IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS,	§	
	§	
***Plaintiff*,**	§	
	§	NO.:_____
v.	§	
	§	
PFIZER, INC.	§	
	§	
***Defendant*.**	§	
	§	
	§	

NOTICE OF REMOVAL

Defendant Pfizer Inc. ("Pfizer") provides notice of the removal of the above-captioned case from the 99th Judicial District Court for Lubbock County, Texas to the United States District Court for the Northern District of Texas pursuant to 28 U.S.C. §§ 1331, 1441, and 1442(a)(1). Removal to this Court is appropriate under the federal officer removal statute, under the Supreme Court's decision in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), and because the claims raised in the Original Petition ("Petition") are completely preempted by the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d and 247d-6e ("PREP Act"). The grounds for removal are more particularly stated as follows:

BACKGROUND

1. On November 30, 2023, the State of Texas filed the Petition, alleging that "Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine" in violation of the Texas Deceptive Trade Practices Act ("DTPA"). Petition at pg. 4, ¶¶ 1-2, 154-69.

2. Specifically, the Petition alleges that Pfizer made false and misleading claims regarding the vaccine's efficacy, duration of protection, ability to reduce transmission of COVID-

19 between persons, and ability to protect against COVID-19 variants; and attempted to "censor persons who sought to disseminate truthful information." Petition ¶¶ 154-69.

3. In making these allegations, the Petition relies on numerous statements from the U.S. Food and Drug Administration ("FDA") providing guidance on communicating efficacy and discussing the Pfizer COVID-19 vaccine, Pfizer's clinical trials, and the FDA's grant of Emergency Use Authorization ("EUA") for the vaccine. *See, e.g.*, Petition ¶¶ 25-26, 30-34, 48-49.

4. Pfizer was served with the Petition on December 1, 2023.

5. Pfizer now files this Notice of Removal of this civil action pursuant to 28 U.S.C. §§ 1331, 1441, and 1442(a)(1).

GROUNDS FOR REMOVAL

A. Federal Officer Removal

6. This is a civil action over which this Court has original jurisdiction under 28 U.S.C. § 1442(a)(1). Under Section 1442, federal officers and their agents may remove cases under the federal officer removal statute based on acts performed under the color of their federal office if they assert a colorable federal defense. *See Latiolais v. Huntington Ingalls, Inc.*, 951 F.3d 286, 291 (5th Cir. 2020); *Williams v. Lockheed Martin Corp.,* 990 F.3d 852 (5th Cir. 2021).

7. The federal officer removal statute is interpreted expansively. *Watson v. Philip Morris Cos.*, 551 U.S. 142, 147 (2007) (noting the text of the federal officer removal statute is "broad, and this Court has made clear that the statute must be liberally construed"). The Supreme Court has mandated a generous interpretation of the federal officer removal statute in favor of removal. *Willingham v. Morgan,* 395 U.S. 402, 406-407 (1969) ("The federal officer removal statute is not narrow or limited."); *Jefferson County, Alabama v. Acker,* 527 U.S. 423, 431 (1999)

(noting that the Supreme Court has "rejected a 'narrow, grudging interpretation' of the [federal officer removal] statute").

8. "[T]o remove under section 1442(a), a defendant must show (1) it has asserted a colorable federal defense, (2) it is a 'person' within the meaning of the statute, (3) that it has acted pursuant to a federal officer's directions, and (4) the charged conduct is connected or associated with an act pursuant to a federal officer's directions." *St. Charles Surgical Hosp., L.L.C. v. Louisiana Health Serv. & Indem. Co*., 990 F.3d 447, 454 (5th Cir. 2021) (quoting *Latiolais*, 951 F.3d at 296).

9. Pfizer satisfies each of the elements for federal officer removal.

i. Pfizer Is A "Person"

10. "[C]orporate entities qualify as 'persons' under § 1442(a)(1)." *Winters v. Diamond Shamrock Chem. Co*., 149 F.3d 387, 398 (5th Cir. 1998), *holding modified by Latiolais* 951 F.3d at 291-92.[1] Pfizer is thus a "person" within the meaning of 28 U.S.C. § 1442(a)(1). *Latiolais*, 951 F.3d at 296-97 (holding corporate federal contractor could remove under the federal officer removal statute).

ii. Pfizer Acted Pursuant To A Federal Officer's Directions

11. "In order to satisfy the 'acting under' requirement, a removing defendant need not show that its alleged conduct was precisely dictated by a federal officer's directive." *St. Charles*, 990 F.3d at 454. "Instead, the 'acting under' inquiry examines the *relationship* between the removing party and the relevant federal officer, requiring courts to determine whether the federal

[1] In *Latiolais*, the Fifth Circuit adopted a more liberal interpretation of the statutory requirement that a federal officer's actions be related to the conduct at issue in the complaint, holding the charged conduct need only be "connected or associated with an act pursuant to a federal officer's directions." *Latiolais*, 951 F.3d at 296. *Latiolais* thus overruled prior case law, including *Winters*, that applied the stricter "direct causal nexus" test. *Id.* at 291-92.

officer exerts a sufficient level of subjection, guidance, or control over the private actor." *Id.* at 455.

12. Courts routinely hold that federal government contractors act pursuant to a federal officer's directions. *See, e.g.*, *Winters*, 149 F.3d at 387; *Latiolais*, 951 F.3d at 296. In *Watson*, the Supreme Court differentiated between companies that merely comply with federal regulations, on the one hand, and government contractors, on the other. *Watson*, 551 U.S. at 153 (citing *Winters*, 149 F.3d at 387). Where a private entity, pursuant to a government contract, "help[s] the Government to produce an item that it needs," *id.*, or supplies a product that the Government otherwise would have to manufacture itself, that contractor acts under a federal officer's directives. *See Zeringue v. Crane Co.,* 846 F.3d 785, 792 (5th Cir. 2017) (holding contractor's "provision of parts in an effort to assist the Navy's construction of vessels satisfies the 'acting under' requirement" and noting "the Navy directed [the contractor] to build parts, and, had [it] not done so, the Navy would have had to build those parts instead"), *holding modified by Latiolais*, 951 F.3d at 291-92.

13. Here, Pfizer acted pursuant to its contract with the United States Government to manufacture an FDA-approved or authorized COVID-19 vaccine and to supply that COVID-19 vaccine to the Government.

14. On July 21, 2020, the U.S. Government entered into an agreement with Pfizer as part of Operation Warp Speed to purchase 100 million doses of Pfizer's COVID-19 vaccine if FDA later authorized or approved it. Petition ¶ 53. The agreement provided an option for the Government to purchase up-to an additional 500 million doses of the vaccine as well. *Id.* ¶¶ 53, 146.

15. This contract was entered under the U.S. Department of Defense's ("DoD") Other Transaction Authority ("OTA"). The key terms of the OTA agreement are found in two instruments: (1) a Base Agreement executed on July 20, 2020 (Ex. B); and (2) a Statement of Work ("SOW") executed on July 21, 2020 (Ex. C).

16. The SOW set specific terms for Pfizer's performance of the contract, including setting anticipated dates for deliverables to the Government (Ex. C at 12-14); requiring Pfizer to develop a Manufacturing Development Plan and a Quality Management Plan for the manufacture of the vaccine (Ex. C at 14); and imposing numerous reporting obligations requiring Pfizer, for example, to

- "[P]rovide [redacted] technical reports providing an update of relevant ongoing non-Government funded activities," including Pfizer's clinical trials for the vaccines.
- Provide "a synopsis of [Pfizer's] Phase 2b/3 clinical trial protocol;" copies of EUA filings; and "interim and final data updates from clinical studies."
- "[P]rovide weekly prototype production status reports."

Ex. C at 11.

17. The FDA granted the initial EUA for the vaccine on December 11, 2020 and, as the Petition acknowledges, at that point the Government became the "principal U.S. purchaser" of the vaccine. Petition ¶¶ 48, 151.

18. On December 22, 2020, the Government invoked the Defense Production Act ("DPA") and modified its agreement with Pfizer to incorporate a "priority rating" under the Health Resources Priorities and Allocations System ("HRPAS").

19. Under the above-described modification, Pfizer's agreement with the Government was given the priority rating "DPA Title I DO-HR," allowing Pfizer priority access to key vaccine

components and ensuring Pfizer could produce and deliver the required quantities of COVID-19 vaccines on Operation Warp Speed's proposed accelerated schedule.

20. Pfizer acted pursuant to a federal officer's directions when, pursuant to the terms of its contract with the Government, it manufactured an FDA-approved or authorized COVID-19 vaccine; provided the Government with updates and deliverables regarding the COVID-19 vaccine as outlined in the SOW; and when it sold and delivered that vaccine to the Government as part of Operation Warp Speed. *See Watson*, 551 U.S. at 153 (explaining a Government contractor falls within the terms of the federal officer removal statute because "the private contractor…is helping the Government to produce an item that it needs"); *Zeringue v. Crane Co*., 846 F.3d at 792.

iii. The Petition's Claims Are Connected Or Associated With Pfizer's Actions Pursuant To Its Contract With The Government.

21. The Fifth Circuit has held that, to satisfy the "relating to" language in Section 1442(a), a federal officer must show only that the conduct charged in the Petition "is connected or associated with an act pursuant to a federal officer's directions." *Latiolais*, 951 F.3d at 296. Although the court previously applied a more stringent "direct causal nexus" test, in 2020, the *Latiolais* court recognized the statutory language "relating to" is broad. *Id.* The court explained that, in adding the phrase "relating to" to the statute, Congress "broadened federal officer removal to actions, not just *causally* connected, but alternatively *connected* or *associated*, with acts under color of federal office." *Id.* at 292.

22. All of the Pfizer conduct charged in the Petition is connected or associated with Pfizer's contract to manufacture and sell an FDA-authorized or approved COVID-19 vaccine to the Government. *See St. Charles Surgical Hosp*, 990 F.3d at 452-53 ("[I]nstead of considering whether there is a 'direct causal nexus' between the removing defendant's actions and a federal

officer's instruction, the proper inquiry centers on whether that defendant's actions 'related to' a federal directive.").

23. The Petition here accuses Pfizer of making misleading public statements concerning the efficacy of the COVID-19 vaccine that the company manufactured and supplied to the Government as part of Operation Warp Speed. Petition at pg. 4, ¶¶ 1-2, 154-69. Each of the statements identified in the Petition was made in response to questions concerning Pfizer's contract with the Government and the company's efforts to fulfill that contract. In this way, the relevant statements were unquestionably "related to" a federal directive and, thus, "connected or associated with" Pfizer's contract with the Government to manufacture and deliver an FDA-authorized vaccine. *See Latiolais*, 951 F.3d at 296 (claims for negligence and failure to warn were sufficiently "connected with" government contractor's refurbishment of the USS *Tappahannock* under a contract with the U.S. Navy).

iv. Pfizer Has Colorable Federal Defenses.

24. A colorable defense need not be proven at this stage of the litigation. *Latiolais*, 951 F.3d at 296-97; *Willingham*, 395 U.S. at 407. "To be 'colorable,' the asserted federal defense need not be clearly sustainable, as section 1442 does not require a federal official or person acting under him to win his case before he can have it removed. Instead, an asserted federal defense is colorable unless it is immaterial and made solely for the purpose of obtaining jurisdiction or wholly insubstantial and frivolous." *Latiolais*, 951 F.3d at 296-97 (quotations omitted). If an alleged federal defense is "plausible, it is colorable." *Id.*

25. Pfizer has multiple colorable federal defenses to the claims alleged in the Petition, including under the PREP Act; the DPA; the Food, Drug, and Cosmetic Act ("FDCA"); the

Primary Jurisdiction Doctrine; the First Amendment; the Political Question Doctrine; and Derivative Sovereign Immunity.

a. PREP Act

26. The claims in the Petition are barred by the PREP Act, which provides: "Subject to the other provisions of this section, a covered person shall be 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 to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 U.S.C. § 247d-6d(a)(1).

27. Pfizer's COVID-19 vaccine is a "covered countermeasure" and Pfizer is a "covered person" under the PREP Act, as stated in the Secretary of Health and Human Services' March 17, 2020 Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 and the numerous renewals of and amendments to that Declaration, through and including the Secretary's most recent declaration on May 12, 2023. *See* Declaration Under the Public Readiness & Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 F.R. 15,198 (Mar. 17, 2020); Eleventh Amendment to Declaration Under the Public Readiness & Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 88 F.R. 30,769 (May 12, 2023).

28. The Petition alleges "Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine" and that, in doing so, Pfizer "caused injury, loss, and damage to [the State], as well as caused adverse effects to the lawful conduct of trade and commerce, thereby directly or indirectly affecting the people of this State." Petition at pg. 4, ¶¶ 8, 140–46. The Petition further requests remedies including, but not limited to, damages, restitution, and disgorgement. *Id.* ¶¶ 172-74.

29. Accordingly, the Petition is a suit under state law with respect to a claim for loss "caused by, arising out of, relating to, or resulting from the administration to and use by" individuals of the Pfizer COVID-19 vaccine, a covered countermeasure. Under 42 U.S.C. § 247d-6d(a)(1), Pfizer is immune from the claims raised in the Petition.

30. The PREP Act further provides:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—…
>
> (a) is different from, or is in conflict with, any requirement applicable under this section; and
> (b) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8).

31. As noted above, the COVID-19 vaccine is a "covered countermeasure," and Pfizer is a "covered person" under the Act. *See* 85 F.R. 15,198; 88 F.R. 30,769. The State of Texas's claims, which attempt to hold Pfizer liable for statements made relating to the design, development, clinical testing, manufacture, distribution, promotion, and safety and efficacy of the COVID-19 vaccine, are "different from, or in conflict with" the PREP Act's requirements, and thus are expressly preempted by federal law.

b. DPA

32. The claims in the Petition are additionally barred by the DPA, which provides: "No person shall be held liable for damages or penalties for any act or failure to act resulting

directly or indirectly from compliance with a rule, regulation, or order issued pursuant to this chapter, notwithstanding that any such rule, regulation, or order shall thereafter be declared by judicial or other competent authority to be invalid." 50 U.S.C. § 4557.

33. Pfizer's agreement with the Government required Pfizer to manufacture and deliver 100 million doses of an FDA-authorized or approved COVID-19 vaccine as part of the Government's response to an unprecedented national emergency. Exs. B, C.

34. On December 22, 2020, the Government modified its agreement with Pfizer to incorporate a "priority rating" under the HRPAS. *See* Sharon LaFraniere and Zach Montague, *Pfizer Seals Deal With U.S. For 100 Million More Vaccine Doses*, N.Y. TIMES, Dec. 23, 2020, https://nytimes.com/2020/12/23/us/politics/pfizer-vaccine-doses-virus.html ("As part of the deal, the [G]overnment agreed to invoke the Defense Production Act to help Pfizer get better access to around nine specialized products it needs to make the vaccine. Under the Korean War-era law, the [G]overnment can secure critical supplies more quickly by assigning a contract a priority rating, forcing suppliers to bump orders from that contractor to the front of the line.").

35. Under the above-described modification, Pfizer's agreement with the Government was given the priority rating "DPA Title I DO-HR," allowing Pfizer priority access to key vaccine components and ensuring Pfizer could produce and deliver the required quantities of COVID-19 vaccines on Operation Warp Speed's proposed accelerated schedule.

36. Pfizer's contract with the Government, as modified, thus falls within the DPA and required Pfizer to manufacture and deliver to the Government, on an accelerated schedule, 100 million doses of the company's COVID-19 vaccine.

37. Pfizer's statements regarding its efforts to fulfill that contract "result[] directly or indirectly from compliance" with the Government's order, and Texas's attempt to hold Pfizer

liable for those statements is precluded under the DPA. *See Winters v. Diamond Shamrock Chem. Co*., 901 F.Supp. 1195, 1202 (E.D. Tex. 1995) (finding supplier of product to the U.S. Army "raised a colorable federal defense under the" DPA sufficient to support removal), *aff'd*, 149 F.3d 387 (5th Cir. 1998); *Invictus Glob. Servs., Inc. v. Insitu, Inc.*, No. 1:21-cv-3161, 2022 WL 3904676, at *3 (E.D. Wash. Mar. 2, 2022) (holding defense contractor raised colorable defense under the DPA sufficient to justify removal).

c. FDCA Preemption

38. The FDCA, 21 U.S.C. § 301 *et seq.*, entrusts the FDA with the authority to regulate prescription drug labeling and advertising, including the labeling and advertising for Pfizer's COVID-19 vaccine.

39. Federal law preempts state law claims when "it is impossible for a private party to comply with both state and federal requirements." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). Where a drug manufacturer complies with relevant FDA regulations and guidelines, the FDCA preempts state-law claims where "success on those claims requires a showing that the FDA requirements themselves were deficient." *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006) (affirming dismissal of state-law negligence claims "based on aspects of the [defendant's] design, manufacture, and marketing that complied with the FDA-approved requirements" because a finding in plaintiff's favor "would be inconsistent with the federal regulatory requirements"); *see also Dusek v. Pfizer Inc*., No. 02-3559, 2004 WL 2191804, at *10 (S.D. Tex. Feb. 20, 2004) (finding state failure-to-warn claims preempted by the FDCA where the defendant issued an FDA-approved label reflecting the FDA's position regarding the at-issue warning).

40. Here, the FDA approved the Pfizer COVID-19 vaccine and its accompanying label, which sets forth information concerning the vaccine's use and efficacy; the FDA also later approved the Pfizer COVID-19 vaccine as a booster to protect against the Delta variant. Petition ¶¶ 48-49, 123-24. Pfizer made public statements consistent with those approvals, yet the State of Texas now argues those statements were false and misleading. These state-law claims essentially argue that statements consistent with the FDA's approvals and the FDA-approved label are false and misleading. Such claims directly conflict with FDA requirements and are preempted under the FDCA.

41. Federal law also impliedly preempts any attempt to enforce the FDCA by parties other than the FDA, because the FDCA "leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with" its substantive provisions. *Buckman Co. v. Plaintiffs' Legal Comm.* 531 U.S. 341, 349 n.4 (2001). Where a state-law claim is premised solely on alleged violations of the FDCA, that claim is impliedly preempted. *Id.* at 353 (finding implied preemption where state-law claims "exist solely by virtue of" alleged violations of FDA requirements); *Vesoulis v. ReShape LifeSciences, Inc.*, No. 21-30367, 2022 WL 989465, at *4 (5th Cir. Apr. 1, 2022) (affirming dismissal of state-law claims based solely on allegations that defendant violated the FDCA).

42. To the extent the State of Texas is claiming Pfizer's statements were allegedly false and misleading because they did not comply with FDA requirements or guidance (*see, e.g.*, Petition ¶ 49), those claims are impliedly preempted and belong to the FDA, not the states.

d. Primary Jurisdiction Doctrine

43. Under the primary jurisdiction doctrine, a district court may "defer[] to an administrative agency for an initial decision on questions of fact or law within the peculiar

competence of the agency." *Occidental Chem. Corp. v. Louisiana Pub. Serv. Comm'n*, 810 F.3d 299, 309 (5th Cir. 2016). "[T]he primary jurisdiction doctrine requires the district court to balance the assistance potentially provided by an agency's specialized expertise against the litigants' certainty of delay." *Id.* at 310.

44. The FDCA entrusts FDA with the authority to approve new drugs and vaccines, and to police advertising and labeling of drugs and vaccines. The FDA, thus, is in the best position to resolve questions concerning the accuracy and propriety of statements Pfizer allegedly made concerning the COVID-19 vaccine, which the FDA itself vetted, authorized, and approved. Indeed, the Petition points to numerous FDA statements and guidelines in support of the State's claims. *See* Petition ¶¶ 25-26, 30-34, 48-49.

45. Under the primary jurisdiction doctrine, the Court, accordingly, should dismiss the Petition in favor of the FDA's expert determination of the questions raised.

e. First Amendment

46. The Petition attempts to hold Pfizer liable for public statements it made concerning the COVID-19 vaccine. This is an improper attempt by the State of Texas to regulate Pfizer's speech, in violation of the First Amendment.

47. Speech, including commercial speech, is protected by the First Amendment so long as that speech is truthful and not misleading.

48. "For commercial speech to come within [the First Amendment], it at least must concern lawful activity and not be misleading." *Gibson v. Texas Dep't of Ins.--Div. of Workers' Comp.*, 700 F.3d 227, 234 (5th Cir. 2012). In evaluating whether speech is protected by the First Amendment, the Court further considers "whether the asserted governmental interest" in regulating the speech is "substantial" and "whether the regulation directly advances the

governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Id.*

49. The Pfizer statements identified in the Petition were truthful, legal, and not misleading. Although the State of Texas argues Pfizer's representations regarding the vaccine were intended to confuse or mislead the public, Pfizer will demonstrate in this proceeding that its statements regarding the vaccine were entirely truthful and based on the information that existed at the time the statements were made.

50. The State of Texas has no legitimate interest in regulating Pfizer's truthful, non-misleading speech concerning the benefits of receiving the COVID-19 vaccine. In fact, the State's attempt to punish Pfizer for spreading truthful, FDA-approved information educating the public regarding the COVID-19 vaccine—in the midst of a national emergency—is contrary to the United States Government's stated goal in Operation Warp Speed to "ensure Americans have priority access to free, safe, and effective COVID-19 vaccines" and to "ensure safe and effective COVID-19 vaccines are available to the American people, coordinating with public and private entities…to enable the timely distribution of such vaccines." Exec. Order No. 13962, Ensuring Access to United States Government COVID-19 Vaccines, 85 F.R. 79,777 (Dec. 11, 2020).

51. Because the State of Texas has no legitimate interest in regulating Pfizer's truthful speech concerning the COVID-19 vaccine, the Petition impermissibly burdens Pfizer's First Amendment rights.

f. Political Question Doctrine

52. Plaintiff's claims are also barred by the Political Question Doctrine. In *Baker v. Carr*, the Supreme Court set forth six independent guidelines for the existence of a political question outside the proper scope of review of the federal judiciary: (1) a textually demonstrable

constitutional commitment of the issue to a coordinate political department; or (2) a lack of judicially discoverable and manageable standards for resolving it; or (3) the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion; or (4) the impossibility of a court's undertaking independent resolution without expressing a lack of the respect due coordinate branches of government; or (5) an unusual need for unquestioning adherence to a political decision already made; or (6) the potentiality of embarrassment from multifarious pronouncements by various departments on one question. 369 U.S. 186, 217 (1962).

53. The relevant inquiry is whether the *resolution of this case* would raise non-justiciable political questions. Here, it is clear that this Court would be drawn inexorably into an inappropriate reexamination of numerous quintessential decisions by the Government—including the DoD, the FDA, and other federal agencies—decisions that are reserved exclusively for the political branches of government. Such issues include Plaintiff's allegations involving Pfizer's efforts to fulfill its mandatory obligations under its rated-order contract. Such a judicial inquiry into Pfizer's conduct pursuant to its contract with the Government would usurp the role of the Executive Branch.

54. Moreover, resolving Plaintiff's claims would require a judgment that is ill-suited to the development of judicial standards. By way of example, it would be inappropriate for this Court to apply state consumer protection standards to the performance of the federal government contract at issue in this case.

55. Accordingly, the Political Question Doctrine is, at a minimum, a colorable federal defense to Plaintiff's Petition.

g. Derivative Sovereign Immunity

56. As a government contractor performing work pursuant to its rated-order contract with the Government, Pfizer is protected from liability under the Derivative Sovereign Immunity doctrine. *See Yearsley v. Ross Constr. Co.*, 309 U.S. 18, 20-21 (1940) ("[Where] it is clear that [] authority to carry out [a] project was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will."); *see also Taylor Energy Co., LLC v. Luttrell*, 3 F.4th 172, 175 (5th Cir. 2021) ("[Derivative sovereign] immunity shields contractors whose work was 'authorized and directed by the Government of the United States' and 'performed pursuant to [an] Act of Congress.'").

57. Pfizer's work was performed pursuant to its contract with the Government, and in accordance with Government directives, and its work conformed to such contract and requirements. As such, Pfizer cannot be held liable for Plaintiff's claims arising from such actions. *See, e.g., Mangold v. Analytic Servs., Inc.*, 77 F.3d 1442, 1447-48 (4th Cir. 1996) (finding that "[e]xtending immunity to private contractors to protect an important government interest is not novel.").

* * *

58. Pfizer satisfies each of the four factors necessary for removal under 28 U.S.C. § 1442(a)(1). Accordingly, this case is properly removed to this Court.

B. Removal Under *Grable*

59. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1441 because the State's claims turn on federal questions "arising under" the laws of the United States. Following the Supreme Court's decision in *Grable*, there is federal question jurisdiction over a case involving only state law claims if any of the state law claims necessarily

raises a federal question "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314.

60. The Supreme Court made clear in *Grable* that federal question jurisdiction does *not* require a plaintiff to assert a violation of a federal statute that provides a private right of action; *Grable* requires only that the complaint raise an appropriate federal question. *Id.* at 315-19.

61. In affirming the removal of the state law claims in *Grable*, the Court held that "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify the resort to the experience, solicitude and hope of uniformity that a federal forum offers on federal issues." *Id*. at 312.

62. Consistent with *Grable*, the Fifth Circuit has held that "federal question jurisdiction exists where (1) resolving a federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Singh v. Duane Morris LLP,* 538 F.3d 334, 338 (5th Cir. 2008). All four of these conditions are present here; although pled solely under the DTPA, each of the State's claims turns on substantial, disputed federal issues. Removal to this Court is, thus, appropriate.

63. As noted above, the Petition relies on numerous FDA statements and guidelines, and argues Pfizer made statements inconsistent with the FDA's instructions. *See* Petition ¶¶ 25-26, 30-34, 48-49. In doing so, the Petition implies that the FDA's EUA process allowed Pfizer to obtain approval for the vaccine without appropriate clinical studies and suggests that the FDA was wrong to approve the Pfizer vaccine for use as a booster and did so only because of "political pressure." Petition ¶¶ 18-20, 48-50, 97-98, 117-124.

64. The Petition's claims thus turn on the federal issues of (1) why FDA approved the Pfizer vaccine; (2) the robustness of the FDA's EUA process, and whether Pfizer appropriately demonstrated the COVID-19 vaccine should qualify for an EUA; (3) whether statements concerning the efficacy of the vaccine were consistent with FDA guidance; and (4) what concerns, if any, FDA expressed regarding Pfizer's clinical trials and subsequent claims regarding the safety and efficacy of the vaccine.

65. These core federal issues are disputed. Pfizer challenges Plaintiff's claim that the FDA did not meaningfully vet and approve the COVID-19 vaccine and that the COVID-19 vaccine has an unfavorable benefit-to-risk ratio. Pfizer additionally disputes that the public statements it made concerning the COVID-19 vaccine were false, misleading, or otherwise inconsistent with FDA guidance. Indeed, Pfizer will demonstrate that the statements identified in the Petition were truthful and consistent with then-available data, which the company submitted to FDA for review.

66. These core federal issues are also substantial. Questions concerning the FDA's approval process and the safety and efficacy of an FDA-approved vaccine that was sold to the federal government raise issues of significant federal importance. This is particularly so in the case of the COVID-19 vaccine, which was manufactured, sold, and distributed pursuant to Operation Warp Speed, through which the federal government put forward an "unprecedented" effort to "ensure Americans have priority access to free, safe, and effective COVID-19 vaccines." Exec. Order No. 13962, 85 F.R. 79,777.

67. Moreover, numerous federal statutes and regulations are central to Plaintiff's claims, including the PREP Act, the FDCA, and the DPA, and adjudication of such claims will require this Court to resolve substantial disputed questions of federal law involving the immunities at issue.

68. Finally, there is a strong interest in having a federal court decide the federal questions raised in the Petition. Although pled under state law, the Petition asks the Court to resolve whether the FDA appropriately authorized and approved Pfizer's COVID-19 vaccine, whether statements Pfizer made about the vaccine were consistent with the FDA's guidelines and recommendations, and whether Pfizer made statements that could be misleading to consumers, where at all relevant times, the "principal U.S. purchaser" of the COVID-19 vaccine was the federal government. Petition ¶ 151.

69. These claims are inherently federal and would benefit from the "experience, solicitude and hope of uniformity that a federal forum offers" on such issues. *Id*. at 312. A federal court's resolution of the federal questions raised in the Petition is appropriate and would not disturb the state-federal balance intended by Congress.

70. Accordingly, as this Court has original jurisdiction under 28 U.S.C. § 1331, this case is properly removed pursuant to 28 U.S.C. § 1441.

C. Complete Preemption Under The PREP Act

71. Plaintiff's Petition is also completely preempted under the PREP Act, and is removable to federal court pursuant to 28 U.S.C. §§ 1331 and 1441.

72. The doctrine of complete preemption is an exception to the well-pleaded complaint rule, providing that "Congress may so completely pre-empt a particular area that any civil complaint raising this select group of claims is necessarily federal in character," and thus removable to federal court. *Metropolitan Life Ins. Co. v. Taylor,* 481 U.S. 58, 63-64 (1987). "The question in complete preemption analysis is whether Congress intended the federal cause of action to be the exclusive cause of action for the particular claims asserted under state law." *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796, 803 (5th Cir. 2011) (quotation omitted)).

73. A defendant may remove on the basis of complete preemption where: "(1) the [at-issue] statute contains a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; (2) there is a specific jurisdictional grant to the federal courts for enforcement of the right; and (3) there is a clear congressional intent that the federal cause of action be exclusive." *Sirek v. Cent. Freight Lines, Inc.*, No. 3:10-CV-2499-G, 2011 WL 2909812, at *3 (N.D. Tex. July 20, 2011).

74. If these factors are met, a state-law claim is completely preempted if the plaintiff "could have brought" the claims under the federal cause of action. *Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004).

75. The PREP Act is a complete preemption statute that expressly and completely preempts the claims raised in the Petition, while at the same time providing an exclusive federal forum for claims seeking to impose civil liability on the manufacturers of COVID-19 vaccines and other pandemic-related countermeasures.

76. The PREP Act, 42 U.S.C. § 247-d-6d, provides: "Subject to the other provisions of this section, a covered person shall be 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 to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." 42 U.S.C. § 247d-6d(a)(1).

77. The sole exception to the PREP Act's expansive immunity provision is "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(d)(1). The United States District Court for the District of Columbia has "exclusive federal jurisdiction" over any action brought pursuant to 42 U.S.C. § 247d-6d(d)(1). 42 U.S.C. § 247d-6d(e).

78. The PREP Act expressly preempts state laws and claims attempting to impose liability related to covered countermeasures:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
> (a) is different from, or is in conflict with, any requirement applicable under this section; and
> (b) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8).

79. On January 8, 2021, the United States Department of Health and Human Services ("HHS") issued an Advisory Opinion which states the "PREP Act is a 'Complete Preemption' Statute."[2] This Advisory Opinion explains "[t]he *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action…as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both."

80. The PREP Act applies to completely preempt the claims raised here. Pfizer's COVID-19 vaccine is a "covered countermeasure" and Pfizer is a "covered person" under the PREP Act, as stated in the Secretary of HHS's March 17, 2020 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

[2] *See* Dep't of Health & Human Servs., *Advisory Opinion 21-01 on the Public Readiness & Emergency Preparedness Act Scope of Preemption Provision*, Jan. 8, 2021, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf.

(85 F.R. 15,198) and the numerous renewals of and amendments to that declaration, through and including the Secretary's most recent declaration dated May 12, 2023 (88 F.R. 30,769).

81. The Petition alleges "Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine" and that, in doing so, Pfizer "caused injury, loss, and damage to [the State], as well has caused adverse effects to the lawful conduct of trade and commerce, thereby directly or indirectly affecting the people of this State." Petition at pg. 4, ¶¶ 8, 140–46.

82. Accordingly, the intentional misrepresentation claims raised in the Petition fall squarely within the PREP Act's broad grant of immunity to the manufacturers of COVID-19 vaccines and other countermeasures, and the State's claims could only have been brought, if at all, pursuant to the "exclusive Federal cause of action" established in 42 U.S.C. § 247d-6d(d)(1).

83. The Petition is thus completely preempted under the PREP Act and is appropriately removed to federal court.

CONCLUSION

84. For the reasons set forth above, this Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1441, and 1442. To the extent that the foregoing bases for federal jurisdiction do not extend to one or more of the State's claims, this Court has supplemental jurisdiction over such claim or claims pursuant to 28 U.S.C. § 1367.

85. This Notice is timely, as it was filed within thirty (30) days after Pfizer was served with the Petition. *See* 28 U.S.C. § 1446(b).

86. Under 28 U.S.C. § 1446(a) and Local Rule 81.1, attached hereto are all the documents required to be attached to this Notice of Removal. *See* Exhibit A.

87. The United States District Court for the Northern District of Texas is the federal judicial district encompassing the 99th Judicial District Court for Lubbock County, Texas, where this suit was originally filed.

88. Accordingly, the present lawsuit may be removed from the 99th Judicial District Court for Lubbock County, Texas to the Lubbock Division of the United States District Court for the Northern District of Texas pursuant to 28 U.S.C. §§ 1331, 1441(a), and 1442.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on December 28, 2023 a copy of the foregoing document was served via the Court's electronic filing system on all counsel of record.

/s/ Meagan D. Self
Meagan D. Self

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS,	§	
	§	
Plaintiff,	§	Civil Action No. _____
	§	
v.	§	
	§	
PFIZER INC.	§	
	§	
Defendant.	§	

INDEX OF DOCUMENTS FILED IN STATE COURT ACTION

Pursuant to Northern District of Texas Local Civil Rule 81.1(a)(4)(A), Pfizer Inc. submits the following Index of Documents Filed in *State of Texas v. Pfizer Inc.*, Case No. DC-2023-CV-1544:

	Date Filed	Description
1.		Docket Sheet – State of Texas v. Pfizer Inc.; Case No. DC-2023-CV-1544
2.	11/30/2023	Petition
3.	11/30/2023	Civil Process Request
4.	12/7/2023	Citation Served – Pfizer, Inc.
5.	12/20/2023	Plea to the Jurisdiction and Answer

Case Information

State of Texasvs.Pfizer, Inc.

DC-2023-CV-1544

Location
Lubbock County - 99th District Court

Case Category
Civil - Other Civil

Case Type
Other Civil

Case Filed Date
11/30/2023

Judge
Hays, J. Phillip

Parties 2

Type	Name	Nickname/Alias	Attorneys
Plaintiff	State of Texas		David G. Shatto
Defendant	Pfizer, Inc.		

