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.: 1:23-cv-01544 (CJN)

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

JUDGE: Hon. Carl J. Nichols

ORAL ARGUMENT REQUESTED

TABLE OF CONTENTS

Page #

TABLE OF AUTHORITIES iii

I. INTRODUCTION 1

II. ARGUMENT 4

A. The PREP Act Requires DOD to Defend Itself in this Court. 4

1. Foundational Considerations 4

2. The PREP Act's Sovereign Immunity Subsection is Unconstitutional. 6

a. The PREP Act's Sovereign Immunity Clause Offends 5th Amendment Due Process. 7

b. Sovereign Immunity Offends the Takings Clause of the 5th Amendment. 9

3. The Court May Sever the Unconstitutional Sovereign Immunity Subsection From the PREP Act and Maintain the Remainder of the Act. 10

B. The PREP Act's Unique Pleading Standards vis-à-vis a Rule 12(b)(6) Motion to Dismiss 11

1. BLA and EUA Vaccines are not Identical and are Legally Distinct. 13

2. DOD Misrepresents that George Watts, Jr., would have Received a Notice to Caregivers Citing [ECF No. 13-1, at 24-25]. 14

3. Defendant's Motion Incorrectly Avers that the Complaint Offered no Evidence that Licensed Vaccines weren't Available to George Watts, Jr. [ECF No. 13-1, at 22] 15

4. Contrary to Defendant's Motion [ECF No. 13-1, at 18], an Enforcement Action is not a Necessary Prerequisite. 15

5. Contrary to Defendant's Motion [ECF No. 13-1, at 25], all Actions and Misstatements of Safety and Efficacy are Attributable to OWS Leadership. 16

6. According to the CDC, Deaths from Myocarditis are not Anomalies. 17

7. DOD's Penchant for Human Experimentation Caused a Known and Obvious Risk of Death That Outweighed Any Benefit. 17

C. The Complaint Satisfies Each and Every Pleading Requirement. 18

1. DOD's 'analysis' is Incomplete. 18

2. The Complaint Properly Alleges DOD Acted Intentionally to Achieve a Wrongful Purpose. 20

3. The Complaint Properly Alleges DOD Acted Knowingly Without Legal or Factual Justification. 21

4. The Complaint Properly Alleges 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. 22

5. Facts Support the Allegation that such Alleged Willful Misconduct Proximately Caused the Injury Claimed. 23

6. Facts Support the Allegation that the Person on whose Behalf the Complaint was filed Suffered Death or Serious Physical Injury. 24

D. DOD's Scienter, Historical Perspective and Context 24

III. CONCLUSION 26

TABLE OF AUTHORITIES

Federal Cases

Alaska Airlines, Inc. v. Brock,
480 U.S. 678 (1987).....10

Alliance of Descendants of Tex. Land Grants v. United States,
37 F.3d 1478 (Fed. Cir. 1994).....9

Ashcroft v. Iqbal,
556 U.S. 662 (1937).....12

Ayotte v. Planned Parenthood of Northern New Eng.,
546 U.S. 320, 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006).....11

Barry v. District of Columbia Board of Elections & Ethics,
448 F. Supp. 1249 (1978) 10

Cannon v. Watermark Ret. Cmtys., Inc.,
45 F.4th 137 (D.C. Cir. 2022).....5, 8

Champlin Refining Co. v. Corporation Commission,
286 U.S. 210, 52 S. Ct. 559, 76 L. Ed. 1062 (1932).....10, 11

Cities Servs. Co. v. McGrath,
342 U.S. 330 (1952).....9

Coker v. Austin,
2022 U.S. Dist. LEXIS 240820 (N.D. Fla. Nov. 8, 2022).....14

Doe #1 v. Rumsfeld,
297 F. Supp. 2d 119 (D.D.C. 2003).....17, 22, 24, 25, 26

Doe v. Austin,
572 F. Supp. 3d 1224 (N.D. Fla. November 12, 2021).....13, 19

Doe v. Rumsfeld,
341 F. Supp. 2d 1 (D.D.C. 2004).....26

Duke Power Co. v. Carolina Envtl. Study Group,
438 U.S. 59 (1978).....8

Firestone v. Firestone,
76 F.3d 1205 (1996).....12

Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.,
561 U.S. 477 (2010).....11

Holy Land Found. for Relief & Dev. v. Ashcroft,
357 U.S. App. D.C. 35 (D.C. Cir. 2003).....12

Hudak v. Elmcroft of Sagamore Hills,
58 F.4th 845 (6th Cir. 2023).....4

INS v. Chadha,
462 U.S. 919 (1983).....10

Luce v. Edelstein,
802 F.2d 49 (2d Cir. 1986).....12

Manyweather v. Woodlawn Manor, Inc.,
40 F.4th 237 (5th Cir. 2022).....4

Marbury v. Madison,
5 U.S. 137 (1803).....1

Martin v. Donley,
886 F. Supp. 2d 1 (D.D.C. 2012).....25, 26

Roman Catholic Diocese v. Cuomo,
141 S. Ct. 63 (2020).....6

Triplett v. Heckler,
1985 U.S. App. LEXIS 21002 (5th Cir. 1985), reh'g denied, 774 F.2d 1160
(5th Cir. 1985), cert. denied, 474 U.S. 1104, 106 S. Ct. 889, 88 L. Ed. 2d 923,
1986 U.S. LEXIS 1244 (1986).....14

United States ex rel. Cimino v. Int'l Bus. Machs. Corp.,
3 F.4th 412 (D.C. Cir. 2021).....12

United States ex rel. Vt. Nat'l Telephone Co. v. Northstar Wireless, LLC,
34 F.4th 29 (D.C. Cir. 2022).....12

United States v. Generix Drug Corp.,
460 U.S. 453, 103 S. Ct. 1298, 75 L. Ed. 2d 198 (1983).....13

United States v. Lee,
106 U.S. 196 (1882).....1

United States v. Stanley,
483 U.S. 669 (1987).....17, 24, 26

Ware v. Hylton,
3 U.S. 199, 1 L. Ed. 568 (1796).....9

Zukerman v. United States Postal Serv.,
961 F.3d 431 (D.C. Cir. 2020) 12

Miscellaneous Cases

United States v. Brandt (The Medical Case), 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10 (1949) 24

United States Constitution

Fifth Amendment 5, 6, 7, 9, 10

United States Code

10 U.S.C
§ 1107 ..... 13, 25

42 U.S.C.
§ 247d–6d 2
§ 247d–6d(a)(1) 4
§ 247d–6d(c)(1)(A)(i) 20
§ 247d–6d(c)(1)(A)(ii) 21
§ 247d–6d(c)(1)(A)(iii) 22
§ 247d–6d(c)(3) 12, 20
§ 247d–6d(c)(5) 15
§ 247d–6d(c)(5)(A) 15
§ 247d–6d(c)(5)(A)(i) 2, 15
§ 247d–6d(e) 4
§ 247d–6d(e)(3)(B) 23
§ 247d–6d(e)(3)(C) 24
§ 247d–6d(e)(9) 6
§ 247d–6d(f) 3, 5, 11
§ 247d–6d(g) 2, 3, 5
§ 247d–6d(i)(3) 16
§ 247d–6e(a) 8
§ 247d–6e(d)(1) 8

Code of Federal Regulations

21 C.F.R. § 600.11 14
21 C.F.R. § 600.20-.21 14

Federal Rules of Civil Procedure

Rule 8 12
Rule 9(b) 12
Rule 11 6
Rule 12(b) 14
Rule 12(b)(1) 3
Rule 12(b)(6) 2, 11, 12, 14, 18
Rule 56 14

Other Authorities

2A J. Moore & J. Lucas, *Moor's Federal Practice*, P 9.03 (2d ed. 1986) 12

Erwin Chemerinsky, *Against Sovereign Immunity*, 53 STANFORD LAW REVIEW 1201, 1205 (2001) 7

Executive Order No. 13,139, 64 Fed. Reg. 54,175 (Sept. 30, 1999) 26

Federal Food, Drug, and Cosmetic Act § 564 13

Selected Adverse Events Reported after COVID-19 Vaccination, Centers for Disease Control and Prevention, CDC.GOV, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (July 13, 2023) 17

Shuster, Evelyne, *Fifty years later: the significance of the Nuremberg Code*, THE NEW ENGLAND JOURNAL OF MEDICINE 337 20 (1997): 1436-40, https://www.nejm.org/doi/full/10.1056/nejm199711133372006 25

Table 4. CICP Claims Compensated (*Fiscal Years 2010 - 2023*), HEALTH RESOURCES AND SERVICES ADMINISTRATION (Data as of Aug. 1, 2023), https://www.hrsa.gov/cicp/cicp-data/table-4 8

The Vaccine Adverse Event Reporting System (VAERS) Results https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=633CCF8C35B3866ABC5623263D27 (last visited September 12, 2023) 8

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All the officers of the government, from the highest to the lowest, are creatures of the law and are bound to obey it.

United States v. Lee, 106 U.S. 196, 220 (1882)

The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection.

Marbury v. Madison, 5 U.S. 137, 163 (1803)

I. INTRODUCTION

With the same vigor of Don Quixote's defense against the charge of the windmills, Defendant Lloyd J. Austin, III, in his official capacity ("Defendant") moves to dismiss [ECF No.

13], the Complaint [ECF No. 1] brought by the Estate of George Watts, Jr., ("Plaintiff") in an attempt to avoid liability for causing the untimely and unnecessary death of twenty-four-year-old George Watts, Jr. By mischaracterizing the Complaint, avoiding a full discussion of sovereign immunity law as it applies to the Public Readiness and Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d, and omitting and overlooking severability, the Department of Defense's ("DOD") motion for dismissal for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure ("Motion") falls short.

Defendant's Motion rests precariously on five fallacies:

1) That legally distinct experimental vaccines and licensed COVID-19 vaccines are interchangeable. [ECF No. 13-1, at 23];

2) That the PREP Act's severability clause 42 U.S.C. § 247d-6d(g)(which Defendant ignores in the Motion) doesn't merit a thorough discussion;

3) That DOD's oversight and direction of Operation Warp Speed ("OWS") inexplicably transformed DOD into a manufacturer or distributor[1] under the Act. [ECF No. 13-1, at 19];

4) That the difference between BLA (Biologics License Application) and EUA (Emergency Use Authorization) is immaterial in this case. [ECF No. 13-1, at 27]; and,

5) That DOD never misled regarding safety and efficacy.

[1] A manufacturer or distributor is a more restrictive classification with more challenging requirements to bring suit under the Act. *See* 42 U.S.C. § 247d-6d(c)(5)(A)(i).

Apparently relying on Rule 12(b)(1) of the Federal Rules of Civil Procedure (though never explicitly stating any basis for this portion of the Motion), Defendant argues that the Court should dismiss the Complaint because a federal actor is immune from suit pursuant to the PREP Act and that Defendant should be allowed to act with impunity, bearing zero responsibility for death (as here) or other serious physical injury resulting from his actions. As shown below, Defendant's argument only highlights the logical inconsistency of upholding the sovereign immunity clause in the PREP Act, *see* 42 U.S.C. § 247d-6d(f), when it already created an exclusive pathway to sue. A statute that creates a claim, but then bars anyone from prosecuting it, is unconscionable as well as unconstitutional. Severability of such an unconstitutional provision is afforded under 42 U.S.C. § 247d-6d(g).

Further, Plaintiff's Complaint is more than sufficient to withstand Defendant's Motion. As a general rule – applicable here – a federal court in ruling on a motion to dismiss must accept the allegations of the complaint as true. Plaintiff's Verified Complaint alleges and pinpoints every enumerated element of willful misconduct, while Defendant's Motion does not properly address each element and does not rebut each fact as pled. DOD in essence defends against a fictional complaint that doesn't exist.

