

15 August 2022

Memorandum for all Members of Congress from Concerned Service Members

Subject: Whistleblower Report of Illegal Department of Defense Activity

- Encl: (1) Pfizer Announcement that Comirnaty will not be produced, NIH Website, 13 Sep 2021
(2) Defense Health Agency Freedom of Information Act Response 21-00359, 20 Apr 2022
(3) Assistant Secretary of Defense Health Affairs, Mandatory Vaccination of Service Members using Pfizer-BioNTech and Comirnaty COVID-19 Vaccines, 14 Sep 2021
(4) Unsigned Proposed Mandatory Vaccination of Service Members Replacement Memo submitted to Dr. Terry Adirim on 20 Oct, 2021
(5) Component Comment Review Matrix for Proposed Military Vaccination of Service Members Memorandum, Submitted 29 Oct 2021
(6) Coker v. Austin, USDC Northern District of Florida, Document 88-1, 20 May 2022
(7) Military Whistleblower Photographs of “Comirnaty-Labeled” vaccine product taken at USCG Sector Juneau, AK, 10 Jun 2022
(8) CDC COVID-19 Vaccine Lot Number and Expiration Date Database
(9) Declaration of 1LT Mark C. Bashaw, US Army, 4 Aug 2022
(10) FDA Comirnaty Supplement Approval, 16 Dec 2021
(11) Declaration of LT Chad R. Coppin, USCG, 30 Jul 2022

1. The undersigned hereby submit this report under the Military Whistleblower Protection Act (10 USC § 1034) as duty requires us to advocate for the rights of all American citizens and for the rights of service members across all branches of the Armed Forces. Pursuant to 28 USC § 1746, the undersigned declare under penalty of perjury as follows:

2. Since 24 August 2021, the Department of Defense (DoD) has unlawfully administered Emergency Use Authorized (EUA) products (i.e., products authorized but not approved by the Food and Drug Administration (FDA)) *as if* they were fully licensed FDA approved products. Military members have not been allowed to exercise their legal right to refuse EUA products, despite the Department of Justice’s (DOJ) assertion that “Comirnaty-labeled” vaccines only became available for the DoD to order on 20 May 2022. Evidence also exists that the new “Comirnaty-labeled” products are not FDA approved in accordance with applicable laws.

3. Americans never lose the right to legally refuse an EUA product. EUA law 21 USC § 360bbb imposes significant responsibilities upon the government to inform Americans of their rights. The only exception to the government’s duty to inform citizens of their rights is in a narrowly defined presidential waiver process for the military per 10 USC § 1107a. This exception only waives the required condition that service members be informed of their right to refuse an EUA product. The 105th Congress passed 10 USC § 1107 into law as part of the Fiscal Year 1998 National Defense Authorization Act as a result of the injuries sustained by Gulf War veterans due to forced administration of investigational new drugs. This was quickly followed by the passage of 10 USC § 1107a, which specifically addressed use of EUA products. Similar to the Constitutional violation of failing to provide a suspect their Miranda Rights, not informing a potential recipient of their right to accept or decline an EUA product, either by presidential waiver or by omission, does not remove the underlying rights protected by statute and the Constitution.

4. Prior to the administration of an EUA product, the recipient is required to be informed *inter alia* of the option to accept or refuse administration of the EUA product, as codified in 21 USC § 360bbb-3(e)(1)(A)(II)(iii). This right is a required condition that the Secretary of Health and Human Services (HHS) shall include for the authorization of any unapproved product covered by an emergency declaration. This means that by law, no one can mandate EUA products and the Government must inform recipients of their right to refuse. Service members are not being informed of the option to refuse administration of EUA products, nor are they provided with any other required information such as the risks associated with the product. Instead, military leadership is coercing service members into accepting administration of EUA products through unlawful threats against their careers and livelihoods. The failure of numerous appeals to leadership, Equal Opportunity complaints, Article 138 requests for redress, Inspector General complaints, and Congressional inquiries filed by the undersigned and those similarly situated, indicate that the military has no intention of following the law or their own regulations. Accordingly, Congress must act swiftly to end this unlawfulness and preserve the rights, readiness, and character of the military.

5. The law justly enshrines the principle that where there is risk, there must be legally effective informed consent. There must be full disclosure of relevant information and it must be absent coercion and undue influence. For risky medical products, like EUA pandemic products, Congress provides complete liability protection against any claim of loss for all persons and entities who are involved in the manufacture, distribution, planning, or administration of those products. 42 USC § 247d-6d(a)2(A) defines loss very broadly, listing everything from death to fear of emotional injury to property loss from business interruptions. For clarity, persons and entities covered by liability protections include product developers, manufacturers, and administrators (health care personnel), as well as all related governmental personnel at the local, state, and federal levels, including members of Congress and the DoD. Accepting administration of an emergency use product means the individual accepts all the health, legal, financial, and medical risks arising from that product.

6. Injured recipients (or their families, in the event of death) who voluntarily received an EUA product only have one legal method to recoup losses: by filing a compensation claim through the Countermeasure Injury Compensation Program (CICP) as per 42 USC § 247d-6e. To date, there are 8,808 total COVID-19 related claims in the CICP. Claims of loss typically have a benefit cap of \$379,000, however HHS has not granted a single dollar to those 8,808 claimants.¹ Due to complete liability protections during declared emergencies, neither the Executive Branch of government nor any manufacturer, developer, producer, or administrator of covered products have any incentive to ensure the safety or efficacy of the products they are providing. The pandemic demonstrated that without congressional action the executive branch and administrative state will continue to baselessly declare and extend emergencies, exercising powers that exceed federal authority.

7. In a memorandum issued on 9 August 2021, Secretary of Defense (SECDEF) Lloyd Austin indicated his comprehension of EUA law, stating, “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, whichever comes first.”² On 23 August 2021, the FDA approved

¹ <https://www.hrsa.gov/cicp/cicp-data#table-1>, accessed 10 Aug 2022

² <https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF>, accessed 10 Aug 2022

(fully licensed) the first COVID-19 vaccine under the trade name Comirnaty®. Of interest, the FDA ended its legal marketing status that same day.³ The next day, SECDEF issued a memorandum that stated “[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance.”⁴ Shortly thereafter, in a posting on the National Institute of Health website, enclosure (1), Pfizer announced they would not produce any of the licensed product “over the next few months while EUA authorized product is still available and being made available for U.S. distribution.” For nine months afterwards, this lack of fully licensed product has been confirmed by hundreds of service members, who have provided military leadership hundreds of complaints, many with photo evidence, indicating all vials found in Military Treatment Facilities were EUA products. A Freedom of Information Act (FOIA) response from the Defense Health Agency (DHA) in April 2022, enclosure (2), confirmed DHA had no record of “Comirnaty” COVID-19 vaccines being ordered, received, in stock, available, or administered to any service member by any service branch (Army, Navy, Marine Corps, Air Force, or Coast Guard).

8. Subordinate commanders failed to adhere to both the law and to SECDEF guidance regarding licensure of products. Military commanders ordered service members to become vaccinated against COVID-19 without consideration for the EUA status of available vaccines. The mandate also set an unrealistic policy of 100% vaccination. DoD instructions clearly provide for religious accommodation and medical exceptions to vaccines, nearly 100% of which are being systematically disapproved. Federal courts have acknowledged that the military’s implementation of these instructions have been so egregious that numerous injunctions have been levied against the DOD for violating the Constitution, Religious Freedom Restoration Act, and DoD policy.

