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CLERK US DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS, FLORIDA

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

LEONARD G. HOROWITZ,
Plaintiff,

vs. Case No. 2:20-cv-00955-JLB-NPM

PFIZER INC., MODERNA, INC. et al.,
Defendants.
_____/

PLAINTIFF'S HOSPITALIZATION COMPOUNDS EVIDENCE OF UNSAFE AND UNFAIR mRNA VACCINE TRADE PRACTICES PREVIOUSLY JUDICIALLY NOTICED ALBEIT DENIED "INJUNCTIVE RELIEF" CONTRARY TO 42 U.S.C § 1986.

LEONARD G. HOROWITZ
Plaintiff, pro se
Post Office Box 150457
Cape Coral, Florida 33915
310-877-3002
editor@medicalveritas.org

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ON AUGUST 6, 2021, Plaintiff Horowitz (hereafter "Plaintiff") was hospitalized at Lee County Hospital in Cape Coral, FL with the diagnosis of pneumonia from multiple bacterial and viral recombinant diseases as predictable and predicted by Plaintiff in previous filings and Judicial Notices to this Court. (**Exhibit 1**)

Plaintiff was wrongly diagnosed, improperly partially treated, and released from the hospital on August 14, 2021. (**Exhibit 1**) He remains under respiratory profusion therapy convalescing at home at the time of this filing.

Plaintiff's diagnosis included: **(a)** initially strep throat; **(b)** subsequently Haemophilus influenzae disease; and **(c)** speculative COVID.

The microbial 'recombinants' (a.k.a., "reassortments") were proximal to the 'antigenic shedding' reported by Pfizer and Moderns's mRNA vaccine testing protocols, albeit generally disregarded.

This disregarded science and medicine has been raised and opposed repeatedly by Plaintiff in his Complaint; in his claims of unfair competition, and in his claims of deceptive trade on false safety advertising, inter alia.

Plaintiff claims a "Civil Conspiracy" to obfuscate related science; and urgently-requested/required "Injunctive Relief" to secure the Plaintiff's commercial rights, civil rights, and health and safety.

Plaintiff's hospitalization, and this filing, corroborates and supplements the attached copy of:

(1) THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA, recently filed intertwined complaint (2:21-cv-00702-CLM; Doc. 15 Filed 07/19/21; **Exhibit 2.** See: p. 45));

(2) Recently "leaked" Pfizer Inc. competing vaccine supply contracts exercised with foreign and domestic governments (**Exhibit 3**); evidencing safety concerns; and

(3) DARPA agent Jon Epstein (i.e., subordinate to EcoHealthAlliance.org Director, Ralph Baric) Public Record containing admissions and disclosures most material to Plaintiff's claims of wrongdoings. Herein, DARPA directs a "cover-up" (i.e., fraudulent concealment) consistent with similar 'liability waiver' statements

committed to hide the co-conspirators' "**potentially sensitive dual use information**," (i.e., for profitable military and commercial concealments of the Pfizer and Moderna vaccines' risks to health and safety).

This DARPA Record was *demanded* to conceal and excuse the 'dual use' information evidencing the co-conspirators' covert-actions in deceptive trade—befitting the "Civil Conspiracy" pursuant to the Pfizer and Moderna vaccines' concealed risks to health and safety opposed by the Plaintiff whistleblower.

These facts, related standards in review, and arguments for this Court's reconsideration of the Plaintiff's (thus far sidestepped) urgings for "Injunctive Relief," are considered in the attached **Memorandum** with **Exhibits 2, 3 and 4**, provided as Judicially-Noticeable evidence.

ABOVE ALL the facts prove clearly-and-convincingly that THE PFIZER AND MODERNA ***SYNTHETIC ANTIGEN DEVICE*** IS THE 'GAIN-OF-FUNCTION' BIOWEAPON central to the torts and crimes brought in this case.

I. INTRODUCTION TO THIS CASE ALLEGING "CIVIL CONSPIRACY" SEEKING "INJUNCTIVE RELIEF"

Plaintiff's claim for damage from "Civil Conspiracy" (Doc. No. 1; pg. 72, § 287) states: "Defendants conspired with one another, as well as other individuals and entities, to perpetrate unlawful acts upon Plaintiff and society, or to perpetrate lawful acts by unlawful means, to wit: Defendants committed unfair and deceptive trade by

issuing deceptive advertisements and falsified science, including vaccine trial reports rife with omissions and misrepresentations, to falsely induce reliance pursuant to claims of COVID-19 [mRNAVACCINE] "safety" and/or "efficacy." [1]

Pursuant to Plaintiff's urging for "Injunctive Relief", the Complaint (Doc. No. 1; pg. 78-79, § 324-328) states:

> It is unconscionable to allow the Defendants to continue unlawfully advertising, selling, or administering their mRNA COVID-19 vaccines without gaining proper 'informed consent.'
>
> It is unconscionable to permit vast expenditures of taxpayer money to pay for pre-orders of vaccines that have been falsely and deceptively advertised by the Defendants or their agents as adequately safe and highly effective.
>
> It is unconscionable to permit the U.S. Food and Drug Administration's (FDA) certification of Defendants' vaccines for safety when FDA simply relies on Defendants limited trial protocol that neglected any and all genetic analyses for these vaccines that are designated by the Defendants as "genetic therapies" claimed to alter or modulate DNA function through mRNA transcription.
>
> It is also unconscionable to permit known environmental risks, including risks to civilization and other species from viral mutations and reassortments from mass inoculations spreading "novel" gene sequences presumed acceptable without adequately researching and considering the consequences.
>
> Accordingly, the public interest and government investment would be best served by entering an injunction against Defendants.

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[1] Under Florida law, "[t]he elements of a civil conspiracy are: (a) a conspiracy between two or more parties, (b) to do an unlawful act or to do a lawful act by unlawful means, (c) the doing of some overt act in pursuance of the conspiracy, and (d) damage to plaintiff as a result of the acts performed pursuant to the conspiracy." *Walters v. Blankenship*, 931 So. 2d 137, 140 (Fla. 5th DCA2006). Generally, an actionable tort or wrong is required. Alternatively, a claim of civil conspiracy may be established if plaintiff "can show some 'peculiar power of coercion' possessed by the conspirators by virtue of their combination, which an individual acting alone does not possess." Walters, 931 So. 2d at 140

The Complaint, page 1, also states in the personal and professional interests of the Plaintiff:

"This Complaint is also authorized by the Florida Private Whistleblower Act (FWA) § 448.102(3);[2] the Defendants' alleged neglect of duty to prevent injuries to the public per 42 USC § 1986; . . ."

II. DEFENDANTS' ARBITRARY AND CAPRICIOUS INFLUENCE IN THIS COURT ENCOURAGES RECONSIDERATION UNDER THE CONFLICTING INTEREST STANDARD ESTABLISHED BY *FICK V. METROPOLITAN LIFE INSURANCE. CO.*, 347 F. SUPP. 2d 1271 – Dist. Court, SD Florida, 2004, INTER ALIA.

A. DEFENDANTS PFIZER AND MODERNA'S ARBITRARY AND CAPRICIOUS INFLUENCE.

ON APRIL 30, 2021 Plaintiff Pfizer filed Doc. No. 66; "Defendant Pfizer Inc.'s Notice of Joinder in Defendant Moderna Inc's Opposition to Plaintiff's Motion for Judicial Notice." Therein, Pfizer and Moderna argue, in essence, that Plaintiff's:

(1) previous judicial notices are moot or frivolous; and

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[2] The Southern District of Florida held that to establish a prima facie case under the Florida Private Whistleblower Act (FWA), *§448.102(3), Fla. Stat.*, a plaintiff must show an actual violation of a law, rule or regulation. *Graddy v. Wal–Mart Stores E., LP*, No. 5:16-CV-9-OC-28PRL (M.D. Fla. Feb. 14, 2017).

As made known previously, during Plaintiff's employment with SCHEIN, he opposed the concealment of evidence material to the federal investigation by CDC and public health officials into the "Florida Dental AIDS Mystery." Upon becoming suspicious about the authenticity of COVID-19 vaccine safety assurances, the Plaintiff/whistleblower researched and analyzed the PFIZER and MODERNA research protocols and allegedly learned that HEARST and related media's advertisements promoting the "novel" mRNA vaccines, especially for medically-compromised persons, were false and misleading pursuant to safety assurances. The misrepresented 'safety" could not be assured to any reasonable degree due to the facts.

(2) substantial public record evidence is to be *disregarded* despite proving clearly-and-convincingly Defendants Pfizer and Moderna hold *special intimate partnerships* with DARPA and the U.S. Government. Accordingly, the Defendants vicariously dismiss points (1) and (2) above; and

(3) Plaintiff Horowitz's warnings, and related hospitalization, had/has no relevance to the express risks and warnings this Plaintiff provided this Court to prevent the precise illnesses, and the precise recombinant pathogenesis, all anticipated, predictable, and predicted by the Plaintiff in his previous filings.

To the contrary, the Defendants vicariously oppose and obfuscate as irrelevant Pfizer's and Moderna's partnership(s) with the DOD's DARPA. Defendants argue these facts are not worthy of this Court's consideration of conflicting interests proximal to foundational commercial and scientific developments of both Pfizer and Moderna's (nano-bioelectronic) mRNA vaccine delivery (hydrogel S-protein anti-genic delivery) device(s).

Nor do Defendants admit, but intentionally conceal and obfuscate, that this cited Public Record knowledge, that is readily verifiable from governmental sources, provides substantial evidence verifying Plaintiff's causes of action (including false safety advertisements, unfair competition, and deceptive trade).

B. DEFENDANTS PFIZER AND MODERNA HOODWINK THIS COURT UNDER ARBITRARY, CAPRICIOUS, AND DUPLICITIOUS INFLUENCE.

"Out of an abundance of caution," Pfizer states the company joins in the arguments and authorities set forth in Moderna's Opposition. But by doing so, Pfizer and Moderna conveniently obfuscates the alleged "Civil Conspiracy" and diverts from the Plaintiff's set of Motions and Judicial Notices that reveal:

(a) Moderna's founder and lead MIT/DARPA agent Robert Langer owns and controls substantial shares in Moderna and the subject mRNA vaccine competitor; and

(b) is implicated in civil and criminal wrongdoing with Robert Langer's co-author—the FBI-indicted Chinese espionage agent, Harvard's Charles Lieber. With federal financing, the two men co-researched, co-produced, and co-published in science, the most important competing commercial component in Defendants' "anti-genic" "novel" vaccine 'therapies.'

Accordingly, Pfizer joined Moderna's opposition to Plaintiff's Judicial Notices, opposing the aforementioned material (arguably urgent) disclosures and life-saving vs. health-risking discoveries. Pfizer and Moderna defended arbitrarily, capriciously, and damagingly: "Plaintiff's Motion vaguely alludes to Pfizer and its Motion to Dismiss Plaintiff's Complaint (Dkt. 54). To the extent Plaintiff seeks judicial notice of these documents in consideration of Pfizer's Motion to Dismiss, Plaintiff has failed to meet his burden to show that each document comes from a source whose accuracy cannot reasonably be questioned and that each document is

relevant to his claims." [See generally Moderna's Opposition; Fed. R. Evid. 201.] [3]

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[3] The Plaintiff asserts that the Defendants' lacking candor, and arbitrary and capricious filings, have damaged Horowitz and needlessly delayed prosecution. This is additionally evidenced by Plaintiff who had previously requested this Court take Judicial Notice of three (3) recently released Public Records opposing the Defendants' motions to dismiss; and supporting the Plaintiff/whistleblower's claims of unfair and deceptive trade and civil conspiracy.

It is public knowledge that Defendants' competitively commercialize "mRNA vaccines." **Exhibits 2 and 3** are filed herein compounding evidence of the "Civil Conspiracy" to fraudulently conceal certain known risks to the Plaintiff's health, safety, free and fair competition, and wrongly-induced vaccine purchasing behaviors endorsed by U.S. Governmental agents and agencies.

To wit, **Exhibit 3** shows Pfizer's republished ("leaked") mRNA vaccine contract with foreign governments (e.g., Albania, Brazil and others), states with bold emphasis added under the caption: **"Commercially Reasonable Efforts" . . .** to accomplish a similar objective [of mRNA vaccine delivery] in its own commercial interests under similar circumstances and considering the relevant risks, uncertainties, limitations and challenges of the development, manufacture, commercialization and distribution of a novel COVID-19 vaccine product, ***taking into account the following factors: actual and potential issues of safety and efficacy, novelty, product profile, the proprietary position, the then current competitive environment for such Product***, the likely timing of the Product's entry into the market, the regulatory environment and status of the Product, compliance with Laws, past performance of the Product and other similar products, the ability to produce or obtain adequate supply of the Product or any components or materials used in the manufacture of the Product and other relevant scientific, technical, operational and commercial factors, in each case as measured by the facts and circumstances at the time such efforts are due.

1.10 "**Conditional Approval**" means a conditional marketing authorization ("**CMA**") or emergency use authorization ("**EUA**") for the Product granted (a) by (i) the United States Food and Drug Administration (the federal agency of the United States Department of Health and Human Services) ("**FDA**") (in the case of an EUA) or (ii) the European Commission (in the case of a CMA) and (b) via an appropriate regulatory mechanism by the (i) National Agency of Medicines and Medical Equipment (**"NAM"**) or (ii) the Minister of Health and Social Protection that allows the Product to be placed on the market in Albania ("**Albanian Conditional Approval**")."

In other words, the Pfizer Contract evidences *extortionate commercialism* in which Pfizer (and similarly Moderna) conceals and contrives lacking liability for the mis-advertised "safe" vaccines.

Furthermore, the U.S. Government's complicity in the alleged "Civil Conspiracy" and commercial/consumer endangerment and fraud is solidly evidenced by **Exhibit 4**. Here, DARPA agent Jon Epstein (subordinate to EcoHealthAlliance.org Director, Ralph Baric), records incriminating facts. Herein, DARPA directs a "cover-up" (i.e., fraudulent concealment) consistent with similar liability waiver statements committed to hide the co-conspirators' "potentially sensitive dual use information," (i.e., for profitable military and commercial concealments).

These facts are intertwined with what is also Public Record knowledge about these vaccines that transmit the Spike-protein antigens risking public health and safety, as now evidenced by the Plaintiff's hospitalization record.

The published consensus science shows that these Pfizer and Moderna vaccines transmit foreign anti-genic proteins that readily induce microbial recombinations risking and causing more threatening "novel" biological agents to emerge from new bacterial and viral recombinations.

Neither to be overlooked, the Pfizer and Moderna vaccines contain genetic material *and* nano-bioelectronic components in their attachment device called the "hydrogel " that compete directly against the Plaintiff's non-drug anti-viral "OxySilver™ with 528" anti-oxidant product.

Plaintiff's three previous Judicially Noticed public records include:

(1) FBI Special Agent Robert Plumb's "CRIMINAL COMPLAINT" Affidavit of January 27, 2020, filed in the United States District Court for the District of Massachusetts, indicting Harvard scientist Charles Lieber[3] for falsely denying the extent of his service to Chinese government-controlled academic and military agents and agencies in Wuhan, China.

a. This record is publicly heralded on the Department of Justice website, https://www.justice.gov/opa/pr/harvard-university-professor-and-two-chinese-nationals-charged-three-separate-china-related; and

b. The "Charging Document" is available for download on the DOJ's link: https://www.justice.gov/opa/press-release/file/1239796/download; and a National Security Division (NSD) document is listed as available below this link, but has presumably been removed and unavailable on the NSD's limited archive; and

c. This public record is important in lieu of the alleged 'fraudulent concealment' by the Government, Modern's Robert Langer, and Harvard's Charles Lieber, in deploying risky, falsely-advertised 'safe' genetic hydrogel spike protein bioelectronic transfer technology, not evidenced of having caused the Plaintiff's hospitalization from recombinant microbiological vectors.

C. A KEY OUTCOME OF DEFENDANTS' PFIZER AND MODERNA'S ARBITRARY, CAPRCIOUS, AND DECEPTIVE CONCEALMENTS, UNACKNOWLDEGED BY THIS COURT IN THE CLAIM OF "CIVIL CONSPIRACY," FEATURES THE 'GAIN-OF-FUNCTION' SYNTHETIC ANTIGENIC BIOWEAPON DISSEMINATION AND 'REASSORTMENT' THAT CAUSED PLAINTIFF'S HOSPITALIZATION.

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(2) National Institutes of Health (NIH) E-mail Records of Dr. Anthony Fauci obtained under the Freedom of Information Act providing 3234 pages of evidence including correspondence with 'inner circle' officials, Fauci's superiors, and allied business agents, several identified and caught acting to conceal the spliced genes from the AIDS virus, HIV-1, within the major bioelectronic, antigenic, therapeutic component of the Defendants' mRNA vaccines.

a. This public record was heralded on numerous mainstream media websites including the *Washington Post*, *New York Times*, and *CNN*, citing BuzzFeed News as the source of the FOIA released documents. See: https://www.documentcloud.org/documents/20793561-leopold-nih-foia-anthony-fauci-emails; and

(3) The U.S. Right to Know public interest group's Freedom of Information ("FOI") obtained e-mails of Dr. Ralph Barack evidencing: (a) leading Teleconference lab virus denialist, Dr. Kristian Anderson, on February 4, 2020 (i.e, two days after the Teleconference), corresponding with Dr. Peter Daszak, a leading bat coronavirus scientist and the President of EcoHealth Alliance financed by the NIH, NIAID, Google, and the Gates Foundation; including in this correspondence Dr. Andrew Pope, Director of the National Academy of Sciences Board on Health Science Policy, Health and Medicine Division, who was urgently required to respond to the Trump Administration's solicitation for a COVID origin investigation issued by the Director of the Office of Science and Technology Policy, Kelvin K. Droegemeier, who wrote to the NAS President, Marcia McNutt, one day earlier, that was one day after the Teleconference (i.e., Monday, February 3, 2020) to secure valid scientific discovery. (See: Exhibit 3, pp. 1-3.); and (b) Dr. Jonathan H. Epstein, Vice President for Science and Outreach (subordinate to Peter Daszak) soliciting Dr. Baric for "dual use safety language" required by DARPA to address the "content, timing, and the extent of distribution of potentially sensitive dual-use information." (Exhibit 3, pg. 4.)

a. This public record, available online, https://www.documentcloud.org/documents/20793561-leopold-nih-foia-anthony-fauci-emails, is a document whose accuracy cannot reasonably be questioned by reason of the express identities, mailing dates, and COVID origin subject matter of Teleconference participants and concerned governmental and private financiers.

Hospital Record **Exhibit 1** evidences the arbitrary, capricious, and fraudulently concealing obfuscation i.e., mixing-up and confusing) of diseases to contrive the Plaintiff's "COVID" diagnosis and wrongful treatment plan. This Public Record corroborates the Plaintiff's Claims, akin to those filed in **Exhibit 2.**

This consistency in wrongdoings is particularly noteworthy regarding the subject hospitalization. The ***"Plaintiffs' Injuries are Within the Zone of Interests,"*** the Arkansas Complaint reads **(Exhibit 2,** p. 42). This Public Record ads the following intelligence submitted by "expert" whistleblower analyzing the Vaccine Adverse Events Reporting System (VAERS) and Medicare and Medicaid data maintained by the Centers for Medicare and Medicaid Services (CMS). "VAERS under-reports deaths caused by the Vaccines by a conservative factor of at least 5. As of July 9, 2021, VAERS reported 9,048 deaths associated with the Vaccines." The expert determined that "the number of deaths occurring with[in] 3 days of injection with the Vaccines exceeds those reported by VAERS by a factor of at least 5, indicating that **the true number of deaths caused by the Vaccines is at least 45,000." (Exhibit 2,** p. 42)

Particularly relevant to Plaintiff's increasing damage, hospitalization, and reported injuries, the expert noted that "in the 1976 Swine Flu vaccine campaign (in which 25% of the U.S. population at that time, 55 million Americans, were vaccinated), the Swine Flu vaccine was deemed dangerous and unsafe, and removed from the market, even though the vaccine resulted in only 53 deaths."

In fact, the Plaintiff's mother, Lily Grubinger/Horowitz of Boston, Massachusetts was one of those "53 deaths." Mrs. Horowitz died after developing the common vaccine-injury autoimmune disease called "Guillian Barre." That disease was treated, as Plaintiff was similarly treated during his Cape Coral hospitalization, using immune-suppressive steroids. These drugs subsequently predisposed Mrs. Horowitz to cancer. After a few radiation treatments and 'drug cocktails,' Mrs. Horowitz's death resulted. But her statistic never was attributed to the vaccine.

D. PLAINTIFF'S DAMAGES AND DEFENDANTS' CONCEALMENTS FALL WITHIN THE 'ZONE-OF-INTEREST' TEST.

> The "zone of interests" test is "*not* 'especially demanding'" *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 130 (2014) (quoting *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012)). The Supreme Court has "conspicuously included the word 'arguably' in the test to indicate that the benefit of any doubt goes to the plaintiff. " *Id.* The test "'forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that' Congress authorized that plaintiff sue." *Collins v. Mnuchin*, 938 F.3d 553, 574 (5th Cir. 2019) (quoting Lexmark, 572 U.S. at 130.). ***The Vaccine injuries and death, and the violations of the constitutionally protected right to bodily integrity and personal autonomy that Plaintiffs assert in the Complaint, are within the zone of interests protected by these statutory provisions, the purpose of which is to tightly limit the circumstances in which potentially harmful medical products can be placed in the stream of commerce and used by the American public prior to their full approval by the FDA.***

The facts in evidence make it clear-and-irrefutable that Plaintiff now suffers, like masses of similarly-situated victims of this PFIZER/MODERNA/DARPA

enterprise in biological warfare and COVID medical/legal mischief, per his hospital record.

Plaintiff's Hospitalization Record (**Exhibit 1**) proves the victim/Plaintiff was damaged by, inter alia, defiance of 42 U.S.C. § 1986. And that others in the public will suffer irreparable injury as these matters are left to fester in the Defendants' arbitrary and capricious diversions and obfuscations.

Finally, the evidence here tilts the balance of hardships and public interest decisively in favor of the Plaintiff; compounds evidence of the unfair and deceptive mRNA vaccine trade by Pfizer and/Moderna; and the Defendants' alleged neglect of duty to prevent injuries to the public per 42 USC § 1986.

III. STANDARD OF REVIEW:

A. DEFENDANTS' ARBITRARY AND CAPRICIOUS INFLUENCE OVER THIS COURT ENCOURAGES RECONSIDERATION UNDER THE CONFLICTING INTEREST STANDARD ESTABLISHED BY *FICK V. METROPOLITAN LIFE INSURANCE. CO.*, 347 F. SUPP. 2d 1271 – Dist. Court, SD Florida, 2004, INTER ALIA.

Given the aforementioned substantial evidence compounding the Defendants' conflicting commercial interests; and specious diversionary filings to hoodwink this Court to delay discovery; and dismiss this case; permitting continuing alleged wrongdoings and mounting damages by Defendants, each

granted all the relief they have sought by contrivance without just entitlement, *Fick* is instructional.

The Eleventh Circuit held that "when a conflict of interest is present, even if the court determines that a reasonable basis existed for the administrator's decision, the administrator's decision should not necessarily prevail. *Torres v. Pittston Company*, 346 F.3d 1324; *HCA Health Servs. v. Employers Health Ins. Co.*, 240 F.3d at 993; *Brown v. Blue Cross*, 898 F.2d at 1561. Instead, the court must continue its inquiry and gauge the self-interest of the [Defendants' clients]." Fick *Op. cit.* "In other words, the reviewing court's decision, when a conflict of interest exists, may not rest merely upon a finding that the administrator's decision was reasonable." *Id.*

As set forth above, *(Id.* at 1284) "the law is well settled that when a court initially determines ***whether the administrator's denial of the claim was correct or whether it was reasonable, the court's review is limited to the facts before the administrator at the time the decision was made.***"

In the case at bar, the Court delayed/denied Plaintiff's claim for Injunctive Relief because it was "reasonable" at the time of ***the court's review" of the limited "facts before the administrator at the time the decision was made.***" *Id.*

However, now that public records are clear-and-convincing and favoring the Plaintiff's relief sought, "the court finds that a conflict of interest exists" (*Id.* that has tainted this judicial process.

Further, it is clear and compelling that Defendants' shady conflicts of interests and false diversionary filings have raised the need to reconsider these proceedings in light of the facts.

Indeed, the burden must now shift as discussed in *Brown*, inter alia. Reconsideration is warranted by "the issue of what evidence a court may review once it must proceed to the next stage of the *Brown* analysis in which the burden shifts to the defendant and the court must consider the self-interest of the administrator" (*Id.*), in this case the Defendants' administration of capricious arguing to protect the Pfizer, Moderna, DARPA, et. al. enterprise.

IV. MEMORANDUM OF LAW

"Federal courts may take judicial notice of any fact 'not subject to reasonable dispute because it … can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.'" Fed. R. Evid. 201(b)(2). In the Eleventh Circuit, courts routinely find that the public records of federal agencies satisfy Rule 201 and consider those records at the motion to dismiss stage. *E.g.*, *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 754–56 (11th Cir. 2011). The FBI's Indictment of Charles Lieber, previously filed for Judicial Notice, is available on the FBI's website,

and cannot be reasonably questioned. Newly submitted Public Records, **Exhibits 2, 3 and 4**, also satisfy appropriateness under Rule 201, as these Public Records are readily available on: (1) the Arkansas Court website; (2) the open source U.S Government Pfizer Contract republished online with multiple open source verifications; and (3) the U.S. Government's DARPA-agented Public Record correspondence with and through the EcoHealthAlliance.org military/commercial contractor.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 US 579 - Supreme Court 1993, judges were encouraged to accept evidence challenging the "scientific orthodoxy" under the Federal Rules of Evidence; and "especially Rule 702" assigns to the trial judge "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* In the case at bar, the Plaintiff is an expert in this field, and the task at hand is discerning a civil conspiracy damaging the Plaintiff and society by allegedly falsely advertising mRNA vaccines as "safe" while disparaging the Plaintiff and competing unfairly against OxySilver™.

A. ELEVENTH CIRCUIT GUIDANCE ON RECONSIDERING THE DEFENDANTS' DIVERSIONARY/SPECIOUS FILINGS

The Eleventh Circuit has indicated that evidence outside of the administrative record may ultimately be appropriate in considering whether a claims administrator acted in its own self-interest under the heightened arbitrary

and capricious standard. *See* Lee v. Blue Cross, 10 F.3d 1547 (11th Cir.1994). After determining from the administrative record that the decision to deny benefits was wrong, but reasonable, the court shifted the burden to the conflicted company to prove that its interpretations were not tainted by selfinterest. Recognizing that the district court only applied an arbitrary and capricious standard and not the heightened arbitrary and capricious standard, the *Lee* court remanded the case and directed the district court to apply the "second prong" of the *Brown* analysis. *Id.* Specifically, the Eleventh Circuit directed the district court on remand to "consider evidence presented by (the plaintiff) to rebut (the defendant's) claims of lack of a profit motive or self-interest and by (the defendant) to demonstrate that its claims decision maximized benefits to participants and beneficiaries." *Id.*

Therefore, this court finds that . . . a reviewing court may consider evidence outside the administrative record when it is actually necessary to gauge the self-interest of the administrator and shift the burden to the defendant to prove that its decision did not advance its own interests at the expense of others.

B. BURDEN OF PROOF UNDER HEIGHTENED ARBITRARY AND CAPRICIOUS STANDARD.

In *Brown,* the Eleventh Circuit held that a "strong conflict of interest exists when the fiduciary making a discretionary decision is also the insurance company responsible for paying the claims." *Id.* at 1568. (emphasis added). In the case at

bar, "fiduciary" Pfizer/MODERNA/DARPA imposing material concealments on this Court is also the public/private enterprise violating laws and shirking duties.

Thus, once it is established that the claims administrator acts under such a conflict of interest, the *Brown* multi-step approach compels the reviewing court to shift the burden to the defendant to prove that a wrong, but reasonable, decision was not tainted by self-interest.

The plaintiff need not prove that the defendant's self-interest was in fact a motivating factor in the decision to deny Plaintiff's claims. "[T]he beneficiary need only show that the fiduciary allowed himself to be placed in a position where his personal interest might conflict with the interest of the beneficiary." *Brown*, 898 F.2d at 1565 (11th Cir.1990). Nor does the Eleventh Circuit require a showing of intentional misconduct in order to shift the burden of proof to the defendant to prove that its decision is not tainted by self-interest. The Eleventh Circuit noted that when conflict of interest is inherent in the situation, a heightened arbitrary and capricious standard should be applied.

CONCLUSION

Plaintiff's Hospitalization Record (Exhibit 1) corroborates facts in the 'Arkansas Case' (**Exhibit (2)**; and compel the Court's reconsideration of the Defendants' arbitrary and capricious, allegedly bad faith, concealments substantive to the Plaintiff's claims, public health and safety.

Chief among Plaintiff's claims of deceptive safety advertising is the now well-evidenced fact that the PFIZER/MODERNA/DARPA "NOVEL" SPIKE-PROTEIN ANTIGEN IS THE "DUAL USE" SYNTHETIC GAIN-OF-FUNCTION BIOWEAPON WRECKING HAVOC ON THE WORLD UNDER THE BRAND CALLED "COVID".

Only uncompromised justice can secure the circumstances; the health, safety, and society, in which Plaintiff's claims arise and are increasingly being justified by the growing illnesses reported—eventually leaving every human susceptible to damage and dying prematurely, proximal to the torts and crimes reported here begging adjudication on the merits.

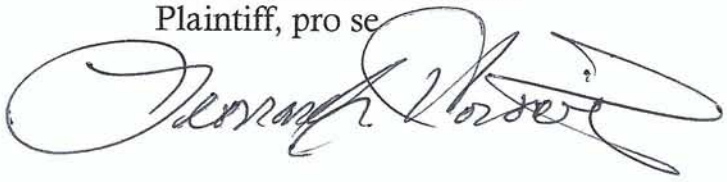
LOCAL RULE 3.01(g) CERTIFICATION

Pursuant to Local Rule 3.01(g), on-or-about August 18, 2021, the undersigned pro se Plaintiff conferred with each of the Defendants by e-mail; sending each a draft copy of this filing for their review. Defendants' opposition to this filing may be presumed.

Respectfully submitted.

DATED: August 18, 2021

/s Leonard G. Horowitz
Plaintiff, pro se



CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of August, 2021, I filed a true and correct copy of the foregoing "**PLAINTIFF'S HOSPITALIZATION COMPOUNDS EVIDENCE OF UNSAFE AND UNFAIR mRNA VACCINE TRADE PRACTICES PREVIOUSLY JUDICIALLY NOTICED ALBEIT DENIED "INJUNCTIVE RELIEF" CONTRARY TO 42 U.S.C § 1986." This filing includes Judicially-Noticed materials** including new **Exhibits 1, 2, 3 and 4**; all filed with the Court's Clerk for customary E-filing. I further certify that I served by E-Mail a copy of the filed document to the following participant(s):

ATTORNEY FOR HENRY SCHEIN, INC.
Thomas J. Cunningham
LOCKE LORD LLP
777 South Flagler Drive
East Tower, Suite 214
West Palm Beach, FL 33401
T: 561- 833-7700
http://Tcunningham@lockelord.com

ATTORNEY FOR PFIZER INC.
Brian T. Guthrie, Esquire
SHOOK, HARDY & BACON L.L.P.
100 N. Tampa St., Suite 2900
Tampa, Florida 33602
T: 813-202-7100 | F: 813-221-8837
E: bguthrie@shb.com
lcintron@shb.com; lmaranto@shb.com

ATTORNEY FOR MODERNA INC.
Nilda M. Isidro
Goodwin Procter LLP
The New York Times Building
620 Eighth Avenue New York, NY 10018
T: 212-459-7224 | F: 646-558-4208

ATTORNEY FOR HEARST CORP.
Legal Department
Hearst Tower in Manhattan
300 West 57th Street and 959 Eighth Avenue,
New York, NY 10019
T: 212-649-2000

HONORABLE JUDGE JOHN BADALAMENTI
HONORABLE MAGISTRATE NICHOLAS MIZELL
United States District Court
for the Middle District of Florida
Ft. Myers Division U.S. Courthouse & Federal Building
2110 First St, Fort Myers, FL 33901
T: 239-461-2000

Leonard G. Horowitz, pro se

1:21 PM Mon Aug 16
kinnser.net

Tested positive for COVID 19 in ER. CXR revealed interstitial alveolar opacities left greater than right. Noted with elevated D dimer. Noted with hypoxia. Started on IV Remdesivir, IV Decadron, given vitamins, Lovenox.

Admitting Diagnosis/Impression:
Acute respiratory failure due to COVID-19 (HCC) [U07.1, J96.00]

Reason for Admission/Provisional Diagnosis:
Patient Active Problem List

Diagnosis	Date Noted
• Acute respiratory failure due to COVID-19 (HCC)	08/06/2021
• Pneumonia due to COVID-19 virus	08/06/2021
• AKI (acute kidney injury) (HCC)	08/06/2021
• Transaminitis	08/06/2021

Medical/Surgical/Family/Social History:
PMH: none
PSH: none reported
FH: none reported
Social History

Tobacco Use	
• Smoking status:	Never Smoker
• Smokeless tobacco:	Never Used
Substance Use Topics	
• Alcohol use:	Not Currently

Prior to Admission Medications & Allergies:
Prior to Admission medications

EXHIBIT 1

ROOM 352 YOUR ROOM PHONE NUMBER IS 424-3333 EXT.62352

LEE MEMORIAL HEALTH SYSTEM

Caring people, caring for people.

SafeLee

Nurse: Michelle/Wendy CNA: Sabreen Date: 8/14/21 Anticipated Discharge: _____

PHONE # 42803 Phone# 61396 Preferred Name: Leonard

CHARGE # 42806 Margan

Physicians:

Dr. Barreda (attending)

Dr. Dosani (pulmonary)

Tests/Treatments/Procedures:

*Oxygen
*Telemetry
*HOB 45 degrees
*IV steriods
*Lovenox

Remdesivir ☒ ☒ ☐ ☐ ☐

Goals/Questions:

Get Better and Stronger

Safety Alerts/Personal Needs:

STOP Please use call button to get assistance

NEW MEDICATIONS

Lovenox-Blood thinner
Side effects: Bruising, Bleeding

Care Team:

CLEANING REQUEST DIAL 42941

Diet:

Food Service Call: 30779 7 am - 7 pm

Activity:

Pain: _____

Goal: _____

New Medications /Education
Side Effects / Teach Back

FILED
2021 Jul-19 PM 01:01
U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR

THE NORTHERN DISTRICT OF ALABAMA

AMERICA'S FRONTLINE DOCTORS, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Civil Action No.
	)	2:21-cv-00702-CLM
XAVIER BECERRA, Secretary of the U.S. Department of Health and Human Services, et al.,	)	
	)	
Defendants.	)	
_____	)	

****

PLAINTIFFS MOTION FOR

PRELIMINARY INJUNCTION

****

EXHIBIT 2

TABLE OF CONTENTS

I. INTRODUCTION

Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called "Pfizer-BioNTech COVID-19 Vaccine,"[1] "Moderna COVID-19 Vaccine"[2] and the "Johnson & Johnson (Janssen) COVID-19 Vaccine"[3] (collectively, the "Vaccines")[4] pursuant to their respective EUAs, and from granting full Food and Drug Administration ("FDA") approval of the Vaccines:

(i) for the under-18 age category;

(ii) for those, regardless of age, who have been infected with SARS-CoV-2 prior to vaccination; and

(iii) until such time as the Defendants have complied with their obligation to create and maintain the requisite "conditions of authorization" under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb–3(e), thereby enabling Vaccine candidates to give truly voluntary, informed consent.

II. SUMMARY OF FACTS

Plaintiffs reference and incorporate herein the facts contained in their Complaint filed on June 10, 2021 (ECF 10).

A. The Unlawful Vaccine Emergency Use Authorizations

(1) 21 U.S.C. § 360bbb–3(b)(1)(C): There is No Emergency

On February 4, 2020, t he Department of Health and Human Services ("DHHS") Secretary declared, pursuant to § 360bbb–3(b)(1)(C), that SARS-CoV-2 created a "public health

[1] Emergency Use Authorization ("EUA") issued December 11, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.
[2] EUA issued December 18, 2020. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.
[3] EUA issued February 27, 2021. *See* https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.
[4] For the sake of clarity of reference, Plaintiffs are using the names given to the Pfizer and Moderna EUA medical products by their manufacturers and the Defendants. However, Plaintiffs reject the highly misleading use of the term "vaccine" to describe the Pfizer and Moderna EUA medical products, since they are not vaccines within the settled meaning of the term and instead are more precisely described as a form of genetic manipulation.

emergency." This initial emergency declaration has been renewed repeatedly and remains in force today. The emergency declaration is the necessary legal predicate for the issuance of the Vaccine EUAs, which have allowed the mass use of the Vaccines by the American public, even before the completion of the standard regimen of clinical trials and FDA approval.

The emergency declaration and its multiple renewals are illegal, since in fact there is no underlying emergency. Assuming the accuracy of Defendants' COVID-19 death data, SARS-CoV-2 has an overall survivability rate of 99.8% globally, which increases to 99.97% for persons under the age of 70, on a par with the seasonal flu. However, Defendants' data is deliberately inflated. On March 24, 2020, DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations — **exclusively for COVID-19**. The rule change states: "COVID-19 should be reported on the death certificate for all decedents where the disease caused *or is assumed to have caused or contributed* to death." In fact, DHHS statistics show that 95% of deaths classed as "COVID-19 deaths" involve an average of four additional co-morbidities. The CDC knew "…the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not."

Similarly, the actual number of COVID-19 "cases" is far lower than the reported number. DHHS authorized the emergency use of the polymerase chain reaction ("PCR") test as a diagnostic tool for COVID-19, with disastrous consequences. The PCR tests are themselves experimental products, authorized by the FDA under separate EUAs. PCR test manufacturers use disclaimers like this in their product manuals: "[t]he FDA has not determined that the test is safe or effective for the detection of SARS-Co-V-2." Manufacturer inserts furnished with PCR test products include disclaimers stating that the PCR tests should NOT be used to diagnose

COVID-19. This is consistent with the warning issued by the Nobel Prize winning inventor of the PCR test that such tests are not appropriate for diagnosing disease.

The way in which the PCR tests are administered guaranties an unacceptably high number of false positive results. Cycle Threshold Value ("CT value") is essentially the number of times that a sample (usually from a nasal swab) is magnified or amplified before a fragment of viral RNA is detected. The CT Value is exponential, and so a 40-cycle threshold means that the sample is magnified around a trillion times. The higher the CT Value, the less likely the detected fragment of viral RNA is intact, alive and infectious.[5]

Virtually all scientists, including Dr. Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless. Dr. Fauci has stated (emphasis below added):

> ***What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule…****We have patients, and it is very frustrating for the patients as well as for the physicians…somebody comes in and they repeat their PCR and it's like 37 cycle threshold…you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it's dead nucleotides, period. In other words, it is not a COVID-19 infection.*[6]

A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at 35-45 cycles in accordance with manufacturer instructions. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted. The chart below shows that all major PCR tests in use in the United States are run at cycles of up to 35 or higher.

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[5] https://www.oralhealthgroup.com/features/the-problems-with-the-covid-19-test-a-necessary-understanding/ (last visited July 15, 2021).

[6] https://1027kearneymo.com/kpgz-news/2020/11/9/covid-tests-may-inflate-numbers-by-picking-up-dead-virus (last visited July 15, 2021).

Manufacturer	Manufacturer's Recommended Cycle Threshold
Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles
Opti Sars CoV-2 RT-PCR Test	45 cycles
Quest SARS-CoV-2rRT-PCR Test	40 cycles
CDC 2019-Novel Coronavirus Real Time (RT-PCR Diagnostic Panel) Test	40 cycles
Wren Labs COVID-19 PCR Test	38 cycles
LabCorp COVID-19 RT-PCR Test	35 cycles

Further, the Defendants and their counterparts in state governments used the specter of "asymptomatic spread" — the notion that fundamentally healthy people could cause COVID-19 in others — to justify the purported emergency. But there is *no credible scientific evidence* that demonstrates that the phenomenon of "asymptomatic spread" is real. On the contrary, on June 7, 2020, Dr. Maria Von Kerkhov, head of the WHO's Emerging Diseases and Zoonosis Unit, told a press conference that from the known research, asymptomatic spread was "very rare." "From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual." She added for emphasis: "it's very rare." Researchers from Southern Medical University in Guangzhou, China, published a study in August 2020 concluding that asymptomatic transmission of COVID-19 is *almost non-existent*. "Asymptomatic cases were least likely to infect their close contacts," the researchers found. A more recent study involving nearly 10 million residents of Wuhan, China found that there were no — zero — positive COVID-19 tests amongst 1,174 *close contacts* of asymptomatic cases, *indicating the complete absence of asymptomatic transmission*.

On September 9, 2020, Dr. Fauci was forced to admit in an official press conference:

> *[E]ven if there is some asymptomatic transmission, in all the history of respiratory borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person,*

even if there is a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers.[7]

(2) § 360bbb–3(c)(1): There is in Fact no Serious or Life-Threatening Disease or Condition

Once an emergency has been declared and while it remains in force, the DHHS Secretary can issue and maintain EUAs "**only if**" (emphasis added) certain criteria are met. One of these criteria is that there is in fact (not simply perceived, projected or declared) "a serious or life threatening disease or condition." For the reasons set forth above in the prior section, SARS-CoV-2 and COVID-19 do not constitute a "serious or life threatening disease or condition" within the meaning of the statute. It also bears noting that the legal purpose of an emergency declaration is to bypass checks and balances typically required under law due to a crisis and that the use of such a declaration for such an arbitrary purpose could undermine the balance of power between the various branches of government.

(3) § 360bbb–3(c)(2)(A): The Vaccines Do Not Diagnose, Treat or Prevent SARS-CoV-2 or COVID-19

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" they are "effective" in diagnosing, treating or preventing a disease or condition.

Centers for Disease Control and Prevention ("CDC") data shows that the Vaccines are not effective in treating or preventing SARS-CoV-2 or COVID-19. Deaths from COVID-19 in those who have received the recommended dosages of the Vaccines increased from 160 as of April 30, 2021 to 535 as of June 1, 2021. Further, a total of 10,262 SARS-CoV-2 "breakthrough infections" of those who have already received the full recommended dosage of the Vaccines

[7] https://www.statnews.com/2021/01/23/asymptomatic-infection-blunder-covid-19-spin-out-of-control/ (last visited July 15, 2021).

were reported to the CDC from 46 states and territories between January 1, 2021 and April 30, 2021.

In studying the effectiveness of a medical intervention in randomized controlled trials (often called the gold standard of study design), the most useful way to present results is in terms of Absolute Risk Reduction ("ARR"). ARR compares the impact of treatment by comparing the outcomes of the treated group and the untreated group. In other words, if 20 out of 100 untreated individuals had a negative outcome, and 10 out of 100 treated individuals had a negative outcome, the ARR would be 10% (20 - 10 = 10). **According to a study published by the NIH, the ARR for the Pfizer Vaccine is a mere 0.7%, and the ARR for the Moderna Vaccine is only 1.1%.**

From the ARR, one can calculate the Number Needed to Vaccinate ("NNV"), which signifies the number of people that must be injected before even one person benefits from the vaccine. The NNV for the Pfizer Vaccine is 119, meaning that 119 people must be injected in order to observe the reduction of a COVID-19 case in one person. The reputed journal the *Lancet* reports data indicating that the NNV may be as high as 217.

There are several factors that reduce any purported benefit of the COVID-19 Vaccines. First, it is important to note that the Vaccines were only shown to reduce symptoms – not block transmission. For over a year now, these Defendants and state-level public health authorities have told the American public that SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19, therefore Americans must mask themselves, and submit to innumerable lockdowns and restrictions, even though they are not manifestly sick. If that is the case, and these officials were not lying to the public, and asymptomatic spread is real, then what is the benefit of a vaccine that merely reduces symptoms? There isn't any.

Secondly, it appears that these Defendants either did lie about asymptomatic spread, or were simply wrong about the science. The theory of asymptomatic transmission — used as the justification for the lockdown and masking of the healthy — was based *solely* upon mathematical modeling. This theory had no actual study participants, and no peer review. The authors made the unfounded assumption that asymptomatic persons were "75% as infectious" as symptomatic persons. But in the real world, healthy false positives turned out to be merely healthy, and were never shown to be "asymptomatic" carriers of anything. Studies have shown that PCR test-positive asymptomatic individuals do not induce clinical COVID-19 disease, not even in a family member with whom they share a home and extended proximity. An enormous study of nearly ten million people in Wuhan, China showed that asymptomatic individuals testing positive for COVID-19 **never** infected others. Since asymptomatic individuals do not spread COVID-19, they do not need to be vaccinated.

(4) § 360bbb–3(c)(2)(B): The Known and Potential Risks of the Vaccine Outweigh their Known and Potential Benefits

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" (emphasis added) the known and potential risks of each Vaccine are outweighed by its known and potential benefits.

The typical vaccine development process takes between 10 and 15 years, and consists of the following sequential stages: research and discovery (2 to 10 years), pre-clinical animal studies (1 to 5 years), clinical human trials in four phases (typically 5 years). Phase 1 of the clinical human trials consists of healthy individuals and is focused on safety. Phase 2 consists of additional safety and dose-ranging in healthy volunteers, with the addition of a control group. Phase 3 evaluates efficacy, safety and immune response in a larger volunteer group, and requires two sequential randomized controlled trials. Phase 4 is a larger scale investigation into longer-

term safety. Vaccine developers must follow this process in order to be able to generate the data the FDA needs in order to assess the safety and effectiveness of a vaccine candidate.

This 10-15 year testing process has been abandoned for purposes of the Vaccines. The first human-to-human transmission of the SARS-CoV-2 virus was not confirmed until January 20, 2020, and less than a year later both mRNA Vaccines had EUAs and for the first time in history this novel mRNA technology was being injected into millions of human beings. As of June 7, 2021, 138 million Americans, representing 42% of the population, have been fully vaccinated.

All of the stages of testing have been compressed in time, abbreviated in substance, and are overlapping, which dramatically increases the risks of the Vaccines. Plaintiffs' investigation indicates that Moderna and Pfizer designed their Vaccines in only two days. It appears that pharmaceutical companies did not independently verify the genome sequence that China released on January 11, 2020. It appears that the Vaccines were studied for only 56 days in macaques, and 28 days in mice, and then animal studies were halted. It appears that the pharmaceutical companies discarded their control groups receiving placebos, squandering the opportunity to learn about the rate of long-term complications, how long protection against the disease lasts and how well the Vaccines inhibit transmission. A number of studies were deemed unnecessary and not performed prior to administration in human subjects, including single dose toxicity, toxicokinetic, genotoxicity, carcinogenicity, prenatal and postnatal development, offspring, local tolerance, teratogenic and postnatal toxicity and fertility. The American public has not been properly informed of these dramatic departures from the standard testing process, and the risks they generate.

Plaintiff America's Frontline Doctors' ("AFLDS") medico-legal researchers have analyzed the accumulated COVID-19 Vaccine risk data, and report as follows:

Migration of the SARS-CoV-2 "Spike Protein" in the Body

The SARS-CoV-2 has a spike protein on its surface. The spike protein is what allows the virus to infect other bodies. It is clear that the spike protein is not a simple, passive structure. The spike protein is a "pathogenic protein" and a toxin that causes damage. The spike protein is itself biologically active, even without the virus. It is "fusogenic" and consequently binds more tightly to our cells, causing harm. If the purified spike protein is injected into the blood of research animals, it causes profound damage to their cardiovascular system, and crosses the blood-brain barrier to cause neurological damage. If the Vaccines were like traditional *bona fide* vaccines, and did not leave the immediate site of vaccination, typically the shoulder muscle, beyond the local draining lymph node, then the damage that the spike protein could cause might be limited.

However, the Vaccines were authorized without any studies demonstrating where the spike proteins traveled in the body following vaccination, how long they remain active and what effect they have. A group of international scientists has recently obtained the "biodistribution study" for the mRNA Vaccines from Japanese regulators. T he study reveals that unlike traditional vaccines, this spike protein enters the bloodstream and circulates throughout the body over several days post-vaccination. It accumulates in a number of tissues, such as the spleen, bone marrow, liver, adrenal glands and ovaries. It fuses with receptors on our blood platelets, and also with cells lining our blood vessels. It can cause platelets to clump leading to clotting, bleeding and heart inflammation. It can also cross the blood-brain barrier and cause brain damage. It can be transferred to infants through breast milk. T he VAERS system includes reports of infants suckling from vaccinated mothers experiencing bleeding disorders in the gastrointestinal tract.

Increased Risk of Death from Vaccines

The government operated VAERS database is intended to function as an "early warning" system for potential health risks caused by vaccines. It is broadcasting a red alert. Of the 262,000 total accumulated reports in VAERS, only 1772 are not related to COVID-19. The database indicates that the total reported vaccine deaths in the first quarter of 2021 represents a 12,000% to 25,000% increase in vaccine deaths, year-on-year. In ten years (2009-2019) there were 1529 vaccine deaths, whereas in the first quarter of 2021 there have been over 4,000. Further, 99% of all reported vaccine deaths in 2021 are caused by the COVID-19 Vaccines, only 1% being caused by the numerous other vaccines reported in the system. It is estimated that VAERS only captures 1% to at best 10% of all vaccine adverse events.

Reproductive Health

The mRNA Vaccines induce our cells to manufacture (virus-free) "spike proteins." The "spike proteins" are in the same family as the naturally occurring syncytin-1 and syncytin-2 reproductive proteins in sperm, ova and placenta. Antibodies raised against the spike protein might interact with the naturally occurring syncytin proteins, adversely affecting multiple steps in human reproduction. The manufacturers did not provide data on this subject despite knowing about the spike protein's similarity to syncytin proteins for more than one year. There are now a very high number of pregnancy losses in VAERS. A study recently published in the New England Journal of Medicine, "Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons," exposes that pregnant women receiving Vaccines during their first or second trimesters suffer an 82% spontaneous abortion rate, killing 4 out of 5 unborn babies. There are worldwide reports of irregular vaginal bleeding without clear explanation. Scientists are concerned that the Vaccines pose a substantial risk to a woman's reproductive system. This increased risk of sterility stems from an increased concentration of the spike proteins in various

parts of the reproductive system after vaccination. Not enough is known to determine the risk of sterility, but it is beyond question that the risk is increased.

A leaked Pfizer document (excerpted below) exposes that Pfizer Vaccine nanoparticles accumulate in the ovaries at an extraordinarily high rate, in concentrations orders of magnitude higher than in other tissues. Billions of aggressive spike proteins are accumulating in very delicate ovarian tissues, the one place in the human body where females carry a finite number of fertile eggs.

SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048)
2.6.5 薬物動態試験の概要表

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED **Test Article: [**

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							%
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--
Blood:Plasma ratio[a]	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--

PFIZER CONFIDENTIAL
Page 7

Each baby girl is born with the total number of eggs she will ever have in her entire life. Those eggs are stored in the ovaries, and one egg is released each month of a normal menstrual cycle. When there are no more eggs, a woman stops menstruating. The reproductive system is

arguably the most delicate hormonal and organ balance of all our systems. The slightest deviation in any direction results in infertility. Even in 2021, doctors and scientists do not know all the variables that cause infertility.

There is evidence to support that the Vaccines could cause permanent autoimmune rejection of the placenta. Placental inflammation resulting in stillbirths mid-pregnancy (second trimester) is seen with COVID-19 and with other similar coronaviruses. There is a case report of a woman with a normally developing pregnancy who lost the otherwise healthy baby at five months during acute COVID-19. The mother's side of the placenta was very inflamed. This "infection of the maternal side of the placenta inducing acute or chronic placental insufficiency resulting in miscarriage or fetal growth restriction was observed in 40% of pregnant women with similar coronaviruses." The mRNA Vaccines may instigate a similar reaction as the SARS-CoV-2 virus. There is a component in the vaccine that could cause the same autoimmune rejection of the placenta, but indefinitely. Getting COVID-19 has been associated with a high risk of mid-pregnancy miscarriage because the placenta fails. The mRNA Vaccines may have precisely the same effect, however, not for just the few weeks of being sick, but forever. Repeated pregnancies would keep failing in mid-pregnancy.

On December 1, 2020, a former Pfizer Vice President and allergy and respiratory researcher, Dr. Michael Yeadon, filed an application with the European Medicines Agency, responsible for approving drugs in the European Union, seeking the immediate suspension of all SARS-CoV-2 Vaccines, citing *inter alia* the risk to pregnancies. As of April 26, 2021, the VAERS database contains over 3,000 reports of failed pregnancies associated with the Vaccines.

Vascular Disease

Salk Institute for Biological Studies researchers in collaboration with the University of San Diego, published in the journal *Circulation Research* that the spike proteins themselves

damage vascular cells, causing strokes and many other vascular problems. All of the Vaccines are causing clotting disorders (coagulopathy) in all ages. The spike proteins are known to cause clotting that the body cannot fix, such as brain thrombosis and thrombocytopenia.

None of these risks has been adequately studied in trials, or properly disclosed to healthcare professionals or Vaccine subjects.

Autoimmune Disease

The spike proteins are perceived to be foreign by the human immune system, initiating an immune response to fight them. While that is the intended therapeutic principle, it is also the case that any cell expressing spike proteins becomes a target for destruction by our own immune system. This is an autoimmune disorder and can affect virtually any organ in the body. It is likely that some proportion of spike protein will become permanently fused to long-lived human proteins and this will prime the body for prolonged autoimmune diseases. Autoimmune diseases can take years to show symptoms and many scientists are alarmed at giving young people such a trigger for possible autoimmune disease.

Neurological Damage

The brain is completely unique in structure and function, and therefore it requires an environment that is insulated against the rest of the body's functioning. The blood-brain-barrier exists so the brain can function without disruption from the rest of the body. This is a complex, multi-layered system, using several mechanisms that keep nearly all bodily functions away from the brain. Three such systems include: very tight junctions between the cells lining the blood vessels, very specific proteins that go between, and unique enzymes that alter substances that do go through the cells. Working together, the blood-brain-barrier prevents almost everything from getting in. Breaching it is generally incompatible with life.

Most unfortunately, the COVID-19 Vaccines — unlike any other vaccine ever deployed — are able to breach this barrier through various routes, including through the nerve structure in the nasal passages and through the blood vessel walls. The resulting damage begins in the arterial wall, extends to the supporting tissue outside the arteries in the brain, and from there to the actual brain nerve cells inside. The Vaccines are programmed to produce the S1 subunit of the spike protein in every cell in every Vaccine recipient, but it is this subunit that causes the brain damage and neurologic symptoms. Elderly persons are at increased risk for this brain damage.

COVID-19 patients typically have neurological symptoms including headache and loss of smell and taste, as well as brain fog, impaired consciousness, and stroke. Researchers have published a paper in the *Journal of Neurological Sciences* correlating the severity of the pulmonary distress in COVID-19 with viral spread to the brain stem, suggesting direct brain damage, not just a secondary cytokine effect. It has been shown recently by Dr. William Banks, professor of Internal Medicine at University of Washington School of Medicine, that the S1 subunit of the spike protein — the part of the SARS-CoV-2 virus that produces the COVID-19 disease and is in the Vaccines — can cross the blood brain barrier. This is even more concerning, given the high number of ACE2 receptors in the brain (the ACE2 receptor is that portion of the cell that allows the spike protein to connect to human tissue). Mice injected with the S1 subunit of the spike protein developed direct damage to the perivascular tissue. In humans, viral spike protein was detected in the brain tissues of COVID-19 patients, but not in the brain tissues of the controls. Spike protein produces endothelial damage.

There are an excessive number of brain hemorrhages associated with COVID-19, and the mechanism suggests that it is the spike protein that is responsible. The federal government's VAERS database shows a dramatic increase in adverse event reporting of neurological damage following injection with the Vaccine.

Year	**Dementia** (reports following injection with Vaccine)	**Brain Bleeding** (reports following injection with Vaccine)
2000	4	7
2010	0	17
2015	0	17
2018	21	31
2019	11	17
2020	12 → (43)	4 → (11)
2021	17 → (251)	0 → (258)

While the full impact of these Vaccines crossing the blood-brain barrier is unknown, they clearly put vaccinated individuals at a substantially increased risk of hemorrhage, neurological damage, and brain damage as demonstrated by the increased instances of such reporting in the VAERS system.

Effect on the Young

The Vaccines are more deadly or harmful to the young than the virus, and that is excluding the unknown future effects on fertility, clotting, and autoimmune disease. Those under the age of 18 face statistically zero chance of death from SARS-CoV-2 according to data published by the CDC, but there are reports of heart inflammation — both myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) — in young men, and at least one documented fatal heart attack of a healthy 15-year old boy in Colorado two days after receiving the Pfizer Vaccine.[8] The CDC has admitted that "[s]ince April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after the mRNA COVID-19 vaccination (Pfizer-BioNTech and Mederna), particularly in adolescents and young adults."

[8] https://archive.is/mEBcV (last visited July 15, 2021).

The Vaccines induce the cells of the recipient to manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, a very strong immune response, including those which can damage their own cells and tissues, including by stimulating blood coagulation.

See also infra Section II.B.

Chronic Disease

Healthy children whose birthright is decades of healthy life will instead face premature death or decades of chronic disease. We cannot say what percentage will be affected with antibody dependent enhancement, neurological disorders, autoimmune disease and reproductive problems, but it is a virtual certainty that this will occur.

Antibody Dependent Enhancement

Antibody Dependent Enhancement ("ADE") occurs when SARS-CoV-2 antibodies, created by a Vaccine, instead of protecting the vaccinated person, cause a more severe or lethal case of the COVID-19 disease when the person is later exposed to SARS-CoV-2 in the wild.[9] The vaccine *amplifies* the infection rather than *preventing* damage. It may only be seen after months or years of use in populations around the world.

This paradoxical reaction has been seen in other vaccines and animal trials. One well-documented example is with the Dengue fever vaccine, which resulted in avoidable deaths. Dengue fever has caused 100-400 million infections, 500,000 hospitalizations, and a 2.5% fatality rate annually worldwide. It is a leading cause of death in children in Asian and Latin American countries. Despite over 50 years of active research, a Dengue vaccine still has not

[9] https://www.nature.com/articles/s41564-020-00789-5 (last visited July 15, 2021).

gained widespread approval in large part due to the phenomenon of ADE. Vaccine manufacturer Sanofi Pharmaceutical spent 20 years and nearly $2 billion to develop the Dengue vaccine and published their results in the *New England Journal of Medicine*, which was quickly endorsed by the World Health Organization. Vigilant scientists clearly warned about the danger from ADE, which the Philippines ignored when it administered the vaccine to hundreds of thousands of children in 2016. Later, when these children were exposed in the wild, many became severely ill and 600 children died. The former head of the Dengue department of the Research Institute for Tropical Medicine (RITM) was indicted in 2019 by the Phillipines Department of Justice for "reckless imprudence resulting [in] homicide," because he "facilitated, with undue haste," Dengvaxia's approval and its rollout among Philippine schoolchildren.[10]

ADE has been observed in the coronavirus setting. The original SARS-CoV-1 caused an epidemic in 2003. This virus is a coronavirus that is reported to be 78% similar to the current SARS-CoV-2 virus that causes the disease COVID-19. Scientists attempted to create a vaccine. Of approximately 35 vaccine candidates, the best four were trialed in ferrets. The vaccines appeared to work in the ferrets. However, when those vaccinated ferrets were challenged by SARS-CoV-1 in the wild, they became very ill and died due to what we would term a sudden severe cytokine storm. The reputed journals *Science*, *Nature* and *Journal of Infectious Diseases* have all documented ADE risks in relation to the development of experimental COVID-19 vaccines. The application filed by Dr. Yeadon with the European Medicines Agency on December 1, 2020 also mentioned the risk from ADE. ADE is discovered during long-term animal studies, to which the Vaccines have not been subjected.

[10] https://trialsitenews.com/philippine-dengue-vaccine-criminal-indictments-includes-president-of-sanofi-pasteur-their-fda (last visited July 15, 2021).

Vaccine-Driven Disease Enhancement in the Previously Infected

See infra section II. C.

More Virulent Strains

Scientists are concerned that universal inoculation may create more virulent strains. This has been observed with Marek's Disease in chickens.[11] A large number of chickens not at risk of death were vaccinated, and now all chickens must be vaccinated or they will die from a virus that was nonlethal prior to widespread vaccination. The current policy to pursue universal vaccination regardless of risk may exert the same evolutionary pressure toward more highly virulent strains.

Blood Supply

Presently, the vaccinated are permitted to donate their spike protein laden blood into the blood supply, which projects all of the risks discussed *supra* onto the general population of unvaccinated blood donees.

Scientists and healthcare professionals all over the world are sounding the alarm and frantically appealing to the FDA to halt the Vaccines. They have made innumerable public statements. Fifty-seven top scientists and doctors from Central and South America are calling for an immediate end to all Vaccine COVID-19 programs. Other physician-scientist groups have made similar calls, among them: Canadian Physicians, Israeli People's Committee, Frontline COVID-19 Critical Care Alliance, World Doctors Alliance, Doctors 4 Covid Ethics, and Plaintiff America's Frontline Doctors. These are healthcare professionals in the field who are seeing the catastrophic and deadly results of the rushed Vaccines, and reputed professors of science and medicine, including the physician with the greatest number of COVID-19 scientific citations

[11] https://en.wikipedia.org/wiki/Marek%27s_disease (last visited July 15, 2021).

worldwide. They accuse the government of deviating from long-standing policy to protect the public. In the past, government has halted vaccine trials based on a tiny fraction — far less than 1% — of the number of unexplained deaths already recorded. The scientists all agree that the spike protein (produced by the Vaccines) *causes disease even without the virus*, which has motivated them to lend their imprimatur to, and risk their reputation and standing on, these public objections.

(5) § 360bbb–3(c)(3): There Are Adequate, Approved and Available Alternatives to the Vaccines

The DHHS Secretary can issue and maintain the Vaccine EUAs "**only if**" (emphasis added) there is no adequate, approved and available alternative to the Vaccines.

There are numerous alternative safe and effective treatments for COVID-19. These alternatives are supported by over 300 studies, including randomized controlled studies. Tens of thousands of physicians have publicly attested, and many have testified under oath, as to the safety and efficacy of the alternatives. Globally and in the United States, treatments such as Ivermectin, Budesonide, Dexamethasone, convalescent plasma and monoclonal antibodies, Vitamin D, Zinc, Azithromycin, Hydroxychloroquine, Colchicine and Remdesivir are being used to great effect, and they are far safer than the COVID-19 Vaccines.[12]

Doctors from the Smith Center for Infectious Diseases and Urban Health and the Saint Barnabas Medical Center have published an *Observational Study on 255 Mechanically Ventilated COVID Patients at the Beginning of the USA Pandemic*, which states: "Causal modeling establishes that weight-adjusted HCQ [Hydroxychloroquine] and AZM [Azithromycin] therapy improves survival by over 100%."[13]

[12] Numerous studies can be reviewed here: https://c19early.com (last visited June 7, 2021).
[13] https://www.medrxiv.org/content/10.1101/2021.05.28.21258012v1 (last visited July 15, 2021).

Observational studies in Delhi and Mexico City show dramatic reductions in COVID-19 case and death counts following the mass distribution of Ivermectin. These results align with those of a study in Argentina, in which 800 healthcare professionals received Ivermectin, while another 400 did not. Of the 800, not a single person contracted COVID-19, while more than half of the control group did contract it. Dr. Pierre Kory, a lung specialist who has treated more COVID-19 patients than most doctors, representing a group of some of the most highly published physicians in the world, with over 2,000 pe er reviewed publications among them, testified before the U.S. Senate in December 2020.[14] He testified that based on 9 m onths of review of scientific data from 30 studies, Ivermectin obliterates transmission of the SARS-CoV-2 virus and is a powerful prophylactic (if you take it, you will not contract COVID-19). Four large randomized controlled trials totaling over 1500 patients demonstrate that Ivermectin is safe and effective as a prophylaxis. In early outpatient treatment, three randomized controlled trials and multiple observational studies show that Ivermectin reduces the need for hospitalization and death in statistically significant numbers. In inpatient treatment, four randomized controlled trials show that Ivermectin prevents death in a statistically significant, large magnitude. Ivermectin won the Nobel Prize in Medicine in 2015 for its impacts on global health.[15]

Inexplicably, the Defendants never formed or assigned a task force to research and review existing alternatives for preventing and treating COVID-19. Instead, the Defendants and others set about censoring both concerns about the Vaccines, and information about safe and effective alternatives.

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[14] https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwji38elkuPxAhWeAp0JHZhzAeMQFnoECAIQAA&url=https%3A%2F%2Fwww.hsgac.senate.gov%2Fdownload%2Fkory12-08-2020&usg=AOvVaw3z2a7PpDLWgyfSrp3miF1y (last visited July 15, 2021).

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692067/ (last visited July 15, 2021).

(6) § 360bbb–3(e)(1)(A)(i) and (ii): Healthcare Professionals and Vaccine Candidates are Not Adequately Informed

Once an EUA has been issued, § 360bbb–3(e) mandates that the DHHS Secretary "shall [ ] establish" conditions "designed to ensure" that both healthcare professionals and Vaccine candidates receive certain minimum required information that is necessary in order to make voluntary, informed consent possible. The required disclosures that the DHHS Secretary are designed to ensure include inter alia (i) that the Vaccines are only authorized for emergency use and not FDA approved, (ii) the significant known and potential risks of the Vaccines, (iii) available alternatives to the Vaccines, (iv) the option to accept or refuse the Vaccines.

The Vaccines are Not Approved by the FDA, but Merely Authorized for Emergency Use

Defendants have failed to educate the American public that the FDA has not actually "approved" the Vaccines, and that the DHHS Secretary has *not* in fact determined that the Vaccines are "safe and effective," and on the contrary has merely determined, in accordance with the proverbial "weasel language" of the EUA statute, that "**it is reasonable to believe**" that the Vaccines "**may be**" effective and that the benefits outweigh the risks. Instead of being so educated, the public is barraged with unqualified "safe and effective" messaging from all levels of federal and state government, the private sector and the media. They hear from no higher authority than the President himself that: "The bottom line is this: I promise you they are safe. They are safe. And even more importantly, they're extremely effective. If you're vaccinated, you are protected."

The public are also unaware of the serious financial conflicts-of-interest that burden Dr. Fauci, the National Institute of Allergies and Infectious Diseases, and the Vaccines and Related Biological Products Advisory Committee which advises and consults Defendants with respect to the Vaccine EUAs, as outlined in the Complaint (ECF 10, ¶¶ 250-256). Without the information

regarding conflicts-of interest, the public cannot assess for themselves the reliability and objectivity of the analysis underpinning the EUAs.

The Significant Known and Potential Risks of the Vaccines

Perhaps the first step in understanding the potential risks of the Vaccines is to understand exactly what they are, and what they are not. The CDC defines a "vaccine" as: "A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose."[16] The CDC defines "immunity" as: "Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."[17]

However, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" do not meet the CDC's own definitions. They do not stimulate the body to produce immunity from a disease. They are a synthetic fragment of nucleic acid embedded in a fat carrier that is introduced into human cells, not for the purpose of inducing immunity from infection with the SARS-CoV-2 virus, and not to block further transmission of the virus, but in order to lessen the symptoms of COVID-19. No published, peer-reviewed studies prove that the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" confer immunity or stop transmission.

Further, the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" are not "vaccines" within the common, lay understanding of the public. Since vaccines were first discovered in 1796 by Dr. Edward Jenner, who used cowpox to inoculate humans against smallpox, and called the process "vaccination" (from the Latin term *vaca* for cow), the

[16] *See* https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited July 9, 2021).
[17] Id.

public has had an entrenched understanding that a vaccine is a microorganism, either alive but weakened, or dead, that is introduced into the human body in order to trigger the production of antibodies that confer immunity from the targeted disease, and also prevent its transmission to others. The public are accustomed to these traditional vaccines and understand them.

The public are fundamentally uninformed about the gene therapy technology behind the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." Referring to the "mRNA technology" in its Vaccine, Moderna admits the "novel and unprecedented nature of this new class of medicines" in its Securities and Exchange Commission filings.[18] Further, it admits that the FDA classes its Vaccine as a form of "gene therapy." No dead or attenuated virus is used in the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine." Rather, instructions, via a piece of lab-created genetic code (the mRNA) are injected into your body that tell your body how to make a certain "spike protein" that is purportedly useful in attacking the SARS-CoV-2 virus.

By referring to the "Pfizer-BioNTech COVID-19 Vaccine" and the "Moderna COVID-19 Vaccine" as "vaccines," and by allowing others to do the same, the Defendants knowingly seduce and mislead the public, short-circuit independent, critical evaluation and decision-making by the consumers of these products, and vitiate their informed consent to this novel technology which is being deployed in the unsuspecting human population for the first time in history.

Meanwhile, the federal government is orchestrating a nationwide media campaign funded with $1 billion — not to ensure that the Defendants meet their statutory disclosure obligations, but solely to promote the purported benefits of the Vaccines. Simultaneously, the Associated Press, Agence France Press, British Broadcasting Corporation, CBC/Radio-Canada, European

[18] *See* www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm (last visited July 6, 2021).

Broadcasting Union (EBU), Facebook, Financial Times, First Draft, Google/YouTube, The Hindu Times, Microsoft, Reuters, Reuters Institute for the Study of Journalism, Twitter, The Washington Post and The New York Times all participate in the "Trusted News Initiative" which has agreed to not allow any news critical of the Vaccines.

Individual physicians are being censored on social media platforms (e.g., Twitter, Facebook, Instagram, TikTok), the modern day "public square." Plaintiff AFLDS has recorded innumerable instances of social media deleting scientific content posted by AFLDS members that runs counter to the prevailing Vaccine narrative, and then banning them from the platform altogether as users. Facebook has blocked the streaming of entire events at which AFLDS Founder Dr. Simone Gold has been an invited guest, prior to her uttering a word. Other doctors have been banned for posting or tweeting screenshots of government database VAERS.

The censorship also extends to medical journals. In an unprecedented move, the four founding topic editors for the *Frontiers in Pharmacology* journal all resigned together due to their collective inability to publish peer reviewed scientific data on various drugs for prophylaxis and treatment of COVID-19.

Dr. Philippe Douste-Blazy, a cardiology physician, former France Health Minister, 2017 candidate for Director of the WHO and former Under-Secretary-General of the United Nations, described the censorship in chilling detail:

> *The Lancet boss said "Now we are not going to be able to, basically, if this continues, publish any more clinical research data, because the pharmaceutical companies are so financially powerful today and are able to use such methodologies, as to have us accept papers which are apparently, methodologically perfect but in reality, which manage to conclude what they want to conclude." … one of the greatest subjects never anyone could have believed … I have been doing research for 20 years in my life. I never thought the boss of The Lancet could say that. And the boss of the New England Journal of Medicine too. He even said it was "criminal" — the word was used by him. That is, if you will, when there is an outbreak like the COVID-19, in reality, there are people … us,*

> *we see "mortality" when you are a doctor or yourself, you see "suffering." And there are people who see "dollars" — that's it.*

In many instances, highly publicized attacks on early treatment alternatives seem to be done in bad faith. For example, one study on Hydroxychloroquine overdosed study participants by administering a multiple of the standard prescribed dose, and then reported the resulting deaths as though they were not a result of the overdose, but from the medication itself administered in the proper dosages. The twenty-seven physician-scientist authors of the study were civilly indicted and criminally investigated, and still the Journal of the American Medical Association has not retracted the article.[19]

The Available Alternatives to the Vaccines

Information regarding available alternatives to the Vaccines has been suppressed and censored equally with information regarding the risks of the Vaccines, as aforesaid.

The Option to Accept or Refuse the Vaccines

The idea of using fear to manipulate the public is not new, and is a strategy frequently deployed in public health. In June 2020, three American public health professionals, concerned about the psychological effects of the continued use of fear-based appeals to the public in order to motivate compliance with extreme COVID-19 countermeasures, authored a piece for the journal *Health Education and Behavior* calling for an end to the fear-mongering. In doing so, they acknowledged that fear has become an accepted public health strategy, and that it is being deployed aggressively in the United States in response to COVID-19:

> *"… behavior change can result by increasing people's perceived severity and perceived susceptibility of a health issue through heightened risk appraisal coupled by raising their self-efficacy and response-efficacy*

[19] https://www.medrxiv.org/content/medrxiv/early/2020/04/16/2020.04.07.20056424.full.pdf (last visited July 15, 2021).

about a behavioral solution. In this model, fear is used as the trigger to increase perceived susceptibility and severity."

In 1956, Dr. Alfred Biderman, a research social psychologist employed by the U.S. Air Force, published his study on techniques employed by communist captors to induce individual compliance from Air Force prisoners of war during the Korean War. The study was at the time and to some extent remains the core source for capture resistance training for the armed forces. The chart below compares the techniques used by North Korean communists with the fear-based messaging and COVID-19 countermeasures to which the American population has been subjected over the last year.

"COMMUNIST COERCIVE METHODS FOR ELICITING INDIVIDUAL COMPLIANCE".*
The Biderman Report of 1956 and COVID-19

Chart of Coercion	COVID-19
Isolation • Deprives individual of social support of his ability to resist • Makes individual dependent upon the captor • Individual develops an intense concern with self.	***Isolation*** • Social distancing • Isolation from loved ones, massive job loss • Solitary confinement semi-isolation • Quarantines, containment camps
Monopolization of Perception • Fixes all attention upon immediate predicament; • Frustrates all actions not consistent with compliance • Eliminates stimuli competing with those controlled by the captor	***Monopolization of perception*** • Restrict movement • Create monotony, boredom • Prevent gathering, meetings, concerts, sports • Dominate all media the 24/7, censor information
Induced Debility and Exhaustion • Weakens mental and physical ability to resist • People …become worn out by tension and fear	***Induced debility*** • Forced to stay at home, all media is negative • not permitted to exercise or socialize
Threats • Cultivates anxiety and despair • Gives demands and consequences for non compliance	***Threats and Intimidation*** • Threaten to close business, levy fines • Predict extension of quarantine, force vaccines • Create containment camps
Occasional Indulgences • Provides motivation for compliance • Hinders adjustment to deprivation. • Creates hope for change, reduces resistance • This keeps people unsure of what is happening.	***Occasional Indulgences*** • Allow reopening of some stores, services • Let restaurants open but only at a certain capacity • Increase more people allowed to gather • Follow concessions with tougher rules
Demonstrate Omnipotence • Demonstrates futility of resistance • Shows who is in charge • Provides positive motivation for compliance	***Demonstrate Ominpotence*** • Shut down entire economies across the world • Create money out of nowhere, force dependency • Develop *total* surveillance with nanochips and 5G
Degradation • Makes resistance seem worse than compliance • Creates feelings of helplessness. • Creates fear of freedom, dependence upon captors	***Humiliation or Degradation techniques*** • Shame people who refuse masks, don't distance • Make people stand on circles and between lines • Make people stand outside and wait in queues • Sanitation stations in every shop
Enforcing trivial demands • Develops habit of compliance • Demands made are illogical and contradictory • Rules on compliance may change • Reinforces who is in control	***Enforcing trivial demands*** • Family members must stand apart • Masks in home and even when having sex • Random limits on people allowed to be together • Sanitizers to be used over and over in a day

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The Chart of Coercion above is drawn from the Biderman Report on communist brainwashing techniques used by the Chinese and North Koreans on captured American servicemen to make them psychological as well as physical prisoners. Dr. Alfred D. Biderman M.A. and presented his Report at the New York Acadamy of Medicine Nov 13, 1956. Compare right column with your experience this year.

After a year of sustained psychological manipulation, the population is now weakened, frightened, desperate for a return of their freedoms, prosperity and normal lives, and especially vulnerable to pressure to take the Vaccine. The lockdowns and shutdowns, the myriad rules and regulations, the confusing and self-contradictory controls, the enforced docility, and the consequent demoralization, anxiety and helplessness are typical of authoritarian and totalitarian conditions. This degree of systemic and purposeful coercion means that Americans cannot give truly free and voluntary informed consent to the Vaccines.

At the same time, the population is being subjected to an aggressive, coordinated media campaign promoting the Vaccines funded by the federal government with $1 billion. The media campaign is reinforced by a system of coercive rewards and penalties designed to induce vaccination. The federal government is offering a range of its own incentives, including free childcare. The Ohio Governor rewarded those Ohio residents accepting the Vaccines by allowing them to enter into the "Vaxamillion" lottery with a total $5 million prize and the chance to win a fully funded college education, while barring entry for residents who decline the Vaccines. In New York, metro stations offer free passes to those receiving the Vaccine in the station. West Virginia is running a lottery exclusively for the vaccinated with free custom guns, trucks and lifetime hunting and fishing licenses, a free college education, and cash payments of $1.5 million and $600,000 as the prizes. Previously, the state offered a $100 savings bond for each injection with a Vaccine. New Mexican residents accepting the Vaccines will be entered into weekly drawings to take home a $250,000 prize, and those fully vaccinated by early August could win the grand prize of $5 million. In Oregon, the vaccinated can win $1 million, or one of 36 separate $10,000 prizes through the state's "Take Your Shot" campaign. Other state and local governments are partnering with fast food chains to offer free pizza, ice cream, hamburgers and other foods to the vaccinated. Many people are desperate following the last year of economic

destruction and deprivation of basic freedoms, and they are especially vulnerable to this coercion.

The penalties take many forms, among them:

- Using guilt and shame to make unvaccinated children and adults feel badly about themselves for refusing the Vaccines.
- Threatening the unvaccinated with false fears and anxieties about COVID-19, especially children who are at no risk statistically.
- Removing the rights of those who are unvaccinated, including:
  - Being prohibited from working
  - Being prohibited from attending school or college
  - Being limited in the ability to travel in buses, trains and planes
  - Being prohibited from traveling outside the United States
  - Being excluded from public and private events, such as performing arts venues.

Most recently, the President has announced an aggressive campaign to visit the homes of the unvaccinated, not for the purpose of ensuring that they have all of the information they might need in order to make fully informed, voluntary decisions about the Vaccines (the information required by § 360bbb–3(e)(1)(A)(i) and (ii)), but instead for the purpose of pressuring them to be injected with the Vaccine so that the Administration can reach its goal of having 70% of the American population vaccinated. He said: "Now we need to go to community by community, neighborhood by neighborhood, and oftentimes, door to door — literally knocking on doors — to get help to the remaining people protected from the virus."[20] The White House press secretary referred to the door-knockers who would enter our communities to pressure us to accept the Vaccines using the language of war, as "strike forces." Then, after Dr. Fauci stated his opinion in mainstream media news outlets that "at the local level . . . there should be more mandates,

[20] *See* "Biden admin launching door-to-door push to vaccinate Americans, sparks major backlash," https://www.foxnews.com/media/biden-admin-door-to-door-coronavirus-vaccines (last visited July 15, 2021).

there really should be", the press secretary announced that the Biden Administration would support state and local Vaccine mandates.[21]

A study recently published in the International Journal of Clinical Practice, "Informed Consent Disclosure to Vaccine Trial Subjects of Risk of COVID-19 Vaccines Worsening Clinical Disease,"[22] concludes:

> *COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the developmentand testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE).* ***This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.***

(emphasis added).

Plaintiffs' expert Dr. Lee Merritt is a fully licensed, board certified surgeon, and has been actively engaged in medical practice for over 35 years. As Chief of Staff, Chief of Surgery and Chief of Credentialing at a regional medical center, she participated in hospital administration and education with respect to *inter alia* informed consent. She states: "I have read the Complaint and Motion for Preliminary Injunction in the above captioned matter, specifically the allegations related to informed consent. I agree with the informed consent allegations contained in the Complaint and Motion for Preliminary Injunction" (*see* Declaration of Dr. Lee Merritt at Exhibit A). Dr. Merritt has provided an example of some of the language that she would recommend using for the purpose of obtaining voluntary, informed consent to the Vaccines.

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[21] *See* "Biden will back local vaccine mandates," https://thehill.com/changing-america/well-being/prevention-cures/562622-biden-will-back-local-vaccine-mandates (last visited July 15, 2021).
[22] *See* https://onlinelibrary.wiley.com/doi/epdf/10.1111/ijcp.13795 (last visited July 17, 2021).

The combined effect of (i) the suppression and censorship of information regarding the risks of the Vaccines, (ii) the failure to inform the public regarding the novel and experimental nature of the mRNA Vaccines, (iii) the suppression and censorship of information regarding alternative treatments, (iv) the failure to inform and properly educate the public that the Vaccines are not in fact "approved" by the FDA, (v) the failure to inform and properly educate the public that the DHHS Secretary has *not* determined that the Vaccines are "safe and effective" and on the contrary has merely determined that "it is reasonable to believe" that the Vaccines "may be effective" and that the benefits outweigh the risks, (vi) the sustained psychological manipulation of the public through official fear-based messaging regarding COVID-19, draconian countermeasures and a system of rewards and penalties, is to remove any possibility that Vaccine recipients are giving voluntary informed consent to the Vaccines. They have no real option to accept or refuse the Vaccines. They are unwitting, unwilling participants in a large scale, ongoing non-consensual human experiment.[23]

(7) § 360bbb–3(e)(1)(A)(iii): Monitoring and Reporting of Adverse Events

VAERS was established in 1986 in order to facilitate public access to information regarding adverse events potentially caused by vaccines. This system is inadequate to the present circumstances, for the following reasons:

- neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, that the DHHS Secretary "has authorized the emergency use of the [Vaccines]" since they are not being informed of the true meaning of the EUAs, specifically, that the Secretary has *not* determined that the Vaccines are "safe and effective" (notwithstanding the President's widely publicized statements to the contrary, which are amplified daily by countless other governmental and private sector statements that the Vaccines are "safe and effective"), and that instead the DHHS Secretary has only determined that he

[23] https://en.wikipedia.org/wiki/Unethical_human_experimentation_in_the_United_States (last visited July 15, 2021).

has "reason to believe" that the Vaccines "may be effective" in treating or preventing SARS-CoV-2 and COVID-19, based on trials of the Vaccines that are not being conducted like any previous trials and are compressed, overlapping, incomplete and in many instances conducted by the Vaccine manufacturers themselves;

- neither healthcare professionals nor Vaccine recipients are being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of "the significant known and potential [ ] risks" of the Vaccines, since there is a coordinated campaign funded with $1 billion to extol the virtues of the Vaccines, and a simultaneous effort to censor information about the inefficacy of the Vaccines in preventing or treating SARS-CoV-2 and COVID-19, Vaccine risks, and injuries and deaths caused by the Vaccine;
- Vaccine recipients are not being informed by the Defendants, who have a financial stake in the intellectual property underlying at least one Vaccine, and who have other financial conflicts of interest, and conditions do not exist ensuring that others will inform them, that there are alternatives to the Vaccines and of their benefits;
- Vaccine recipients are not being informed by the Defendants, and conditions do not exist ensuring that others will inform them, of their "option to accept or refuse" the Vaccines, since they have been saturated with unjustified fear-messaging regarding SARS-CoV-2 and COVID-19, psychologically manipulated, and coerced by a system of rewards and penalties that render the "option to [ ] refuse" meaningless; and
- Appropriate conditions do not exist for "the monitoring and reporting of adverse events" since only a fraction (as low as 1%) of adverse events are reported to VAERS by physicians fearing liability, and the Defendants have established a parallel reporting system for COVID-19 that is not accessible by Plaintiffs or the rest of the public.

A 2011 report by Harvard Pilgrim Healthcare for DHHS stated that fewer than 1% of all vaccine adverse events are reported to Defendants: "[F]ewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."[24]

To illustrate, while the CDC claims that "Anaphylaxis after COVID-19 vaccination is rare and occurred in approximately 2 to 5 people per million vaccinated in the United States

[24] Harvard Pilgrim Health Care, Inc., Electronic System for Public Health Vaccine Adverse Event Reporting System, *AHRQ* 2011.

based on events reported to VAERS,"[25] a recent study by Mass General Brigham found "severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations."[26] This is 50 to 120 times more cases than reported by VAERS and the CDC, meaning that only between 0.8% and 2% of all anaphylaxis cases are being reported by the Defendants. The underreporting is inexplicable, since it is mandatory for healthcare professionals to report this reaction to the Vaccines,[27] and the reactions typically occur within 30 minutes of vaccination.[28]

Uniquely for COVID-19, the CDC has developed a parallel system called "V-Safe." V-Safe is an app on a smart phone which people can use to report adverse events. Plaintiffs' investigation indicates that vaccine subjects who are provided with written information are given the V-Safe contact information. Plaintiffs cannot access V-Safe data, since it is controlled exclusively by the CDC. Plaintiffs are concerned that the information in V-Safe exceeds that in VAERS, in terms of volume and kind, defying Congressional intent in creating VAERS.

In summation, VAERS is inaccurate, and the federal government is failing to provide data from other sources such as V-Safe, Medicare/Medicaid, the military, etc. Informed consent cannot be given without an understanding of risk and Plaintiffs cannot help but wonder why the Defendants would fail to disclose this critical information related to risk to the public, particularly in light of the fact that they have had the time and resources to study and extend the authorizations on the Vaccines, build an enormous Vaccine marketing machine, and roll out Vaccine clinics all over the nation.

[25] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.
[26] *See* https://jamanetwork.com/journals/jama/fullarticle/2777417.
[27] *See* https://www.fda.gov/media/144413/download.
[28] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

B. The Under-18 Age Category

In the United States, those younger than 18 years of age accounted for just 1.7% of all COVID-19 cases.[29] Essentially no severe cases of COVID-19 were observed in those aged 10 through 18 years. This group accounted for just 1% of reported cases, almost all of which were very mild.[30] A study recently published in the British Medical Journal concludes: "In contrast to other respiratory viruses, children have less severe symptoms when infected with the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."[31] Hospitalization due to COVID-19 is incredibly rare among youth, and overstated. The American Academy of Pediatrics[32] reported:

> *…these studies underscore the importance of clearly distinguishing between children hospitalized with SARS-Co-V-2 found on universal testing versus those hospitalized for COVID-19 disease. Both demonstrate that reported hospitalization rates greatly overestimate the true burden of COVID-19 disease in children.*

Professor Hervé Seligmann, an infectious disease expert and biomedical researcher with over 100 peer-reviewed international publications, of the University of Aix-Marseille, has scrutinized the official COVID-19 statistics and figures of Israel, which has vaccinated 63% of its population, and fully vaccinated 57% of its population. Professor Seligmann sees no benefit in vaccinating those under 18, and significant risk of harm:

> *There are several theories about why the risk of death is so low in the young including that the density of the ACE2 receptors that the virus uses to gain entry into cells is lower in the tissue of immature animals and this is expected to be true also in humans. However, the vaccines induce the cells of the recipient to*

[29] Coronavirus Disease 2019 in Children - United States, February 12-April 2, 2020. *MMWR. Morbidity and Mortality Weekly Report* 69:422-426.
[30] Tsabouri, S. et al. (2021), Risk Factors for Severity in Children with Coronavirus Disease 2019: A Comprehensive Literature Review. *Pediatric Clinics of North America* 68:321-338.
[31] Zimmermann P, Curtis N Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections Archives of Disease in Childhood 2021;106**:**429-439.
[32] Ioannidis, J.P.A. (2020) Infection fatality rate of COVID-19 inferred from seroprevalence data. Bull. World Health Organ. -:BLT.20.265892.

> *manufacture trillions of spike proteins with the pathology described above. Because immune responses in the young and healthy are more vigorous than those in the old, paradoxically, the vaccines may thereby induce, in the very people least in need of assistance, strong immune responses, including those which can damage their own cells and tissues as well as by stimulating blood coagulation. Experts predict that vaccination will greatly increase the very low COVID-19 risks experienced by the younger population … vaccination-associated mortality risks are expected at least 20 times greater below age 20 compared to the very low COVID19-associated risks for this age group.*[33]

CDC data indicates that children under 18 have a 99.998% COVID-19 recovery rate with no treatment. This contrasts with over 45,000 deaths (*see* below) and hundreds of thousands of adverse events reported following injection with the Vaccines. The risk of harm to children may be as high as 50 to 1. Thus, children under 18 are at no statistically significant risk of harm from SARS-CoV-2 and COVID-19. Administering Vaccines to this age group knowingly and intentionally exposes them to unnecessary and unacceptable risks.

Plaintiffs' expert Dr. Angelina Farella is a fully licensed, board certified pediatrician, actively practicing for over 25 years, and has vaccinated in excess of 10,000 pa tients (see Declaration of Angelina Farella, MD at Exhibit B). Dr. Farella states, in her professional medical opinion: "There are 104 children age 0-17 who have died from Covid-19 and 287 from Covid + Influenza out of roughly 72 million children in America. This equals ZERO risk. There is NO public interest in subjecting children to experimental vaccination programs, to protect them from a disease that does not threaten them." Dr. Farella also opines, with respect to the lack of testing designed to ensure the safety of this subpopulation:

> *Vaccines take years to safely test. It's not only the number of people tested but the length of time that is important when creating new vaccines. Emergency Use Authorization was granted prematurely for adolescents, before ANY trials were completed. Moderna is scheduled to complete trials on October 31, 2022, and Pfizer is scheduled to complete trials on April 27, 2023. There were no trial*

[33] Seligmann, H., (2021), Expert Evaluation on Adverse Effects of the Pfizer COVID-19 Vaccination. *See* https://www.researchgate.net/publication/351441506_Expert_evaluation_on_adverse_effects_of_the_Pfizer-COVID-19_vaccination (last visited July 8, 2021).

> *patients under the age of 18. The FDA and these pharma companies are currently allowing children 12 years old to receive this shot, when they were never studied in the trials.* ***Never before in history have we given medications that were not FDA approved to people who were not initially studied in the trial.***

Section 360bbb–3(c)(2) requires the Secretary to base decisions on "data from adequate and well-controlled clinical trials". Clearly, the Secretary has exceeded his statutory authority with respect to the under-18 subpopulation.

Meanwhile, local governments are hastily passing laws eliminating the requirement for parental consent, and even parental knowledge, of medical treatments administered to children as young as 12. This is intended to pave the way for children to be vaccinated at school, without parental knowledge or consent.

Children in the 12-18 age group are not developmentally capable of giving voluntary, informed consent to the Vaccines. Their brains are rapidly changing and developing, and their actions are guided more by the emotional and reactive amygdala and less by the thoughtful, logical frontal cortex. Hormonal and body changes add to their emotional instability and erratic judgment. Children also have a well-known and scientifically studied vulnerability to pressure from peers and adults. This age group is particularly susceptible to pressure to do what others see as the right thing to do — in this case, to be injected with the Vaccine "for the sake of other people and society."

Injecting this under-18 subpopulation with the Vaccines threatens them with immediate, potentially life-threatening harm. The documented risks of injecting this subpopulation with the Vaccines far outweigh the purported benefits.

C. Those Previously Infected with SARS-CoV-2

Medical studies show that those with preexisting immunity have long lasting and robust natural immunity to SARS-CoV-2.[34] A recent Cleveland Clinic study[35] demonstrates that natural immunity acquired through prior infection with COVID-19 is stronger than any benefit conferred by a Vaccine, rendering vaccination unnecessary for those previously infected. A comparative study by Goldberg *et al* "questioned the need to vaccinate previously-infected individuals" and noted that previously infected individuals had 96.4% immune protection from COVID-19, versus 94.4% in those injected with the Vaccine.[36]

The Israeli Ministry of Health has released data showing that Israelis who had been previously infected with SARS-CoV-2 (and were not also vaccinated) were far less likely to become re-infected with the virus than those in the population who had been injected with the Vaccines.[37] Of the more then 7,700 new cases detected during the recent wave that commenced in May 2021, only 72, or less than 1%, were people who had previously been infected with SARS-CoV-2 and were never vaccinated. By contrast, over 3,000 cases, or 40%, were people who became infected for the first time, in spite of being vaccinated. The 72 instances of re-infection represent a mere 0.0086% of the 835,792 Israelis who are known to have recovered from the virus.

The immutable laws of immunology continue to function during COVID-19 (meaning those who are previously recovered from such an infection have acquired the ability to recognize disease and can effectively neutralize the infection before it takes hold), as evidenced by the fact

[34] *See* https://www.nature.com/articles/d41586-021-01442-9, and https://www.thelancet.com/journals/lancet /article/PIIS0140-6736(21)00782-0/fulltext (last visited July 14, 2021).
[35] Shrestha, N., Burke, P., Nowacki, A., Terpeluk, P., Gordon, S. (2021), Necessity of COVID-19 Vaccination in Previously Infected Individuals. See https://www.medrxiv.org/content/ 10.1101/2021.06.01.21258176v2 (last visited July 8, 2021).
[36] *See* https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.full.pdf (last visited July 13, 2021).
[37] *See* https://www.israelnationalnews.com/News/News.aspx/309762 (last visited July 15, 2021).

that persons who have had SARS-CoV-1, a virus which is 22% dissimilar to the current strain, are still immune from SARS-CoV-2 18 years later.[38] Laypersons are misled to believe that when antibodies gradually diminish as expected, immunity is gone when in fact, immunity remains[39] quiescent deeper in the body, in the bone marrow[40], plasma, ready to be activated should the threat reemerge. This is normal immunology.

Not only is a Vaccine unnecessary in this subpopulation, it is more likely to cause harm. Scientists have observed vaccine-driven disease enhancement in the previously infected. The FDA admits that many people receiving a Vaccine either are or were previously infected with SARS-CoV-2, or have or previously had COVID-19.[41] Upon injection with the Vaccines, this population has reported serious medical harm, including death.[42] There is an immediately higher death rate worldwide upon receiving a Vaccine, generally attributed to persons having recently been infected with COVID-19. A person who previously had SARS-CoV-2, and then receives a Vaccine, mounts an antibody response to the Vaccine that is between 10 and 20 times stronger than the response of a previously uninfected person. The antibody response is far too strong and overwhelms the Vaccine subject. Medical studies show severe Vaccine side effects in persons previously infected with COVID-19.[43] A study published in the New England Journal of Medicine noted antibody titers 10-45 times higher in those with preexisting COVID-19 immunity after the first Vaccine injection, **with 89% of those seropositive reporting adverse side-effects.**[44] This substantial risk is suppressed in mainstream national news. Groups of scientists are demanding improved pre-assessment due to "Vaccine-driven disease enhancement"

[38] See https://www.nature.com/articles/s41586-020-2550-z (last visited July 14, 2021).
[39] https://www.medpagetoday.com/infectiousdisease/covid19/92836 (last visited July 14, 2021).
[40] https://www.nature.com/articles/s41586-021-03647-4 (last visited July 14, 2021).
[41] *See* https://www.fda.gov/media/144245/download (last visited July 13, 2021).
[42] *See* https://www.bridgemi.com/michigan-health-watch/three-michigan-people-who-died-after-vaccine-actually-had-earlier-covid; https://www.bmj.com/content/bmj/373/bmj.n1372.full.pdf (last visited July 13, 2021).
[43] See https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1.full.pdf (last visited July 13, 2021).
[44] See https://www.nejm.org/doi/10.1056/NEJMc2101667 (last visited July 13, 2021).

in the previously infected, a subpopulation which has been excluded from clinical trials. The failure to protect a subpopulation at higher risk, such as this one, is unprecedented. Injecting this subpopulation with the Vaccines, without prescreening, threatens them with immediate, potentially life-threatening harm.

Plaintiffs' expert Dr. Richard Urso is a fully licensed, board certified, practicing medical doctor (see Declaration of Dr. Richard Urso at Exhibit C). Dr. Urso has treated over 300,000 patients in his career, including over 450 C OVID-19 recovered patients. In his professional medical opinion:

> *COVID recovered patients are at extremely high risk to a vaccine. They retain an antigenic fingerprint of natural infection in their tissues. They have all the requisite components of immune memory. Vaccination may activate a hyperimmune response leading to a significant tissue injury and possibly death.*
>
> *I have read the Complaint and Motion for Preliminary Injunction in the above captioned matter, specifically the allegations related to the dangers to members of the population who have already had Covid-19. I agree with the allegations contained in the Complaint and Motion for Preliminary Injunction.*

Pre-screening can be accomplished in the traditional way by (1) obtaining relevant personal and family medical history including prior COVID-19 symptoms and test results, (2) obtaining antibody and T-Detect testing from indeterminate persons, (3) obtaining rapid PCR screening testing on all persons (using at least the standard cycle thresholds set forth *infra*). If the prescreening results are positive, the Vaccine candidate must be excluded. The documented risks of indiscriminately injecting this subpopulation with the experimental Vaccines far outweigh the purported benefits.

For additional support of the foregoing sections, and this Motion for Injunctive Relief generally, please see the duly sworn Declaration of Dr. Peter A. McCullough, attached hereto and incorporated herein with reference to Exhibit L.

D. Whistleblower Testimony: 45,000 Deaths Caused by the Vaccines

Plaintiffs' expert Jane Doe[45] is a computer programmer with subject matter expertise in the healthcare data analytics field, and access to Medicare and Medicaid data maintained by the Centers for Medicare and Medicaid Services (CMS) (*see* Declaration of Jane Doe at Exhibit D). Over the last 20 years, she has developed over 100 distinct healthcare fraud detection algorithms for use in the public and private sectors. In her expert opinion, VAERS under-reports deaths caused by the Vaccines by a conservative factor of at least 5. As of July 9, 2021, VAERS reported 9,048 deaths associated with the Vaccines. Jane Doe queried data from CMS medical claims, and has determined that the number of deaths occurring with 3 days of injection with the Vaccines exceeds those reported by VAERS by a factor of at least 5, indicating that **the true number of deaths caused by the Vaccines is at least 45,000.** She notes that in the 1976 Swine Flu vaccine campaign (in which 25% of the U.S. population at that time, 55 million Americans, were vaccinated), the Swine Flu vaccine was deemed dangerous and unsafe, and removed from the market, even though the vaccine resulted in only 53 deaths.

The gross and willful under-reporting of Vaccine-caused deaths, which is substantiated by Jane Doe's Declaration, and also by other independent data points considered as part of Plaintiffs' due diligence, is profoundly important on a number of levels. This evidence increases the likelihood of Plaintiffs' success on the merits by: (1) making it impossible (a) that the DHHS Secretary can reasonably conclude, as required by § 360bbb–3(c)(2)(B), that "the known and potential benefits of [the Vaccines] outweigh the known and potential risks of [the Vaccines]",

[45] Plaintiffs' expert Jane Doe is a whistleblower who fears for her personal safety and that of her family, and reprisal, including termination and exclusion from her chosen profession for the duration of her working life, for disclosing the evidence contained in her Declaration at Ex. D. Plaintiffs will present the Court with a motion for an appropriately tailored protective order seeking to preserve the confidentiality of Jane Doe's identity. In the meantime, Defendants are not prejudiced, since they can respond to the substance of Jane Doe's Declaration and challenge her expert qualification without knowing her true identity. Plaintiffs' counsel have in their possession a copy of this same Declaration of Jane Doe, signed by the witness in her actual name.

(b) that the DHHS Secretary has succeeded in creating conditions, as required by § 360bbb–3(e)(1)(A)(i)(II) and (ii)(II), that ensure that healthcare professionals and Vaccine candidates are informed of the "significant known and potential [ ] risks" of the Vaccines, and (c) that the DHHS Secretary has succeeded in creating conditions, as required by § 360bbb–3(e)(1)(A)(iii), for the monitoring and reporting of adverse events; and (2) sealing Plaintiffs' argument that the FDA's "citizen petition" process (discussed *infra* in section III(1)) is "inadequate and not efficacious" and that its pursuit by Plaintiffs would have been a "futile gesture" by showing Defendants' bad faith. The evidence makes it irrefutable that Plaintiffs and others in the public will suffer irreparable injury (discussed *infra* in section III(2)) if this Motion is denied. Finally, the evidence tilts the balance of hardships and public interest (discussed *infra* in Section III(3) decisively in favor of Plaintiffs.

III. LAW AND ANALYSIS

In the 11th Circuit, a district court may grant preliminary injunctive relief when:

> *"a party establishes each of four separate requirements: (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest."*

Jones v. Governor of Fla., 950 F.3d 795, 806 (11th Cir. 2020). However, the court has "considerable discretion…in determining whether the facts of a situation require it to issue an injunction." eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (internal quotations and citations omitted).

A. Likelihood of Success on the Merits

As a threshold matter, parties seeking a preliminary injunction "are not required to prove their claim, but only to show that they [are] likely to succeed on the merits." Glossip v. Gross, 135 S. Ct. 2726, 2792 (2015); Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 22 (2008).

While the burden of persuasion remains with the Plaintiffs, the "burdens at the preliminary injunction stage track the burdens at trial." Gonzales v. O Centro Espírita Beneficente Uniã do Vegetal, 546 U.S. 418, 428–30 (2006). For the purposes of a preliminary injunction, this burden of proof can be shifted to the party opposing the injunctive relief after a *prima facie* showing, and the movant should be deemed likely to prevail if the non-movant fails to make an adequate showing. Id.

(1) Plaintiffs Have Standing

Plaintiffs have standing to assert these claims. They have demonstrated that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that it is likely to be redressed by a favorable decision." Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992).

Plaintiffs have alleged specific physical injuries caused by the Vaccines, death caused by the Vaccines, actual and threatened loss of employment, and violations of their constitutionally protected rights to personal autonomy, bodily integrity, and to work in a profession of their choosing, each of which constitutes "an invasion of a legally protected interest" that is "concrete," "particularized," and "actual or imminent, not conjectural or hypothetical" as required under Spokeo, Inc. v. Robins, 136 S.Ct. 1540, 1548 (2016). Their pleadings are supported by Declarations made under oath.

The participation of third parties in the chain of causation does not defeat Plaintiffs' claims or their standing, since their injuries are "fairly traceable" to the Defendants. *See* Simon

v. Eastern Kentucky Welfare Rights Org., 426 U.S. 26, 45 n.25 (1976) (noting cases providing that privately inflicted injury is traceable to government action if the injurious conduct "would have been illegal without that action"); National Wildlife Federation v. Hodel, 839 F.2d 694, 705 (D.C. Cir. 1988) ("The Supreme Court's decisions on this point show that mere indirectness of causation is no barrier to standing, and thus, an injury worked on one party by another through a third party intermediary may suffice."); Telephone and Data Systems, Inc. v. FCC, 19 F.3d 42, 47 (D.C. Cir. 1994) ("injurious private conduct is fairly traceable to the administrative action contested in the suit if that action authorized the conduct or established its legality" . . . "the relief sought would constitute a 'necessary first step on a path that could ultimately lead to relief fully redressing the injury'" . . . "the relief requested 'will produce tangible, meaningful results in the real world.'"); Motor & Equip. Mfrs. Ass'n v. Nichols, 142 F.3d 449, 457-58 (D.C. Cir. 1998) (petitioner had standing to challenge government action based on the independent conduct of third parties where evidence demonstrated that the challenged action "resulted in an almost unanimous decision" by those third parties to take action that harmed the petitioner); America's Community Bankers v. FDIC, 200 F.3d 822, 827-28 (D.C. Cir. 2000) ("an agency does not have to be the direct actor in the injurious conduct, but that indirect causation through authorization is sufficient to fulfill the causation requirement for Article III standing."); Consumer Federation of America v. F.C.C., 348 F.3d 1009, 1012 (D.C. Cir. 2003) ("When an agency order permits a third-party to engage in conduct that allegedly injures a person, the person has satisfied the causation aspect of the standing analysis.").

A favorable decision of this Court will likely redress Plaintiffs' injuries. The Vaccine-injured Plaintiffs continue to suffer the adverse effects of the Defendants' wrongdoing, and their physical injuries are still unfolding. Their personal injuries can be redressed in the usual way, by

an award of civil money damages for pain and suffering, emotional distress, economic loss and medical monitoring.

(2) Defendants' