IN THE UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

ESTATE OF GEORGE WATTS, JR.,
488 Barnes Hill Road
Lockwood, NY 14589

Plaintiff,

v.

LLOYD J. AUSTIN III in his official Capacity as Secretary of the UNITED STATES DEPARTMENT OF DEFENSE
1000 Defense Pentagon
Washington, DC 20301

Defendant.

CASE NO.:_____

VERIFIED COMPLAINT FOR WILLFUL MISCONDUCT AGAINST THE UNITED STATES DEPARTMENT OF DEFENSE BY PLAINTIFF ESTATE OF GEORGE WATTS, JR.

I. PRELIMINARY STATEMENT

1. Plaintiff Estate of George Watts, Jr. (hereinafter "Estate") seeks damages from Defendant United States Department of Defense ("DOD") for its willful misconduct that caused the death of George Watts, Jr., (hereinafter "Mr. Watts").

2. The certified Bradford County Coroners' Office's Coroner's Comprehensive Report of Death Investigation clearly documents Mr. Watts' vaccine-induced death and the proximate causal connection: to wit, the "Primary Cause" of death is "Covid-19 vaccine-related myocarditis" (Exh. 1, 2 of 13) as does its referenced and attached Lourdes Hospital Pathology Report Autopsy, by Pathologist Robert Stoppacher, M.D., determining: "[b]ased on

consideration of the autopsy examination findings, review of available records, and toxicologic analysis, the death of Mr. Watts, to a reasonable degree of medical certainty, is ascribed to COVID-19 vaccine-related myocarditis." (Exh. 1, 7 of 13.)

3. Mr. Watts received two doses of Pfizer vaccines (Exh. 1, 5 of 13)—an unlicensed product produced under the auspices of the DOD through its leadership role in Operation Warp Speed ("OWS")—later renamed the HHS-DOD COVID-19 Countermeasures Acceleration Group ("CAG").[1]

4. Through its officials, the DOD directed and oversaw vaccine development, and directed supply, production, and distribution with HHS to provide support.[2]

5. DOD caused accelerated production and then pushed out hundreds of millions of vaccines for hundreds of millions of Americans while engaging in a deliberate and calculated mass-deception campaign specifically designed to obfuscate the fact that OWS' vaccines weren't licensed "safe and effective," were merely experimental, and legally could only be characterized as "may be effective" but could not be pronounced safe.

6. By intentionally blurring the line of the critical distinction between "licensed" and "experimental," DOD duped millions of Americans, including Mr. Watts, into being DOD's human subjects in its medical experiment, the largest in modern history. While Mr. Watts cared about the safety of OWS' vaccines, DOD sadly did not.

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[1] Alyssa M. Hundrup, *HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues*, Report to Congressional Addresses, UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE (January 19, 2022), p. 7, para. 2, https://www.gao.gov/assets/gao-22-104453.pdf (last visited May 25, 2023).

[2] *Id.* at p. 7, para. 3.

7. DOD's stated goal was to maximize vaccine uptake across all population groups. At all times relevant to the complaint, DOD accomplished its task through ongoing deception that caused the death of Mr. Watts.

8. DOD oversaw production and directed distribution of the two injections of the unlicensed Pfizer-BioNTech COVID-19 vaccine ("vaccine") (lot #FD0809 and lot # FD8448) that killed Mr. Watts.

9. The U.S. Government, including the DOD, is a "covered person" under the Public Readiness and Emergency Preparedness ("PREP") Act.[3] The United States remained in possession and control of these vaccines until administration[4] into Mr. Watts' body. The Pfizer-BioNTech COVID-19 vaccine is a "covered countermeasure" under the PREP Act.[5]

II. JURISDICTION AND VENUE

10. This action is brought under 42 U.S.C. § 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures. In particular, Estate brings suit under 42 U.S.C. § 247d-6d(d), which provides "an exclusive Federal cause of action against a covered person [such as the DOD] for death or serious physical injury proximately caused by willful misconduct . . . by such covered person."

11. PREP provides blanket immunity for covered persons such as the DOD with a sole exception for willful misconduct. The enumerated sovereign immunity for the United States and an agency such as the DOD (42 U.S.C. § 247d-6d(f)) is unconstitutional since foreclosing all

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[3] 42 U.S.C. § 247d–6d(i)(2)(A).

[4] *How to Enroll as a COVID-19 Vaccination Provider*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html#:~:text=*At%20this%20time%2C%20all%20COVID,until%20administered%20to%20the%20recipient (last visited May 25, 2023).

