UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ESTATE OF GEORGE WATTS, JR.,

Plaintiff,

v.

LLOYD J. AUSTIN III in his official capacity as Secretary of the United States Department of Defense,

Defendant.

Civil Action No. 1:23-cv-01544 (CJN)

DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

INTRODUCTION

The Secretary of Defense, in his official capacity, moves to dismiss Plaintiff's complaint, ECF No. 1 ("Compl."), which brings a single claim for willful misconduct under the Public Readiness and Emergency Preparedness Act ("PREP Act" or "Act"), 42 U.S.C. § 247d-6d(c)(1)(A). Plaintiff has sued the Secretary of Defense to recover for the unfortunate death of Mr. George Watts, Jr., allegedly caused by the COVID-19 vaccine. But the complaint does not allege any direct connection between Mr. Watts and the Department of Defense (DoD), let alone any action on the part of DoD that could plausibly constitute willful misconduct. Instead, the complaint seeks compensation based on DoD's alleged role in encouraging the general public to receive the COVID-19 vaccine and assisting private parties to produce and distribute COVID-19 vaccines. The Court should dismiss this case in its entirety.

First, this Court does not have jurisdiction over Plaintiff's claim. Plaintiff concedes that sovereign immunity bars his claim against government officials sued in their official capacity. Compl. ¶ 11. Plaintiff does not identify any applicable waiver of sovereign immunity but instead argues that sovereign immunity is unconstitutional. Those arguments are unsupported by the text of the Constitution and case law.

Second, even if this Court had jurisdiction, the case should still be dismissed for failure to state a claim. To make out a claim under the PREP Act, a complaint must plead the elements of willful misconduct, which must be alleged with particularity, *see* 42 U.S.C. § 247d-6d(e)(3). The crux of Plaintiff's allegation is that DoD sought to encourage mass vaccinations, but nothing in the complaint comes close to meeting the statutory definition of "willful misconduct." For example, the complaint identifies statements from the Secretary of Defense and other DoD officials about the safety of the vaccines, but those statements were consistent with the evidence reviewed as part of the Food and Drug Administration's ("FDA") emergency use authorization

and recommendations for use issued by the Centers for Disease Control and Prevention ("CDC"). Moreover, there are no allegations that Mr. Watts ever heard any statement made by a DoD official about COVID-19 vaccines or relied on any particular DoD statement when deciding to receive the COVID-19 vaccine. Instead, Plaintiff seeks to recover from the Secretary of Defense based on DoD's alleged role in encouraging the public at large to get vaccinated during the COVID-19 pandemic and in directing distribution of the COVID-19 vaccine at the time of his vaccination. Compl. ¶¶ 32, 78. That is not enough to meet the stringent standard set out in the PREP Act.

For these reasons and others, Defendant moves to dismiss the complaint. Because the issues identified in this motion cannot be remedied through additional pleading, the Court should dismiss Plaintiff's claim with prejudice.

BACKGROUND

I. Statutory and Regulatory Background

In the event of a current or potential public health emergency, the Secretary of the Department of Health and Human Services ("HHS") is empowered to take certain actions for the general welfare. The Secretary may issue a declaration under the PREP Act after making the determination that a disease, health condition, or other threat to health constitutes a public health emergency or there is a credible risk that it may in the future constitute such an emergency. *See* 42 U.S.C. § 247d-6d(b). A PREP Act declaration identifies certain countermeasures as "covered countermeasures," and provides "covered persons"—including the United States, and manufacturers and distributors of those countermeasures—with "immun[ity] from suit and liability under Federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of [such] covered countermeasure" during a public-health emergency. *Id.* § 247d-6d(a)(1), (b)(1). Under the statute, "Covered countermeasure" includes (1) "a biological product . . . that is authorized for emergency

use," and (2) a "qualified, pandemic or epidemic product," including "a biological product . . . that is licensed . . . to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic." *Id.* §§ 247d-6d(i)(1)(A), (1)(C), (7)(A). Those allegedly injured by a covered countermeasure may file a claim under the Countermeasures Injury Compensation Program. *Id.* § 247d-6e(a).

The PREP Act's statutory liability protection does not extend to claims "for death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). "Willful misconduct" is defined in the statute as "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." *Id.* § 247d-6d(c)(1)(A). And while the United States is identified as a "covered person," *id.* § 247d-6d(i)(2)(A), the PREP Act does not waive federal sovereign immunity and it does not "abrogate or limit any defense or protection available to the United States," *id.* § 247d-6d(f).[1]

The Secretary of the HHS may also declare that circumstances justifying an emergency use authorization ("EUA") exist and issue an EUA for vaccines or other products intended for use in diagnosing, treating, or preventing the disease or condition that caused the emergency. *See* 21 U.S.C. § 360bbb-3(b)(1), (c). The Secretary of HHS may issue an EUA only if several statutory factors are satisifed, including:

> (1) that there has been a declaration of public health emergency that involves an agent that can cause "a serious or life-threatening disease or condition;
>
> (2) that, based on the totality of scientific evidence available . . . including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

[1] The PREP Act also requires that willful misconduct claims be brought in the U.S. District Court for the District of Columbia and assigned to a three-judge panel. *See* 42 U.S.C. § 247d-6d(d)(5), (e)(1).