9. The DoD induced confusion by publishing memoranda asserting that the FDA-approved Comirnaty® could be used interchangeably with EUA products. Assistant Secretary of Defense for Health Affairs (ASD HA), Dr. Terry Adirim, wrote a 14 September 2021 memorandum, enclosure (3), stating “these two vaccines are interchangeable and DoD health care providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine.” In her memorandum, she cited the FDA’s Q&A website to justify use of EUA Pfizer-BioNTech vaccines in lieu of Comirnaty®. The website provided medical advice regarding the use of the EUA product to complete a “vaccination series,” stating medical providers could use the two products “interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns.”⁵ The FDA website did not address the legal difference between the products, nor was it a determination of biosimilarity or interchangeability, which has specific requirements per 42 USC § 262(k) - Licensure of Biological Products as Biosimilar or Interchangeable. The law cites critical requirements for interchangeable products, including that: 1) a sponsor must submit an application for licensure of the biosimilar product, 2) both products become fully licensed before being declared interchangeable, and 3) per 42 USC § 262(k)(7)(A), “[a]pproval of an application under this subsection [Licensure of Biological Products as Biosimilar or Interchangeable] may not be made effective by the Secretary until the date that is 12 years after

³ The approval of Comirnaty® listed the marketing beginning and end date as 23 Aug 2021.

⁴ <https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF>, accessed 10 Aug 2022

⁵ <https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna>, accessed 10 Aug 2022

the date on which the reference product was first licensed under subsection (a).” By law, no product may be legally declared interchangeable with Comirnaty[®] until at least 24 August **2033**. As further evidence, the FDA’s authoritative source for approved biologics, the “Purple Book,” lists “no interchangeable data at that time” for Comirnaty[®].⁶ Dr. Adirim, and every military commander who cited her memo as justification for their unlawful orders, ignored the legal distinction between the two products, most notably that one was a licensed product and the other an EUA product, which comes with an inherent right to refuse. This legal distinction was clearly cited by the FDA in every Pfizer BioNTech and Moderna EUA re-issuance letter since full licensure.⁷

10. The DoD cannot claim ignorance with regard to the legal differences between an EUA product and a licensed product that purports to be medically interchangeable but has not become statutorily interchangeable per 42 USC § 262(k). SECDEF statements reflected comprehension of legal requirements associated with EUA products. Additionally, an unsigned memo that was developed by the DoD to replace Dr. Adirim’s 14 September 2021 memo, enclosure (4), provided specific guidance that if a service member rejected the EUA product, Health Care Providers should secure and offer the fully licensed product “prior to any punitive action being taken against the Service Member.” An official internal review, enclosure (5), provided by reviewers of this memo, demonstrates the subsequent attempt to cover up the DoD’s grievous mistake. One comment even acknowledges that this correction “subverts” the current vaccination policy and may open up the service to “increased litigation from individuals who have been mandated since 24 August to be vaccinated.” The correction memo was ultimately rejected, demonstrating DoD’s awareness and support of illegal prosecution of military members, and a lack of integrity to resolve the situation.⁸

11. When the DOD’s unlawful misrepresentation of interchangeability began to fail in federal court, the DoD and DOJ began to allege that the Pfizer EUA vaccine products were compliant with Biologics License Application (BLA) requirements. They coined the term “BLA-Compliant” in an effort to argue that mandating an EUA product was lawful. BLA requirements, however, include an obligation to properly label biologic products. EUA products are not compliant with BLA requirements because the EUA label does not match the BLA approved product label (i.e. Comirnaty[®]). Senior DoD officials, supported by the DOJ, misrepresented, circumvented, obfuscated, and ultimately violated U.S. law to achieve the unreasonable and detrimental goal of 100% vaccination of the military. Military leadership’s disregard for U.S. law has not been limited to vaccines. COVID-19 test kits⁹ and masks¹⁰, all of which are EUA products, have been mandated as well.

12. Until May 2022, EUA products were the only COVID-19 vaccines available to the U.S. military. FDA approved vaccines were not available. In spite of this, military leaders coerced and

⁶ <https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty>, 10 Aug 22

⁷ See page 16 of the most recent EUA reissuance letter for an example: <https://www.fda.gov/media/150386/download>, accessed 10 Aug 2022.

⁸ In this same memo, the author admits they are “operating under the belief that the lot issue is a distinction without a difference from a... legal perspective.” They also admit that to reverse course and admit “that the distinction does matter would probably require significant remedial actions.” See page 5 of enclosure (5) to read these comments.

⁹ <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>, accessed 14 Aug 22

¹⁰ <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>, accessed 14 Aug 22

attempted to force administration of EUA products on unwilling service members, pursuing punitive action against many who did not comply. On 20 May 2022, the DOJ filed a memorandum on behalf of the defendants (Austin, et al), enclosure (6), in the Coker v. Austin case in Federal District Court for the Northern District of Florida in which they attempted to undermine the plaintiff's legal standing to challenge in court by asserting that "[w]hile they [the plaintiffs] may believe that FDA-approved vaccines are "not available," the Comirnaty-labeled vaccine is in fact available for DoD to order as of today's date [20 May 2022]." Shortly thereafter, "Comirnaty-labeled" products began appearing in very limited quantities on military installations, including the "Comirnaty-labeled" product seen in enclosure (7). The sudden appearance of "Comirnaty-labeled" vials indicate that the DoD was mandating the use of EUA vaccines for nine months prior to May 2022.

13. In accordance with 21 USC § 360bbb-3(c), the Secretary of HHS may only authorize a product for emergency use if there is no fully licensed product available. The HHS Secretary is further obligated by 21 USC § 360bbb-3(g) to review the progress made by fully licensed products and potentially revoke a product's emergency authorization if a fully licensed product becomes available. If the "Comirnaty-labeled" products identified in enclosure (7) are licensed products, the HHS Secretary should have revoked the various authorizations enabling unapproved EUA biological products to remain on the market. These revocations have not occurred.

14. The status of the new "Comirnaty-labeled" product is also in question. The CDC maintains a database, enclosure (8), of "all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA) for distribution in the United States."¹¹ The vial depicted in enclosure (7), which is "Comirnaty-labeled," has the lot number FW1331. This lot number appears in the CDC EUA database as testified by military whistleblower, 1LT Mark Bashaw, per enclosure (9). Misrepresenting an EUA manufactured lot of vaccine product as a fully licensed product is a violation of labeling requirements per 42 USC § 262.

15. Further evidence of potential fraud related to the "Comirnaty-labeled" product pictured in enclosure (7) is Pfizer's admission that the vaccine product with lot number FW1331 was not produced in a BLA approved manufacturing facility. The 16 December 2021 FDA approval letter licensing Comirnaty[®], enclosure (10), specifies that the licensed product be manufactured at the Pfizer Manufacturing facility in Puurs, Belgium. Per the testimony provided by LT Coppin in enclosure (11), Pfizer admits that Lot Number FW1331 was actually manufactured in France, not in the approved facility in Belgium. Fully licensed products are required to follow all Biologic License Application requirements. Affixing a "Comirnaty-label" on a product that has not followed all BLA requirements constitutes fraudulent labeling – a federal crime.

16. With regard to fraudulent labeling, 42 USC § 262(b) clearly states that "[n]o person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark." The penalties for such violations are stated in 42 USC § 262(f): "Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding \$500 or by imprisonment not exceeding one year, or by both such fine and imprisonment." It is also important to note that fraud voids liability protections and consent agreements. The DoD and its distributed commands (and commanders) may be exposing

¹¹ Enclosure (8) is the database intro page: <https://vaccinecodeset.cdc.gov/LotNumber>, accessed 5 Aug 2022

themselves to significant liability by willfully misrepresenting these biologics. Furthermore, as there is no long-term safety data for these products, a link between COVID-19 vaccination and long-term health problems could have a crippling impact on the future readiness of our military. Fraudulent activity and health impacts could result in extraordinary cost to the taxpayer. These challenges add to the DoD's current recruiting and retention crisis brought on by the systemic violation of rights and the destruction of sacred trust with service members.

17. The military is hemorrhaging outstanding military men and women of conscience, who are attempting to defend the rule of law at great personal cost. The DoD has unlawfully discharged thousands of service members for exercising their legal right to decline emergency use products. Ensuring timely DoD adherence to U.S. law requires Congressional action. As the oversight authority, you have the ability to investigate the HHS Secretary's recurring declarations of emergency, as well as potential crimes associated with unlawful administration of EUA products and biologic product labeling fraud. Failure to take swift action will cause continued, irreversible harm to the basic human rights of American citizens while further damaging our national security.