[5] 42 U.S.C. § 247d-6d(i)(1)(C).

redress violates due process enshrined in the 5th Amendment and its central promise and assurance that all levels of American government must abide by the law and provide fair procedures particularly in instances such as this where Mr. Watts was "deprived of life." The enumerated sovereign immunity for the United States and an agency such as the DOD is also an unconstitutional taking in violation of the 5th amendment. A "legal cause of action is property within the meaning of the Fifth Amendment." *Alliance of Descendants of Tex. Land Grants v. United States*, 37 F.3d 1478, 1481 (Fed. Cir. 1994) (citing *Cities Servs. Co. v. McGrath*, 342 U.S. 330, 335-36 (1952); *Ware v. Hylton*, 3 U.S. 199, 245, 1 L. Ed. 568 (1796)). Moreover, a "legal cause of action" is a "compensable property interest" under the Takings Clause. Accordingly, a plaintiff who pleads that a federal measure has extinguished his cause of action, without providing just compensation, has adequately pleaded a violation of the Takings Clause. The DOD's unconstitutional protection is severable under 42 U.S.C. § 247d-6d(g), rendering "the remainder of this section and the application of such remainder to any person or circumstance . . . [un]affected," consequently the DOD is liable to Estate for willful misconduct under PREP and subject to this Court's jurisdiction as enumerated by statute.

12. This Court has exclusive jurisdiction over this action pursuant to 42 U.S.C. § 247d-6d(e)(1), which provides that "[a]ny action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia."

13. Prior to filing in this Court, the Countermeasures Injury Compensation Program ("CICP") requirement must be exhausted.

14. Mr. Watts' survivor's signed CICP Request for Benefits Form (Exh. 2, 1-6 of 6), dated August 19, 2022, was sent by U.S.P.S. addressed to the U.S. Department of Health and Human Services ("HHS"), HRSA's CICP Program at 5600 Fishers Lane, 08N186B, Rockville,

Maryland 20857, via United States Postal Service Express 1-day on August 22, 2022. (Exh. 3.) The receipt confirms HHS received it the following day. (Exh. 4.)

15. 42 U.S.C. § 247d-6e(d)(1) provides that if the HHS Secretary fails to make a final determination 240 days after filing a Request for Benefits, a party may bring a civil action.

16. Here, the 240-day period expired on April 20, 2023 and no final determination was made. Therefore Plaintiff has exhausted CICP's exclusive remedy requirement and this action is properly brought here in this Court.

17. Under OWS, DOD directed but did not manufacture or distribute. Therefore, the Attorney General and/or Secretary of Health and Human Services' enforcement action prerequisite under 42 U.S.C. § 247d-6d(c)(5)(A)(i) is inapplicable. Defendant DOD, the lead agency in OWS, reports directly to the President.

III. PARTIES

18. The Estate of Mr. Watts is represented by Mr. Watts' father, George Watts, Sr., who was appointed as administrator by the Surrogate's Court of the State of New York, Chemung County, on May 19, 2023.

19. The DOD is an agency of the executive branch of the U.S. government. The DOD is currently led by Lloyd J. Austin III, Secretary of Defense. Through its officials, the DOD oversaw the development and distribution of COVID-19 vaccines. Specifically, DOD performed the following roles: (1) "director of vaccine development—directed and oversaw development and testing of vaccines in coordination with the six vaccine companies that were part of the CAG"; (2) director of supply, production, and distribution—"implemented and oversaw acquisition of supplies and vaccines, including having DOD officials embedded in vaccine production factories to assist with supply chain management and development of a federal

governmental plan to distribute these items to the jurisdictions and other federal agencies and programs"; and (3) director of security and assurance—"developed security measures for the CAG, and a security plan to support production and distribution of vaccines and supplies from the development phase to distribution."[6]

IV. BACKGROUND

A. DOD and its Role in Operation Warp Speed

20. On January 31, 2020, the Secretary of HHS declared the 2019 Novel Coronavirus outbreak a public health emergency.

21. On March 17, 2020, Pfizer signed a letter of intent with BioNTech, a German immunotherapy company, to co-develop a COVID-19 vaccine.

22. As of that date, no mRNA vaccine had been licensed, authorized or manufactured at such a scale.

23. DOD, Pfizer and BioNTech engaged in what they characterized as "the most ambitious vaccine development program in history."[7]

24. Inside Pfizer, the endeavor was referred to as "Project Light Speed" and was intended "to make the impossible possible."

25. On May 15, 2020, the White House announced OWS, a partnership between HHS and DOD.

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[6] Alyssa M. Hundrup, *HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues, supra*, p. 7, para. 2.

[7] Kate Silver, *Shot of a Lifetime: How Pfizer and BioNTech Developed and Manufactured a COVID-19 Vaccine in Record Time*, PFIZER, https://www.pfizer.com/news/articles/shot_of_a_lifetime_how_pfizer_and_biontech_developed_and_manufactured_a_covid_19_vaccine_in_record_time (last visited May 25, 2023).

26. According to a Pfizer Press Release, "[u]nder the agreement, the U.S. government will receive 100 million doses of BNT162, the COVID-19 vaccine candidate jointly developed by Pfizer and BioNTech, after Pfizer successfully manufactures and obtains approval or Emergency Use Authorization from U.S. Food and Drug Administration (FDA)."[8] OWS aimed to begin delivery of 300 million doses of a COVID-19 vaccine by January 2021.