Events 4

Date	Event	Type	Comments	Documents
11/30/2023	Filing	Petition	20231130 Pfizer Petition	20231130182947098_776328_20231130 Pfizer Petition.pdf
11/30/2023	Filing	REQUEST	Civil Process Request_State v Pfizer	20231130192151441_777274_Civil Process Request_State v Pfizer.pdf
12/7/2023	Filing	CSRV - Citation Served		CX1976259777-Pfizer Inc. co CT Corporation System Registered Agen Proof.pdf
12/20/2023	Filing	PLJV - Plea To Jurisdiction / Venue	2023.12.20 Pfizer Inc.'s Plea to the Jurisdiction and Answer and Affirmative Defenses	2023.12.20 Pfizer Plea to the Jurisdiction and Answer.pdf

Version: 2023.11.1.93

CAUSE NO. DC-2023-CV-1544 MK

STATE OF TEXAS, *Plaintiff,*	§	IN THE DISTRICT COURT OF
v.	§	LUBBOCK COUNTY, TEXAS
PFIZER, INC., *Defendant*.	§	_____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE DISTRICT JUDGE:

The COVID-19 vaccines are the miracle that wasn't. At the end of 2020, Defendant Pfizer, Inc. (Defendant or Pfizer) broadcast to the world that its COVID-19 vaccine was "95% effective." Based on this and other statements made by Pfizer touting the efficacy of its new vaccine, Americans were given the impression that Pfizer's vaccine would end the coronavirus pandemic and lift the omnipresent veil of fear and uncertainty from an anxious public. Placing their trust in Pfizer, hundreds of millions of Americans lined up to receive the vaccine. Contrary to Pfizer's public statements, however, the pandemic did not end; it got worse. More Americans died in 2021, with Pfizer's vaccine available, than in 2020, the first year of the pandemic. This, in spite of the fact that the vast majority of Americans received a COVID-19 vaccine, with most taking Pfizer's. Indeed, by the end of 2021, official government reports showed that in at least some places a ***greater percentage of the vaccinated were dying from COVID-19 than the unvaccinated***. Pfizer's vaccine plainly was not "95% effective."

How did this happen? How did Pfizer's vaccine achieve such widespread adoption, yet fall short of the stated goal of ending the pandemic? In a nutshell, Pfizer deceived the public. First, Pfizer's widespread representation that its vaccine possessed 95% efficacy against infection was highly misleading from day one. That number was only ever legitimate in a solitary, highly-technical, and artificial way—it represented a calculation of the so-called "relative risk reduction"

for vaccinated individuals in Pfizer's then-unfinished pivotal clinical trial. But FDA publications indicate "relative risk reduction" is a misleading statistic that "unduly influence[s]" consumer choice. Indeed, per FDA: "when information is presented in a relative risk format, the risk reduction *seems* large and treatments are viewed more favorably than when the same information is presented" using more accurate metrics.

Here, the proof is in the pudding. While Pfizer's 95% figure made its vaccines *seem* highly effective, the truth was quite different. When it began making those claims, Pfizer possessed on average only *two months* of clinical trial data from which to compare vaccinated and unvaccinated persons. Of 17,000 placebo recipients, only 162 acquired COVID-19 during this two-month period. Based on those numbers, vaccination status had a negligible impact on whether a trial participant contracted COVID-19. The risk of acquiring COVID-19 was *so small* in the first instance during this short window that Pfizer's vaccine only fractionally improved a person's risk of infection. And a vaccine recipient's *absolute* risk reduction—the federal Food & Drug Administration's (FDA) preferred efficacy metric—showed that the vaccine was *merely 0.85% effective*. Moreover, according to Pfizer's own data, preventing *one* COVID-19 case required vaccinating *119*. That was the simple truth. But Pfizer's fusillade of public representations bore no resemblance to reality.

Having seeded the marketplace with its misleading "95% effective" representation, Pfizer expanded its deception campaign across several fronts:

- ***First, duration of protection***: FDA recognized when it first authorized Pfizer's vaccine that it was "not possible" to know how effective the vaccine would remain beyond two months. But in early 2021, Pfizer deliberately created the false impression that its vaccine had durable and sustained protection, going so far as to withhold highly relevant data and information from the consuming public showing that efficacy waned

rapidly.

- ***Second, transmission***: FDA warned Pfizer that it "needed" additional information to determine whether the vaccine protected against "transmission" of COVID-19 between persons. But Pfizer instead engaged in a fear-mongering campaign, exploiting intense public fears over the year-long pandemic by insinuating that vaccination was necessary for Americans to protect their loved ones from contracting COVID-19.
- ***Third, variant protection***: Pfizer knowingly made false and unsupported claims about vaccine performance against variants, including specifically the so-called Delta variant. The vaccine performed remarkably poorly against the Delta variant, and Pfizer's own data confirmed this fact. Nonetheless, Pfizer told the public that its vaccine was "very, very, very effective against Delta."

Pfizer's product, buoyed by the company's misrepresentations, enriched the company enormously. But, while Pfizer's misrepresentations piled up, its vaccine's performance plummeted. Beginning in late 2020, multiple countries heavily relied on Pfizer's recently approved vaccine in their first inoculation campaigns. Due to widespread public participation, vaccination rates soared. Beneath the surface of Pfizer's misrepresentation-fueled success, however, myriad pieces of information demonstrate how Pfizer's vaccine failed to live up to its claims of efficacy. For example, shortly after Delta's emergence in Israel in 2021 (the informational canary in the coalmine, according to Pfizer), the vaccine's relative risk reduction dropped precipitously—*from 64% in June 2021 to 39% just one month later*. Granular data collected by governments worldwide revealed that upon Delta's introduction, the number of deaths among the fully vaccinated spiked for months. Indeed, certain jurisdictions reported *negative vaccine efficacy* in late 2021 and early 2022—meaning a greater percentage of vaccinated persons contracted, and even died from, COVID-19 than unvaccinated. Others found that the percentage of people infected with COVID-

19 *increased* over time, even in the face of widespread vaccine penetration. In the U.K., for example, infection rates were 7.0% from April 26, 2020 to December 7, 2020 (before the approval and distribution of Pfizer's product), but 24.2% from May 18, 2021 to December 13, 2021, and 33.6% from December 14, 2021 to February 21, 2022.

How did Pfizer respond when it became apparent that its vaccine was failing and the viability of its cash cow under threat? By intimidating those spreading the truth, and by conspiring to censor the vaccine's critics. Pfizer labeled as "criminals" those who spread facts about the vaccine. It accused them of spreading "misinformation." And it coerced social media platforms to silence prominent truth-tellers. Indeed, Pfizer even went so far as to request that social media platforms silence a ***former FDA director*** because his comments could "driv[e] news coverage" critical of the vaccine.

It is of no moment that Pfizer had FDA-authorization to distribute its vaccine on an emergency basis during the peak of its deception campaign. FDA's abbreviated sign-off did not afford Pfizer with a blank check to serially disseminate misrepresentations to the public to enrich itself at the expense of a frightened public, much less did FDA's authorization confer absolution on Pfizer when later held to account. Simply put, Pfizer cannot attempt to hide behind FDA to shield its deception from scrutiny, especially where, as here, FDA itself *explicitly* cautioned the company that it did not have adequate data to support various claims it made. In short, nothing FDA said or did during Pfizer's lengthy campaign of misrepresentations remotely validated the company's actions at the heart of this case.

In summary, Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine and censored persons who threatened to disseminate the truth in order to facilitate fast adoption of the product and expand its commercial opportunity. In light of the multi-billion dollar bet that Pfizer made on the vaccine and its need to quickly establish the product as the marketing leader, Pfizer

was heavily incentivized to, and in fact did, make misrepresentations intended to confuse and mislead the public in order to achieve widespread adoption of its vaccine. This suit seeks to hold Pfizer responsible for its scheme of serial misrepresentations and deceptive trade practices.

I. JURISDICTION

1. This action is brought by the Texas Attorney General's Office through its Consumer Protection Division in the name of the State of Texas (Plaintiff or the State) and in the public interest, pursuant to the authority granted by section 17.47 of the Texas Deceptive Trade Practices Act (DTPA). The State brings this action on the grounds that Pfizer has engaged in "false, deceptive, and misleading acts and practices in the course of trade and commerce" as defined in, and declared unlawful by, subsections 17.46(a) and (b) of the DTPA, at all times described below.

2. In enforcement actions filed pursuant to section 17.47 of the DTPA, the Attorney General may seek civil penalties, redress for consumers, and injunctive relief. In addition, the Attorney General may pursue reasonable attorneys' fees and litigation expenses in connection with the prosecution of the instant action, in accord with Texas Government Code section 402.006(c).

II. DISCOVERY

3. The discovery in this case should be conducted under Level 3 pursuant to Texas Rule of Civil Procedure 190.4. Restrictions concerning expedited discovery under Texas Rule of Civil Procedure 169 do not apply because the State's seeks non-monetary injunctive relief as part of its claims.

4. In addition to injunctive relief, the State claims entitlement to monetary relief in an amount greater than $1,000,000, including civil penalties, reasonable attorney's fees, litigation expenses, restitution, and costs.

III. DEFENDANT

5. Defendant PFIZER, INC. is a corporation organized under the laws of Delaware, with its principal office and place of business located at 1209 Orange Street, in the City of Wilmington, Delaware. Pfizer marketed and distributed its COVID-19 vaccine in Texas. Pfizer conducts business in Texas. At the time of filing, its registered agent for service of process is CT Corporation System, 1999 Bryan St., Ste. 900, Dallas, Texas 75201.

6. Wherever it is alleged herein that Pfizer did any act, it is meant that performed or participated in the act or that Pfizer's officers, directors, agents, employees, or person under Pfizer's control performed or participated in the act on behalf of and under the authority of Pfizer.

IV. VENUE

7. Venue of this suit lies in Lubbock County, Texas, pursuant to DTPA subsection 17.47(b), because Pfizer has done business in Lubbock County and because transactions at issue in this suit have occurred in Lubbock County.

V. PUBLIC INTEREST

8. The State has reason to believe that Pfizer is engaging in or has engaged in the unlawful acts or practices set forth below. In addition, the State has reason to believe that Pfizer has caused injury, loss, and damage to it, as well has caused adverse effects to the lawful conduct of trade and commerce, thereby directly or indirectly affecting the people of this State. Therefore, the Consumer Protection Division of the Office of the Attorney General initiates this proceeding in the public interest. *See* DTPA § 17.47.

VI. PRE-SUIT NOTICE

9. The Consumer Protection Division provided Pfizer notice of the general nature of unlawful conduct challenged herein at least seven days before filing suit, as potentially required by subsection 17.47(a) of the DTPA.

VII. FACTUAL ALLEGATIONS

A. Relevant Background on Emergency Use Authorizations.

10. Under federal law, FDA must approve any new drug product prior to a manufacturer making it available to the consuming public. *See, e.g.*, 21 U.S.C. § 355 (drugs); 42 U.S.C. § 262 (biologics).[1] FDA maintains and follows a rigorous approval process for virtually all drug products submitted for approval. This formalized process requires a manufacturer to submit voluminous amounts of scientific data and information for purposes of persuading FDA that the proposed drug is safe and effective for its intended use. Conducting the scientific testing necessary to support a viable new drug application ordinarily takes many years, followed by time-consuming internal FDA review before a manufacturer obtains approval.

11. FDA has an alternative, radically different drug authorization power known as the "Emergency Use Authorization" (EUA) process. The EUA process, however, is rarely used and only available when the United States Secretary of Health and Human Services declares an emergency. 21 U.S.C. § 360bbb-3(a)(1), (b).

12. By law, the EUA process requires a much lower quantum of scientific evidence and FDA review to obtain marketing authorization compared to the typical process. This reduced scrutiny is justifiable in cases of true emergency on the theory that even a hastily tested drug with uncertain efficacy and safety is better than having nothing at all. *See* Jonathan Iwry, *From 9/11 to COVID-19: A Brief History of FDA Emergency Use Authorization* (Jan. 28, 2021). Federal law further cabins the availability of reduced scrutiny under the EUA process to circumstances where

[1] Whereas "drugs" are "chemically synthesized" with "known" structure, "most biologics are complex mixtures that are not easily identified or characterized," including those "manufactured by biotechnology [that are] heat sensitive and susceptible to microbial contamination." FDA, *What Are 'Biologics' Questions and Answers* (Feb. 6, 2018). The regulatory regime for drug versus biologic approval, however, is highly similar.

"there is *no* adequate, approved, and available alternative to the product" under consideration. 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

13. As part of the ordinary review process, FDA "shall" deny approval if "there is a ***lack of substantial evidence*** that the drug ***will have*** the effect it purports or is represented to have." 21 U.S.C. § 355(d)(5) (emphasis added). *See also* 42 U.S.C. § 262(a)(2)(C) (requiring proof that biologic product actually "***is . . . potent***" before granting approval) (emphasis added). In sharp contrast, FDA has the discretion to grant an EUA if the applicant shows that its product "***may*** be effective" in treating the relevant disease or condition. 21 U.S.C. § 360bbb-3(c)(2)(A) (emphasis added). In keeping with the above, FDA has stated that the EUA process "provides for a lower level of evidence" of "effectiveness" compared to the robust evaluation the agency typically uses for formal approvals. *See* FDA, *Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders* 8 (Jan. 2017) (FDA EUA Guidance). Importantly, FDA will approve EUA products on incomplete information and considers it unlikely that "comprehensive effectiveness data" will be available before an EUA grant. *Id.* at 14.

14. In addition, FDA ordinarily "shall" deny approval if the applicant "do[es] ***not*** show that such drug ***is*** safe." 21 U.S.C. § 355(d)(2) (emphasis added). *See also* 42 U.S.C. § 262(a)(2)(RB) (biologic approved only if it actually "*is . . . safe*") (emphasis added). On the other hand, FDA may grant an EUA so long as the applicant shows that the "known and potential benefit of the product" merely "***outweigh[s]*** the known and potential risks." 21 U.S.C. § 360bbb-3(c)(2)(B) (emphasis added).

15. The procedural framework for formal drug approval compared to EUA grants also underscores the substantive difference between the two processes. An application for formal approval must contain full reports of the scientific studies and testing undertaken to demonstrate whether a proposed drug is safe and effective for its intended use. An applicant typically must

conduct animal testing before it can even begin human testing. After successfully completing the animal testing stage, an applicant must next submit for FDA approval an investigational new drug application (INDA) that explains the scientific basis for proceeding with human testing. *See, e.g.*, FDA's Drug Review Process: Continued (Aug. 24, 2015).

16. Upon approval for human testing, an applicant commences "[c]linical testing for safety and effectiveness requir[ing] three or sometimes four phases" in succession. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007). Specifically:

A. Phase 1 studies include 20-80 persons and are principally designed to measure safety. A Phase 1 study may also provide very "early evidence on effectiveness."

B. Phase 2 studies consist of "well controlled" and "closely monitored" clinical trials of several hundred persons to evaluate both efficacy and short-term side effects and risks.

C. Phase 3 studies consist of "expanded clinical trials of several hundred to several thousand subjects." These pivotal trials are designed to "gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis" for a drug's labeling.

D. Phase 4 studies are not automatically performed, but sometimes are necessary to "delineate[] additional information about the drug's risks, benefits, and optimal use."

17. All told, the research, development, and formal evaluation and approval process for new drugs requires a staggering amount of time. For example, one study found that "[b]etween

January 2010 and June 2020, the FDA approved 21 vaccines" (outside of the EUA process) and that "[t]he median premarket clinical development period" ***exceeded eight years***. Jeremy Puthumana et al., *Speed, Evidence, and Safety Characteristics of Vaccine Approvals by the US Food and Drug Administration*, JAMA Intern Med. 2021;181(4):559-560.0.

18. In sharp contrast, the EUA statute expressly contemplates a more *ad hoc* process for drug development, testing, and authorization. Unlike the standard approval pathway, FDA does *not* require "adequate and well-controlled clinical trials" to grant an EUA; clinical trial results need only be submitted "*if available*." 21 § U.S.C. 360bbb-3(c)(2) (emphasis added). Instead of abiding by a rigid regulatory process for testing and approval, FDA invites EUA applicants to dialogue with FDA on a case-by-case basis to evaluate what procedures and testing best suits the specific circumstances. *See* FDA EUA Guidance at 10.

19. Consistent with the above, the EUA statute also reflects Congress's expectation that EUA products will likely have inferior guarantees of safety and efficacy compared to formally approved drugs. For this reason, among others, unlike traditionally approved drugs, Congress mandated that FDA directly inform "health care professionals administering" the EUA product of any "significant known and potential benefits and risks." 21 U.S.C. § 360bbb-3(e)(1)(A)(II) (emphasis added). Similarly, Congress directed FDA to ensure that individuals *receiving* the product obtain the same information. *Id.* § 360bbb-3(e)(1)(A)(II).

20. In addition, FDA has issued specific guidance for COVID-19 vaccine EUAs. *See, e.g.*, FDA *Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry* (Mar. 31, 2022) (FDA COVID-19 EUA Guidance). Consistent with FDA's general guidance document, the agency's COVID-19-specific guidance made clear that an EUA grant does not reflect a fulsome or even complete efficacy determination. Specifically, FDA announced that it would grant EUAs based on *interim data*, and, upon issuing an EUA, the agency expected an

applicant to "continue to collect data in any ongoing trials" for purposes of supporting a formal approval. *Id.* at 4. *See also id.* at 10 ("FDA acknowledges the potential to request an EUA for a COVID-19 vaccine based on an interim analysis of a clinical endpoint from a Phase 3 efficacy study.").

B. The Regulation of Deceptive Marketing of Vaccines and Drugs.

21. Multiple overlapping federal and state laws regulate and forbid misrepresentations and other deceptive trade practices by drug and vaccine manufacturers.

22. The federal Food, Drug, and Cosmetic Act (FDCA) prohibits "misbrand[ing]" of regulated products. 21 U.S.C. § 331(c). A product is misbranded under federal law if its "labeling" contains misleading content or if the manufacturer's "advertising" is misleading. *Id.* § 331(n). This determination must take into account whether the "advertising fails to reveal facts material in the light of representations" at issue. *Id.*

23. Additionally, the Federal Trade Commission (FTC) Act prohibits deceptive behavior in commerce generally. 15 U.S.C. § 45. And the Covid-19 Consumer Protection Act expressly made the FTC Act's deceptive conduct bar applicable to any representations "associated with the treatment, cure, prevention, mitigation, or diagnosis of covid-19." Public Law 116-260, 134 Stat 1182, Title XIV, Section 1401(b)(1).

24. The Texas Health and Safety Code contains prohibitions that closely resemble those under federal law. Like the FDCA, Texas law prohibits "misbranded" products, which broadly encompasses "advertising" for the product at issue, as well as material omissions within the advertising. Tex. Health & Safety Code § 431.003. Texas's DTPA also prohibits "false, misleading, or deceptive acts" generally. Tex. Bus. & Com. Code § 17.46(a). In particular, Texas's statutory bar on deceptive conduct specifically incorporates applications and interpretations of the FTC Act. *Id.* § 17.46(c).

25. In addition to these general prohibitions applicable to drug and vaccine manufacturers' marketing, FDA has issued more granular guidance on specific kinds of misrepresentations that are highly relevant here. Specifically, FDA has emphatically recognized that the average consumer is unable to properly interpret and evaluate statistical representations in context, particularly with respect to the benefits of pharmaceutical products. *See* FDA, *Communicating Risks and Benefits: An Evidence-Based User's Guide* 53 (2011) (asserting that "innumeracy" "plagues Americans" and has a "profound impact" on their "ability to understand . . . risks and benefits of treatment options").

26. FDA has issued detailed guidance on how to accurately convey risks and efficacy to patients using statistics. In particular, the agency has recognized at least three possible ways to numerically convey the risks and efficacy associated with a given pharmaceutical product: (1) absolute risk reduction, (2) relative risk reduction, and (3) number needed to treat. *Id.* at 56.

27. *First,* absolute risk represents the likelihood that an individual experiences a particular treatment outcome. For example, an individual might have a baseline 1 in 10,000 chance of developing a certain cancer—Cancer X (a .01% baseline risk). Absolute risk reduction measures the reduction in the baseline risk if the individual engages in some course of treatment. For example, an individual might take an experimental drug intended to lower the risk of Cancer X, such that the baseline risk drops from 1 in 10,000 to 1 in 20,000 (a .005% post-treatment risk). The absolute risk reduction is calculated by subtracting the post-treatment risk rate from the baseline risk rate (.01% minus .005%). Therefore, in this hypothetical the absolute risk reduction is 0.05%.

28. *Second*, relative risk represents the likelihood of an individual experiencing a certain treatment outcome by comparing two scenarios. For example, the same individual as above has a baseline 1 in 10,000 chance of developing Cancer X, and a 1 in 20,000 chance if she takes a specific experimental treatment. Therefore, her relative risk of Cancer X if she takes the treatment

is half of her risk if she does not. The same individual, then, experiences a relative risk reduction of 50% from the treatment. In other words, relative risk reduction reflects the percentage of baseline risk that is removed as a result of the new therapy.

29. *Third*, "number needed to treat" (NNT) reflects the number of patients that would have to be treated by a particular intervention in order to prevent one additional negative outcome. A drug with a NNT of 10 means 10 people require treatment with the drug to avoid one negative outcome that the drug is intended to prevent.

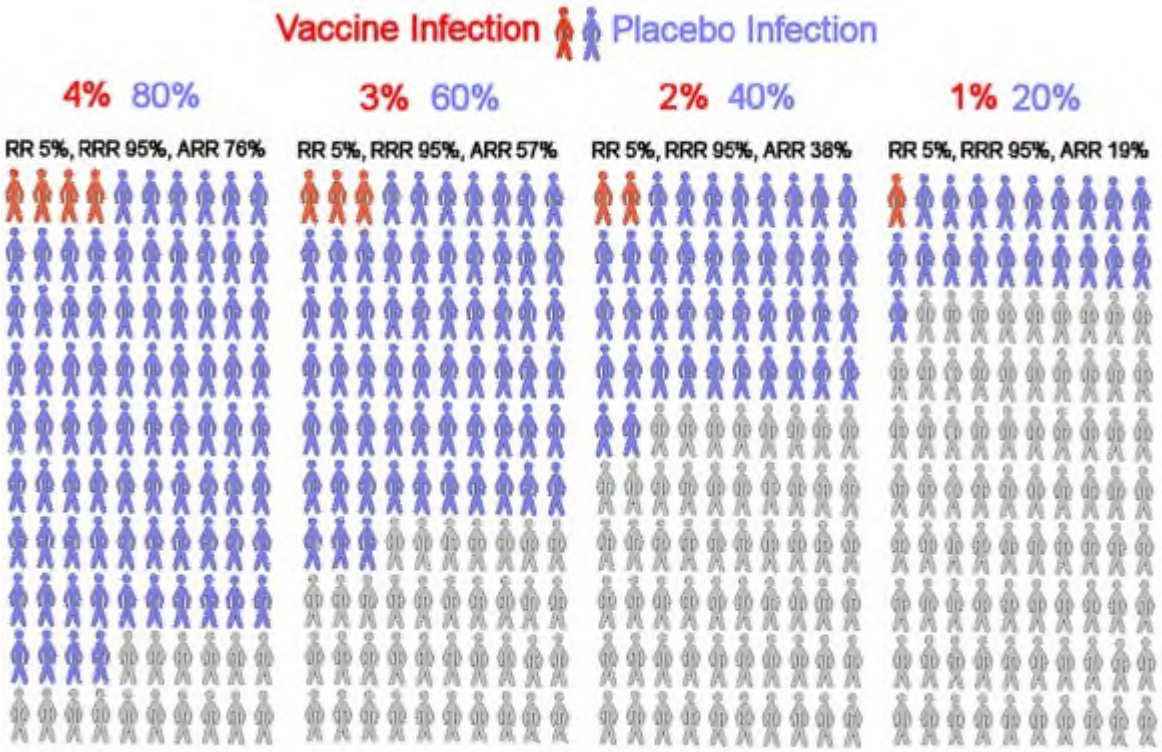
30. As the foregoing illustrates, absolute risk reduction, relative risk reduction, and NNT are drastically different numerical ways to measure and depict the substance of treatment efficacy, and they can generate significantly different numbers to convey the same product's efficacy. FDA recognizes this, and specifically advises industry against using relative risk reduction alone. FDA has made clear that "When information is presented" in this "relative risk format" the amount risk "reduction *seems* large and treatments are viewed more favorably than when the same information is presented using an absolute risk format." *Id.* at 56 (emphasis added).

31. Accordingly, FDA instructs drug manufacturers and industry participants to "[p]rovide absolute risks, not just relative risks" because patients "are unduly influenced when risk information is presented using a relative risk approach." Presenting patients with only relative risk reduction metrics results, in FDA's own words, "in suboptimal decisions." *Id*. Notably, FDA scientists have published literature in highly respected, peer-reviewed journals explaining how relative risk reduction can be "misused" to "exaggerate" a drug's benefits. Stadel et al., *Misleading use of risk ratios* 365 The Lancet 1306-1307 (Apr. 9, 2005).

32. FDA's concerns with reliance on relative over absolute risk reduction metrics is well founded. Specifically, many scientists have observed that a vaccine's benefit "at a given relative risk could vary considerably as the baseline risk changes." Ronald B. Brown, *Relative risk*

reduction: Misinformative measure in clinical trials and COVID-19 vaccine efficacy, 1 Dialogues in Health (Dec. 2022). The potential for substantial variation is a principal reason why describing efficacy in terms of relative risk is so misleading and uninformative for the public.

33. The following graphic illustrates how wildly differing disease infection/vaccine protection configurations can generate identical relative risk reduction numbers—in the graphic, 5% across all four configurations—that obscure the underlying reality of vaccination. By contrast, the graphic depicts how absolute risk reduction takes these differences into account by capturing and reporting the differing overall reduction in infection levels across configurations.



Id.

34. In sum, "[w]ithout reporting the [absolute risk reduction] and correcting the public's misunderstanding of vaccine efficacy, dissemination of vaccine efficacy as the [relative risk reduction] is meaningless and misleading disinformation." *Id.*

C. Pfizer's Narrow Emergency Use Authorization for the COVID-19 Vaccine and FDA's Limited Response.

35. On January 31, 2020, the U.S. Secretary of HHS declared a public-health emergency related to COVID-19. Shortly thereafter, on March 13, 2020, the President declared a national emergency.

36. On March 17, 2020, Pfizer and BioNTech SE announced that the companies had agreed to co-develop and distribute a potential vaccine for COVID-19 based on so-called mRNA technology.[2] The collaboration built on earlier research and development work undertaken by the companies to develop mRNA-based vaccines for influenza. Pfizer believed that a commercially successful COVID-19 vaccine could very well generate billions, if not tens of billions, of dollars in revenues and profits, and even more significantly validate mRNA technology. In the end, Pfizer could stand in the highly desirable position of having a potentially cutting-edge vaccine platform that could revitalize the legacy pharmaceutical company using COVID-19 revenues to fund commercial endeavors more broadly for years to come.

37. Demonstrating its importance as a business opportunity, Pfizer invested $2 billion dollars in total in the COVID-19 vaccine project, with the vast majority incurred in 2020. Notably, Pfizer did not take any money from the United States government in conjunction Operation Warp Speed to provide financial support for vaccine research and development. The Pfizer-U.S. government supply agreement entered into on July 22, 2020, *see infra* ¶¶ 52-55, provided that Pfizer fully retained all patents and other intellectual property arising from the project.

38. On November 20, 2020, Pfizer submitted an EUA request for its COVID-19 vaccine, designated "BNT162b2." *See* FDA, *Emergency Use Authorization (EUA) for an*

[2] The technology uses a novel genetics-based approach called messenger RNA; no mRNA vaccine had been approved to prevent infectious disease prior to Pfizer and Moderna's COVID-19 vaccines.

Unapproved Product Review Memorandum (Dec. 11, 2020) (FDA PFIZER EUA). As part of that application, Pfizer submitted "safety and efficacy data from an *ongoing* Phase 3" trial—not a completed clinical trial. *Id.* at 6. The specifics of that trial bear great relevance to the efficacy representations Pfizer made immediately after receiving the EUA.

39. Pfizer's EUA application primarily relied on a single clinical trial known as "C4591001" that combined Phases 1, 2, and 3. *Id.* at 12.[3] Pfizer commenced Phase 1 trials on April 23, 2020 in a very limited number of subjects. On July 27, 2020, after receiving initial Phase 1 results, Pfizer began enrolling subjects in a joint Phase 2/3 trial. *Id.* at 23. Participants were randomized into two equally sized groups and received "2 doses of either BNT162b2 or placebo, 21 days apart." *Id.* at 13. For purposes of the EUA, Pfizer monitored those subjects' status and whether they developed COVID-19 through November 14, 2020. *Id.* at 23.

40. The Phase 2/3 study investigated two primary efficacy endpoints—that is, the metrics used to determine whether the vaccine had its intended effect. As described by FDA, the first primary efficacy endpoint measured "COVID-19 incidence per 10,000 person-years of follow-up in participants without serological or virological evidence of past SARS-CoV-2 infection before and during vaccination regimen—cases confirmed ≥ 7 days after Dose 2." *Id.* at 13 (emphasis in original).[4] In plain English, the first endpoint sought to measure how often COVID-19 occurred in persons seven days after the second vaccine dose, among persons who had presumably not been infected with COVID-19 before that time.

[3] Pfizer also conducted a preliminary Phase 1 trial known as BNT162-01. Given that the trial involved only 12 participants and tested different vaccine formulations and dosing regimens than BNT162b2, FDA did not deem it material for purposes of issuing the EUA. *Id.*

[4] FDA used "SARS-CoV-2" to refer to the disease agent itself and "COVID-19" to refer to the resulting sickness. That distinction is immaterial for purposes of this Original Petition, which on occasion uses the terms interchangeably.

41. The second primary efficacy endpoint measured "COVID-19 incidence per 1000 person-years of follow-up in participants with and without evidence of past SARS-CoV-2 infection before and during vaccination regimen—cases confirmed ≥ 7 days after Dose 2." *Id.* (emphasis in original). In lay terms, the second endpoint sought to measure how often COVID-19 arose seven days after the second vaccine dose, among all persons, including those who may have been infected some earlier time.

42. In the Phase 2/3 trial, Pfizer used a specific standard to determine when a participant had contracted COVID-19 for purposes of the two primacy efficacy endpoints. Specifically, "the case definition for a confirmed COVID-19 case was the presence of at least one" of several COVID-19 symptoms in the participant *in addition to* "a positive" COVID-19 test. *Id.* at 14. In other words, an individual with a COVID-19 infection *alone*, as determined by a diagnostic test, would not qualify as an actual COVID-19 case for purposes of evaluating the vaccine's efficacy.

43. The study results submitted to FDA comprised 43,448 participants, including 21,720 who received the Pfizer vaccine and 21,728 who received a placebo. Although Pfizer "initially enrolled approximately 30,000 participants" in July 2020, the "enrolled study population had a median follow-up of less than 2 months" when it finally submitted the data to FDA. *Id.* at 17. That is at least partly because Pfizer belatedly added 14,000 additional participants, which substantially reduced the median follow-up time. Indeed, as of November 14, 2020, FDA found that only 43.9% of vaccine recipients completed at least two months of follow-up after receiving the second dose. *Id.* at 16.

44. Pfizer's clinical trial results showed that as of November 14, 2020, 8 out of 17,411 participants (0.04%) who received its vaccine and did not have evidence of a prior infection experienced a defined COVID-19 case during the trial. *Id.* at 23. The results further showed that as of November 14, 2020, 162 out of 17,511 participants (0.9%) in the placebo group who did not

have evidence of a prior infection experienced a defined COVID-19 case during the trial. The relative risk reduction between the placebo group and the treatment group was 95%. *Id.* Put differently, the relative risk reduction metric reflects the percentage of baseline risk of COVID-19 infection present in the control/placebo group that Pfizer's vaccine removed, not the amount of risk reduction present in the overall population.

45. However, the absolute risk reduction for defined COVID-19 cases was only 0.85%. As previously noted, a vaccine's absolute risk reduction is determined by subtracting the post-treatment risk rate from the baseline risk rate. Using Pfizer's Phase 2/3 data, this calculation is performed by subtracting the post-treatment risk rate of 0.04% (8/17,411 persons) found in the vaccine group from the baseline risk rate of 0.9% (162/17,511 persons) found in the placebo group, which after rounding yields 0.85%. This less-than-one-percent total reduction in risk is a product of the fact that *very few people* in either the placebo or treatment group qualified as a defined COVID-19 case.

46. In addition, the NNT according to Pfizer's results was 119. In other words, the trial showed that it was necessary for 119 people to receive Pfizer's vaccine in order to avoid a single defined COVID-19 case.[5]

47. Other results from the initial Phase 2/3 trial called into significant question how efficacious the vaccine was in a more practical sense. As noted above, Pfizer designed the trial such that "defined COVID-19 cases" were counted starting only seven days after a participant received the second of two shots (at least 28 days after the first shot). Put differently, COVID-19 cases that occurred *before* that point—that is, between shot one and seven days after shot two—were not considered when evaluating the efficacy of Pfizer's vaccine. That was a highly significant

[5] Overall, the results for Pfizer's other primary efficacy endpoint (persons "with and without evidence of prior SARS-CoV-2 infection") were not materially different.

qualifier because 409 "[s]uspected" COVID-19 cases occurred *after* the participant received the first vaccine shot, but before seven days elapsed after taking the second shot. *Id.* at 41. By contrast, only 287 suspected COVID-19 cases occurred among placebo recipients in that same interval. In other words, *more people in the trial's treatment group experienced COVID-19 than in the placebo group,* even though the former had taken *at least one ostensibly immunity enhancing dose.*

48. On December 11, 2020, FDA issued an EUA for Pfizer's vaccine. The FDA-reviewed fact sheet for providers and patients re-produced some of Pfizer's clinical trial results, but did not make or endorse any distinct representations submitted by Pfizer regarding efficacy.

49. Notably, FDA went out of its way to expressly state that Pfizer's results did not support several important vaccine characteristics that are highly relevant to Pfizer's representations to the public. *Id.* at 49-51. Specifically, FDA made the following findings:

A. "[I]t is *not possible* to assess sustained efficacy over a period longer than 2 months." In other words, the clinical trial thus far showed nothing about long-term efficacy.

B. "Data are limited to assess the effect of the vaccine against *asymptomatic* infection." The clinical trials, after all, primarily evaluated *symptomatic* infection.

C. The clinical trials did not provide meaningful data on *mortality*—instead, "A large number of individuals at high risk of COVID-19 and higher attack rates would be needed to confirm efficacy of the vaccine against" death.

D. Finally, that "[a]dditional evaluations . . . will be needed to assess the effect of the vaccine in preventing virus shedding and transmission."

D. Pfizer Embarks on a Campaign to Systemically Mislead the Public About the Effectiveness of Its COVID-19 Vaccine to Secure Public Uptake and Win Highly Lucrative Government Contracts.

50. Notwithstanding the serious limitations in Pfizer's clinical trial data, after receiving the EUA on December 11, 2020, Pfizer embarked on a multifaceted and systemic campaign to mislead the public into believing that its COVID-19 vaccine was substantially more effective than in reality. Pfizer repeatedly made material misrepresentations on at least four different dimensions related to vaccine efficacy: (1) the claim of broad "95% efficacy"; (2) claims related to vaccine efficacy against transmission; (3) claims related to the duration of vaccine protection; and (4) claims about the efficacy of the vaccine against variants, including specifically the Delta variant.

51. In late 2020, Pfizer faced challenging competitive conditions and internal business realities with respect to its COVID-19 vaccine. Several significant competitors in the global pharmaceutical and vaccine market had viable vaccine candidates under development, including AstraZeneca, Johnson & Johnson, Novavax, and Sanofi/GSK, with some of those likely to obtain EUA authorizations around the time as Pfizer. In particular, just like Pfizer, Moderna had developed a vaccine using mRNA technology on the cusp of FDA approval.

