Exhibit 502

Naomi Wolf and Her Legal Team Got the Strategy to Take Down Pfizer Right

Pfizer committee massive fraud against the US government, nullifying their contract with the US Military and shattering Pfizer's legal Immunity

https://karenkingston.substack.com/p/naomi-wolf-and-her-legal-team-got-83e

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Pfizer committed massive fraud against the US government, nullifying their contract with the US Military and shattering Pfizer's legal immunity.

JUL 12, 2023



July 12, 2023: On July 5, 2023, Naomi Wolf and Daily Clout's attorney, Scott Street, <u>sent</u> <u>a letter to the US Department of Justice</u> rightly proclaiming that Pfizer committed massive fraud against the US government, <u>not *with*</u> the government. You can find a copy of the <u>letter here</u>.

Naomi Wolf and her legal team got the strategy to take down Pfizer right.

MICHELLE D. VOLK KRISTEN J. WRIGHT Chaf Departing Officer	TEL (619) 234-2542 LOS ANGELES OFFICE: 201 SOUTH LAKIL AVITALI, SUITE 300 PASADINA, CA 9100	A state of the second sec
Also Admitted: Calenda ⁴ Tecnsphonia ^{4*} Necula ^{4**}	TEL, (31), 394-3909 97 CONVERSE PREDERIC LOSSEN MUTURELLETEN ROBERT F. RODOLDY, JR.	
July 5, Fraud Section Commercial Litigation Branch U.S. Department of Justice	2023 <u>Via U.S. Mail</u>	
175 N Street, NE Washington, DC 20002		
Re: Fraud related to the procurement of t	he Pfizer COVID-19 Vaccine	
Dear Sir or Madam:		
We write on behalf of our clients, Dr. Nao Department of Justice to bring a claim against Pfiz government to agree to buy Pfizer's mRNA COV	ter, Inc., for fraud in inducing the United States	
The government declared COVID-19 a nat 2020, President Trump announced Operation War the Department of Defense ("ODD") and the Dep ("HIRS"). OWS's goal, according to a government was to create a vaccine that would "prevent what is could sweep come October, November."	p Speed ("OWS"), a joint initiative between artment of Health and Human Services a official who spoke to <i>Science</i> in May 2020,	
According to the Science article, the key fi and the potential to make hundreds of millions of effort, with Peter Hotez of the Baylor College of N which you can collect enough efficacy and safety	Aedicine saying that he did not "see a path by	
Pfizer did not develop its mRNA shot in th biotechnology company in Germany. But, after le	e United States. It partnered with BioNTEch, a arning that the United States government had	

Although Naomi Wolf and I have never spoken, I have a great deal of respect for her hard work, commitment to justice, and shining light on the truth.

I believe that a successful legal strategy to take down Pfizer must;

- 1. Decouple Pfizer from the US government and military, as the Pfizer DoD contract states more than a half-dozen times.
- 2. Clearly demonstrate how Pfizer was contracted to operate under the FD&C Act in order to deliver a safe and effective vaccine, but operated outside of the FDA laws that regulate the US biologics industry by committing massive fraud against the US government and the American people.
- 3. By operating in complete disregard of, and outside of the FDA safety biologics laws, Pfizer engaged in criminal human experimentation on adults and children with a bioweapon.

The following is an example Kingston Report article detailing how Pfizer violated US clinical safety laws and their DOD contract, thereby committing criminal human experimentation on innocent children and adults with a bioweapon. (Originally posted on January 13, 2023.)

10 Reasons to Criminally Charge Pfizer NOW

Originally posted January 13, 2023: You can <u>NOT contract to commit a crime</u>, any crime. Just to be clear, Pfizer can not go through the entire Initial New Drug (IND) application process, Phase 1/2/3, Biological License Application (BLA), pay the \$3 million dollar Pharmaceutical Drug User Fee (PDUFA), FDA-approval, post-marketing clinical requirements, and manufacture and market FDA-approved product and then claim that under their contract with the DoD they were instructed to perform the clinical trials and receive FDA-approval as a part of a psyop. This is the most ridiculous story I have heard so far in an attempt to defend Pfizer's EUA vaccine immunity shield which is completely shattered.

The only reason why Pfizer is getting away with murder is because Pfizer is influencing the narrative that we are listening to from trusted leaders and media platforms on both sides of the COVID-19 isle to convince the entire population of the United States that their injectable COVID-19 mRNA lipid nanoparticle bioweapons are;

- 1. safe and effective vaccines,
- 2. vaccines gone wrong, or
- 3. bioweapons, but Pfizer is following orders from the US military under a secret military contract and under EUA law Pfizer has legal immunity, so there is nothing we can do about it.

These are all false statements.

"Pfizer's Operation Warp Speed (OWS) contract with the DoD was to develop a vaccine that effectively prevented SARS-CoV-2 infection (COVID-19 disease) and that met the safety and efficacy regulatory standards of an FDA-EUA authorized or FDA-approved vaccine." - Karen Kingston, January 13, 2023

As we read through the <u>DoD contract</u>, it's clear that Pfizer is in charge of communications with the FDA. Per the FDA documents, Pfizer exerted extreme influence over the FDA forcing the FDA to ignore safety flags during the clinical trials, thereby strong-arming the FDA to fraudulently authorize and then fraudulently approve a bioweapon as a safe and effective vaccine.