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

Executed on 15 August, 2022.

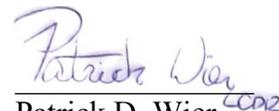

John S. McAfee
Colonel, USAF


Jon C. Cheek
Lt. Colonel, US Army


Olivia K. Degenkolb
Commander, USN


Robert A. Green Jr.
Commander, USN


David I. Beckerman
Major, USAF


Patrick D. Wier
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Joshua P. Hoppe
Capt, USMC


Chad R. Coppin
LT, USCG


Mark C. Bashaw
1LT, US Army



NEWS: DailyMed Announcements

SEPTEMBER 13, 2021

Pfizer received FDA BLA license for its COVID-19 vaccine

Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older ([COMIRNATY](#)). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename.

At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels.

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Enclosure (1)

Enclosure 10. DHA FOIA Response (Redacted)



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

April 20, 2022



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

Dear [REDACTED]:

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

A review of your request shows that you are seeking:

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

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

Your appeal must be written and postmarked within 90 calendar days of the date of this letter, should cite the above referenced case number, and should be clearly marked "Freedom of Information Act Appeal." To submit electronically, email DHA.FOIAappeals@mail.mil. To submit via postal delivery, send your written appeal to:

Defense Health Agency
FOIA Service Center
Attention: FOIA Appellate Authority
7700 Arlington Boulevard, Suite 5101
Falls Church, VA 22042-5101

Enclosure (2)

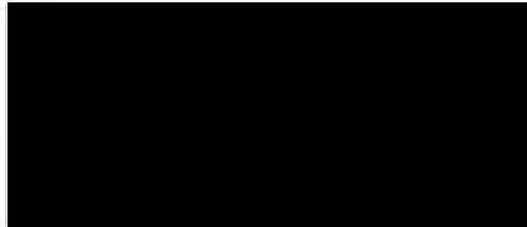
In addition, please note you have the right to seek dispute resolution services from the DHA FOIA Public Liaison via the following contact information:

Defense Health Agency
Enterprise Administration and Systems Integration Division
Attn: DHA FOIA Public Liaison
7700 Arlington Blvd, Suite 5101
Falls Church, VA 22042-5101
Email: DHA.FOIAPublicLiaison@mail.mil
Phone: 1+ (571) 438-2740

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Federal FOIA Ombudsman's office offers mediation services through the Office of Government Information Services (OGIS) to help resolve disputes between FOIA requesters and Federal agencies. You may contact OGIS via the following:

National Archives and Records Administration
Office of Government Information Services
8601 Adelphi Road - OGIS
College Park, MD 20740-6001
Email: ogis@nara.gov
Phone: 1+ (202) 741-5770 or Toll Free: 1-877-684-6448

If you have any questions about the processing of your request under the FOIA, please contact the DHA FOIA Requester Service Center at (703) 275-6017, or email us at DHA.FOIA@mail.mil.



FOIA Officer
DHA FOIA Requester Service Center



ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND
RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND
RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER
AND RESERVE AFFAIRS)
DIRECTOR, DEFENSE HEALTH AGENCY

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

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the Comirnaty vaccine, made by Pfizer-BioNTech, as a two-dose series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the Comirnaty vaccine. Per FDA guidance, these two vaccines are “interchangeable” and DoD health care providers should “use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine.”¹

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

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

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

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

¹ FDA, “Q&A for Comirnaty (COVID-19 Vaccine mRNA),” <https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna>, accessed September 10, 2021.



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

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

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

SMITH.DAVID.
J.1085480975

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

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

RECOMMENDATION: Sign the action memo next under.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CATMS2010202125C87X/UPR003415-21

Enclosure (4)



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

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

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

- References: (a) Pfizer-BioNTech/COMIRNATY[®] Fact Sheet for Healthcare Providers
Administering Vaccine
(b) Vaccine Information Fact Sheet for Recipients and Caregivers²
(c) Centers for Disease Control and Prevention's Morbidity and Mortality
Weekly Report³

This memorandum rescinds and replaces Assistant Secretary of Defense for Health Affairs Memorandum, "Mandatory Vaccination of Service Members using the Pfizer-BioNTech COVID-19 and Comirnaty[®] COVID-19 Vaccines," dated September 14, 2021.

On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the Biologics License Application (BLA) for the Pfizer-BioNTech/Comirnaty[®] vaccine, manufactured by Pfizer-BioNTech, as a two-dose primary series for prevention of coronavirus disease 2019 (COVID-19) in persons aged 16 years or older. Previously, on December 11, 2020, the FDA issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine, which has the same formulation as the BLA produced Pfizer-BioNTech/Comirnaty[®] vaccine. Pfizer-BioNTech/COMIRNATY[®] Fact Sheet for Healthcare Providers Administering Vaccine (reference (a)), Vaccine Information Fact Sheet for Recipients and Caregivers (reference (b)), and the Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report (reference (c)), "Comirnaty has the same formulation and can be used interchangeably with the Pfizer-BioNTech COVID-19 vaccine used under EUA without presenting any safety or effectiveness concerns."

Consistent with FDA guidance, the Department of Defense (DoD) health care providers will utilize both the EUA-manufactured Pfizer-BioNTech COVID-19 vaccine and the BLA-manufactured Pfizer-BioNTech/Comirnaty[®] COVID-19 vaccine interchangeably for the purpose of vaccination Service members in accordance with Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," dated August 24, 2021. Service members who request the BLA-manufactured Pfizer-BioNTech/Comirnaty COVID-19 vaccine for the primary two-dose series shall be informed of FDA guidance on Pfizer-BioNTech/Comirnaty[®]'s BLA formulation being the same as the Pfizer-BioNTech COVID-19 vaccine manufactured under (EUA and that FDA and CDC has advised that the two vaccines can be used interchangeably without presenting any safety or

effectiveness concerns. If a Service member, after medical counseling, declines administration of the EUA-manufactured Pfizer-BioNTech COVID-19 vaccine but will accept the BLA-manufactured product, DoD health care providers should engage with their logistics chain to secure and administer the BLA-manufactured Pfizer-BioNTech/Comirnaty[®] product prior to any punitive action being taken against the Service member

Please direct any questions or comments to the following email address: dha.ncr.ha-support.mbx.policy-hrpo-kmc@mail.mil.

Gilbert R. Cisneros, Jr.

SELECT A CLASSIFICATION
DoD ISSUANCE COORDINATION RESPONSE

COMPONENT COORDINATOR RESPONSE

October 29, 2021

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

On behalf of my Component, my formal response to this issuance is: Nonconcur. Below are comments that detail my Component's objections to this issuance.

My point of contact for this action is Lt Col David Sayers, usaf.pentagon.af-sg.mbx.team-covid-19@mail.mil.

X

HENDRIX.CHRISTINA.
MARIE.1253311483

Digitally signed by
HENDRIX.CHRISTINA.MARIE.1253
311483
Date: 2021.10.29 20:30:05 -04'00'

Double-click the 'X' to insert a digital signature
or print and sign a hard copy.