52. In 2020, before obtaining EUA grants from FDA, vaccine manufacturers began competing for and entering into supply agreements with national governments. For example, in May 2020 AstraZeneca reached the first agreement with the U.S. government to supply 300 million doses of its vaccine. On the heels of AstraZeneca, Novavax and Sanofi/GSK each landed separate 100 million-dose deals over the next two months.

53. On July 22, 2020, Pfizer announced that the company and the U.S. government had entered into a $1.95 billion supply agreement under which Pfizer would provide 100 million vaccine doses upon EUA approval, with the government having the option to acquire up to 500 million more doses. Pfizer understood that if its vaccine achieved widescale penetration amongst the public and the government exercised the option even in part, industry participants and national governments would interpret such events as validation of Pfizer's vaccine. That, in turn, would

expand commercial opportunities for the product both in the United States and abroad.

54. The need for the U.S. government to exercise the purchase option and the strength of competition provided Pfizer with a clear and strong incentive to prioritize rapid and widespread penetration of its vaccine in the United States amongst the public. That incentive was strengthened by Pfizer's and its management's need to make good on the decision to take the significant risk by investing $2 billion of the company's own capital in the COVID-19 projects, while at the same time foregoing substantial financial support from the government, thus avoiding the negative fallout associated with a high-profile failure.

55. To advance its commercial interests, Pfizer began laying groundwork to mislead the public *well before* it received the EUA for its vaccine. For example, in July 2020, Pfizer CEO Albert Bourla talked about how "the vaccine [works] in humans." He said that it creates immune responses that are "able to kill the virus" and that "th[e] vaccine can neutralize the virus." But, as the EUA data later showed, Pfizer measured efficacy only against *symptomatic* COVID-19—not whether the vaccine "neutralized" or "killed" the virus. Time, *Pfizer CEO Albert Bourla Raises Expectations That the Pharmaceutical Giant Can Deliver a COVID-19 Vaccine by Fall* (Updated: July 12, 2020, Originally Published: July 9, 2020).

Misrepresentations concerning 95% relative risk reduction

56. As soon as Pfizer received the preliminary clinical trial results it ramped up its misleading campaign. For example, on November 9, 2020, Pfizer issued a press release describing certain results from its Phase 2/3 trial to an eagerly awaiting public. The press release repeatedly touted how the trial showed that BNT162b2 was "more than 90% effective in preventing COVID-19 in [p]articipants." However, as explained above, this broad representation was based on and reflected the vaccine's relative risk reduction only—not the more important absolute risk reduction number.And Pfizer's press release nowhere mentioned or explained the distinction between

absolute and relative risk reduction, much less disclosed the fact that the misleading statements in its marketing promotion press release were based on relative risk reduction or that the absolute risk reduction equaled only 0.85%. At bottom, however, Pfizer concealed and, ultimately, never informed the public of the highly material fact that amongst the general population Pfizer's own trial results showed that the vaccine would reduce the incidence of the non-vaccinated contracting COVID-19 ***by less than one percent.***

57. Moreover, the press release included statements from Pfizer CEO Dr. Albert Bourla emphasizing the broad effectiveness of its vaccine. Bourla stated that the trial's efficacy data "provides the initial evidence of our vaccine's ability to *prevent COVID-19*." He further expounded, "With today's news, we are a significant step closer to providing people around the world with a much-needed breakthrough to help bring an end to this global health crisis."

58. Pfizer's Phase 2/3 trial, however, did not support these statements. As previously noted, Pfizer's study was designed to evaluate efficacy on a narrow basis—that is, whether participants contracted symptomatic COVID-19 after receiving the vaccine. Moreover, Pfizer's data in its EUA submission that purported to answer that question could do so only for a limited period of time (two months after the second dose). As described above, even FDA recognized that further evaluation was required to determine whether Pfizer's vaccine prevented contracting asymptomatic COVID-19, or the duration of protection it conferred. *See supra* ¶ 49.

59. In making these statements, Bourla exacerbated the misleading nature of his and the company's 90%+ efficacy claim by broadly and recklessly claiming that the vaccine prevented COVID-19 full stop and would end the global pandemic. These statements had no scientific basis and were well outside the boundaries of Pfizer's narrowly designed Phase 2/3 trial.

60. Pfizer disseminated further deceptive promotional marketing material in the form of a press release on November 18, 2020, touting its "vaccine efficacy rate of 95%." Pfizer's highly

anticipated press release failed to mention that its central efficacy representation relied on the confusing, misleading, and uninformative relative risk reduction calculation. Nor did it distinguish relative risk reduction from absolute risk reduction or NNT, much less provide the calculations for those to counteract the cloud of deception cast by this and previous Pfizer press releases. Finally, the press release did not disclose other pieces of critical information, such the absence of knowledge regarding the vaccine's duration of protection and ability to prevent transmission.

61. Taken alone and in combination, Pfizer's misleading statements created the false impression that 95% of vaccine recipients would never obtain COVID-19, full stop.

62. Because of the extraordinary fear amongst the American public stemming from the pandemic and its attendant social and economic problems, Pfizer understood that mainstream media outlets would adopt and broadly disseminate the company's statements about its COVID-19 vaccine—especially those about effectiveness—and could readily anticipate that the media would serve as an amplifier of its deception campaign. Indeed, prominent mainstream media outlets rapidly picked up on, and perpetuated, Pfizer's misleading talking points.

63. For example, on November 18, 2020, Forbes broadcast the headline that "Pfizer-BioNTech Says Covid-19 Vaccine Is 95% Effective." In the news report, Forbes parroted Pfizer's deceptive and misleading press release from earlier in the day, adopting Pfizer's claim that "new trial data showed it to be 95% effective, following initial news of 90% efficacy in its Phase 3 trials."

64. On the same day, CNN reported that "Pfizer and BioNTech say final analysis shows coronavirus vaccine is 95% effective with no safety concerns," writing, "A final analysis of the Phase 3 trial of Pfizer's coronavirus vaccine shows it was 95% effective in preventing infections, even in older adults, and caused no serious safety concerns." And CBS likewise reported that "Pfizer and its partner BioNTech announced . . . test results show[ing] their vaccine candidate was

95% effective at preventing COVID-19."

65. Pfizer's misrepresentations extended well beyond this 95% efficacy statement. Over the following year, Pfizer would go on to mislead the public across multiple critical COVID-19-related dimensions, including specifically the ability of the vaccine to prevent viral transmission from asymptomatic to uninfected people, the reality of waning vaccine efficacy, and the vaccine's ineffectiveness against the Delta variant.

Misrepresentations regarding transmission

66. As explained above, Pfizer's clinical trial did not evaluate whether the vaccine prevented COVID-19 transmission or shedding, a fact that FDA emphasized when it granted the EUA. Among other limitations, the Phase 2/3 trial did not consider participants infected by COVID-19 during its duration who remained asymptomatic to qualify as a confirmed COVID-19 case for purposes of the primary efficacy endpoints. *See supra* ¶¶ 42, 49.B. Nevertheless, over the following year Pfizer made multiple false and misleading statements about vaccine efficacy against asymptomatic infection and ability to prevent transmission.

67. For example, on or around December 14, 2020, Albert Bourla admonished viewers in a CNBC interview that "I [will] repeat once more. The decision not to vaccinate will not affect only your health or your life," but also "[u]nfortunately it will affect the lives of others, and likely the lives of the people you love the most." CNBC, *CNBC Transcript: Pfizer Chairman and CEO Albert Bourla Speaks with CNBC's "Squawk Box" Today* (Dec. 14, 2020. He underscored in the same interview that persons do not "have the luxury to think about" whether to take the vaccine, or whether to "wait a few months." The most reasonable implication to the public here is that vaccination would prevent transmission; otherwise, it makes no sense to say one's vaccination decision was relevant not only to their own health, but also the health of "people you love."

68. Similarly, in a March 31, 2021 press release, Pfizer emphasized in conjunction with

new results on vaccine efficacy in adolescents that "[i]t is very important to enable [adolescents] to get back to everyday school life and to meet friends and family while protecting them and their loved ones." However, just like Pfizer's main Phase 2/3 trial, Pfizer's clinical trial in adolescents did not evaluate transmission. Similarly, it was highly misleading to convey to the public that adolescent vaccine uptake was important for adolescents to "protect . . . their loved ones."

69. On June 8 Albert Bourla also tweeted that "[w]idespread vaccination is a **critical** tool to help stop transmission."

70. And in an interview on or around June 14 Albert Bourla once again emphasized that "[t]he decision to vaccinate or not is not going to affect only your life but unfortunately will affect the health of others" including "people you love most." CBS Mornings, *Pfizer CEO Albert Bourla on vaccine supply, herd immunity* (June 14, 2021).

71. ***Pfizer's clinical trial data did not support any of these statements***. Moreover, data that Pfizer would later submit for formal approval of its vaccine likewise confirmed that Pfizer lacked *bona fide* data that could substantiate these statements. *See infra* ¶ 96.

72. Pfizer's false and misleading statements had a cascading effect in the media, which through multiple formats repackaged and disseminated Pfizer's deception campaign to the public. For example, on May 19, 2021, CNN published "10 reasons why young, healthy people should get vaccinated," and featured as one reason that "If young people don't get vaccinated, it could leave everyone vulnerable."

Misrepresentations regarding waning efficacy

73. As previously discussed in detail, Pfizer's clinical trial did not evaluate vaccine efficacy beyond two months, and FDA emphasized the same fact in its EUA evaluation, *supra* ¶¶ 43, 49.B.

74. This limitation represented a critical gap in Pfizer's efficacy data, particularly in

light of the fact that Pfizer and the scientific community more broadly knew that the vaccine's efficacy *would* likely wane. For example, existing literature was replete with findings based on the previous SARS-CoV virus clearly indicating that there likely would be "*substantial* waning" at some time after initial inoculation. Jayanathan et al., *Immunological considerations for COVID-19 vaccine strategies* Nature (Sept. 2020) (emphasis added). For this reason, among others, Pfizer was, at minimum, on notice that it was "possible that the populations that receive the first round of vaccines will have waning immunity and require boosting." *Id.* And the scientific community expressed that "effective planning of mass immunization campaigns and strategies [for COVID-19] will require knowledge of the duration of such protection." Mehrotra et al., *Clinical Endpoints for Evaluation Efficacy in COVID-19 Vaccine Trials* (Feb. 2021). Quickly determining the duration of protection—and properly conveying that information to the public—was critical in light of this backdrop.

75. Nevertheless, over the course of 2021, Pfizer issued numerous false and misleading statements obfuscating the facts about waning protection. Pfizer even went so far as to conceal and withhold contrary internal data. In sum, Pfizer knowingly cultivated the false impression that its COVID-19 vaccine provided long-lasting immunity to perpetuate its deception campaign and prevent a loss in public confidence in the vaccine's overall efficacy.

76. For example, in a February 2021 interview CEO Albert Bourla was asked "how long" vaccine protection lasted. Bourla responded that "at 6 months, the protection is robust."[6] At this time, however, Pfizer's clinical trial data had *not* yet even collected six months of post-vaccination data for its participants. NBC News, *Exclusive Interview with Pfizer CEO Albert Bourla* (Feb. 25, 2021). And, in fact, the data Pfizer had collected at that point indicated that

[6] NBC News, *Exclusive Interview with Pfizer CEO Albert Bourla* (February 25, 2021).

efficacy was *already waning*. *See infra* ¶¶ 80, 94.

77. In March 2021, Pfizer's own clinical trial results revealed *substantial* waning efficacy. *See infra* ¶¶ 80, 94. Nevertheless, on March 31, 2021 and April 1, 2021, Pfizer released press releases that obfuscated and failed to disclose this critical information. First, on March 31, 2021, Pfizer issued a press release simply stating that its vaccine has a 100% efficacy rate for adolescents, with no disclosure about waning efficacy. And on April 1, 2021, Pfizer issued a press release with "updated" results on its original clinical trial, claiming 91.3% efficacy and emphasizing "high vaccine efficacy observed through up to six months," again, without disclosing material facts about the significant waning as time progressed.

78. On April 1, 2021, Albert Bourla tweeted that the vaccine was 100% effective against a South African variant. https://twitter.com/AlbertBourla/status/1377618480527257606. That was based on a study with a highly limited sample size—specifically, a mere nine observed COVID-19 cases out of only 800 persons. As a result, the confidence interval for the inherently misleading relative risk reduction metric ranged as low as 53.5%, meaning massive uncertainty existed over the precise level of protection that the vaccine conferred against this variant. Additionally, Pfizer had no reason to believe that its vaccine would have greater potency against the South African variant than against the original strain. Indeed, Pfizer separately confirmed that its vaccine induced a *lower* "antibody response" to this variant compared to the original.

79. Continuing Pfizer's deception campaign, on or around April 15, Bourla represented that Pfizer had new data addressing "duration of the immunity" and that the vaccine provided "extremely, extremely high protection" against COVID-19 infection. Jerusalem Post, *Pfizer CEO: Third COVID-19 Vaccine, Annual Booster Shots Likely Scenario* (April 15, 2021).

80. Contrary to its public deception campaign, Pfizer knew by around mid-March 2021 that vaccine efficacy quickly deteriorated. *See infra* ¶ 94. But, while Pfizer knowingly and widely

disseminated misleading statements about vaccine efficacy duration, it withheld specific and highly material information that undermined those claims from the public until July 28, 2021. On that date, Pfizer published the ultimate clinical trial results in pre-print in medRxiv. At around that time, the media ran articles perpetuating Pfizer's misleading impression that this represented "new data" when in fact Pfizer had sat on the data for months in a transparent attempt to not undermine the successful deception campaign and rising vaccine uptake.

81. Pfizer's false and misleading statements and omissions about the duration of vaccine protection had a cascading effect in the media, and were repeated in multiple formats to the public. Relying on Pfizer's statements, the media repeatedly parroted Pfizer's misleading claim that the COVID-19 vaccines would "be effective" for at least "six months and counting." On April 1 for example, NBC published an article parroting how "Pfizer and BioNTech said Thursday that trials suggest their vaccine" showed "high levels of protection against Covid-19 six months after their second dose."

82. Similarly, on April 1, 2021, U.S News and World Report reported that "Pfizer Coronavirus Vaccine Protection Lasts At Least Six Months." And at around the same time, Yahoo! News similarly published that "Pfizer-BioNTech COVID-19 Shot Safe, Effective Through Six Months After Second Dose."

Misrepresentations regarding efficacy against the Delta variant

83. On June 1, 2021, the Center for Disease Control (CDC) announced that a mutation of the original COVID-19 virus known as the Delta variant had become the "dominant variant" in the United States. By the end of July, CDC Director Rochelle Walensky testified to Congress that the Delta variant was responsible for the vast majority (83%) of COVID-19 infections in the United States. *See, e.g., Cheyenne Haslett, Delta variant now makes up 83% of cases, CDC director says, pressed on booster shots* ABC News (July 20, 2021)Indeed, former FDA Commissioner and Pfizer

board of director's member Scott Gottlieb publicly claimed that "for most people," a Delta infection would amount to "the most serious virus that they get in their lifetime in terms of risk of putting them in the hospital." *See* Aya Elamroussi & Holly Yan, *The Delta variant is so contagious, those unprotected will likely get it, a Trump administration FDA chief says* CNN (July 18, 2021).

84. Pfizer's clinical trial did not evaluate vaccine efficacy against SARS-CoV-2 variants. Nevertheless, Pfizer publicly made multiple false and misleading statements about its vaccine's efficacy against SARS-CoV-2 variants, including specifically the Delta variant.

85. For example, on or around March 24, 2021, Bourla stated that "I don't worry about variants," emphasizing that "the worst thing is to start making vaccines for things that we don't need." The most reasonable interpretation of Bourla's statement was that Pfizer's then-current vaccine was effective against variants.

86. Bourla compounded this misrepresentation by claiming a seemingly impossible "100%" vaccine efficacy rate against variants, such as the South African variant, even though Pfizer's Phase 2/3 trial did not test efficacy against this variant. Bourla used this remarkable representation to leap even further and claim that "[n]o variant identified so far . . . escapes the protection of our vaccine."

87. Having exposed the public to a steady barrage of misleading statements concerning variants generally, Pfizer extended the deception campaign to the Delta variant specifically. For instance, on or about June 14, 2021, Bourla stated he was "quite comfortable" that Pfizer's vaccine would "cover" the Delta variant. CBS Mornings, *Vaccinating The World Pfizer CEO on Efficacy Against Variants, Boosters, and Donating Doses* (June 14, 2021).

88. Pfizer continued to make misleading statements concerning the efficacy of its vaccine against the Delta variant throughout the summer. The following are representative

examples of Pfizer's continued campaign of deception:

A. On or around June 24, 2021, a Pfizer medical director told the media that Pfizer's "data from those places where the Indian variant, Delta, has [become] the common variant, point to our vaccine being very effective, around 90%." Maayan Lubell, *Pfizer says COVID vaccine is highly effective against Delta variant*, Reuters (June 24, 2021).

B. On or around July 28, 2021, Bourla stated that Pfizer is "very very confident that a third dose, a booster [of the original vaccine], will take up the immune response to levels that will be enough to protect against the delta variant."

C. On August 16, 2021, Pfizer issued a press release touting how a booster would "preserve and even exceed the high levels of protection against . . . relevant variants."

D. And on August 23, 2021, Bourla represented that "[t]he current vaccine is very, very, very effective against Delta."

89. In fact, however, what little data was available on vaccine efficacy against Delta during this time period devastated Pfizer's unsupported claims. *See infra* ¶¶ 110-16, 120-22.

90. Just like Pfizer's other misrepresentations, Pfizer's false and misleading statements about vaccine efficacy against the Delta variant had a cascading effect in the media and were repeated in multiple formats to the public.

91. As alleged above, Pfizer knowingly misrepresented the efficacy of its COVID-19 vaccine on multiple dimensions with the intent to facilitate the vaccine's adoption and expand its commercial opportunity. And Pfizer's strategy succeeded spectacularly. Exploiting the widespread fear and anxiety over the pandemic and the public's trust in new vaccines to end it, Pfizer's deception campaign quickly accelerated and Pfizer's vaccine assumed the position of market

leader in the United States, and thereafter maintained nearly 70% market penetration among the public by the end of 2021. Pfizer's position as the market leader for COVID-19 vaccines was established on a worldwide basis when the U.S. government decided to exercise its right to buy 500 million more doses from Pfizer over the course of 2021.

E. Clinical Trial Results and Real-World Data Confirm the Misleading Nature of Pfizer's Baseless Efficacy Representations.

92. At the same time as Pfizer executed its public deception campaign, data both in Pfizer's hands and in the scientific community more broadly was sharply undermining what Pfizer was telling the public.

93. ***Formal FDA Approval Data.*** First, Pfizer's clinical trial that supported the EUA grant continued to generate results up through March 13, 2021. Pfizer used the data collected up through that time point in its application requesting formal FDA approval of its COVID-19 vaccine, which it submitted to the agency on May 18, 2021. *See* FDA, Summary Basis for Regulatory Action on COMIRNATY 1, 18 (Nov. 8, 2021).

94. Pfizer's data as of March 13 showed a material decrease in efficacy corresponding to the time after a subject received dose two. Specifically, whereas the risk reduction rate for the window beginning seven days after Dose 2 and ending less than two months thereafter stood at 96%, the relative risk reduction for the window beginning four months after Dose 2 and ending six months after Dose 2 collapsed to 83.7%. *See* COMIRNATY CRM at 51-52.

95. Moreover, ***none*** of the clinical trial data in the formal approval application supported efficacy against the Delta variant. *See id.* at 52 ("Updated efficacy analyses were conducted in March 2021, prior to the emergency of the B.1.617.2 (Delta) variant in the US."). FDA recognized that this posed a major problem, noting that it was "[u]ncertain[]" whether Pfizer's vaccine possessed "effectiveness against SARS-CoV-2 variants that are different from

those circulating" as of March 13, 2021—when Pfizer's trial ended. *Id.* at 95.

96. FDA further recognized the existence of "[u]ncertaint[y]" regarding the "duration of protection" and, relatedly, whether Pfizer's vaccine protected against "asymptomatic infection and transmissibility of the virus." *Id.* at 95.

97. There were also problems with the integrity of the data itself. After FDA granted the EUA, Pfizer gave clinical trial participants the ability to "unblind" themselves. This meant that people in the original placebo group had the opportunity to get vaccinated *before* the clinical trial ended.

98. However, when FDA initially granted Pfizer's EUA, the agency emphasized that it was "critical" for Pfizer to "continue to gather data about the vaccine even after it is made available under EUA." FDA PFIZER EUA at 11. To this end, FDA sharply cautioned Pfizer against "immediately unblind[ing] their trials upon issuance of an EUA." *Id.* "FDA and its advisers pushed hard for volunteers to remain on placebo as long as possible to gather more safety and efficacy data." Matthew Harper, Pfizer and BioNTech speed up timeline for offering Covid-19 vaccine to placebo volunteers STAT NEWS (Jan. 1, 2021).

99. Nevertheless, according to Pfizer's own data, by January 21, 2021, ***7,446*** participants who received placebo during the trial had elected to take the actual vaccine. Contrary to FDA's directive, Pfizer's "aim" was for *every* placebo subject to "have the opportunity to receive their first dose of" the vaccine by March 1, 2021. Pfizer.com., *Pfizer-BioNTech COVID-19 Vaccine Trial Overview*. Accordingly, by the time Pfizer's trial ended on March 13, almost all placebo participants had been unblinded and given BNT162b2. *See* FDA, BLA Clinical Review Memorandum for COMIRNATY 67 (Aug 23, 2021) ("Overall, 19,525 original placebo participants were unblinded and received BNT162b2.") (COMIRNATY CRM)

100. FDA's review of the formal application also revealed significant safety concerns.

Specifically, "FDA and CDC identified serious risks for myocarditis and pericarditis following administration of" Pfizer's vaccine, including "some cases [that] required intensive care support." FDA, Summary Basis for Regulatory Action on COMIRNATY 23 (Nov. 8, 2021). Indeed, there were 38 deaths during the clinical trial. COMINARTY CRM at 70. The majority of deaths were in the ***vaccinated*** (twenty-one vaccine recipient deaths versus seventeen placebo deaths). *Id.* Many of the vaccinated deaths were a result of "[c]ardiac conditions." *Id.* at 71.

101. FDA ultimately concluded that it was "unlikely" the vaccine caused any deaths. *Id.* But the deaths are nevertheless critical because they underscore that Pfizer's vaccine unequivocally failed at preventing persons from dying on the whole. *Id.* The clinical trials produced ***no*** evidence that Pfizer's vaccine prevented death altogether, even if there was evidence that the vaccine (temporarily) prevented some COVID-19 cases.

102. Over the course of 2021, additional data points emerged corroborating the fact that Pfizer had no scientific support to justify many of its efficacy claims. Indeed, much of this data undermined Pfizer's efficacy claims.

103. ***Transmissibility data.*** Substantial additional evidence emerged throughout 2021 showing that Pfizer's vaccine did not prevent transmission. On July 30, 2021, the CDC released a devastating report about an outbreak of COVID-19 at large gatherings in Barnstable County, Massachusetts. *See* CDC, *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gathering—Barnstable County, Massachusetts, July 2021* (Aug. 6, 2021). The CDC's analysis demonstrated that vaccinated persons caused a significant outbreak of symptomatic COVID-19 among other *vaccinated* persons at multiple large public gatherings in a Massachusetts. Of the COVID-19 infections associated with the outbreak, nearly three quarters occurred in fully vaccinated persons, a plurality of which

had received Pfizer's vaccine. *Id.*[7]

104. In addition, the medical journal The Lancet published a study on October 29, 2021, showing that vaccinated individuals caused infections within their households *at materially the same rate as unvaccinated individuals.* Specifically, "fully vaccinated individuals" infected with COVID-19 caused approximately 25% of persons in their household to contract COVID-19, whereas "unvaccinated individuals" with COVID-19 caused infections within their household at a rate of 23%. *See* Singanayagam et al., *Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study* The Lancet (Oct. 29, 2021). Another study published in October 2021 found that to the extent vaccination prevents "[t]ransmission," that transmission reduction "decline[s] over time" and "attenuate[s] substantially" for Pfizer recipients a mere "3 months post-second" dose. Eyre et al., *The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission* medRxiv (Oct. 15, 2021).

105. ***Waning Efficacy Data.*** Substantial additional evidence also emerged throughout 2021 showing that Pfizer's vaccine had serious waning efficacy, bolstering the conclusion that Pfizer lacked a scientific basis when it represented that its vaccine had robust and long-lasting efficacy in the first instance.

106. For example, in many respects, including with regard to waning efficacy, Israel's data was considered the gold standard. Indeed, Pfizer's Chief Scientific Officer, Philip Dormitzer, expressed that Israel was "sort of [a] laboratory" and that "[w]hat we see happening in Israel happens again in the US a couple months later." This makes sense because the vast majority of

[7] Moreover, the vaccine apparently did not reduce the rate of hospitalization. Five persons in total were hospitalized, and four of those were vaccinated. The one unvaccinated person "had multiple underlying medical conditions." *Id.*

Israelis received the Pfizer vaccine. But Israel's data showed time and again that vaccine efficacy waned rapidly.

107. By June 6, 2021, Israel's Health Ministry was reporting that vaccine relative risk reduction at preventing infection *and* symptomatic disease fell to just 64%. On August 30, 2021, an Israeli study found a "strong effect of waning immunity in all age groups after six months." Goldberg et al., *Waning immunity of the BNT162b2 vaccine: A nationwide study from Israel* (Aug. 30, 2021). Individuals who received their second dose in March 2021 were *160%* more protected than those who received their second dose a mere two months earlier.

108. According to an FDA presentation, 60% of Israel's severe COVID in July and August 2021 occurred in vaccinated people. FDA, Vaccines and Related Biological Products Advisory Committee Meeting Slideshow at 12 (Sept. 17, 2021).

109. United States-based studies performed by CDC yielded similar results. On September 24, 2021, the CDC issued a report on efficacy against hospitalization. While it found the vaccine had an average 91% relative risk reduction rate against hospitalization two months after dose two, that efficacy quickly dropped to 77% at only three months later. *See* CDC, Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March-August 2021 (Sept. 24, 2021).

110. ***Delta variant data***: Substantial evidence also emerged showing that the vaccine had little, and arguably *negative* efficacy against the Delta variant. As such, this subsequent evidence confirmed that Pfizer had no factual basis to make its efficacy representations about Delta in the first instance.

111. On or around July 23, 2021, the Israeli Health Ministry announced, while "the delta variant [wa]s the dominant strain," that "Pfizer and BioNTech's Covid-19 vaccine is just 39%

effective." CNBC, *Israel says Pfizer Covid vaccine is just 39% effective as delta spreads, but still prevents severe illness* (July 23, 2021). Illustrating the precipitous drop in vaccine efficacy against Delta, Israeli officials estimated efficacy at 64% just weeks before.

112. Worse, in September 2021, FDA's Vaccines and Related Biological Products Advisory Committee recognized that Israel was experiencing its worst "levels of infection (delta variant) in spite of widespread" vaccination. FDA, Vaccines and Related Biological Products Advisory Committee Meeting Slideshow at 10 (Sept. 17, 2021).

113. There is also evidence that the Pfizer vaccine did little, or perhaps nothing, to prevent *death* from the Delta variant. Specifically, the United Kingdom's Office for National Statistics retained and publicized remarkably granular vaccine efficacy statistics during COVID-19, broken out according to unvaccinated, vaccinated, or boosted deaths involving COVID-19 on a per-month basis. This is highly informative data because Pfizer's vaccine was the most used COVID-19 vaccine in the U.K. In March 2021, for example, U.K. data shows 1,309 unvaccinated deaths involving COVID-19, versus only 35 deaths involving COVID-19 in persons 21 days or more after their second dose. In other words, in the early days after vaccination, Pfizer's product appeared to at least be effective at preventing death. But by July 2021—during Delta's peak—those numbers were nearly flipped. Specifically, in July 2021, there were only 331 unvaccinated deaths involving COVID-19. But there were ***750*** deaths involving COVID-19 among persons 21 days or more after their second dose.

114. The overall trend in the U.K. of (1) decreasing deaths among the unvaccinated, along with (2) increasing deaths among the vaccinated, increased in a dramatic way for months after the Delta variant inundated the U.K. For example, in October 2021, the U.K.'s data showed 419 unvaccinated deaths involving COVID-19. But there were ***2,102*** deaths involving COVID-19 in persons 21 days or more after the second vaccine dose. Indeed, even though relatively few

people had received booster shots by October 2021, there were also 163 deaths involving COVID-19 among persons who had received a booster shot.

115. Data from other jurisdictions was arguably even worse. Scotland published granular information, including specifically the ratio of persons vaccinated (or not) who were infected with, hospitalized, or died because of COVID-19. That data devastates Pfizer's claims of vaccine efficacy against Delta. For example, in late December 2021 and early January 2022, Scotland's official reports demonstrate *negative* vaccine efficacy. Put differently, a *greater* ratio of vaccinated persons acquired COVID-19 than unvaccinated persons. For example, in the last week of 2021, Scotland's data shows approximately 1,000 COVID-19 cases for every 100,000 unvaccinated persons, but 2,550 cases for every 100,000 vaccinated persons. The ratio of boosted persons who acquired COVID-19 (1,526.50 out of 100,000) was likewise higher than among unvaccinated persons.

Table 13: COVID-19 age-standardised case rate per 100,000 individuals by vaccine status, seven-day rolling average from 10 May 2021 to 21 January 2022

	Unvaccinated			1 Dose		
Week	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
25 December - 31 December 2021	9,486	998,916	**966.34** (932.78 - 999.89)	3,355	347,509	**1,408.50** (1,346.45 - 1,470.54)
01 January - 07 January 2022	9,060	988,860	**922.84** (892.58 - 953.11)	3,040	340,199	**1,397.40** (1,329.08 - 1,465.72)
08 January - 14 January 2022	3,684	980,373	**423.87** (400.75 - 447.00)	1,111	338,860	**556.69** (509.91 - 603.47)
15 January - 21 January 2022	2,696	976,349	**297.18** (278.32 - 316.05)	779	318,752	**386.90** (350.61 - 423.19)
	2 Doses			Booster or 3 Doses		
Week	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals	No. tested positive by PCR	Population	Age-standardised case rate per 100,000 with 95% confidence intervals
25 December - 31 December 2021	50,658	1,524,657	**2,549.61** (2,520.21 - 2,579.02)	30,055	2,429,633	**1,526.50** (1,504.02 - 1,548.97)
01 January - 07 January 2022	34,347	1,122,958	**2,416.51** (2,381.77 - 2,451.25)	35,449	2,847,489	**1,360.84** (1,345.00 - 1,376.67)
08 January - 14 January 2022	9,614	997,216	**885.69** (859.48 - 911.91)	13,950	2,982,334	**494.45** (485.58 - 503.32)
15 January - 21 January 2022	6,027	932,716	**568.49** (548.76 - 588.22)	10,495	3,070,963	**374.56** (366.97 - 382.14)

116. Scotland's official reports likewise show the ratio of vaccinated persons who *died* because of COVID-19 in late December 2021 and early January 2022 was higher than the ratio among unvaccinated persons. For example, the age-standardized mortality rate among the

unvaccinated from COVID-19 in the week of December 18, 2021 was 1.69 for every 100,000 individuals. But for the vaccinated in the same week, the rate was more than triple—6.55 out of 100,000.

Table 15: Number of confirmed COVID-19 related deaths by vaccination status at time of test and age-standardised mortality rate per 100,000, 18 December 2021 to 14 January 2022

	Unvaccinated			1 Dose		
Week	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
18 December - 24 December 2021	6	1,568,607	**1.69** (0.22 - 3.16)	7	356,597	**15.36** (2.89 - 27.82)
25 December - 31 December 2021	9	1,560,599	**5.41** (0.77 - 10.06)	1	347,533	**0.36** (0.00 - 1.06)
01 January – 07 January 2022	12	1,550,542	**7.60** (2.38 - 12.83)	3	340,224	**7.42** (0.00 - 16.28)
08 January – 14 January 2022	16	1,542,053	**10.40** (4.07 - 16.73)	3	338,887	**4.79** (0.00 - 11.13)
	2 Doses			Booster or 3 Doses		
Week	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals	No. of deaths	Population	Age Standardised Mortality Rate per 100,000 with 95% confidence intervals
18 December - 24 December 2021	24	1,868,657	**6.55** (3.80 - 9.30)	15	2,069,874	**0.33** (0.16 - 0.49)
25 December - 31 December 2021	21	1,524,657	**7.14** (3.87 - 10.42)	9	2,429,634	**0.21** (0.07 - 0.34)
01 January – 07 January 2022	26	1,122,958	**12.00** (7.21 - 16.79)	21	2,847,490	**0.46** (0.26 - 0.65)
08 January – 14 January 2022	33	997,216	**14.05** (8.88 - 19.22)	71	2,982,335	**1.50** (1.15 - 1.85)

117. ***Pfizer's booster dose data***. Pfizer's own data assembled to gain authorization for booster shots also eviscerated the representations the Pfizer had made to the public and made clear that the company knew it had no scientific evidence to support making the false statements in the first instance. On August 23, 2021, FDA approved Pfizer's Biologics License Application for "Comirnaty"—the trade name for BNT162b2. Two days later, on August 25, Pfizer sought a supplemental approval for booster shots of Comirnaty in persons sixteen years or older. *See* FDA Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum 4 (Sept. 21, 2021) (FDA Booster Amendment). However, the agency's independent Vaccines and Related Biological Products Advisory Committee (VRBPAC) overwhelmingly recommended FDA ***deny***

approval, citing "concerns about insufficient data." FDA Booster Amendment at 5. [8]

118. On September 21, 2021, Pfizer re-submitted the same data in the form of an amendment to its original December 2020 EUA. Pfizer took this step because, as noted previously, an EUA grant requires a lower amount of proof of efficacy and safety compared to a formal FDA approval.

119. Even by EUA standards, however, Pfizer's data was remarkably weak. As FDA noted, "[e]fficacy against COVID-19 was not evaluated following the booster dose" in a well-controlled and appropriately designed clinical study. Instead, Pfizer proposed proving the "effectiveness of the booster dose" against the original COVID-19 strain using so-called "immunobridging analyses" comparing antibody rates from persons one month after a booster to the same rates from persons one month after the original two-dose series.

120. In response, FDA requested that Pfizer provide information on how the two-dose series performed in persons vaccinated in July and August 2021—the period corresponding with Delta. This represented a critical dataset because if the two-dose series failed to protect against the then-dominant Delta variant, it would be reasonable to conclude that a booster of the same vaccine would not either. The supplemental data that Pfizer submitted did not support approval. As FDA noted, Pfizer's data "appear[ed] to indicate that the incidence of SARS-CoV-2 during the analysis period . . . was 70.3 cases per 1,000 person-years." By comparison, the *placebo group* in the Phase 2/3 study in the original EUA had an incidence rate of 72.9 cases per 1,000 person years. In other words, ***vaccinated*** persons experienced nearly identical rates of COVID-19 infection in July and August 2021 as ***unvaccinated*** persons when Pfizer originally submitted its clinical trial results to FDA in November 2020.

[8] FDA's VRBPAC is an independent committee designed to provide expert advice to FDA on vaccine and other biological product issues.