27. In July 2020, DOD awarded Pfizer an Other Transaction Agreement ("OTA" or "vaccine contract") under the authority of 10 U.S.C. § 2371b to scale up manufacture of its vaccine candidate.

28. Under the vaccine contract,[9] Pfizer would manufacture hundreds of millions of doses of mRNA-based COVID-19 vaccine using the Pfizer-BioNTech unique mRNA delivery system and its associated cold chain requirements, under pandemic conditions. The U.S. Army vaccine contract confirms the initial order required FDA-approval or authorization.[10]

29. On December 11, 2020, Pfizer formally received an Emergency Use Authorization ("EUA") from the FDA for its unapproved medical product.

30. The EUA and the vaccine contract virtually assured Pfizer would never face liability in any U.S. court of law:

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[8] *Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2*, PFIZER (Jul. 22, 2020), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-agreement-us-government-600(last visited May 25, 2023).

[9] Department of the Army and Pfizer Contract, *Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for "COVID-19 Pandemic — Large Scale Vaccine Manufacturing Demonstration* (*Pfizer, Inc.*), REF: Pfizer Request for Technical Direction Letter, RPP 20-11 Under OTA W15QKN-16-9-1002 For Objective PRE-20-11, Dated 20 July 2020, DEPARTMENT OF THE ARMY, U.S. ARMY CONTRACTING COMMAND (Jul. 21, 2020), https://www.hhs.gov/sites/default/files/pfizer-inc-covid-19-vaccine-contract.pdf (last visited May 25, 2023).

[10] *Id.* at p. 8, 1.2 SCOPE.

> The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act declaration of equal or greater scope.[11]

31. The DOD's agreement not to release or use Pfizer's vaccine under any circumstances unless PREP protection applied strongly suggests that neither party had complete confidence in the vaccine they jointly developed. DOD eliminated risk to both HHS and Pfizer, essentially guaranteeing that neither of those parties would ever defend a case in court absent an enforcement action by the HHS Secretary or the U.S. Attorney General, as provided for by statute. 42 U.S.C. § 247d-6d(c)(5)(A)(i).

32. OWS' Chief Operating Officer, Army General Gustave Perna urged the healthcare community "to convey a message that these vaccines are safe and efficacious, and that vaccination is important" as a counterpoint to "widespread misinformation" in the general public about vaccines and the lack of need for vaccination against the disease.[12] In fact, DOD intentionally led the spread of misinformation and actively encouraged healthcare providers to join in its deception.

33. General Perna intentionally misled the public about COVID-19 vaccines, claiming they were "safe and effective" despite the lack of any formal FDA licensure ("approval") to support these claims, yet he continued to "push" the vaccines on the public.[13]

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[11] *Id.* at p. 21, PREP Act 11.1.

[12] Military Health System Communications Office, *Hepburn: DOD role in Operation Warp Speed was 'transformative*,' HEALTH.MIL (Dec. 11, 2020), https://health.mil/News/Articles/2020/12/11/Hepburn-DOD-role-in-Operation-Warp-Speed-was-transformative (last visited May 25, 2023).

[13] C. Todd Lopez, *Perna: Whole-of-America Operation Warp Speed effort 'remarkable feat*,' JBSA News, JOINT BASE SAN ANTONIO (Dec. 31, 2020), https://www.jbsa.mil/News/News/Article/2460191/perna-whole-of-america-operation-warp-speed-effort-remarkable-feat/ (last visited May 25, 2023).

34. General Perna's aim was clear: "We want the American people to have confidence that the cadence we have established will ensure safe and effective vaccines are delivered to them accordingly."[14]

35. On December 12, 2020, the DOD News reported:

> "'The massive logistical planning our military has contributed to Operation Warp Speed gives me even more pride in the talent and dedication of our service members,'" Acting Defense Secretary Christopher C. Miller said in a statement yesterday. "'They have been crucial in bringing a safe and effective vaccine to the American people and in restoring the health of our country.'"[15]

36. By January 19, 2021, DOD reported that 35,761,800 vaccine doses had been delivered.[16]

37. Secretary of Defense Lloyd J. Austin III released a video message on February 24, 2021, in which he too asserted that their vaccines were safe and effective, assuring the public that these "vaccines have undergone intensive safety monitoring, and . . . they are safe and they are effective and . . . millions of your fellow citizens have already taken them with little to no side effects."[17]

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[14] Jim Garamone, *Operation Warp Speed Goes on Offense Against COVID-19*, DOD News, U.S. DEPARTMENT OF DEFENSE (Dec. 19, 2020), https://www.defense.gov/News/News-Stories/Article/Article/2452585/operation-warp-speed-goes-on-offense-against-covid-19/ (last visited May 25, 2023).

[15] Terri Moon Cronk, *Operation Warp Speed Official: First COVID-19 Vaccines to Arrive Monday*, DOD News, U.S. DEPARTMENT OF DEFENSE (Dec. 12, 2020), https://www.defense.gov/News/News-Stories/Article/Article/2445137/operation-warp-speed-official-first-covid-19-vaccines-to-arrive-monday/ (last visited May 25, 2023).