> (A) the product may be effective in diagnosing, treating, or preventing . . . such disease or condition"; and
>
> "(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product[;]" and
>
> (3) "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition[.]"

Id. § 360bbb–3(c).[2]

II. Factual Background

In early 2020, HHS Secretary Alex Azar, II, declared COVID-19 a public health emergency, Compl. ¶ 69, and specifically defined "covered countermeasures" under the PREP Act to include any "vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19," 85 Fed. Reg. 15198-01 (Mar. 17, 2020). The HHS Secretary also took steps necessary to enable emergency use authorization of COVID-19 vaccines by making a determination of a public health emergency under 21 U.S.C. § 360bbb-3(b)(1)(C), *see* 85 Fed. Reg. 7316 (Feb. 7, 2020), and finding that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic," 85 Fed. Reg. 18250 (Apr. 1, 2020).[3]

On March 17, 2020, Pfizer and BioNTech, two pharmaceutical companies, signed a letter of intent to co-develop a COVID-19 vaccine. Compl. ¶ 21. In July 2020, HHS and DoD entered

[2] Defendant understands the complaint's references to "FDA-approved" vaccines to mean vaccines that have been granted Biologics License Application ("BLA") approval by the FDA. The process for issuing an EUA is different than BLA approval. FDA's Center for Biologics Evaluation and Research will approve a BLA if it determines that (1) the product "is safe, pure, and potent;" (2) "the facility in which the product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent;" and (3) the applicant "consents to the inspection of the facility that is the subject of the application." 42 U.S.C. § 262(a)(2)(C).

[3] The public health emergency determination under 21 U.S.C. § 360bbb-3 was subsequently updated. *See* 88 Fed. Reg. 16644 (Mar. 20, 2023).

into an agreement to purchase "100 million doses of . . . the COVID-19 vaccine candidate jointly developed by Pfizer and BioNTech, after Pfizer successfully manufactures and obtains approval or emergency use authorization from" FDA. *Id.* ¶ 26 & n.8. That agreement "expressly acknowledges and agrees that the HHS Declaration . . . providing [PREP Act] immunity from suit and liability is applicable," and the U.S. Government would not "use, or authorize use of" the vaccine unless such use "is protected from liability."[4]

On December 11, 2020, FDA issued an EUA for the Pfizer-BioNTech COVID-19 vaccine ("EUA vaccine"), pursuant to 21 U.S.C. § 360bbb-3. Compl. Ex. 6 at 1. According to the complaint, DoD served as the "director of supply, production and distribution" of the COVID-19 vaccines,[5] and DoD officials including Army General Gustave Perna, Acting Secretary of Defense Christopher C. Miller, and Secretary of Defense Lloyd J. Austin, III, made public statements representing that the COVID-19 vaccines—including EUA vaccines—were safe and effective. Compl. ¶¶ 19, 32, 34-35, 37-38.

On August 23, 2021, FDA approved the biologics license application (BLA) for the COVID-19 vaccine developed by Pfizer and BioNTech and labeled Comirnaty, Compl. Ex. 6 at 2,

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[4] Department of the Army, U.S. Army Contracting Command, 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.), at 20 (Jul. 21, 2020), https://perma.cc/9Y49-7P9G (cited in Compl. ¶ 28, n.9).

[5] While "COVID-19 vaccines" is not defined in the complaint, it is a matter of public record that EUAs were granted to multiple COVID-19 vaccines developed by different pharmaceutical companies. *See, e.g.*, U.S. Food & Drug Admin., FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine (Dec. 18, 2020), https://perma.cc/D232-BK53; *Phillips v. Bureau of Prisons*, 591 F.2d 966, 969 (D.C. Cir. 1979) (courts may consider "matters of general public record" on motion to dismiss); *Bega v. Jaddou*, No. 22-02171 (BAH), 2022 WL 17403123, at *3 (D.D.C. Dec. 2, 2022) (court may take judicial notice of information on federal agency website), *aff'd sub nom.*, *Da Costa v. Immigr. Inv. Program Off.*, No. 22-5320, 2023 WL 5313526 (D.C. Cir. Aug. 18, 2023).

determining that it was safe, pure, and potent, and otherwise met the conditions for approval. *See* 42 U.S.C. § 262(a)(2)(C); Compl. ¶ 47. At the same time that FDA licensed Comirnaty, it further provided that the licensed Comirnaty vaccine contained "the same formulation as the EUA-authorized vaccine," and "the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns." Compl. Ex. 6 at 2 n.8. The two vaccines remained "legally distinct with certain differences that do not impact safety or effectiveness," *id.*, including that the BLA-approved vaccine would be marketed under the "trade name, Comirnaty."[6] For at least some time after Comirnaty received BLA approval, Pfizer did not produce products with Comirnaty labels; at that time, there was an existing supply of EUA vaccines. *Supra* n.6 (quoted in Compl. ¶ 75).