Pfizer is obviously the criminal in this case and can be criminally charged now.

If I was an advisor in a criminal case, here's a few examples on how I would eviscerate many of the fraudulent claims (extrinsic fraud) currently being made. Extrinsic fraud is when an attorney or expert witness misrepresents material facts or law so that victims are unable to take effective civil or criminal action.

Fraudulent Claims Made by Experts and Attorneys

1. Pfizer's DoD Contract was for a Prototype, NOT a Vaccine. FALSE.

FALSE. Per the contract, the vaccine prototypes were part of a manufacturing demonstration, however the 'vaccine prototypes' would be categorized as emergency use authorized (EUA) or FDA-approved vaccines *after* receiving FDA authorization or FDA approval. If vaccine prototypes never received FDA authorization or approval, then they would have remained manufacturing prototypes and never distributed as vaccines to the US civilian population.

Pfizer's original <u>Operation Warp Speed contract</u> with the DoD was to produce 100 million doses of a vaccine (vaccine prototype) *capable of providing protection against SARS-CoV-2* and related coronaviruses (variants) *subject to* FDA technical, clinical and regulatory success (laws and guidance).

	Statement of Work		
	For		
	COVID-19 PANDEMIC-LARGE SCALE VACCINE MANUFACTURING		
	DEMONSTRATION		
	RPP #: 20-11 KarenKingston.Substack		
	Project Identifier: 2011-003		
	Consortium Member: Member		
	Title of Proposal: COVID-19 PandemicLarge Scale Vaccine Manufacturing Demonstration		
	Requiring Activity: Joint mission between the Department of Health and Human Services and		
	Department of Defense to combat COVID-19		
	1.0 INTRODUCTION, SCOPE, AND OBJECTIVES		
	1.1 Introduction		
	This Statement of Work (the "Statement of Work") is hereby entered into, effective as of July 21,		
https://www.hhs.gov/si	2020, pursuant of that critical Project Agreement by and between MCDC and Pfizer dated as of		
	July 21, 2020 ("this Agreement" or "Project Agreement").		
es/default/files/pfizer-	Sulf 21, 2020 (unstratectured of Troject Agreement).		
nc-covid-19-vaccine-	An outbreak of respiratory disease caused by a novel coronavirus was first detected in China in		
contract.pdf	late 2019 and has now spread worldwide, including the United States ("US"). The virus has been		
	named Severe Acute Respiratory Disease Coronavirus-2 ("SARS-CoV-2") and causes		
	Considered Discourse 2010 (RCOVID 102) Or Leasen 20, 2020 the Leasenfaired House		
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Therefore, in response to a request by the Government, <u>Pfizer is proposing to manufacture at-scale</u> and fill-finish, for provision to the Government, <u>a state-of-the-art candidate vaccine</u>, <u>developed in</u> collaboration with BioNTech and capable of providing protection against the SARS-CoV-2 threat and related coronaviruses, subject to technical, clinical and regulatory success.

Therefore, in response to a request by the Government, Pfizer is proposing to manufacture at-scale and fill-finsh, for provision to the Government, a state-of-the-art candidate vaccine, developed in collaboration with BioNTeeh and capable of providing protection against the SARS-CoV-2 threat and related coronaviruses, subject to technical, clinical and regulatory success.

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Pfizer's mRNA vaccines COULD NOT have been made available to the American public until after FDA regulatory approval per Sec 564 of the FD&C Act for an EUA authorized product or Sect 351 of PHS Act for a FDA-approval of a biological product based on successful clinical trial data. This Statement of Work is designed toward establishing production capacity and distribution infrastructure sufficient to ensure that doses of the vaccine manufactured under this Agreement can be made available immediately for administration in the US, if clinical trials are successful and the FDA grants an Emergency Use Authorization ("EUA") under Section 564 of the Federal Food, Drug, and Cosmetic Act or Biologics License Application ("BLA") licensure under Section 351(a) of the Public Health Service Act (hereafter "FDA-approved or authorized").

1.1.2 ACTIVITIES UNDERTAKEN WITHOUT GOVERNMENT FUNDING

This section describes activities that Pfizer and BioNTech have been performing and will continue to perform without use of Government funding. These activities are described solely for background and context for the Government-funded deliverables itemized in Section 4.

A. Regulatory Planning

Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization. Given that these clinical trials are regulated by the FDA and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command. BioNTech is the Investigational New Drug ("IND") holder, while Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

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If the FDA failed to provide authorization or approval, then Pfizer's manufactured vaccine doses would *not* be made available to the US or global market.



The collaboration has rapidly advanced multiple COVID-19 vaccine candidates into human clinical testing based on BioNTech's proprietary mRNA vaccine platforms, with the objective of ensuring rapid worldwide access to the vaccine, if approved. The collaboration leverages Pfizer's broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network. The two companies are jointly conducting clinical trials, and will also work jointly to commercialize the vaccine upon regulatory approval.