121. FDA also requested that Pfizer submit other specific data to support effectiveness of a vaccine booster dose against the Delta variant. *Id.* at 19. Pfizer responded with "exploratory descriptive analyses" of data measuring antibody levels collected in a limited Phase 1 study of individuals who received a booster dose. That study included only *twenty-three people* and, as a result, only "[a] very limited number of serum samples were available for this analysis." And Pfizer used a non-validated method for ascertaining whether a booster increased the antibody levels. The increased antibodies in this highly limited pool of people was the full extent of Pfizer's showing that a booster would be effective against Delta.

122. Pfizer's untested "antibodies only" approach to demonstrating efficacy against Delta was also remarkable because, at the very same time, FDA was publicly taking the position that antibodies did not constitute evidence of protection. For example, on May 19, 2021, FDA explained in a publicly issued report that "results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time." FDA, *Antibody Testing is not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication* (May 19, 2021).

123. Under political pressure from the White House, FDA ultimately granted Pfizer's EUA amendment for booster shots for a massive share of the population. *See* Sarah Owermohle, *Biden's top-down booster plan sparks anger at FDA*, Politico (Aug. 31, 2021). Politico further reported that "two top vaccine regulators resigned" as a result of the White House pressure. FDA, however, made clear the myriad limitations present in Pfizer's booster submission, and heavily qualified its approval. FDA stated that not only did Pfizer continue to lack data to directly demonstrate efficacy of a booster dose "to provide additional protection against the currently circulating Delta variant," but also to "directly demonstrate" booster efficacy against "clinical disease outcomes from" COVID-19 altogether. In sum, FDA concluded that Pfizer's limited data

only "support[ed]"—it did not demonstrate—the mere "potential" that the booster dose *could possibly* provide enhanced protection against Delta. *Id.* at 29.

124. In addition, FDA drew attention to two repeated shortcomings in Pfizer's COVID-19 data. First, FDA recognized that it was not "possible to assess" the amount of time a booster worked beyond just "1 month." Second, FDA determined that Pfizer had not submitted data to establish the "effectiveness of a booster dose against transmission." FDA Booster Amendment at 29.

F. Pfizer Intimidated and Silenced Persons Who Spread Information About the Vaccine that Undermined Its False Efficacy Narrative.

125. Pfizer also took overt action to intimidate and silence persons who spread factual information about vaccine efficacy. On information and belief, Pfizer engaged in this misconduct to prolong the effectiveness of the company's deception campaign, thereby maintaining the false impression that its COVID-19 vaccine had more efficacy than in reality. Over the course of 2021, Pfizer's censorship campaign helped secure commitments to purchase at least 415 million and 2.7 billion doses from the U.S. and foreign governments respectively, displacing Pfizer's rivals and achieving the status of first-choice vaccine.

126. One of the persons Pfizer sought to intimidate and silence was journalist Alex Berenson. Throughout early 2021, Berenson maintained a highly active Twitter page with hundreds of thousands of followers where he explained his findings and views concerning COVID-19, Pfizer's vaccine, and other related issues. Many of Berenson's claims were true at the time he made them and have been corroborated by subsequent data and analyses. Indeed, it recently has been revealed that Pfizer had reason to *know* of the veracity of Berenson's claims when he made them and that the company nonetheless plotted to silence Berenson and eliminate his speech from public discourse. Ultimately, Pfizer succeeded in having Berenson censored and widely derided as

a "conspiracy theorist" for his views that dared to challenge Pfizer's deception campaign.

127. For example, on August 24, 2021, Dr. Scott Gottlieb complained directly to Twitter about Berenson's content that was being "promoted on Twitter." Gottlieb claimed that this content was the reason "why Tony [presumably Anthony Fauci] needs a security detail."

From: **Scott Gottlieb, MD** <scott.gottlieb@gmail.com>
Date: Tue, Aug 24, 2021 at 3:26 PM
Subject: Fwd: Quite frankly
To: [redacted]@twitter.com>

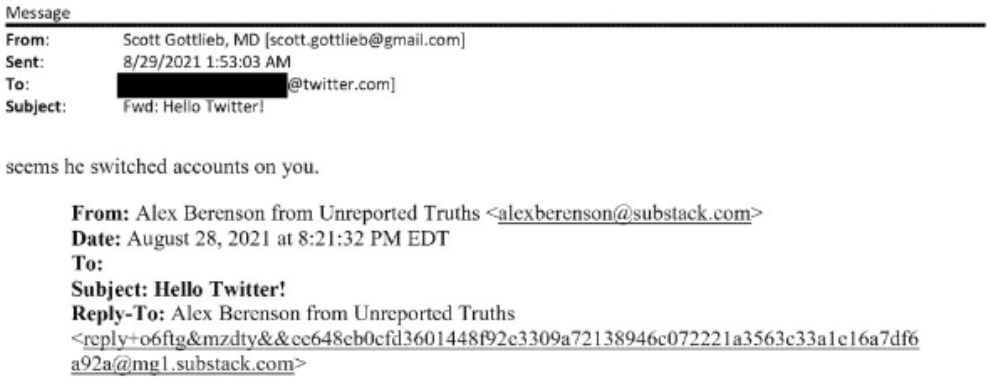
This is whats promoted on Twitter. This is why Tony needs a security detail.

From: Alex Berenson from Unreported Truths <alexberenson@substack.com>
Date: August 24, 2021 at 3:04:38 PM EDT
Subject: Quite frankly
Reply-To: Alex Berenson from Unreported Truths
<reply+o0pj7&mzdty&&ac14c9c6f744799332435cdc1fcb904cf27f6d068cb41dad8165c3fd5788d762@mg1.substack.com>

128. At this time, Gottlieb led Pfizer's regulatory and compliance committee and was one of seven members of Pfizer's executive committee. On information and belief, Pfizer was aware that Twitter might permanently ban Berenson if his account incurred a sufficient number of perceived violations of Twitter policy. Twitter's internal communications indicate that just three days after Gottlieb's email Twitter employees met with the senior Pfizer executive and discussed Berenson's assumed violations of Twitter policy, including Berenson's so-called "4th COVID-19 strike."

129. On August 28, Berenson tweeted that Pfizer's vaccine "doesn't stop infection . . . [o]r transmission," as well as that it has a "limited window of efficacy." These were indisputably true statements based on the scientific record at that time, including data from Pfizer's own studies, as well as FDA's own findings. Nevertheless, Gottlieb emailed this tweet to senior Twitter employees. Given the context of Gottlieb's communications with Twitter at that time, this was likely intended to provoke Twitter into banning Berenson's account. Later that same day, Twitter permanently suspended Berenson's account.

130. Shortly after his permanent suspension, Berenson created a new account on Twitter. On August 29, Gottlieb emailed Twitter to flag this new account, telling Twitter that it "seems he switched accounts on you."



Message

From: Scott Gottlieb, MD [scott.gottlieb@gmail.com]
Sent: 8/29/2021 1:53:03 AM
To: [redacted]@twitter.com]
Subject: Fwd: Hello Twitter!

seems he switched accounts on you.

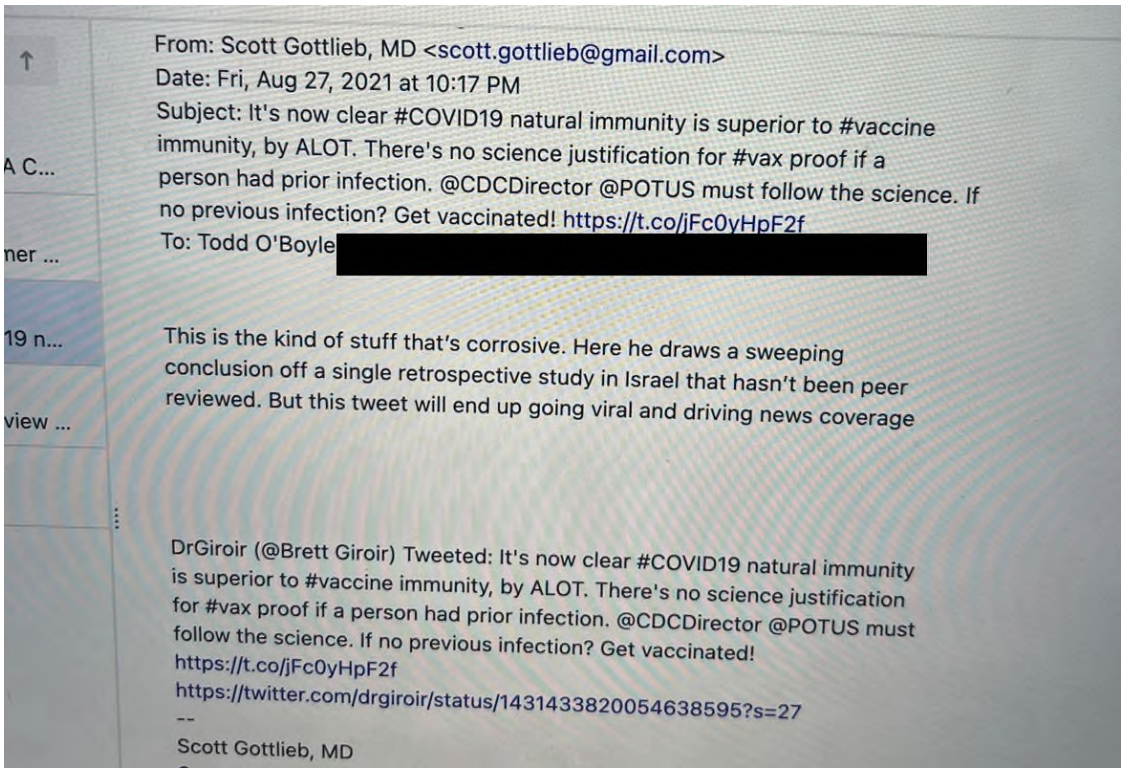
From: Alex Berenson from Unreported Truths <alexberenson@substack.com>
Date: August 28, 2021 at 8:21:32 PM EDT
To:
Subject: Hello Twitter!
Reply-To: Alex Berenson from Unreported Truths
<reply+o6ftg&mzdty&&ec648cb0cfd3601448f92c3309a72138946c072221a3563c33a1c16a7df6a92a@mg1.substack.com>

131. Pfizer's campaign against Berenson had the goal and effect of eliminating a prominent skeptic of Pfizer's vaccine and deceptive marketing campaign touting the vaccine's ability to combat COVID-19, as well as a source of truthful information that undercut Pfizer's misrepresentations to the public.

132. Pfizer targeted many other skeptics in addition to Berenson. Gottlieb persistently contacted senior persons at Twitter and, on information and belief, other social media platforms, in a clandestine effort to silence challengers to Pfizer's deceptive scheme to promote sales and use of its vaccine products. For example, in August 2021, former FDA Director Brett Giroir tweeted that "#COVID19 natural immunity is superior to #vaccine immunity, by A LOT," and stated "no science justification" exists to demand proof of vaccination from an already infected person.

133. On August 27, Gottlieb quickly moved to squelch his fellow FDA alumnus, flagging Giroir's tweet to Gottlieb's Twitter contacts. Illustrating that Pfizer understood the need to protect its highly lucrative vaccine platform from information spreading to the general public that undermined its previous misrepresentations of efficacy, Gottlieb took pains to emphasize the

risk that Giroir's comments would "driv[e] news coverage." In a moment of candor, Gottlieb acknowledged that Giroir's tweet would be "corrosive" to the public's confidence in Pfizer's vaccine.



From: Scott Gottlieb, MD <scott.gottlieb@gmail.com>
Date: Fri, Aug 27, 2021 at 10:17 PM
Subject: It's now clear #COVID19 natural immunity is superior to #vaccine immunity, by ALOT. There's no science justification for #vax proof if a person had prior infection. @CDCDirector @POTUS must follow the science. If no previous infection? Get vaccinated! https://t.co/jFc0yHpF2f
To: Todd O'Boyle [redacted]

This is the kind of stuff that's corrosive. Here he draws a sweeping conclusion off a single retrospective study in Israel that hasn't been peer reviewed. But this tweet will end up going viral and driving news coverage

DrGiroir (@Brett Giroir) Tweeted: It's now clear #COVID19 natural immunity is superior to #vaccine immunity, by ALOT. There's no science justification for #vax proof if a person had prior infection. @CDCDirector @POTUS must follow the science. If no previous infection? Get vaccinated!
https://t.co/jFc0yHpF2f
https://twitter.com/drgiroir/status/1431433820054638595?s=27
--
Scott Gottlieb, MD

134. Based on his access to Twitter and previous experience, Gottlieb had ample reason to believe that his act of flagging this content would likely result in Twitter taking adverse action against Giroir. And, sure enough, Twitter flagged Giroir's tweet as "misleading." Notwithstanding Pfizer's disinformation scheme, Israeli Ministry of Health data from this exact time period unequivocally supported Girior's claim that natural immunity was superior to vaccine immunity. Goldberg et al., *Protection and waning of natural immunity and hybrid COVID-19 immunity* (Dec. 5, 2021).

135. On September 3, 2021, according to reports from persons given access to Twitter's internal files, Gottlieb engaged in similar conduct regarding another prominent skeptic. Specifically, Gottlieb complained to Twitter about a post noting, "Sticks and stones may break my

bones but a viral pathogen with a child mortality rate of <>0% has cost our children nearly three years of schooling." On information and belief, Pfizer employed multiple other methods, directly or indirectly, with the intent to provoke and ultimately cause censorship on social media platforms of content adverse to sales or consumption of its vaccine. Recent reporting has revealed that a Pfizer-funded entity benevolently known as the "Public Good Projects" regularly corresponded with Twitter for the purpose of suppressing content critical of the vaccines. *See* Lee Fang, *COVID-19 Drugmakers Pressured Twitter to Censor Activists Pushing for Generic Vaccine* (Jan. 16, 2023).

136. In addition to coercing social media platforms to censor truthful information that undermined Pfizer's false statements and misrepresentations, Pfizer affirmatively intimidated vaccine skeptics to perpetuate its scheme to confuse and deceive the public.

137. For example, on November 9, 2021, CEO Albert Bourla charged that persons who spread so-called "misinformation" concerning COVID-19 vaccines are "criminals" who have "literally cost millions of lives."

138. On that same day, Pfizer Tweeted a message with the clear implication that persons questioning the efficacy of Pfizer's vaccine are spreading "misinformation."

G. The Public Relied on Pfizer's Misleading Marketing to Its Detriment.

139. As set forth above, Pfizer knowingly and recklessly engaged in a multi-faceted

scheme to mislead the American public about the efficacy of its COVID-19 vaccine, including making affirmative misrepresentations, withholding material information, and taking steps to censor and suppress individuals who disseminated truthful information adverse Pfizer's deceptive scheme to increase sales and consumption of its vaccine. As a result of its deceptive conduct, Pfizer sold hundreds of millions of doses to the U.S. government, and its vaccine quickly penetrated the market through widespread public adoption. In an April 22, 2022, securities filing, Pfizer recognized, "the market share of our COVID-19 vaccine has continued to grow, representing 70% of all doses distributed across the U.S. and EU."

140. As a result of Pfizer's unlawful misconduct, Pfizer immunized approximately 3.5 million people, in Texas, by the end of October 2021 – representing about double that of Moderna and Johnson and Johnson, combined. As of November 10, 2023, Texans have been administered almost 30 million Pfizer doses. Pfizer's vaccines represent the majority of vaccines administered in and distributed into the state.

141. Pfizer misrepresented and obscured the truth about highly relevant aspects concerning its vaccine's efficacy, thereby directly impacting the public's decision-making process concerning vaccination status to their detriment. Specifically, Pfizer's deception prevented and hindered the public from obtaining information material to properly balancing the benefits and risks of its vaccine. Therefore, the public was lulled into misunderstanding and misperceiving the vaccine's actual level of effectiveness, and this flawed understanding inherently distorted the risk/benefit analysis in Pfizer's favor by artificially inflating the vaccine's perceived efficacy.

142. Pfizer's distortion of the public vaccination decision is particularly harmful because Pfizer's vaccine possesses significant safety concerns. As previously noted, FDA's review of Pfizer's formal application concluded that "FDA and CDC *identified serious risks for myocarditis* and pericarditis following administration of" the Pfizer's vaccine, including "some cases [that]

required intensive care support." FDA, Summary Basis for Regulatory Action on COMIRNATY 96 (Nov. 8, 2021).

143. Myocarditis is a serious medical condition involving inflammation of the heart that reduces the muscle's ability to pump blood. Severe myocarditis weakens the heart such that the remainder of the body doesn't receive enough blood. As a result, blood clots can form in the heart, leading to a stroke or heart attack. Many of the vaccinated deaths in Pfizer's full Phase 2/3 study were a result of "[c]ardiac conditions." *See supra* ¶ 100.

144. Pfizer's misrepresentations resulted in the public engaging in an artificial and flawed consideration and balancing of Pfizer's vaccine's benefits and risks, including that of myocarditis, when making their vaccination decision. Had the public known the truth about the efficacy of Pfizer's COVID-19 vaccine, a substantial portion would likely have opted for an alternative or foregone inoculation altogether.

145. In addition, the public was more susceptible to trusting and acting upon Pfizer's misrepresentation campaign because of the significant levels of fear and anxiety amongst the public regarding the negative health, financial, and social impacts caused by the pandemic. Pfizer further capitalized on the public's vulnerabilities by misleadingly casting itself and its vaccine as the champions of "science" that would bring about an end of the pandemic and return America to normal.

H. Pfizer Has Been Grossly and Unfairly Enriched by Its Deceptive Acts.

146. As set forth above, Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine to facilitate its adoption and expand its commercial opportunity. Pfizer's plan was successful. Buoyed by a pervasive campaign of misrepresentations, Pfizer's vaccine quickly established itself as the market leader in the United States, achieving nearly 70% market penetration among the public by the end of 2021. Pfizer secured the goal of cementing itself as the

leading vaccine on a worldwide basis when the U.S. government exercised its right under its supply agreement to purchase an additional 500 million doses over the course of 2021.

147. Pfizer received roughly $12 billion for the 600 million doses it provided under the initial supply agreement, which ended on or about October 29, 2021, earning $7.8 billion in revenue.

148. In addition, in June 2022 Pfizer and the U.S. government announced a new supply agreement covering 105 million additional doses and providing the government with the ability to buy 195 million more. For this agreement, Pfizer raised the price of its vaccine by over 50%, receiving $3.2 billion for the sale.

149. Pfizer has been unfairly enriched by securing, retaining, and utilizing for its own purposes the revenues and profits attributable to its unlawful deceptive trade practices in the promotion, marketing, and sale of its COVID-19 vaccine in the United States.. In addition to the breath-taking windfall in the United States, Pfizer reaped tens of billions of dollars more in revenues and profits from selling over 4 billion doses of its COVID-19 vaccine to other national governments and purchasers over the course of the pandemic, including 2.7 billion doses alone in 2021.

150. As a direct and proximate result of the deceptive acts challenged here, Pfizer increased its financial revenues in 2021 by an eye-popping ***$38.4 billion***, nearly all of which represented proceeds from the sale of its COVID-19 vaccine, almost ***doubling Pfizer's revenue*** from 2020. And in 2022, Pfizer reported revenues of ***$37.8 billion***. Taken together, Pfizer's revenues and profits on COVID-19 provides more than ample financial nest egg for the company's ultimate goals of revitalizing the business and, relatedly, expanding the mRNA platform into new vaccines.

151. In addition, while the U.S. government was initially Pfizer's principal U.S.

purchaser, Pfizer had plans all along to commercialize its vaccine to the public and consumers along more traditional payor models. And more recently Pfizer has in fact converted to traditional payment and distributions models, with State Medicaid, private insurance, and individual consumers picking up the tab. *See, e.g.*, Letter from HHS Secretary on COVID-19 Vaccine Coverage (Sept. 22, 2023). But Pfizer still has not cured its false and misleading representations about its vaccine, which were crucial to Pfizer securing and maintaining the vaccine's level of success. And Pfizer's commercialization of the vaccine into the normal payor model occurs as the company is entrenched—thanks to its misrepresentations—as the dominant COVID-19 vaccine provider in the United States with little realistic prospect of losing that position.

XII. DTPA VIOLATIONS

152. The State incorporates and adopts by reference the allegations pled in this Original Petition, including paragraphs ¶¶ 1-151, as if fully set forth herein.

153. As alleged herein, Pfizer has in the course and conduct of trade and commerce, with the requisite mental state, engaged in various false, misleading, or deceptive acts or practices declared unlawful by and in violation of section 17.46(a) of the DTPA, including by intentionally, knowingly, and/or recklessly engaging in conduct specifically defined to be false, deceptive, or misleading under section 17.46(b).

Count I: Misrepresentations Concerning Relative Risk Reduction.

154. Pfizer misrepresented that its vaccine was 95% effective at preventing COVID- 19 infections in all people, when in fact the data Pfizer relied on was inapposite for such representations, and Pfizer distorted the truth.

155. Pfizer chose a self-serving and deceptive metric reflecting percentage reduction in the rate of infection present in its limited Phase 2/3 trial *on a relative basis*, not the absolute risk reduction for its vaccine, information that it withheld from the consuming public. *See supra* ¶¶ 43-

46, 56-65.

156. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count II: Misrepresentations Concerning Durability of Protection.

157. Pfizer misrepresented that its vaccine provided durable and sustained protection against COVID-19 infection, *see supra* ¶¶ 73-82, when in fact FDA had previously informed the company that it was not possible to know the duration of the vaccine's effectiveness beyond two months. *See supra* ¶¶ 43, 49.A,

158. Data revealed throughout the course of 2021 demonstrated that protection from Pfizer's vaccine waned rapidly. *See supra* ¶¶ 94, 96, 105-09, 120.

159. Moreover, Pfizer withheld highly relevant data not only showing that efficacy waned rapidly but confirming that Pfizer's representations about durable efficacy were unwarranted and deceiving when made. *See supra* ¶ 80.

160. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count III: Misrepresentations Concerning Transmission.

161. Pfizer misrepresented that vaccination against COVID-19 prevented "transmission" between persons, *see supra* ¶¶ 66-72, including from vaccinated persons with symptomatic or asymptomatic COVID-19 infections, when in fact FDA previously made clear to Pfizer that more information was needed to make transmission-related claims. *See supra* ¶¶ 42, 47, 49.B, 49.D.

162. Data developed throughout the course of 2021 revealed that Pfizer's vaccine was highly ineffective at preventing vaccinated persons from transmitting infections to other persons. *See supra* ¶¶ 96, 103-04.

163. Pfizer created this false impression by exploiting the heightened fear and uncertainty amongst the public, insinuating that vaccination constituted an imperative to protect loved ones. *See supra* ¶¶ 68-70.

164. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count IV: Misrepresentations Concerning Protection Against Variants.

165. Pfizer misrepresented that its vaccine had substantial efficacy against COVID-19 variants—in particular, the Delta variant. *See supra* ¶¶ 83-90. At minimum, Pfizer created the false impression and led the public to reasonably believe that the vaccine performed comparatively well against variants as compared to the initial virus.

166. In reality, Pfizer clearly lacked data to support such claims, and the modest amount in its possession instead pointed to the opposite conclusion, as well as underscored the baselessness of Pfizer's claims in the first instance. *See supra* ¶¶ 95, 110-16, 120-22.

167. In doing so, Pfizer violated sections 17.46(a), 17.46(b)(5), 17.46(b)(7), and 17.46(b)(24) of the DTPA.

Count V: Scheme to Conceal Vaccine Underperformance.

168. Pfizer created the false impression that its vaccine provided a substantially greater amount of protection against COVID-19 infection than what it afforded in reality. Pfizer undertook a continuous and widespread campaign comprised of the deceptive concerning alleged above for the purpose of misleading the public about the efficacy of its vaccine, *see supra* ¶¶ 125-38.

169. This course deceptive conduct was reinforced and extended by Pfizer's efforts to censor persons who sought to disseminate truthful information that would undermine is its ongoing deception. *See supra* ¶¶ 125-38.

170. In doing so, Pfizer violated sections 17.46(a) and 17.46(b)(8) of the DTPA.

XIII. CONDITIONS PRECEDENT

171. All conditions precedent to Plaintiff's claims for relief have been performed or have occurred.

XIV. PRAYER

172. The State prays that the Court permanently enjoin Pfizer from violating the DTPA by, for example, enjoining Pfizer from:

A. making representations about the efficacy of its COVID-19 vaccine the same as, or similar to, the misrepresentations outlined in this petition; and

B. coordinating with social media platforms to silence truthful speech about Pfizer's COVID-19 vaccine efficacy.

173. The State further requests that Defendant be ordered to pay to the State of Texas:

A. Civil penalties of up to $10,000.00 per violation of the DTPA, which when aggregated together exceed the sum of $10 million;

B. Pre-judgment and post-judgment interest on all awards of restitution, damages, or civil penalties, as provided by law; and

C. All costs of Court, costs of investigation, and reasonable attorney's fees pursuant to Texas Government Code section 402.006(c).

174. The State further requests that the Court:

A. Decree that all of Defendants' fines, penalties or forfeitures are not dischargeable in bankruptcy. *See* 11 U.S.C. Section 523(a)(7).

B. Award the State all further relief, at law or in equity, including but not limited to disgorgement, to which it is justly entitled.

Respectfully submitted,

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Attorney General of Texas

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Pauline Sisson on behalf of David Shatto
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Envelope ID: 82100457
Filing Code Description: Petition
Filing Description: 20231130 Pfizer Petition
Status as of 11/30/2023 1:11 PM CST

Associated Case Party: State of Texas

Name	BarNumber	Email	TimestampSubmitted	Status
Ryan Baasch		ryan.baasch@oag.texas.gov	11/30/2023 12:32:53 PM	SENT
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CIVIL/CRIMINAL PROCESS REQUEST

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CAUSE NUMBER: DC-2023-CV-1544 **CURRENT COURT:** 99th

TYPE OF INSTRUMENT (See Reverse for Type): Plaintiff's Original Petition **QUANTITY**: 01

FILE DATE OF MOTION: 11/30/23
MONTH / DAY / YEAR

SERVICE TO BE ISSUED ON:

1. NAME: Pfizer, Inc. c/o CT Corporation System

ADDRESS: 1999 Bryan St., Ste. 900

Dallas, TX 75201-3136

AGENT (If Applicable): CT Corporation System, Registered Agent

TYPE OF SERVICE / PROCESS TO BE ISSUED (See Reverse for Specific Type): Citation

SERVICE BY (check one):

☒ e-SERVICE ☐ LUBBOCK CO. CONSTABLE ☐ LUBBOCK CO. SHERIFF

☐ ATTORNEY PICK-UP ☐ CERTIFIED MAIL ☐ MAIL

☐ CIVIL PROCESS SERVER – Authorized Person to Pick-Up: Phone:

CIVIL PROCESS SERVER'S EMAIL ADDRESS: Please email the citation to the Attorney General's Office - pauline.sisson@oag.texas.gov

☐ PUBLICATION ☐ POSTING

☐ OTHER (Please Explain):

DISTRICT ATTORNEY USE ONLY:

☐ - DA (Name of Person Requesting): EXT:

ATTORNEY (OR ATTORNEY'S AGENT) REQUESTING SERVICE:

NAME: David Shatto, Assistant Attorney General TEXAS BAR NO. / ID NO.: 24104114

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EMAIL ADDRESS: david.shatto@oag.texas.gov *and* pauline.sisson@oag.texas.gov

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INSTRUMENTS TO BE SERVED:

_____ORIGINAL PETITION
_____AMENDED PETITION
_____SUPPLEMENTAL PETITION

_____COUNTERCLAIM
_____AMENDED COUNTERCLAIM
_____SUPPLEMENTAL COUNTERCLAIM

_____CROSS-ACTION
_____AMENDED THIRD-PARTY PETITION
_____SUPPLEMENTAL THIRD-PARTY PETITION

_____INTERVENTION
_____AMENDED INTERVENTION
_____SUPPLEMENTAL INTERVENTION

_____INTERPLEADER
_____AMENDED INTERPLEADER
_____SUPPLEMENTAL INTERPLEADER

_____INJUNCTION

_____MOTION TO MODIFY/ENFORCE

_____SHOW CAUSE ORDER

_____TEMPORARY RESTRAINING ORDER

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CITATION
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HIGHWAY COMMISSIONER
CITATION BY PUBLICATION
NOTICE
SHORT FORM NOTICE

PRECEPT (SHOW CAUSE)
RULE 106 SERVICE

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WRITS:
ATTACHMENT (PROPERTY)
ATTACHMENT (WITNESS)
ATTACHMENT (PERSON)

CERTIORARI

EXECUTION
EXECUTION AND ORDER OF SALE

GARNISHMENT BEFORE JUDGMENT
GARNISHMENT AFTER JUDGMENT

HABEAS CORPUS
INJUNCTION
TEMPORARY RESTRAINING ORDER

PROTECTIVE ORDER (FAMILY CODE)
PROTECTIVE ORDER (CIVIL CODE)

POSSESSION (PERSON)
POSSESSION (PROPERTY)

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Pauline Sisson on behalf of David Shatto
Bar No. 24104114
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Envelope ID: 82103711
Filing Code Description: REQUEST
Filing Description: Civil Process Request_State v Pfizer
Status as of 11/30/2023 1:37 PM CST

Associated Case Party: State of Texas

Name	BarNumber	Email	TimestampSubmitted	Status
Pauline Sisson		pauline.sisson@oag.texas.gov	11/30/2023 1:24:06 PM	SENT
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Filed 12/7/2023 6:54 PM
Sara L. Smith
Lubbock County - 99th District Court
Lubbock County, Texas

CAUSE NO. DC2023CV1544

The State of Texas	§	**IN THE COURT OF**	TB
	§		
Plaintiff,	§		
VS.	§	**LUBBOCK COUNTY, TEXAS**	
	§		
Pfizer, Inc	§		
Defendant.	§	**99TH DISTRICT COUNTY**	

AFFIDAVIT OF SERVICE

"The following came to hand on **Nov 30, 2023, 2:21 pm**,

CITATION AND PLAINTIFF'S ORIGINAL PETITION,

and was executed at **1999 BRYAN STREET, DALLAS, TX 75201** within the county of **DALLAS** at **10:27 PM** on **Fri, Dec 01 2023**, by delivering a true copy to the within named

PFIZER, INC. C/O CT CORPORATION SYSTEM REGISTERED AGENT: CT CORPORATION SYSTEM, ACCEPTED BY TERRI THONGSAVAT, SOP INTAKE

in person, having first endorsed the date of delivery on same.

I am a person over eighteen (18) years of age and I am competent to make this affidavit. I am a resident of the State of Texas. I am familiar with the Texas Rules of Civil Procedure as they apply to service of Process. I am not a party to this suit nor related or affiliated with any herein, and have no interest in the outcome of the suit. I have never been convicted of a felony or of a misdemeanor involving moral turpitude. I have personal knowledge of the facts stated herein and they are true and correct."

My name is **JayKob McArter**, my date of birth is **08-04-2000**, and my address is **4425 W AIRPORT FWY., SUITE 356, IRVING, TX 75062**, and **United States of America**. I declare under penalty of perjury that the foregoing is true and correct.

Executed in **Lubbock** County, State of **TX**, on **December 01, 2023**.

JayKob McArter
Certification Number: PSC-20627
Certification Expiration: 11/30/2025

Cause No. DC-2023-CV-1544

TB

STATE OF TEXAS,	§	**IN THE DISTRICT COURT OF**
	§	
***Plaintiff*,**	§	
	§	
v.	§	**LUBBOCK COUNTY, TEXAS**
	§	
PFIZER, INC.	§	
	§	
***Defendant*.**	§	**99TH JUDICIAL DISTRICT**
	§	
	§	

PFIZER INC.'S PLEA TO THE JURISDICTION
AND ANSWER AND AFFIRMATIVE DEFENSES

Defendant Pfizer Inc. ("Pfizer") files this (I) Plea to the Jurisdiction; and (II) Answer and Affirmative Defenses to Plaintiff's Original Petition ("Petition"), and would show the Court as follows:

I.

PLEA TO THE JURISDICTION

Pursuant to Texas Rule of Civil Procedure 85, Pfizer hereby states that the Court lacks jurisdiction over this case.

1. The Plaintiff asserts claims against Pfizer under the Texas Deceptive Trade Practices-Consumer Protection Act ("DTPA"). However, the federal Public Readiness and Emergency Preparedness Act (the "PREP Act") provides Pfizer with immunity from such suit and liability:

> Subject to the other provisions of this section, a covered person shall be 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 to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1).

2. Pfizer's COVID-19 vaccine is a "covered countermeasure" and Pfizer is a "covered person" under the PREP Act, as stated in the Secretary of Health and Human Services' initial "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19," 85 F.R. 15,198 (Mar. 17, 2020), and the numerous renewals of and amendments to that declaration, through and including the Secretary's most recent declaration, 88 F.R. 30,769 (May 12, 2023), which remains in effect today.

3. The Petition alleges "Pfizer intentionally misrepresented the efficacy of its COVID-19 vaccine" and that, in doing so, Pfizer "caused injury, loss, and damage to [the State], as well has caused adverse effects to the lawful conduct of trade and commerce, thereby directly or indirectly affecting the people of this State." Petition at pg. 4, ¶¶ 8, 140–46. The Petition further requests restitution, damages, and disgorgement, among other remedies. Petition ¶¶ 172-74.

4. Accordingly, the Petition is a suit under state law with respect to a claim for loss "caused by, arising out of, relating to, or resulting from the administration to and use by" individuals of the Pfizer COVID-19 vaccine, a covered countermeasure. Plaintiff's claims are thus preempted, and Pfizer is thus immune from this suit.

5. The PREP Act provides a narrow exception to immunity, creating "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(d)(1). The United States District Court for the District of Columbia has exclusive jurisdiction to hear such claims. 42 U.S.C. § 247d-6d(e)

6. The intentional misrepresentation claims raised in the Petition fall squarely within the PREP Act's broad grant of immunity to the manufacturers of COVID-19 vaccines and other

countermeasures, and the State's claims could only have been brought, if at all, pursuant to the "exclusive Federal cause of action" established in 42 U.S.C. § 247d-6d(d)(1).

7. In addition, there is no jurisdiction over Plaintiff's asserted claims under the DTPA because:

a. At all times relevant to the Petition, the sole consumer of the company's COVID-19 vaccine was the United States Government, not the State or any of its citizens or residents;

b. The misrepresentations alleged in the Petition did not occur in the conduct of any "trade" or "commerce" as those terms are defined in the DTPA;

c. Pfizer did not make any statement nor take any action that had the capacity or tendency to deceive the consumer;

d. Pfizer did not represent to the consumer that any goods had sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have;

e. Pfizer is not liable because Pfizer did not represent to the consumer that any goods were of a particular standard, quality, or grade, or that any goods are of a particular style or model, when they were of another;

f. Pfizer did not disparage the goods, services, or business of another by false or misleading representation of facts;

g. Pfizer did not fail to disclose any then-available information concerning goods with the intent to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed;

h. Plaintiff's claims arise out of Pfizer's written contract to sell the COVID-19 vaccine to the United States Government; that contract related to a "transaction, project, or

set of transactions" involving total consideration in excess of $100,000; in negotiating the contract, the Government was represented by legal counsel neither identified, suggested, nor selected by Pfizer; and the contract did not involve the consumer's residence. *See* Tex. Bus & Com. Code § 17.45(f).