Mr. Watts allegedly received two doses of Pfizer/BioNTech's EUA vaccine, on August 27, 2021, and September 17, 2021, as was apparently required by his community college for him to attend in-person classes. Compl. ¶¶ 44-45. Mr. Watts purportedly waited to receive the vaccine until the Comirnaty vaccine was "FDA-approved [as] 'safe and effective.'" *Id*. ¶¶ 46-47. While Mr. Watts allegedly preferred to receive the Comirnaty vaccine, "having been convinced of the vaccine's purported robust safety," the complaint alleges that he received the EUA vaccine. *Id*. ¶ 48. Mr. Watts allegedly "suffered numerous adverse health consequences from the vaccines, which ultimately resulted in his untimely death." *Id*. ¶ 49. His death certificate lists his cause of death as "COVID-19 vaccine-related myocarditis." Compl. Ex. 7.

Mr. Watts's surviving family members submitted a claim for death benefits to the Countermeasures Injury Compensation Program ("CICP") based on Mr. Watts's post-vaccine

[6] *RxNorm October 2021 Monthly Release*, NLM Technical Bulletin (Oct. 2021) (cited in Compl. ¶ 75 & n.28).

death. *See* Compl. Ex. 3 at 1-2. According to the complaint, the CICP claim is still pending. *See* Compl. ¶¶ 14-16. Mr. Watts's estate now seeks damages from the Secretary of Defense for Mr. Watt's death, claiming that DoD's actions in connection with the EUA vaccine constitute "willful misconduct."

ARGUMENT

I. Sovereign Immunity Bars Plaintiff's Claim.

This Court lacks jurisdiction because "sovereign immunity bars suits for money damages against officials in their official capacity absent a specific waiver by the government." *Simpson v. Fed. Bureau of Prisons*, No. 1:19-CV-03173 (CJN), 2020 WL 95814, at *3 (D.D.C. Jan. 8, 2020) (quoting *Clark v. Library of Cong.*, 750 F.2d 89, 103 (D.C. Cir. 1984)) (cleaned up).

The complaint brings a single claim under the PREP Act against one defendant—Secretary Austin—sued in only his official capacity as Secretary of Defense. *See* Compl. ¶ 19. A suit brought against a federal government official in his official capacity is the equivalent of a suit against the United States. *See Simpson*, 2020 WL 95814, at *3. This Court must therefore dismiss this case for lack of jurisdiction unless Plaintiff identifies an applicable waiver of sovereign immunity. *Id.* The complaint does not do so. The only part of the complaint that discusses sovereign immunity at all concedes that the PREP Act does not waive sovereign immunity over suits brought against the United States. Compl. ¶ 11; *see* 42 U.S.C. § 247d-6d(f) ("Nothing in [the PREP Act] shall be construed . . . to waive sovereign immunity . . ."). This Court thus lacks jurisdiction and must dismiss the case.

Instead of identifying some applicable waiver of sovereign immunity that would allow PREP Act claims against federal officials in their official capacity, Plaintiff argues that dismissing his case on sovereign immunity grounds would be unconstitutional for two reasons. First, Plaintiff claims that sovereign immunity protection against claims for damages "violates due process

enshrined in the 5th Amendment." Compl. ¶ 11. Second, Plaintiff argues that sovereign immunity "is also an unconstitutional taking in violation of the 5th Amendment." *Id.* Neither argument is correct.

A. Sovereign Immunity Does Not Violate Due Process.

The doctrine of sovereign immunity is consistent with the Constitution. "When the Constitution was ratified, it was well established in English law that the Crown could not be sued without consent in its own courts." *Alden v. Maine*, 527 U.S. 706, 715 (1999). The framers understood that the Constitution would not upset that long tradition and that the federal sovereign would not be amenable to suit without its consent. *See* Federalist No. 81 (Alexander Hamilton) ("It is inherent in the nature of sovereignty not to be amenable to the suit of an individual *without its consent.*" (emphasis in original)).

The Fifth Amendment's Due Process Clause does not operate as a general waiver of sovereign immunity. Plaintiff points to no case to support the argument that the Fifth Amendment's due process clause waives federal sovereign immunity, and nothing in the text or the history of the Fifth Amendment supports such a conclusion. Indeed, the Supreme Court has frequently and consistently applied sovereign immunity since the early days of the Republic. *See, e.g.*, *Cohens v. Virginia*, 19 U.S. (6 Wheat.) 264, 411-12 (1821) ("The universally received opinion is, that no suit can be commenced or prosecuted against the United States; that the judiciary act does not authorize such suits."); *United States v. Clarke*, 33 U.S. (8 Pet.) 436, 444 (1834) ("As the United States are not suable of common right, the party who institutes such suit must bring his case within the authority of some act of congress, or the court cannot exercise jurisdiction over it."); *see also Green v. Presidential Bank*, No. 1:20-CV-00183 (UNA), 2020 WL 2800676, at *1 (D.D.C. May 29, 2020) (dismissing a due process claim against the United States because the government had not waived sovereign immunity).

The Supreme Court continues to consistently apply this bedrock doctrine, explaining that the principle that "waiver of the Federal Government's sovereign immunity must be unequivocally expressed in statutory text" is a "critical requirement firmly grounded in our precedents." *Lane v. Pena*, 518 U.S. 187, 192 (1996); *see also F.A.A. v. Cooper*, 566 U.S. 284, 290 (2012) (sovereign immunity barred claims for damages based on mental or emotional distress); *Dep't of the Army v. Blue Fox, Inc.*, 525 U.S. 255, 265 (1999) (sovereign immunity bars creditors from enforcing liens on Government property or funds).