Instead of focusing on any alleged shortcomings of the actual Complaint, Defendant's Motion improperly attempts to shift the focus away from DOD's indisputable liability for hornswoggling Americans into participating in its deadly mass human experiment – one that far surpassed the reach of the lethal medical experimentation that led to the U.S. Military Tribunal of Nazi doctors in Nuremberg some 75 years earlier.

DOD's experiment pushed several hundred million free vaccines on a trusting American public with an intentionally deceptive promise that the vaccines were safe and efficacious, while

Operation Warp Speed ("OWS") kept detailed records and an ongoing tally of the severely injured and the dead.

II. ARGUMENT

A. The PREP Act Requires DOD to Defend Itself in this Court.

1. Foundational Considerations

The PREP Act is like a series of concentric chokers – endlessly suffocating any hope of redress for injuries caused by COVID-19 vaccines, particularly against the federal government. First, the PREP Act provides extraordinary liability protection:

> Subject to certain limitations, a covered person [such as the DOD] is immune 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 or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure.

42 U.S.C. § 247d–6d(a)(1).

Generally speaking, the PREP Act forecloses state-based wrongful death, recklessness, product liability, and negligence claims; it also forecloses claims under the Federal Tort Claims Act, along with every other traditional remedy that would otherwise be available to an individual who is injured or killed as a result of another's malfeasance. "The sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct[.] 247d-6d(d)(1)." *Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 855 (6th Cir. 2023). "Willful misconduct is a more 'stringent standard' of liability than 'recklessness' or 'any standard of negligence.'" *Manyweather v. Woodlawn Manor, Inc.,* 40 F.4th 237, 243 (5th Cir. 2022). 42 U.S.C. § 247d-6d(e) "lays out a set of carefully controlled pretrial and trial procedures for subsection (d) willful misconduct cases, which it channels to the

D.D.C." *Cannon v. Watermark Ret. Cmtys., Inc*., 45 F.4th 137, 144 (D.C. Cir. 2022) "In providing for a willful misconduct exception, Congress included detailed forum, discovery, pleading, and proof-of-scienter provisions. . . ." *Id.* at 148.

Despite the fact that federal government actors and agencies are "covered persons" subject to willful misconduct claims, the Act goes further and, under the auspices of "sovereign immunity," cuts off redress for those injured by federal government actions and agencies.

That sovereign immunity clause states:

> Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28 (relating to tort claims procedure).

42 U.S.C. § 247d–6d(f).

Defendant's sovereign immunity defense is unconstitutional because it strips Plaintiff's last and only remaining avenue for recovery, violates due process and constitutes an unconstitutional "taking" under the Fifth Amendment of the U.S. Constitution.

Severing the sovereign immunity clause of the Act is allowed under the black letter of the PREP Act itself; it states:

> Severability. If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

42 U.S.C. § 247d–6d(g).

Excising this one unconstitutional provision of the Act leaves the remaining provisions intact and unaffected. Severance still provides DOD with "covered person" status under the PREP Act and with all the extraordinary protection it confers. Since Defendant's willful

misconduct has been pled and exposed, DOD must be held to answer for its grievous wrongdoing.

Contrary to Defendant's suggestion that Plaintiff dismiss and refile in the Court of Federal Claims [ECF No. 13-1, at 11-12], the PREP Act permits a single cause of action (willful misconduct), with filing permitted in this one venue, only after Plaintiff overcomes nearly impassible roadblocks for remuneration – strict pre-litigation hurdles, clear and convincing evidence to prove willful misconduct, verification and attested-to causation by a non-treating physician, while being threatened with harsh Rule 11 sanctions "sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct."[2] Plaintiff has met each and every one of these prerequisites, and the Court should allow this strong case to move forward.

2. The PREP Act's Sovereign Immunity Subsection is Unconstitutional.

> **"*But even in a pandemic, the Constitution cannot be put away and forgotten*."**
>
> *Roman Catholic Diocese v. Cuomo*, 141 S. Ct. 63, 68 Opinion (Per Curiam) (2020)

> **"*Even if the Constitution has taken a holiday during this pandemic, it cannot become a sabbatical*."** (Justice Gorsuch, concurring) *Id.* at 70.

The PREP Act's enumerated sovereign immunity for the United States is unconstitutional since foreclosing all redress, including against the government, violates the due process enshrined in the Fifth Amendment. Its central promise is that all levels of American government must abide by the law and provide fair procedures, particularly in life-or-death instances such as this one. Sovereign immunity is not mentioned in the U.S. Constitution. Violating the Due

[2] 42 U.S.C. § 247d–6d(e)(9)

Process and Takings Clauses of the Fifth Amendment to the Constitution is unconstitutional, however, and the sovereign immunity clause here is such a violation.

As constitutional scholar Erwin Chemerinsky has stated: "The text of the constitution is silent about sovereign immunity. Not one clause of the first seven articles even remotely hints at the idea of governmental immunity from suits. No constitutional amendment has bestowed sovereign immunity on the federal government."[3] Chemerinsky further noted that: "[s]overeign immunity also frustrates the supremacy of federal law by preventing the enforcement of the constitution. . . . [and] makes the laws of the United States subordinate to the will of men and women making government decisions."[4]

Defendant fails to cite a single case on point on the constitutionality of sovereign immunity under the PREP Act. Defendant's cases are inapposite because none involves a statute that first eliminates all existing avenues of relief; then provides a vehicle for a lawsuit against the federal government in Federal District Court with carefully prescribed prerequisites; but in a later provision retains the sovereign immunity defense, precluding any possibility for relief. This final defense cannot be surmounted unless it is found to be unconstitutional. The PREP Act is uniquely different from the cases Defendant cites, and this is a case of first impression.

a. The PREP Act's Sovereign Immunity Clause Offends 5th Amendment Due Process.

Without severability, the PREP Act deprives Plaintiff of due process by cutting off any possibility of relief for the death Defendant's willful malfeasance caused. "Even as correctly applied, PREP Act immunity cuts off forms of relief that might otherwise have been available to

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[3] Erwin Chemerinsky, *Against Sovereign Immunity*, 53 STANFORD LAW REVIEW 1201, 1205 (2001), https://lawcat.berkeley.edu/record/1117915?ln=en.