8. Moreover, Pfizer is immune from Plaintiff's claims under the government contractor defense and/or the doctrine of derivative sovereign immunity.

9. Finally, there is no jurisdiction over the Plaintiff's asserted claims under the DTPA because the resolution of the claims would require the Court to decide non-justiciable political questions entrusted by Congress to various Executive Branch agencies including, but not limited to, the U.S. Department of Defense and the U.S. Food and Drug Administration.

II.

ORIGINAL ANSWER

A. GENERAL DENIAL

Subject to the aforesaid Plea to the Jurisdiction, pursuant to Rule 92 of the Texas Rules of Civil Procedure, Pfizer generally denies the allegations in the Petition and demands strict proof thereof. Pfizer further reserves the right to answer in greater particularity at a later time.

B. AFFIRMATIVE DEFENSES AND SPECIFIC DENIALS

Subject to the aforesaid Plea to the Jurisdiction and General Denial, without assuming any burden that it would not otherwise bear or admitting that it is in any way liable to Plaintiff, Pfizer asserts the following affirmative and other defenses:

1. Plaintiff's Petition fails to state claims for which relief can be granted in favor of Plaintiff.

2. Plaintiff's claims are preempted by federal law and any regulations or rules promulgated thereunder, including but not limited to, the federal Food, Drug, and Cosmetic Act ("FDCA"), associated U.S. Food and Drug Administration ("FDA") regulations, and the PREP Act, 42 U.S.C. §247d-6d.

3. Pfizer is immune from Plaintiff's claims under the immunity provisions of the PREP Act, 42 U.S.C. § 247d-6d(a)(1), and the Defense Production Act, 50 U.S.C. § 4557.

4. Pfizer is immune from Plaintiff's claims under the government contractor defense.

5. Pfizer is immune from Plaintiff's claims under the doctrine of derivative sovereign immunity.

6. Plaintiff's claims constitute an impermissible burden on federal laws, regulations, and policy relating to the development and marketing of prescription drugs in violation of the Supremacy Clause of the United States Constitution.

7. Plaintiff's claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the FDCA and regulations promulgated thereunder.

8. Plaintiff's claims are barred, in whole or in part, by the First Amendment of the United States Constitution and/or Article I, § 8 of the Texas Constitution.

9. Plaintiff's claims should be dismissed under the primary jurisdiction doctrine.

10. Plaintiff's claims should be dismissed under the political question doctrine.

11. Plaintiff's claims should be dismissed under the learned intermediary doctrine.

12. To the extent Plaintiff alleges any Texas citizen suffered any injury or damage, Plaintiff's claims are barred, in whole or in part, because no causal relationship exists between any conduct by Pfizer and the claimed injuries or damages.

13. To the extent Plaintiff alleges any Texas citizen suffered any injury or damage, any claim for restitution or payment of damages must be reduced, diminished, and/or barred in proportion to the wrongful or negligent conduct of persons or entities other than Pfizer, including other parties in this case and/or third parties, under the principles of equitable allocation, recoupment, set-off, proportionate responsibility, contributory negligence, comparative negligence, and/or comparative fault.

14. To the extent any relief sought by Plaintiff would be duplicative of relief sought by Plaintiff or other plaintiffs in other lawsuits, subjecting Pfizer to the possibility of multiple recoveries, such recovery is barred by the Fifth and Eight Amendments of the United States Constitution, the Texas Constitution, and the common law.

15. To the extent any of Plaintiff's claims or the issues raised by any Plaintiff's claims have been previously litigated, such claims or issues are barred, in whole or in part, from any recovery under the doctrines of res judicata and/or collateral estoppel.

16. Plaintiff's claims are barred, in whole or in part, by the doctrine of laches.

17. Plaintiff's claims are barred, in whole or in part, by the doctrine of waiver.

18. Plaintiff's claims are barred, in whole or in part, by the doctrine of estoppel or quasi estoppel.

19. Plaintiff's claims are barred, in whole or in part, by the doctrine of unclean hands.

20. Plaintiff's claims are barred, in whole or in part, pursuant to applicable statutory and common law regarding limitations on awards, caps on recovery, and setoffs.

21. Pfizer is not liable because Pfizer acted reasonably and with due care and substantially complied with all applicable statutes, regulations, ordinances, and/or other laws.

22. Pfizer is not liable because Pfizer did not misrepresent any fact, nor did it make any statement that was false or misleading.

23. Pfizer is not liable under the DTPA—Texas's primary consumer protection statute—because, at all times relevant to the Petition, the sole "consumer" of the company's COVID-19 vaccine was the United States Government, not the State or any of its citizens or residents. *See* Tex. Bus & Com. Code § 17.45(4).

24. Pfizer is not liable because the misrepresentations alleged in the Petition did not occur in the conduct of any "trade" or "commerce" as those terms are defined in the DTPA. *See id.* § 17.45(6).

25. Pfizer is exempt from liability because the State of Texas's claims arise out of Pfizer's written contract to sell the COVID-19 vaccine to the United States Government; that contract related to a "transaction, project, or set of transactions" involving total consideration in excess of $100,000; in negotiating the contract, the Government was represented by legal counsel neither identified, suggested, nor selected by Pfizer; and the contract did not involve the consumer's residence. *See id.* §17.49(f).

26. Pfizer is not liable because Pfizer did not make any statement nor take any action that had the capacity or tendency to deceive consumers.

27. Pfizer is not liable because Pfizer did not represent that any goods had sponsorship, approval, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have.

28. Pfizer is not liable because Pfizer did not represent that any goods were of a particular standard, quality, or grade, or that any goods are of a particular style or model, when they were of another.

29. Pfizer is not liable because Pfizer did not disparage the goods, services, or business of another by false or misleading representation of facts.

30. Pfizer is not liable because Pfizer did not fail to disclose any then-available information concerning goods with the intent to induce a consumer into a transaction into which the consumer would not have entered had the information been disclosed.

31. Pfizer specifically denies that any Pfizer-related entity is jointly and severally liable with any other Pfizer-related entity or any other defendant or person.

32. Pfizer reserves the right to assert the applicability of the law of another jurisdiction or other jurisdictions with respect to any claim by Plaintiff.

33. Pfizer reserves the right to amend or supplement its affirmative defenses as additional facts are revealed during discovery or other investigation.

PRAYER

For the reasons stated above, Pfizer prays that the Court dismiss the Petition and all claims and causes of action stated therein and render judgment that Plaintiff take nothing, that Pfizer Inc. recover its reasonable and necessary attorneys' fees and costs of court, and for all other relief, at law and in equity, to which it may show itself to be justly entitled.

[*signature page follows*]

Dated: December 20, 2023

Respectfully submitted,

/s/ Meagan D. Self

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CERTIFICATE OF SERVICE

I certify that on December 20, 2023, I served the foregoing document on all counsel of record via the Court's CM/ECF system.

/s/ Meagan D. Self
Meagan D. Self

Automated Certificate of eService

This automated certificate of service was created by the efiling system. The filer served this document via email generated by the efiling system on the date and to the persons listed below. The rules governing certificates of service have not changed. Filers must still provide a certificate of service that complies with all applicable rules.

Rose Chambers on behalf of Meagan Self
Bar No. 24078453
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Envelope ID: 82780954
Filing Code Description: PLJV - Plea To Jurisdiction / Venue
Filing Description: 2023.12.20 Pfizer Inc.'s Plea to the Jurisdiction and Answer and Affirmative Defenses
Status as of 12/21/2023 8:45 AM CST

Associated Case Party: State of Texas

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Ryan Baasch		ryan.baasch@oag.texas.gov	12/20/2023 6:17:46 PM	SENT
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Associated Case Party: Pfizer, Inc.

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Case Contacts

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EXHIBIT B

BASE AGREEMENT

BETWEEN

ADVANCED TECHNOLOGY INTERNATIONAL (ATI)
315 SIGMA DRIVE
SUMMERVILLE, SC 29486

AND

Pfizer, Inc.
235 E 42nd St,
New York, NY 10017

MEDICAL CBRN DEFENSE CONSORTIUM (MCDC) BASE AGREEMENT NO.: 2020-532

Authority: MCDC Other Transaction Agreement (OTA) No. W15QKN-16-9-1002 and 10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act (NDAA), Public Law (P.L.) 114-92.

This Agreement is entered into between the Advanced Technology International hereinafter referred to as the "Consortium Management Firm (CMF)," and Pfizer Inc., hereinafter referred to as "Project Agreement Holder." This Agreement constitutes the entire understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior representations and agreements. It shall not be varied except by an instrument in writing of subsequent date duly executed by an authorized representative of each of the parties. The validity, construction, scope and performance of this Agreement shall be governed by the laws of the state of South Carolina, excluding its choice of laws rules.

ADVANCED TECHNOLOGY INTERNATIONAL	FOR THE PROJECT AGREEMENT HOLDER Pfizer Inc.
(Signature) [redacted] Jul 20 2020	[redacted] (Signature)
(Name & Title)	[redacted] (Name & Title)
(Date)	July 20, 2020 (Date)

Article I. SCOPE OF THE AGREEMENT

Section 1.01 Background

The U.S. Army Contracting Command-New Jersey (ACC-NJ) is entering into a Section 815 Prototype Other Transaction Agreement (OTA) with the Medical CBRN Defense Consortium, c/o Advanced Technology International 315 Sigma Drive, Summerville, SC 29486. The Joint Project Manager for Medical Countermeasure Systems (JPM-MCS) through the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) seeks to collaborate with the MCDC to carry out a coordinated research and development program. An OTA is being proposed with the purpose of conducting Research and Development into medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel. The MCDC was formed in response to the Government's expressed interest to engage with an industry consortium comprised of traditional and nontraditional government contractors, small and large businesses, for-profit and not-for-profit entities, academic organizations and their affiliates for the purpose of entering into an OTA for prototype projects.

Under the OTA and associated awards, the Government, along with the non-government members from the MCDC, shall perform coordinated planning and research and development prototype efforts designed to encompass the areas contained within the scope of this OTA as listed in Article I, Section 1.03.

Section 1.02 Definitions

"Academic Research Institution" means accredited institutions (colleges, universities or other educational institutions) of higher learning in the U.S.

"Agreement" refers to the Base Agreement between the Medical CBRN Defense Consortium (MCDC) Consortium Management Firm (CMF) Advanced Technology International (ATI) and the Project Agreement Holder.

"Agreements Officer (AO)" is the U.S. Army Contracting Command – New Jersey's warranted Contracting Officer authorized to sign the final OTA for the Government.

"Agreements Officer Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects and assist in agreement administration of the specific project; the AOR shall only assist in agreement administration of the specific project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

"Basket" is an electronic file containing proposals that have been submitted by MCDC Members in response to Requests for Prototype Proposals (RPP), reviewed by the Government, and favorably evaluated in accordance with the procedures outlined in Section 1.03 of this Article.

"Cash Contribution" means a MCDC member organization's financial resources expended to conduct a project awarded under this Agreement. The cash contribution can be derived from MCDC member organization funds or outside sources or may also come from non-federal contract or grant revenues or from profit or fee on a federal procurement contract. A MCDC member organization's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds can be utilized as a cash contribution provided those funds identified by the MCDC member organization are to be spent on the conduct of a project's Statement of Work. Prior IR&D will not be considered as part of the MCDC member organization's cash or in kind contributions nor will fee be considered on the Project Awards that include cost sharing. Cash contributions include the funds a MCDC member organization will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), subcontractor efforts expended on a project, and restocking the parts and material consumed under a project.

"Consortium Management Firm (CMF)" refers to the organization acting on behalf of the MCDC to execute and administer the efforts under the Other Transaction Agreement for this program as defined in the specific agreement

entered into between the MCDC and the CMF. The current CMF is Advanced Technology International (ATI). The MCDC reserves the right to replace the CMF at any time.

"Cost Share" means resources expended by the PAH on the proposed project SOW and subject to the direction of the AOR. There are two kinds of cost share: cash contribution and in-kind contribution. Cost Share may only be proposed and collected on cost-reimbursement type agreements.

"Contracting Activity" means an element of an agency designated by the agency head and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency which has been delegated contracting authority through its agency charter.

"Date of Completion" is the date on which all work is completed or the date on which the period of performance ends.

"Development" means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service) for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

"Effective Date" means the date when this Agreement is signed and executed by the Agreements Officer for the Government.

"Government" means the US Government and its departments and agencies.

"Government Fiscal Year" means the period commencing on October 1 and ending September 30 of the following calendar year.

"In Kind Contribution" means the MCDC member organization's nonfinancial resources expended by the MCDC member organization to conduct a project, such as wear and tear on in-place capital assets like machinery or the prorated value of space used for the conduct of a project, and the reasonable fair market value (appropriately prorated) of equipment, materials, and other property used in the conduct of the project.

"JPM-MCS" means the Joint Project Manager-Medical Countermeasure Systems Office created for the advanced development of medical countermeasures for chemical and biological defense. The JPM-MCS is also the program management office for this overall effort. The JPM-MCS includes an array of stakeholders involved in the development of prototype hardware, software, and system technologies.

"Milestone" means a scheduled event signifying the completion of a major deliverable or a set of related deliverables.

"Medical CBRN Defense Consortium" is the consortium formed by industry in response to the Government's expressed interest to quickly provide the warfighter with safe and effective chemical, biological, radiological, and nuclear countermeasures. The MCDC is comprised of Traditional and Nontraditional Defense Contractors, including small and large (other than small) businesses, for profit, and not for profit entities, and academic research institutions. The MCDC was originally named the National Chemical and Biologic Defense Consortium.

"MCDC Executive Committee" is the Executive Committee, comprised of Traditional and Nontraditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and academic research institutions.

"MCDC Members" means the Nontraditional and Traditional Defense Contractors, including small and large businesses, for profit and not for profit entities, and Academic Research Institutions that are members in good standing of the MCDC.

"Nontraditional Defense Contractor" with respect to applicable authority, means an entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to section 1502 of title 41 and the regulations implementing such section.

"Other Transaction Agreement (OTA)" refers to the Section 815 Other Transaction Agreement between the Government and the MCDC by its Consortium Management Firm, Advanced Technology International, Agreement No. W15QKN-16-9-1002.

"Other Transactions for Prototype Projects" refers to this type of Other Transaction Agreement (OTA). Section 815 of Public Law 114-92 authorizes the use of OTAs, under the authority of 10 U.S.C. 2371(b), under certain circumstances for prototype projects directly relevant to enhancing the mission effectiveness of military personnel and supporting the platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. This type of OTA is treated by DoD as an acquisition instrument, commonly referred to as an "other transaction" for a prototype project or Section 815 "other transaction".

"Parties" means the Consortium Management Firm, Advanced Technology International, and the Project Agreement Holder where collectively identified and "Party" where each entity is individually identified.

"Payable Milestone" means that once a milestone has been met (see definition of "milestone"), the Government can approve payment to the MCDC of a predetermined dollar amount in relation to performance of a particular project under the Other Transaction Agreement.

"Program Manager" means the Technical Administrator for the Program (located at the JPM-MCS) responsible for Government oversight of the MCDC OTA program.

"Project" refers to the scope of work being completed under a Project Agreement.

"Project Agreement (PA)" means that agreement between the MCDC, by its CMF, and the MCDC member entity whose proposal is evaluated and competitively selected by the Government for funding, establishing the scope of work, terms and conditions for the MCDC member entity performance and payment under the Government funded project. Project Agreements shall comply with all provisions contained within the OTA and any other supporting documents referenced therein. The Project Agreement is initiated by the CMF based on the Technical Direction Letter sent by the Government to the CMF.

"Project Agreement Holder (PAH)" means the MCDC member entity issued a Project Agreement by the CMF.

"Technical Direction Letter (TDL)" is a Government document to be issued to the CMF reflecting the Government's decision to select and fund all or part of a particular proposal submitted by a MCDC member or team of MCDC members through the RPP process conducted under this OTA. The TDL shall establish the scope of work, terms and conditions for performance and payment and include the MCDC member proposal selected for Government funding. Where a specific Government agency laboratory, test facility, center or other location will be used by the MCDC member entity in performance of the Project Agreement, it will be identified and the cost of such use, whether Government-contributed or MCDC member reimbursed, will be identified in the TDL.

"United States Army Contracting Command – New Jersey Contracting Activity" (ACC-NJ) means the contracting activity who is designated as the lead Government organization in charge of executing the Program.

"White Paper" means a document limited to a few pages prepared and submitted by a MCDC member(s) in response to a Government solicitation issued under the terms and conditions of the OTA that briefly describes and summarizes a technology idea or concept for an indicated research area in a Government-specified format. The White Papers are evaluated by the Government to determine whether submission of a full proposal on the summarized concept or idea might be warranted. To the extent that a MCDC member(s) desires to include

proprietary information in the white paper it shall be identified and marked in accordance with the terms for protection of information under Article VIII. Confidential Information.

Section 1.03 Scope

The Government in conjunction with the MCDC member entities shall perform a coordinated research and development program designed to support the DoD's medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel. The mission of JPM-MCS is to provide the U.S. military forces and the nation safe, effective, and innovative medical solutions to counter Chemical Biological Radiological and Nuclear (CBRN) threats. Under the OTA and associated Project Agreements, the Government along with the Consortium member entities, shall perform coordinated planning and research and development prototype efforts in support of the JPM-MCS mission through the development of products in three (3) major Medical Countermeasure Systems (MCS) objective areas:

- Detection: Systems and devices to identify CBRN agents and assist in making medical decisions
- Prevention: Prophylaxis, pretreatment, and post-exposure prophylaxis
- Treatment: Therapeutics (post-exposure, post-symptomatic)

The Government will determine which endeavors to pursue and projects to fund. At any time throughout the term of the OTA, the Government may address the needs for the desired MCS objective areas or other related Government needs as they arise. The MCDC and the Government agree that other organizations and agencies within the U.S. Government may participate in the collaborative activities through a Memorandum of Agreement or other such arrangement. It is anticipated that these other organizations may include JPEO-CBD and DTRA.

Request for Prototype Proposal (RPP) Process:

Once the Government identifies a need under one of the MCS objective areas above, the Government will issue a Request for Prototype Proposal (RPP). The RPP will include a Request for White Papers (RWP) and/or a Request for Prototype Proposal (RPP) to the Consortium Management Firm (CMF). Due dates will be indicated for each. The CMF shall in turn issue a similar request to MCDC's member entities, for which the Government will review and evaluate all responses. The Government will be solely responsible for evaluation of the white papers and/or proposal submissions, as applicable. If the RPP includes a RWP, only members submitting white papers will be permitted to submit full proposal submissions. Based on the evaluation of the white papers, the Government will make a recommendation on whether the member should or should not submit a full proposal submission. Any member submitting a white paper, regardless of the Government's recommendation, may submit a proposal.

MCDC member white papers and proposals shall be submitted to the CMF in accordance with the RPP instructions which will include evaluation criteria and a Statement of Work (SOW) template on the due date indicated in the RPP. The CMF will review white paper and proposal submissions for completeness and format compliance. The CMF shall in turn prepare and transmit MCDC's member's white papers and proposals to the Government for evaluation. The Government will be responsible for technical evaluation and selection of the projects from the proposals submitted. The CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government Agreement Officer will review this assessment and make the final determination regarding whether the negotiated project cost is fair and reasonable. All Project Agreements will be subject to discussions/negotiations and proposal updates, as appropriate, prior to execution.

Once all steps are complete, the Government will issue a Technical Direction Letter (TDL) to the CMF for the authorization and execution of the selected project to be performed by the selected MCDC's member entity(ies). Once the CMF receives notification of selection of a project for funding via TDL, the CMF will enter into a Project Agreement with the MCDC member.

A modification will be included with the TDL, which will include the funding for the negotiated and agreed-upon project. After receipt of the TDL and review and execution of the funding modification, the CMF shall enter into a Project Agreement (PA) with MCDC member whose project was selected. MCDC CMF shall administer the Government-funded Project Agreements. The Government's designated Agreements Officer Representative (AOR)

for the specific project will supervise the technical work performed by MCDC's member entity in execution of the PA. The Government reserves the right to revise the terms and conditions of these projects in accordance with Article III, Section 3.04.

Placement in the Electronic "Basket File":

Qualifying proposals, not eligible for current funding, may be entered into an electronic basket and subject to award for up to thirty-six (36) months. The RPP will contain the available ratings and their definitions to be assigned to proposals as a result of the technical evaluation as well as which specific ratings will qualify a proposal for inclusion in the Basket. The Government reserves the right to determine which, if any, proposals are to be selected according to the published criteria.

Once in the Basket, a proposal may be identified for award by the Government based on Government need and availability of funding. The Government reserves the right to 1.) request that the MCDC member who submitted the identified proposal, scale or otherwise adjust the original proposal, and to 2.) fund all or part of the identified proposal. The MCDC member will have an opportunity to update their proposal, as applicable, if selected from the basket. The Government will review any updated information provided by the MCDC member and/or CMF. Upon the Government's decision to fund such a proposal from the Basket, the CMF will receive notification of the award decision through a TDL whereupon the CMF will enter into a Project Agreement with the indicated MCDC member as required.

A selected proposal will reside in the Basket for thirty-six (36) months from the date the corresponding RPP is closed unless funded or the submitting MCDC member requests in writing beforehand to have it removed.

SBIR Phase III Project Requests

It will be incumbent upon the MCDC member, on their own with some general support and guidance from the CMF, to find a Government Technical POC with both (1) available funding and (2) an interest in furthering technology developed under a current or prior SBIR project. Upon doing so, the Government Technical POC will coordinate the feasibility of placing the award under the OTA with the Government AO and OTA Program Manager and the following areas will be considered when making a determination for appropriateness of award under the OTA:

- How the proposed effort derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements;
- How the proposed effort fits within the definition of a prototype effort related to medical, pharmaceutical, and diagnostic technologies to enhance mission effectiveness of military personnel in accordance with the statutory requirement;
- How the proposed effort fits within the overall scope of work and the goals and objectives of the OTA.

Should the Government AO and the OTA Program Manager determine it is appropriate to award the SBIR Phase III under the OTA, the Government AO will send a proposal request to the MCDC member through the CMF, as is standard for any Government request under the OTA. The CMF will provide a cost analysis summary to the Government Agreements Officer (AO) for consideration in the Government's award determination. The Government will evaluate the proposal, conduct any necessary negotiations through the CMF, and make an award determination. If the Government makes the determination to award to the MCDC member, the Government AO will issue a TDL letter to the CMF, resulting in the issuance of a Project Agreement between the CMF and MCDC member.

SBIR Phase III awards under this Agreement shall include the Data Rights provisions and Data Rights granted to the MCDC member contained within Article XI of this Agreement. All administrative, reporting, and other aspects of awards made for SBIR Phase III efforts under this Agreement will be in accordance with the terms and conditions of the OTA. MCDC Members must have been awarded and performed under a previous SBIR Phase I and/or Phase II contract in order to qualify for SBIR Phase III award under this Agreement.

Section 1.04 Goals/Objectives

The following goals/objectives will be pursued through the execution of the OTA:

- Accelerate the development of mission critical technologies in the areas of concern from applied research into advanced development.
- Deliver therapeutic MCM prototypes targeting viral, bacterial, and biological toxin targets of interest to the DOD. MCM prototypes are drug products that have completed all or part of the activities required to support FDA licensure. This may include meeting warfighter requirements of protection against an aerosolized route of exposure.
- Deliver enabling technologies that will support the development and regulatory review of MCM prototypes. The enabling technologies can include animal models of viral, bacterial or biological toxin disease and pathogenesis (multiple routes of exposure), assays, diagnostic technologies or other platform technologies applicable to development and regulatory review of MCM.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Chemical threats. This will include diagnosis of, and prophylaxis and treatment for, exposure to traditional and emerging chemical nerve agent threats, as well as other emerging chemical threat agents other than nerve agents.
- Develop prototype candidates for the prophylaxis, treatment and diagnosis of Radiological and Nuclear threats. This will include prototype candidates for diagnosis of, and prophylaxis and treatment for Acute Radiation Syndrome.
- Develop soldier-carried autoinjector delivery devices for single drug administration. Develop soldier-carried autoinjector delivery devices for administration of two or more drugs.
- Develop vaccine-manufacturing platforms that offer early stage manufacturing flexibility and diversity using a deep knowledge of protein(s) expression in a biological system that is reproducible and scalable, and preferably with direct FDA experience. The goal is to manufacture and test identified protective molecule(s) and target molecule(s) (along with associated reagents and standards) in multiple scalable, flexible manufacturing platforms encompassing a diverse array of manufacturing systems (e.g., insect, mammalian, live viral, plant, *E.coli*, yeast, etc.) for use in appropriate animal model(s) and in Phase 1 trials.
- Pharmaceutical development will address the FDA Animal Rule, as appropriate.
- Utilize adjuvants and excipients supporting the ability to develop up to 300,000 equivalent doses within 60 days at clinical quality.
- Support a family of systems diagnostic approach that increases the speed, accuracy, and confidence of agent identification and disease diagnosis. Diagnostic areas include those for organisms that circulate freely and at relatively high numbers at or near the onset of symptoms, organisms that circulate in low numbers early in infection but then integrate with host cells, organisms that have significant genomic diversity from strain to strain, and non-BW agents such as toxins/chemical agents/radiological agents that do not replicate and require low quantities to cause illness.
- Support the Defense Biological Products Assurance Office (formally the Critical Reagents Program), the principal DoD resource of high quality, validated, and standardized biological reference materials, reagents, and assays, as necessary.
- DoD Advanced Development and Manufacturing Capabilities: To facilitate lessons learned and to ensure DoD MCM product development schedules are not impacted, the consortium will consider Advanced Development and Manufacturing (ADM) capability contractors for biologics manufacturing activities for monoclonal antibodies, vaccines, and recombinant proteins may utilize the DoD funded facility.
- Pursue collaborative research with non-traditional technology providers in a manner that enables effective transition of technologies to Government prototyping programs during any phase of life cycle support (affordability, manufacturability, sustainment, etc.).

Section 1.05 Reports

The MCDC member organizations conducting projects in accordance with this Agreement shall maintain records of the activities performed and funding expended under the projects and the results of any studies analyses, tests, and other investigations conducted. Based on the progress of the funded projects and other information known to the AO or authorized designee, the MCS Program Office shall review the relevant projects throughout the period to determine if any changes to planning or budget are required. If such a change is expected which will cause a need to modify the OTA, the Technical Direction Letter or an individual Project Agreement may be modified to incorporate such changes. The AO is the only authorized representative of the Government who may make modifications to the OTA. PAHs shall submit the following reports to the CMF who will review and provide one cumulative report detailing status of all funded projects to the MCS Program Office.

a.) Project Agreement Quarterly Report. The report will have two major sections:

(i) Technical Status Report. The technical status report will detail technical progress to date and report on all problems, technical issues or major developments during the reporting period. Each of the topics described below shall be addressed for the effort performed:

(1) A comparison of actual accomplishments with the goals and objectives of the project established for the period.

(2) Reasons why established goals and objectives were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost variances.

(4) A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors, and titles.

(5) Papers presented at meetings, conferences, seminars, etc.

(ii) Business Status Report. The business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a quarterly accounting of current expenditures. Any major deviations from the agreed to project plans shall be explained with discussion of proposed actions to address the deviations. The report will also include an accounting of interest earned on Government Funds, if any. It is not expected that any interest will accrue under the Project Agreement(s), as milestone payments will be tracked and adjusted accordingly. In any event, the Government reserves the right to require interest amounts in excess of $250 per year to be remitted to the US Treasury.

b.) Annual Technical Report. Annual technical reports are required for projects whose periods of performance are greater than one year. The PAH's report will provide a concise and factual discussion of the significant accomplishments and progress during the year covered by the report.

c.) Final Technical Report.

(i) Final Technical Report (FTR). A Final Technical Report shall be submitted to the CMF within thirty (30) calendar days of the completion of the Project Agreement. This report will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the effort. Each of the topics described above shall be addressed as appropriate for the effort performed. Upon receipt, the AOR will review and provide any comments within 30 days. If necessary, the PAH will update the FTR within 30 days of receipt of AOR's comments. Once the CMF has informed PAH that the FTR has been approved by the AOR, the PAH shall forward a copy of the FTR to the Defense Technical Information Center, Attn. DTIC-O, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218.

(ii) Format. The cover and title page shall be Standard Form (SF) 298, Report Documentation Page. Item 13 of the form should contain a 100 to 200 word abstract summarizing technical progress during the reporting period. Style should be third person singular using past tense. Jargon, special symbols or notations, subscripts, mathematical symbols or foreign alphabet letters are not permitted. All pages should be prepared for acquisition and distribution by the Defense Technical Information Center (DTIC). All pages should be good quality for copying purposes. The report shall be prepared in accordance with American National Standards Institute (ANSI) document Z39.18-1987, "Scientific and Technical Reports: Organization, Preparation, and Production," which may be obtained from American National Standards Institute Incorporated, 1430 Broadway, New York, NY, 10018. The FTR front page shall be marked in a conspicuous place with a distribution statement to denote the extent of its availability for distribution, release, and disclosure without additional approvals or authorizations.

d.) Final Business Status Report. The final business status report shall provide summarized details of the resource status of the Project Agreement, including the status of the contributions by all participants. This report will include a final accounting of cumulative expenditures. If a project is terminated prior to the end of a quarter or a year and sufficient funding is available, the PAH, through the CMF, must submit a final technical and business status report in the same format as detailed herein.

Note: Deficiencies in regulatory reports must be adequately assessed by the Government, MCDC and the individual performer, or consortium as a whole, to come to resolution.

Article II. TERM

Section 2.01 The Term of this Agreement

The period of performance for this Agreement is from the effective date, which is the date of last signature, to April 7, 2036. If at any time funds expended exceed the amount obligated on a Project Agreement prior to the expiration of the term, the Parties have no obligation to continue performance and may elect to cease their efforts at that point. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

Section 2.02 Termination of this Agreement by Mutual Agreement

Except for the rights and obligations with respect to proprietary information and/or specific intellectual property agreements between or amongst the Government, the CMF and the MCDC member organizations, unless extended by mutual written agreement of the Parties, this Agreement shall automatically terminate by written agreement of the Parties. Unless otherwise directed by the AO through the CMF, individual Project Agreements pursuant to this Agreement shall also terminate upon the termination of this Agreement.

Section 2.03 Termination Provisions

Subject to a reasonable determination that the program, or a project funded under the program, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA or a specific project, in whole or in part, if the AO determines that a termination is in the Government's interest. The AO shall terminate by delivering to the MCDC through its CMF a Notice of Termination specifying the extent of termination and the effective date.

After receipt of a Notice of Termination, and except as directed by the CMF, the PAH shall immediately proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

(1) Stop work and direct its subawardees to stop work as specified in the notice.

(2) Place no further subagreements or orders (referred to as orders in this clause) for materials, services, or facilities, except as necessary to complete the continued portion of the project.

(3) Terminate all orders to the extent they relate to the work terminated.

(4) Assign to the Government, as directed by the AO, all right, title, and interest of the PAH under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.

(5) With approval or ratification to the extent required by the AO, the CMF may settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this clause.

(6) Provide CMF, and/or obtain from the subawardees under the terminated portion of the Agreement a transfer of title to the following where applicable and deliver to the Government --

(i) The fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the work terminated; and

(ii) The completed or partially completed plans, drawings, information, and other property that, if the order had been completed, would have been required to be furnished to the Government.

(7) Complete performance of any work not terminated, if applicable.

(8) Take any action that may be necessary, or that the AO may direct through the CMF, for the protection and preservation of the property related to this project that is in the possession of the PAH(s) or any subawardee and in which the Government has or may acquire an interest.

(9) Use commercially reasonable efforts to sell, as directed or authorized by the CMF, any property of the types referred to under Article II. Section 2.03 Termination Provisions, (6)(i) and (ii); provided, however, that the PAH:

(i) is not required to extend credit to any purchaser and

(ii) may arrange for the subawardee who was performing the terminated work to acquire the property under the conditions prescribed by, and at prices approved by, the CMF.

(iii) will in no event be required to continue with such efforts for more than three (3) months after notice by the CMF to sell or disposition such property.

(10) The PAH has no obligation to continue to cost share on the terminated project or terminated portion of the project.

The requirement for at least 1/3 cost share of the total project cost by the PAH is assessed prior to award. In the event that during the course of the performance of the Project Agreement any of the parties to the Project Agreement believe the cost sharing funds available will be insufficient, the PAH shall notify the CMF within twenty-five (25) days of the event that gave rise to the insufficient cost sharing funds. CMF will notify the Government within five (5) days of receiving such notice from the PAH. The Government will determine whether it is in its best interest to either renegotiate the scope and/or terms of the Project Agreement to meet the cost share requirement or terminate the Project Agreement in whole or in part.

The proceeds of any transfer or disposition of project property will be applied to reduce any payments to be made by the Government under that particular project, including credited to the price or cost of the work, or paid in any other manner directed by the CMF.

In the event of a termination of the Project Agreement, the Government shall have patent rights as described in Article X, Patent Rights, and rights in Data as described in Article XI, Data Rights. Failure of the PAH and Government to agree to an equitable adjustment shall be resolved pursuant to Article VII, Disputes.

Section 2.04 Termination Cost

The CMF will negotiate with the Government and PAH in good faith equitable reimbursement for work performed toward accomplishment of the task or tasks of individual projects. The Government will allow full credit for the Government share of the obligations properly incurred by a PAH prior to termination. Costs incurred by a PAH during a suspension or after termination of a project are not allowable unless the CMF expressly authorizes them in either the notices of suspension, termination, or subsequently. Other PAH's costs incurred during a suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(a) The costs result from obligations which were properly incurred by the PAH before the effective date of the suspension or termination, are not in anticipation of it, and in the case of a termination, are non-cancellable; and

(b) The costs would be allowable if the project was not suspended or the award expired normally at the end of the funding period in which the termination takes effect.

Section 2.05 Close-out Procedure.

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the agreement are met, the following closeout procedures apply:

(a) Definitions.

(i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by the PAH.

(ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(iii) "Disallowed costs" – those charges that the Government or its representative determines to be unallowable, in accordance with the terms and conditions stated in this Agreement.

(b) Upon request, the Government shall make prompt payments to the PAH through the CMF for allowable reimbursable costs under the MCS Project Agreement being closed out.

(c) The PAH shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by the PAH for use in the performance of the Project Agreement.

(d) The CMF shall obtain from the PAH within 90 calendar days after the date of completion of an MCS Project Agreement all financial, performance, and other reports required as a condition of the MCS Project Agreement. The CMF may grant extensions when requested by the PAH.

(e) When authorized, the CMF shall make a settlement for any upward or downward adjustments to the Government's share of costs after these reports are received based on final, actual expenditures in accordance with the Termination Costs provision of the Agreement.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) The PAH shall account for any property received from the Government.

Section 2.06 Stop Work

As directed by the AO, the CMF may, at any time, by written order to the PAH, require the PAH to stop all, or any part, of the work called for under this Agreement or any Project Agreement for a period of 90 days after the written order is delivered to the PAH, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this section. Upon receipt of the order, the PAH shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered to the PAH, or within any extension of that period to which the parties shall have agreed, the CMF shall either:

(a) Cancel the stop-work order; or

(b) Terminate the work covered by the Project Agreement as provided in Article II, Term and Termination.

If a stop work order issued under this clause is canceled, the PAH shall resume work. The CMF shall make an equitable adjustment in the delivery schedule or Project Agreement estimated cost/price, or both, and the Government's share of the Project Agreement shall be modified, in writing, accordingly, if—

(1) The stop-work order results in an increase in the time required for, or in the PAH's cost properly allocable to, the performance of any part of the Project Agreement; and

(2) The PAH asserts its right to the adjustment within 30 days after the end of the period of work stoppage; provided, that, if the Government decides the facts justify the action, the Government through the MCDC CMF may receive and act upon a proposal submitted at any time before final payment under the Project Agreement.

If a stop work order is not canceled and the work covered by the Project Agreement is terminated in accordance with Article II, the MCDC CMF shall work with the PAH to negotiate an equitable reimbursement in accordance with Article II. Section 2.03, Termination Provisions.

Article III. MANAGEMENT OF THE PROJECT

Section 3.01 The Medical CBRN Defense Consortium (MCDC)

The MCDC, as defined in the OTA, was formed to work with the Government and provide input in developing technologies to support the Department of Defense's (DoD) medical, pharmaceutical, and diagnostic requirements as related to enhancing the mission effectiveness of military personnel ultimately resulting in fully executed research and development prototype projects selected by the Government. Every Member in this MCDC is independent of the other, and there is no affiliation between the MCDC members within the definition of 13 C.F.R. 121.103 of the Federal Small Business Regulations and no such affiliation is intended either by the formation or implementation of the MCDC.

As appointed by the MCDC Executive Committee, the CMF has the authority to execute the Other Transaction Agreement (OTA) on behalf of the MCDC and has the responsibility for day to day overall administration of this Agreement, subject to the supervision of the MCDC Executive Committee.

Section 3.02 The following MCDC decisions are subject to the ACC-NJ approval:

1. Changes to the MCDC Articles of Collaboration if such changes substantially alter the relationship of the MCDC and the Government as originally agreed upon when the OTA was executed;
2. Changes to, or elimination of, any ACC-NJ funding allocation to any MCDC Member as technically and/or financially justified.

Section 3.03 Management and Project Structure

Technical and project management of the coordinated research program established under this Agreement shall be accomplished through the management structures and processes detailed in this Article.

The Government competitively selected the MCDC, organized by its Consortium Management Firm Advanced Technology International, a Section 501(c)(3) nonprofit organization. MCDC has entered into an agreement with Advanced Technology International authorizing Advanced Technology International to enter into this OTA as the consortium manager, engage in overall day to day management of the MCDC under the guidance of and as designated by the MCDC Executive Committee, including technical, programmatic, reporting, financial, administrative and contractual matters and administer Project Agreements required for performance under this OTA.

As established by funded projects under the OTA, the Government Program Manager shall fully participate in the appropriate program technical meetings held by the MCDC. The AORs and Other Government personnel, as deemed appropriate, also may participate in the technical portion of these meetings.

Section 3.04 Modifications

As a result of scheduled meetings, end of program reviews, or at any time during the term of the OTA, research progress or results may indicate that a change in the OTA's scope, objectives or Term would be beneficial to program objectives. Recommendations for modifications, including justifications to support any changes to the OTA Scope, will be documented in a letter and submitted by the PAH to the CMF, who will then forward it to the Program Manager with a copy to the AO. This documentation letter will detail the technical, chronological, and financial impact of the proposed modification to the OTA. The Program Manager shall be responsible for the review and verification of any recommendations to revise or otherwise modify the OTA Scope or other proposed changes to the terms and conditions of the OTA and subsequently this Agreement.

With regard to projects the Government determines to fund as a result of the RPP process specified in the Agreement Scope, any PAH recommendations for modifications, including justifications to support any changes to the funded projects, will be documented in a letter and submitted by the CMF to the AO with a copy to the Government Agreements Officer Representative designated for the particular project. The AO shall be responsible for review of proposed changes and for all modifications to the terms and conditions of the project awards. The CMF shall modify the Project Agreement(s) in the event of any such modifications or changes to the project.

Management of Projects

(1) Performance of the work on each project is subject to the technical direction of the AOR designated in the Project Agreement. For the purposes of this clause, technical direction includes the following:

   a. Direction to the PAH, which shifts work emphasis between work areas or tasks, requires pursuit of certain lines of inquiry, fills in details or otherwise serves to accomplish the objectives described in the statement of work;
   b. Guidelines to the PAH that assist in the interpretation of drawings, specifications or technical portions of work description.
   c. Review and, where required by the Project Agreement, approval of technical reports, drawings, specifications, or technical information to be delivered by the PAH under the Project Agreement.

   The AOR shall monitor the PAH's performance with respect to compliance with the technical requirements of the Project Agreement.

(2) Technical direction must be within the general scope of work stated in the Project Agreement. Technical direction may not be used to
   a. Assign additional work under the Project Agreement;

b. Increase or decrease the estimated Project Agreement cost, fee (if any), or the time required for the project performance;
c. Change any of the terms, conditions or specifications of the Project Agreement; or
d. Accept non-conforming work.

As such, no verbal or written request, notice, authorization, direction or order received by the PAH shall be binding upon the MCDC, CMF or Government, or serve as the basis for a change in the Project Agreement cost or any other provision of the Project Agreement, unless issued (or confirmed) in writing by the MCDC CMF Contractual Representative designated in the Project Agreement.

(3) The PAH shall immediately notify the MCDC CMF Contractual Representative whenever a written change notification has been received from anyone other than the MCDC CMF Contractual Representative, which would affect any of the terms, conditions, cost, schedules, etc. of the Project Agreement, and the PAH is to perform no work or make any changes in response to any such notification or make any claim on the MCDC through its CMF or Government, unless the MCDC CMF Contractual Representative directs the PAH, in writing, to implement such change notification.

Article IV. AGREEMENT ADMINISTRATION

Administrative and contractual matters under this Agreement shall be referred to the following representatives of the parties:

MCDC: Advanced Technology International
MCDC Contracts
[redacted]

Project Agreement Holder: [redacted]

Each party may change its representatives named in this Article by written notification to the other parties.

Agreements Officer Representative (AOR): AOR will be designated by the Government on a per project basis.

Article V. OBLIGATION AND PAYMENT

Section 5.01 Obligation:

Except as specified in Article VII: Disputes, the CMF's liability to make payments to the PAH is limited only to those funds obligated under the Project Agreement(s). The CMF may incrementally fund the Project Agreement(s). If modification becomes necessary in performance of projects, pursuant to Article V of this Agreement, the CMF and the PAH shall establish and execute a revised Schedule of Payable Milestones consistent with the current Project Agreement.

Section 5.02 Project Payments:

The detailed instructions for project payments will be included in the Technical Direction Letter to be issued by the CMF on a project by project basis.

Section 5.03 Accounting System Requirements:

Prior to the submission of invoices, the PAH shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and the requirements of this Agreement. The PAH shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds under this Agreement. Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

Section 5.04 Invoicing Instructions:

Project Payable Milestones: The PAH shall segregate and track all individual project costs separately and shall document the accomplishments of each Payable Milestone under each Project Agreement. A Payable Milestones report shall be detailed on a project basis and submitted with each request to the AOR or designee for approval.

Section 5.04 a. Payment Method Types

Project Agreements will be issued as either a fixed price milestone payment method or a cost reimbursement milestone payment method as described below.

(a) *Fixed Price Milestone Payment Method:* Payments shall be made in accordance with the Payable Milestone Schedule of each Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The Payable Milestone Schedule may be revised as appropriate and deemed necessary by issuance of a bilateral modification to the Project Agreement. Quarterly reviews by the AOR and the CMF will assess the need for revisions to the Payable Milestone Schedule. An acceptable invoice for adjustable fixed price milestone payments is one that (on the invoice or on the Payable Milestone Report):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone; and

(iii) lists the milestone cost negotiated and contained in each Project Agreement

(b) *Cost Reimbursable Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Task Assignment):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(c) *Cost Plus Fixed Fee Milestone Payment Method (with not to exceed ceiling):* Payment is contingent

upon satisfactory progress toward completion of milestones as delineated in Project Agreement. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. The PAH will normally fund any costs incurred above this maximum amount. Either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base t Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a description of supplies and services, labor costs, subcontractor costs, material costs, travel costs, other direct costs, fixed fee and extended totals;

(iv) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(v) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

(d) *Cost Reimbursable, Cost Sharing Milestone Payment Method (with not to exceed ceiling):* Payment is contingent upon satisfactory progress toward completion of milestones as delineated in Project Agreement and acceptable cost share. Payment shall be made based on actual costs incurred in completing milestones up to the maximum amount allowable under the applicable Project Agreement, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. Per (ii) below, either a Status Report identifying any associated technical tasks and the progress toward completion of each milestone, a Deliverable Report, or a Milestone Report is required concurrent with the invoice. An acceptable invoice for reimbursable payment is one that (on the invoice or on the attached Status, Deliverable, or Milestone Report in accordance with each Project Agreement):

(i) contains the date of invoice and the Base Agreement number and Project Agreement number;

(ii) identifies any associated technical milestones and the progress toward completion of each milestone;

(iii) includes a report of the cost share expended towards the accomplishment of the SOW tasks and/or milestones. This cost share report may be attached to the invoice if contractor practices make inclusion of such information on the invoice itself impractical. If the cost share report is separate from the invoice, it must be signed by an authorized representative. This cost share report must contain a breakout of the cost share by cost element similar to the level of detail required on the invoice and any in-kind contributions. The preferred method of reporting cost share is to provide an invoice for actual cost incurred with a value for the cost shared amount and the value to be reimbursed by the Government through the CMF;

(iv) includes a description of supplies and services, labor costs, subcontractor costs, material costs,

travel costs, other direct costs, and extended totals;

(v) indicates the current period and cumulative man-hours and costs incurred through the period indicated on the invoice; and

(vi) contains the following certification statement:

"I certify that the amounts invoiced are for costs incurred in accordance with the agreement, the work reflected has been performed, and prior payment has not been received."

Authorized Signature _____

Section 5.04 b. Submission of Invoices

Invoices may be submitted no more frequently than monthly. The PAH shall submit invoices and any necessary supporting documentation via email to MCDC-invoices@ati.org.

For Cost type Project Agreements, the PAH's final invoice (completion invoice) will be clearly indicated as such and shall indicate the cumulative amounts incurred and billed to completion, and a written certification of the total hours expended. Actual project costs incurred and cost share performance, if applicable, of each project shall be reported and reviewed each quarter.

Section 5.04 c. Payment Terms

Payment terms are NET 30 days after CMF's receipt of an acceptable invoice. An acceptable invoice is one that meets the conditions described in Article V Section 5.04a. Payment Method Types.

Section 5.05 Advance Payments:

On a per project basis, advance payments may be approved by the AO. If the AO has approved advance payments, there will be a requirement to establish a separate interest bearing account. The PAH sets up and maintains funds in a separate interest bearing account unless one of the following applies:

(1) The PAH receives less than $120,000 in Federal awards per year;

(2) The best reasonably available interest bearing account would not expect to earn interest in excess of $250 per year on such cash advances;

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected cash resources for the project; or

(4) The advance payments are made one time to reduce financing costs for large up-front expenditures and the fund will not remain in the PAH's account for any significant period of time.

Where a separate interest bearing account is set up, any interest earned should be remitted annually to the CMF. CMF shall forward the funds to the Government as directed by the AO. Interest payments shall be made payable to the U.S. Treasury.

Section 5.06 Limitation of Funds:

Except as set forth in Article VII, the Government's financial liability will not exceed the amount obligated for projects and available for payment.

Section 5.07 Financial Records and Reports:

The PAH shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for Project Agreement funding provided under this Agreement, should cost sharing procedures be implemented for funding a particular project. PAH's relevant financial records are available and subject to examination or audit on behalf of the ACC-NJ for a period not to exceed five (5) years after final payment of the PAH's project. The AO or designee shall have direct access to sufficient records and information of the PAH to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Government using Government auditors or, at the request of the PAH, by the requesting PAH's external CPA accounting firm at the expense of the requesting PAH.
AGREEMENT

Article VI. NONTRADITIONAL DEFENSE/COST SHARING

In accordance with provisions of 10 USC 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L. 114-92, which provides the Department of Defense (DoD) authority to enter into transactions *other than* contracts, grants, or cooperative agreements, the Department of Defense (DoD) has the authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or the improvement of platforms, systems, components, or materials in use by the armed forces. Section 815 revised the definition for the term ‘nontraditional defense contractor’ as defined in Article I. Section 1.01, Definitions.

Each MCDC Member Organization must meet the definition of a Nontraditional Defense Contractor or have at least one Nontraditional Defense Contractor participating to a significant extent in the performance of an awarded Project Agreement. Examples of what might be considered a significant extent or significant contribution include, but may not be limited to supplying new key technologies or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance.

If significant Nontraditional Defense Contractor participation cannot be fulfilled, the Member Organization must provide at least one third cost share of the value of the Project Agreement awarded to the Member Organization. Proposals that fail to comply with this requirement will not be awarded under the OTA.

Cost Sharing is not required under this Other Transaction Agreement for projects that contain significant nontraditional defense contractor participation. Where both Parties agree, cost sharing may be considered on a per project basis under terms and conditions to be agreed to by the Parties and in accordance with the “Other Transactions” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors without a significant nontraditional defense contractor teaming partner, a one third cost share of the project costs is required as described in the “Other Transaction” (OT) Guide For Prototype Projects dated January 2001. For traditional Government contractors with significant nontraditional defense contractor participation, cost sharing is not required for Projects under this OTA.

Throughout the period of performance of any Project Agreement, the Government AO and AOR will actively monitor Nontraditional Defense Contractor participation and/or cost sharing to ensure compliance with this provision in accordance with implementation guidance from HQDA and/or OSD. The PAH will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

Article VII. DISPUTES

Section 7.01 General

For the purposes of this Article, "Parties" means the CMF, the PAH and the Government where collectively identified and "Party" where each entity is individually identified. The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

Section 7.02 Dispute Resolution Procedures

Any disagreement, claim or dispute among the Parties concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the ACC-NJ, Center Director for Emerging Technologies, in the interest of justice, waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the ACC-NJ, Center Director for Emerging Technologies. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ACC-NJ, Center Director for Emerging Technologies, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

If requested within thirty (30) calendar days of the ACC-NJ, Center Director for Emerging Technologies' decision, further review will be conducted by the Chair of the MCDC Executive Committee and the ACC-NJ Associate Director. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the Chair of the MCDC Executive Committee and the ACC-NJ, Associate Director (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law, including but not limited to the right to seek extraordinary relief under Public Law 85-804. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

Section 7.03 Limitation of Liability and Damages

In no event shall the liability of the MCDC PAH or any other entity performing research activities under a Project Agreement exceed the funding such entity has received for their performance of the specific Project Agreement under which the dispute arises.

No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Article VIII. CONFIDENTIAL INFORMATION

Section 8.01 Definitions

(1) "Disclosing Party" means CMF, MCDC PAHs, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) "Receiving Party" means CMF, MCDC PAHs, or the Government who receives Confidential Information disclosed by a Disclosing Party.
(3) "Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the PAH. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if -

(a) The owner thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

Section 8.02 Exchange of Information:

Neither the Government nor MCDC on behalf of the MCDC member entities or PAHs nor the CMF shall be obligated to transfer Confidential Information independently developed by the Government or the MCDC member entities or PAHs or the CMF absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

Section 8.03 Authorized Disclosure:

The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article VIII entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

Section 8.04 Return of Proprietary Information:

Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

Section 8.05 Term:

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Section 8.06 Flow Down

The PAH shall flow down the requirements of this Article VIII to their respective personnel, member entities, agents, subawardees (including employees) at all levels, receiving such Confidential Information under this OTA.

Article IX. PUBLICATION AND ACADEMIC RIGHTS

Section 9.01 Use of Information.

For the purposes of this Article, “Parties” means the PAH and the Government where collectively identified and “Party” where each entity is individually identified.

Subject to the provisions of Article VIII, Confidential Information, Article IX, Publication and Academic Rights, and Article XI Data Rights, the PAH and the Government shall have the right to publish or otherwise disclose information and/or data developed by the Government and/or the respective MCDC PAH under the Research Project. The PAH and the Government (and its employees) shall include an appropriate acknowledgement of the sponsorship of the Research Projects by the Government and the MCDC PAH in such publication or disclosure. The Parties shall have only the right to use, disclose, and exploit any such data and Confidential Information in accordance with the rights held by them pursuant to this Agreement. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of the Government or the PAH.

Section 9.02 Publication or Public Disclosure of Information

(a) Classified Project Agreements

If a release of Confidential Information or Trade Secrets is for a classified Project Agreement, the provisions of the DoD Security Agreement (DD Form 441) and the DoD Contract Security Classification Specification (DD Form 254) apply.

(b) Review or Approval of Technical Information for Public Release.

(1) At least 30 days prior to the scheduled release date PAH shall submit to the CMF a copy of the information to be released. In turn, CMF shall submit to the Government AOR a copy of the information to be released.

The Government AOR is hereby designated as the approval authority for the AO for such releases.

(2) Where the PAH is an Academic Research Institution performing fundamental research on campus. PAH shall provide papers and publications for provision to the CMF for provision to the Government AOR for review and comment 30 days prior to formal paper/publication submission. However, if that Academic Research Institution incorporates into its research results or publications artifacts produced by and provided to these institutions on behalf of other (non-educational institution) MCDC PAHs (or has authors listed on the paper who are not employees or students of the Academic Research Institution) then the procedures in Section 9.02(a) ABOVE must be followed.

(3) Parties to this Agreement are responsible for assuring that an acknowledgment of government support will appear in any publication of any material based on or developed under this OTA, using the following acknowledgement terms:

> "Effort sponsored by the U.S. Government under Other Transaction number W15QKN-16-9-1002 between the MCDC, and the Government**.** The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

(4) Parties to this Agreement are also responsible for assuring that every publication of material based on or developed under this project contains the following disclaimer:

> "The views and conclusions contained herein are those of the authors and should not be interpreted as necessarily representing the official policies or endorsements, either expressed or implied, of the U.S. Government.

The PAH shall flowdown these requirements to its subawardees, at all tiers.

(c) Notices. To avoid disclosure of Confidential Information or Trade Secrets belonging to an MCDC member entity or PAH and/or the Government and the loss of patent rights as a result of premature public disclosure of patentable information, the PAH that is proposing to publish or disclose such information shall provide advance notice to the MCDC, through its CMF, and identify such other parties as may have an interest in such Confidential Information. The CMF shall notify such parties at least thirty (30) calendar days prior to any PAH's submission for publication or disclosure, together with any and all materials intended for publication or disclosure relating to technical reports, data, or information developed by the parties during the term of and pursuant to this Agreement. The Government must notify the MCDC, through its CMF, of any objection to disclosure within this thirty (30) day period, or else the PAH, shall be deemed authorized to make such disclosure.

(d) Filing of Patent Applications. During the course of any such thirty (30) calendar day period, the PAH shall provide notice to the CMF as to whether it desires that a patent application be filed on any invention disclosed in such materials. In the event that a PAH and/or the Government desires that such a patent be filed, the PAH or the Government proposing to publish or disclose such materials agrees to withhold publication and disclosure of such materials until the occurrence of the first of the following:

(1) Filing of a patent application covering such invention, or

(2) Written agreement, from the AO and the CMF (on behalf of the PAH to whom such Confidential Information belong) that no patentable invention is disclosed in such materials.

(3) Further, during the course of any such 90 calendar day period, the PAH shall notify the AO and the Government, through the CMF, if PAH believes any of its Confidential Information have been included in the proposed publication or disclosure and shall identify the specific Confidential Information or Trade Secrets that need to be removed from such proposed publication. The Government and the CMF on behalf of the PAH proposing the publication or disclosure of such materials agrees to remove from the proposed publication or disclosure all such Confidential Information so identified by the CMF.

Article X. PATENT RIGHTS

Section 10.01 Definitions

“Invention” means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

“Made” when used in relation to any invention means the conception or first actual reduction to practice of such invention.

“Practical application” means to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

“Subject Invention” means any invention of the MCDC’s PAH or its subcontractors of any tier conceived or first actually reduced to practice in the performance of work on a Project Agreement under this Agreement.

"Background Invention" means any invention, or improvement to any invention, other than a Subject Invention, made by a PAH (or their subcontractors of any tier) that was conceived, designed, developed, produced, and/or actually reduced to practice prior to performance of the Agreement or outside the scope of work performed under this Agreement.

Section 10.02 Allocation of Principal Rights

The PAH, or its subcontractor to the extent such is proper assignee of the invention, shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article, Executive Order 12591 and 35 U.S.C § 202. In the event that a PAH consists of more than one entity or person, those entities or persons may allocate such right, title interest between themselves or others as they may agree in writing. With respect to any Subject Invention in which the PAH retains title, the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. The PAH may elect to provide full or partial rights that it has retained to other parties. The Government shall have the right to use any products or processes used for test and evaluation (including materials for testing or assays) in any other project pursued on behalf of the U.S. Government.

Section 10.03 Invention Disclosure, Election of Title, and Filing of Patent Application

(1) The PAH shall disclose each Subject Invention to the CMF within four (4) months after the inventor discloses it in writing to his company personnel responsible for patent matters. The disclosure to the CMF shall be in the form of a written report and shall identify the Agreement under which the invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure.

(2) If the PAH determines that it does not intend to retain title to any such invention, the PAH shall notify the CMF, in writing, within nine (9) months of disclosure. However, in any case where publication, sale or public use has initiated the one (1) year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the ACC-NJ through CMF to a date that is no more than six (6) months prior to the end of the project.

(3) The PAH shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The MCDC PAH may elect to file patent applications in additional countries (including the European Patent Office and the Patent Cooperation Treaty) within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

(4) After considering the position of the CMF on behalf of the PAH, a request for extension of the time for disclosure election, and filing under this Article IX, paragraph C, may be approved by ACC-NJ, which ACC-NJ approval shall not be unreasonably withheld.

Section 10.04 Conditions When the Government May Obtain Title

Upon written request to the CMF, the PAH shall convey to the Government title to any Subject Invention under any of the following conditions:

(1) If the PAH fails to disclose or elects not to retain title to the Subject Invention within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that the Government may only request title within sixty (60) days after learning of the failure of the PAH to disclose or elect within the specified times.

(2) In those countries in which the PAH fails to file patent applications within the times specified in Section 10.03 of this Article X, Patent Rights; provided, that if the PAH has filed a patent application in a country after times specified in Section 10.03 of this Article X, Patent Rights, but prior to its receipt of the written request by the Government through the CMF, the PAH shall continue to retain title in that country; or

(3) In any country in which the PAH decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

Section 10.05 Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File

The Parties agree that:

(1) The PAH shall retain a non-exclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if the PAH fails to disclose the invention within the times specified in Section 10.03 of this Article X, Patent Rights. PAH's license extends to the domestic (including Canada) subsidiaries and affiliates, if any, of the PAH within the corporate structure of which the PAH is a party and includes the right to grant licenses of the same scope to the extent that PAH was legally obligated to do so at the time the Project Agreement was funded. The license is transferable only with the approval of the Government, except when transferred to the successor of that part of the business to which the invention pertains. Government approval for license transfer shall not be unreasonably withheld.

(2) The PAH domestic license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an

exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. This license shall not be revoked in that field of use or the geographical areas in which the PAH has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the Government to the extent the PAH, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the Government shall furnish the CMF, and the CMF shall forward to the PAH, a written notice of the Government's intention to revoke or modify the license, and the PAH shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

Section 10.06 Action to Protect the Government's Interest

(1) The PAH shall execute or have executed and promptly deliver to CMF all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which the PAH elects to retain title, and (ii) convey title to the Government when requested under Section 10.04 of this Article X, Patent Rights, and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

(2) The PAH agrees to require, by written agreement, that its employees working on Project Agreements, other than clerical and non-technical employees, agree to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format acceptable to the CMF, each Subject Invention made under this Agreement in order that the CMF on behalf of the PAH can comply with disclosure provisions of Section 10.03 of the Article X, Patent Rights, and to execute all papers necessary to file the patent applications on the Subject Invention and to establish the Government's rights in the Subject Invention. The PAH acknowledges and shall instruct its employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The PAH shall notify the CMF of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) days before the expiration of the response period required by the relevant patent office.

(4) The PAH shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with U.S. Government support under Agreement No. W15QKN-16-9-1002 awarded by the ACC-NJ to the MCDC. The Government has certain rights in the invention."

Section 10.07 Lower Tier Agreements

The PAH shall include the Article X, Patent Rights, suitably modified to identify the parties, in all lower tier agreements, regardless of tier, for experimental, development, or research work.

Section 10.08 Reporting on Utilization of Subject Inventions

The PAH shall submit, on request during the term of the Project Agreement, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the PAH or its licensees or assignees. Such reports shall include information regarding the status of development date of first commercial sale or use, gross royalties received by the PAH, and such other data and information as the agency may reasonably specify. The PAH also agrees to provide additional reports as may be requested by the Government, through CMF, in connection with any march-in proceedings undertaken by the Government in accordance with Section 10.10 of this Article X, Patent Rights. Consistent with 35 U.S.C. § 205, the Government

agrees it shall not disclose such information to persons outside the Government without permission of the MCDC on behalf of the PAHs.

Section 10.09 Preference for American Industry

Notwithstanding any other provision of the Article X, Patent Rights, the PAH is not to grant to any person the exclusive right to use or sell any Subject Invention in the United States or Canada unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention shall be manufactured substantially in the United States or Canada. However, in individual cases, the requirements for such an agreement may be waived by the Government upon a showing by the PAH that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

Section 10.10 March-in Rights

The PAH agrees that, with respect to any Subject Invention in which its PAH has retained title, the Government, through CMF, has the right to require the PAH to obtain and grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the PAH refuses such a request, the Government has the right to grant such a licensee itself if the Government determines that:

(1) Such action is necessary because the PAH or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the PAH, assignee, or their licensees;

(3) Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the PAH, assignee, or licensees; or

(4) Such action is necessary because the Agreement required by Section 10.09 of this Article X, Patent Rights, has not been obtained or waived or because a licensee who has the exclusive right to use or sell any Subject Invention in the United States is in the breach of such Agreement.

Section 10.11 Opportunity to Cure

Certain provisions of this Article X, Patent Rights, provide that the Government may gain title or license to a Subject Invention by reason of the PAH's action, or failure to act, within the times required by this Article X, Patent Rights. Prior to claiming such rights (including any rights under Article X, Section 10.10 March-In Rights), the Government will give written notice to MCDC, through its CMF, and CMF will convey such written notice to PAH, of the Government's intent, and afford the PAH a reasonable time to cure such action or failure to act. The length of the cure period will depend on the circumstances, but in no event will be more than 60 days. PAH may also use the cure period to show good cause why the claiming of such title or right would be inconsistent with the intent of this Agreement in light of the appropriate timing for introduction of the technology in question, the relative funding and participation of the parties in the development, and other factors.

Section 10.12 Background Information

In no event shall the provisions set forth in this Article X apply to any Background Inventions or Patents. The PAHs or their subcontractors shall retain the entire right, title, and interest throughout the world to each such Inventions and Patents that each party has brought through MCDC to the project issued under this Agreement and the Government shall not have any rights under this Agreement. Projects to be funded under this Agreement will list Background Inventions and Patents anticipated to be used on the project; such listing may be amended by the parties as appropriate to reflect changes in such plans.

Section 10.13 Survival Rights

Provisions of this Article X shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this Article, differing rights in patents may be negotiated among the Parties to each individual project on a case-by-case basis.

Article XI. DATA RIGHTS

This is a Data Rights Clause specifically tailored for this OTA to address respective rights of the Government and MCDC on behalf of its actual or prospective MCDC PAHs to such Data as is owned, developed, to be developed or used by an actual or prospective MCDC member entity or PAH (1) as identified in a MCDC member entity(ies) proposal submitted to the Government through the CMF in response to a competitive Government OTA call for proposals, and (2) when such proposal is selected by the Government for funded performance and the Project Agreement is issued by the CMF to that MCDC member entity for performance of such Government OTA project.

Section 11.01 Definitions

(1) "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a)(1) (Jun 1995).

(2) "Commercial Computer Software License" means the license terms under which commercial computer software and Data (as defined in this OTA) is sold or offered for sale, lease or license to the general public.

(3) "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(4) "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.

(5) "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.

(6) "Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(7) "Data" as used in this Article of the Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.

(8) "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(9) "Government purpose rights" means the rights to use, modify, duplicate or disclose the "Data" licensed with such rights under this OTA within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes. Under this Agreement, the period of Government purpose rights shall be no less than ten (10) years and during such time the MCDC member entity or PAH developing or providing such Data to the Government with government purpose rights shall have the sole and exclusive right to use such Data for commercial purposes. In the event this Data is used to perform another project issued to that MCDC member entity or PAH under this OTA during this ten (10) year period, the period of

government purpose rights shall be extended an additional ten (10) years starting with the date of completion of performance of the additional project.

(10) “Limited rights” as used in this Article is as defined in DFARS 252.227-7013(a)(13) (Nov 1995).

(11) “Restricted rights” as used in this Article is as defined in DFARS 252.227-7014(a)(14) (Jun 1995).

(12) “Specially Negotiated License Rights” are those rights to Data that have been specifically negotiated between the Government and the MCDC on behalf of the member entity or PAH whose proposal is selected by the Government under a call for proposals issued under the OTA.

(13) “Technical data” means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(14) “Unlimited rights” as used in this Article is as defined n DFARS 252.227-7013(a)(16).

Section 11.02 Data Categories

(1) Category A is the Data developed and paid for totally by private funds, or the PAH's (or its subcontractor's) IR&D funds and it is Data to which the PAH (or its subcontractor) retains all rights. Category A Data shall include, but not be limited to,

> (a) Data as defined in this Article and any designs or other material provided by the PAH for a project under this Agreement which was not developed in the performance of work under that project, and for which the PAH retains all rights.
>
> (b) Any initial Data or technical, marketing, or financial Data provided at the onset of the project by any of the MCDC member entities or PAHs. Such Data shall be marked “Category A” and any rights to be provided to the Government for such Data under a specific project shall be as identified in the proposal submitted to the Government and included into the Technical Direction Letter and CMF issued Project Agreements.

(2) Category B is any Data developed under this OTA with mixed funding, i.e. development was accomplished partially with costs charged to a PAH’s indirect cost pools and/or costs not allocated to a PAH’s Project Agreement under this OTA, and partially with Government funding under this OTA. Any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(3) Category C is any Data developed exclusively with Government funds under this OTA. Research and Development performed was not accomplished exclusively or partially at private expense. Under this category,

> (a) the Government will have Government Purpose Rights in Data developed exclusively with Government funds under a project funded by the Government under this OTA that is:
>
> > (i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;
> >
> > (ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Data created in the performance of the OTA that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Data necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

The Government can only order such Data as is developed under the OTA project where the order request is made within one (1) year following OTA project completion. In the event the Government orders such Data, it shall pay the PAH the reasonable costs for all efforts to deliver such requested Data, including but not limited to costs of locating such Data, formatting, reproducing, shipping, and associated administrative costs.

(b) The Government shall have unlimited rights in Data

(i) Otherwise publicly available or that has been released or disclosed by PAH without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(ii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(iii) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with—

(1) Government Purpose Rights or limited rights and the restrictive condition(s) has/have expired; or

(2) Government purpose rights and the PAH's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.

(c) However, any Data developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data.

(d) Further, the Government's rights to Commercial Computer Software and Data licensed under a Commercial Computer Software License under this OTA, and the treatment of Data relating thereto, shall be as set forth in the Commercial Computer Software License.

(4) The parties to this Agreement understand and agree that the CMF shall require PAHs stamp all documents in accordance with this Article and that the Freedom of Information Act (FOIA) and Trade Secrets Act (TSA) apply to Data.

Section 11.03 Allocation of Principal Rights

(1) The Government shall have no rights to Category A Data.

(2) The Government shall have immediate Government Purpose Rights to Category B or C Data upon delivery or project or Agreement completion (whichever is earlier), except that

(a) where the PAH whose Data it is, is a small business as defined under the Small Business Innovation research Program (SBIR) under 15 U.S.C. 638, and such data was developed under a project designated by the Government in the RPP as an SBIR program project, such PAH automatically shall be entitled to a delay in the start of the Government Purpose Rights period for at least five (5) years from project completion, or such longer period as may be negotiated among the Government and MCDC on behalf of the PAH, and

(b) The CMF, at the request of small business or an other than small business MCDC member entity or PAH, may request on such member entity's or PAH's behalf a delay of the start of Government Purpose Rights in Category B or C Data for a period not to exceed five (5) years from project or Agreement completion (whichever is earlier). Such requests will only be made in those cases where the CMF has provided information from the affected actual or prospective PAH demonstrating the need for this additional restriction on Government use and shall be submitted to the ACC-NJ AO for approval, which approval shall not be unreasonably withheld. In the event of any dispute regarding approval of this request, the parties agree to treat this as a dispute and shall follow the provisions of Article VII, Disputes.

(c) for Article XI.Section 11.02 3(c) Category C Data, the Government shall have only the rights established under prior agreements.

(d) for Article XI.Section 11.02 3(d) Category C Data, the Government shall only have the rights set forth in the Commercial Computer Software Data license agreement.

(3) Data that will be delivered, furnished, or otherwise provided to the Government as specified in a specific project award funded under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(4) Each proposal submitted by the MCDC member entities in response to a Government call for proposals under this OTA shall include a list of the Category A, B and C Data to be used or developed under the proposal if selected. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The Government AO will incorporate the list of Category A, B and C Data and the identified rights therefor in the award document.

Following issuance of a Technical Direction Letter and subsequent CMF issuance of the Project Agreement to the Government selected MCDC member entity (the PAH), the PAH shall update the list to identify any additional, previously unidentified, Data if such Data will be used or generated in the performance of the funded work. Rights in such Data shall be as established under the terms of this Agreement, unless otherwise asserted in a supplemental listing and agreed to by the Government.

Section 11.04 Marking of Data

Except for Data delivered with unlimited rights, Data to be delivered under this Agreement subject to restrictions on use, duplication or disclosure shall be marked with the following legend:

Use, duplication, or disclosure is subject to the restrictions as stated in the Agreement between the U.S. Government and the MCDC, Agreement No. W15QKN-16-9-1002, Project Title and the MCDC Project Agreement with [insert name of company] No. _____.

It is not anticipated that any Category A Data will be delivered to the Government under this Agreement.

In the event commercial computer software and Data is licensed under a commercial computer software license under this OTA, a Special License rights marking legend shall be used as agreed to by the parties.

The Government shall have unlimited rights in all unmarked Data. In the event that a PAH learns of a release to the Government of its unmarked Data that should have contained a restricted legend, the CMF on behalf of the member entity or PAH will have the opportunity to cure such omission going forward by providing written notice to the Government AO within three (3) months of the erroneous release.

Section 11.05 Copyright

The PAHs reserve the right to protect by copyright original works developed under this Agreement. All such copyrights will be in the name of the individual PAH. The PAH(s) hereby grant to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under this agreement, and to authorize others to do so.