B. Sovereign Immunity Does Not Violate the Takings Clause.

Dismissing this case based on sovereign immunity also would not constitute an unconstitutional taking. Plaintiff argues that dismissing this case based on sovereign immunity would be a taking because a "legal cause of action is property within the meaning of the Fifth Amendment." Compl. ¶ 11 (citing *All. of Descendants of Tex. Land Grants v. United States*, 37 F.3d 1478, 1481 (Fed. Cir. 1994); *Cities Servs. Co. v. McGrath*, 342 U.S. 330, 335-36 (1952); *Ware v. Hylton*, 3 U.S. (3 Dall.) 199, 245 (1796)).

First, nothing was "taken" from Plaintiff for Fifth-Amendment purposes, because the long-standing principle of sovereign immunity means that he never had a viable, actionable claim against the United States in the first instance. *See Sharkey v. United States*, 17 Cl. Ct. 643, 648 (1989) ("properly assert[ing] its sovereign immunity . . . defense" means "that plaintiffs had no legally protected property interest in a cause of action against the government" and thus did "not allege the elements of a taking"). When Congress passed the PREP Act, it declined to waive sovereign immunity over actions brought pursuant to that Act.

Even if Plaintiff had a viable claim that was later extinguished, Plaintiff's federal statutory cause of action under the PREP Act would not be the type of cause of action that gives rise to a compensable property right subject to the Takings Clause. The Federal Circuit has explained that

a cause of action can sometimes be a "recognized" property right covered by the Takings Clause, but only if that cause of action relates to "real property, physical property, or intellectual property." *Adams v. United States*, 391 F.3d 1212, 1225 (Fed. Cir. 2004).[7] A cause of action based on "a statutory right to be paid money" is not a property right for purposes of the Takings Clause. *Id.*; *see also Campbell v. United States*, 134 Fed. Cl. 764, 777 (2017), *aff'd*, 932 F.3d 1331 (Fed. Cir. 2019). At best, Plaintiff's cause of action is an (unresolved) statutory claim for money under the PREP Act, so it is not a recognized property right covered by the Takings Clause.

Plaintiff's federal statutory cause of action under the PREP Act is also too speculative to be a recognized property right under the Takings Clause because "a highly contingent property interest is not afforded the protections of the Takings Clause." *Campbell*, 134 Fed. Cl. at 778. In *Campbell*, the court concluded that plaintiffs did not have a non-speculative property interest in their tort claims against new General Motors, because "[a]t the time that the property interest arose, the government possessed the discretion to extinguish, or not extinguish, that property interest."[8] *Id*. The same is true here. At the time Plaintiff's claim arose, the United States' entitlement to sovereign immunity had not been waived, and at all relevant times, the United States "possessed the discretion to extinguish, or not extinguish" any cause of action brought against it. *Id.*

[7] The case cited by Plaintiff involved a cause of action related to real property, which is why it could be considered a property right subject to the Takings Clause. *See* Compl. ¶ 11 (citing *All. of Descendants of Tex. Land Grants*, 37 F.3d at 1481). That is not the case here.

[8] *Campbell* dealt with the government's bailout of General Motors and its alleged role in the company's restructuring by the bankruptcy court. *See* 134 Fed. Cl. at 767-69, 776. As part of that restructuring, "new" General Motors acquired most of "old" General Motors's assets but would not be liable for personal injury claims that plaintiffs held against the "old" General Motors. *Id.* at 768. Plaintiffs claimed that the extinguishment of their right to assert successor liability claims against the "new" General Motors was a taking. *Id.* at 774.

Even if Plaintiff's statutory cause of action could be considered a property right under the Fifth Amendment, Plaintiff cannot show that exercising sovereign immunity is an unconstitutional taking. Dismissing a cause of action against federal officials based on sovereign immunity "is not a compensable taking." *Julian v. United States*, 658 F. App'x 1014, 1017 (Fed. Cir. 2016) (holding that dismissal of claims based on sovereign immunity did not violate Fifth Amendment takings clause) (citing *Julian v. Rigney*, No. 4:13-CV-00054, 2014 WL 1207980, at *9 (W.D. Va. Mar. 24, 2014), *aff'd sub nom.*, *Julian v. U.S. Dep't of Agric.*, 585 F. App'x 850 (4th Cir. 2014)); *Sharkey*, 17 Cl. Ct. at 648 (1989).[9]

Finally, even if Congress's decision not to waive sovereign immunity were a taking, this Court would have to dismiss this case for lack of jurisdiction because Plaintiff would likely need to bring his claim to the Court of Federal Claims. "[A] claim for just compensation under the Takings Clause must be brought to the Court of Federal Claims in the first instance, unless Congress has withdrawn the Tucker Act grant of jurisdiction in the relevant statute." *Horne v. Dep't of Agric.*, 569 U.S. 513, 527 (2013) (citation omitted).[10] Plaintiff has not identified any

[9] Courts also have regularly held that extinguishing legal claims by asserting (or re-asserting) foreign sovereign immunity is not a taking. *Aviation & Gen. Ins. Co., Ltd. v. United States*, 882 F.3d 1088, 1098–99 (Fed. Cir. 2018) (recognizing a property interest in legal claims against Libya, but concluding that reinstatement of foreign sovereign immunity did not amount to an unconstitutional taking under the Fifth Amendment); *Alimanestianu v. United States*, 888 F.3d 1374, 1384 (Fed. Cir. 2018) (extinguishing claims against Libya based on foreign sovereign immunity was not a taking); *Abrahim-Youri v. United States*, 139 F.3d 1462, 1468 (Fed. Cir. 1997) (extinguishing claims against Iran was not an unconstitutional taking); *Belk v. United States*, 858 F.2d 706, 710 (Fed. Cir. 1988) (extinguishing claims against Iran was not an unconstitutional taking).