[4] *Id.* at 1211, 1213.

people harmed by diagnostics, treatments, or vaccines. Cognizant of that effect, Congress also established a 'Covered Countermeasure Process Fund' to compensate for such harms. Id. § 247d-6e(a)." *Cannon*, 45 F.4th at 139. In the event that these funds are not made available under the Countermeasure Injury Compensation Program ("CICP") process after 240 days and willful misconduct can be alleged, then suit may be filed in this Court.[5]

It is a violation of due process, however, for Congress to extinguish and replace federal and state statutory and common law injury claims by an administrative compensation program unless that replacement program provides a reasonable, prompt, and equitable mechanism for compensating victims. *See Duke Power Co. v. Carolina Envtl. Study Group*, 438 U.S. 59, 93 (1978).

As of August 1, 2023, only four CICP claims for death or serious bodily injury from COVID-19 vaccines have been paid under the Covered Countermeasure Process Fund.[6] *See* 42 U.S.C. § 247d-6e(a). While it may not foreclose *all* relief, it is not adequate, prompt, timely, reasonable or equitable.

It is appalling that only four paltry sums – $2,019.55 for anaphylaxis; $1,582.65 for myocarditis; $1,032.69 for myocarditis; $3,957.66 for myocarditis – have been paid under CICP to four out of 21,301 deaths, 103,790 hospitalizations, 19,661 permanent disabilities, and 16,178 life threatening reactions[7] caused by COVID-19 vaccines reported to the Federal Vaccine Adverse Event Reporting System. (These numbers are significantly higher number than the

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[5] 42 U.S.C. § 247d–6e(d)(1).

[6] *Table 4. CICP Claims Compensated* (*Fiscal Years 2010 – 2023*), HEALTH RESOURCES AND SERVICES ADMINISTRATION (Data as of Aug. 1, 2023), https://www.hrsa.gov/cicp/cicp-data/table-4.

[7] The Vaccine Adverse Event Reporting System (VAERS) Results https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=633CCF8C35B3866ABC5623263D27 (last visited September 12, 2023).

1,266 Deaths and 3,247 hospitalizations from the beginning of OWS through February 2021.) *See* Exhibit 5 [ECF No. 1-1, at 22].

Not only is the CICP insufficient to satisfy due process, but here due process is further offended when a Plaintiff, upon exiting the CICP program, has absolutely no remedy against willful misconduct – the only possible claim – against federal agencies and actors hiding behind the shield of sovereign immunity.

To remove Plaintiff's last and only remaining avenue of redress solely against the government, when the government has overseen all the medical countermeasures, is a cruel violation of due process of law.

b. Sovereign Immunity Offends the Takings Clause of the 5th Amendment.

In conjunction with the remainder of the PREP Act, the sovereign immunity clause is unconstitutional and severable since it would deprive Plaintiff of the 5th Amendment right to just compensation for deprivation of his life. DOD incorrectly asserts that a violation of the Takings Clause requires that the government take physical property without just compensation. The Motion cites a case on point but provides the wrong conclusion. According to that Court: "The claimants do not in this suit allege a taking of the land in Texas itself. Rather they allege that the United States took away their legal right to sue for compensation for that land." *Alliance of Descendants of Tex. Land Grants v. United States*, 37 F.3d 1478, 1481 (Fed. Cir. 1994). The Court further held: "Because a legal cause of action is property within the meaning of the Fifth Amendment . . . claimants have properly alleged possession of a compensable property interest" under the takings clause. *Id*. (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)) (emphasis added).

Plaintiff has shown that the PREP Act extinguishes all existing state and federal causes of action providing the "willful misconduct" claim in their stead, *except* when it comes to federal actors, who are protected by the PREP Act's sovereign immunity clause. Foreclosing all remedies constitutes an unconstitutional taking in violation of the 5th amendment since a "legal cause of action" is a "compensable property interest" under the Takings Clause. *Id*.

If this Court were to grant Defendant's Motion based on sovereign immunity, then all avenues for just compensation would be extinguished, violating the Takings Clause.

3. The Court May Sever the Unconstitutional Sovereign Immunity Subsection From the PREP Act and Maintain the Remainder of the Act.

Although arguments have been made that the PREP Act itself is unconstitutional, that analysis is beyond the scope of this memorandum. What is germane here is whether a clearly unconstitutional provision should be excised – and if so, whether the PREP Act would remain as a fully operative statute. The answer to both questions is yes, yet Defendant's Motion utterly ignores the PREP Act's pivotal severability upon which this Motion turns.

"Th[e Supreme] Court has held that the inclusion of [a severability] clause creates a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision. *See INS v. Chadha*, 462 U.S. [] 932; *Champlin Refining Co. v. Corporation Comm'n of Oklahoma*, 286 U.S. [] 235. In such a case, unless there is strong evidence that Congress intended otherwise, the objectionable provision can be excised from the remainder of the statute." *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987). Here, Congress provides a vehicle to allow suit against the Government to proceed.

In 1978, *Barry v. District of Columbia Board of Elections & Ethics*, 448 F. Supp. 1249, 1255, this Court held:

> The applicable rule was established by the Supreme Court in *Champlin Refining Co. v. Corporation Commission*, 286 U.S. 210, 234, 52 S. Ct. 559, 565, 76 L. Ed. 1062 (1932):
>
> The unconstitutionality of a part of an Act does not necessarily defeat or affect the validity of its remaining provisions. Unless it is evident that the legislature would not have enacted those provisions which are within its power, independently of that which is not, the invalid part may be dropped if what is left is fully operative as a law.