In the event Data is exchanged with a notice indicating that the Data is protected under copyright as a published, copyrighted work and it is also indicated on the Data that such Data existed prior to, or was produced outside of this Agreement, the Party receiving the Data and others acting on its behalf may reproduce, distribute, and prepare derivative works for the sole purpose of carrying out that Party's responsibilities under this Agreement with the written permission of the Copyright holder.

Copyrighted Data that existed or was produced outside of this Agreement and is unpublished - having only been provided under licensing agreement with restrictions on its use and disclosure - and is provided under this Agreement shall be marked as unpublished copyright in addition to the appropriate license rights legend restricting its use, and treated in accordance with such license rights legend markings restricting its use.

The PAHs are responsible for affixing appropriate markings indicating the rights of the Government on all Data delivered under this Agreement.

The Government agrees not to remove any copyright notices placed on Data and to include such notices on all reproductions of the Data.

Section 11.06 Data First Produced by the Government:

As to Data first produced by the Government in carrying out the Government's responsibilities under this OTA and which Data would embody trade secrets or would comprise commercial or financial information that is privileged or confidential if obtained from the CMF on behalf of any PAH, such Data will, to the extent permitted by law, be appropriately marked with a suitable notice or legend and maintained in confidence by the CMF and any PAH to whom disclosed for three (3) years after the development of the information, with the express understanding that during the aforesaid period such Data may be disclosed and used by the CMF or any PAH, including its respective employees or subcontractors of any tier, (under suitable protective conditions) by or on behalf of the Government for Government purposes only.

Section 11.07 Prior Technology

(1) Government Prior Technology: In the event it is necessary for the Government to furnish the CMF or any MCDC member entity or PAH, including their respective employees or their subcontractors of any tier, with Data which existed prior to, or was produced outside of this Agreement, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used only for the purpose of carrying out their responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of non-disclosure agreements by CMF, PAHs, PAH subcontractors of any tier and their respective employees to whom such Data is provided for use under the OTA. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the Government.

(2) CMF and PAH Prior Technology: In the event it is necessary for the CMF or any PAH to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. Neither the CMF nor any PAH shall be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by the CMF on behalf of itself or PAHs.

(3) Oral and Visual Information: If information which the PAH (including their subcontractors of any tier and their respective employees) considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government and/or CMF, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government and/or CMF within ten (10) calendar days after such oral or visual disclosure, or the Government and/or CMF shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. Upon Government and/or CMF request, additional detailed information about the exchange will be provided subject to restrictions on use and disclosure.

(4) Disclaimer of Liability: Notwithstanding the above, neither the Government nor the CMF shall be restricted in, nor incur any liability for, the disclosure and use of:

(a) Data not identified with a suitable notice or legend as set forth in this Article; nor

(b) Information contained in any Data for which disclosure and use is restricted under Article VIII entitled "Confidential Information" above, if such information is or becomes generally known without breach of the above, is properly known to the Government or CMF or is generated by the Government or CMF independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without restriction, or is included in Data which the PAH has furnished, or is required to furnish to the Government or CMF without restriction on disclosure and use.

(5) Marking of Data: Any Data delivered under this Agreement shall be marked with a suitable notice or legend.

Notwithstanding the Paragraphs in this Article, differing rights in Data may be negotiated among the Parties to each individual project on a case-by-case basis.

Section 11.08 Lower Tier Agreements

The PAH shall include this Article, suitably modified to identify the parties, in all subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

Section 11.09 Survival Rights

Provisions of this Article shall survive termination of this Agreement under Article II.

Notwithstanding the terms of this in this Article, differing rights in data may be negotiated among the Parties to each individual Technology Project Agreement on a case-by-case basis.

Article XII. EXPORT CONTROL

Export Control

(1) Information subject to Export Control Laws/International Traffic in Arms Regulation (ITAR):

Public Law 90-629, « Arms Export Control Act, » as amended (22 U.S.C. 2751 et. seq.) requires that all unclassified technical data with military application may not be exported lawfully without an approval, authorization, or license under EO 12470 or the Arms Export Control Act and that such data require an approval, authorization, or license under EO 12470 or the Arms Export Control Act. For purposes of making this determination, the Military Critical Technologies List (MCTL) shall be used as general guidance. All documents determined to contain export controlled technical data will be marked with the following notice:

WARNING- this document contains technical data whose export is restricted by the Arms Export Control Act (Title 22, U.S.C., and Sec 2751, et seq.) or the Export Administration Act of 1979, as amended, Title 50, U.S.C., App. 2401 et seq. Violations of these export laws are subject to severe criminal penalties. Disseminate in accordance with provision of DOD Directive 5230.25.

(2) Flowdown.

The PAH shall include this Article, suitably modified, to identify all Parties, in all Project Agreements or lower tier agreements. This Article shall, in turn, be included in all sub-tier subcontracts or other forms of lower tier agreements, regardless of tier.

Article XIII. TITLE AND DISPOSITION OF PROPERTY

Section 13.01 Definitions

In this Article, “property” means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

Section 13.02 Title to Property

No significant items of property are expected to be acquired under this Agreement by the PAH. Title to any item of property valued $10,000.00 or less that is acquired by the PAH pursuant to a Project Agreement with the MCDC, in performance of the project issued to the PAH under this OTA shall vest in the PAH upon acquisition with no further obligation of the Parties unless otherwise determined by the Government AO. Should any item of property with an acquisition value greater than $10,000.00 be required, the PAH through the CMF shall obtain prior written approval of the Government AO. Title to this property shall also vest in the MCDC member entity or PAH upon acquisition. That PAH shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this clause shall not be considered as in exchange for services in performance of the project, but shall be considered a Government contribution to the project.

Section 13.03 Government Furnished Property

The Government may provide the PAH Government Furnished Property (GFP) to facilitate the performance of individual projects under this Other Transaction Agreement. Such GFP will be specifically identified to a particular project and incorporated into the applicable Project Agreement. The GFP shall be utilized only for the performance of that individual project unless a specific exception is made in writing by the Agreements Officer.

The PAH shall assume the risk of and be responsible for any loss or destruction of, or damage to, any Government Furnished Property while in its possession or control, with the exception of reasonable wear and tear or reasonable and proper consumption. All property shall be returned at the end of the Project Agreement in as good as condition as when received with the exception of said reasonable wear and tear or in accordance with the provisions of the Project Agreement regarding its use. The PAH shall obtain explicit written authorization for any transfer or disposition of Government Furnished Property.

Article XIV. CIVIL RIGHTS ACT

This Agreement and any resulting Project Agreement is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. It is the responsibility of each PAH to assure the PAH has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act (Attachment 1).

Article XV. NO SMALL BUSINESS AFFILIATION

Reserved

Article XVI. ANTITRUST

In the MCDC Articles of Collaboration, members agree to comply with all applicable U.S. laws, including U.S. antitrust laws. The MCDC is recognized under the National Cooperative Research and Production Act of 1993 and the MCDC will be similarly filing under the Act.

Article XVII. SECURITY & OPSEC

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information (CDI) will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

Work performed by a PAH under a Project Agreement may involve access to Controlled Unclassified Information (CUI). All Controlled Unclassified Information (CUI) developed under this Agreement will be managed in accordance with DoD Manual 5200.01, Volume 4 dated February 24, 2012. Contractor personnel shall comply with applicable Technology Protection Plans (TPP), Interim Program Protection Plans (IPPP) and/or Program Protection Plans (PPP). If a project involves a Controlled Unclassified Information (CUI) effort, the below listed Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS), and ARDEC clauses will be incorporated into the Project Agreements by reference with the same force and effect as if they were given in full text.

(1) Each project Scope of Work will be provided by the Agreements Officer Representative (AOR) to the Joint Project Manager- Medical Countermeasure Systems Office for dissemination to the appropriate Fort Detrick COMSEC officer prior to award for review.
(2) Each project Scope of Work will be subject to Ft. Detrick policy and procedure according to DoD 5220.22-M, (National Industrial Security Program Operating Manual, NISPOM), as deemed applicable and appropriate during the security review process and prior to award. Additional COMSEC requirements may be required at other locations/facilities (based on service/command requirements).
(3) Specific applicable policies, instructions, and regulations will be identified in each project. Throughout the life of the Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply. The following is a snapshot of key regulatory documents, policies, regulations, etc. that may be applicable at time of project award.
    a) DoDM 5200.01 DoD Information Security Program, 24 Feb 12
    b) DoD 5200.2-R Personnel Security Regulation, Jan 87
    c) DoDD 5220.22 National Industrial Security Program, 28 Feb 06
    d) DoDI 5200.01, Information Security Program and Protection of Sensitive Compartmented Information, 24 Feb 2012
    e) DoD 5400.7-R, DOD Freedom of Information Act, Sept 98
    f) DoDD 2000.12, Antiterrorism Program, 18 Aug 03
    g) FAR Clause 4.402, Safeguarding Classified Information Within Industry

h) FAR Clause 52.204-2, Security Requirements, Aug 1996

(4) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - "The security level for this agreement is UNCLASSIFIED."

(5) Anti-Terrorism Level I Training. This provision is for PAH employees with an area of performance within an Army controlled installation, facility or area. All PAH employees requiring access to Army installations, facilities and controlled access areas shall complete AT Level I awareness training within sixty (60)-calendar- days after project start date or effective date of incorporation of this requirement into the project, whichever is applicable. PAH(s) shall submit certificates of completion for each affected employee and PAH employee, to the AOR or to the Agreements Officer, if an AOR is not assigned, within thirty (30)-calendar-days after completion of training by all employees or personnel. AT level I awareness training is available at the following website: https://atlevel1.dtic.mil/at.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is for PAH employees with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

(7) Anti-Terrorism Awareness Training for PAH Personnel Traveling Overseas. This standard language text requires U.S.-based PAH employees to make available and to receive Government provided area of responsibility (AOR) specific AT awareness training as directed by AR 525-13. Specific AOR training content is directed by the combatant commander with the unit Anti-terrorism Officer (ATO) being the local point of contact.

(8) iWATCH Training. This standard language is for PAH employees with an area of performance within an Army- controlled installation, facility or area. PAH(s) shall brief all employees on the local iWATCH program (training standards provided by the requiring activity ATO). This local developed training will be used to inform employees of the types of behavior to watch for and instruct employees to report suspicious activity to the AOR. This training shall be completed within sixty (60)-calendar-days of a Project Agreement award and within sixty (60)-calendar- days of new employees' commencing performance with the results reported to the AOR NLT thirty (30)-calendar-days after Project Agreement award.

(9) Impact on PAH performance during increased FPCON during periods of increased threat. During FPCONs Charlie and Delta, services may be discontinued / postponed due to higher threat. Services will resume when FPCON level is reduced to Bravo or lower.

(10) Random Antiterrorism Measures Program (RAMP) participation. PAH personnel working on an installation are subject to participation in Installation RAMP security program (e.g. vehicle searches, wearing of ID badges, etc.).

(11) PAH Employees Who Require Access to Government Information Systems. All PAH employees with access to a government information system must be registered in the ATCTS (Army Training Certification Tracking System) at commencement of services, and must successfully complete the DOD Information Assurance Awareness prior to access to the IS and then annually thereafter.

(12) For projects that Require an OPSEC Standing Operating Procedure/Plan. The PAH shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer, per AR 530-1, Operations Security. This plan will be submitted by MCDC on behalf of the PAH(s) to the AO for coordination of approvals. This SOP/Plan will include the Government's critical information, why it needs to be protected, where it is located, who is responsible for it and how to protect it. In addition, MCDC shall identify an individual who will be an OPSEC Coordinator. MCDC will ensure this individual becomes OPSEC Level II certified per AR 530-1.

(13) For projects that Require OPSEC Training. Per AR 530-1, Operations Security, new PAH employees assigned by the PAH(s) to perform under a MCDC Project Agreement must complete Level I OPSEC awareness training within thirty (30)-calendar-days of their reporting for duty. All PAH employees performing under an OPSEC-designated project must complete annual Level I OPSEC awareness training. Level I OPSEC awareness training is available at the following website: http://cdsetrain.dtic.mil/opsec/.

(14) For Information assurance (IA)/information technology (IT) training. All PAH employees must complete the DoD IA awareness training before issuance of network access and annually thereafter. All PAH(s) working IA/IT functions must comply with DoD and Army training requirements in DoDD 8570.01, DoD 8570.01-M and AR 25-2 within six (6) months of employment.

(15) For information assurance (IA)/information technology (IT) certification. Per DoD 8570.01-M , DFARS 252.239-7001 and AR 25-2, the PAH employees supporting IA/IT functions shall be appropriately certified upon Project Agreement award. The baseline certification as stipulated in DoD 8570.01-M must be completed upon Project Agreement award.

(16) For PAH personnel authorized to accompany the Force. DFARS Clause 252.225-7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States. The clause shall be used in projects that authorize PAH personnel to accompany U.S. Armed Forces deployed outside the U.S. in contingency operations; humanitarian or peacekeeping operations; or other military operations or exercises, when designated by the combatant commander. The clause discusses the following AT/OPSEC related topics: required compliance with laws and regulations, pre-deployment requirements, required training (per combatant command guidance) and personnel data required.

(17) For projects requiring Performance or Delivery in a Foreign Country, DFARS Clause 252.225-7043, Antiterrorism/Force Protection for Defense Contractors Outside the U.S. The clause shall be used in projects that require performance or delivery in a foreign country. This clause applies to both contingencies and non-contingency support. The key AT requirement is for non-local national PAH personnel to comply with theater clearance requirements and allows the combatant commander to exercise oversight to ensure the PAH’s compliance with combatant commander and subordinate task force commander policies and directives.

(18) For projects requiring the PAH to obtain U.S. Government Common Access Cards, installation badges, and/or access passes, the PAH shall return all issued U.S. Government Common Access Cards, installation badges, and/or access passes to the AOR when the project is completed or when the PAH employee no longer requires access to the installation or facility.

(19) For projects that require access to Potential Critical Program Information (PCPI) / Critical Program Information (CPI):

a) The PAH shall comply with the associated Interim Program Protection Plan (IPPP) / Program Protection Plan (PPP) / or Technology Protection Plan (TPP). The PAH shall comply with DOD, DA and AMC technology protection requirements in DODI 5200.39, AR 70-1, DA PAM 70-3 and AMC-R-380-13.

(20) Work by the Consortium Management Firm (CMF) and Project Agreement Holder/Consortium Member (PAH) under Project Agreements may involve access to Controlled Unclassified Information (CUI) as well as information classified as "Confidential", "Secret", or "Top Secret". The CMF and the PAH and their employees who work on such Project Agreements shall comply with (1) the Security Agreement (DD Form 441), including the National Industrial Security Program Operation Manual (DOD 5220.22M), (2) any revisions to that manual that may be issued, and (3) the Agreement security classification specification (DD form 254) if included, and all security requirements including but not limited to OPSEC plans and those security requirements specific to the individual projects. During the course of this Agreement the Parties may determine that information developed by the PAH and/or the Government pursuant to this Agreement shall be treated as classified. Such information shall be classified in accordance with DOD 5220.22M.

a) Each project Scope of Work will be provided by the AOR to the AOR's local Security Office prior to award for review. For classified efforts that Security Office will provide the overall Security Classification Specification (DD Form 254). The PAH will be responsible for providing a copy of any Subcontract Security Classification Specification (DD Form 254) to lower tier awards.

b) If a Project Agreement involves a classified effort or a Controlled Unclassified Information (CUI) effort, Department of Defense Directives, Federal Acquisition Regulation (FAR) and the Defense Federal Acquisition Regulation Supplement (DFARS) clauses by reference, and local clauses will be incorporated with the same force and effect as if they were given in full text shall be incorporated into this agreement.

c) Specific applicable policies, instructions, and regulations will be identified in each Project Agreement. Throughout the life of the Project Agreement, if any policy, instruction, or regulation is replaced or superseded, the replacement or superseding version shall apply.

d) Agreement Structure

i) Research and Development under these Project Agreements will be in accordance with the Other Transaction Agreement (OTA) between the United States Army Contracting Command – New Jersey (ACC-NJ) and the MCDC in care of its Consortium Management Firm (CMF), Advanced Technology International (ATI).

ii) Within the Project Agreements, sharing of classified information will be on a need to know basis as directed in required Project Agreements.

iii) Upon Project Agreement completion or termination, the PAH must:

(1) Return ALL classified information received or generated under the Project Agreement;
(2) Destroy all of the classified information; or,
(3) Request retention for a specified period of time

Flowdown for OPSEC/Security Requirements:

MCDC shall include the aspects of this Article as they pertain to each project requirement. Each project will include specific OPSEC / Security requirements within each SOW and RPP. The requirements delineated within each project, in turn, shall be included in all sub-tier subcontracts or other forms of lower-tier agreements, regardless of tier.

Article XVIII. SAFETY

The PAH shall adhere to all local, state, and federal rules and regulations required in maintaining a safe and non-hazardous occupational environment throughout the duration of the project. At a minimum, the PAH shall provide the following reports and materials on an as needed basis:

Accident/Incident Report: The PAH shall report immediately any major accident/incident (including fire) resulting in any one or more of the following: causing one or more fatalities or one or more disabling injuries; damage of Government property exceeding $10,000; affecting program planning or production schedules; degrading the safety of equipment under a project, such as personnel injury or property damage may be involved; identifying a potential hazard requiring corrective action. The PAH shall prepare the report (DI-SAFT-81563) for each incident.

Material Safety Data Sheets (MSDS): The PAH shall prepare and maintain MSDS for all materials used and generated under this Agreement.

Environmental Requirements include the following:

Pollution Prevention: Consideration should be given to alternative materials and processes in order to eliminate, reduce, or minimize hazardous waste being generated. This is to be accomplished while minimizing item cost and risk to item performance.

Environmental Compliance: All activities must be in compliance with Federal, State, and local environmental laws and regulations, Executive orders, treaties, and agreements. The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during the conduct of efforts undertaken under this Agreement.

Hazardous Waste Report: The PAH shall evaluate the environmental consequences and identify the specific types and amounts of hazardous waste being generated during this Agreement. The PAH shall submit a Hazardous Waste Report IAW DI-MGMT-80899.

Disposal Instructions for Residual/Scrap Materials: The PAH shall dispose of all residual and scrap materials generated from this Agreement, including high explosives. The PAH shall specify the anticipated quantities, methods, and disposal costs.

Article XIX. REPRESENTATIONS AND WARRANTIES

Section 19.01 Representations and Warranties of All Parties

Each Party to this Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

Section 19.02 Limitations

Except as expressly provided herein, no party to this Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this agreement, or (2) any invention conceived and/or reduced to practice under this agreement, or (3) any other intellectual property developed under this Agreement, and each party to this Agreement specifically disclaims any implied warranty of merchantability or warranty of fitness for a particular purpose.

Article XX. LIABILITY OF THE PARTIES

Section 20.01 Waiver of Liability

With regard to the activities undertaken pursuant to this Agreement, no Party shall make any claim against the others, employees of the others, the others' related entities (e.g., Government, contractors, subcontractors, etc.), or employees of the others' related entities for any injury to or death of its own employees or employees of its related entities, or for damage to or loss of its own property or that of its related entities, whether such injury, death, damage or loss arises through negligence or otherwise, except in the case of willful misconduct.

Section 20.02 Damages

The Parties shall not be liable to each other for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

Section 20.03 Extension of Waiver of Liability

The PAH agrees to extend the waiver of liability as set forth above subawardees at any tier under an Project Agreement by requiring them, by contract or otherwise, to agree to waive all claims against the Parties to this Agreement.

Section 20.04 Applicability

Notwithstanding the other provisions of this article, this Waiver of Liability shall not be applicable to:

(1) Claims between the PAH and the CMF regarding a material breach, noncompliance, or nonpayment of funds;

(2) Claims for damage caused by willful misconduct; and

(3) Intellectual property claims.

Section 20.05 Limitation of Liability

In no case shall the CMF, or the PAH's financial liability exceed the amount obligated by the Government or committed as a Cash Contribution or In-kind Contribution by a MCDC member entity under a Project Agreement. Nothing in this Article shall be construed to create the basis of a claim or suit where none would otherwise exist.

Article XXI. GENERAL PROVISIONS

Section 21.01 Fees

The PAH will not be constrained from the payment of an appropriate fee or profit for the effort being conducted on a Project Agreement when cost share is not being contributed. The fees shall be specific to the individual Project Agreements and negotiated on project by project basis.

Section 21.02 Waiver

No waiver of any rights shall be effective unless assented to in writing by the party (Government, MCDC, CMF, or PAH) to be charged, and the waiver of any breach or default shall not constitute a waiver of any other right hereunder or any subsequent breach or default.

Section 21.03 Section Headings

The headings and subheadings of the sections of this Agreement are intended for convenience of reference only and are not intended to be a part of, or to affect the meaning or interpretation of this Agreement.

Section 21.04 Severability

In the event that any provision of this Agreement becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement shall continue in full force and effect without said provision; Provided that no such severability shall be effective if the result of such action materially changes the economic benefit of this Agreement to the Parties.

Section 21.05 Force Majeure

No failure or omission by the CMF or the MCDC PAH in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of the Parties, including but not limited to, the following: acts of God; Acts or omissions of any Government; Any rules, regulations or orders issued by any Governmental authority or by any officer, department, and agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; and invasion and provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the occurrence of one or more of the above mentioned causes.

Section 21.06 Regulatory Affairs

Development and production of medical products and processes fall under the purview of the Food and Drug Administration (FDA) and research on these products involving animal or human studies is regulated by other laws, directives, and regulations. Project Awards under this Agreement that involve work in support of or related to FDA regulatory approval will address contingencies for Government access to regulatory rights in the event of product development abandonment or failure. Efforts conducted under this OTA shall be done ethically and in accordance with all applicable laws, directives, and regulations.

The Government shall ensure performance includes regulatory expertise and guidance for candidate medical countermeasure development efforts:

(1) This includes allowing the government to discuss/negotiate in partnership with the consortium how to assume appropriate risk in regulatory strategies. The government will review, negotiate, and come to consensus with the PAH on product-specific risk-based decisions.

(2) PAHs will use all regulatory programs to accelerate the pace of candidate medical countermeasure development, including fast-track status, and as appropriate meeting requirements for priority review vouchers, applying for breakthrough therapy and accelerated approval as appropriate (see FDA Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics).

(3) PAH will provide FDA submissions to the government such as all documentation requested by FDA and all proposals to FDA.

(4) PAH will allow the government to monitor all FDA communications by listening to teleconferences and attending meetings.

(5) PAH will allow the government to attend regulatory site visits and audits, and actively participate in all third-party audits.

(6) PAH will comply with Quality Assurance according to negotiated standards with the government on reports, material for Interim Fielding Capability (such as Emergency Use Authorization or Expanded Access Protocols), product for trials, prototypes, etc.

(7) PAH will provide strategies to address contingencies that could arise from regulatory directives, and regulatory failures.

Section 21.07 Radioactive Materials

PAH shall ensure compliance with the provisions of Title 10 CFR 21. This regulation establishes procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

Section 21.08 Recombinant DNA

PAH shall ensure that all work involving the use of recombinant DNA will be in compliance with guidance provided at the following website: http://www4.od.nih.gov/oba (National Institutes of Health [NIH] Guidelines for Research Involving Recombinant DNA Molecules).

Section 21.09 Required Compliance for Use of Laboratory Animals

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the PAH is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office,. The PAH shall receive written approval to begin research under the applicable protocol proposed for a Project Agreement from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the PAH and Principal Investigator. A copy of this approval will be provided to the ACC-NJ for the official file. Non-compliance with any provision of this clause may result in the termination of award. Information is provided at the following website http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_regulations. The PAH will conduct advanced development/pivotal studies including human safety studies, animal efficacy studies or clinical studies required for approval using validated endpoints, and other studies as deemed necessary by the FDA for licensure of the candidate product in adherence to current Good Laboratory Practice regulations, current Good Clinical Practice regulations, and all other applicable FDA regulations in the conduct of non-clinical and clinical studies as defined by FDA guidance (21 CFR Parts 210-211).

Section 21.10 Required Compliance for Use of Human Subjects

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol in accordance with 45 CFR Part 46. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following website: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo.

Section 21.11 Required Compliance for use of Human Anatomical Substances

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to ACC-NJ, from the CMF, for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award. Information is provided at the following web site: http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo

Section 21.12 Compliance with current Good Manufacturing Processes (cGMP)

Manufacturing Standards as appropriate for the level of prototype Material used for clinical trials, pivotal non-clinical studies, consistency lots, and other uses as defined in regulatory plans should be compliant with current Good Manufacturing Processes (cGMP) as defined by FDA guidance (21 CFR Parts 210-211). If at any time during the life of the award, the PAH fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the PAH shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure.

Section 21.13 Registration with Select Agent Program

Where required, consortium members performing studies and tasks using select biological agent or toxins should be registered with the program with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied. Listings of select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

Section 21.14 Duty-Free Entry

(a) *Definitions*. As used in this clause –

(1) "Component," means any item supplied to the Government as part of an end product or of another component.
(2) "Customs territory of the United States" means the 50 States, the District of Columbia, and Puerto Rico.
(3) "Eligible product" means –
(i) "Designated country end product" as defined in the Trade Agreements clause;
(ii) "Free Trade Agreement country end product" other than a "Bahrainian end product" or a "Moroccan end product" as defined in the Buy American Act – Free Trade Agreements – Balance of Payments Program; or
(iii) "Canadian end product" as defined in Alternate I of the Buy American Act – Free Trade Agreements – Balance of Payments Program.
(4) "Qualifying country" and "qualifying country end product" have the meanings given in the Trade Agreements clause, the Buy American Act and Balance of Payments Program clause, or the Buy American Act—Free Trade Agreements—Balance of Payments Program.

(b) Except as provided in paragraph (i) of this clause, or unless supplies were imported into the customs territory of the United States before the date of a Project Agreement or the applicable subcontract, the price of this Agreement shall not include any amount for duty on-
(1) End items that are eligible products or qualifying country end products;
(2) Components (including, without limitation, raw materials and intermediate assemblies) produced or made in qualifying countries, that are to be incorporated in U.S – made end products to be delivered under an Project Agreement; or
(3) Other supplies for which the PAH estimates that duty will exceed $200 per shipment into the customs territory of the Unites States

(c) The PAH shall –
(1) Claim duty-free entry only for supplies that the PAH intends to deliver to the Government under an Project Agreement, either as end items or components of end items; and
(2) Pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use, other than –
(i) Scrap or salvage; or
(ii) Competitive sale made, directed, or authorized by the Agreements Officer.

(d) Except as the PAH may otherwise agree, the Government will execute duty-free entry certificates and will afford such assistance as appropriate to obtain the duty-free entry of supplies –
(1) For which no duty is included in the Project Agreement price in accordance with paragraph (b) of this clause; and
(2) For which shipping documents bear the notation specified in paragraph (e) of this clause.

(e) For foreign supplies for which the Government will issue duty-free entry certificates in accordance with this clause, shipping documents submitted to Customs shall –
(1) Consign the shipments to the appropriate –
(i) Military department in care of the PAH, including the PAH's delivery address; or

(ii) Military installation; and

(2) Include the following information:

(i) Prime Agreement number and, if applicable, delivery order number.

(ii) Number of the subcontract for foreign supplies, if applicable.

(iii) Identification of the carrier.

(iv) (A) For direct shipments to a U.S. military installation, the notation: "UNITED STATES GOVERNMENT DEPARTMENT OF DEFENSE Duty-Free Entry to be claimed pursuant to Section XXII, Chapter 98, Subchapter VIII, Item 9808.00.30 of the Harmonized Tariff Schedule of the United States. Upon arrival of shipment at the appropriate port of entry, District Director of Customs, please release shipment under 19 CFR Part 142 and notify Commander, Defense Contract management Agency (DCMA) New York, ATTN: Customs Team, DCMAE-GNTF, 207 New York Avenue, Staten Island, New York, 10305-5013, for execution of Customs Form 7501, 7501A, or 7506 and any required duty-free entry certificates."

(B) If the shipment will be consigned to other than a military installation, e.g., a domestic contractor's plant, the shipping document notation shall be altered to include the name and address of the contractor, agent, or broker who will notify Commander, DCMA New York, for execution of the duty-free certificate. (If the shipment will be consigned to a contractor's plant and no duty-free entry certificate is required due to a trade agreement, the PAH shall claim duty-free entry under the applicable trade agreement and shall comply with the U.S. Customs Service requirements. No notification to Commander, DCMA New York, is required.)

(v) Gross weight in pounds (if freight is based on space tonnage, state cubic feet in addition to gross shipping weight.)

(vi) Estimated value in U.S. dollars.

(vii) Activity address number of the contract administration office administering the prime contract, e.g., for DCMA Dayton, S3605A.

(f) *Preparation of customs forms.*

(1)(i) Except for shipments consigned to a military installation, the PAH shall –

(A) Prepare any customs forms required for the entry of foreign supplies into the customs territory of the United States in connection with this Agreement; and

(B) Submit the completed customs forms to the District Director of Customs, with a copy to DCMA NY for execution of any required duty-free entry certificates.

(ii) Shipments consigned directly to a military installation will be released in accordance with sections 10.101 and 10.102 of the U.S. Customs regulations.

(2) For shipments containing both supplies that are to be accorded duty-free entry and supplies that are not, the PAH shall identify on the customs forms those items that are eligible for duty-free entry.

(g) The PAH shall –

(1) Prepare (if the PAH is a foreign supplier), or shall instruct the foreign supplier to prepare, a sufficient number of copies of the bill of lading (or other shipping document) so that at least two of the copies accompanying the shipment will be available for use by the District Director of Customs at the port of entry;

(2) Consign the shipment as specified in paragraph (e) of this clause; and

(3) Mark on the exterior of all packages –

(i) "UNITED STATES GOVERNMENT, DEPARTMENT OF DEFENSE"; and

(ii) The activity address number of the contract administration office administering the prime Agreement.

(h) The PAH through the MCDC CMF shall notify the ACO in writing of any purchase of eligible products of qualifying country supplies to be accorded duty-free entry, that are to be imported into the customs territory of the United States for delivery to the Government or for incorporation in end items to be delivered to the Government. The PAH through the MCDC CMF shall furnish the notice to the ACO immediately upon award to the supplier and shall include in the notice –

(1) The PAH's name, address, and Commercial and Government Entity (CAGE) code;

(2) Prime Agreement number and Project Agreement number;

(3) Total dollar value of the prime Agreement or Project Agreement number;

(4) Date of the last scheduled delivery under the prime Agreement or Project Agreement number;
(5) Foreign supplier's name and address;
(6) Number of the subcontract for foreign supplies;
(7) Total dollar value of the subcontract for foreign supplies;
(8) Date of the last scheduled delivery under the subcontract for foreign supplies;
(9) List of items purchased;
(10) An agreement that the PAH will pay duty on supplies, or any portion thereof, that are diverted to nongovernmental use other than –
  (i) Scrap of salvage; or
  (ii) Competitive sale made, directed, or authorized by the Agreements Officer;
(11) Country or origin; and
(12) Scheduled delivery date(s).

(i) This clause does not apply to purchases of eligible products or qualifying country supplies in connection with this Agreement if –
  (1) The supplies are identical in nature to supplies purchased by the PAH or any subcontractor in connection with its commercial business; and
  (2) It is not economical or feasible to account for such supplies so as to ensure that the amount of the supplies for which duty-free entry is claimed does not exceed the amount purchased in connection with this Agreement.

(j) The PAH shall –
  (1) Insert the substance of this clause, including this paragraph (j), in all subcontracts for –
    (i) Qualifying country components; or
    (ii) Nonqualifying country components for which the PAH estimates that duty will exceed $200 per unit;
  (2) Require subcontractors to include the number of this Agreement on all shipping documents submitted to Customs for supplies for which duty-free entry is claimed pursuant to this clause; and
  (3) Include in applicable subcontracts –
    (i) The name and address of the ACO for this Agreement;
    (ii) The name, address, and activity address number of the contract administration office specified in this Agreement; and
    (iii) The information required by paragraphs (h)(1), (2), and (3) of this clause.

Section 21.15 Follow-On Production

10 U.S.C. § 2371b, Section 815 authorizes the use of a follow-on production contract (FAR) or transaction (OTA). In order to be eligible for follow-on production, the following criteria is required: (1) the follow-on shall be awarded to the same participants named in the Project Agreement; (2) competitive procedures were used to award the Project Agreement in question; and (3) the Project Agreement was successfully completed. This Agreement was the result of competitive procedures, and competitive procedures are used to award individual projects under this Agreement. The Agreements Officer shall be responsible for documenting whether or not a Project Agreement was successfully completed. Follow-on production efforts shall be strictly limited to the scope of the successfully completed prototype. This Agreement will not be used to award follow-on production efforts; Government customers will be responsible for working with their contracting personnel.

All Project Agreements shall include the following statement:

"In accordance with 10 U.S.C. § 2371b(f), and upon a determination that this competitively awarded prototype project has been successfully completed, this prototype project may result in the award of a follow-on production contract or transaction without the use of competitive procedures."

Article XXII. ASSIGNMENT OF AGENCY

Section 22.01 Assignment.

Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party.

Article XXIII. ORDER OF PRECEDENCE

In the event of any inconsistency between the general terms of this Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Agreement; (2) Attachments to the Agreement; (3) the Project Agreement documentation (including but not limited to the PAH proposal selected for funding by the Government). In any event, specifically negotiated Project Agreement terms will govern over general terms of this Agreement.

Article XXIV. EXECUTION

This Agreement constitutes the entire Agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the PAH and the CMF Contracting Representative designated in this Agreement.

Attachment I – Assurance of Compliance with Title VI of the Civil Rights Act of 1964

Statement of Assurance of Compliance with
Title VI of the Civil Rights Act of 1964
For MCDC Member Organizations

The Pfizer Inc. hereby agrees that it will comply with the provisions of the Title VI Civil Rights Act of 1964 as amended (42 U.S.C 2000-d) and all requirements imposed pursuant thereto, to the end that, in accordance with Title VI of that Act and the Regulation, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any MCDC Project for which the MCDC member organization receives Federal financial assistance from the Government.

The MCDC member organization agrees that compliance with this assurance constitutes a condition of continued receipt of Federal financial assistance, and that it is binding upon the MCDC member organization, its successors, transferees and assignees for the period during which such assistance is provided.

The MCDC member organization further recognizes and agrees that the United States shall have the right to seek judicial enforcement of this assurance.

The person or persons whose signature(s) appear(s) below is/are authorized to sign this assurance, and commit the MCDC member organization to the above provisions.

[redacted]

_____
Signature of Authorized Official

[redacted]

_____
Title of Authorized Official

Pfizer Inc.

_____
Name of MCDC Member Organization

July 20, 2020

_____
Date

EXHIBIT C

DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

21 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for "COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration" (Pfizer, Inc.)