[16] *Statement by Acting Secretary of Defense Christopher Miller on Operation Warp Speed Vaccine Doses Delivered Today*, U.S. DEPARTMENT OF DEFENSE (Jan. 19, 2021), https://www.defense.gov/News/Releases/Release/Article/2476213/statement-by-acting-secretary-of-defense-christopher-miller-on-operation-warp-s/ (last visited May 25, 2023).

[17] Lloyd J. Austin III, *SecDef COVID-19 Vaccine Message*, U.S. DEPARTMENT OF DEFENSE (Feb. 24, 2021), https://www.defense.gov/Multimedia/Videos/videoid/784646/ (last visited May 25, 2023).

38. On February 25, 2021, General Perna reported that 90 million vaccines had been delivered nationwide. He further stated, "we have developed two safe and effective vaccines," and "we steadily increased our manufacturing capacity that will result in enough doses available to all Americans by this summer."[18]

39. Rather than candidly telling the American public that the vaccines were merely "authorized" under the FDA's EUA criteria—that they were not fully licensed ("approved") and had not been found to be "safe and effective"—DOD officials intentionally blurred the line between EUA status and licensure as a means to deceive the public into accepting the vaccines as if they had been FDA approved. The "safe and effective" mantra was DOD's ruse to ensure accelerated distribution of their experimental vaccines.

40. The DOD by then was well aware that their vaccines were the cause of thousands of serious adverse events experienced by people who had been injected with their experimental vaccines. In fact from December 2020 through February 2021, 1,266 Deaths and 3,247 hospitalizations had been reported to the CDC's Vaccine Adverse Events Reporting System (VAERS). (See Exh. 5.)[19] The DOD lied when it announced safety and efficacy in light of this damning information.

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[18] *Senate Hearing on Defense Department Response to Coronavirus Pandemic*: General Perna Says 90 Million Vaccine Doses Have Been Delivered Nationwide, C-SPAN (Feb. 25, 2021), https://www.c-span.org/video/?c4948330/general-perna-90-million-vaccine-doses-delivered-nationwide (last visited May 25, 2023).

[19] The user must click on the link, accept the disclaimer, then select the "Request Form" tab in the upper left. https://wonder.cdc.gov/controller/saved/D8/D341F501 (last visited May 25, 2023).

41. A report to Congress detailed OWS' strategy to "achieve maximum uptake of the vaccine across all population groups." That was OWS' "principal purpose and objective."[20] The report continued, "[t]he federal government is procuring hundreds of millions of doses of safe and effective vaccines, and has contracted with McKesson for purposes of vaccine distribution, such that no American will be charged for either the COVID-19 vaccine or its distribution."[21] By providing the vaccine to the public at no cost, DOD enticed and encouraged recipients to be unwitting human subjects in its mass experiment under false pretenses with false assurances that its vaccine was both safe and effective. DOD toyed with people's lives.

42. Further evidencing this mass, highly documented human experiment, the U.S. government requires and maintains detailed records concerning COVID-19 vaccine recipients, such as dose number, lot number, recipient name and ID, recipient date of birth, recipient sex, and recipient address. Vaccine providers must report death, life-threatening adverse events, inpatient hospitalization, or prolongation of existing hospitalization.[22]

B. Death of George Watts – Timeline of Events

43. Decedent George Watts, Jr. was a 24-year-old male who was attending classes at Corning Community College in Corning, New York before his untimely death on October 27, 2021.

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[20] *From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, p. 1, https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf (last visited May 25, 2023).

[21] *Id.* at p. 7.

[22] *FAQs for Private and Public Healthcare Providers About Implementing the CDC COVID-19 Vaccination Program in Provider Practices*: What are the Reporting Requirements for the CDC COVID-19 Vaccination Program? CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vaccines/covid-19/vaccine-providers-faq.html (last visited May 25, 2023).

44. In the summer of 2021, Mr. Watts learned that Corning Community College had mandated the COVID-19 vaccine for all students who wanted to attend classes in person rather than remotely.[23] The policy allowed for a "35 day grace period from the date (August 23, 2021) of FDA vaccine approval . . . by which date all students who intend to engage in-person at SUNY CCC campus locations must provide evidence of receiving the full vaccination series . ."

45. Mr. Watts took two doses of the Pfizer-BioNTech COVID-19 vaccine because the school otherwise barred him from attending in-person classes.

46. Mr. Watts waited until Comirnaty, another Pfizer vaccine that is legally distinct from the experimental Pfizer-BioNTech EUA vaccine, was licensed by the FDA before he would receive a COVID-19 vaccination.

47. Despite waiting for what he thought would be the FDA-approved vaccine, Mr. Watts did not receive the FDA-approved, "safe and effective" Comirnaty vaccine.