"Generally speaking, when confronting a constitutional flaw in a statute, we try to limit the solution to the problem," severing any "problematic portions while leaving the remainder intact..." *Ayotte v. Planned Parenthood of Northern New Eng.*, 546 U.S. 320, 328-329, 126 S. Ct. 961, 163 L. Ed. 2d 812 (2006). Because "[t]he unconstitutionality of a part of an Act does not necessarily defeat or affect the validity of its remaining provisions," *Champlin Refining Co. v. Corporation Comm'n of Okla.*, 286 U.S. 210, 234(1932), the 'normal rule' is 'that partial, rather than facial, invalidation is the required course[.]'" *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 508 (2010).

Severability is appropriate here because: (1) Plaintiff targets only one constitutionally offensive clause of the Act[8]; (2) if that clause is struck, a fully-operative law will remain; (3) all willful misconduct elements as pled are sufficient to implicate DOD; and (4) severability rightfully confirms that DOD must defend itself against allegations of willful misconduct on a level playing field like any other defendant once unconstitutional protections are removed.

B. The PREP Act's Unique Pleading Standards vis-à-vis a Rule 12(b)(6) Motion to Dismiss

The PREP Act's burden of proof requires:

[8] 42 U.S.C. § 247d-6d(f)

> In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.[9]

At this stage, Plaintiff is not required to prove all elements of the case to survive the Defendant's motion to dismiss. Rather, in a motion to dismiss pursuant to Rule 12(b)(6), the reviewing court treats the complaint's factual allegations as true, and must grant the benefit of all inferences that can be derived from the facts alleged. *See Holy Land Found. for Relief & Dev. v. Ashcroft*, 357 U.S. App. D.C. 35, 38 (D.C. Cir. 2003). Under heightened pleading standards, "… plaintiffs alleging claims [in an anti-fraud statute] must satisfy the 'plausibility' pleading standard set forth in Federal Rule of Civil Procedure 8, as well as the heightened 'particularity' standard set forth in Rule 9(b). *Cimino*, 3 F.4th at 421." *United States ex rel. Vt. Nat'l Telephone Co. v. Northstar Wireless, LLC,* 34 F.4th 29, 38 (D.C. Cir. 2022). Under Rule 8, the complaint must "contain 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 (1937). At the preliminary pleading stage, this court must "construe the complaint liberally," to grant the plaintiff "the benefit of all inferences that can be derived from the facts alleged." *Zukerman v. United States Postal Serv.*, 961 F.3d 431, 436 (D.C. Cir. 2020). Plaintiff's Verified Complaint satisfies all of the heightened pleading requirements to state a claim for DOD's willful misconduct-induced death.

In the event this Court determines Plaintiff's Verified Complaint does not satisfy the PREP Act's heightened requirements, it must afford leave to amend since "leave to amend is …almost always" allowed to cure deficiencies in pleading fraud. *Luce v. Edelstein*, 802 F.2d 49, 56 (2d Cir. 1986) (quoting 2A J. Moore & J. Lucas, *Moor's Federal Practice*, P 9.03 at 9-34 (2d ed. 1986)). *Firestone v. Firestone*, 76 F.3d 1205, 1209 (1996)

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[9] 42 U.S.C. § 247d-6d(c)(3).

1. BLA and EUA Vaccines are not Identical and are Legally Distinct.

Defense counsel conveniently frames the bulk of a substantive attack on the pleadings around a recently debunked concept that BLA and EUA vaccines are identical, thereby alleging that plaintiff meets none of the elements of willful misconduct.

The District Court in Florida didn't accept this same defense counsel's same argument in another recent case, finding: "For starters, FDA licensure does not retroactively apply to vials shipped before BLA approval." "Thus, as a legal matter, vaccines sent before August 23[, 2021]—and vaccines produced after August 23[, 2021] in unapproved facilities—remain 'product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.'" "This distinction is the basis for the FDA's comment that the BLA-compliant vials and the EUA-compliant vials are 'legally distinct, even though their chemical formulation is identical.[]'" "Thus, the DOD cannot rely on the FDA to find that the two drugs are legally identical for § 1107a purposes." *Doe v. Austin*, 572 F. Supp. 3d 1224, 1233 (N.D. Fla. November 12, 2021).

The District Court informed DOD and its counsel: "Indeed, the Summary Basis for Regulatory Action lists a redacted excipient for BLA-approved Comirnaty that does not appear on the ingredient list in the EUA letter." "In *Generix*[10], the Supreme Court held that two products with the same active ingredients were nonetheless not the same 'drug' under the FDCA where the district court had found that their different excipients created a reasonable possibility that the unlicensed drug was 'less safe and effective' than the licensed one.'" *Id.* at 1230

"A fully approved FDA-compliant vaccine is not always the same as its EUA counterpart. There are restrictions on the manner and location of FDA-approved vaccines, for

[10] *United States v. Generix Drug Corp.*, 460 U.S. 453, 455-57, 103 S. Ct. 1298, 75 L. Ed. 2d 198 (1983)

example, that do not apply to EUA products, which have more relaxed manufacturing specifications. *See, e.g.*, 21 C.F.R. §§ 600.11, 600.20-.21." *Coker v. Austin*, 2022 U.S. Dist. LEXIS 240820, *13 (N.D. Fla. Nov. 8, 2022).[11] Curiously, Defendant's Motion makes no mention of these relevant laws.

As a matter of law, Defendant's Motion must be denied or else converted to a motion for summary judgment[12] because Defendant departed from the allegations contained in the Complaint. [ECF No. 13-1, at 19-23] In the Motion, Defendant unilaterally offers disputed science regarding COVID-19 vaccine safety suggesting it cannot be held accountable for its own false statements. If necessary and requested by the Court, Plaintiff is prepared to address such separate issues. But to do so Plaintiff would at least request to do so after discovery into Defendant's new claims.

2. DOD Misrepresents that George Watts, Jr., would have Received a Notice to Caregivers Citing [ECF No. 13-1, at 24-25].

Defendant intimates that George Watts, Jr., assumed the risk based on prior notice. Defendant's Motion calls the Court's attention to "Compl. Ex. 6 at 2, n.6." However Footnote 6 does not refer to domestic vaccines; it reads: "In the June 25, 2021 revision, FDA clarified terms and conditions that relate to **export** of Pfizer-BioNTech COVID-19 Vaccine from the United

[11] Pseudonym replaced.