[10] The Tucker Act provides that the Court of Federal Claims has jurisdiction over claims against the United States for money damages over $10,000 "founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491(a)(1); *see* 28 U.S.C. § 1346(a)(2) (extending jurisdiction over suits against the United States to district courts where the amount in controversy is less than $10,000).

statute that has withdrawn Tucker Act jurisdiction over any takings claim in this case, so his claim for an unconstitutional taking must be brought, if anywhere, in the Court of Federal Claims.

II. Plaintiff Fails to State a Claim Under the PREP Act.

A. Legal Standard

In addition to the clear bar of sovereign immunity, the complaint should be dismissed because Plaintiff fails to state a viable PREP Act claim for "willful misconduct." Under Rule 12(b)(6), a plaintiff must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "When deciding a motion to dismiss under 12(b)(6), courts must construe the pleadings broadly and assume that the facts are as plaintiff alleges[.]" *Joorabi v. Pompeo*, 464 F. Supp. 3d 93, 98-99 (D.D.C 2020). "[H]owever, threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," and "courts are not obligated to accept as true a legal conclusion couched as a factual allegation." *Id.* at 99 (citation omitted). Courts "may consider 'the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint,' or 'documents upon which the plaintiff's complaint necessarily relies even if the document is produced not by the plaintiff in the complaint but by the defendant in a motion to dismiss.'" *In re Domestic Airline Travel Antitrust Litig.*, 221 F. Supp. 3d 46, 54-55 (D.D.C. 2016) (quoting *Ward v. D.C. Dep't of Youth Rehab. Servs.*, 768 F.Supp.2d 117, 119 (D.D.C. 2011)). Courts may also take judicial notice of "factual content found on official public websites of government agencies." *Bega v. Jaddou*, No. 22-02171 (BAH), 2022 WL 17403123, at *3 (D.D.C. Dec. 2, 2022) (collecting cases), *aff'd sub nom.*, *Da Costa v. Immigr. Inv. Program Off.*, No. 22-5313, 2023 WL 5313526 (D.C. Cir. Aug. 18, 2023).

Plaintiff brings a single cause of action, alleging that DoD is liable for "willful misconduct pursuant to 42 U.S.C. § 247d-6d(c)(1)(A)." Compl. at 20. To state a claim for "willful misconduct" under the PREP Act, a plaintiff must allege "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). The PREP Act establishes a federal "standard for liability that is more stringent than a standard of negligence in any form or recklessness." *Id.* § 247d-6d(c)(1)(B). By its terms, the statute also demands a heightened pleading standard, requiring that "the complaint shall plead with particularity each element of the plaintiff's claim," including "each act or omission, by each covered person sued, that is alleged to constitute willful misconduct" and "facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed." *Id.* § 247d-6d(e)(3). Finally, the statute includes a verification requirement that allegations in the complaint not based on "the knowledge of the deponent" be "specifically identified as being alleged on information and belief." *Id.* § 247d-6d(e)(4)(B). Under these clear standards, Plaintiff has failed to plead a viable claim.

B. Plaintiff Fails to Plead Willful Misconduct Because No Enforcement Action has Been Taken in Connection with the Alleged DoD Acts.

Plaintiff alleges two vague categories of "acts" by DoD that it contends constitute willful misconduct. *First*, Plaintiff claims that multiple statements made by DoD officials representing that the COVID-19 vaccines were "safe and effective" "intentionally misled the public about COVID-19 vaccines." Compl. ¶¶ 32-39. This "'safe and effective' mantra," as Plaintiff puts it, was allegedly a DoD "ruse to ensure accelerated distribution of their experimental vaccines" by deceiving the public into believing that the vaccine received FDA approval, which requires an FDA determination that the vaccine is "safe and effective," rather than an EUA, which requires an

FDA determination that the vaccine "may be effective" and that "the known and potential benefits of the product" outweigh "the known and potential risks of the product." Compl. ¶¶ 39, 71; *see supra* n.2. *Second*, Plaintiff alleges that after FDA approved Pfizer's Comirnaty BLA on August 23, 2021, DoD "intentionally allowed only the existing EUA . . . vaccine stock to remain in distribution." Compl. ¶¶ 47, 74, 76; Compl. Ex. 6 at 2. In doing so, DoD allegedly "capitalized on a quintessential 'bait and switch' fraud" by "blurring . . . the key distinction between the experimental and the licensed" Pfizer vaccines. Compl. ¶¶ 73, 78.