Pfizer and BioNTech have already made substantial progress, outside this Statement of Work and without use of any Government funding, towards the demonstration of technical and manufacturing feasibility, including through the initiation of Phase 1/2 studies evaluating the likelihood of safety, tolerability and immunogenicity in the US and in Germany. The goal of the program is to rapidly develop and obtain regulatory licensure for a vaccine for use in adults ≥ 18 years of age, followed by a possible pediatric and/ or maternal indication (to protect ~4M US pregnant women at risk each year). Both companies aspire to have an FDA-approved or authorized vaccine ready for administration in the US by October 31, 2020. Based on current information, Pfizer and BioNTech anticipate a 2-dose per patient regimen.

https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

This means that the 'vaccine prototypes' would be categorized as emergency use authorized (EUA) vaccines after receiving FDA authorization and then FDA-approved vaccines after receiving FDA-approval. The term prototype is a legal term confirming the reduction in process clause in the contract, confirming Pfizer as the original inventor of the vaccine technology whether it be FDA-approved or FDA-authorized.

2. BioNTech is the Clinical Trial Sponsor and EUA/BLA Holder, NOT Pfizer. FALSE.

FALSE. The <u>contract</u> states that Pfizer and BioNTech will work jointly together on the clinical trials and the commercialization for the vaccine upon regulatory approval (EUA authorization or FDA approval/BLA approval).

(b) (4)

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https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

Although part of the contract states that BioNTech is the regulatory sponsor and the EUA/BLA holder, per the contract Pfizer was instructed to act as the clinical trial sponsor and EUA/BLA holder, and in fact, has acted in those roles.

B. Clinical and Regulatory Approach

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BioNTech is the regulatory sponsor for trials of the vaccine and will be the applicant in the US for an EUA and/or a BLA, and will ultimately be the holder of any such approval issued in the US. Pfizer is BioNTech's authorized agent to FDA. As noted above, Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf © Karen Kingston 2022

Any attorney or contract expert worth their weight in salt would point out that Section B. Clinical and Regulatory is nullified by Section A. Regulatory Planning which designates;

- 1. Pfizer as the regulatory sponsor when the <u>contract states</u>, "Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials..." and
- 2. Pfizer and BioNTech as the EUA/BLA holder when the <u>contract states</u>, "*Pfizer*, and with its collaboration partner, BioNTech will seek FDA approval or authorization for the vaccine."
 - A. Regulatory Planning

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One example on how Pfizer acted as the sponsor is when Pfizer paid the approximate \$3 million Prescription Drug User Fee Act (PDUFA Fee) in May of 2021 when submitting

for FDA approval.

Date:	08/23/2021	
From:	Ramachandra Naik, PhD, Review Committee Chair, DVRPA/OVRR	
BLA STN:	125742/0	
Applicant:	BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)	➡ KarenKingston.Substack
Submission Receipt Date:	May 18, 2021	
PDUFA Action Due Date:	January 16, 2022 4	Prescription Drug User Fee Act DATE
Proper Name:	COVID-19 Vaccine, mRNA	
Proprietary Name:	COMIRNATY	
Indication:	Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older	

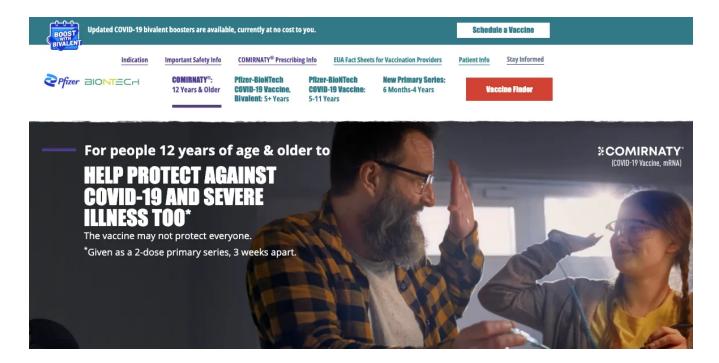
Summary Basis for Regulatory Action

Recommended Action: The Review Committee recommends approval of this product.

https://www.fda.gov/media/151733/download

3. BioNTech is the Marketer for COMIRNATY, NOT Pfizer. FALSE.

FALSE. Per the COMIRNATY website, Pfizer and BioNTech are currently marketing and distributing FDA-approved <u>COMIRNATY</u> in the United States for adults and children 12-years of age and older.



4. There is NO FDA-approved COMIRNATY Available in the United States. FALSE.

FALSE. Per the National Drug Code (NDC) database, FDA-approved and

COMIRNATY-labeled product was available in the United States on December 22, 2021.

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The above image is from a <u>video of a soldier in possession of the FDA-approved</u> <u>COMIRNATY</u> and reading the NDC code that was issued for FDA-approved product available in the United States beginning on December 22, 2021 from the COMIRNATY vial.

5. The Military Controlled the FDA Clinical Trials, So Pfizer is Not Liable. FALSE.

FALSE. Per the <u>DoD contract</u>, Pfizer and BioNTech initiated the Phase 1/2 trials independent of any contract or work done with the US military.