Coordinating Official's Name: JOHN A. FEDRIGO

Coordinating Official's Position Title: Acting Assistant Secretary (Manpower and Reserve Affairs)

Coordinating Official's Component: Department of the Air Force

SELECT A CLASSIFICATION

DoD ISSUANCE COORDINATION RESPONSE: Issuance Type and Number, "Title"						
CLASS	#	PAGE	PARA	BASIS FOR NON-CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL
Choose an item.	1	1	Throug hout	<input type="checkbox"/>	<p>Coordinator Comment and Justification: This memo uses Comirnaty® and COMIRNATY® throughout the document.</p> <p>Coordinator Recommended Change: Use either all upper case throughout the document.</p> <p>Originator Response: Choose an item.</p> <p>Originator Reasoning:</p>	AFMRA/SG3PM 703-681-9307 usaf.pentagon.af- sg.mbx.team-covid- 19@mail.mil
U	2		2	<input type="checkbox"/>	<p>Coordinator Comment and Justification: original:</p> <p>“Pfizer-BioNTech/COMIRNATY® Fact Sheet for Healthcare Providers Administering Vaccine (reference (a)), Vaccine Information Fact Sheet for Recipients and Caregivers (reference (b)), and the Centers for Disease Control and Prevention’s Morbidity and Mortality Weekly Report (reference (c)), “Comirnaty has the same formulation and can be used interchangeably with the Pfizer-BioNTech COVID”</p> <p>is an incomplete sentence</p> <p>Coordinator Recommended Change: consider leading in with IAW with the following references, etc... OR ADD <u>states</u>: “COMIRNATY has the same formulation...”</p> <p>Originator Response: Choose an item.</p> <p>Originator Reasoning:</p>	AFMRA/SG3PM 703-681-9307 usaf.pentagon.af- sg.mbx.team-covid- 19@mail.mil

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CLASS	#	PAGE	PARA	BASIS FOR NON-CONCUR?	COMMENTS, JUSTIFICATION, AND ORIGINATOR JUSTIFICATION FOR RESOLUTION	COMPONENT AND POC NAME, PHONE, AND E-MAIL
U	3		3	<input type="checkbox"/>	<p>Coordinator Comment and Justification: Admin change</p> <p>Coordinator Recommended Change: change vaccination to vaccinating “and the BLA-manufactured Pfizer-BioNTech/Comirnaty® COVID-19 vaccine interchangeably for the purpose of vaccinating Service members in accordance with Secretary of Defense Memorandum,”</p> <p>Originator Response: Choose an item.</p> <p>Originator Reasoning:</p>	<p>AFMRA/SG3PM 703-681-9307 usaf.pentagon.af-sg.mbx.team-covid-19@mail.mil</p>
U	4		3		<p>Coordinator Comment and Justification: Admin change</p> <p>Coordinator Recommended Change: remove parenthesis from (EUA and add a period at end of last sentence “the Pfizer-BioNTech COVID-19 vaccine manufactured under EUA and that FDA and CDC has advised that the two vaccines can be used interchangeably without presenting any”</p> <p>Originator Response: Choose an item.</p> <p>Originator Reasoning:</p>	<p>AFMRA/SG3PM 703-681-9307 usaf.pentagon.af-sg.mbx.team-covid-19@mail.mil</p>

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Choose an item.	5	2	1	<input type="checkbox"/>	<p>Coordinator Comment and Justification: This counseling can be provided by a Commander or someone in the chain of command. Medical can be available to answer any specific questions.</p> <p>Coordinator Recommended Change: Remove "medical". "If a Service member, after medical counseling, declines administration of the EUA-manufactured Pfizer-BioNTech COVID-19 vaccine but will accept the BLA-manufactured product, DoD health care providers should engage with their logistics chain to secure and administer the BLA-manufactured Pfizer-BioNTech/Comirnaty® product prior to any punitive action being taken against the Service member"</p> <p>Originator Response: Choose an item.</p> <p>Originator Reasoning:</p>	<p>AFMRA/SG3PM 703-681-9307 usaf.pentagon.af-sg.mbx.team-covid-19@mail.mil</p>

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	6	1-2	all	☒	<p>Coordinator Comment and Justification: Significant concerns with the memo statement "Service members who request the BLA-manufactured Pfizer-BioNTech/Comirnaty COVID-19 vaccine for the primary two-dose series shall be informed of FDA guidance on Pfizer-BioNTech/Comirnaty®'s BLA formulation being the same as the Pfizer-BioNTech COVID-19 vaccine manufactured under (EUA and that FDA and CDC has advised that the two vaccines can be used interchangeably without presenting any safety or effectiveness concerns. If a Service member, after medical counseling, declines administration of the EUA-manufactured Pfizer-BioNTech COVID-19 vaccine but will accept the BLA-manufactured product, DoD health care providers should engage with their logistics chain to secure and administer the BLA-manufactured Pfizer-BioNTech/Comirnaty® product prior to any punitive action being taken against the Service member."</p> <p>The memo states the vaccines can be used interchangeably; however, this paragraph would suggest DoD considers them different, and as different, cannot carry out punitive action against the Service member until they have the opportunity for a BLA-manufactured vaccine. This subverts our current DAF vaccination mandate and may open up the Air Force for increased litigation from individuals who have been mandated since 24 August to be vaccinated. If there is no difference that can otherwise be communicated, we recommend non-concur with this paragraph as it subverts current policy. We are all operating under the belief that the lot issue is a distinction without a difference from a health/safety/medical/legal perspective. As the services have taken action, possibly include adverse action, based on a belief that the distinction is one without meaningful difference, OSD retrenchment signifying that the distinction does matter would probably require significant remedial actions.</p> <p>Coordinator Recommended Change: Non-concur as written.</p> <p>Originator Response: Choose an item.</p>	<p>AFMRA/SG3PM 703-681-9307 usaf.pentagon.af-sg.mbx.team-covid-19@mail.mil</p>

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					Originator Reasoning:	

SELECT A CLASSIFICATION

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HOW TO FILL OUT THE DD 818 MATRIX

GENERAL GUIDANCE:

- **To sort table** by page/paragraph number, hover your mouse over the top of the first cell in the "page" column until a downward arrow appears; click and drag to the right to select both page and para columns. Under Paragraph on the Home ribbon, select A-Z button, set to sort by Column 3 and then Column 4, and select "OK." **To add new rows**, copy and paste a blank row to keep consistent formatting. **To add automatic numbering to column 2**, select entire column and click on the Numbering button under Paragraph on the Home ribbon.

COORDINATING OSD AND DOD COMPONENTS:

- Do not use the DD Form 818-1.
- Fill in the memo indicating your Component's position on the issuance. Fill in the authorized coordinator's name, position, and Component. The authorized coordinator (digitally) signs the response after the comment matrix has been completed. **Making additional changes after filling in a digital signature invalidates and removes the signature.**
- Use the comment matrix to provide comments to the OSD Component that created the issuance. Complete the header and footer and Columns 1 -7:

COLUMN 1 Enter the classification of the comment. If any material is **classified**, follow DoDM 5200.01 guidance for marking the document. If all comments are unclassified, mark the header and footer and ignore the column.

COLUMN 2 Order comments by the pages/paragraphs that they apply to in Columns 3 and 4.

COLUMNS 3&4 As stated.

COLUMNS 5 Only mark this box if you non-concur with the issuance and the comment in the applicable row is part of the basis for that non-concur. A nonconcur is typically used only when an issuance contains: (a) a violation of the law or contradiction of Executive Branch policy or of existing policy in a DoDD, DoDI, or other instrument approved by the Secretary or Deputy Secretary of Defense; or (b) an unnecessary risk to safety, life, limb, or DoD materiel; waste or abuse of DoD appropriations; or unreasonable burden on a DoD Component's resources.

COLUMN 6 Place only one comment per row. Enter your comment, justification, and recommended changes in the first two areas provided. If any material is **classified**, follow DoDM 5200.01 guidance for marking the document.

COLUMN 7 As stated.

SELECT A CLASSIFICATION

DoD ISSUANCE COORDINATION RESPONSE: Issuance Type and Number, "Title"						
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- **Review** the comments, **resolve** any conflicting views, and **confirm** that the completed matrix accurately represents your Component's position. Upload the form to the DoD Directives Program Portal in **Microsoft Word format (.docx)**, with the signed memo representing your Component's position.

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

BENJAMIN COKER, *et al.*,

Plaintiffs,

v.

LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*,

Defendants.

Case No. 3:21-cv-01211-AW-HTC

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO COMPEL**

As pertinent here, Plaintiffs challenge the Food and Drug Administration’s (“FDA”) approval of the Biologics License Application (“BLA”) for the Comirnaty COVID-19 vaccine (including its explanation that certain lots of vaccine with an Emergency Use Authorization label are still BLA-compliant), and the Department of Defense’s (“DoD”) requirement that service members become vaccinated against COVID-19 with an FDA-approved vaccine. Plaintiffs contend that Comirnaty is “not available,” they have “been denied” Comirnaty and a BLA-compliant vaccine, and DoD’s requirement therefore violates their “informed consent rights.”

Defendants propounded targeted discovery requests on March 25, 2022, requesting (as relevant here) the documents identified in Plaintiffs’ initial disclosures (RFP 2) and information on which Plaintiffs would—or would not—take Comirnaty, Spikevax (the Moderna vaccine approved by the FDA), or a BLA-compliant vaccine (Interrogatories 3-8). Exs. 1-2. Plaintiffs’ responses on April 24 failed to include any documents responsive to RFP 2 and provided non-responsive answers that failed to respond to the substance of Interrogatories 3-8. Ex. 3 at 2-3. Undersigned counsel then engaged Plaintiffs’ counsel in multiple meet and confer discussions on April 29, May 6, May 16, and May 18 in an attempt to avoid seeking judicial intervention. Exs. 3-5. Through that process, Plaintiffs provided just three documents out of the many listed in their initial disclosures in response to RFP 2, and declined to provide

a further response to Interrogatories 3-8. Ex. 4 at 2; Ex. 5 at 1-2. Because the information requested is undeniably relevant and proportional to the needs of the case—indeed, Plaintiffs have never objected or suggested otherwise—Defendants request that the Court grant their motion and compel Plaintiffs’ full and complete responses to RFP 2 and Interrogatories 3-8.¹

STANDARD OF REVIEW

“Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case.” Fed. R. Civ. P. 26(b)(1). The Supreme Court has “construed broadly” what constitutes relevant discovery, *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978), and the Federal Rules “strongly favor full discovery whenever possible,” *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985). The party resisting discovery “bears the burden of establishing lack of relevancy or undue burden.” *Gober v. City of Leesburg*, 197 F.R.D. 519, 521 (M.D. Fla. 2000).

ARGUMENT

I. Defendants are Entitled to the Documents Identified in Plaintiffs’ Initial Disclosures (RFP 2).

RFP 2: “Any and all documents identified in your initial disclosures in this

¹ Plaintiffs do not object to Defendants’ motion as untimely, as the instant dispute arose within the last two weeks of discovery and Defendants diligently attempted to resolve it without court intervention. *See* Dkt. No. 48 ¶ 8; Ex. 4 at 5.

action.” Ex. 1 at 5. Plaintiff’s initial disclosures identified broad categories of documents, including “medical exemption requests and related documents (e.g., antibody tests)” and “medical records.” Ex. 6 at 3-4.

Plaintiffs did not assert any objections to this request. Ex. 7 at 3; *see also Griffin v. GEICO Gen. Ins. Co.*, 2011 WL 13235056, at *2 (N.D. Fla. Oct. 25, 2011) (“Failure to make a proper timely objection, even though a party had one to make, waives the objection.”). Plaintiffs responded:

“Plaintiffs’ Rule 26(a)(1) disclosures state that Plaintiffs are in possession of: administrative record materials; medical exemption requests and documents related to their medical exemption requests; Plaintiffs’ medical records; Plaintiff’s personnel records; and Plaintiffs’ religious accommodation requests and appeals, and materials related to those requests or appeals. Defendants are already in possession of those documents. Please also see the documents produced in PL00001-00053 and PL00054-00103.” Ex. 7 at 3.

Plaintiffs’ document production, however, only contains antibody/COVID-19 test results for Plaintiffs Cothran, Morgan, and Stermer. Ex. 5 at 1. The production contains no other “related documents (e.g., antibody tests)” and no “medical records” for any Plaintiff, *id.*, even though eight other Plaintiffs listed those documents in their initial disclosures, Ex. 6.

By definition, this information is “relevant to any party’s claim or defense.” Fed. R. Civ. P. 26(b)(1). Initial disclosures reflect a party’s identification of the documents within its possession, custody, or control that it “may use to support its

claims or defenses.” Fed. R. Civ. P. 26(a)(1)(A)(ii). The information is also proportional to the needs of the case, as the broad categories of documents in Plaintiffs’ initial disclosures makes it impossible for Defendants to know precisely what Plaintiffs may rely on in support of their claims, and includes documents beyond Defendants’ possession, custody, or control. Ex. 6.² Plaintiffs have never contested the relevance and proportionality of this request. Ex. 7 at 3. Thus, Defendants are “entitled to copies of the documents which were . . . disclosed pursuant to Rule 26,” *G.R. Harvill, Inc. v. Patel*, 2012 WL 13049555, at *3 (S.D. Ala. Feb. 16, 2012), and this Court should compel Plaintiffs to produce full and complete copies of the “related documents (e.g., antibody tests)” and “medical records” identified in their initial disclosures in response to RFP 2. *See also Diaz v. Goat Express, LLC*, 2021 WL 8199899, at *3-4 (N.D. Fla. June 1, 2021) (compelling production); *Whyte v. Alston Mgmt., Inc.*, 2011 WL 13107428, at *1 (S.D. Fla. July 27, 2011); *Mid-State Aftermarket Body Parts, Inc. v. Truck Ins. Exch.*, 2006 WL 2079940, at *2 (E.D. Ark. July 24, 2006); *Jenkins v. Miller*, 2019 WL 5558601, at *4 (D. Vt. Oct. 29, 2019).

II. Defendants are Entitled to Responsive Answers to Interrogatories 3-8.

Interrogatories 3 & 5: “Please identify any and all Plaintiffs who would take Comirnaty[/Spikevax], if available.” Ex. 2 at 5.

² Plaintiffs’ note that “Defendants are already in possession of those documents,” Ex. 7 at 3, is incorrect, as demonstrated by the three antibody/COVID-19 test results Plaintiffs produced from third-party medical providers.

Interrogatories 4 & 6: “Please identify any and all Plaintiffs who would not take Comirnaty[/Spikevax], if available.” *Id.*

Plaintiffs gave substantially the same objection and response to these requests:

“Plaintiffs object because this interrogatory is speculative. Defendants ask Plaintiffs whether they would take Comirnaty[/Spikevax] ‘if available,’ although Comirnaty[/Spikevax] is not available and Defendants admit they are not in possession of Comirnaty. Plaintiffs are thus required to guess whether they will receive a vaccine that may *never* be available to Plaintiffs. In other words, Plaintiffs must respond to a hypothetical that cannot occur right now and may never occur. Furthermore, this interrogatory requires Plaintiffs to speculate and provide answers without knowing whether or not the Department of Defense COVID-19 vaccine mandate will still be in effect when Comirnaty[/Spikevax] is ‘available.’ And for those Plaintiffs who have pending religious accommodation requests or appeals, they are improperly asked to guess whether they would take Comirnaty[/Spikevax] without knowing how Defendants might rule on their religious objections.

Considering these objections and without waiving same, Plaintiffs respond that they are committed to following lawful orders, subject to their religious beliefs, their rights of refusal, their medical needs, and whether the recommended medical treatments have received lawful and appropriate approval.” Ex. 8 at 3-5.

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

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

Plaintiffs’ speculation objection is unfounded. Ex. 8 at 3-5. While they may believe that FDA-approved vaccines are “not available,” the Comirnaty-labeled vaccine is in fact available for DoD to order as of today’s date. Nor does a responsive answer require any speculation: Plaintiffs are the only ones who can determine, yes or no, whether they would take Comirnaty or Spikevax. *See also* Fed. R. Civ. P. 33(a)(2) (noting that an interrogatory is not objectionable merely because it asks for an opinion). And Plaintiffs are the ones who have asserted challenges to the DoD vaccination requirement, notwithstanding the pendency of certain of their religious accommodation requests and appeals; they cannot use those pending requests both as a sword (in nevertheless moving forward with their claims) and as a shield (in resisting discovery intended to probe their standing to bring such claims). The Court should compel full and complete responses that answer the substance of Interrogatories 3-6. *See Bailey v. TransUnion LLC*, 2020 WL 13132941, at *12 (N.D. Ga. Apr. 24, 2020) (responding party “must answer the substance of the interrogatory”).

Interrogatory 7: “Please identify any and all Plaintiffs who would take a BLA compliant vaccine, if available.” Ex. 2 at 6.

Interrogatory 8: “Please identify any and all Plaintiffs who would not take a BLA compliant vaccine, if available.” *Id.*

Plaintiffs did not object and gave the same response to both Interrogatories:

“Plaintiffs respond that they are committed to following lawful orders, subject to their religious beliefs, medical needs, their rights of refusal, and whether the recommended medical treatments have received lawful and appropriate approval. BLA-compliant vaccines – which Defendants defined as ‘an EUA-labeled vaccine’ are not FDA approved and are thus not subject to the DOD Mandate.” Ex. 8 at 5.³

These Interrogatories seek relevant and proportional information for the same reasons as Interrogatories 3-6. In response to the Court’s preliminary injunction opinion identifying BLA-compliant vaccines as a point of contention and noting that no Plaintiff claimed to have been denied a BLA-compliant dose, Plaintiffs filed an amended complaint attempting to address that deficiency. Thus, Defendants are entitled to know which Plaintiffs would (or would not) take a BLA-compliant vaccine—information that goes directly to Plaintiffs’ standing and the merits of their claim. Moreover, Plaintiffs have waived any objections to these Interrogatories, *see Griffin*, 2011 WL 13235056, at *2, and the Court should therefore compel full and complete responses that address the substance of Interrogatories 7-8.

CONCLUSION

Defendants respectfully request that the Court compel Plaintiffs’ full and complete responses to RFP 2 and Interrogatories 3-8.

³ Plaintiffs misstate Defendants’ definition of “BLA compliant.” *See* Ex. 3 at 2 n.2.

Dated: May 20, 2022

Respectfully submitted,

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General

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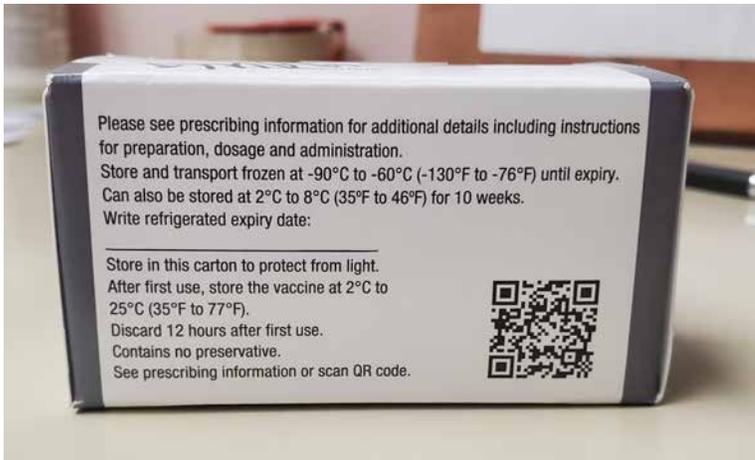
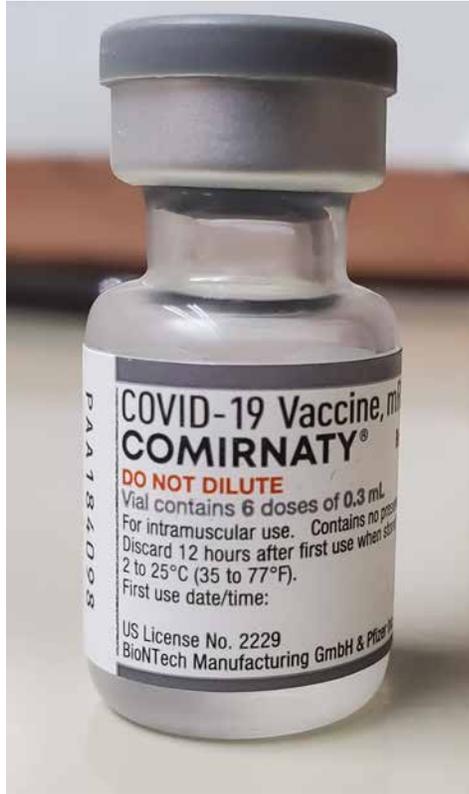
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Counsel for Defendants

Military Whistleblower Photographs of Comirnaty-Labeled vaccine product
Taken at USCG Sector Juneau, Alaska on 10 June 2022





COVID-19 Vaccine Lot Number and Expiration Date Report

Important Note!

The Centers for Disease Control and Prevention (CDC) COVID-19 Vaccine Lot Number and Expiration Date Report is available to public health, healthcare, and pharmacy organizations located within the United States for vaccine administration, inventory, and reporting purposes.

Access to this report is strictly managed by registration only. Registration will not be granted for personal use or to confirm validity of vaccination. Registration requests will be denied for the following users:

- Using personal emails (e.g., Gmail, Yahoo, MSN)
- Seeking the report to verify vaccinations
- Located outside of the US jurisdiction and territories

CDC does not store individual vaccination records. Individuals seeking this information should contact the organization that administered their vaccine or their respective [state immunization registry](#). Click the following link for additional resources to [assist people in finding their vaccination record](#).

General Information and FAQs

The COVID-19 Vaccine Lot Number and Expiration Date Report is available via registration only. Registered users can access COVID-19 vaccine lot numbers and expiration dates provided to CDC by the vaccine manufacturers from downloadable tabular files for use in vaccine administration, inventory management, and jurisdictional immunization information systems. **These files contain all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA) for distribution in the United States.** The downloadable file includes the manufacturer, the National Drug Codes (NDCs) for Unit of Sale (boxes/cartons) and Unit of Use (vials) for each lot number, and the manufacture date and expiration date.

Reports will be updated daily Monday through Friday as new lots are released by each manufacturer, or as updates are made to the lot expiration dates. Please note that as manufacturers confirm their product stability data, some expiration dates may be updated.

How do I register to request access to lot number and expiration date report?

Access to lot number and expiration date information is controlled for security reasons. To request access to the lot number and expiration date data files, complete the registration page, acknowledge the terms and conditions for access and use of the data, and create a password. We will evaluate your request and send the registration approval decision within 48 hours to the email address you provided during registration. If approved, the email will include a link and instructions for accessing the report.

How can this report help improve data quality and processes?

Correctly entered lot number and expiration date data improve the ability to monitor product safety; identify issues with lots; trace or decrement inventory; and identify expired product that may not have been administered. **The vials and cartons for COVID-19 vaccines authorized under EUAs are not 2D barcoded following the standards used for products licensed by the US Food and Drug Administration,** so lot number and expiration dates may not be scanned into systems. Lot information must be entered manually in many cases, which increases the risk for errors and omissions in the reported data.

CDC encourages systems to use these new files as a reference that can be integrated into workflows to assist in capturing and validating lot number and expiration date information. Manufacturers will continue to provide QR codes on their products that link to their sites, where individual lot expiration dates can be looked up.

UNITED STATES SENATE
SENATOR RON JOHNSON
Senate Homeland Security and Governmental Affairs Committee
328 Hart Senate Office Building
Washington, DC 20510

DECLARATION OF 1LT. MARK C. BASHAW IN SUPPORT OF SENATOR RON JOHNSON
INVESTIGATION INTO THE SAFETY AND EFFICACY OF COVID-19 VACCINES

1. My name is 1LT Mark C. Bashaw. I am over 18 years of age, and I am not suffering under any mental disability and am competent to make this declaration under penalty of perjury. I am able to read and write, and I make this Declaration voluntarily and of my own free will and accord. No one has used any threats, force, pressure, or intimidation to make me sign this Declaration, nor has anyone offered or given to me any monetary or non-monetary compensation or reward for making this Declaration. I understand that I am making this Declaration under the penalty of perjury. I have read the statements in this Declaration, and they are my understanding of the facts. Any medical opinion provided in this Declaration is based upon a reasonable degree of medical certainty. I have personal knowledge, experience and understanding of these matters, and I make this Declaration in support of the truth of the contents contained herein.
2. This Declaration is a communication and testimony solicited by and made to a Member of Congress. I make this Declaration as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034.
3. I make this affidavit, as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034, in support of the above referenced MOTION as expert testimony in support thereof.
4. The opinions expressed here are my own and arrived at from my persons, professional and educational experiences taken in context, where appropriate, by scientific data, publications, treatises, opinions, documents, reports, and other information relevant to the subject matter and are not those of the Army or Department of Defense or any component thereof.
5. I am an active duty commissioned Officer in the U.S. Army. I currently serve at the APHC at Aberdeen Proving Ground (APG), Maryland. I serve in the Preventative Medicine (67C) career field and my specialty is Entomology (72B). My official duties include participating in fact-finding inquiries and investigations to determine potential public health risk to DoD personnel from diseases caused by insects and other non-battle related injuries. I received an Associates of Science in Environmental Studies through the Community College of the Air Force (CCAF) 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.

6. I enlisted in the U.S. Air Force on 17 January 2006 and currently have 16 years of total active federal military service (TAFMS). I have served tours overseas to include Japan, Republic of Korea, Germany and multiple deployments to Africa, Middle East, and Central America. I directly commissioned in the U.S. Army Medical Service Corps in September 2019. I initially attended the Direct Commission Course at Fort Sill, OK, followed by the Basic Officer Leadership Course at Fort Sam Houston, TX. I was then stationed at the APHC in January 2020. While at the APHC, I have successfully served as the Headquarters and Headquarters Company (HHC) Commander from May 2020 to July 2021. Currently, I serve in the Entomological Science Division as a Medical Entomologist.

7. My specific duties at the Entomological Science Division within Army Public Health Center (APHC) required that I participate in fact-finding information regarding entomological threats to public health and safety, and properly communicate the risk to our Soldiers. These threats included insect borne diseases, zoological, and other potential non-battle related issues. I also supervised three enlisted Soldiers (Preventative Medicine Specialists, 68S). Additionally, I worked in a mosquito insectary to help with quality checks and standard operating procedures (SOPs). My official duties also include supporting the Army Public Health Program (Army Regulation 40-5) by sustaining the readiness of the force by protecting Army personnel from potential and actual harmful exposures to chemical, biological, radiological, nuclear, and high yield explosive (CBRNE) warfare agents; endemic communicable diseases; food, water, and vector-borne diseases; zoonotic diseases; ionizing and nonionizing radiation; combat and operational stressors; heat, cold, altitude, and other environmental extremes; environmental and occupational hazards; toxic industrial chemicals and toxic industrial materials.

8. Throughout the implementation of the experimental emergency use authorized (EUA) COVID19 mRNA injections, I was aware of enormous safety signals in the Centers for Disease Control's (CDC) Vaccine Adverse Event Reporting System (VAERS). In September and October of 2021, I started communicating these concerns to the Army Public Health Center COVID19 Task Force to get the Risk Communication Strategy changed to include the concerning VAERS data and frontline doctor testimony. I was ignored. Shortly thereafter, I was targeted for not participating with COVID19 experimental emergency use authorized products (masks, tests, and mRNA injections). I was then charged with Article 92 UCMJ and sent to a Special Court Martial (United States v 1LT Mark Bashaw) on 28-29 April 2022. I was convicted and sentenced to "no additional punishment" by the Judge. I explained throughout the court martial that these COVID19 experimental EUA products are dangerous and deadly. I also gave testimony regarding my initial and formal Article 138 UCMJ complaint that was initiated on 26 November 2021 against my commander, after I was unlawfully discriminated against on 23 November 2021.

9. On 29 July 2022, I registered for a CDC Vaccine Lot Number and Expiration Date Report Account. Within the DOD and USCG, there have been questions with certain "Comirnaty Labeled" vial lots that have been showing up on base medical clinics. Many medical personnel and commanders around the DoD and USCG have been claiming these are the FDA Approved and Licensed vials. **However, these lot numbers are listed on the CDC's Emergency Use Authorized (EUA) COVID19 Lot Listing.**

10. The following is an excerpt from the CDC's COVID-19 Vaccine Lot Number and Expiration Date Report Database, **“These files contain all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA) for distribution in the United States. The downloadable file includes the manufacturer, the National Drug Codes (NDCs) for Unit of Sale (boxes/cartons) and Unit of Use (vials) for each lot number, and the manufacture date and expiration date.”**

11. Using the CDC's database, I was able to verify that the “Comirnaty Labeled” vials with lot number FW1331, that has shown up on various U.S. military and U.S. Coast Guard bases (Whistleblower Declaration: LT Chad Coppin, USCG, 30July2022), **is listed on CDCs COVID-19 Vaccines under Emergency Use Authorized (EUA) List.** There's obviously confusion as to why experimental COVID19 EUA vials are still being manufactured and new EUA authorizations are being granted (i.e., NOVAVAX), if we have a “supposed” fully FDA Approved and Licensed vials available. There's also confusion as to why this alleged fully FDA Approved and Licensed product is on the CDC's official EUA Lot Listing.

12. As of 22 July 2022, there have been 29,790 deaths from these experimental EUA COVID19 injections and 1,357,940 adverse injuries, according to the CDC's VAERS data. There's also been 1,000 peer review studies about the adverse injuries related to these experimental EUA COVID19 injections (<https://community.covidvaccineinjuries.com/compilation-peer-reviewed-medical-papers-of-covid-vaccine-injuries/>). Additionally, on 06 January 2022, a federal court ordered the FDA to release the COVID19 vaccine documents. It was these documents that the FDA relied heavily on to facilitate a fully FDA Approved and Licensed COVID19 injection. These documents also corroborate the concerning safety signals.

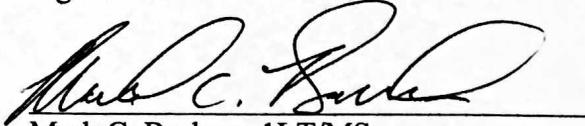
13. Important to note that “Covered Persons” (i.e., U.S. Government, manufacturer, distributor....) with respect to administration or use of a “covered countermeasure” (i.e., EUA COVID19 mRNA injections, masks, and tests) “shall be immune from suit and liability.... (Title 42 U.S.C. Section 247d-6d [a] [1]).” Also, Title 21 U.S.C. 360bbb-3 has important “Required Conditions” associated with EUA products and Title 10 U.S.C. section 1107a has important requirements, specifically for Service Members. **According to Army FRAGO 5, “Commanders will ensure sufficient doses of Department of Defense Approved vaccines are on hand and available for their unit. Soldiers may at any time still voluntarily receive any other vaccine approved for emergency use.”** Again, according to the CDC lot listing, **the only vial lots that exist are under emergency use authorization.** Therefore, required conditions such as, the right to accept or refuse participation with such EUA products is a **REQUIRED CONDITION** per Title 21 and Title 10 sections listed above.

14. To date, there are no available FDA Approved masks and tests for the prevention and/or detection of COVID19 (SARS-CoV-2), they are all EUA and fall under the same federal statutes listed above. These EUA products have been weaponized against individuals who lawfully chose not to participate with the experimental EUA COVID19 injections. However, everyone has the right to accept or refuse such experimental EUA products without fear of reprisal, again, according to the federal statutes above. However, Commanders around the DoD are initiating reprisal against their Service Members. This is an unlawful practice.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: 04 August 2022

Signature:


Mark C. Bashaw, 1LT/MS

Maryland State
Anne Arundel County

On 08/04/2022 date before me, as Notary and as Jurat Certificate of Acceptance by court officer, Mark Charles Bashaw personally appeared and proved to me on the basis of satisfactory evidence to be the man whose Name is subscribed to the within attached instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his autograph on the instrument the man executed, the instrument.

I certify under PENALTY OF PERJURY under the lawful laws of Maryland State and the STATE OF MARYLAND that the foregoing paragraph is true and correct Witness my hand and official seal.

Signature  seal
of Notary/Republic

David A. Chiodaroli
NOTARY PUBLIC
Anne Arundel County
MARYLAND
MY COMMISSION EXPIRES August 11, 2025

Our STN: BL 125742/36

SUPPLEMENT APPROVAL

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

December 16, 2021

Dear Mr. Patel:

We have approved your request submitted and received on November 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), to include a new 30 microgram dose formulation (Tris/Sucrose) of COMIRNATY manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs) facility.

LABELING

We hereby approve the draft content of labeling including the Package Inserts submitted under amendment 10, dated December 13, 2021, and the draft carton and container labels submitted under amendment 6, dated December 9, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Inserts submitted on December 13, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on December 9, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125742, at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Jerry P. Weir, Ph.D.
Director
Division of Viral Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

UNITED STATES SENATE
SENATOR RON JOHNSON
328 Hart Senate Office Building
Washington, DC 20510

DECLARATION OF LT CHAD R. COPPIN

1. My name is LT Chad R. Coppin. I am over 18 years of age, and I am not suffering under any mental disability and am competent to make this declaration under penalty of perjury. I am able to read and write, and I make this Declaration voluntarily and of my own free will and accord. No one has used any threats, force, pressure, or intimidation to make me sign this Declaration, nor has anyone offered or given to me any monetary or non-monetary compensation or reward for making this Declaration. I understand that I am making this Declaration under the penalty of perjury. I have read the statements in this Declaration, and they are my understanding of the facts. I have personal knowledge, experience and understanding of these matters, and I make this Declaration in support of the truth of the contents contained herein.

2. This Declaration is a communication and testimony solicited by and made to a Member of Congress. I make this Declaration as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034.

3. I am a Lieutenant in the United States Coast Guard (USCG) currently serving at Sector Juneau as the Prevention Chief of Inspections Division. My next rotation date for future assignment is 01 July 2024, which also coincides with my retirement eligibility date after attaining 22 overall years of active-duty service with 10 years as a commissioned officer.

4. I enlisted in the USCG in March 2002. Upon graduating Basic Training I was assigned to USCGC HEALY, an icebreaker out of Seattle, WA. After two deployments conducting missions in the Arctic Circle and down south to McMurdo, Antarctica, I was selected to attend the Airman program in North Bend, Oregon in pursuit of Aviation Maintenance Technician (AMT) A-school. Upon successful completion and graduation from AMT A-school I was advanced to E-4 in December 2003 and began my USCG aviation career. I served at AIRSTA Barber's Point, Hawaii and AIRSTA Sacramento, CA spanning 2004-2014 as an aviation mechanic and aircrew aboard the mighty HC-130H Hercules. I earned my Basic Aircrew, Dropmaster, Sensor Systems Operator (Instructor), and Flight Engineer (Instructor) qualifications. As an E-5 Flight Engineer, my command entrusted me with the greatest level of responsibility acting as the conduit between the Pilots (commissioned officers) and the enlisted aircrew. Our missions included long range Search and Rescue (SAR), Law Enforcement (LE) and medical evacuation missions with an area of responsibility spanning the Pacific Ocean, from Japan to Central and South

America. I was in charge of running aircraft systems, managing in-flight emergency procedures, conducting ground maintenance evolutions while deployed to foreign countries and qualifying other enlisted members into various aircrew positions. During my tour at AIRSTA Sacramento, I completed my Bachelor's Degree (Magne Cum Laude) in Aeronautical Science through Embry-Riddle Aeronautical University and was selected to attend Officer Candidate School (OCS) at the US Coast Guard Academy. I departed AIRSTA Sacramento and reported to OCS in January 2014.

5. I received my commission as an Ensign (O1-E) in May 2014 and transferred to Sector Puget Sound in Seattle, WA to start my new career path as an Operational Ashore Prevention Officer. I earned numerous vessel inspection qualifications, provided new construction oversight for small passenger vessels, inspected large foreign container ships, oil tankers and the Washington State Ferry System. I interacted daily with the public and advised on federal regulations while maintaining commercial vessel operator compliance within our maritime transportation system. I transferred to USCG District Thirteen in Seattle, WA in 2017 working for District Prevention Waterways (dpw), whose office is responsible for managing federal waterways, Aids to Navigation (ATON) and ensuring the safety of the boating public in Washington, Oregon, Idaho and Montana. In August 2020 I transferred to my current unit Sector Juneau, AK where I now serve as Chief of Inspections Division responsible for regulatory oversight of foreign and domestic vessel operations within Southeast Alaska. Since recruit training, I have now served honorably for over 20 years, and I will continue to do so, God willing.

6. As a commissioned officer in the United States Coast Guard, it is my responsibility to uphold the Coast Guard's core values of Honor, Respect, and Devotion to Duty. It is for this reason that I present the following information that brings into question the ability of the Department of Defense (DoD) and the Department of Homeland Security (DHS) to continue to push the lawful order of making service members partake in the injection of the "Comirnaty labeled" Covid-19 shots that recently appeared at select military installations across the country. On June 10th, 2022 a shipment of 60 Comirnaty vials packaged in six boxes of ten vials, was received by my Coast Guard medical clinic in Juneau, AK. I found this interesting as they arrived unannounced to any service members and to date, FDA approved Comirnaty labeled vials had never been seen in the USA. Prior to this date, only emergency use authorization shots have been available to fulfill the DoD/DHS mandate. I inquired to my medical staff as to where these Comirnaty labeled vials came from and it was revealed that the vials were shipped to our medical clinic from the US ARMY at Ft. Detrick, MD. I called Ft. Detrick with the information I had received in an email regarding the shipping and arrival instructions of Comirnaty to our Coast Guard unit. A US Army civilian contractor answered my call and confirmed they had sent our unit the package of 60 vials (6 boxes of 10 vials each) of Comirnaty "grey cap". He explained to me that the Comirnaty labeled vials were sent to Ft. Detrick from the Kalamazoo, MI Pfizer plant and Ft. Detrick then shipped them to our USCG bases. I requested any information about manufacturing locations of this product and he mentioned that I would have to call Pfizer at Kalamazoo, MI for any additional information and that he had nothing further to provide me.

7. After many hours working through Pfizer's customer service phone numbers to no avail, I eventually made contact with a Pfizer customer service representative on July 7, 2022 who could assist me with my question. The Pfizer Customer Service representative was able to look up our Lot number FW 1331 and stated as heard in the recording I have provided, that Lot FW1331 was manufactured in France. It was manufactured on January 28th, 2022 and expires on December 31, 2022. No other specific information regarding what Pfizer location, city or address in France was provided.

8. The significance of the France manufacturing location is that it is not an authorized manufacturing location as per the FDA's Comirnaty BLA Supplement Approval letter dated December 16, 2021. As written in the supplement approval letter to Mr. Patel, it states, "*We have approved your request submitted and received on November 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), to include a new 30 microgram dose formulation (Tris/Sucrose) of COMIRNATY manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs) facility.*"

9. The significance of this to service members is that we are being told that our military medical clinics at select locations across the country have the FDA approved Comirnaty. Pfizer has stated on this recorded phone call that Lot number FW 1331 was manufactured in France which makes this not an FDA approved version for distribution in the United States of America according to the approved manufacturing locations declared in its BLA license. This invalidates the claim presented by Commanding Officers at Department of Defense and United States Coast Guard installations that the Comirnaty labeled vaccine being offered is actually FDA approved. Commanding Officer's are using this shipment of Comirnaty from Ft. Detrick to try and convince and coerce the remaining unvaccinated service members into compliance with their order to receive a fully FDA approved Covid-19 vaccine.

10. It is my hope that this information will generate an investigation to confirm the manufacturing locations of Comirnaty Lot FW1331 and other Lot numbers being shipped to US military installations from Ft. Detrick, MD. To date, Coast Guard medical clinics nor Pfizer has produced any documentation attesting to the manufacturing location of the Comirnaty labeled vials currently being offered to service members.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on July 30, 2022.

Signature:



Chad R. Coppin, LT