[12] If a district court questions the validity or credibility of any allegations, then it converts a motion to dismiss into a motion for summary judgment. "[The District Court] erred in not following the procedures that Rule 12(b) requires in such a case. In particular because it considered material outside pleadings in deciding [defendant's] motion." "[I]t should have converted the Rule 12(b)(6) motion for dismissal into a Rule 56 motion for summary judgment and observed the procedural requirements that Rules 12(b) and 56 prescribe." *Triplett v. Heckler*, 1985 U.S. App. LEXIS 21002, *6; (5th Cir.), reh'g denied, 774 F.2d 1160 (5th Cir. 1985), cert. denied, 474 U.S. 1104, 106 S. Ct. 889, 88 L. Ed. 2d 923, 1986 U.S. LEXIS 1244 (1986)."

States." (emphasis added). George Watts received his vaccine in the United States, not abroad, making Defendant's reference irrelevant.

3. Defendant's Motion Incorrectly Avers that the Complaint Offered no Evidence that Licensed Vaccines weren't Available to George Watts, Jr. [ECF No. 13-1, at 22].

According to Plaintiff's Verified Complaint:

> 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.' (ECF No. 1, ¶ 75)

Clearly, Plaintiff has pled that, at all times relevant, Comirnaty was unavailable.

4. Contrary to Defendant's Motion [ECF No. 13-1, at 18], an Enforcement Action is not a Necessary Prerequisite.

Defendant's memo correctly cites the exclusion for 42 U.S.C. § 247d-6d(c)(5) regulated activity of a manufacturer. However, Pfizer-BioNTech performed that task – there is no "DOD-brand" vaccine.

Plaintiff's Complaint ¶ 17 clarified:

> 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.

Defendant offers nothing to contradict this distinction.

DOD's lead role in OWS does not fit the PREP Act's definition of a manufacturer under 42 U.S.C. § 247d-6d(c)(5)(A), which provides:

> (4) Manufacturer The term "manufacturer" includes— (A) a contractor or subcontractor of a manufacturer; (B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a

> covered countermeasure; and (C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

Defendant is also not a distributor. The complaint alleges, "[t]he federal government …has contracted with McKesson for purposes of vaccine distribution..." [ECF No. 1, at ¶ 41].

The PREP Act defines a "distributor" as follows:

> (3) Distributor The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

42 U.S.C. § 247d-6d(i)(3)

Since Defendant is neither a manufacturer nor distributor, no enforcement action by the Attorney General or the Secretary of the Department of Health and Human Services is required before Plaintiff may file a claim.

5. Contrary to Defendant's Motion [ECF No. 13-1, at 25], all Actions and Misstatements of Safety and Efficacy are Attributable to OWS Leadership.

Defendant DOD was the lead agency in OWS [ECF 1, at ¶ 3], and its Chief Operating Officer was Army General Gustave Perna [ECF 1, at ¶ 32]. As OWS lead, DOD is responsible for misrepresentations of safety and efficacy by OWS's C.O.O. Gen Perna [ECF 1, at ¶¶ 32, 33, 34, and 38.], for comments of Acting Defense Secretary Christopher C. Miller [ECF 1, at ¶ 35], as well as for Secretary Austin's misrepresentations of safety and efficacy. [ECF 1, at ¶37].

6. According to the CDC, Deaths from Myocarditis are not Anomalies.

> Data from VSD and from VAERS indicate that rates of myocarditis after COVID-19 vaccination are highest among males in their late teens and early 20s, usually following the second dose of the vaccine.[13]

George Watts, Jr., fell within this category since he was 24 years old at the time of death. His death was not an anomaly.

7. DOD's Penchant for Human Experimentation Caused a Known and Obvious Risk of Death That Outweighed Any Benefit.

DOD's Motion ignores its lurid history of experimentation, without making a single mention of the *Doe v. Rumsfeld* cases where this Court repeatedly enjoined its vaccine experiments on military service members. Plaintiff's allegations are supported with specifics of DOD's intentional misrepresentation to achieve nationwide, non-consensual, mass-human experimentation. Scienter is shown since DOD knew its misrepresentations were devoid of factual or legal justification and that all along. DOD disregarded the known, obvious and highly-probable risk that the harm created by non-consensual human experimentation would outweigh any benefit.

This is not the first time DOD has experimented on Americans; for example, see *United States v. Stanley*, 483 U.S. 669 (1987), detailing the government's program to secretly administer doses of lysergic acid diethylamide (LSD) to service members, and *Doe #1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003) when this Court stopped the DOD's mandate of investigational anthrax vaccines dead in its tracks by enjoining DOD from turning Americans into human guinea pigs.

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[13] *Selected Adverse Events Reported after COVID-19 Vaccination*, Centers for Disease Control and Prevention, CDC.GOV, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html (July 13, 2023).

Declaratory and injunctive relief may not be available under the PREP Act, but this case must be allowed to go forward to send a clear signal that human experimentation by the DOD shall not be tolerated as it again asks this Court, 20 years later, to turn a blind eye to deaths caused by its newer, larger and deadlier mass experiment foisted upon American civilians.

Unlike ubiquitous reports of *mysterious* sudden deaths, George Watts, Jr.'s cause of death is unambiguously due to DOD's COVID-19 vaccine. The Coroner's report [ECF 1-1, at 2-6], the Pathology report Autopsy [ECF 1-1, at 7-10], and the Certificate of Death [ECF 1-1, at 36] prove this fact. The Affidavit of Sanjay Verma, M.D., [ECF 1-2, at 3] affirms their findings.

C. The Complaint Satisfies Each and Every Pleading Requirement.

This case demonstrates with medical certainty that DOD's OWS vaccines and fraudulent misrepresentations proximately caused George Watts, Jr.'s death. The Complaint satisfies each and every one of the PREP Act's pleading requirements.