(b) (4)

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https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

The <u>contract</u> clearly states that clinical trials are regulated by HHS and the FDA and that the US military is not involved.

A. Regulatory Planning

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Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization. Given that these clinical trials are regulated by the FDA and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command. BioNTech is the Investigational New Drug ("IND") holder, while Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA. https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

The <u>contract</u> clearly states that Pfizer is in charge of all communications with the FDA.

A. Regulatory Planning

Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization. Given that these clinical trials are regulated by the FDA and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command. BioNTech is the Investigational New Drug ("IND") holder, while Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

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6. The US Military Controls the FDA Data of US Citizens Injected with mRNA Vaccines, So Pfizer is Not Liable. FALSE.

FALSE. Per the <u>contract</u>, all of the data related to Pfizer's COVID-19 mRNA vaccines was and will continue to be generated by Pfizer (and BioNTech) without government funding, and Pfizer owns all of the data.

KarenKingston.Substack 7.2 Data The Government recognizes that all data relating to the vaccine has been and will continue to be generated by Pfizer and its collaboration partner, BioNTech, without the use of Government funding. As between Pfizer and the Government, Pfizer shall own any and all data generated by Pfizer and/or BioNTech (i) as of the Effective Date of this Statement of Work, or (ii) after the Effective Date of this Statement of Work, outside the scope of this Statement of Work ("Background Data"). As between Pfizer and the Government, Pfizer also shall own any and all data generated by Pfizer 17 This Statement of Work includes proprietary and confidential commercial data of Pfizer Inc. that shall not be disclosed outside the MCDC Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Statement of Work and negotiate any subsequent award. If, however, an agreement is awarded as a result of, or in connection with, the submission of this data, the MCDC Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MCDC Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction are set forth on each page of this Statement of Work. US 168054648v17 https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

Per <u>the contract</u>, Pfizer controls the format of the data and is under no obligation to provide custom reports to the US military.

3.2 Management and Reporting

As set forth more fully in Section 11.7, the provisions of this Section 3.2 hereby supersede and

As set forth more fully in Section 11.7, the provisions of this Section 3.2 hereby supersede and replace, in their entirety, Section 1.05 of the Base Agreement.

Pfizer will not employ any new or other Project Management components and Pfizer shall have no obligation to provide any custom reports to the Government except as provided herein. The Government acknowledges that Pfizer plans to utilize existing Pfizer-formatted reports to provide this information to the Government as described in the Deliverable table below at Section 4.0.

Pfizer shall provide (b) (4) technical reports providing an update of relevant ongoing non-Government funded activities.

Pfizer shall provide, (b) (4)

a synopsis of the Phase 2b/3 clinical trial protocol, which synopsis shall include [Overview of the Protocol, Objectives and Endpoints, Statistical Methods, and Schedule of Activities].

Pfizer shall provide copies of EUA and BLA filings, as well as interim and final data updates from clinical studies in a format determined by Pfizer.

Pfizer shall provide weekly prototype production status reports, including the number of batches produced, doses in the batch, and release status of the finished doses.

In addition to regular reporting requirements, during the period of performance, Pfizer shall use diligent efforts to notify the Government (b) (4) of any event, risk, formal or informal

https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

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7. Pfizer's COVID-19 mRNA Vaccines were Manufactured by the Military and Outside of the United States. FALSE.

FALSE. Per the <u>contract</u>, Pfizer is in charge of CMC (chemistry, manufacturing and controls) manufacturing for their COVID-19 mRNA vaccines. Pfizer established US manufacturing facilities for manufacturing mRNA vaccines in the United States.

As background, to help ensure delivery of the doses, Pfizer is undertaking the following CMC ← activities:

1. Continue with BioNTech to manufacture initial clinical trial material for EU and US Phase 1/2/3 studies, through mRNA production in Germany and EU (Puurs, Belgium for fill-finish) and drug product/labelling operations at EU CMOs and establish EU based supply chain for lipid nanoparticle (LNP) formulation, fill, finish and distribution for commercial supply.

2. Complete knowledge transfer of the technology and manufacturing process from BioNTech (and its CMO partners) to Pfizer in order to establish the process at Pfizer in the US, **(b) (4)**

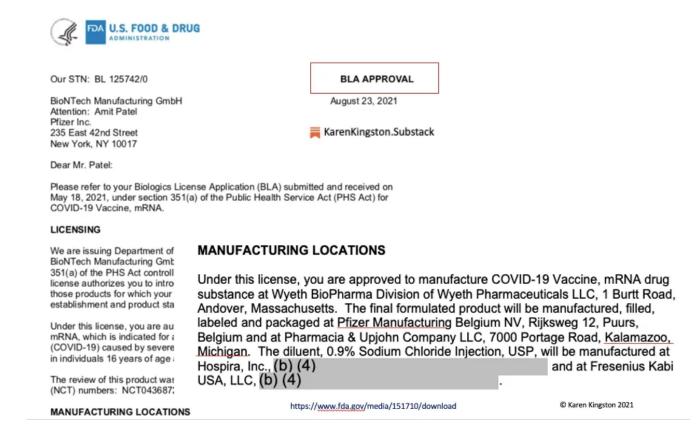
3. Obtain all raw material supplies for manufacturing. This may include support of existing third-party suppliers of raw materials, qualifying new third-party suppliers and/or inhouse production of certain raw materials, (b) (4)

4. Establish (b) (4) mRNA (drug substance), lipid nanoparticle (LNP) formulation/fill finish (drug product) capacity for GMP Covid-19 pandemic supply of the RNA-based COVID-19 vaccine on US soil.

5. Develop the shipping model for the -80 °C drug product in consultation with CDC.

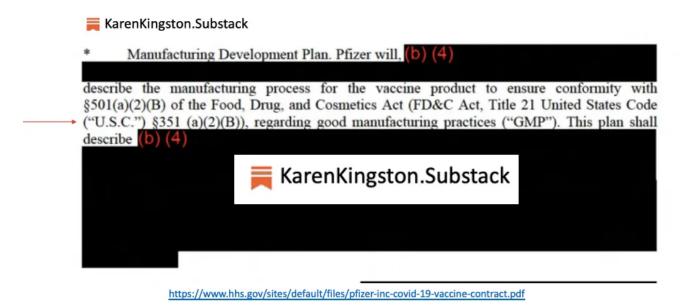
https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

Per the <u>FDA approval letter</u>, FDA-approved COVID-19 mRNA vaccines were approved to be manufactured at Pfizer's facility in Kalamazoo, MI.



8. Pfizer is Not Liable if Vaccines Contain Toxic Substances Because the mRNA Vaccines Are Not Subject to Good Manufacturing Practice Laws. FALSE.

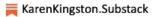
FALSE. While EUA laws waive GMP (good manufacturing practices), the <u>military</u> <u>contract</u> clearly contracts that Pfizer will ensure conformity with GMP per the Food & Drug Consumer Protection Act, 21 USC 351a2B. This is important because Pfizer can not claim they didn't know what was in the vials due to a lack of GMP requirements as they were contracted to adhere to GMP.



9. Pfizer is NOT Liable because the Vaccine Technology Manufactured under the Military Contract is owned by the US Government and NOT Pfizer. FALSE.

FALSE. Per <u>the contract</u>, all inventions conceived in performance of the contract are owned by Pfizer; "As between Pfizer and the Government, all inventions conceived or first actually reduced to practice in the performance of this Statement of Work ("Subject Inventions") shall be owned by Pfizer." If the military did develop the nanotechnology, the military transferred the US intellectual property over to Pfizer's ownership.

7.1 Inventions



As between Pfizer and the Government, Pfizer shall hereby retain all of its rights, titles and interests in and to any and all inventions conceived and reduced to practice by Pfizer and/or BioNTech (i) as of the Effective Date of this Agreement, or (ii) after the Effective Date of this Agreement, outside the scope of this Statement of Work ("Background Inventions"). Pfizer does not grant to the Government any license to practice the Background Inventions under this Agreement.

As between Pfizer and the Government, all inventions conceived or first actually reduced to practice in the performance of this Statement of Work ("Subject Inventions") shall be owned by Pfizer. If invented solely by Pfizer, Pfizer will be able to elect, in its discretion, whether to hold Subject Inventions as trade secrets, and holding a Subject Invention as a trade secret will not forfeit title to the Government. Pfizer does not grant to the Government a license to practice any Subject Inventions on behalf of the Government.

https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

Furthermore, Pfizer may withhold trade secrets from the government; "If invented solely by Pfizer, Pfizer will be able to elect, in its discretion, whether to hold Subject Inventions as trade secrets, and holding a Subject Invention as a trade secret will not forfeit title to the Government."

10. Pfizer Can NOT Be Charged Criminally Because They Have Immunity as a Covered Person per the PREP Act and Contract. FALSE.

FALSE. This brings me back to my first point, you can not contract to commit a crime. While Pfizer is designated as a Covered Person in the contract, the contract and the immunity it grants is predicated on developing a medical countermeasure to COVID-19, not a bioweapon.

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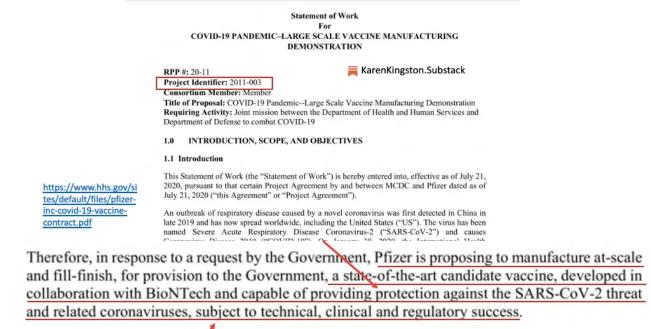
Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012, and on June 8, 2020, 85 Fed. Reg 34740 (together, the "Prep Act Declaration"):

- (i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Pfizer's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency in accordance with Section III of the PREP Act Declaration; and
- (iii) Pfizer is a "Covered Person" per Section V of the PREP Act Declaration. https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf

Pfizer is NOT a Covered Person. Per the manufacturing responsibilities designated to Pfizer in the contract, Pfizer is the manufacturer and the sponsor, just like Moderna and J&J are manufacturers in their contracts, because that is reality.

In reality, Pfizer can no more claim immunity as a 'covered person' just because the DoD randomly claimed as such at the end of the contract, than they can identify as a 'fairy princess with US government immunity to unleash a bioweapon on the US civilian population and call it fairy dust.'

Now back to reality, the 'countermeasure' Pfizer was contracted to manufacture *is a vaccine* capable of providing protection against SARS-CoV-2 and related coronaviruses (variants) *subject to* FDA technical, clinical and regulatory success (laws, regulatory guidance and *bona fide* research).



Therefore, indesponse to a request by the Government, Pfizer is proposing to manufacture at-scale and fill-finsh, for provision to the Government, a state-of-the-art candidate vaceine, developed in collaboration with BioNTech and capable of providing protection against the SARS-CoV-2 threat and related coronaviruses, subject to technical, clinical and regulatory success.

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However, Pfizer did not develop an effective vaccine against SARS-CoV-2 and its variants. Furthermore, **Pfizer instructed the FDA** to disregard safety signals to stop the clinical trials thereby engaging in fraudulent and criminal trials that are not *bona fide* research.

Per <u>Pfizer's November 2020 submission</u>, **Pfizer instructed the FDA** to disregard unfavorable reactogenecity data from 100 children ages 12 through 15 years of age.

years of age are not available for the reporting period. Reactogenicity data from a total of 100 adolescents 12 through 15 years of age enrolled in C4591001 Phase 2/3 were provided in the EUA submission. However, the Sponsor did not request inclusion of this age group in the EUA

Solicited reactogenicity data in adolescents 16-17

because the available data, including number of participants and follow-up duration, were 15 KarenKingston.Substack Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum insufficient to support favorable a benefit-risk determination at this time. Therefore, the reactogenicity data for participants 12 through 15 years of age are not presented in this document. https://www.fda.gov/media/144416/download <u>Reactogenicity events</u> in these children may have been and likely included; myocarditis, multi-system inflammatory system, heart attacks (sudden death), stroke, convulsions, and death. FDA/CBER Plans for Monitoring COVID-19 Vaccine Safety & Effectiveness Presented by: Steve Anderson, PhD, MPP - Dir. Office of Biostats & Epidemiology, CBER October 22, 2020 - Vaccines & Related Biological Products Advisory Committee (VRBPAC)Meeting KarenKingston.Substack FDA Safety Surveillance of COVID-19 Vaccines : **DRAFT** Working list of possible adverse event outcomes ***Subject to change*** Guillain-Barré syndrome Deaths Acute disseminated encephalomyelitis Acute dist Transverse myelitis Encephalitis/myelitis/encephalomyelitis moningoencephalitis/meningitis/ 12.42b1i/b2; minated intravascular coagulation thromboembolism Pregnancy and birth outcomes Arthritis and arthralgia/joint pain Narcolepsy and cataplexy **Kawasaki disease** Anaphylaxis Multisystem Inflammatory Syndrome Acute myocardial infarction in Children Myocarditis/pericarditis Vaccine enhanced disease 2022 ANALYSIS Autoimmune disease Karen Kingston© https://www.fda.gov/media/143557/download?fbclid=IwAR1SooRjTDuhBPqM4TiD3O7vYgX4eAp3CCqB75zCk04CMve_OzgtMNPfNkc

Pfizer informed the FDA that 409 patients came down with COVID-19 or reactogenecity symptoms (see above list that includes death) within 7 days of their first or second injectio. **Pfizer informed the FDA** that they did not include these cases as adverse events or as COVID-19 because they may have been severe reactions to the injections and the subjects did not have a positive PCR test, so Pfizer simply did not count them, in caae they were unconfirmed COVID-19 cases. Pfizer told the FDA their shots were causing disease, disabilities and death, but to simply disregard unfavorable evidence that the shots are bioweapons.

Symptomatic but "NOT CONFIRMED" COVID-19 within 7 DAYS After Dose 1 or 2, pg. 41

Suspected COVID-19 Cases

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Among 3,410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1,594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group. It is possible that the imbalance in suspected COVID-19 cases occurring in the 7 days postvaccination represents vaccine reactogenicity with symptoms that overlap with those of COVID-19. Overall though, these data do not raise a concern that protocol-specified reporting of suspected, but unconfirmed COVID-19 cases could have masked clinically significant adverse events that would not have otherwise been detected.

https://www.fda.gov/media/144416/download

In the <u>November 2020 FDA submission</u>, Pfizer states that they do not know how their mRNA vaccine protects against SARS-CoV-2.

Pfizer's Biological License Application FDA Approval Date: August 23, 2021 Analysis Karen Kingston© 2022

5. Clinical Pharmacology = KarenKingston.Substack

Pharmacodynamic data, comprised of humoral immune responses to COMIRNATY, were obtained in the clinical studies. The data demonstrated that COMIRNATY induces a humoral immune response against the SARS-CoV-2 spike protein. The exact immunologic mechanism that confers protection against SARS-CoV-2 is unknown.