DoD's actions do not meet the statutory definition of "willful misconduct" because Plaintiff identifies no enforcement action against DoD or the manufacturer or distributor of the vaccine in question. The PREP Act provides that an alleged "act or omission by a manufacturer or distributor . . . shall not constitute 'willful misconduct'" where "neither the Secretary [of HHS] nor the Attorney General has initiated an enforcement action with respect to such act or omission." 42 U.S.C. § 247d-6d(c)(5)(A)(i). The complaint alleges that DoD "directed and oversaw vaccine development, and directed supply, production, and distribution," including that DoD "caused accelerated production and then pushed out hundreds of millions of vaccines." Compl. ¶¶ 4, 5. Given Plaintiff's allegations that DoD had a central role in the manufacturing and distribution of the EUA vaccine, the fact that no enforcement action has been undertaken against DoD for its alleged acts, *see* Compl. ¶ 17, or against the manufacturer or distributor that DoD supposedly supervised, means that Plaintiff cannot meet the statutory definition of "willful misconduct" for a PREP Act violation.

C. Plaintiff Fails to Plead with Particularity any Act or Omission Knowingly Undertaken Without Legal or Factual Justification.

As to the first category of alleged acts—DoD's safe and effective "mantra," Compl. ¶ 39—the complaint does not plead with particularity that DoD's representations knowingly lacked a

factual justification. DoD's representations that the vaccine was safe and effective were consistent with the evidence reviewed as part of FDA's EUA authorization:

> FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, **did not identify specific safety concerns** that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 **confirmed the vaccine was 95% effective** . . . .

Compl. Ex. 6 at 3 (emphasis added). "On June 23, 2021, after reviewing available evidence including that for risks of myocarditis, [CDC's Advisory Committee on Immunization Practices (ACIP)] determined that the benefits of using mRNA COVID-19 vaccines under the FDA's EUA clearly outweigh the risks in all populations, including adolescents and young adults."[11] The CDC thereafter continued to recommend the use of Pfizer/BioNTech's EUA-vaccine for those aged 12 years and older.[12]

Since DoD's statements align with FDA's statements and CDC's recommendations, Plaintiff cannot show that DoD's statements were knowingly made without factual justification. Indeed, courts have dismissed cases in the public health context even under an "arbitrary and capricious" standard when plaintiffs' theory conflicted with CDC and FDA statements. *See Lloyd v. Sch. Bd. of Palm Beach Cnty.*, 570 F. Supp. 3d 1165, 1185 (S.D. Fl. 2021) (dismissing for failure

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[11] Gargano et al., *Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021*, 70 Morbidity & Mortality Wkly. Rep. 977 (July 9, 2021), https://perma.cc/49YJ-2UAH. The Morbidity and Mortality Weekly Report is a CDC publication and may appropriately be considered as a matter of judicial notice. *See Bega*, 2022 WL 17403123, at *3.

[12] Ctrs. For Disease Control & Prevention, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States* (August 1, 2021), https://web.archive.org/web/20210801074918/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html.

to state a claim in part because "the Court cannot find that Defendants are irrational for following the recommendations of the CDC"); *Denis v. Ige*, 538 F. Supp. 3d 1063, 1078 (D. Haw. 2021) (dismissing for failure to state a claim because "it is clearly reasonable for state and local officials to follow the CDC's guidance").

Plaintiff suggests that DoD should not have relied on FDA's own statements about safety and efficacy or CDC's recommendations because of reports of adverse events submitted to CDC and FDA's Vaccine Adverse Events Reporting System ("VAERS"). *See* Compl. ¶ 40. But as the documents attached to Plaintiff's complaint make clear, "a report to VAERS does not mean that . . . the vaccine caused or contributed to the adverse event (possible side effect)." Compl. Ex. 5; *see* Compl. Ex. 6 at 9, 11 (requiring VAERS reports in the event of certain adverse events, "irrespective of attribution to vaccine"). The CDC itself continued to recommend that everyone eligible receive the COVID-19 vaccination, despite the reports of some possible side effects in the VAERS database, including myocarditis. In August 2021, FDA concluded that despite the risk of myocarditis, "when used under the conditions described in [the EUA] authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks." Compl. Ex. 6 at 5. In short, the VAERS reports, by themselves, are insufficient to establish "above the speculative level," *Twombly,* 550 U.S. at 555, that DoD's statements about safety were knowingly made without factual justification. This is especially true where, as here, the subject-matter experts at the CDC responsible for setting the nation's immunization recommendations reviewed the same body of data and concluded that the benefits of the EUA vaccines "clearly outweigh" the risks. *See supra* n.11.[13]

[13] The complaint also asserts that DoD's July 2020 contract with Pfizer "strongly suggests that neither party had complete confidence in the vaccine" because it stated that the product would be

Plaintiff's claim that after Comirnaty was approved by FDA, DoD allegedly directed exclusive distribution of the EUA vaccine to mislead the public into accepting the EUA vaccine is also insufficient to meet the statute's high bar. As a threshold issue, Plaintiff's complaint lays no foundation for personal knowledge in support of those allegations. And while Plaintiff does not plead the claim on information and belief (as required for allegations not within personal knowledge), Plaintiff cites no evidence or public statements supporting that DoD "allowed only the existing EUA Pfizer-BioNTech vaccine stock to remain in distribution" after approval of Comirnaty. Compl. ¶¶ 74, 76, 77; s*ee* 42 U.S.C. § 247d-6d(e)(4)(B). Nor does Plaintiff provide specific details to back up that allegation, such as who made the decision to distribute only the EUA vaccine, why they did so, and how long the exclusive distribution lasted. *See* 42 U.S.C. § 247d-6d(e)(3)(A) (requiring that "each act or omission" be pleaded with particularity); *Alemu v. Dep't of For-Hire Vehicles*, 327 F. Supp. 3d 29, 45 (D.D.C. 2018) (recognizing in context of Rule 9(b), that particularity requirement "requires a complaint to . . . state the who, what, where, when, and how surrounding the fraudulent conduct" (citations omitted)). The lack of specific allegations regarding DoD's conduct is especially glaring when the complaint also alleges that the decision of what vaccine product to produce and distribute was made by *Pfizer*. *See* Compl. ¶ 75.

Even assuming that DoD was responsible for Pfizer distributing only the EUA vaccine for a time (an assumption unsupported by any particular or plausible allegations), and assuming that alleged responsibility could constitute an "act" under the PREP Act, the complaint does not allege any facts supporting that DoD knowingly acted without factual or legal justification. When

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covered by the PREP Act. Compl. ¶¶ 27-31 & nn.9-11. Such provision is irrelevant to DoD's views on the vaccine's viability at the time of its alleged acts months later, because (a) DoD entered into the contract nearly six months before FDA evaluated the vaccine and issued the EUA, *id*. ¶¶ 27, 29, 32; and (b) HHS, not DoD, made the determination to invoke PREP Act immunity for the vaccine, *id*. ¶ 57; 42 U.S.C. §§ 201(c), 247d-6d(b)(1).

approving Comirnaty, FDA determined that the EUA vaccine and Comirnaty vaccine were functionally interchangeable: "The licensed [Comirnaty] vaccine has **the same formulation** as the EUA-authorized vaccine and the products can be used **interchangeably** to provide the vaccination series **without presenting any safety or effectiveness concerns**." Compl. Ex. 6 at 2 n.8 (emphasis added). FDA also reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine and authorized its continued use after approving the BLA for Comirnaty, because there was "not sufficient approved [BLA-labeled] vaccine available for distribution to this population [individuals 16 years of age and older] in its entirety at the time." Compl. Ex. 6, at 5, n.9. DoD's alleged distribution of the EUA vaccine after Comirnaty's FDA approval was consistent with FDA's statement that the vaccines could be used "interchangeably" and was further justified by FDA's determination that Comirnaty, which had the same formulation as the EUA vaccine, met the statutory standards for approval.

D. Plaintiff Fails to Plead DoD Acted Intentionally to Achieve a Wrongful Purpose.

The complaint also fails to plead that DoD acted with the intent to mislead the public into believing that the EUA vaccine received FDA BLA approval. *First*, Plaintiff does not plead with particularly that DoD acted with a wrongful purpose. It claims in conclusory fashion that DoD "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." Compl. ¶ 86. But absent any *factual* allegations to show DoD was motivated by a desire to turn the public "into unwitting guinea pigs," Compl. ¶ 98, the complaint fails to satisfy even the basic plausibility standard of pleading required under the rules of federal procedure, let alone the PREP Act's heightened standard. *See Iqbal*, 556 U.S. at 678 ("complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'" (quoting *Twombly*, 550

U.S. at 570)). As the complaint acknowledges, DoD sought to promote "maximum uptake of the vaccine across all population groups." Compl. ¶ 99. This aim, without more, is also consistent with a proper purpose of promoting public health and mitigating a deadly pandemic. *Cf. Iqbal*, 556 U.S. at 678 (*"*Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" (quoting *Twombly*, 550 U.S. at 557)).

Second, the complaint alleges no facts to support that DoD acted with the intention of misleading the public about the distinction between an FDA authorization and approval or the safety of the EUA vaccine. *See Presidential Bank, FSB v. 1733 27th St. SE LLC*, 271 F. Supp. 3d 163, 169 (D.D.C. 2017) ("The court need not accept as true inferences unsupported by facts set out in the complaint or legal conclusions cast as factual allegations." (citations omitted)). This is particularly true of the assertion that DoD directed exclusive distribution of the EUA vaccine to further blur any distinction between it and Comirnaty when it acted consistent with FDA's statement that the products may be used interchangeably. *See Twombly*, 550 U.S. at 570 (dismissing complaint that failed to "nudge[] their claims across the line from conceivable to plausible").

To the contrary, DoD and other agencies were transparent with recipients and the public about the risks of vaccination. At the time of Mr. Watts's vaccination, a risk of myocarditis was known and publicized. While the CDC continued to recommend that all eligible adults receive the EUA COVID-19 vaccine, *see supra* nn.11 & 12, information about the risk of myocarditis and pericarditis was required to be shared with those receiving the COVID-19 vaccine, including Mr. Watts. *See* Compl. Ex. 6 at 2, n.6 ("In the June 25, 2021 revision . . . [t]he Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following

administration of the Pfizer-BioNTech COVID-19 Vaccine."). Similarly, in the only statement described in the complaint attributed to Defendant Secretary Austin, he encouraged the public to visit the CDC website, *see* Compl. ¶ 37, n.17, which had information about vaccination recommendations, safety information, efficacy data, links to relevant studies, and VAERS reports—*i.e.* the data Plaintiff claims suggested to DoD that the EUA vaccine was causing complications, *see supra* at 16.[14]

E. Plaintiff Does Not Plead with Particularity that DoD Acted 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.

Plaintiff fails to state a claim for the additional reason that the complaint does not plead with particularity that DoD acted "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)(iii). In fact, FDA engaged in a similar "risk-benefit analysis" in granting the EUA, Compl. ¶ 71, and determined "based on the totality of the scientific evidence available, that the known and potential benefits of [the EUA] Vaccine outweigh the known and potential risks of the [EUA] vaccine, for the prevention of COVID-19 in individuals 16 years of age and older," Compl. Ex. 6 at 3. And in the months preceding Mr. Watts's vaccination, CDC further "determined that the benefits of using" the EUA vaccine "clearly outweigh the risks of myocarditis and pericarditis in all people aged 12 years or older." *Supra* n.11. Plaintiff pleads no facts to support his allegation that DoD had reason to doubt FDA and CDC's assessments or that DoD was aware of any specific "obvious risk" presented by the EUA vaccine that made it "highly probable" that the EUA vaccine's harms would outweigh its benefits. *See* 42 U.S.C. § 247d-6d(c)(1)(A)(iii). DoD's reliance on the medical

[14] *See Vaccine Adverse Event Reporting System (VAERS)*, Ctrs. for Disease Control & Prevention, http://web.archive.org/web/20210228213502/https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html.

expertise of these specialized agencies cannot even be considered unreasonable, *see Lloyd*, 2021 WL 5353879, at *13; *Denis*, 538 F. Supp. 3d at 1078, let alone meet the more stringent pleading standard of the PREP Act.

Furthermore, FDA's approval of a vaccine with the same formulation as the EUA vaccine demonstrates that any risks associated with DoD's promotion of the EUA vaccine did not make it highly probable that the harm would outweigh the benefit. The Comirnaty vaccine contained "the same formulation as the EUA-authorized vaccine," and FDA concluded that the two "products can be used interchangeably . . . without presenting any safety or effectiveness concerns." Compl. Ex. 6 at 2 n.8. Given that Plaintiff pleads that the Comirnaty vaccine is "safe and effective," Compl. ¶ 47, Plaintiff cannot allege that DoD's purported encouragement and distribution of the EUA vaccine *instead of* the Comirnaty vaccine—*i.e.*, the same formulation of vaccine—created any known or obvious risk of harm.

F. Plaintiff Does Not Plead that the Alleged Acts Proximately Caused Injury.

Finally, Plaintiff cannot plead proximate cause with particularity. *See* 42 U.S.C. § 247d-6d(e)(3)(B). Proximate cause requires that "the injury is the natural and probable consequence of the negligent or wrongful act and ought to be foreseen in light of the circumstances." *Burnett v. Al Baraka Inv. & Dev. Corp*., 274 F. Supp. 2d 86, 105 (D.D.C. 2003) (citations omitted). The alleged DoD actions were not the cause of Mr. Watt's unfortunate post-vaccination death.

Plaintiff fails to plead that DoD's representations regarding the safety and efficacy of the EUA vaccine caused Mr. Watts's injury. There are no allegations that Mr. Watts ever heard or read any DoD statement the complaint cites regarding COVID-19 vaccines, much less that he specifically relied on it. Instead, the complaint alleges DoD generally misled the public at large into believing that FDA's EUA process was the same as its BLA approval process. But the DoD statements alleged in the complaint do not even specifically reference Pfizer's EUA vaccine, just

"COVID-19 vaccines" generally, Compl. ¶¶ 33-34, 37, and individuals like Mr. Watts would have received a notice informing them of the risk of myocarditis prior to consenting to vaccination, *see* Compl. Ex. 6 at 2, n.6.

Moreover, according to the complaint itself, Mr. Watts was not misled; he was aware at the time of his vaccination that the EUA vaccine was different than a BLA-approved product and, thus, sought to "wait[] until Comirnaty . . . was licensed by the FDA before he would receive a COVID-19 vaccination." Compl. ¶ 46. Given this, Plaintiff cannot plead that any of the alleged statements made specifically by DoD caused Mr. Watts to accept the EUA vaccine mistakenly believing it to have been BLA approved. And, the distinction between EUA and BLA-approved products is immaterial for purposes of this case where Plaintiff concedes the FDA-approved vaccine was "safe and effective," Compl. ¶¶ 47, and the FDA stated that the two products were "interchangeabl[e]," Compl. Ex. 6 at 2 n.8.

For the same reason, DoD's alleged exclusive distribution of the EUA vaccine instead of the Comirnaty vaccine was not a proximate cause of harm. The complaint does not, and cannot, allege how Mr. Watt's receipt of an EUA-authorized vaccine caused his harm where Plaintiff concedes that a vaccine with the same formulation was "safe and effective," Compl. ¶¶ 47. Nor can Plaintiff allege how such harm was foreseeable to DoD where FDA stated that the two vaccines "can be used interchangeably . . . without presenting any safety or effectiveness concerns." Compl. Ex. 6 at 2 n.8.

CONCLUSION

For any and all of the foregoing reasons, the Court should dismiss Plaintiff's claim with prejudice.

Dated: September 1, 2023 Respectfully submitted,

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