-Oriented counseling, and includes the leader's facts and observations prior to the counseling.)*

On 30 November 2021, you knowingly and willfully disobeyed a lawful order from CPT McCarthy, HHC, APHC Commander. Specifically, you were ordered to do the following and did not comply:

You were ordered to put on a face mask inside BLDG 1607, and you refused to do so.

This instance constitutes a violation of Article 92, UCMJ- Failure to Obey an Order in that you were issued lawful orders by your Commander, you had knowledge of the orders, you had a duty to obey the orders, and you failed to obey the orders.

PART III - SUMMARY OF COUNSELING

Complete this section during or immediately subsequent to counseling.

Key Points of Discussion:

The purpose of this counseling is to document your disobeying direct orders and violating Article 92 of the Uniform Code of Military Justice.

On 30 November 2021, you entered BLDG 1607 and were directed by CPT McCarthy to put on a face mask. This order is in accordance with local federal mandates and installation Health Protection guidelines. You declined to put on a mask. CPT McCarthy again told you to put on a mask, and you refused a second time.

You were previously seen with a mask on in federal facilities and buildings prior to this interaction.

In the MFR from the Deputy Secretary of Defense on 28 July 2021, it states: "In areas of substantial or high community transmission, DoD requires all Service members, Federal employees, on site contractor employees, and visitors, regardless of vaccination status, to wear a mask in an indoor setting in installations and other facilities owned, leased or otherwise controlled by DoD."

Per paragraph 3. f. (5) of Operation Order 21-53 (COVID-19 STEADY-STATE OPERATIONS – USAMEDCOM) from Headquarters, US Army Medical Command on 07 September 2021:"(5) Read and comply with Deputy Secretary of Defense Memorandum updated mask guidance for all DoD installations and other facilities, 28 July 2021. In areas of substantial or high community transmission, DoD requires all service members, federal employees, on-site contractor employees, and visitors, regardless of COVID-19 vaccination status, to wear masks indoors on DoD installations/facilities. Data on low, moderate, substantial and high community transmission per location can be found at the CDC COVID data tracker websites, https://covid.cdc.gov/covid-data-tracker/ and https://covid.cdc.gov/covid-data-tracker/#global-counts-rates."
In the APG Memorandum from 04AUG2021 with Subject line "Aberdeen Proving Ground Installation Policy for Face Covering Requirements", paragraphs 2 and 3.

All documents can be accessed at the following links:
--https://media.defense.gov/2021/Jul/28/2002814362/-1/-1/1/UPDATED-MASK-GUIDELINES-FOR-ALL-DOD-INSTALLATIONS-AND-OTHER-FACILITIES-OSD006862-21-FOD-FINAL.PDF
--https://mitc.amedd.army.mil/sites/G357/G33%20OPERATIONS/MEDCOMOrdersPublication/OPORDs_FRAGORDs_WARNORDs/FY21%20OPORDs_FRAGORDs_WARNORDs/OPORD%2021-53%20(COVID-19%20STEADY%20STATE%20OPERATIONS)/OPORD%2021-53%20(COVID-19%20STEADY%20STATE%20OPERATIONS).pdf
--https://home.army.mil/apg/application/files/1216/2868/5588/APGInstallationMaskPolicy_Aug2021.pdf

This decision by you puts yourself and everyone around you at risk for the transmission of COVID-19. We are located in Harford County, MD. This county is currently at a High transmission level per the CDC website. Additionally, this limits your capabilities to utilize federal facilities and resources.

I am counseling you for the conduct noted above. Continued behavior of this nature may result in the initiation of a bar to reenlistment, administrative action to include your separation from the service, and punitive action under the UCMJ. If this conduct continues, action may be initiated to involuntarily separate you from the service under AR 635-200. If you are involuntarily separated, you could receive an Honorable, General Under Honorable Conditions, or Other Than Honorable discharge. If you receive an Honorable Discharge, you will be qualified for most benefits resulting from your military service. If you receive a General Under Honorable Conditions Discharge or an Other Than Honorable Discharge, you may be disqualified from reenlisting in the service for some period, and you may be incligible for many, if not all, veterans benefits to include but not limited to the Montgomery G.I. Bill and post-9/11 G.I. Bill. If you receive a General Under Honorable Conditions or Other Than Honorable Discharge, you may face difficulty obtaining civilian employment as employers may have low regard for less than Honorable discharges.

OTHER INSTRUCTIONS

This form will be destroyed upon: reassignment *(other than rehabilitative transfers)*, separation at ETS, or upon retirement. For separation requirements and notification of loss of benefits/consequences see local directives and AR 635-200.

Plan of Action *(Outlines actions that the subordinate will do after the counseling session to reach the agreed upon goal(s). The actions must be specific enough to modify or maintain the subordinate's behavior and include a specified time line for implementation and assessment (Part IV below)*

LT Bashaw will wear a mask in all applicable areas.

Session Closing: *(The leader summarizes the key points of the session and checks if the subordinate understands the plan of action. The subordinate agrees/disagrees and provides remarks if appropriate.)*

Individual counseled: ☐ I agree ☐ disagree with the information above.

Individual counseled remarks:

Signature of Individual Counseled: _____ Date: _____

Leader Responsibilities: *(Leader's responsibilities in implementing the plan of action.)*

Service Member refused to sign counseling.

Signature of Counselor: MCCARTHY.ALEXANDER.P.[redacted] Digitally signed by MCCARTHY.ALEXANDER.[redacted] Date: 2021.12.06 15:40:28 -05'00' Date: 20211206

PART IV - ASSESSMENT OF THE PLAN OF ACTION

Assessment: *(Did the plan of action achieve the desired results? This section is completed by both the leader and the individual counseled and provides useful information for follow-up counseling.)*

Counselor: _____ Individual Counseled: _____ Date of Assessment: _____

Note: Both the counselor and the individual counseled should retain a record of the counseling.

Reply Reply All Forward

DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21(UNCLASSIFIED)

EXHIBIT F

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)

To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)

Cc: Tally, Phillip R SFC USARMY 1 MED BDE (USA)

Bcc: [redacted]

Attachments: LT_Bashaw_Comments to 4856~1.pdf (78 KB)

Monday, December 06, 2021 3:37 PM

CPT McCarthy, please see my comments attached in regards to the three counselings that I have received thus far.

Also, I respectfully ask that you send me over the DA FORM 5248-R, in regards the suspension of my security clearance that I was notified of on 30NOV21 via DA FORM 4856. Standing by for your signed version for the 4856 counseling that just occurred via phone. Thank you.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division U.S. Army Public Health Center

Entomological Sciences Division (Bldg. E-5800) Army Public Health Center
8638 40th Street
Aberdeen Proving Ground, MD
21010-5403

Phone: (410)-436-5419
Email: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
Sent: Monday, December 06, 2021 3:27 PM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)
Subject: RE: Refusal to wear a Mask Counseling (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
Please see the attached counseling. Thank you

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

EXHIBIT F

Comments Submitted In regards to DA FORM's 4856 performed by CPT Alexander McCarthy on 16SEP21, 30NOV21, and 06DEC21

BLUF: The order to submit to mask-wearing over the face is unlawful since all COVID-19 masks are Emergency Use Authorized, not FDA approved. The order to submit to weekly testing is unlawful since all COVID-19 Tests kits (PCR/Antigen) are Emergency Use Authorized, not FDA approved. The order to submit to EUA vaccines is unlawful. The only FDA Approved "vaccine" for COVID-19 is Comirnaty, and it is considered legally distinct from the EUA Pfizer one available. It has also been determined that the Pfizer Comirnaty FDA Approved CV19 "vaccine" and the EUA Pfizer vaccine have been determined by a Federal Judge that they are NOT INTERCHANGABLE (https://childrenshealthdefense.org/defender/judge-allen-winsor-pfizer-eua-comirnaty-vaccines-interchangeable/).

According to the law, EUA products (masks, tests, vaccines) require informed consent and cannot be coerced and cannot be mandated unless through written exemption from the President (which has not occurred for COVID testing or vaccines). This order demands compliance when there is no lawful means to do so, therefore, this order is unlawful.

The concerns that I am raising is that EUA products cannot be required or mandated for service members unless through written waiver by the President of the United States in accordance with Section 564 of the Food, Drug, and Cosmetic Act, codified at 21 U.S Code § 360bbb-3 and 10 U.S. Code § 1107a (attachment 3). Conditions are designated to ensure that the individuals to whom EUA products are administered are informed of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. Under certain circumstances, the President can waive the option to accept or refuse administration of a product; however, such a waiver has not been issued.

The concern is that this is a violation of the laws of the United States to require, coerce, or force acceptance of an unlicensed medical product. This is a principle of many humanitarian regulations, codes, and laws from around the world (U.S. Law, Federal Regulations, DoD Instructions, the Nuremburg Code, etc.). It is coercive to bar a member form their place of work, dining facilities, morale and welfare facilities, etc. or to subject them to disciplinary action.

A general order or regulation is lawful unless it is contrary to the Constitution, the laws of the United States, or lawful superior orders or for some other reason is beyond the authority of the official issuing it. Additionally, an order must not conflict with the statutory or constitutional rights of the person receiving the order.

EXHIBIT G

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older and is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

A third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date		Updated Expiry Date
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

If not stored between -90°C to -60°C (-130°F to -76°F), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F).

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[2]

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) with other COVID-19 vaccines to complete the vaccination series.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Dose Preparation

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *(see Storage and Handling)*.

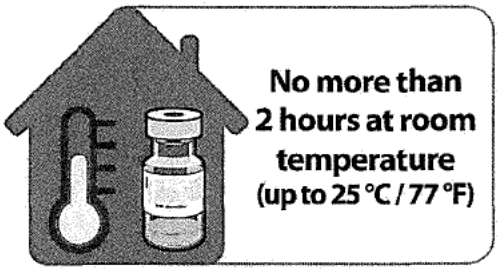
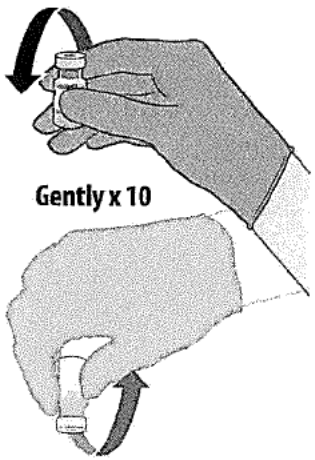
[2] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- Refer to thawing instructions in the panels below.

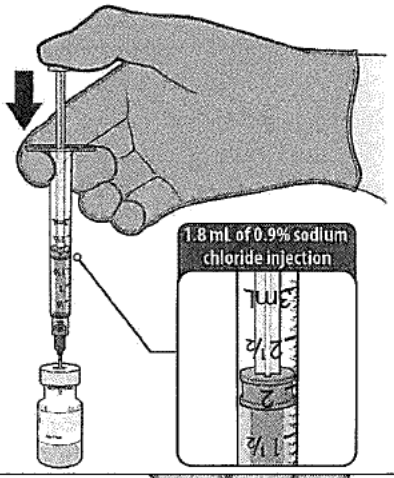
Dilution
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

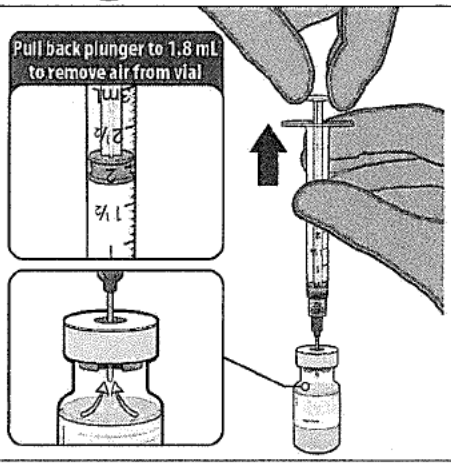
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month. o Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.

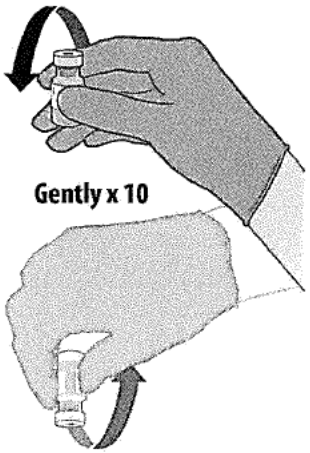
DILUTION



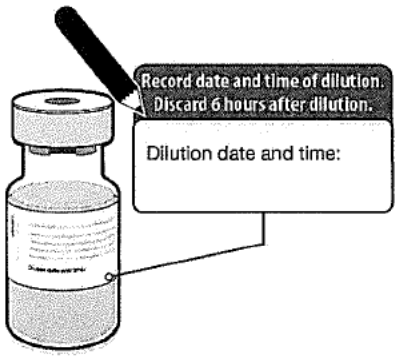
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

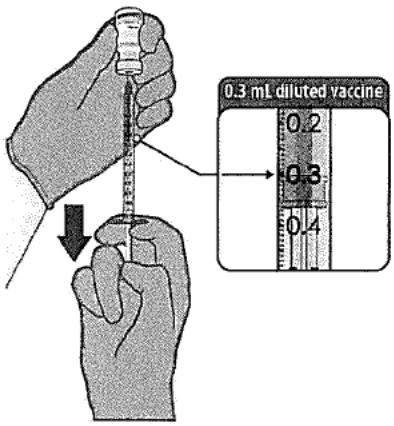


- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.



- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.

	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse Reactions in Clinical Trials
Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Adverse Reactions in Post Authorization Experience
Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, and pain in extremity (arm) have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Vaccine Information Fact Sheet) prior to the individual receiving each dose of Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.

- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION[3]

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 12 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

[3] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for use in individuals 16 years of age and older. COMIRNATY (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years of age and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise. COMIRNATY (COVID-19 Vaccine, mRNA) has the same formulation as the Pfizer-BioNTech COVID-19 Vaccine. These vaccines can be used interchangeably to provide the COVID-19 vaccination series.[4]

There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM

This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients). For information regarding provider

[4] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 12 years of age and older and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise. FDA-approved COMIRNATY is also authorized in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-11.4

Revised: 23 August 2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

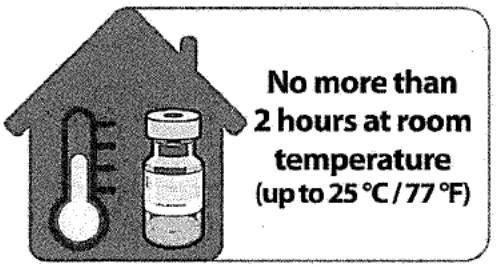
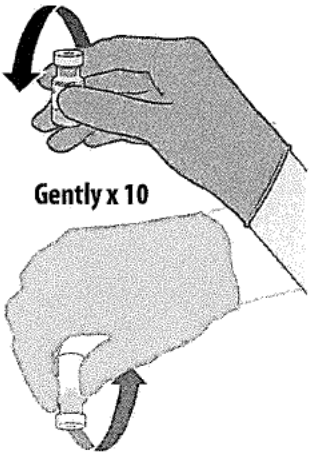
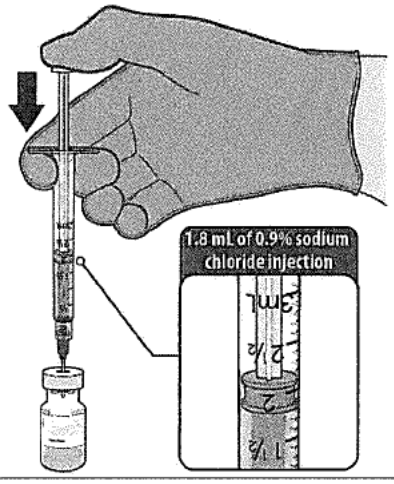
2.1 Preparation for Administration

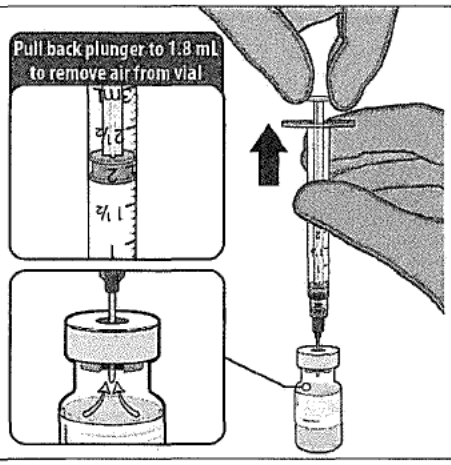
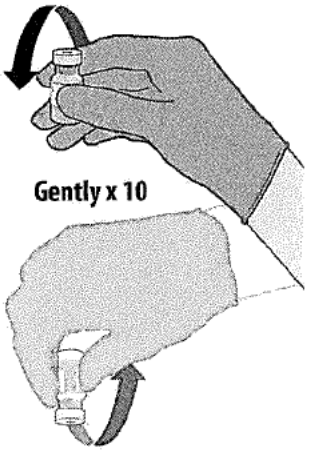
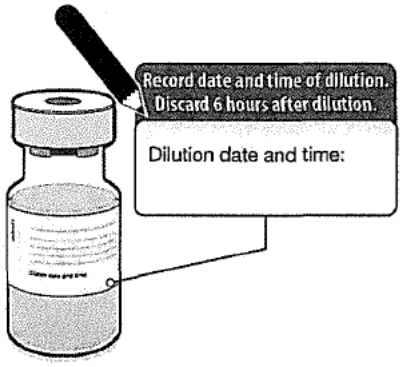
Prior to Dilution

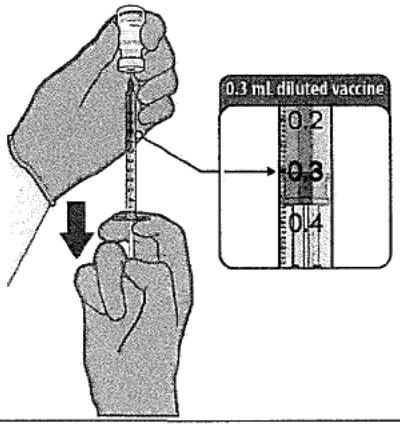
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month. o Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule for Individuals 12 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[5] There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) to complete the vaccination series.

[5] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.5 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

This bolded statement is not in the COMIRNATY Package Insert as of 23 AUG 21.

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. [6] To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

These statements do not appear in the COMIRNATY package insert as of 23 AUG 21.

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

COMIRNATY insert uses the term "vaccine" in place of "drug".

The following five paragraphs contain varying details that differ from the COMIRNATY package insert.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 12 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 46,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively) and 2,260 adolescents are 12 through 15 years of age (1,131 and 1,129 in the vaccine and placebo groups, respectively).

[6] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

In Study 2, all participants 12 to <16 years of age, and participants 16 years of age and older in the reactogenicity subset, were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination]. Tables 1 through 6 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID 19 Vaccine and placebo.

Participants 16 Years of Age and Older

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older had been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants 16 years and older enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Solicited Local and Systemic Adverse Reactions **The study data and details on pages 33-31 vary from COMIRNATY package insert.**

Across both age groups, 18 through 55 years of age and 56 years and older, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18 Through 55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, in 99 individuals who had undergone various solid

organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported in recipients who were followed for one month following post Dose 3.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7,960, placebo = 7,934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

In Study 2 in which 10,841 participants 16 through 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2.

The higher frequency of reported unsolicited non-serious adverse events among Pfizer-BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Adolescents 12 Through 15 Years of Age

In an analysis of Study 2, based on data up to the cutoff date of March 13, 2021, 2,260 adolescents (1,131 Pfizer-BioNTech COVID-19 Vaccine; 1,129 placebo) were 12 through 15 years of age. Of these, 1,308 (660 Pfizer-BioNTech COVID-19 Vaccine and 648 placebo) adolescents have been followed for at least 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine. The safety evaluation in Study 2 is ongoing.

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among adolescents who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the adolescents who received the Pfizer-BioNTech COVID-19 Vaccine, 50.1% were male and 49.9% were female, 85.9% were White, 4.6% were Black or African American, 11.7% were Hispanic/Latino, 6.4% were Asian, and 0.4% were American Indian/Alaska Native.

Solicited Local and Systemic Adverse Reactions

The mean duration of pain at the injection site after Dose 1 was 2.4 days (range 1 to 10 days), for redness 2.4 days (range 1 to 16 days), and for swelling 1.9 days (range 1 to 5 days) for adolescents in the Pfizer-BioNTech COVID-19 Vaccine group.

Table 5: Study 2 – Frequency and Percentages of Adolescents With Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	**Placebo Dose 1 N[a]=1127 n[b] (%)**	**Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)**	**Placebo Dose 2 N[a]=1078 n[b] (%)**
Redness[c]				
Any (>2 cm)	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling[c]				
Any (>2 cm)	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Pain at the injection site[d]				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0 (0.0)	7 (0.6)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 6: Study 2 – Frequency and Percentages of Adolescents with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Adolescents 12 Through 15 Years of Age – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Fever				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
Headache[c]				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)
Chills[c]				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0 (0.0)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1127 n[b] (%)	Placebo Dose 1 N[a]=1127 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1097 n[b] (%)	Placebo Dose 2 N[a]=1078 n[b] (%)
Vomiting[d]				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0 (0.0)	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhea[e]				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
New or worsened muscle pain[c]				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0 (0.0)	6 (0.5)	2 (0.2)
New or worsened joint pain[c]				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0 (0.0)	4 (0.4)	0 (0.0)
Use of antipyretic or pain medication[f]	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

In the following analyses of Study 2 in adolescents 12 through 15 years of age (1,131 of whom received Pfizer-BioNTech COVID-19 Vaccine and 1,129 of whom received placebo), 98.3% of study participants had at least 30 days of follow-up after Dose 2.

Serious Adverse Events

The fact sheet does not state which of the "serious adverse events" listed below on p. 31 were reported by the 0.4%.

Serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.1% of placebo recipients. There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 5.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 5.8% of placebo recipients. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy plausibly related to the study intervention were imbalanced, with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (7) vs. the placebo group (1). There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

6.2 Post Authorization Experience

The following adverse reactions have been identified during post authorization use of Pfizer-BioNTech COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Gastrointestinal Disorders: diarrhea, vomiting
Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS[7]

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

[7] Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 12 through 18 years of age is based on safety and effectiveness data in this age group and in adults.

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 12 years of age.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical*

Trial Results and Supporting Data for EUA (18.1)]. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

11.5 Use in Immunocompromised

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, safety and effectiveness of a third dose of the Pfizer-BioNTech COVID-19 vaccine have been evaluated in persons that received solid organ transplants. The administration of a third dose of vaccine appears to be only moderately effective in increasing potentially protective antibody titers. Patients should still be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

COMIRNATY package insert states "Study 2 is an ongoing..." The term "ongoing" does not appear in the below statements.

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants

with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion of Study 2, based on data accrued through November 14, 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 7 presents the specific demographic characteristics in the studied population.

Table 7: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	**Placebo (N=18,379) n (%)**
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years[b]	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[c]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[d]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. 100 participants 12 through 15 years of age with limited follow-up in the randomized population received at least one dose (49 in the vaccine group and 51 in the placebo group). Some of these participants were included in the efficacy evaluation

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	Placebo (N=18,379) n (%)

depending on the population analyzed. They contributed to exposure information but with no confirmed COVID-19 cases, and did not affect efficacy conclusions.

c. Includes multiracial and not reported.

d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index ≥30 kg/m^2)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 8.

Table 8: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 through 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]

First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 through 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. No confirmed cases were identified in adolescents 12 through 15 years of age.
f. Credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

18.2 Efficacy in Adolescents 12 Through 15 Years of Age

A descriptive efficacy analysis of Study 2 has been performed in approximately 2,200 adolescents 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cutoff date of March 13, 2021.

The efficacy information in adolescents 12 through 15 years of age is presented in Table 9.

Table 9: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1005 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=978 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 through 15 years of age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)
First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1119 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=1110 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 through 15 years of age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

18.3 Immunogenicity in Adolescents 12 Through 15 Years of Age

In Study 2, an analysis of SARS-CoV-2 50% neutralizing titers 1 month after Dose 2 in a randomly selected subset of participants demonstrated non-inferior immune responses (within 1.5-fold) comparing adolescents 12 through 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after Dose 2 (Table 10).

Table 10: Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Adolescents 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) –Participants Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine			
		12 Through 15 Years n[a]=190	16 Through 25 Years n[a]=170	12 Through 15 Years/ 16 Through 25 Years	
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Noninferiority Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (up to 1 month after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. Protocol-specified timing for blood sample collection.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12 through 15 years of age] – Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).
e. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
f. SARS-CoV-2 50% neutralization titers (NT50) were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

18.4 Immunogenicity in Solid Organ Transplant Recipients

From an independent report *(Kamar N, Abravanel F, Marion O, et al. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. N Engl J Med)*, a single arm study has been conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) 97±8 months previously. A third dose of the Pfizer-BioNTech COVID-19 vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Among the 59 patients who had been seronegative before the third dose, 26 (44%) were seropositive at 4 weeks after the third dose. All 40 patients who had been seropositive before the third dose were still seropositive 4 weeks later. The prevalence of anti-SARS-CoV-2 antibodies was 68% (67 of 99 patients) 4 weeks after the third dose.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2). After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information

regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date		Updated Expiry Date
August 2021	→	November 2021
September 2021	→	December 2021
October 2021	→	January 2022
November 2021	→	February 2022
December 2021	→	March 2022
January 2022	→	April 2022
February 2022	→	May 2022

If not stored between -90°C to -60°C (-130°F to -76°F), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F).

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Vaccine Information Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

Manufactured by
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Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1457-11.4

Revised: 23 August 2021

AFFIDAVIT OF FACT

MARK CHARLES BASHAW

I, Mark Charles Bashaw, hereby declare as follows:

1. I am an active duty commissioned Officer in the U.S Army. I currently serve at the Army Public Health Center (APHC) at Aberdeen Proving Ground (APG), Maryland. I serve in the Preventative Medicine (67C) career field and my specialty is Entomology. My official duties include participating in fact-finding inquiries and investigations to determine potential risk to personnel from diseases caused by insects and other non-battle related injuries.

2. I received an Associates of Science in Environmental Studies through the Community College of the Air Force in 2010, a Bachelor of Science degree in Management Studies from the University of Maryland, University College in 2013, and a Master of Science in Entomology from the University of Nebraska Lincoln in 2018.

3. I enlisted in the U.S Air Force in January 2006 and currently have close to 16 years of total active federal military service. I have served tours overseas to include Japan, Republic of Korea, Germany and multiple deployments to Africa, Middle East, and Central America. I direct commissioned in the U.S Army Medical Service Corps in September 2019. I initially attended the Direct Commission Course at Fort Sill followed by the Basic Officer Leadership Course at Fort Sam Houston, TX. I was then stationed at the Army Public Health Center in January 2020.

While at the Army Public Health Center, I have successfully served as the HHC Company Commander from May 2020 to July 2021 and currently serve in the Entomological Science Division as an Entomologist.

4. On 29 July 2020, I sent an e-mail to the Army Public Health Center Director Mr. John Resta (since retired) and Dr. Raul Mirza. I asked the following: "if the Army Medical Community was looking at the efficacy of Hydroxychlorquine as a prophylaxis and/or potential treatment to fight COVID-19 within the Army?" The response was as follows, "the available literature in this area is in favor of Hydroxychloroquine NOT being a suitable treatment or prophylactic medication against SARS-CoV-2" (EXHIBIT B).

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5. On 8 September 2021, I attended a virtual Army Public Health Center Town Hall with the Director and Deputy Director of APHC. I posted as a guest in the chat box the following, "Is the Army and/or DoD discussing the efficacy of Ivermectin, HCQ, Zinc, Vitamin D, Vitamin C used as a solid therapeutic prophylaxis and/or treatment of CV19?" (EXHIBIT B). The verbal response that I received was that these are not effective and for individuals to just go get the COVID-19 "vaccines."

6. Throughout the rollout of these rushed COVID19 "vaccines," I was tracking on the Vaccine Adverse Event Reporting System (VAERS). I started to see the numbers and deaths climb. I knew something was wrong.

7. On 24 September 2021, I became aware of LTC Theresa Long's Affidavit.

8. On 25 September 2021, I sent an e-mail to the Army Public Health Center's COVID-19 Task Force titled, "COVID19 Vaccine Risks" (Exhibit C). In this e-mail, I provided paragraph # 36 of LTC Long's affidavit, a link to her affidavit, attached APHCs COVID19 Risk Communication Strategy (EXHIBIT D), and the current VAERS data at the time (15,386 cases where vaccine targets COVID-19 and patients died and 726,965 adverse side effects documented, as of 17SEP2021.)" I stated and asked the following, "attached is APHC's official risk communication strategy that was final as of 24 August 2021. I noticed Best of Practice talking point # 3"Explain the known risks of not getting vaccinated." However, I didn't see a best of practice talking point about the "Known risks of getting vaccinated." Is this not contained within the document, or did I miss it? If not, why not? Is the Army looking into these adverse sides affects brought up above? Lastly, to date, how many Service Member has died from COVID19?" On 28 September 2021, the APHC COVID19 Task Force responded back. They only mentioned of minor side effects and stated, "If you have had a severe allergic reaction to other vaccines, ask your doctor if you should get a COVID-19 vaccine." There was no acknowledgement of LTC Long's affidavit, and they referenced the following, "Defense Health Agency, Immunization Healthcare Division tracks adverse events for those in the Military Healthcare System and those reported in CCIRs."

9. On 30 September 2021, I contacted Defense Health Agency Operations Center and asked the following question, "Is there a data base that you all use to track adverse events related to vaccination? If not, what is the DoD protocol for reporting vaccine adverse events?" (Exhibit E).

10. On 14 October 2021 at 0940EST, I asked for a status update on my initial inquiry of 30 September 2021 (Exhibit F).

11. On 14 October 2021 at 1254EST, I received a response from COL Tonya Rans the Chief, Immunization Healthcare Division, DHA-Public Health. She stated, "All adverse events following immunization need to be reported to CDC's Vaccine Adverse Event Reporting System (VAERS)" (EXHIBIT G).

12. On 25 October 2021, again, I contacted the Army Public Health Center's COVID-19 Task Force. I asked the following, "Will APHC be changing their CV19 Vaccine Risk Communication Strategy (24August2021) to include dangers such as Death and other Adverse Events from the vaccines for COVID19?" I also stated the following, "According to VAERS, to date there has been 17,128 cases where Vaccine targets COVID19 and Patient Died and 818,044 adverse events." (EXIBIT H). As of 3 December 2021, I have yet to receive a response in regard to my question, and APHC's "Risk Communication Strategy for Mandatory Vaccinations" is still posted in MilSuite, and unedited since 24 August 2021 (EXHIBIT I).

13. On 23 November 2021 at 1113, the APHC HHC Commander, called to inform me that I would now need to be COVID-19 Tested at least 1-2 times a week, according to Army FRAGO 10. I stated that this was unlawful. I felt as though I was being discriminated against. I also informed him that I didn't want my personal medical information floating around. I asked to be sent the Army FRAGO 10, and at 1515EST I received the FRAGO (EXHIBIT J).

14. On 24 November 2021, via e-mail, I stated that this FRAGO was unlawful and blatant discrimination against my firmly held beliefs in a response to the HHC Commander (EXHIBIT K.)

15. On 26 November 2021, I sent an initial Article 138 initial inquiry IAW AR 27-10 to the HHC Commander via e-mail. My intent of the initial redress was to know if he was aware of the

EUA laws that govern emergency use products, and to know if he was merely conveying these orders (EXHIBIT L).

16. On 29 November 2021, the HHC Commander sent me another e-mail stating, I must test for COVID-19 or telework. I responded with the following, "Per AR 27-10 you have 13 more days to respond to my Informal Article 138 Inquiry that was sent 26NOVEMBER2021 (Attached). These orders are unlawful. This is blatant discrimination based on my firmly held beliefs. I will be reporting for duty in the morning at building E5800. The duties I conduct are on site."

17. On 29 November 2021 at 1429 EST, my Department of the Army Civilian Supervisor called to inform me that she was made aware I was unvaccinated against COVID-19 and was also aware that I had a Religious Accommodation pending. She explained that because of these facts, I was to get tested in the morning before showing up to work. I told her that I didn't appreciate the fact that my personal medical information was floating around outside the authorized channels. I also stated that I felt I was being discriminated against and this was unfair. She completely understood my position and stated that she was simply relaying a message. I told her that I would see her in the morning when I arrive on site to perform my duties prior to ending the phone call.

18. On 30 November 2021 at 0915EST, I arrived at Aberdeen Proving Ground, Army Public Health Center to perform my duties. I did not participate in EUA testing/products.

19. On 30 November 2021 at 0921EST, the HHC Commander called to ask if I was on base working. I stated, I was at the Entomological Science Division building performing my duties. A short while later, the HHC Commander texted me to inform me of a counseling at 1430EST in his office.

20. On 30 November 2021 at 1430EST, I showed up to the HHC Commander's office. The following witnesses were present: LTC Dennis Rufolo, 1SG Phillip Tally, SGT Alexis Danenhower. The commander counseled me via DA FORM 4856 (Exhibit N). After he read the counseling off, he then verbally asked if I would now follow the order to get tested. I stated, "This is not a lawful order." He asked again, and I responded the same. He then ordered me to turn in my security access badge and informed me that the Army Public Health Center Director,

COL Alisa Wilma had suspended my security clearance. I handed the security badge over and then proceeded to read off a hand delivered version of the initial Article 138 informal redress request and the EUA laws (EXHIBIT O). I left with an unsigned copy of the DA FORM 4856. The following day the HHC Commander sent me the adverse action FLAG (EXHIBIT P) and a signed version on the counseling DA FORM 4856.

21. On 6 December 2021, the HHC Commander contacted me via e-mail to inform me that I was to be counseled about not wearing a mask during the 30 November 2021 counseling session described above. The counseling was telephonic, and the HHC Commander sent over the DA FORM 4856 prior to the phone call (EXHIBIT R) Upon completion of the counseling, I sent over comments in regard to the counseling sessions that occurred on 12 September 2021, 30 November 2021, and 06 December 2021 (EXHIBIT S). Again, I provided the established laws that govern EUA products within the comments.

22. On 8 December 2021, the HHC Commander e-mailed to ask me the following, "could elaborate in more detail about the claim of discriminating against you as well as the harassment with phone calls." I responded with the following, "Based on my firmly held beliefs I've been singled out, harassed, and discriminated against. My personal medical information was shared outside the authorized chain of command. I've been ordered to take a test that an individual has the absolute right to refuse, per the law. I was never given an option, nor informed consent. I made this clear. I inquired and requested redress on multiple occasions. I was then continuously singled out, and then counseled. I was then stripped of my security clearance, access to place of duty, records flagged, and charged with Article 92 all because of my firmly held beliefs. I am also trying to ensure adherence to the established EUA laws. None of this is lawful. Again, I respectfully request IAW 27-10. Thank you." He sent a follow e-mail asking the following, "1LT Bashaw, Thank you. Can you elaborate on how you believe the few phone calls were harassment?" I responded with the following, "HHC Commander, my complaint is as follows and has been since 26NOV21. I am being blatantly discriminated against based on my firmly held beliefs. I also cannot comply with an unlawful order. Respectfully, I am requesting to be redressed IAW 27-10 in regard to the initial Article 138 request that was sent on 26NOV21. I understand that you acknowledged receipt of that email on 01DEC21. On 06DEC21, again, I was discriminated against. Actions were taken against me via DA FORM 4856 and Article 92.

However, this is not a lawful order. I have been transparent throughout. I don't want to be singled out or treated any different, based on my religious views. Would you be willing to remove the FLAG on my record?" (EXHIBIT T & EXHIBIT U)

23. Again, on 8 December 2021, my access to the Army vpn on my government-issued laptop and internet stopped working. I lost access to sending and receiving e-mail via my .mil account. I notified the HHC Commander of this on 9 December 2021 and gave him an alternate personal e-mail account in which he could email any correspondence (EXHIBIT V).

24. As of today, 9 December 2021, I am still awaiting initial redress response IAW 27-10.

OPINION

25. I feel like this is complete reprisal, harassment, and discrimination against me. I was extremely transparent with the HHC Commander in regard to my complaint and request for redress through the 26 November to 30 November 2021. Instead, my security access to my place of duty was revoked, my security clearance was suspended, my record was flagged, my access to the APG was restricted, and I am being charged/threatened with an Article 92, Failure to Obey an Order.

26. I also can't help but think that my questions in regard to COVID-19 therapeutic treatments and deaths/adverse reactions to the COVID19 "vaccines" might have spurned on such aggressive retaliation against me.

27. My job as a medical health professional is to protect our service members at all costs. I will never leave a brother or sister on the battlefield. I will never subject my brothers or sisters to unnecessary risk. It is my absolute conclusion that the COVID19 "vaccines" are a serious danger to our Service Members, and this MUST be transparently communicated far and wide!

STATUS

26. As a man, I am a creation of God-Almighty and a follower of God's laws first and foremost, and the laws of man when they are not in conflict (Leviticus 18:3,4). Pursuant to Matthew 5:33-37 and James 5:12, let my yea be yea, and my nay be nay, as supported by Federal

Public Law 97-280, 96 Stat. 1211 - "Whereas the Bible, the Word of God, has made a unique contribution in shaping the United States as a distinctive and blessed nation and people" and "Whereas Biblical teachings inspired concepts of civil government that are contained in our Declaration of Independence and the Constitution of the United States" and "Whereas the Bible is "the rock on which our Republic rests." I will never be bullied into sacrificing my personal beliefs. As an Officer in the U.S Army, I will always stand up for what is right, and honor my Oath of the Constitution.

I declare under penalty of perjury under the laws of the United States of America, pursuant to 28 U.S.C. § 1746, that the foregoing is true and correct to the best of my knowledge, information and belief.

Dated: December 9, 2021

Respectfully submitted,

Mark C. Bashaw, 1LT/MS

APPENDIX A

EXHIBIT A

From: Mirza, Raul Alexander CIV USARMY MEDCOM APHC (USA)
To: Resta, John J CIV USARMY MEDCOM APHC (USA); Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Cc: Mcdannald, Jennifer J COL USARMY MEDCOM APHC (USA); Millikan Bell, Amy M CIV USARMY MEDCOM APHC (USA)
Subject: RE: Hydroxichlorquine Question (UNCLASSIFIED)
Date: Wednesday, July 29, 2020 8:56:27 AM

CLASSIFICATION: UNCLASSIFIED

1LT Bashaw,

I am not aware of any current studies within DoD, although this does not necessarily mean someone might not be looking into this drug and its affect on SARS-CoV-2. The available literature in this area is in favor of Hydroxychloroquine NOT being a suitable treatment or prophylactic medication against SARS-CoV-2.

-----Original Message-----
From: Resta, John J CIV USARMY MEDCOM APHC (USA)
Sent: Wednesday, July 29, 2020 8:53 AM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>
Cc: Mcdannald, Jennifer J COL USARMY MEDCOM APHC (USA) <jennifer.j.mcdannald.mil@mail.mil>; Millikan Bell, Amy M CIV USARMY MEDCOM APHC (USA) <amy.m.millikanbell.civ@mail.mil>; Mirza, Raul Alexander CIV USARMY MEDCOM APHC (USA) <raul.a.mirza.civ@mail.mil>
Subject: RE: Hydroxichlorquine Question (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Mark,

I think there were a couple of clinical trials w/in our hospitals as a treatment, but don't really track that. I'm not aware of any evidence that it has any prophylactic capabilities, but Dr. Millikan may know.

J. Resta

410.436.2307 (Office)
410.322.7794(Cell)
praeparet pessimus

-----Original Message-----
From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Sent: Wednesday, July 29, 2020 8:20 AM
To: Resta, John J CIV USARMY MEDCOM APHC (USA) <john.j.resta.civ@mail.mil>; Mirza, Raul Alexander CIV USARMY MEDCOM APHC (USA) <raul.a.mirza.civ@mail.mil>
Cc: Mcdannald, Jennifer J COL USARMY MEDCOM APHC (USA) <jennifer.j.mcdannald.mil@mail.mil>
Subject: Hydroxichlorquine Question

Hi Mr. Resta and Dr. Mirza, in regards to Hydroxichlorquine, is the Army Medical Community looking at the efficacy of Hydroxichlorquine as a prophylaxis and/or potential treatment to fight COVID-19 within the Army?

Respectfully,

Mark C. Bashaw
1LT, MS
HHC Commander

U.S Army Public Health Center

8252 Blackhawk Road
Aberdeen Proving Ground, MD 21230-

Mobile: 443-910-7444
Desk: 410-436-8394
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED

EXHIBIT A

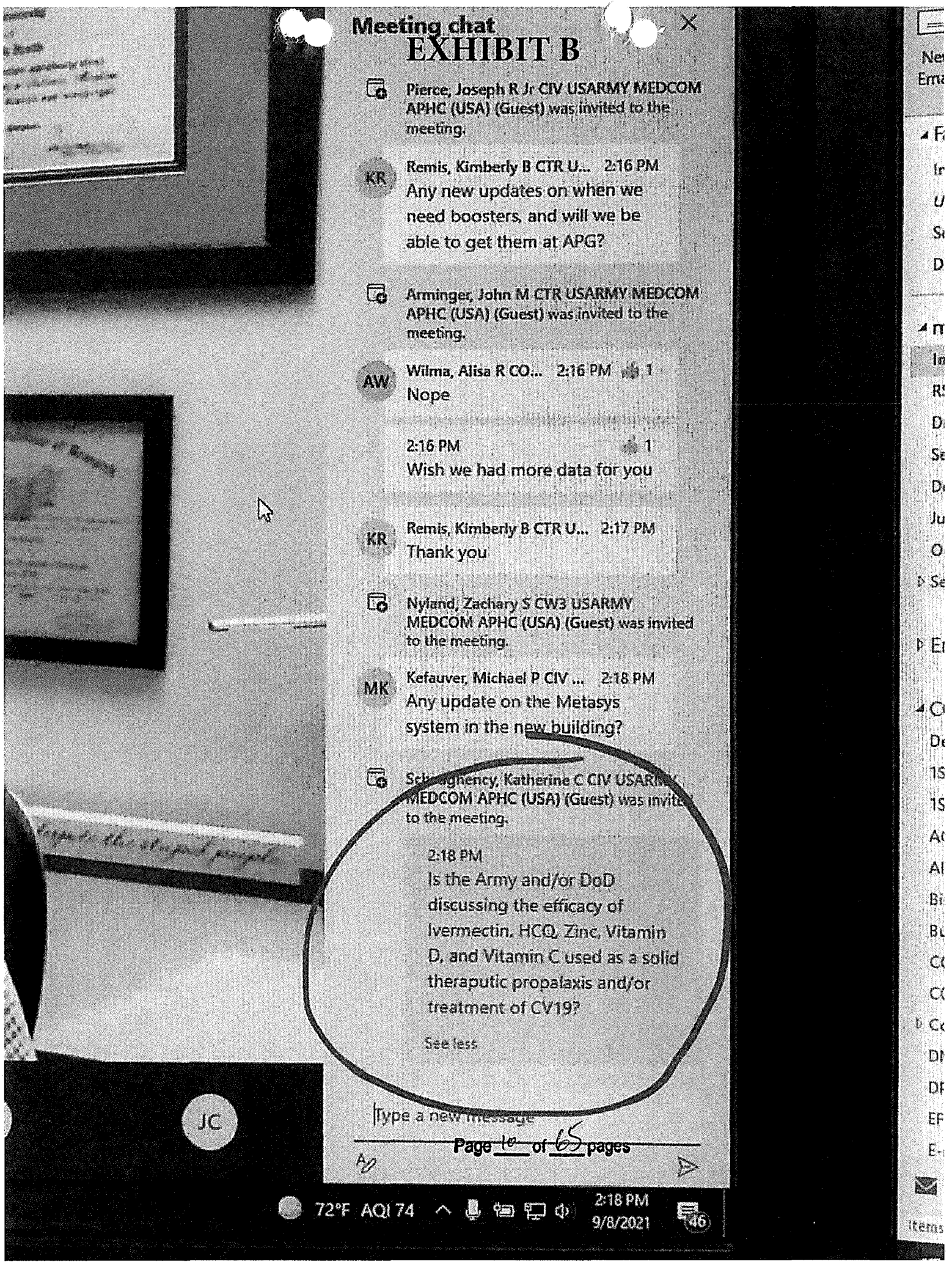
Meeting chat
EXHIBIT B
Pierce, Joseph R Jr CIV USARMY MEDCOM APHC (USA) (Guest) was invited to the meeting.
KR
Remis, Kimberly B CTR U... 2:16 PM
Any new updates on when we need boosters, and will we be able to get them at APG?
Arminger, John M CTR USARMY MEDCOM APHC (USA) (Guest) was invited to the meeting.
AW
Wilma, Alisa R CO... 2:16 PM 1
Nope
2:16 PM 1
Wish we had more data for you
KR
Remis, Kimberly B CTR U... 2:17 PM
Thank you
Nyland, Zachary S CW3 USARMY MEDCOM APHC (USA) (Guest) was invited to the meeting.
MK
Kefauver, Michael P CIV ... 2:18 PM
Any update on the Metasys system in the new building?
Schlaghency, Katherine C CIV USARMY MEDCOM APHC (USA) (Guest) was invited to the meeting.
2:18 PM
Is the Army and/or DoD discussing the efficacy of Ivermectin, HCQ, Zinc, Vitamin D, and Vitamin C used as a solid theraputic propalaxis and/or treatment of CV19?
See less
Type a new message
JC
Page 16 of 65 pages
72°F AQI 74
2:18 PM
9/8/2021
46

EXHIBIT C

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
To: USARMY APG MEDCOM APHC Mailbox COVID-19 Task Force
Cc: Starbuck, Steven M CIV USARMY MEDCOM APHC (USA)
Bcc: [redacted]
Subject: RE: COVID19 Vaccine Risks (UNCLASSIFIED)
Date: Wednesday, September 29, 2021 11:13:00 AM

CLASSIFICATION: UNCLASSIFIED

CV19 Task Force,

Thank you for the response.

Do you have any further information on the Defense Health Agency, Immunization Healthcare Division that tracks adverse events? Is there a POC and/or org box?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

From: USARMY APG MEDCOM APHC Mailbox COVID-19 Task Force <usarmy.apg.medcom-aphc.mbx.covid-19-task-force@mail.mil>
Sent: Tuesday, September 28, 2021 8:07 AM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>
Cc: USARMY APG MEDCOM APHC Mailbox COVID-19 Task Force <usarmy.apg.medcom-aphc.mbx.covid-19-task-force@mail.mil>; Starbuck, Steven M CIV USARMY MEDCOM APHC (USA) <steven.m.starbuck.civ@mail.mil>
Subject: RE: COVID19 Vaccine Risks (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

1LT Bashaw,

Thank you for reaching out the APHC COVID-19 Task Force and the opportunity to evaluate your questions.

In response to: Also, attached is APHC's official risk communication strategy that was final as of 24August2021. I noticed Best of Practice talking point # 3"Explain the known risks of not getting vaccinated." However, I didn't see a best of practice talking point about the "Known risks of getting vaccinated." Is this not contained within the document, or did I miss it? If not, why not?

Answer: Thank you for your inquiry. The risk communication strategy includes the recommendation to explain vaccine side effects, as the seventh bullet under Best Practice 3: Explain the known risks of not getting vaccinated.

- "Medical information should be explained to the stakeholders, which
  - Focuses on increasing trust in the vaccine.
  - Highlights the science of the vaccination process and how it works.
  - Describes normal and expected side effects."

This strategy document is meant to accompany Public Affairs Guidance, which includes talking points specific to vaccine side effects. Additionally, supporting briefing slides (https://www.milsuite.mil/book/docs/DOC-1013496) include the following information on known vaccine side effects:

Some known, minor side effects are expected following immunization. These are normal signs that your body is building protection.

- At the site of injection:
  - > Pain > Swelling
- Throughout your body:
  - > Fever > Tiredness
  - > Chills > Headache
- You may feel flu-like symptoms which could impact your ability to complete routine activities, but they should resolve in a few days.
- Currently, two of the available COVID-19 vaccines require two doses to complete the series. The third authorized vaccine requires a single dose.
- It takes time for your body to build protection after any vaccination.
- You are considered fully vaccinated two weeks after receipt of the last dose of vaccine.
- If you have had a severe allergic reaction to other vaccines, ask your doctor if you should get a COVID-19 vaccine.

Additional information on vaccine side effects is available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.

In response to: Is the Army looking into these adverse sides affects brought up above?

Answer: The Defense Health Agency, Immunization Healthcare Division tracks adverse events for those in the Military Healthcare System and those reported in CCIRs.

In response to: How many Service Member has died from COVID19?

Answer: According to the Disease Reporting System-internet (DRSi) we have had 8 active duty service members pass due to COVID-19.

Thank you again for contacting the APHC COVID-19 Task Force. Please let us know if we can be of further assistance.

V/r,

Lindsey Kneten and COVID-19 APHC Task Force
Army Public Health Center
usarmy.apg.medcom-aphc.mbx.covid-19-task-force@mail.mil
https://phc.amedd.army.mil/topics/campaigns/covid19/

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Sent: Saturday, September 25, 2021 2:00:42 PM (UTC-05:00) Eastern Time (US & Canada)
To: USARMY APG MEDCOM APHC Mailbox COVID-19 Task Force
Subject: COVID19 Vaccine Risks (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

CV19 Task Force,

Please see attached sworn affidavit from LTC Theresa Long MD, MPH, FS, US Army.

Below, I am quoting item #36 of the affidavit, followed up with some personal questions that I would like addressed:

"36. I personally observed the most physically fit female Soldier I have seen in over 20 years in the Army, go from Colligate level athlete training for Ranger School, to being physically debilitated with cardiac problems, newly diagnosed pituitary brain tumor, thyroid dysfunction within weeks of getting vaccinated. Several military physicians have shared with me their firsthand experience with a significant increase in the number of young Soldiers with migraines, menstrual irregularities, cancer, suspected myocarditis and reporting cardiac symptoms after vaccination. Numerous Soldiers and DOD civilians have told me of how they were sick, bed[1]ridden, debilitated, and unable to work for days to weeks after vaccination. I have also recently reviewed three flight crew members' medical records, all of which presented with both significant and aggressive systemic health issues. Today I received word of one fatality and two ICU cases on Fort Hood; the deceased was an Army pilot who could have been flying at the time. All three pulmonary embolism events happened within 48 hours of their vaccination. I cannot attribute this result to anything other than the Covid 19 vaccines as the source of these events. Each person was in top physical condition before the inoculation and each suffered the event within 2 days post vaccination. Correlation by itself does not equal causation, however, significant causal patterns do exist that raise correlation into a probable cause; and the

burden to prove otherwise falls on the authorities such as the CDC, FDA, and pharmaceutical manufacturers. I find the illnesses, injuries and fatalities observed to be the proximate and causal effect of the Covid 19 vaccinations." https://freerepublic.com/focus/f-bloggers/3997925/posts

According to VAERS database, there have been 15,386 cases where vaccine targets COVID-19 and patients died and 726,965 adverse side effects documented, as of 17SEP2021:
https://www.medalerts.org/vaersdb/findfield.php?EVENTS=on&PAGENO=50&PERPAGE=10&ESORT=&REVERSESORT=&VAX=(COVID19)&VAXTYPES=(COVID-19)&DIED=Yes
https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19

Also, attached is APHC's official risk communication strategy that was final as of 24August2021. I noticed Best of Practice talking point # 3"Explain the known risks of not getting vaccinated." However, I didn't see a best of practice talking point about the "Known risks of getting vaccinated." Is this not contained within the document, or did I miss it? If not, why not?

Is the Army looking into these adverse sides affects brought up above?

Lastly, to date, how many Service Member has died from COVID19?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: [redacted]6
Email: [redacted]

CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED

U.S. Army Public Health Center

EXHIBIT D

CUI

COVID-19 RISK COMMUNICATION STRATEGY FOR REQUIRED PROTECTIVE MEASURES

For use within the COVID-19 Communication Taskforce

Controlled by: OTSG/MEDCOM
Controlled by: APHC/HPW
CUI Category: PRVCY
Limited Dissemination Control: FEDCON
POC: Mamie Carlson, [redacted]

General Medical: 500A

APHC

The information provided is designed to deliver subject matter expert recommendations on the risk communication approach regarding the required protective measure of COVID-19 vaccination for all DOD personnel (Active Duty and Civilian) as of 23 August 2021. The recommendations provided are intended for use by the COVID-19 Communication Task Force in campaigns and products. For questions about the risk communication proposals in this document, please contact the U.S. Army Public Health Center (APHC) Health Risk Communication Division (HRCD).

Table of Contents

Best Risk Communication Practices for Required Protective Measures

Risk Communication Principles and Theories

Effective risk communication on vaccine directives and administration requires the alignment of complex factors. These include trust between the communicator and the stakeholder(s), stakeholder involvement, and emotional responses to risk. Risk communication is the "process of exchanging information among interested parties about the nature, magnitude, significance, or control of a risk." Once a required protective measure is put in place, intense emotional states can lead to a wide variety of public responses.[1] In this case, it is necessary to strengthen the risk communication component of messaging and campaign efforts to provide the stakeholder with all of the essential information about the immunization process.

Unvaccinated DOD Service members and Civilians will be the target stakeholders once COVID-19 vaccination is required. These stakeholders may be skeptical, fearful, angry, and/or confused. Risk communication provides a two-way dialogue between leaders and subject matter experts and their target stakeholders so that the correct target stakeholders receive accurate information.

In addition to the risk communication techniques that have demonstrated success in public health interventions, an informal literature review highlighted methods of public health communication, which provide further insight for a COVID-19 communication strategy. The Army leadership heavily weighs Army force protection against the risks of public health interventions, which is shown throughout the history of required protective measures. This analysis is often not described effectively enough to fully impact the public's behavior or opinion. The analysis of previous public health campaigns shows the need to educate and communicate with the entirety of the DOD workforce.

[1] Covello, Vincent T. The EPA's Seven Cardinal Rules of Risk Communication. U.S. Environmental Protection Agency, 1988. orau.gov/cdcynergy/erc/Content/activeinformation/resources/EPA_Seven_Cardinal_Rules.pdf

Recommended Best Practices

1) **Have an informed plan** – Know what you want to achieve and how you will do it before beginning your efforts. Techniques include to—
    - Have a clear goal of communicating expectations and consequences.
    - Deliver the right message.
    - Know who else is talking to your stakeholders.
    - Be consistent.

2) **Speak to the Stakeholder Interests, not your own** –Connecting with the values and concerns of your stakeholders will help you improve your communication efforts. "Four of the primary negative emotions in risk are anger, sadness, fright and anxiety." [2] Techniques include to—
    - Be familiar with stakeholder concerns, fears, or issues related to the policy.
    - Ask stakeholders what they know and think about the vaccine and listen to them, meet them where they are, understand their position, and talk with them about their concerns.
    - Note any confusion about the policy or expectations/consequences.
    - Build trust by listening; refrain from approaching the conversation as a debate.

3) **Explain the known risks of not getting vaccinated.** Techniques include to—
    - Start with the impacts and paint an evidence-based picture of what impacts will be to them, their family, their community, and the military (e.g., continued community spread, potential severe illness, hospitalization, death, potential spread to those most vulnerable, potential inabilities to travel, reduced temporary duty (TDY) opportunities, perhaps penalties/discipline).
    - Be honest and open about what you do not know.
    - Avoid scare tactics and threats.
    - Avoid comparisons to other vaccines.
    - Focus on messages, which note that vaccines protect the entire force to enable continued mission success across the globe.
    - Highlight unique exposure possibilities due to the nature of the worldwide DOD mission (e.g., deployment missions, training exercises, TDY requirements, CONUS/OCONUS locations with moderate to high transmission).
    - Medical information should be explained to the stakeholders, which—
        - Focuses on increasing trust in the vaccine.

[2] Cone, Joe. Hold that Thought! Questioning Five Common Assumptions about Communicating with the Public. Oregon Sea Grant, 2008. www.vims.edu/research/units/centerspartners/map/climate/docs_climate/HoldThatThought.pdf

- Highlights the science of the vaccination process and how it works.
- Describes normal and expected side effects.

4) **Work with Trusted Sources.** Techniques include to—
   - Know who your stakeholder listens to and find the leaders and vaccinated role models they trust.
   - Establish a partnership with these trusted sources and invite them to participate in the discussion opportunities/dialogues.
   - Work together to share consistent information.
   - Assemble subject matter experts who can provide assistance and answers regarding Command responsibility for non-compliance, medical/health benefits of the required protective measure, and legal issues or concerns surrounding the requirement.

5) **Use Multiple Ways to Communicate.** Techniques include to—
   - Deliver the messages and conduct the discussion in a way your stakeholders like to receive this type of information.
   - Stakeholders will need to hear the message multiple times, so use multiple formats to improve your chances of reaching the stakeholder.
   - Be certain to consider educational and cultural relevance.

Lines of Effort for Effective Risk Communication Dialogue on Mandatory Vaccines

Recommended Lines of Effort

1) **Provide opportunities for discussion and dialogue using key messages and techniques.**
    - Town Halls:
        - Invite those who are interested in the information related to the requirement and the policy.
    - Small group discussions:
        - Engage at the company, or squad level.
    - One-on-one dialogue:
        - Announce times for open one-on-one discussions or office visits with leaders.
        - Helpful for those who may wish to have more privacy to discuss.

2) **Develop key messages to use while engaging with target stakeholders - support discussion on the safety and prevention culture in the DOD.**

    Purpose of Key Message:
    - The Army has a culture of safety and risk assessments that weigh all options for protection.
    - The Army requires protective measures for Service members in all aspects of the mission (i.e., Kevlar, armor, hearing protection).
    - The Army mission is global, and safety and protection measures for deployment and TDY include various prevention strategies, training and applications.
    - Service members will be less likely to get severely ill, be hospitalized or die from the COVID-19 virus if they are vaccinated.
    - Service members will be better protected when working in high transmission locations.
    - More than 1.2 million Service members around the world have already received at least one dose of the COVID 19 vaccine[3], supporting a safe and effective response to the virus.

    Key Messages and Preparations:
    - Format:
        - No more than three key messages per opportunity of discussion.

[3] DoD News. DOD VACCINATION ADMINISTRATION TO DOD POPULATION. Coronavirus: DOD Response, 2021. https://www.defense.gov/Explore/Spotlight/Coronavirus-DOD-Response/

  - Create message, then pretest the message with colleagues and experts.
    - Prepare for anticipated questions, concerns, and doubts (https://health.mil/Reference-Center/Frequently-Asked-Questions?query=covid&isDateRange=0&broadVector=000&newsVector=0000000&refVector=000000100000000&refSrc=1; https://www.opm.gov/faqs/topic/pandemic/index.aspx?fid=10260ea7-b31e-4227-b0e4-94d4804b2c8a).
- Type:
  - Educational:
    - Protection from exposure both CONUS/OCONUS.
    - Protection of family, friends, community.
    - Protection of populations who cannot be vaccinated.
  - Informational:
    - Benefits of getting vaccine.
    - Clinical trials for vaccine demonstrate that vaccination reduces critical illness, hospitalization, and death from COVID-19.
- Resources:
  - Trusted Partner sources:
    - Coordinated with trusted sources and POCs.
    - Medical POC.
    - Chaplain.
    - Leadership, chain of command.
    - Legal/ Jag.

3) **Execution of Opportunities for Engagement—Host Opportunity for Discussion.** Regardless of the duration of the discussions or dialogue, be consistent with the key message and resources.
   - Be sure to engage in discussion that can fill knowledge gaps related to the current key messages and talking points.
   - Be certain to provide time to answer questions related to command responsibilities.
   - Provide clear policy information, expectations, benefits, and consequences (e.g., timeline, locations, and reporting processes). Be honest.

Communication Channel Strategies for Awareness

Resources and Channels for Trends and Perceptions

Social Media (Twitter, Facebook, Instagram):

- Watch for comments and how often a post was shared. This may provide insight regarding how local stakeholders are feeling and what their concerns may be.
- Look out for questions that stakeholder's post (these can be sources of misconceptions or credible information).
- Which social media items are the most popular? Using the media that has the most viewers will reach more stakeholders.

News Media:

- What places do Service members normally turn to for news? What misconceptions are being reported?
- News media have an agenda that is separate from the Army mission (but not necessarily always in opposition).

Note: Although the below are not official Army resources or accounts, they do provide insight and trends related to the community perceptions.

LinkedIn:

- Gives good insight into the workforce groupthink that can happen in communities. Recommend searching key topics to see what conversations come up in the local area.

Reddit:

- Reddit can be a minefield of misinformation, but will demonstrate what misconceptions are being spread through local communities.

Google Analytics:

- While an unusual tactic, Google analytics can give the communicator an idea of the metrics around a sensationalized topic. A communicator can find the trending words, posts, images, and graphs for the time period of interest in a local area, as well as find what data people are searching for the most.

Channel Application Tools

Once trends and community perceptions are gathered, the below communication channels can be used as tools and leveraged to communicate with the target stakeholders.

Push Media:

- Know which parts of the installation are most frequented and who frequents these places to push the best announcements in the most effective ways.
- Push announcements and notifications are not dialogue; these are best used to deliver a short notice to the public. These include:
  - Memorandum (announce town halls or discussion).
  - Emails, posters, and flyers (short announcements).

Official Social Media:

- Sprinklr (use with social media accounts/posts to highlight which posts/accounts are most successful/effective at delivering messages).
- Twitter, Facebook, Instagram (share infographics, announcements, policy updates).

Conclusions drawn from Articles and Resources

Throughout its history, the Army has strived to ensure that Service members and Civilians have access to all necessary safety and protection measures available. Additionally, the Army has weighed the risks and benefits of protective measures and public health when developing policy and guidance for the Force. While Service members and Civilians are often exposed to disease while performing missions across the globe, they can also carry those diseases back home to their families and communities. Accordingly, it is critical to protect the health of personnel and their loved ones through policy and mitigation strategies.

COVID-19 poses a serious health risk to Service members, Civilians, their Families, communities, and the Army as a whole. Service members and Civilians take protective measures every day to protect themselves and others from health threats—the COVID-19 vaccine is one more measure in a long line of others that have supported the health and safety of the Force.

Despite strong evidence that the COVID-19 vaccines are safe and effective, significant numbers of the DOD population remain hesitant to get the vaccine. Some Service members and Civilians have expressed concern over the safety and efficacy of available COVID-19 vaccines. Many of their concerns reveal legitimate risk vs. benefit fears that stem from the history of vaccines. These concerns include but are not limited to fertility and pregnancy, side effects, and unknown long-term adverse health outcomes. Individuals with these concerns need the opportunity to speak with a qualified and trusted medical source. Additionally, there are individuals who have received a great deal of misinformation or subscribe to cultural or political views that are hard to unseat, even when provided factual information. As such, there will be a population within the DOD who will not be receptive to communication efforts, as well as a small percentage of the DOD workforce who will resist the requirement and may choose to leave their current positions.

Service Members and Civilians must ultimately accept the consequences of their decision if they choose not to comply with immunization requirements. Individuals can make their own informed risk vs. benefit decision in regards to this vaccination program and their decision will impact their subsequent behaviors and associated outcomes (i.e., to receive vaccine or refuse vaccine and incur any resulting disciplinary or other administrative actions). It is APHC's responsibility to provide facts in a credible and compassionate manner, to address stakeholder concerns and questions, and to remain honest and transparent in outlining requirements and reasons supporting those requirements.

Articles and Resources

https://www.milsuite.mil/book/groups/army-public-health-centers-medical-threat-briefings/pages/covid-19

APHC Public Health Assessment Division, Health Promotion and Wellness Directorate (August 2021). COVID-19 Vaccination Perceptions and Messaging Formative Evaluation briefing slides.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7025e2.htm?s_cid=mm7025e2_x

CDC conducted nationally representative household panel surveys during March–May 2021, to examine attitudes toward COVID-19 vaccination and vaccination intent among young adults. Results showed nearly one fourth of those aged 18–39 years were probably going to be vaccinated or were unsure about whether to be vaccinated, and nearly one fourth reported that they would probably not or would definitely not be vaccinated.

https://www.defensenews.com/news/your-army/2021/06/17/the-shadow-of-anthrax-the-voluntary-covid-19-vaccination-effort-owes-much-to-past-failures/

The handling of the anthrax vaccine becoming mandatory was arguably institutionally damaging to the trust of the soldiers in the healthcare interventions, and thus the voluntary option of the COVID- 19 vaccine might be the most effective way forward.

https://www.health.mil/-/media/Images/MHS/Infographics/TRICARE-COVID-19-Vaccine-Toolkit/TRICARE-Communications_Vaccine-Confidence_Graphic_Vaccines-Save-Lives_Final.ashx

History proves that vaccine side effects do not compare to the symptoms of the diseases that vaccines protect against.

https://health.mil/News/Articles/2021/02/01/DOD-experts-explain-The-science-behind-the-COVID-19-vaccines

DOD experts explain the medical and scientific features behind the COVID-19 vaccines.

https://abcnews.go.com/Politics/military-make-covid-19-vaccine-mandatory/story?id=78689440

Nearly 70% of all military personnel have received at least one dose of a COVID-19 vaccine, but there has discussion about whether the Pentagon should make vaccinations mandatory for the ranks should the Food and Drug Administration formally approve the vaccine in the future in order to get more of the population vaccinated.

https://www.armytimes.com/news/pentagon-congress/2021/07/01/prepare-for-mandatory-covid-vaccines-in-september-army-tells-commands/

While COVID-19 vaccinations in the U.S. military are taking place under the same emergency use authorization that has allowed vaccinations to take place in the general

population, Pentagon officials have said publicly that they would make the vaccinations mandatory, as is done with more than a dozen other vaccines, should the FDA formally approve the vaccine.

https://www.militarytimes.com/news/pentagon-congress/2021/07/06/military-weighing-mandatory-covid-19-vaccine-after-full-fda-approval/

Article discusses the pros and cons of mandatory vaccines after FDA approval of the COVID- 19 licensure that is expected soon.

Review of Disease Intervention Approaches Marble Pandemics.docx

An essay on the development of disease interventions that have been both effective and ineffective during the history of the Army.

https://www.usnews.com/news/health-news/articles/2021-07-26/medical-groups-call-for-vaccine-mandate-for-health-care-workers

More than 50 medical groups issued a joint statement on Monday calling for health care and long-term care employers to mandate COVID-19 vaccinations for employees. Signatories of the statement include major health care groups such as American Medical Association, the American College of Physicians, the American Academy of Pediatrics and the American Public Health Association.

https://www.wfxrtv.com/news/health/coronavirus/when-will-covid-vaccines-get-full-fda-approval/

The FDA granted priority review status to Pfizer's COVID vaccine application—for use in people 16 and older—on July 16, giving 6 months to review Pfizer's clinical trial information. Approval could be held up until January of 2022. The way the FDA's vaccine program is designed should help it in its efforts to expedite the full approval of COVID vaccines.

https://www.military.com/daily-news/2021/07/24/many-soldiers-still-arent-vaccinated-whats-armys-plan.html

Thousands of soldiers are still not vaccinated against COVID-19, and Army leaders are moving to educate the unvaccinated as the deadly Delta variant sweeps through the country. Vaccine hesitancy mostly spurs from health concerns and latching onto misinformation mostly found on social media. Some soldiers have health concerns, even if experts say the research does not back up those fears.

https://www.nytimes.com/2021/07/30/us/politics/military-vaccinations.html

Although most of the Soldiers on Army installations are vaccinated, others have concerns and are taking advantage of a rare piece of discretion not often granted to the rank and file.

Compulsory shots are standard operating procedure for the military, which requires troops to be vaccinated for at least a dozen diseases. Of the 1,336,000 Active Duty members of the military, about 64 percent are fully vaccinated, for the military, that rate is unacceptably low.

https://www.govexec.com/workforce/2021/07/many-va-employees-apprehensive-about-vaccine-mandate-department-begins-implementation/184202/

Many employees at the Veterans Affairs Department are voicing frustration with the COVID-19 vaccine mandate. About 70% of DOD individuals are currently vaccinated, meaning about 35,000 must now decide whether to be vaccinated or face potential consequences. VA has not specified what exactly will happen to employees who decline, saying only in a memorandum that anyone who fails to certify vaccination "may face disciplinary action up to and including removal from federal service."

https://news.yahoo.com/us-military-covid-vaccine-mandatory-185948954.html

President Biden announced that federal civilian workers would be required to be vaccinated against COVID-19, yet did not extend that mandate to members of the military. The military has a complicated history around requiring active duty to be vaccinated. Biden could immediately order that members of the military be vaccinated against COVID-19, though such a move would likely create a backlash, as it did with anthrax.

https://wjla.com/news/coronavirus-vaccine/a-rise-in-covid-19-cases-at-the-us-mexico-border

Migrants are making their way to the United States with insufficient resources to help or process them and many of them infected with COVID-19. Concerns are rising after reports that more than 50,000 migrants have been released into the interior of the United States.

https://www.cnn.com/2021/08/02/health/us-coronavirus-monday/index.html

To avoid lockdowns, people in the United States will have to wear masks at indoor gatherings even if they are vaccinated and have kids mask up in schools. A "silver lining" of the surge in Covid-19 cases caused by the Delta variant is that more Americans appear to be at the tipping point of understanding the importance of Covid-19 vaccinations.

https://www.kitv.com/story/44424175/honolulu-police-and-hawaii-army-national-guard-host-free-covid19-testing-in-chinatown

The Honolulu Police Department and members of the Hawaii Army National Guard are joining in on COVID-19 testing efforts. They administered more than 40 free tests in 1 day. Guard members conduct the tests in the alleyway next to the Chinatown Substation. The swabs are courtesy of a partnership between the Hawaii Army National Guard and the Department of Health.

https://www.military.com/daily-news/2021/07/30/vaccine-push-increases-dod-will-start-asking-troops-ifthey-got-shot.html

The Defense Department is requiring all uniformed and Civilian personnel to attest to whether they have received the vaccine against COVID-19, as part of the government's effort to kick-start vaccinations. Those who have not been vaccinated will have to wear a mask and physically distance themselves from others.

https://health.mil/News/Articles/2021/07/30/COVID19-Vaccines-Benefits-Still-Outweigh-the-Risks

Only a small fraction of people in the military community has experienced breakthrough infections after receiving a COVID-19 vaccination - and none of them have died. Evidence shows how effective the vaccine has been and he encouraged all service members and others to get fully vaccinated.

Immunization to protect the US Armed Forces: heritage, current practice, and prospects - PubMed (nih.gov)

Americans serving with the U.S. Armed Forces need protection from the dangerous infections that they can contract during training, based on occupation, during overseas deployment, or because of underlying health status. This article consolidates content from several previous historical reviews, adds additional sources, and cites primary literature regarding military contributions and accomplishments.

https://www.yahoo.com/news/delta-surges-u-military-braces-171232365.html

With the Delta variant surging, the Pentagon appears poised to do something it has not so far - mandate vaccinations to safeguard against COVID-19. Half the U.S. Armed Forces are already fully vaccinated, a number that climbs when counting only Active Duty troops, excluding National Guard and reserve members. Vaccination rates are highest in the Navy, which suffered from a high-profile outbreak last year on aircraft carrier. About 73% of sailors are fully vaccinated.

EXHIBIT E

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
To: "dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil"
Bcc: [redacted]
Subject: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED)
Date: Thursday, September 30, 2021 10:22:00 AM

CLASSIFICATION: UNCLASSIFIED

Team,

Is there a data base that you all use to track adverse events related to vaccination?

If not, what is the DoD protocol for reporting vaccine adverse events?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

CLASSIFICATION: UNCLASSIFIED

EXHIBIT F

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
To: DHA NCR DHA Ops Mailbox RFI-MGR; DHA NCR Pub Health Mailbox Operation
Cc: DHA NCR DHA Ops Mailbox DHA-OPS-Center
Subject: RE: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED//FOUO)
Date: Thursday, October 14, 2021 9:40:00 AM

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Team, is there any status on this?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

From: DHA NCR DHA Ops Mailbox RFI-MGR <dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil>
Sent: Thursday, September 30, 2021 11:18 AM
To: DHA NCR Pub Health Mailbox Operation <dha.ncr.pub-health.mbx.operation@mail.mil>
Cc: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>; DHA NCR DHA Ops Mailbox DHA-OPS-Center <dha.ncr.dha-ops.mbx.dha-ops-center@mail.mil>
Subject: RE: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED//FOUO)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Public Health,

Lt Bashaw is respectfully inquiring IRT adverse event data/ event reporting.

Please feel free to ref. his email below.

Best,

DHA Operations Center
Defense Health Agency (DHA)
7700 Arlington Blvd
Falls Church VA 22042

Phone: 703-681-7588
DHA DOC NIPR: dha.ncr.dha-ops.mbx.dha-ops-center@mail.mil
DHA DOC DCIR: dha.ncr.dha-ops.mbx.dcir-mgr@mail.mil
DHA DOC RFI: dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil
DHA DOC SIPR: dha.ncr.healthcare-ops.mbx.dhahcoopsoperations@mail.smil.mil
NIPR: carlos.j.lopez35.ctr@mail.mil

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>
Sent: Thursday, September 30, 2021 10:23 AM
To: DHA NCR DHA Ops Mailbox RFI-MGR <dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil>
Subject: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Team,

Is there a data base that you all use to track adverse events related to vaccination?

If not, what is the DoD protocol for reporting vaccine adverse events?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: [redacted]
Email: [redacted]

CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY
CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

EXHIBIT G

From: Rans, Tonya Sue Col USAF DHA IMMUNIZATION (USA)
To: DHA NCR DHA Ops Mailbox RFI-MGR; DHA NCR Pub Health Mailbox Operation
Cc: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA); DHA NCR DHA Ops Mailbox DHA-OPS-Center
Subject: RE: #CAT-1581: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED//FOUO)
Date: Thursday, October 14, 2021 12:54:37 PM

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

Greetings-

All adverse events following immunization need to be reported to CDC's Vaccine Adverse Event Reporting System (VAERS)

https://vaers.hhs.gov/index.html
https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Safety-Adverse-Events/Reporting-Vaccine-Health-Problems/VAERS-Information

Very Respectfully,

//SIGNED//
Tonya Rans, MD, FACAAI
Col, USAF, MC
DHHQ 3M375
Chief, Immunization Healthcare Division, DHA-Public Health
[redacted]

The NDAA FY19, Section 711 PH Transformation milSuite site was established to serve as a resource where NDAA FY19, Section 711 PH news and updates will be provided.

https://www.milsuite.mil/book/groups/reform-of-the-mhs-ndaa2017/projects/ndaa-fy19-section-711-public-health-transformation/overview

The NDAA FY19 PH Transition Inbox was established for you to provide your questions and comments on NDAA FY19, Section 711 transition planning activities.

DHA.NCR.PUB-Health.MBX.NDAA-FY19-PH-Transition@mail.mil

From: DHA NCR DHA Ops Mailbox RFI-MGR <dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil>
Sent: Thursday, October 14, 2021 12:47 PM
To: Rans, Tonya Sue Col USAF DHA IMMUNIZATION (USA) <tonya.s.rans.mil@mail.mil>; DHA NCR Pub Health

Mailbox Operation <dha.ncr.pub-health.mbx.operation@mail.mil>
Cc: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>; DHA NCR DHA Ops Mailbox DHA-OPS-Center <dha.ncr.dha-ops.mbx.dha-ops-center@mail.mil>; DHA NCR DHA Ops Mailbox RFI-MGR <dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil>
Subject: #CAT-1581: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED//FOUO)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

DHA Ops Message
From: DHA Ops
To: IHD, Public Health

ALCON;

You were mentioned as the OPR/CPR POC for the following RFI: #CAT-1581: COVID19 Vaccine Risks/Adverse Events.

>>

From: Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Subject: COVID19 Vaccine Risks/Adverse Events.

Description: Is there a data base that you all use to track adverse events related to vaccination? If not, what is the DoD protocol for reporting vaccine adverse events?

POC: [redacted], (410) 436-5436

Suspense Date: 19 October 2021

Suspense Time: 1500

>>

Please respond to this email with any information regarding this RFI. Thank you.

Very Respectfully,

Jonathan Fitzgerald, MA
Operations Analyst | Cayuse Holdings
Defense Health Agency (DHA)
7700 Arlington Blvd
Falls Church VA 22042
Phone: 703-681-7762
DHA DOC NIPR: dha.ncr.dha-ops.mbx.dha-ops-center@mail.mil
DHA DOC DCIR: dha.ncr.dha-ops.mbx.dcir-mgr@mail.mil
DHA DOC RFI: dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil
DHA DOC SIPR: dha.ncr.healthcare-ops.mbx.dhahcoopsoperations@mail.smil.mil
NIPR: jonathan.d.fitzgerald7.ctr@mail.mil

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

EXHIBIT H

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
To: USARMY APG MEDCOM APHC Mailbox COVID-19 Task Force
Bcc: [redacted]
Subject: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED)
Date: Monday, October 25, 2021 9:25:00 AM
Attachments: RE #CAT-1581 COVID19 Vaccine RisksAdverse Events (UNCLASSIFIEDFOUO).msg

CLASSIFICATION: UNCLASSIFIED

CV19 Task Force,

Will APHC be changing their CV19 Vaccine Risk Communication Strategy (24August2021) to include dangers such as Death and other Adverse Events from the vaccines for COVID19?

According to VAERS, to date there has been 17,128 cases where Vaccine targets COVID19 and Patient Died and 818,044 adverse events.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: [redacted]
Email: [redacted]

From: DHA NCR DHA Ops Mailbox RFI-MGR <dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil>
Sent: Thursday, October 14, 2021 2:43 PM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>
Cc: DHA NCR DHA Ops Mailbox DHA-OPS-Center <dha.ncr.dha-ops.mbx.dha-ops-center@mail.mil>; DHA NCR DHA Ops Mailbox RFI-MGR <dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil>
Subject: Response to #CAT-1581: COVID19 Vaccine Risks/Adverse Events (UNCLASSIFIED//FOUO)

CLASSIFICATION: UNCLASSIFIED//FOR OFFICIAL USE ONLY

DHA Ops Message
From: DHA Ops
To: 1LT Bashaw

Good afternoon 1LT Bashaw;

DHA Ops has worked your RFI, please see the below response from Col. Rans, Chief, Immunization Healthcare Division.

All adverse events following immunization need to be reported to CDC's Vaccine Adverse Event Reporting System (VAERS)

https://vaers.hhs.gov/index.html
https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Safety-Adverse-Events/Reporting-Vaccine-Health-Problems/VAERS-Information

Very Respectfully,

//SIGNED//
Tonya Rans, MD, FACAAI
Col, USAF, MC
DHHQ 3M375
Chief, Immunization Healthcare Division, DHA-Public Health
[redacted]

Please let us know if this satisfies your ask, sir!

After 24 hours, DHA Ops will consider this RFI closed.

Thanks again and have a great rest of your day!

Very Respectfully,

Jonathan Fitzgerald, MA
Operations Analyst | Cayuse Holdings
Defense Health Agency (DHA)
7700 Arlington Blvd
Falls Church VA 22042
Phone: 703-681-7762
DHA DOC NIPR: dha.ncr.dha-ops.mbx.dha-ops-center@mail.mil
DHA DOC DCIR: dha.ncr.dha-ops.mbx.dcir-mgr@mail.mil
DHA DOC RFI: dha.ncr.dha-ops.mbx.rfi-mgr@mail.mil
DHA DOC SIPR: dha.ncr.healthcare-ops.mbx.dhahcoopsoperations@mail.smil.mil
NIPR: [redacted]

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EXHIBIT I

Suite
Account
Support
Logout
miBook
Sites
Groups
People
Places
CUI_COVID-19 Vaccination Perceptions and Messaging Formative Evaluation Results_Phase II 20210823 COVID_final.pdf
Version 1
Created by David Bolin on Aug 24, 2021 8:23 PM. Last modified by David Bolin on Aug 24, 2021 8:23 PM
CUI_COVID-19 Vaccination Perceptions and Messaging Formative Evaluation Results_Phase II 20210823 COVID_final.pdf
Edit
Manage versions
Export to PDF
More
Type here to search
72°F Mostly cloudy

General Instructions For All Screening Tests of Unvaccinated Personnel

EXHIBIT J

- If the individual being tested has any of the common COVID-19 Symptoms (*fever, cough and/or shortness of breath, lost of taste/smell, etc.)* should not be tested and not allowed access to the site
- **These tests are over the counter tests, NOT CLINICAL diagnostic assays,** and should be performed at the workplace. The Medical Treatment Facility is only responsible for rapid antigen testing their own unvaccinated MTF staff.
- All of these test kits are rapid antigen tests that provide immediate results.
- Test observers and individuals being rested should read all of the instructions before beginning the test.

General Requirements for Testing Areas:

- Close to a sink, as handwashing is the first and last step. If this is not feasible, the use of alcohol based sanitizer can be a substitute until proper handwashing can be performed.
- In a less active area to provide privacy and allow for proper social distancing (6 feet).
- The testing room must be inside a building, with an ambient room temperature of between 67 °F (19.4 °C) and 82° F (27.8 °C).. Temperatures outside of this range may affect the test.
- Storage of testing kits must be secured, and held at ambient room temperature of between 67 °F (19.4 °C) and 82° F (27.8 °C).. Temperatures outside of this range may affect the kit.
- Each individual needs to complete 2 tests spaced out in the designated time intervals and both tests ***MUST*** be performed with the same brand of kit. Testing organizers must ensure that there is a system in place to ensure this.
- Provide results to the designated Human Resource POC or Supervisor.

Requirements for Testing Program:

- Designate who will observe exams
- Determine how results will be physically provided to supervisor/HR POC
- Determine exactly where/how positive tests will be confirmed, create specific plan that can by printed and provided to individuals
- Set up area for testing and test kit storage
- Ensure that all PII/PHI is protected
- Designate how testing area will be cleaned in-between uses
- Have cleaning materials and gloves available
- Determine disposal of all testing trash

Antigen Testing Results

Positive Results:

- Report positive results to your HR POC or Supervisor
- Supervisor will record and safeguard results in accordance with local procedures established by that Activity.
- Must undergo confirmatory COVID-19 molecular (e.g. PCR) testing that is performed by a CLIA/CLIP approved laboratory using an EUA assay.
- This may be the installation's MTF, other options such as the individual's primary medical provider, or another testing provider (Urgent Care Centers, Local/State Health Departments).
- The supervisor will distribute instructions with specific details or options for individuals that test positive, in accordance FHP 23.2.

Negative Results:

- Report negative results to your HR POC or Supervisor
- Supervisor will record and safeguard results in accordance with local procedures established by that Activity.
- Schedule for a re-test using THE SAME brand of test kit

Invalid Results:

- Report invalid results and retest results to your HR POC or Supervisor.
- Supervisor will record and safeguard results in accordance with local procedures established by that Activity.
- Test must be repeated with unopened test kit.
- Follow kit protocol for the retest.

QuickVue^{tm} SOP

- Read ***ALL*** of QuickVue^{tm} User Instructions before beginning testing procedures
- Have a device that can be used to track time (clock, stop watch, cell phone, etc.)
- The testing room must be inside, with an ambient room temperature of between 67° F and 82° F. Temperatures outside of this range may effect the test.
- Storage of QuickVue^{tm} Testing Kits must be secured, and held at ambient room temperature of between 67° F and 82° F. Temperatures outside of this range may affect the kit.
- Each individual needs to complete 2 tests that are no more than 48 hours apart. Ideally Test #1 on Day 0, and Test #2 on Day 2 – with the tests being performed at approximately the same time of day.
- Both tests ***MUST*** be performed with the same brand of testing kit. Testing organizers must ensure that there is a system in place to ensure this.
- Compare results with the instructions from the kit.
- Provide results to your designated Human Resource POC or your Supervisor.
- If results are positive follow guidance for confirmatory testing.
- If results are invalid, repeat test with new, unopened test kit

Orasure IntelliSwab^{tm} Rapid Test

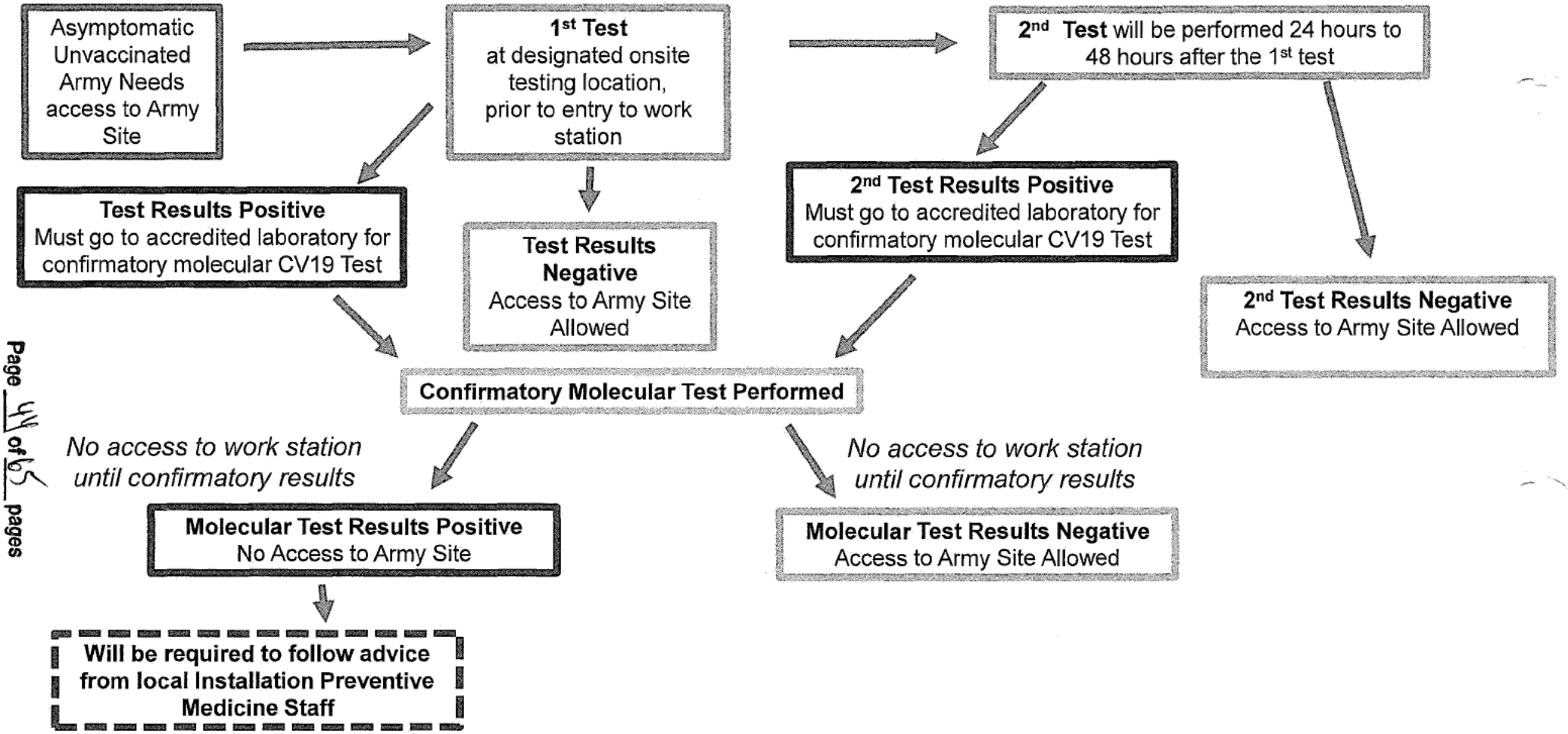
- Read ***ALL*** of Orasure Inteliswab^{tm} User Instructions before beginning testing procedures.
- Have a device that can be used to track time (clock, stop watch, cell phone, etc.).
- The testing room must be inside, with an ambient room temperature of between 67° F and 82° F. Temperatures outside of this range may effect the test.
- Storage of Testing Kits must be secured, and held at ambient room temperature of between 67° F and 82° F. Temperatures outside of this range may affect the kit.
- Each individual needs to complete 2 tests that are no more than 48 hours apart. Ideally Test #1 on Day 0, and Test #2 on Day 2 – with the tests being performed at approximately the same time of day.
- Both tests ***MUST*** be performed with the same brand testing kit. Testing organizers must ensure that there is a system in place to ensure this.
- Compare results with the instructions from the kit.
- Provide results to your designated Human Resource POC or your Supervisor.
- If results are positive follow guidance for confirmatory testing.
- If results are invalid, repeat test with unopened testing kit.

Abbot BinaxNOW^{tm} Antigen Self Test

- Read ***ALL*** of Abbot BinaxNOW^{tm} Antigen Self Test User Instructions before beginning testing procedures.
- Have a device that can be used to track time (clock, stop watch, cell phone, etc.).
- The testing room must be inside, with an ambient room temperature of between 67° F and 82° F. Temperatures outside of this range may effect the test.
- Storage of Testing Kits must be secured, and held at ambient room temperature of between 67° F and 82° F. Temperatures outside of this range may affect the kit.
- Each individual needs to complete 2 tests that are no more than 48 hours apart. Ideally Test #1 on Day 0, and Test #2 on Day 2 – with the tests being performed at approximately the same time of day.
- Both tests ***MUST*** be performed with the same kit. Testing organizers must ensure that there is a system in place to ensure this.
- Compare results with the instructions from the kit.
- Provide results to your designated Human Resource POC or your Supervisor.
- If results are positive follow guidance for confirmatory testing.
- If results are invalid, repeat test following instructions.

Calendar Week Testing Flow Chart

Performed 2 times per week (Sunday thru Saturday), intended for those working on site



One Time Testing Flow Chart

Intended for those who need one day access to the site
(i.e. a full time teleworker who needs to come on site for a single day meeting)

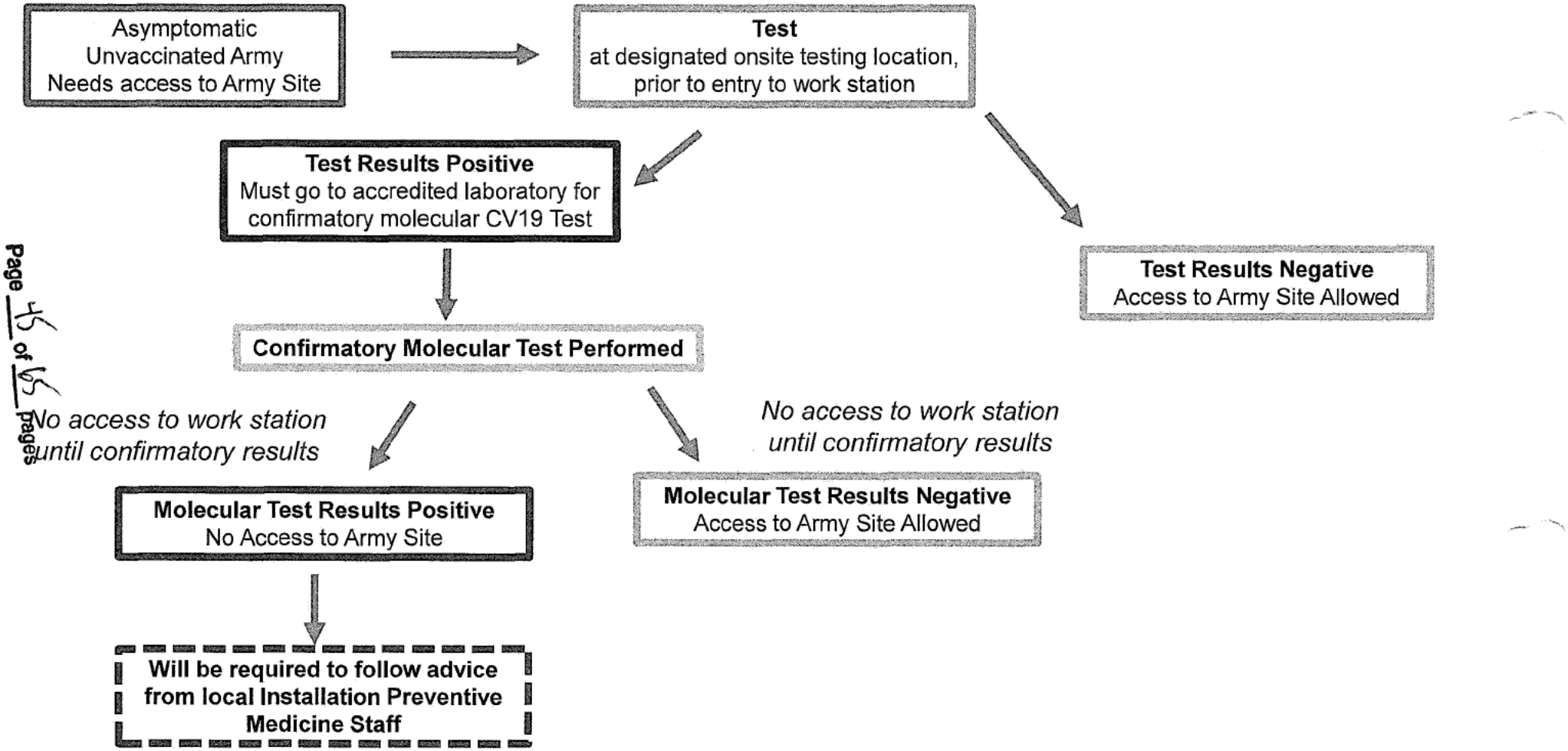


EXHIBIT K

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA); Mcnemee, Richard B Jr LTC USARMY MEDCOM APHC (USA)
Subject: RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)
Date: Wednesday, November 24, 2021 10:25:00 AM

CLASSIFICATION: UNCLASSIFIED

This is blatant discrimination based on my firmly held religious beliefs. These are unlawful orders.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
<[redacted]
Sent: Wednesday, November 24, 2021 10:22 AM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <[redacted]
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) <[redacted]
Richard B Jr LTC USARMY MEDCOM APHC (USA) [redacted]
Subject: RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
You are more than welcome to disagree with the order. Does this mean that you will likely refuse the weekly COVID testing?

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

U.S Army Public Health Center

8252 Blackhawk Road
Aberdeen Proving Ground, MD 21230

Mobile: 610-348-3876
Work Cell: 443-910-7444
[redacted]

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) [redacted]
Sent: Wednesday, November 24, 2021 9:57 AM
To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
[redacted]
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) [redacted] Mcnemee, Richard B Jr LTC USARMY MEDCOM APHC (USA) [redacted]
Subject: RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

This is blatant discrimination based on my firmly held religious beliefs. These are unlawful orders.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
[redacted]
Sent: Wednesday, November 24, 2021 9:46 AM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) [redacted]
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) <[redacted]
Subject: RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLAS[redacted]

CLASSIFICATION: UNCLASSIFIED

Mark,
I am not going to create a 4856 for this, everything is laid out in the FRAGO. From our conversation earlier about it, that served as the direct order to comply. If you do refuse to be tested then we

would proceed as normal of a failure to obey a direct order as any other order. Please let me know if you need anything else, I will send you what OPS has put together as well.

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

U.S Army Public Health Center
8252 Blackhawk Road
Aberdeen Proving Ground, MD 21230

Mobile: 610-348-3876
Work Cell: 443-910-7444
[redacted]

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) [redacted]
Sent: Tuesday, November 23, 2021 4:48 PM
To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
[redacted]
Subject: RE: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Alex, please go ahead and send over the 4856. Also, what are the ramifications for not testing?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

[redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
[redacted]
Sent: Tuesday, November 23, 2021 5:13 PM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>

Subject: FW: FRAGO 10 to HQDA EXORD 225-21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Mark, as discussed

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

U.S Army Public Health Center
8252 Blackhawk Road
Aberdeen Proving Ground, MD 21230

Mobile: 610-348-3876
Work Cell: 443-910-7444
[redacted]

CLASSIFICATION: UNCLASSIFIED
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CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED

EXHIBIT L

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)
Subject: Informal Article 138 Inquiry (UNCLASSIFIED)
Date: Friday, November 26, 2021 1:18:00 PM
Importance: High

CLASSIFICATION: UNCLASSIFIED

CPT McCarthy, I am considering filing an Article 138 Complaint. Per AR 27-10 I am required to submit an informal inquiry first. Please consider this as my informal inquiry in an attempt to resolve my complaints.

To clarify, are you requiring me to:
Self-test on a 2 times per week basis utilizing EUA test products?

Will you provide the "informed consent" required by law?

Are you aware that the law provides me the absolute right to refuse use of an EUA Product?

Please explain whether your order for me and others to be vaccinated is your order or merely an order you are yourself conveying.

Please explain whether your order for me to test frequently to return to work is your order or one that you are merely conveying.

Please provide any documentation that you base your order(s) on or you claim you are merely conveying.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
[redacted]

CLASSIFICATION: UNCLASSIFIED

EXHIBIT M

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)
Subject: RE: Telework status (UNCLASSIFIED)
Date: Monday, November 29, 2021 4:21:00 PM
Attachments: Informal Article 138 Inquiry (UNCLASSIFIED).msg

CLASSIFICATION: UNCLASSIFIED

CPT McCarthy, Per AR 27-10 you have 13 more days to respond to my Informal Article 138 Inquiry that was sent 26NOVEMBER2021 (Attached).

These orders are unlawful. This is blatant discrimination based on my firmly held beliefs.

I will be reporting for duty in the morning at building E5800. The duties I conduct are on site.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
<[redacted]
Sent: Monday, November 29, 2021 4:10 PM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) <mark.c.bashaw.mil@mail.mil>
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) <phillip.r.tally.mil@mail.mil>
Subject: RE: Telework status (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
To follow up on the other email about the testing requirements etc from LTC Rufolo and our other conversations.
You are being ordered to be tested in order to return to work. All necessary information is included in the Operation Order and FRAGOs. If you refuse to be tested you have to stay home and telework until you are tested. Also if you refuse to be tested then we will treat the situation as such and handle it from there with the necessary follow on actions.

For your test. Report to BLDG 1930 between 0730-0830 to the Staff Duty desk and have the SDO contact LTC Shearer. He will walk you through the self-test and supervise the completion of it.

If you have any further issues or concerns please let me know, thank you.

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

U.S Army Public Health Center
8252 Blackhawk Road
Aberdeen Proving Ground, MD 21230

Mobile: 610-348-3876
Work Cell: 443-910-7444
[redacted]

From: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) [redacted]
Sent: Friday, November 26, 2021 10:22 AM
To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
[redacted]
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) [redacted]
Subject: RE: Telework status (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Alex, could you please clarify, am I being ordered to telework? I supervise Soldiers and perform duties on site at E5800.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division
U.S. Army Public Health Center

Entomological Sciences Division Army Public Health Center
8638 40th Street (Bldg. E-5800)
Aberdeen Proving Ground, MD 21010-5403

Phone: (410)-436-5436
Email: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
[redacted]
Sent: Wednesday, November 24, 2021 9:48 AM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA) [redacted]
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA) <[redacted]
Subject: Telework status (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Mark,
I meant to mention as well, to follow up from the email from LTC Rufolo on the testing procedures etc, you should telework until further notice. Until either the OTC tests come in or you go out and get them on your own, but we are fine with you waiting until the tests come in. I just needed to make sure I communicated that with you. Thank you

Very Respectfully,
Alexander McCarthy
CPT, MS
HHC Commander
Eagle 6

U.S Army Public Health Center
8252 Blackhawk Road
Aberdeen Proving Ground, MD 21230

Mobile: 610-348-3876
Work Cell: 443-910-7444
[redacted]

CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED

EXHIBIT N

DEVELOPMENTAL COUNSELING FORM

For use of this form, see ATP 6-22.1; the proponent agency is TRADOC.

DATA REQUIRED BY THE PRIVACY ACT OF 1974

AUTHORITY:	5 USC 301, Departmental Regulations; 10 USC 3013, Secretary of the Army.
PRINCIPAL PURPOSE:	To assist leaders in conducting and recording counseling data pertaining to subordinates.
ROUTINE USES:	The DoD Blanket Routine Uses set forth at the beginning of the Army's compilation of systems or records notices also apply to this system.
DISCLOSURE:	Disclosure is voluntary.

PART I - ADMINISTRATIVE DATA

Name *(Last, First, MI)*	Rank/Grade	Date of Counseling
BASHAW, MARK	1LT/O-2	30NOV2021

Organization	Name and Title of Counselor
HHC, APHC	CPT Alexander McCarthy, Commander

PART II - BACKGROUND INFORMATION

Purpose of Counseling: *(Leader states the reason for the counseling, e.g. Performance/Professional or Event-Oriented counseling, and includes the leader's facts and observations prior to the counseling.)*

On 30 November 2021, you knowingly and willfully disobeyed two lawful orders from CPT McCarthy, HHC, APHC Commander. Specifically, you were ordered to do the following and did not comply:

Provide proof of a negative COVID-19 test before coming into your place of duty on 30 NOV 2021 or alternatively reporting to BLDG 1930 between 0730-0830 on 30 NOV 2021 to have a COVID-19 test administered. You failed to provide proof of a negative COVID-19 test and failed to report to BLDG 1930 as ordered.

You were ordered to leave your office on 30 NOV 2021 after your refusal to provide proof of a negative COVID-19 test. You refused the order and remained in your office.

Both of these instances constitute violations of Article 92, UCMJ- Failure to Obey an Order in that you were issued lawful orders by your Commander, you had knowledge of the orders, you had a duty to obey the orders, and you failed to obey the orders.

PART III - SUMMARY OF COUNSELING

Complete this section during or immediately subsequent to counseling.

Key Points of Discussion:

The purpose of this counseling is to document your disobeying direct orders and violating Article 92 of the Uniform Code of Military Justice.

On 29 November 2021, you were ordered to take a COVID-19 test prior to coming into the office. This is in accordance with HQDA EXORD 225-21.

On 30 Nov 2021 you ignored the orders and went to your office in BLDG 5800. CPT McCarthy then directed you to be tested or go home to telework. You did not comply and remained at your office.

You have now disobeyed 2 direct lawful orders. To be preemptively screened for COVID-19 and to telework until further notice.

You were also afforded the opportunity to get a different COVID test prior to reporting to work.

IAW AR 380-67, Personnel Security Program, para 8-2 and 8-3, the APHC Director is suspending your security clearance.

I am giving you another opportunity to comply with the order to get a COVID-19 test at BLDG E-1930. If you still refuse to be tested, then I as the Commander, will restrict your access to all APHC buildings and initiate restrictions to APG installation.

Prior to making your decision, please consider speaking with the APG Chaplain. The APG Chaplain's number is 410-278-4333. If you need the assistance of Trial Defense Services, you can contact the office at Ft. Meade.

I am counseling you for the conduct noted above. Continued conduct of this nature may result in initiation of a bar to reenlistment, administrative action to include your separation from the service, and/or punitive action under the UCMJ. If this conduct continues, action may be initiated to involuntarily separate you from the service under AR 635-200. If you are involuntarily separated, you could receive an Honorable, General Under Honorable Conditions, or Other Than Honorable discharge. If you receive an Honorable Discharge, you will be qualified for most benefits resulting from your military service. If you receive a General Under Honorable Conditions Discharge or an Other Than Honorable Discharge, you may be disqualified from reenlisting in the service for some period and you may be ineligible for many, if not all, veterans benefits to include but not limited to the Montgomery G.I. Bill and post-9/11 G.I. Bill. If you receive a General Under Honorable Conditions or Other Than Honorable Discharge, you may face difficulty obtaining civilian employment as employers may have low regard for less than Honorable discharges.

OTHER INSTRUCTIONS

This form will be destroyed upon: reassignment *(other than rehabilitative transfers)*, separation at ETS, or upon retirement. For separation requirements and notification of loss of benefits/consequences see local directives and AR 635-200.

Plan of Action *(Outlines actions that the subordinate will do after the counseling session to reach the agreed upon goal(s). The actions must be specific enough to modify or maintain the subordinate's behavior and include a specified time line for implementation and assessment (Part IV below)*

1. LT Bashaw will take a COVID-19 Test in accordance with HQDA EXORD 225-21 to prove a negative result.

2. If LT Bashaw refuses the above order, I will consider that LT Bashaw be flagged and potentially charged under Article 92 of the UCMJ.

Session Closing: *(The leader summarizes the key points of the session and checks if the subordinate understands the plan of action. The subordinate agrees/disagrees and provides remarks if appropriate.)*

Individual counseled: ☐ I agree ☐ disagree with the information above.

Individual counseled remarks:

Signature of Individual Counseled: _____ Date: _____

Leader Responsibilities: *(Leader's responsibilities in implementing the plan of action.)*

APHC Badge was confiscated from LT Bashaw and SM refused to sign counseling statement.

Signature of Counselor: MCCARTHY.ALEXANDER.P[redacted] Digitally signed by MCCARTHY.ALEXANDER.P[redacted] Date: 2021.11.30 16:20:35 -05'00' Date: 20211130

PART IV - ASSESSMENT OF THE PLAN OF ACTION

Assessment: *(Did the plan of action achieve the desired results? This section is completed by both the leader and the individual counseled and provides useful information for follow-up counseling.)*

Counselor: _____ Individual Counseled: _____ Date of Assessment: _____

Note: Both the counselor and the individual counseled should retain a record of the counseling.

EXHIBIT O

DEPARTMENT OF THE ARMY
ARMY PUBLIC HEALTH CENTER
BUILDING 5158
8252 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MD 21010-5403

30 November 2021

MEMORANDUM FOR CPT ALEXANDER MCCARTHY, HHC COMMANDER, APHC

SUBJECT: Informal Article 138 UCMJ Complaint Redress

1. On 26 November 2021, I, 1LT Mark C. Bashaw, sent you an informal Article 138 UCMJ redress and inquiry, per Army Regulation 27-10. I informed you that FRAGO 10 is an unlawful order. I also informed you that this was blatant discrimination of my firmly held religious beliefs. As of today, you have 12 more days to redress my complaint that was sent electronically via e-mail on 26 November 2021. Also, a reminder to the initial redress was sent again on 29 November 2021. Again, today I am informing you in person of this complaint with SGT Alexis Danenhower as my witness, and I am handing you a printout of the laws that govern emergency use authorized products (links within). Cease and desist all discrimination against me, and any others who might fall into the same situation within your unit. Stop the release of my personal medical information to inviduals outside the authorized chain of command. Stop harassing me with coercive phone calls and isolation meetings in your office.

2. I will continue to carry out the duties that were bestowed upon me by Law. I will continue to honor my Oath of Office to the United States of America. I request redress to my informal Article 138 UCMJ complaint IAW AR 27-10. If a resolution, or a lack of response to my initial complaint goes unsuccessful, I will then press forward with further actions IAW AR 27-10. It is my recommendation that you seek counsel.

3. The point of contact for this request is the undersigned at [redacted]

Encls:
1. EUA Laws

MARK C. BASHAW
1LT, MS

EUA LAWS

The information below lays out the US laws that govern the administration of Emergency Use Authorized (EUA) products for military personnel.

EUA products cannot be mandated for use on military personnel without informing us of the possible benefits or harms of the products and our right to refuse their administration.

21 U.S.C. 360bbb-3 says that individuals who are administered an EUA product must be informed of the "significant known and potential benefits and risks of such use" and "of the option to accept or refuse administration of the product" and "of the alternatives to the product that are available." The intent of this law is that the member has the ability to refuse the EUA product due to any potential harm that may come from administering an EUA product in or on their body.

The FDA has not approved any Covid tests. They have issued EUAs.

Additionally the SECDEF, in his 9 Aug 21 memo, stated; "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 Administration (FDA) licensure."

Based on this memo, since an EUA vaccine would require a presidential waiver, so would an EUA test. 10 U.S.C. 1107a says that the President can waive aspects of the requirements laid out in Title 21, but no such waiver has been signed to date.

The links for the two Titles and the SECDEF's memo are below.

SECDEF Memo: https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF

21 U.S.C. 360bbb-3: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section360bbb-3&num=0&edition=prelim

10 U.S.C. 1107a: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title10-section1107a&num=0&edition=prelim

EXHIBIT P

For Official Use Only

REPORT TO SUSPEND FAVORABLE PERSONNEL ACTIONS (FLAG)

For use of this form, see AR 600-8-2; the proponent agency is DCS, G-1.

SECTION I - ADMINISTRATIVE DATA

1. NAME (Last, First, MI)	2. SSN	3. RANK
BASHAW, MARK CHARLES	[redacted]	1LT

4. ☐ On Active Duty ☐ Not on Active Duty ☐ On ADT

5. ETS/ESA/MRD

6. UNIT ASSIGNED AND ARMY COMMAND
W03HAA USA PUBLIC HEALTH CENTER US ARMY MED COMMAND

7. STATION (Geographical Location)
ABERDEEN PROV GND, MD

8. HR OFFICE CONTROLLING FLAGGING ACTION AND TELEPHONE NUMBER
W4QVAA USAG ABERDEEN PG

9. THIS ACTION IS TO:

☑ Initiate a flag (Sections II and IV Only)

☐ Remove Flag (Sections III and IV Only)

SECTION II - INITIATE A FLAG

10.

☑ A FLAG IS INITIATED, EFFECTIVE 20211130 FOR THE FOLLOWING REASON:

NON-TRANSFERABLE

☑ ADVERSE-ACTION (A)

☐ INVOLUNTARY SEPARATION/DISCHARGE-FIELD INITIATED (B)

☐ REFERRED OER, AER, OR RELIEF FOR CAUSE NCOER (D)

☐ SECURITY VIOLATION/LOSS OF SECURITY CLEARANCE (E)

☐ HQDA DELAY OF PROMOTION/COMMAND ACTION (F)

☐ COMMANDER'S INVESTIGATION (L)

☐ LAW ENFORCEMENT INVESTIGATION (M)

☐ NOT RECOMM/AUTO PROM-PV2,PFC OR SPC (P)

☐ ADMIN NON-DEPLOYABLE RETENTION POLICY FOR NON-DEPLYABLE SLDR (R)

☐ NOT RECOMMENDED FOR AUTOMATIC PROMOTION TO 1LT/CW2 (T)

☐ DRUG ABUSE ADVERSE ACTION (U)

☐ ALCOHOL ABUSE ADVERSE ACTION (V)

☐ HQDA INITIATED INVOLUNTARY SEPARATION/DISCHARGE (W)

☐ OTHER (X), Reason: ____

TRANSFERABLE

☐ PUNISHMENT PHASE(ADVERSE ACTION) (H)
Date Punishment Complete: ____

☐ LACK OF CERTIFICATION- AMEDD BR (I)

☐ PHYSICAL FITNESS TEST FAILURE (PFT FAILURE) (J)

☐ ARMY BODY COMPOSITION PROGRAM (K)

☐ NON-COMPLIANCE WITH 10 USC 10206 (N)

☐ JAG ADVOCATES, LEGAL ADMIN, PARALEGALS LACK OF LICENSE/CERT (O)

☐ LAUTENBERG AMENDMENT (Q)

☐ NO APPROVED FAMILY CARE PLAN (S)

SECTION III - REMOVE A FLAG

11.

☐ A FLAG (CODE: ___) IS REMOVED, EFFECTIVE _____ FOR THE FOLLOWING REASON:

☐ FINAL-FAVORABLE REPORT (C)

☐ FINAL-UNFAVORABLE REPORT (D)

☐ FINAL-OTHER REPORT (E)

☐ DELETE-ERRONEOUS FLAG (Z)

SECTION IV - AUTHENTICATION

DISTRIBUTION
1 - Unit Commander
1 - S-1/MPD
1 - Soldier
1 - Commander, gaining unit (transfer flag only)
1 - HRC (only if Soldier is on a HQDA selection list)

NAME, RANK, TITLE, AND ORGANIZATION	SIGNATURE	DATE
Alexander McCarthy, Commander, HHC, APHC	MCCARTHY.ALEXANDER.P.1[redacted] Digitally signed by MCCARTHY.ALEXANDER.P.[redacted] Date: 2021.12.01 08:29:45 -05'00'	

DA FORM 268, MAY 2016 PREVIOUS EDITIONS ARE OBSOLETE APD LC v1.00ES

Privacy Act Data in Accordance With Privacy Act of 1974
Dispose of this Properly

EXHIBIT Q

DEPARTMENT OF THE ARMY
ARMY PUBLIC HEALTH CENTER
BUILDING 5158
8252 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MD 21010-5403

29 November 2021

MEMORANDUM FOR RECORD

SUBJECT: Phone Call Summary

1. On 29 November 2021 at 1429EST, Mrs. Rosanne Radavich, my current supervisor within the Entomological Science Division, Army Public Health Center, Aberdeen Proving Ground, MD called to inform me that I would need to be tested for COVID19 based on Army FRAGO 10.

2. I informed her that I felt this was unfair and I was being targeted based upon my firmly held religious beliefs. I also explained that this was discriminatory base on my personal medical history and religious views. I explained that all the COVID19 test products are currently under emergency use authorization. She stated that she assumed I was vaccinated. I explained that my personal medical information is between me and the commander, and I do not know how she obtained this information. I explained that I will continue to serve in the capacity in which I have been authorized to do so. I also stated that I don't understand why all of the sudden the unvaccinated are now being targeted. I have been successfully carrying out my duties in person at this base since 02 January 2020.

3. Lastly, I informed her that I submitted an Informal Article 138 UCMJ Inquiry to CPT Alexander McCarthy, HHC Commander APHC. I concluded the phone conversation by stating how unfair and discriminatory this FRAGO is, and that I would see her in the morning when I reported for duty.

4. The point of contact for this request is the undersigned at [redacted] or [redacted]

[redacted]

MARK C. BASHAW
1LT, MS

EXHIBIT R

DEVELOPMENTAL COUNSELING FORM

For use of this form, see ATP 6-22.1; the proponent agency is TRADOC.

DATA REQUIRED BY THE PRIVACY ACT OF 1974

AUTHORITY:	5 USC 301, Departmental Regulations; 10 USC 3013, Secretary of the Army.
PRINCIPAL PURPOSE:	To assist leaders in conducting and recording counseling data pertaining to subordinates.
ROUTINE USES:	The DoD Blanket Routine Uses set forth at the beginning of the Army's compilation of systems or records notices also apply to this system.
DISCLOSURE:	Disclosure is voluntary.

PART I - ADMINISTRATIVE DATA

Name *(Last, First, MI)*	Rank/Grade	Date of Counseling
BASHAW, MARK	1LT/O-2	03DEC2021

Organization	Name and Title of Counselor
HHC, APHC	CPT Alexander McCarthy, Commander

PART II - BACKGROUND INFORMATION

Purpose of Counseling: *(Leader states the reason for the counseling, e.g. Performance/Professional or Event-Oriented counseling, and includes the leader's facts and observations prior to the counseling.)*

On 30 November 2021, you knowingly and willfully disobeyed a lawful order from CPT McCarthy, HHC, APHC Commander. Specifically, you were ordered to do the following and did not comply:

You were ordered to put on a face mask inside BLDG 1607, and you refused to do so.

This instance constitutes a violation of Article 92, UCMJ- Failure to Obey an Order in that you were issued lawful orders by your Commander, you had knowledge of the orders, you had a duty to obey the orders, and you failed to obey the orders.

PART III - SUMMARY OF COUNSELING

Complete this section during or immediately subsequent to counseling.

Key Points of Discussion:

The purpose of this counseling is to document your disobeying direct orders and violating Article 92 of the Uniform Code of Military Justice.

On 30 November 2021, you entered BLDG 1607 and were directed by CPT McCarthy to put on a face mask. This order is in accordance with local federal mandates and installation Health Protection guidelines. You declined to put on a mask. CPT McCarthy again told you to put on a mask, and you refused a second time.

You were previously seen with a mask on in federal facilities and buildings prior to this interaction.

In the MFR from the Deputy Secretary of Defense on 28 July 2021, it states: "In areas of substantial or high community transmission, DoD requires all Service members, Federal employees, on site contractor employees, and visitors, regardless of vaccination status, to wear a mask in an indoor setting in installations and other facilities owned, leased or otherwise controlled by DoD."

Per paragraph 3. f. (5) of Operation Order 21-53 (COVID-19 STEADY-STATE OPERATIONS – USAMEDCOM) from Headquarters, US Army Medical Command on 07 September 2021:"(5) Read and comply with Deputy Secretary of Defense Memorandum updated mask guidance for all DoD installations and other facilities, 28 July 2021. In areas of substantial or high community transmission, DoD requires all service members, federal employees, on-site contractor employees, and visitors, regardless of COVID-19 vaccination status, to wear masks indoors on DoD installations/facilities. Data on low, moderate, substantial and high community transmission per location can be found at the CDC COVID data tracker websites, https://covid.cdc.gov/covid-data-tracker/ and https://covid.cdc.gov/covid-data-tracker/#global-counts-rates."
In the APG Memorandum from 04AUG2021 with Subject line "Aberdeen Proving Ground Installation Policy for Face Covering Requirements", paragraphs 2 and 3.

All documents can be accessed at the following links:
--https://media.defense.gov/2021/Jul/28/2002814362/-1/-1/1/UPDATED-MASK-GUIDELINES-FOR-ALL-DOD-INSTALLATIONS-AND-OTHER-FACILITIES-OSD006862-21-FOD-FINAL.PDF
---https://mitc.amedd.army.mil/sites/G357/G33%20OPERATIONS/MEDCOMOrdersPublication/OPORDs_FRAGORDs_WARNORDs/FY21%20OPORDs_FRAGORDs_WARNORDs/OPORD%2021-53%20(COVID-19%20STEADY%20STATE%20OPERATIONS)/OPORD%2021-53%20(COVID-19%20STEADY%20STATE%20OPERATIONS).pdf
---https://home.army.mil/apg/application/files/1216/2868/5588/APGInstallationMaskPolicy_Aug2021.pdf

This decision by you puts yourself and everyone around you at risk for the transmission of COVID-19. We are located in Harford County, MD. This county is currently at a High transmission level per the CDC website. Additionally, this limits your capabilities to utilize federal facilities and resources.

I am counseling you for the conduct noted above. Continued behavior of this nature may result in the initiation of a bar to reenlistment, administrative action to include your separation from the service, and punitive action under the UCMJ. If this conduct continues, action may be initiated to involuntarily separate you from the service under AR 635-200. If you are involuntarily separated, you could receive an Honorable, General Under Honorable Conditions, or Other Than Honorable discharge. If you receive an Honorable Discharge, you will be qualified for most benefits resulting from your military service. If you receive a General Under Honorable Conditions Discharge or an Other Than Honorable Discharge, you may be disqualified from reenlisting in the service for some period, and you may be ineligible for many, if not all, veterans benefits to include but not limited to the Montgomery G.I. Bill and post-9/11 G.I. Bill. If you receive a General Under Honorable Conditions or Other Than Honorable Discharge, you may face difficulty obtaining civilian employment as employers may have low regard for less than Honorable discharges.

OTHER INSTRUCTIONS

This form will be destroyed upon: reassignment *(other than rehabilitative transfers)*, separation at ETS, or upon retirement. For separation requirements and notification of loss of benefits/consequences see local directives and AR 635-200.

Plan of Action *(Outlines actions that the subordinate will do after the counseling session to reach the agreed upon goal(s). The actions must be specific enough to modify or maintain the subordinate's behavior and include a specified time line for implementation and assessment (Part IV below)*

LT Bashaw will wear a mask in all applicable areas.

Session Closing: *(The leader summarizes the key points of the session and checks if the subordinate understands the plan of action. The subordinate agrees/disagrees and provides remarks if appropriate.)*

Individual counseled: ☐ I agree ☐ disagree with the information above.

Individual counseled remarks:

Signature of Individual Counseled: Date:

Leader Responsibilities: *(Leader's responsibilities in implementing the plan of action.)*

Service Member refused to sign counseling.

Signature of Counselor: MCCARTHY.ALEXANDER.P.[redacted] Digitally signed by MCCARTHY.ALEXANDER.[redacted] Date: 2021.12.06 15:40:22 -05'00' Date: 20211206

PART IV - ASSESSMENT OF THE PLAN OF ACTION

Assessment: *(Did the plan of action achieve the desired results? This section is completed by both the leader and the individual counseled and provides useful information for follow-up counseling.)*

Counselor: Individual Counseled: Date of Assessment:

Note: Both the counselor and the individual counseled should retain a record of the counseling.

Reply Reply All Forward

RE: DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21 (UNCLASSIFIED)

EXHIBIT S

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)

To: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)

Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)

CPT McCarthy,

My complaint is as follows and has been since 26NOV21: I am being blatantly discriminating against based on my firmly held beliefs. I also cannot comply with an unlawful order.

Respectfully, I am requesting my complaint be redressed IAW 27-10 in regard to the initial Article 138 request that was sent on 26NOV21. I understand that you acknowledged receipt of this on 01DEC21.

On 06DEC21, again, I was discriminated against. Actions were taken against me via DA FORM 4856 and Article 92. However, this is not a lawful order. I have been transparent throughout. I don't want to be singled out or treated any different, based on my religious views. Would you be willing to remove the FLAG on my record?

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division U.S. Army Public Health Center

Entomological Sciences Division (Bldg. E-5800) Army Public Health Center
8638 40th Street
Aberdeen Proving Ground, MD
21010-5403

Phone: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
Sent: Wednesday, December 08, 2021 12:17 PM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)
Subject: RE: DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
Thank you.
Can you elaborate on how you believe the few phone calls were harassment?

Very Respectfully,
Alexander McCarthy

Reply Reply All Forward

RE: DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21 (UNCLASSIFIED)

EXHIBIT T

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)

To: [redacted]

Cc: [redacted]

Wednesday, December 08, 2021 9:20 AM

CPT McCarthy,

Based on my firmly held religious beliefs, I've been singled out, harassed, and discriminated against. My personal medical information was then shared outside the authorized chain of command. I've been ordered to take a test that an individual has the absolute right to refuse, per the law. I was never given an option, nor informed consent. I made this clear. I inquired and requested redress on multiple occasions. I was then continuously singled out, and then counseled. I was then stripped of my security clearance, access to place of duty, records flagged, and charged with Article 92 all because of my firmly held religious beliefs. I am also trying to ensure adherence to the established EUA laws. None of this is lawful.

Again, I respectfully request redress IAW 27-10. Thank you.

Respectfully,

Mark C. Bashaw
1LT, MS
Entomologist, Entomological Sciences Division U.S. Army Public Health Center

Entomological Sciences Division (Bldg. E-5800) Army Public Health Center
8638 40th Street
Aberdeen Proving Ground, MD
21010-5403

Phone: (410) 436-5419
Email: [redacted]

From: Mccarthy, Alexander P CPT USARMY MEDCOM APHC (USA)
Sent: Tuesday, December 07, 2021 8:20 PM
To: Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)
Cc: Tally, Phillip R 1SG USARMY MEDCOM APHC (USA)
Subject: RE: DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
In regards to the informal inquiry I would like more information to appropriately respond
Can you elaborate in more detail about the claim of discriminating against you as well as the harassment with phone calls.

Thank you

RE: DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21 (UNCLASSIFIED)

EXHIBIT U

Bashaw, Mark C 1LT USARMY MEDCOM APHC (USA)

To: [redacted]

Cc: [redacted]

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Subject: RE: DA FORM 4856 Comments for 16SEP21; 30NOV21; 06DEC21 (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

LT Bashaw,
Thank you
Can you elaborate on how you believe the few phone calls were harassment?

Very Respectfully,
Alexander McCarthy

EXHIBIT V

From: **markbashaw1** markbashaw1@protonmail.com
Subject: Email Contact - LT Bashaw
Date: December 9, 2021 at 09:06
To: [redacted]
Cc:

CPT McCarthy, due to my suspension of my security clearance, I can no longer access my army.mil email. Please send correspondence here to my personal address. Thank you.

Respectfully,

LT Bashaw

Sent with ProtonMail Secure Email.