Nov 2020 https://ww.fda.gov/media/151733/download

In the <u>August 23, 2021, FDA approval</u> of Pfizer's biological license application (BLA), the FDA states that Pfizer had NOT provided any DATA to demonstrate that the vaccine was effective; Missing Information = Vaccine Effectiveness.

Pfizer FDA BLA, pg. 25 Missing Information: Vaccine Effectiveness

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Pharmacovigilance Plan (PVP)

The Applicant's proposed pharmacovigilance plan (version 1.1) includes the following important risks and missing information:

- Important identified risks: Anaphylaxis; Myocarditis and Pericarditis
- Important potential risk: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)
- Missing information: Use in pregnancy and lactation; Vaccine effectiveness; Use in pediatric individuals <12 years of age

In addition to routine pharmacovigilance, the Applicant will conduct the postmarketing studies listed in Section 11c Recommendation for Postmarketing Activities.

Adverse event reporting under 21 CFR 600.80 and the postmarketing studies in Section 11c are adequate to monitor the postmarketing safety for COMIRNATY.

https://www.fda.gov/media/151733/download

Per *important identified risks* and *important potential risks*, the FDA confirmed that the data Pfizer did provide confirms that the mRNA injections cause severe diseases such as myocarditis, pericarditis, and likely causes vaccine-associated enhanced disease and vaccine-associated enhanced respiratory disease.

In a post-hoc analysis, Pfizer confirmed with the FDA that the risk of COVID-19 increases over time in study participants after they received a second dose of the COVID-19 mRNA injections.

6.4.6. COVID-19 cases among C4591001 study participants during the Delta variant surge

Responding to an FDA request, Pfizer performed a post hoc analysis of protocol-specified COVID-19 cases accrued during the period of July 1, 2021 through August 31, 2021 (corresponding to the Delta variant surge) among participants 16 years of age and older who completed the 2-dose primary series. The analysis compared rates of COVID-19 among participants who completed the 2-dose primary series early in the study (i.e., those who were originally randomized to BNT162b2) vs. those who completed the 2-dose primary series later in the study (i.e., those who were originally randomized to placebo and then crossed over to BNT162b2). Study participants included in the analysis were those who remained at risk for first occurrence of COVID-19 following the BNT162b2 primary series (i.e., participants who previously reported COVID-19 or who received additional study vaccinations after the primary series were excluded). The analysis used data extracted on September 2, 2021 from the study's live database; the datasets were not submitted to FDA.

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https://www.fda.gov/media/152176/download

Although not independently verified by FDA, the post hoc analysis appears to indicate that the incidence of SARS-CoV-2 during the analysis period among 18,727 study participants originally randomized to BNT162b2 (mean of 9.8 months post-Dose 2 at the beginning of the analysis period) was 70.3 cases per 1,000 person-years, compared with an incidence of 51.6 cases per 1,000 person-years among 17,748 study participants originally randomized to placebo and crossed over to BNT162b2 (mean of 4.7 months post-Dose 2 at the beginning of the analysis period). An additional analysis appears to indicate that incidence of COVID-19 generally increased in each group of study participants with increasing time post-Dose 2 at the start of the analysis period. Only 3 severe COVID-19 cases were reported during the analysis period, all of which occurred among study participants originally randomized to BNT162b2.

Biological agents that do not prevent infection or disease, are not done under *bona fide* research, and in fact *cause* infection, disease, and death are not a vaccines....they are <u>bioweapons</u>.

18 U.S.C. Ch.10: BIOLOGICAL WEAPONS

§175. Prohibitions with respect to biological weapons (c) Definition.—For purposes of this section, the term "for use as a weapon" includes the development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for other than prophylactic, protective, bona fide research, or other peaceful purposes.

mRNA 'vaccines' do not prevent infection, hospitalization or death. mRNA injections cause disease, disabilities and death. The FDA research was criminal and fraudulent. COVID-19 mRNA injections are the legal textbook definition of a bioweapon.

https://uscode.house.gov/view.xhtml?path=/prelim@title18/part1/chapter10&edition=prelim

Pfizer was contracted by the US military to manufacture a safe and effective vaccine against SARS-CoV-2. Pfizer somehow strong-armed the FDA into ignoring all safety signals in order to enable Pfizer to knowingly and intentionally manufacture, distribute and promote bioweapons, specifically lipid nanoparticle technologies encoded to produce the Wuhan-Hu-1 SARS-CoV-2 S-2P spike protein, as a safe and effective vaccines.