48. Instead, Mr. Watts received his first dose of DOD's EUA Pfizer-BioNTech COVID-19 injection on August 27, 2021, at Guthrie Robert Packer Hospital ("Guthrie") in Sayre, Pennsylvania after having been convinced of the vaccine's purported robust safety.

49. Mr. Watts suffered numerous adverse health consequences from the vaccines, which ultimately resulted in his untimely death, according to both the coroner's and pathologist's reports (Exh. 1, 1-11 of 13.)

50. Mr. Watts experienced medical symptoms after his first dose of the experimental COVID-19 injection that worsened after Mr. Watts received a second dose of the EUA Pfizer-BioNTech COVID-19 injection on September 17, 2021, also at Guthrie. (Exh. 2, 2 of 6.)

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[23] *Fall 2021 at SUNY CCC*, Fall 2021 Semester Plans for SUNY Corning Community College, SUNY CORNING COMMUNITY COLLEGE, https://www.corning-cc.edu/fall-2021-semester-plans.php (last visited May 25, 2023).

51. After receiving the second dose, he developed extremity numbness, difficulty grasping and holding onto objects, sinus infection**,** cough, and light sensitivity.

52. On October 12, 2021, Mr. Watts visited the emergency department at Guthrie complaining of a sore throat, sinus congestion, and a cough. He also reported to medical staff a lump on the left side of his neck. (Exh. 1, 5 of 13.)

53. He was prescribed Augmentin and took Mucinex and Nyquil. He followed these medical instructions but did not improve and continued to decline.

54. On October 19, 2021, Mr. Watts once more returned to the Guthrie emergency department.

55. He expressed concern that his cough had worsened and that his health had not improved despite a week of antibiotics.

56. He reported that he had vomited while coughing the previous night.

57. On October 27, 2021, while at home conversing with his mother, Mr. Watts began to cough up blood.

58. He became suddenly unresponsive and was found to have no respirations or pulse.

59. His mother immediately called 911 and began CPR.

60. Upon arrival at the emergency room, Mr. Watts was unresponsive and in cardiac arrest. He was declared dead in the emergency room.

61. Mr. Watts had no past medical history to explain his sudden death. (Exh. 1, 4 of 13.)

62. According to his Certificate of Death, Mr. Watts died of "COVID-19 vaccine-related myocarditis. (Exh. 7.)

C. Death of George Watts – Post Mortem

63. The accompanying affidavit of Dr. Sanjay Verma M.D., who did not treat Mr. Watts, attests that Mr. Watts suffered death as alleged in this complaint based on certified medical records (Exh. 1, 1-13) and explains the basis for his belief that Mr. Watts' death was proximately caused by the administration of a covered countermeasure, DOD's experimental Pfizer-BioNTech vaccine.[24]

64. Post-mortem nasopharyngeal testing was negative for COVID-19. (Exh. 1, 8 of 13.)

65. Exhibit 8 shows the lot numbers of the shots Mr. Watts received. The COVID-19 BioNTech & Pfizer Expiry Tool confirms that Mr. Watts received the experimental EUA vaccine, not Comirnaty. The EUA Pfizer-BioNTech COVID-19 vaccines initially had expiry dates one year from the date of manufacture.[25] The July 31, 2022 expiry dates for both lots received by Mr. Watts (Lot # FD0809 and Lot # FD8448) confirm that the vaccines received by Mr. Watts were manufactured on July 31, 2021 (last confirmed April 6, 2023).

66. On July 31, 2021, when these vaccines were manufactured, DOD was in charge of OWS.

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[24] 42 U.S.C. § 247d-6d(e)(4)(C)(i)-(ii).

[25] On December 23, 2022, CDC announced that the FDA had extended the expiration date for Pfizer-BioNTech COVID-19 vaccines (monovalent and bivalent) from twelve to eighteen months from manufacturer date. *Pfizer-BioNTech COVID-19 Vaccine: Expiration Date Extension and Beyond-Use Date*, CENTER FOR DISEASE CONTROL AND PREVENTION (Dec. 23, 2022), https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/Pfizer-ExpirationExtBUD-508.pdf (last visited May 25, 2023).

V. STATUTORY BACKGROUND

A. The Public Readiness and Emergency Preparedness (PREP) Act

67. The PREP Act authorizes the Secretary of HHS ("Secretary") to issue a PREP Act declaration. The declaration provides immunity from liability except for willful misconduct "for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions."[26]

68. The sole exception to PREP Act immunity[27] for "covered persons" such as DOD is death or serious physical injury caused by "willful misconduct."

69. On January 31, 2020, Alex M. Azar, II, the HHS Secretary, declared a public health emergency as of January 27, 2020, pursuant to § 319 of the Public Health Service Act, 42 U.S.C. § 247d, *et seq*.

70. Section 564 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 360bbb-3, authorizes the FDA to issue an EUA for a vaccine under certain emergency circumstances, allowing a vaccine to be introduced and administered to the public even when the product has not gone through the review process necessary for approval and licensure.

71. In an emergency, the HHS Secretary may issue an EUA if he concludes the following: (1) existence of a serious or life-threatening disease; (2) a product "may be effective" in treating or preventing it; (3) there is "no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;" (4) a risk-benefit analysis that measures both the known and potential benefits of the product against the known

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[26] *Public Readiness and Emergency Preparedness* (*PREP*) *Act*, Administration for Strategic Preparedness and Response, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx (last visited May 25, 2023).

[27] 42 U.S.C. § 247d-6d(d)(1).

and potential risks of the product is positive; and (5) that the patient's option to accept or decline the product is protected through informed consent. 21 U.S.C. § 360bbb-3(c)(1)-(5).

72. On December 11, 2020, the FDA issued an EUA for use of the Pfizer-BioNTech COVID-19 vaccine to prevent COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the FFDCA.

B. DOD Intentionally Left Only Unlicensed Product in Distribution in the United States at the Time of Mr. Watts' Death

73. As described below, DOD capitalized on a quintessential "bait and switch" fraud with respect to Pfizer's legally distinct EUA and FDA licensed COVID-19 vaccines.

74. Mr. Watts – who was willing to take the licensed Comirnaty vaccine – fell victim to DOD's scheme and paid with his life. He waited for Comirnaty and was instead given the EUA vaccine – the only one DOD intentionally allowed to be left in distribution.

75. At all times relevant to this complaint, DOD never initiated distribution of Comirnaty. On September 13, 2021, the National Library of Medicine within the National Institutes of Health, reported, "[a]t present, Pfizer does not plan to produce any product with these new [Comirnaty National Drug Codes] and labels over the next few months while [EUA] product is still available and being made available for U.S. distribution."[28]

76. In spite of the FDA declaring that the licensed "safe and effective" Comirnaty is "legally distinct" from the Pfizer EUA product (Exh. 6 FN. 8), DOD's sleight of hand intentionally allowed only the existing EUA Pfizer-BioNTech vaccine stock to remain in distribution at the time Mr. Watts received his second dose.

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[28] *RxNorm October 2021 Monthly Release*, NLM TECHNICAL BULLETIN, National Library of Medicine, National Institutes of Health, NLM Tech Bull. 2021 Sep-Oct;(442):b10, https://www.nlm.nih.gov/pubs/techbull/so21/brief/so21_rxnorm_october_release.html (last visited May 25, 2023).

77. DOD continued to exclusively allow distribution of its never-deemed-safe-and-effective EUA vaccine.

78. DOD's directing the exclusive distribution of its deadly EUA vaccine after licensure of another product caused Mr. Watts to be misled by further blurring to an even greater extent the key distinction between the experimental and the licensed—a key distinction that, from OWS' inception through the time of Mr. Watts' death, never concerned DOD in the least.

C. DOD Intentionally Blurred the Line Between Licensed and Experimental

79. A vaccine that has received a biologics license number has FDA "full approval" status, and has been deemed by the FDA to be "safe, pure, and potent" and has completed robust, well-controlled clinical trials. 42 U.S.C. §§ 262(a)(2)(C)(i)(I), 262(a)(2)(D).

80. In stark contrast, an EUA may be granted for medical products "that 'may be effective' to prevent, diagnose, or treat serious or life-threatening diseases or conditions . . . . The 'may be effective' standard . . . provides for a lower level of evidence than the 'effectiveness' standard that FDA uses for product approvals."[29]

81. The EUA vaccine that killed Mr. Watts was never FDA licensed, and never proven safe and effective—rather it had already been proven deadly. DOD knew full well that an EUA vaccine can only lawfully be characterized as "may be effective,"[30] as was the investigational anthrax vaccine the DOD illegally pushed on its service members in the 1990's.

82. In an earlier decision relating to that anthrax vaccine, this same Court ruled that coercion eviscerating informed consent violates federal law: "Congress has prohibited the

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[29] Guidance Document: *Emergency Use Authorization of Medical Products and Related Authorities*, U.S. FOOD & DRUG ADMINISTRATION (Jan. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities (last visited Apr 26, 2023).

[30] *Id*.

administration of investigational drugs to service members without their consent. This Court will not permit the government to circumvent this requirement." *Doe #1 v. Rumsfeld*, 341 F. Supp. 2d 1, 19. (D.D.C. 2004). "The United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Doe # 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135. (D.D.C. 2003)

83. Based on that decision alone, there is no doubt that the DOD was clearly aware of the legal distinctions between investigational, experimental products (here Pfizer-BioNTech's EUA vaccine) and FDA-approved products such as Comirnaty.

84. The DOD vaccine that killed Mr. Watts was not and still is not licensed. In fact, as of April 18, 2023, the vaccine that killed Mr. Watts, "the monovalent . . . Pfizer-BioNTech COVID-19 vaccine[] [is] no longer even authorized for use in the United States." That EUA has since been revoked.[31]

D. DOD's Actions Constitute Human Experimentation Without Consent

85. DOD's concealed, vast scope of the COVID-19 vaccine experiment it foisted on the public free of charge with detailed records kept, and DOD's repeated, illegal false assurances of safety and effectiveness furthered its nefarious aim of widespread public acceptance. DOD's intended wrongful purpose was non-consensual American human experimentation.

86. DOD continually and knowingly engaged in massive, deliberate deception and exaggeration to create demand in order to push the vaccines into the arms of as many Americans as possible, making the majority of the country (including Mr. Watts) unknowing participants in its mass human experiment.

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[31] FDA News Release: *Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines*, U.S. FOOD & DRUG ADMINISTRATION (Apr. 18, 2023), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines (last visited May 25, 2023).

87. DOD's mass experiment violates the most serious protections against human experimentation. United States courts examining the Nuremberg judgments have recognized that "[t]he universal and fundamental rights of human beings identified by Nuremberg . . . are the direct ancestors of the universal and fundamental norms recognized as *jus cogens*" from which no derogation is permitted, irrespective of the consent or practice of a given state. *Siderman de Blake v. Republic of Argentina*, 965 F.2d 699, 715 (9th Cir. 1992) (*cited in Sampson v. F.R.G.*, 250 F.3d 1145, 1150 (7th Cir. 2001))."[32]

88. The Seventh Circuit's conclusion that action that contravenes the Nuremberg Code's first principle constitutes a crime against humanity is a lucid indication of the international legal significance of the prohibition on nonconsensual medical experimentation. Similarly, U.S. Supreme Court Justices have recognized, "[t]he medical trials at Nuremberg in 1947 deeply impressed *upon the world* that experimentation with unknowing human subjects is morally and legally unacceptable." *United States v. Stanley*, 483 U.S. 669, 687, 107 S. Ct. 3054 (1987) (Brennan, J., concurring in part and dissenting in part) (emphasis added); *see also id*. at 709-10 (O'Connor, J., concurring in part and dissenting in part).[33]

89. The American public unknowingly succumbed to DOD's experiment. DOD's deliberate concealment of its human experiment caused Mr. Watts' death.

E. DOD Failed to Live Up to Its Duty

90. The perception of DOD's public trust can best be summarized as follows:

> "The nation expects more from the military officer: It expects a living portrayal of the highest standards of moral and ethical behavior. The expectation is neither fair nor unfair; it is a simple fact of the profession. The future of the services and the

[32] *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 179 (2d Cir. 2009).

[33] *Id.*

> well-being of its people depend on the public perception and fact of the honor, virtue and trustworthiness of the officer corps."[34]

91. However, now retired United States Army four-star general, and former OWS Chief Operating Officer, General Perna and DOD's deceit here is all too common according to an Army War College study:

> "This study found that many Army officers, after repeated exposure to the overwhelming demands and the associated need to put their honor on the line to verify compliance, have become ethically numb. As a result, an officer's signature and word have become tools to maneuver through the Army bureaucracy rather than being symbols of integrity and honesty. Sadly, much of the deception that occurs in the profession of arms is encouraged and sanctioned by the military institution as subordinates are forced to prioritize which requirements will actually be done to standard and which will only be reported as done to standard. As a result, untruthfulness is surprisingly common in the U.S. military even though members of the profession are loath to admit it."[35]

VI. COUNT ONE – WILLFUL MISCONDUCT PURSUANT TO 42 U.S.C. § 247d-6d(c)(1)(A)

92. Plaintiff realleges paragraphs 1 through 91 as if fully set forth herein.

93. Plaintiff has met all applicable prerequisites prior to bringing the instant action.

94. The elements of willful misconduct are as follows:

> The term "willful misconduct" shall, for purposes of Subsection (d), denote an act or omission that is taken—
>
> (i) intentionally to achieve a wrongful purpose;
> (ii) knowingly without legal or factual justification; and
> (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.
> 42 U.S.C. § 247d-6d(c)(1)(A)

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[34] *The Armed Forces Officer*, American Information Services Department of Defense (1988), p. 3, MARINES.MIL, https://www.marines.mil/portals/1/Publications/NAVMC%202563.pdf (last visited May 25, 2023).

[35] Leonard Wong & Stephen J. Gerras, *Lying to Ourselves: Dishonesty in the Army Profession*, U.S. ARMY WAR COLLEGE STRATEGIC STUDIES INSTITUTE (Feb. 2015), p. ix, https://publications.armywarcollege.edu/wp-content/uploads/2022/11/2321.pdf (last visited May 25, 2023).

A. DOD Intentionally Undertook Acts In Order To Achieve a Wrongful Purpose

1. DOD's Acts

95. From the outset of DOD's leadership role in OWS through the time of Mr. Watts' vaccine-induced death, DOD's procurement, oversight of distribution, and misrepresentation of an EUA vaccine deliberately misled Mr. Watts and the public at large by blurring the critical distinction between EUA and fully licensed vaccines.

96. DOD's initial order with Pfizer-BioNTech was conditioned upon the FDA granting an EUA or licensure. This is an important fact since the DOD, from the outset, was unconcerned if their vaccines were experimental or licensed. After the August 23, 2021, licensure, DOD took advantage of the inaccurate public perception that the investigational vaccines DOD left in distribution were licensed. They were not. This final step in DOD's intentional, continued deception and disinformation campaign wrongfully and illegally misled Mr. Watts into accepting the deadly, unlicensed Pfizer-BioNTech investigational vaccines that DOD intentionally left in circulation.

97. Once again, the distinction between licensure or authorization was of little or no consequence to the DOD so long as the lingering impression that their products were "safe and effective" remained—a distinction that had deadly consequences for Mr. Watts, who died from the DOD vaccines he trusted to be "safe and effective" licensed products.

2. DOD's Achievement of a Wrongful Purpose

98. DOD knew full well it did not have a legal right to accelerate public acceptance under false pretenses that its investigational vaccines were safe and effective based on DOD's

past litigation in this Court on precisely this point – DOD did not have a legal right to turn the public and Mr. Watts into unwitting guinea pigs.

99. DOD's calculated strategy accomplished its "principal purpose and objective" of "maximum uptake of the vaccine across all population groups," by promoting "vaccine confidence and uptake." DOD achieved its wrongful purpose by continued, calculated deception.

3. DOD had no Legal or Factual Justification to Conduct its Nation-Wide Human Experiment

100. Based on prior decisions by the D.C. District and Circuit Courts, DOD clearly understood that, under the law, an EUA investigational product is much different than a licensed vaccine and that claims it could legally make regarding an investigational product were different from legal claims for an FDA-approved product. "Safe and effective" is a term that may be applied to fully licensed products only. DOD was well aware of this based on the first *Doe v. Rumsfeld* decision.

101. DOD joined the ranks of the infamous when it conned Mr. Watts, and the whole American public, to unknowingly serve as "guinea pigs for experimental vaccines" thereby violating the Nuremberg Code's first principle: "The voluntary consent of the human subject is absolutely essential."[36] DOD's non-consensual mass human experimentation on the American public and Mr. Watts is not factually or legally justifiable.

4. DOD Disregarded the Known and Obvious Risk

102. DOD ignored fundamental norms recognized as *jus cogens* and codified in the Nuremberg Code by illegally turning the entire American public and Mr. Watts into human

[36] *Nuremberg Code: Directives for Human Experimentation*: The Protection of Human Subjects, The Office of Research Integrity, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation (last visited May 25, 2023).

subjects. DOD refused to acknowledge past wrongs cited by this Court in *Doe v. Rumsfeld*, when DOD ordered an initial 100 million[37] doses and agreed to purchase up to 600 million additional doses[38] of a prototype simply upon the issuance of the FDA's EUA rather than licensure. DOD acted as if this important distinction was of no consequence, and then continually misrepresented safety and efficacy of its EUA COVID-19 vaccines distributed until Mr. Watts' death. All these factors combined prove DOD utterly disregarded the illegality and the obvious risk inherent in its program.

103. Since DOD was the lead for implementing most vaccine-related initiatives within the CAG, they bear responsibility. Any benefit that could be derived from turning Americans into unwitting participants in its mass-human experiment is far outweighed by the harm caused by DOD's complete and utter disregard for lawful conduct.

104. Based on DOD's continued, calculated deception strategy, Mr. Watts was duped into taking DOD's deadly Pfizer-BioNTech EUA vaccine, which was the only version that DOD allowed to remain in distribution at the time of Mr. Watts' untimely death.

105. But for DOD's willful misconduct in engaging in deception to garner acceptance by Mr. Watts and the American public, and directing its supply, production, and distribution of experimental products under deliberately false pretenses, Mr. Watts would not have died.

106. DOD proximately caused Mr. Watts' death since DOD's hands-on direction of the deadly vaccines' production, promotion and distribution was a substantial factor in causing Mr. Watts' death. It was reasonably foreseeable that deadly consequences would result from DOD's

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[37] Department of the Army and Pfizer Contract, *Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for "COVID-19 Pandemic — Large Scale Vaccine Manufacturing Demonstration* (*Pfizer, Inc.*), *supra*.

[38] Amy Rose, *Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2 (Pfizer, Inc.), supra.*

leaving an experimental product as the only available vaccine in distribution. It was reasonably foreseeable that DOD's non-consensual human experimentation conducted on Mr. Watts who was reasonably and justifiably convinced, based on DOD's continued acts of deliberate deception, that DOD's vaccines were licensed, safe and effective would have deadly consequences. Mr. Watts' death was a natural and probable consequence of DOD's conduct since Mr. Watts, believing he was receiving safe and effective vaccines, received the deadly ones DOD intentionally allowed as the only vaccines to be left in distribution. DOD therefore directly and proximately caused Mr. Watts' death by vaccination.

PRAYER FOR RELIEF

WHEREFORE Estate prays for general, special, compensatory and punitive damages along with such further relief as this Court deems proper.

Dated: May 25, 2023

Signed _____

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