REF: Prizer Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 20 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-11 on 09 June 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Pfizer, Inc. as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Pfizer, Inc. to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Pfizer, Inc.'s proposal for "COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The price proposed that has been analyzed by the Government, you are hereby directed to issue a Project Agreement to Pfizer, Inc. for the subject project. The total project value has been determined fair and reasonable and Pfizer, Inc.'s proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed $1,950,097,500.00. The break-out of the costs is as follows: $1,950,000,000.00 to perform project efforts included in the SOW and $97,500.00 for the Consortium Management Firm (CMF) Administrative Cost. The CMF Administrative Cost was approved as a "Special Allocation" for Operation Warp Speed (OWS) Prototype Projects executed under the MCDC OTA. The effort currently has $1,950,097,500.00 of available funding, comprised of $1,950,000,000.00 for the Project Agreement, $67,500.00 for the CMF Special Allocation, and $30,000 for other, non G&A, ATI costs, which will be incurred, tracked,

and invoiced in accordance with Article V of the OTA. The COVID-19 work shall be tracked separately using the funding obligated via modification P00076. In alignment with the special allocation conditions, it is noted that this project has a base period of performance (b) (4) , with a projected completion date of (b) (4) . A customized clause for the special allocation, will be incorporated into the funding modification for this prototype project.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: MCDC2011-003 – Pfizer - 7-21-2020
Attachment 2: SOW Appendix 1 Clause for MCDC Consortium Other Transaction Authority Agreements

Statement of Work
For
COVID-19 PANDEMIC–LARGE SCALE VACCINE MANUFACTURING DEMONSTRATION

RPP #: 20-11
Project Identifier: 2011-003
Consortium Member: Member
Title of Proposal: COVID-19 Pandemic--Large Scale Vaccine Manufacturing Demonstration
Requiring Activity: Joint mission between the Department of Health and Human Services and Department of Defense to combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

This Statement of Work (the "Statement of Work") is hereby entered into, effective as of July 21, 2020, pursuant to that certain Project Agreement by and between MCDC and Pfizer dated as of July 21, 2020 ("this Agreement" or "Project Agreement").

An outbreak of respiratory disease caused by a novel coronavirus was first detected in China in late 2019 and has now spread worldwide, including the United States ("US"). The virus has been named Severe Acute Respiratory Disease Coronavirus-2 ("SARS-CoV-2") and causes Coronavirus Disease 2019 ("COVID-19"). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization ("WHO"), declared the outbreak a "Public Health Emergency of International Concern". On January 31, the US Department of Health and Human Services Secretary ("HHS"), Alex M. Azar II, declared a Public Health Emergency for the US to aid the nation's healthcare community in responding to COVID-19. On March 11, 2020, WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID-19 outbreak a national emergency. The Government has identified COVID-19 vaccine candidates that are progressing rapidly through advanced research and development activities.

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

Pfizer and BioNTech's program aims to revolutionize the vaccine field by providing an mRNA candidate that, itself, has several key advantages, including the efficiency and flexibility of the platform – which is apparent by the pace of the vaccine development and the unprecedented phase

1/2/3 trial design that it supports. A clear fundamental difference of this candidate over more traditional modalities, such as viral vector vaccines, is that mRNA is delivered by protein-free lipid nanoparticles, which is believed to abolish the risk of anti-vector immunity and permit boosting to maximize the level and duration of immune responses.

The mRNA vaccine technology is also intended to enable quick scale up of production, which is critical for bringing a COVID-19 vaccine to market to address this urgent medical need while preserving high quality and safety standards.

The intent of this prototype project is to demonstrate that Pfizer has the business and logistics capability to manufacture 100M doses of its currently unapproved mRNA-based COVID-19 vaccine for the Government (b) (4), using the Pfizer/BioNTech unique mRNA delivery system and its associated cold chain requirements, under pandemic conditions. This prototype project aims to significantly accelerate and secure US access to this promising medical countermeasure based on domestic manufacturing.

1.1.1 BACKGROUND

(b) (4), Pfizer and BioNTech entered into an agreement for the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection (the "Pfizer/BioNTech Agreement"). Under the Pfizer/BioNTech Agreement, (b) (4)

for the prevention of COVID-19 (b) (4)

for the prevention of COVID-19 (b) (4)

(b) (4)

(b) (4) [redacted]

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

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

This Statement of Work is designed toward establishing production capacity and distribution infrastructure sufficient to ensure that doses of the vaccine manufactured under this Agreement can be made available immediately for administration in the US, if clinical trials are successful and the FDA grants an Emergency Use Authorization ("EUA") under Section 564 of the Federal Food, Drug, and Cosmetic Act or Biologics License Application ("BLA") licensure under Section 351(a) of the Public Health Service Act (hereafter "FDA-approved or authorized").

1.1.2 ACTIVITIES UNDERTAKEN WITHOUT GOVERNMENT FUNDING

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

A. Regulatory Planning

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

B. Clinical and Regulatory Approach

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

Prior to commencing clinical development, on February 6, 2020, BioNTech obtained feedback from the Paul Ehrlich Institute ("PEI") on plans for rapid vaccine development in response to the COVID-19 outbreak following a Scientific Advice Meeting. Based on the PEI feedback, BioNTech refined the clinical program plan and prepared a detailed protocol for FIH clinical study (BNT162). Additionally, a meeting was held by BioNTech on February 24, 2020 with the Chinese CDC to discuss a possible Special Review Procedure.

In Germany, BioNTech began a Phase 1/2 study (BNT162-01) in late April 2020. BNT162-01 is a dose-escalation trial investigating the safety and immunogenicity of COVID-19 mRNA vaccine candidates in healthy adults. The primary objective of the study is to describe the safety and tolerability profiles of prophylactic BNT162 vaccine candidates after a single dose (for saRNA) or two doses separated by 21 days (uRNA and modRNA candidates). The secondary objective of the study is to describe the immune response to the vaccine in healthy adults, as measured by a functional antibody assay, such as virus neutralization.

Informed by BNT162-01, the Phase 1/2 US study (C4591001) of the vaccine candidates started in May 2020. Pfizer and BioNTech utilized this approach to efficiently optimize formulation and dose selection in the clinic. Study C4591001 is a single, multistage and multi-phase trial (including the pivotal efficacy portion) designed to generate the data needed to achieve FDA approval or authorization for use of one of the vaccine candidates. This is a randomized, placebo-controlled, observer-blind, dose-finding and vaccine candidate-selection study in healthy adults. The study is evaluating the safety, tolerability, and immunogenicity of the COVID-19 mRNA vaccine candidates.

The study consists of 3 stages:

Stage 1: to identify preferred vaccine candidate(s), dose level(s), number of doses, and schedule of administration (with the first 15 participants at each dose level of each vaccine candidate comprising a sentinel cohort);

Stage 2: an expanded-cohort stage; and

Stage 3: a final candidate/dose large-scale stage.

Using this approach, Pfizer and BioNTech are efficiently working towards selection of final candidate/dose level.

The study currently is being amended to incorporate a pivotal efficacy study design. Therefore, the study would be converted to a single Phase 1/2/3 study. The pivotal study portion (*i.e.*, Phase 2b/3) is expected to enroll up to ~30,000 subjects (1:1 randomized between vaccine and placebo).

Upon gathering adequate safety and immunogenicity/efficacy data in a sufficient number of subjects, Pfizer believes the vaccine candidate could, with FDA's agreement, be administered under EUA.

As background, Pfizer's and BioNTech's activities to ensure provision of vaccine on a timely schedule may include the following discrete activities, depending on emerging data and regulatory guidance.

Activity	**Success Criteria**	**Estimated Timing**
Candidate, dose, and regimen selection	Decision endorsed by Pfizer-BioNTech Joint Steering Committee	(b) (4)
Phase 2b/3 Study Start	Requires FDA (CBER) approval	(b) (4)
Phase 1/2/3 Demonstration of immunogenicity, efficacy (interim analysis) and safety	Adequate efficacy and safety data supports EUA application	(b) (4)
EUA Submission to Support Use in American Population	Acceptance of EUA submission	(b) (4)
BLA Submission to Support Use in American Population	Agreement from FDA (CBER) that proposed licensure package (preclinical, clinical, CMC) is acceptable	(b) (4)
EUA Issuance to Support Use in American Population	EUA issued	(b) (4)
BLA Approval to Support Use in American Population	BLA approval	(b) (4)
Post-Approval Commitments Agreed	Agreement with FDA	(b) (4)

C. Chemistry Manufacturing Controls (CMC)

Pfizer will complete the necessary CMC and scale-up activities to demonstrate the ability to manufacture 100M doses (b) (4) . Pfizer will use diligent efforts to manufacture and quality release (using Pfizer's quality system) 100M doses within the US in a non-preservative multi-dose vial (b) (4)

Pfizer currently estimates potential production rates (b) (4) With GMP production expected to commence (b) (4) for drug product, this plan would allow for ~40M doses to be supplied under this Statement of Work in (b) (4). As Pfizer validates the facilities and makes continuous process improvements, Pfizer currently anticipates such production rate to increase starting in (b) (4) Should clinical data indicate that a lesser amount of dosage may be needed, there could be an increase in the anticipated potential number of doses supplied in (b) (4) .

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

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

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

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

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

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

In parallel, Pfizer is prepared to also evaluate alternative options including:

1. Conduct necessary stability and development studies to establish (b) (4)

2. Conduct necessary formulation and stability studies to develop (b) (4)

The CMC program may include, but not be limited to: (a) (b) (4) ; (b) drug substance development; (c) drug product development (LNP formulation, fill-finish); (d) analytical development in GLP and GMP setting; (e) GLP and GMP manufacturing; and (f) and shipping of -80 ºC frozen product.

(a) (b) (4)

(b) Drug Substance Development: Pfizer shall scale-up its capabilities for process optimization, manufacture, analysis, release of GMP materials (mRNA) and securing necessary raw materials from third party providers. For drug substance manufacture, Pfizer seeks to build-out the existing purification suite located at Pfizer's (b) (4) Pfizer shall supply incremental resources to transfer/implement new technology and GMP manufacturing processes, including technical experts, quality professionals, analytical technicians, and trained operational staff.

(c) Drug Product Development (Lipid Nanoparticle (LNP Formulation, Fill-Finish)): Activities Pfizer shall perform may include, but are not be limited to, securing of necessary lipids for formulation and manufacturing process development for BNT162; defining the formulation; and initial development of manufacturing process and analytical methods. Pfizer will undertake to (b) (4)

(d) Analytical Development: Analytical development may include, but not be limited to: methods transfer participation at receiving site and in-process testing support; process verification on commercial equipment; media fill runs; engineering trials; registration batch manufacture; and registration batch stability (pivotal stability) testing. (b) (4)

(e) GLP and GMP Manufacturing: Packaging, storage and distribution of clinical trial supplies for Phase 1/2 will be conducted by (b) (4)

(f) Shipping of -80 ºC frozen product: Pfizer is evaluating extension of current clinical packaging configuration using soft boxes and dry ice. (b) (4) As background, to maintain a timely completion schedule of the vaccine, Pfizer is aspiring to undertake the following discrete activities, without Government funding:

(b) (4)

1.2 Scope

The scope of this prototype project is the demonstration by Pfizer of the supply and logistics capability to manufacture and distribute to the Government of 100M doses of a novel mRNA-based vaccine that has received FDA-approval or authorization based on demonstration of efficacy (hereafter FDA-approved or authorized). The criteria for successful Emergency Use Authorization (EUA) are described in *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders, January 2017*; and *Development and Licensure of Vaccine to Prevent COVID-19: Guidance for Industry June 2020*. The successful provision of these doses shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections. While pre-clinical, clinical, and chemistry/manufacturing/controls (CMC) activities are described in the Background section of this Statement of Work, the Parties acknowledge and agree that such activities not related to the large-scale manufacturing demonstration are out-of-scope for this prototype project as Pfizer and BioNTech have and will continue to fund these activities, without the use of Government funding.

1.3 Objective

(a) Prototype Project

As set forth more fully in Section 11.7, the provisions of this Section 1.3 hereby supersede and replace, in their entirety, the provisions of Section 21.15 of the MCDC Base Agreement, 2020-532 (July 2018) ("Base Agreement").

Consistent with the Government's objectives under Operation Warp Speed, Pfizer intends to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act (to the extent required for COVID-19 medical countermeasures, as defined by relevant FDA guidance), to manufacture and deliver vaccine. Success of the prototype project is defined as manufacture of 100M doses of Pfizer and BioNTech's mRNA-based COVID-19 vaccine and, upon FDA-approval or authorization as described above, delivery of those doses in accordance with Section 6.0.

This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of completion of the prototype project during the ongoing COVID-19 pandemic and unprecedented threats to several components of the prototype project. In addition, this is a prototype project because Pfizer will demonstrate and prove-out the at-scale, multi-lot proprietary manufacturing activities in order to assess the feasibility to support the necessary quantity of safe and effective doses required for vaccination of the U.S. population and deliver those doses within challenging cold chain requirements in accordance with Section 6.0. Successful completion of the prototype project will demonstrate Pfizer's capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with limited advance notification and (ii) distribute large quantities of the FDA-approved or authorized drug product in accordance with Section 6.0. For clarity, any manufacturing and delivery of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutually acceptable production agreement between Pfizer and the Government.

(b) Follow-On Production Contract/Options

In accordance with 10.U.S.C. § 2371b(f), and upon a determination that the prototype project is successful, or at the accomplishment of particularly favorable or unexpected results that would justify transition to production, the Government and Pfizer may enter into a non-competitive, mutually-acceptable, follow-on production agreement for additional manufacturing of the vaccine without the use of competitive procedures, which agreement shall reflect an unfunded option on the basis set forth in the following paragraph (the "Option").

Under the Option, the Government may request that Pfizer produce and deliver up to 500M additional doses for purchase by the Government for delivery (b) (4) [redacted] Any order placed pursuant to the Option Agreement will provide for a

minimum of 100M doses, provided that the aggregate number of doses ordered under the Option shall not exceed 500M.

Upon any request pursuant to the Option, Pfizer shall inform the Government of appropriate lead times based on purchase of raw materials, capacity reservation and other factors, and Pfizer and the Government shall mutually agree on an appropriate estimated delivery schedule. Each order under the Option will be subject to the reasonably acceptance of Pfizer, it being understood that Pfizer shall have no obligation to accept any order pursuant to the Option that would involve (b) (4)

As promptly as practicable following the effective date of this Agreement, the Government and Pfizer will agree in principle upon a form of production agreement reflecting the Option that can be executed as a binding agreement promptly upon Government request following such determination, demonstration, or accomplishment.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Procedures, 21 CFR 210 and 211.

3.0 REQUIREMENTS

Pfizer shall conduct manufacturing activities to support production and distribution of vaccine doses after the final vaccine candidate from its development program is selected (currently expected to occur in July 2020). Subject to the terms and conditions of this Agreement, including without limitation Sections 3.1, 6.0, 11.5 and 11.6, Pfizer shall use diligent efforts to manufacture, quality release (using Pfizer's quality system), and deliver 100M doses of an FDA-approved or authorized vaccine in a preservative-free, multi-dose vial no later than the end of the period of performance (as defined in Section 3.1).

Pfizer anticipates providing the vaccine, subject to FDA approval or authorization, as -80 ºC frozen product that needs to be maintained at or below that temperature prior to dosing. The Government acknowledges that Pfizer's responsibility for cold chain will cease upon delivery in accordance with Section 6.0.

Pfizer anticipates providing the vaccine, subject to FDA-approval or authorization, as a concentrate that needs to be diluted at point of use prior to dosing. Vaccinators will need to use locally sourced 0.9% Sodium Chloride Injection, USP (Normal Saline), syringes and needles.

3.1 Period of Performance

The total proposed duration of this prototype initiative is (b) (4) with an expected completion date (b) (4) (the "period of performance"). If FDA-approval or authorization is not issued by October 31, 2020

as estimated in Section 1.1.2 above, and Pfizer expects it will be unable to timely complete performance, then the Parties will discuss in good faith a contract modification to shift forward the estimated delivery schedule to reflect the difference in time period between October 31, 2020 and the date of actual regulatory approval or authorization.

As a result of these discussions, the Government shall have the unilateral ability to extend the Period of Performance of this prototype project in increments of up to thirty (30) days at a time. In no event can this unilateral right to extend the period of performance require performance (b) (4) or result in a requirement for Pfizer to demonstrate the ability to manufacture more than 100M doses.

Notwithstanding the efforts and estimated dates set forth throughout this Statement of Work, and as set out more fully in Sections 11.5 and 11.6, both Parties recognize that the vaccine is currently in Phase 1/2 clinical trials and that, despite the diligent efforts of Pfizer and BioNTech in research, and development and manufacturing, the prototype project may not be successful due to technical, clinical, regulatory or manufacturing challenges or failures.

3.2 Management and Reporting

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

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

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

Pfizer shall provide, (b) (4) a synopsis of the Phase 2b/3 clinical trial protocol, which synopsis shall include [Overview of the Protocol, Objectives and Endpoints, Statistical Methods, and Schedule of Activities].

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

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

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

FDA communication, or other issue that would be reasonably expected to materially change the anticipated schedule by one week or more.

Except for reports expressly contemplated in this Statement of Work, Pfizer and the Government agree that Pfizer will not be subject to any reporting requirements contemplated in Section 1.05 of the Base Agreement.

4.0 DELIVERABLES

As set forth more fully in Sections 11.5 and 11.6, the Government understands that the dates set forth below are Pfizer's best estimate, as of the Execution Date of this Agreement, of its development and manufacturing timelines, and that these timeframes are subject to significant risks and uncertainties. Pfizer will promptly notify the Government of any event(s) that would be reasonably expected to materially alter projected Estimated Due Date for Deliverables 4.1 through 4.20.

The Government agrees that it will not resell any of the deliverables to any third party.

Deliverables

Del. #	Deliverable Description	Estimated Due Date	Format	SOW Reference	Government Role	Data Rights
4.1	Project Kick-Off materials	(b) (4)	Telecon. and related slides	--	Review	(b) (4)
4.2	Phase 2b/3 Clinical Trial Synopsis	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.3	Provision of PL 115-92 Sponsor Authorization Letter	(b) (4)	--	--	Review/ Approve	(b) (4)
4.4	(b) (4) Updates on Prototype Production Status	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.5	(b) (4) Business and Technical Report	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)

4.6	EUA Filing	[redacted]	Pfizer-determined format	[redacted]	Review	(b) (4)
4.7	BLA Filing	[redacted]	Pfizer-determined format	[redacted]	Review	(b) (4)
4.8	Delivery of 100M doses	(b) (4)	--	[redacted]	Receipt	(b) (4)
4.9	Release documentation for delivered doses	(b) (4)	Pfizer-determined format	[redacted]	Review	(b) (4)
4.10	Supply Chain Resiliency Plan or Pfizer Equivalent	(b) (4)	Pfizer-determined format	[redacted]	Review & Comment	(b) (4)
4.11	Manufacturing Data Requirement or Pfizer Equivalent	(b) (4)	Pfizer - determined format	[redacted]	Review & Comment	(b) (4)
4.12	Product Development Source Material & Manufacturing Reports and Projections	(b) (4)	Pfizer-determined format	[redacted]	Review & Comment	(b) (4)
4.13	Work Location Report or Pfizer Equivalent	(b) (4)	Pfizer-determined format	[redacted]	Review & Comment	(b) (4)
4.14	Facility Security Plan or Pfizer Equivalent	(b) (4)	Pfizer-determined format	[redacted]	Review & Comment	(b) (4)
4.15	Confirmation of Registration and Listing with FDA	(b) (4)		[redacted]	Review	(b) (4)

4.16	Formal Written Responses from the FDA	[redacted]		[redacted]	Review	(b) (4)
4.17	FDA Inspection and Compliance Notices, Observations and Responses	[redacted]		[redacted]	Review	(b) (4)
4.18	Manufacturing Development Plan*	(b) (4)		[redacted]	Review	(b) (4)
4.19	Quality Management Plan**	(b) (4)		[redacted]	Review	(b) (4)
4.20	Shipping Specifications and Details	(b) (4)		[redacted]	Review	(b) (4)

* Manufacturing Development Plan. Pfizer will, (b) (4) describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code ("U.S.C.") §351 (a)(2)(B)), regarding good manufacturing practices ("GMP"). This plan shall describe (b) (4)

** Quality Management Plan. Pfizer will, (b) (4) provide a quality management plan (b) (4)

The Government acknowledges that, as set forth more fully in Section 1.1.2, the above deliverables (other than the delivery of doses contemplated by Section 4.5) are being prepared without the use of Government funding.

As used herein, the term "Limited" means "limited rights" as that term is defined in DFARS 252.227.7013(a)(14).

5.0 MILESTONE PAYMENT SCHEDULE

As set forth more fully in Section 11.7, the provisions of this Section 5 supersede and replace, in their entirety, the provisions of 5.04b of the Base Agreement.

As the clinical trials and validation of the product presentation are ongoing, the estimated timing of delivery of doses is subject to change. Provided the FDA has granted approval or authorization, the 100M doses will be provided by Pfizer to the Government on a Firm Fixed Price per dose basis in accordance with the Milestone Payment Schedule. Due to variances in fill/finish yield, Pfizer shall invoice for and the Government, through the Consortium Management Firm (CMF), shall pay for actual quantities delivered, at a rate of $19.50 per dose. Subject to regulatory and technical success, Pfizer shall use its diligent efforts to provide the Government the full 100M doses on or before the final delivery date.

Upon release, Pfizer will ship the doses to the Government as set forth in Section 6.0, below. Pfizer expects to invoice the Government (through the CMF) every month for released doses that have been shipped during each such monthly period. The CMF will pay all such invoices within thirty (30) days of receipt thereof. Pfizer shall submit invoices via email to MCDC-invoices@ati.org.

(b) (4)			
		Total (Include Payment Type; FFP):	**$1.95B**
	(b) (4)		

Except as contemplated by the Option, the price per dose set forth in this Statement of Work is provided in connection with Operation Warp Speed and this specific Statement of Work only. This price shall not serve as the basis for pricing under any separate government contracts between Pfizer and HHS, the Department of Defense, or any other Department or agency of the Government by application of most favored customer, most favored nations, or any other contract or program-specific terms.

For clarity, the Government will have no right to withhold payment in respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine. In such event, the Parties will work in good faith to establish an appropriate course of action for delivered doses which have not yet been administered. By way of illustrative example only, (b) (4)

6.0 SHIPPING PROVISIONS

In coordination with the Government, Pfizer will conduct a demonstration of the shipping process prior to the first delivery of doses at a time mutually agreed by the Parties. As set forth in Section 4.0, Pfizer agrees to share specifications and details associated with the shipping process and containers to enable the Government to adequately plan and prepare for potential distribution of the vaccine.

Pfizer will notify the Government the date by which doses will become available for delivery. The Government will confirm dosage orders by ship-to location (b) (4) in advance of those dates; *provided* that each such ship-to location will abide by the specifications provided by Pfizer or will otherwise be agreed by Pfizer and the Government. The number of ship-to locations and the manner of delivery shall be identified to create an efficient delivery of the doses, subject to mutual agreement of the parties. The recommended delivery quantity for each ship-to location is (b) (4)

(b) (4)

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

As set forth more fully in Section 11.7, the provisions of this Section 7.0 supersede and replace, in their entirety, the provisions of Article X (Patent Rights), Article XI (Data Rights) of the Base Agreement.

7.1 Inventions

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

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

Notwithstanding the foregoing, and as set forth more fully in Section 1.1.2, the Government acknowledges that it is not funding the research or development of the vaccine, or CMC/process development in respect thereof. As such, neither Pfizer nor the Government anticipate the conception or reduction to practice of any Subject Inventions.

The Government acknowledges that the Bayh-Dole Act does not apply to or govern this Agreement. Given that the Government will not fund the conception or reduction to practice of Background Inventions or Subject Inventions hereunder, this Agreement shall neither (i) give the Government any rights to "march-in," as that term is defined in 35 U.S.C. § 203, nor (ii) subject Pfizer to the manufacturing requirements of 35 U.S.C. § 204.

7.2 Data

The Government recognizes that all data relating to the vaccine has been and will continue to be generated by Pfizer and its collaboration partner, BioNTech, without the use of Government funding.

As between Pfizer and the Government, Pfizer shall own any and all data generated by Pfizer and/or BioNTech (i) as of the Effective Date of this Statement of Work, or (ii) after the Effective Date of this Statement of Work, outside the scope of this Statement of Work ("Background Data"). As between Pfizer and the Government, Pfizer also shall own any and all data generated by Pfizer

within the scope of this Statement of Work ("Subject Data"). For the avoidance of doubt, the parties do not anticipate Pfizer generating any Subject Data using Government funding.

Pfizer hereby grants the Government a non-exclusive license to use any Background Data and Subject Data contained in the deliverables pursuant to Section 4, but solely to the extent necessary for the Government to perform its obligations under this Agreement and arrange administration of the doses delivered in accordance with FDA and other applicable regulations.

The Government will provide Pfizer with no less than thirty (30) days' written notice prior to releasing, in response to a Freedom of Information Act (FOIA) request, any document submitted by Pfizer to Government. During this 30-day period, Pfizer shall have the right to notify Government which documents, if any, contain trade secrets of Pfizer, BioNTech or their respective collaboration partners (or other information legally withholdable from release under FOIA).

7.3 Regulatory Rights

Pfizer will seek and anticipates that it will achieve FDA-approval or authorization and commercialization of Pfizer and BioNTech's mRNA-based Vaccine against SARS-CoV-2 Coronavirus (the "Technology").

Pfizer and the Government agree to the following:

Communications. Pfizer will provide the Government with all formal written responses from the FDA regarding the Technology (b) (4) .

Pfizer also shall use diligent efforts to provide to the USG Government any and all FDA inspection and compliance notices, observations, and responses from Pfizer (b) (4) The Government shall limit distribution of these documents to HHS and DoD regulatory personnel, and may share the substance of the documents to others within the DoD and HHS that have a need to know.

DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Pfizer recognizes that only the DoD can utilize PL 115-92. (b) (4) Pfizer shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) (b) (4)

8.0 SECURITY / EXPORT CONTROL

As set forth more fully in Section 11.7, the provisions of this Section 8 supersede the provisions of Article XII (Export Controls). The following requirements of Article XVII (Security and

OPSEC) of the Base Agreement are not applicable and are therefore self-deleting and replaced by this Section: all references to CUI and CDI, sub-paragraphs (1) through (20) excepting sub-Paragraphs (3)(e), (4), and (20)(d).

The security classification for this effort is Unclassified. As it is currently not anticipated that any Controlled Unclassified Information ("CUI") will be obtained under this Statement of Work, other than Pfizer proprietary information, DFARS 252.204-8012 shall not apply. In addition, the training requirements of Article XVII of the Base Agreement shall not apply. However, if CUI is provided, Pfizer will keep all such information confidential and will only give access to such information to persons with a legitimate need for such access.

Pfizer agrees to comply with all applicable laws regarding commodities and technology subject to this Statement of Work. Pfizer will submit plans and reports as set forth in Section 4.0 above addressing the security topics generally contemplated by Appendix 1 to this Statement of Work. The Government acknowledges that these plans will reflect Pfizer's established security procedures in place with respect to its facilities and information security, which are at least as protective as would be customary for a global company. Pfizer will use commercially reasonable efforts to implement any further procedures/precautions reasonably requested by the Government with respect to Statement of Work and Appendix 1, at Pfizer's sole discretion and as long as such implementation would not adversely impact Pfizer's ordinary operation of its facilities and systems in connection with its other business and products.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

Intentionally Left Blank.

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

As set forth more fully in Section 11.7, the provisions of this Section 10.0 supersede and replace, in their entirety, the provisions of Article XIII (Title and Disposition of Property) of the Base Agreement.

There will be no Government furnished equipment, and no equipment will be funded by the Government under this Statement of Work.

11.0 OTHER

11.1 PREP Act.

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and

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

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Pfizer's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency in accordance with Section III of the PREP Act Declaration; and

(iii) Pfizer is a "Covered Person" per Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this Agreement, as long as Pfizer's activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

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

11.2 Terminations. As set forth more fully in Section 11.7, the provisions of this Section 11.2 hereby supersede and replace, in their entirety, Sections 2.03 and 2.06 of the Base Agreement:

(a) (b) (4) [redacted].

(b) Stop-Work Orders. Except as required by applicable law or regulation, or judicial or administrative order, the Government shall not have the authority to issue a Stop-Work Order to halt the work contemplated under this Statement of Work.

(c) Consequences of Termination. In the event of termination of this Agreement pursuant to this Section 11.2, or expiration of this Agreement at the end of the period of performance as set forth in Section 3.1, this Agreement shall forthwith become null and void and have no effect, without any liability on the part of any Party; *provided*, *however*, that Sections 7, 11 and 12 hereof, and Article VIII (Confidential Information) of the Base Agreement, shall survive any termination or expiration of this Agreement; and *provided*, *further*, that the termination or expiration of this Agreement shall not release any Party hereto of any liability, including any outstanding payments of the Government for doses previously delivered hereunder, which at the time of termination or expiration had already accrued to the other party in respect to any act or omission prior thereto.

11.3 Audits. As set forth more fully in Section 11.7, the provisions of this Section 11.3 hereby supersede and replace, in their entirety, the provisions of Section 5.07 (Financial Records and Reports) of the Base Agreement.

Pfizer's relevant financial records shall not be subject to audit until the Government has provided funds to Pfizer. These records will be subject to audit for a period not to exceed three (3) years after final payment under this Agreement. Pfizer shall have the right to request use of a third-party audit firm to audit Pfizer's books and records maintained in connection with this Agreement; however, in accordance with 10 U.S.C. § 2371b(c) for a period not to exceed three (3) years after final payment under this Agreement, the Comptroller General shall have access to examine the records of any party to the agreement or any entity that participates in the performance of the agreement.

11.4 Disputes. As set forth more fully in Section 11.7, Section 7.02 of the Base Agreement is hereby amended to add the following at the end of said section:

The Government's breach of this Statement of Work may result in money damages and nothing in the Project Agreement (if any) or Base Agreement prevents Pfizer from seeking relief in the United States Court of Federal Claims pursuant to 28 U.S.C. § 1491.

11.5 Timing Estimates. All timing estimates set forth in this Statement of Work are subject to change based on emerging data, regulatory guidance, and manufacturing and technical developments, among other risks.

11.6 Limitation of Liability. The Government acknowledges and agrees that Pfizer's efforts to develop and manufacture a vaccine intended to prevent COVID-19 disease caused by SARS-CoV-2 are aspirational in nature and subject to significant risks and uncertainties. Accordingly, notwithstanding anything to the contrary in this Statement of Work or the Base Agreement, Pfizer shall have no liability for any failure to develop, obtain or maintain U.S. regulatory approval or authorization of such a vaccine in accordance with the estimated schedule described in this Statement of Work.

Even if a vaccine is successfully developed and obtains U.S. regulatory approval or authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with the estimated delivery dates set forth in this Statement of Work to the extent any such change in delivery dates is based on emerging data, regulatory guidance, manufacturing and technical developments, or other risks outside Pfizer's control; *provided*, *however*, Government retains the right to terminate this Agreement or to issue a Stop-Work Order, as specifically contemplated in Sections 11.2(1) and 11.2(b).

(b) (4) [redacted]. This Section 11.6 supersedes the Base Agreement's other liability provisions solely to the extent they are inconsistent with this Statement of Work.

11.7 Order of Precedence. Notwithstanding the provisions of Article XXIII (Order of Precedence) of the Base Agreement, the Parties hereby expressly agree that to the extent any provision of the Project Agreement (if any) or this Statement of Work conflicts with any provision of the Base Agreement, the provision of the Project Agreement (if any) or this Statement of Work, as applicable, shall supersede and replace, in the entirety, the conflicting provision of the Base Agreement and control the relationship of the Parties.

Without limiting the generality of the foregoing, this Section 11.7 shall supersede Article XXIII (Order of Precedence) of the Base Agreement and the terms of this Statement of Work shall constitute "specifically negotiated Project Agreement terms" referenced in the last sentence thereof.

This Statement of Work hereby supersedes, without limitation, the following provisions of the Base Agreement: Section 1.05 (Reporting Requirements), Section 2.03 (Termination Provisions), Section 2.06 (Stop-Work), Section 5.07 (Financial Records and Reports), Section 8.05 (Term), Article IX (Publications), Article X (Patent Rights), Article XI (Data Rights), XII (Export Controls), Article XIII (Title and Disposition of Property), Article XVII (Security and OPSEC), and Sections 21.6-21.15 (Regulations) and the integration clause above the signature block to the Base Agreement.

11.8 (b) (4) [redacted]

11.9 Non-Traditional Defense Contractor. Pfizer has self-certified that Pfizer meets the definition of a "Nontraditional Defense Contractor" as defined in the Base Agreement and therefore is not subject to the cost-sharing requirement referenced in Article VI of the Base Agreement.

11.10 Confidentiality. As set forth more fully in Section 11.7, the provisions of this Section 11.10 hereby supersede and replace, in their entirety, the provisions of Section 8.05 of the Base Agreement.

The obligations of the Receiving Party under this Section shall continue for a period of ten (10) years from the conveyance of Confidential Information. If Pfizer shall need to disclose trade secret information to the Government, Pfizer and the Government will first determine in good faith whether the Government desires to receive any such trade secret information and if the Government so desires to receive such trade secret information, all such information shall be held by the Government in confidence in perpetuity.

11.11 Announcements. Neither Pfizer nor the Government shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Pfizer and the Government hereunder, without the prior written consent of the other, such consent not to be unreasonably withheld or delayed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction. Notwithstanding the foregoing, Pfizer and (its collaboration partners) shall have the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its Covid-19 development program, without the Government's consent or involvement. This section supersedes and replaces Article IX of the Base Agreement.

12.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6) [redacted]

MAILING ADDRESS:
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: BARDA/ASPR/HHS

Appendix 1: Clause for MCDC Consortium Other Transaction Authority Agreements

Standard Language OWS for Consortium OTA

Required MCDC Base Agreement Modifications

The Medical CBRN Consortium (MCDC) Base Agreement, Article XVII, SECURITY & OPSEC shall apply to this Project Agreement. In addition, the below language shall replace Paragraph 6 of Article XVII of the MCDC Base Agreement.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

Required SOW Language for Deliverables (in body of SOW or Deliverables Section)

Information Security

Classification guidance for Operation Warp Speed - The security level for this agreement is UNCLASSIFIED.

"Controlled technical information," "covered contractor information system," "covered defense information," "cyber incident," "information system," and "technical information" are defined in DFARS Clause 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting.

Personnel Security

In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days after contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) Production rates and lead times shall be understood and communicated to the Contracting/Agreement Officer or the Contracting/Agreement Officer's Representative as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location
d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

Manufacturing Data Requirements:

The Contractor shall submit within 30 calendar days after award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

Product Development Source Material and Manufacturing Reports and Projections:

The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.

The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates", on any contract/agreement that is manufacturing product

- Contractor will submit Product Development Source Material Report
  - Within month of contract award
  - Within 30 days of substantive changes are made to sources and/or materials
  - Or on the 6th month contract anniversary.
- Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification
- The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission
- If corrective action is recommended, Contractor must address all concerns raised by the Government in writing

Contractor Locations:

The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.
Contractor will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

Required SOW Language for Security Section

This project requires an OPSEC Plan and a Security Plan.

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Operation Warp Speed and Project Agreement security requirements and prime contractor security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Agreement Officer for review and approval by Operation Warp Speed security subject matter experts. The performance of work under the Project Agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use

	• system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months.

	f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.

	b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.

Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. **Transportation Security** Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with the Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements Description: The partner facility shall notify the Agreement Officer within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	