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3. Chemistry, Manufacturing and Controls (CMC)

a. Product Quality

BLA STN:	125742/0
Applicant:	BioNTech Manufacturing GmbH (in partnership with Pfizer, Inc.)
Submission Receipt Date:	May 18, 2021
PDUFA Action Due Date:	January 16, 2022
Proper Name:	COVID-19 Vaccine, mRNA
Proprietary Name:	COMIRNATY

COMIRNATY Manufacturing Overview

The mRNA in COMIRNATY is a single-stranded, 5'-capped mRNA encoding the fulllength SARS-CoV-2 spike glycoprotein derived from the Wuhan-Hu-1, isolate (GenBank MN908947.3 and GenBank QHD43416.1). The antigen-coding RNA sequence is codonoptimized and contains two proline mutations ((b) (4)), which ensures an antigenically optimal trimerized pre-fusion confirmation (S-2P). The RNA also contains common structural elements, including 5'-cap, 5'-UTR, 3'-UTR, and poly(A) tail, all of which are designed for mediating high RNA stability and translation efficiency. During RNA transcription, (b) (4) is replaced with the (b) (4) . This nucleoside substitution has been demonstrated to enhance translation of in vitro transcribed mRNA while reducing its reactogenicity.

https://www.fda.gov/media/151733/download

18 USC Ch. 10: BIOLOGICAL WEAPONS From Title 18—CRIMES AND CRIMINAL PROCEDURE PART I-CRIMES

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Avoiding Military Combat in WWIII

Pfizer's contract with the US military and any immunity it provided is unlawful, illegal and criminal, as Pfizer knowingly and willingly developed and released a bioweapon on the US civilian population. Pfizer's actions are in violation of the <u>Uniform Code of</u> <u>Military Justice</u> and the Geneva Convention.

KarenKingston.Substack B. Grave Breaches of the Law of War

While every violation of the Law of War may be punishable under the UCMJ, not every violation will amount to a grave breach of the Law of War. However, it would be inaccurate to say, as was asserted by US Central Command (CENTCOM) in the aftermath of the MSF incident, that the "[t]he label 'war crimes'" applies only to "*intentional acts*—*intentionally* targeting civilians or *intentionally* targeting protected objects."¹⁰⁸ Rather, for the United States, even "grave breaches" of the Law of War—those defined in the 1949 Geneva Conventions¹⁰⁹—can result from culpable negligence.¹¹⁰ In particular, the *Targeting Supplement* makes this clear in articulating the following grave breaches defined in the 1949 Geneva Conventions as being potentially implicated in the targeting context:

- "[W]ilful killing" of protected persons;
- "[W]ilfully . . . causing serious injury to body or health" to protected persons;
- "Willful harm to protected property provided damage thereto is "extensive"; and
- "Culpably negligent harm to protected property . . . provided the harm was the product of the 'wanton' form of culpable negligence, and the damage caused was 'extensive.""¹¹¹

https://cdn.vanderbilt.edu/vu-wp0/wp-content/uploads/sites/78/2018/06/07014136/8.-MeierHill_Final-Review_Formatted.pdf

In my opinion, <u>Lieutenant General Kirillov</u> ordered European, Asian, and African nations to nullify their contracts with Pfizer and initiate criminal investigations earlier this year in order to decouple Pfizer from the US government and avoid starting WWIII.

Americans Can Take Responsibility to Remove the Weapons from our Communities

Every state in the United States of America has specific criminal charges that can be brought against the regulatory team members at Pfizer for developing, distributing, marketing and making readily available a bioweapon (or weapon of mass destruction) to the American people under the guise of a safe and effective vaccine.

If you know of victims who have been harmed by Pfizer vaccines, you can utilize the evidence I provide and your state laws to file criminal charges against Pfizer's mRNA vaccine regulatory and marketing team members and have arrest warrants issued.

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2022 Florida Statutes

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(f) "Vector" means a living organism or molecule, including a recombinant molecule or biological product that may be engineered through biotechnology, capable of carrying a biological agent or toxin to a host.

(2) A person who, *without lawful authority*, manufactures, possesses, sells, delivers, sends, mails, displays, uses, threatens to use, attempts to use, or conspires to use, or who makes readily accessible to others a weapon of mass destruction commits a felony of the first degree, punishable by imprisonment for a term of years not exceeding life or as provided in s. <u>775.082</u>, s. <u>775.083</u>, or s. <u>775.084</u>, and if death results, commits a capital felony, punishable as provided in s. <u>775.082</u>.

(3) Any person who, *without lawful authority*, manufactures, possesses, sells, delivers, mails, sends, displays, uses, threatens to use, attempts to use, or conspires to use, or who makes readily accessible to others, a hoax weapon of mass destruction commits a felony of the second degree, punishable as provided in s. <u>775.082</u>, s. <u>775.083</u>, or s. <u>775.084</u>.

Analysis Karen Kingston© 2021 https://m.flsenate.gov/Statutes/790.166

Pfizer's Immunity is Based on the Narrative We've Been Told

Push back on trusted experts refusing to call the injections bioweapons or who are spinning the laws, evidence, government contracts, and Pfizer's own documents to try and convince us that there is 'nothing we can do' to hold Pfizer accountable for developing and unleashing a bioweapon on civilian American adults and children.

Nothing about what Pfizer has done is legal or protected under any US laws and is in violation of state laws against the use of bioweapons. You can not legally unleash a bioweapon on a civilian population.(period).