1. DOD's 'analysis' is Incomplete.

Defendant tries in vain to convince this Court that the PREP Act's elements of willful misconduct, although pled directly and plainly, cannot be satisfied. [ECF 13-1, at 6]. Defendant's strategy appears to be obfuscation, as defense counsel offers non-sequiturs and discusses elements out of order from the statute.

The Motion's segment A [ECF No. 13-1, at 17-18] is a mistaken paraphrasing of willful misconduct and Rule 12 (b)(6). Without applied analysis, Defendant concludes: "Under these clear standards, Plaintiff has failed to plead a viable claim." *Id.* at 13. Probably the reason defense counsel avoids applying the law to the facts is that all the facts in the Complaint meet the elements.

The Motion's segment B [ECF No. 13-1, at 18-19] fares no better. In a creative attempt to transform DOD into a manufacturer, Defendant misstates the complaint by contending that "DOD's 'central role' in manufacturing and distribution of the EUA vaccine…" turns overseeing and directing into manufacturing and distributing. Based on this attempt to rewrite the complaint, Defendant alleges that "Plaintiff fails to plead willful misconduct" because "no enforcement action has been undertaken …" *Id.* at 13. Clearly Defendant fails to rebut what is pled. Additionally, 'central role' is a vague term and is not an accurate recitation of the PREP Act's definition of a manufacturer or distributor. DOD is not a manufacturer in the same manner that the federal government is not the manufacturer of milk in a school lunch program.

Segment C is three and a half pages long [ECF No. 13-1, at 19-23], yet it makes no mention of this Court's prior rulings against human experimentation. Defendant completely ignores the distinction between EUA and BLA, what representations may be made regarding safety and efficacy, and how DOD's misrepresentations turned Americans into experimental human subjects. By statute, an EUA vaccine categorically may not be classified as safe and effective; only BLA vaccines may make this claim. The complaint clearly makes out the case that DOD never cared about this critical distinction between EUA and BLA. As Judge Winsor previously informed counsel, DOD cannot rely on FDA claims that the two vaccines are identical when there is a probability that the difference in the products raises safety concerns and BLA status doesn't apply retroactively. *See Doe v. Austin*, 572 F.Supp.3d at 1234.

Defendant's segment D [ECF No. 13-1, at 23-25] misconstrues the Complaint in that the Motion changes willful misconduct's first element to "DoD acted with a wrongful purpose" but nonetheless concludes that the allegation is implausible. Further, Defendant ignores the Complaint's details of how DOD knowingly misled the public regarding the experimental nature

of EUA vaccines. Defendant's claim that DOD was transparent with the public, particularly in light of DOD's bait and switch, is untenable because DOD never cared about the important distinction between BLA and EUA vaccines from the time it ordered EUA vaccines until it left them in exclusive circulation.

The Motion's segment E [ECF No. 13-1, at 25-26] ignores that Plaintiff's allegations of DOD's violations of the Nuremberg Code and DOD's repeated human experimentation outweigh any benefit. Defendant ignores that DOD never cared about the distinction between BLA and EUA from OWS's infancy through the time George Watts, Jr., died as a result of DOD's deceit.

Defendant's segment F [ECF No. 13-1, at 26-27] also misses the point that DOD left the EUA vaccine in place, and never cared about the legal distinction that caused George Watts, Jr.'s reasonable reliance on DOD's willful and knowing misrepresentations, which proximately caused his death. Defendant also confuses DOD's action of leaving the EUA vaccine in place with whether or not George Watts Jr. heard DOD's statements.

2. The Complaint Properly Alleges DOD Acted Intentionally to Achieve a Wrongful Purpose.[14]

42 U.S.C. § 247d-6d (c)(3) requires that willful misconduct be pled with particularity to allege that cause of action with respect to the use of a covered countermeasure.

Defendant contends that "Plaintiff does not plead with particularly [*sic*] that DoD acted with a wrongful purpose." [ECF No. 13-1, at 23] These are two separate issues. As pled, the act of deception was intended to achieve a wrongful purpose. [ECF No. 1, at 21-22] A non-consensual experiment is the harm as pled to accelerate public acceptance under false pretenses. Instead, Defendant only claims that willful misconduct can't be satisfied based on an incorrect

[14] 42 U.S.C. § 247d-6d(c)(1)(A)(i)

argument that Defendant is a manufacturer or distributor. DOD was neither. According to the complaint:

a. "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." (¶ 95)

b. "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." (¶ 96)

Defendant leaves this issue unaddressed.

3. The Complaint Properly Alleges DOD Acted Knowingly Without Legal or Factual Justification.[15]

Defendant claims "Plaintiff fails to plead with particularity any act or omission knowingly undertaken without legal or factual justification." [ECF No. 13-1, at 19] That is incorrect. According to the Complaint:

a. "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 into unwitting guinea pigs." (¶ 98)

b. "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." (¶99)

c. "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

[15] 42 U.S.C. § 247d-6d(c)(1)(A)(ii).

products only. DOD was well aware of this based on the first *Doe v. Rumsfeld* decision." (¶100)

Defendant leaves this issue unaddressed.

4. The Complaint Properly Alleges 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.[16]

Defendant claims 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. [ECF No. 13-1, at 25-26] According to the Complaint:

a. "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" . . ." "DOD's non-consensual mass human on the American public and Mr. Watts is not factually or legally justifiable." (¶101)

b. "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 subjects. DOD refused to acknowledge past wrongs cited by this Court in *Doe v. Rumsfeld*, when DOD ordered an initial 100 million doses and agreed to purchase up to 600 more additional doses 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 obvious risk inherent in its program." (¶102 (footnotes omitted).)

c. "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." (¶103.)

Defendant leaves this issue unaddressed.

[16] 42 U.S.C. § 247d-6d(c)(1)(A)(iii)

5. Facts Support the Allegation that such Alleged Willful Misconduct Proximately Caused the Injury Claimed.[17]

Defendant contends Plaintiff does not plead that the alleged acts proximately caused injury. Defendant claims since BLA and EUA are identical; there is no harm, so no foul. Defendant misrepresents Plaintiff's assertion that DOD's bait and switch couldn't have occurred if there is no difference between EUA and BLA. Once again Judge Winsor informed both Defendant and counsel that there is a difference between EUA and BLA and that interchangeability in a series doesn't confer equivalency (*supra*). This element is properly pled.

a. "Based on DOD's continued, calculated deception campaign, 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." (¶ 104)

b. "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." (¶105)

c. "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 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. Watt's death by vaccination." (¶ 106.)

Defendant leaves this issue unaddressed.

[17] 42 U.S.C. § 247d-6d(e)(3)(B)

6. Facts Support the Allegation that the Person on whose Behalf the Complaint was filed Suffered Death or Serious Physical Injury.[18]

The Coroner's report [ECF No. 1-1, at 2-6], the Pathology report Autopsy [ECF No. 1-1, at 7], and the Certificate of Death [ECF No. 1-1, at 36] prove death. The Affidavit of Sanjay Verma, M.D., [ECF No. 1-2, at 3] confirms causation "to a reasonable degree of medical certainty that such death was proximately caused by decedent's COVID-19 vaccination."

D. DOD's Scienter, Historical Perspective and Context

The PREP Act forces Plaintiff to frame DOD's actions with unfortunate historical parallels to military experimentation during the Second World War. Such straight-talk is required to satisfy the elements of willful misconduct. DOD's history and proclivity for human experimentation is no stranger to this Court and should come as no surprise to the public.

DOD's well-documented leadership role in orchestrating OWS, touted as a self-proclaimed success, disguises the dark underbelly of DOD's deliberate non-consensual human experimentation. As pled, DOD's intention to deceive is the bedrock first element it needed to convince the public of the blatant lie that its experimental vaccines were safe and effective. DOD did this to achieve the wrongful purpose of human experimentation.

DOD knew it had no factual or legal justification to conduct human experimentation on American civilians or service members following this Court's ruling in *Doe #1 v. Rumsfeld*, 297 F. Supp. 2d 119 (2003), DOD's experience in *United States v. Brandt* (The Medical Case), 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, pp. 181-182 (1949) and in *United States v. Stanley*, 483 U.S. 669, 687 (1987) wherein

[18] 42 U.S.C. § 247d-6d (e)(3)(C).

Justice O'Connor wrote in her opinion[19]:

> . . . it is important to place the Government's conduct in historical context. The medical trials at Nuremberg in 1947 deeply impressed upon the world that experimentation with unknowing human subjects is morally and legally unacceptable. The United States Military Tribunal established the Nuremberg Code as a standard against which to judge German scientists who experimented with human subjects. Its first principle was: The voluntary consent of the human subject is absolutely essential.
>
> A New England Journal of Medicine article defined voluntary consent as follows:
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.[20]

As in this case, *Doe #1 v. Rumsfeld* involved an investigational drug. "Since the 1997 initiation of the vaccination program, there have been several "challenges to the legality of orders requiring military personnel to take [AVA].[] Notably, in 2003, Judge Emmet Sullivan of this Court ruled that, with regard to inhalation anthrax, "AVA is an investigational drug . . . [that was] being used for an unapproved purpose" in violation of 10 U.S.C § 1107. *Id.* ¶ 35 (citing *Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003)). He then granted the plaintiffs' request for a preliminary injunction and enjoined the vaccination program. Id." *Martin v. Donley*, 886 F. Supp. 2d 1, 4 (D.D.C. 2012).

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[19] concurring in part and dissenting in part

[20] Shuster, Evelyne, *Fifty years later: the significance of the Nuremberg Code*, THE NEW ENGLAND JOURNAL OF MEDICINE 337 20 (1997): 1436-40, https://www.nejm.org/doi/full/10.1056/nejm199711133372006.

In 1999, the President signed Executive Order 13139, "pursuant to which DoD must obtain informed consent from each individual member of the armed forces before administering investigational drugs and under which waivers of informed consent are granted only "when absolutely necessary." Exec. Order No. 13,139, 64 Fed. Reg. 54,175 (Sept. 30, 1999). In August 2000, DoD formally adopted these requirements in DoD Directive 6200.2." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 6 (D.D.C. 2004).

"Nevertheless, on June 28, 2002, the DoD resumed the vaccination program with 'mandatory inoculation[s] for [high risk] military personnel…'" *Martin v. Donley*, 886 F. Supp. 2d at 4.

"Absent an informed consent or presidential waiver, 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). That didn't deter DOD from doing it again.

In *Stanley*, Justice O'Connor aptly opined:

> If this principle [that voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical and legal concepts] is violated the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much.

United States v. Stanley, 483 U.S. 669, 710 (1987) (concurring in part and dissenting in part).

III. CONCLUSION

Plaintiff's Verified Complaint satisfies each and every element of willful misconduct to clearly and convincingly allege that DOD vaccines proximately caused George Watts, Jr.'s death. If there is no remedy against the DOD under the PREP Act, willful misconduct is incentivized while human life is rendered worthless.

The Court must allow this case to move forward by excising the PREP Act's unconstitutional sovereign immunity provision so that Plaintiff may pursue damages sufficient to compensate and deter repetition of such deadly, unethical and unlawful conduct by DOD or others similarly situated.

The Constitution's promise of due process of law guarantees no less. As such, Defendant's Motion must be denied in its entirety.

Respectfully Submitted,

Dated: September 15, 2023

Signed

RAY L. FLORES II, Attorney at Law
Torrey Reserve North Court
11622 El Camino Real Suite 100
San Diego, CA 92130
California State Bar Number: 233643
D.C. District Court I.D. No.: CA00173
Phone: (858) 367-0397
Email: rayfloreslaw@gmail.com

PROOF OF SERVICE BY ECF

I hereby certify that on September 15, 2023, I electronically filed the foregoing with the Clerk of the District Court using the CM/ECF system, which sent notification of such filing to Defendant's Counsel.

/s Ray L. Flores II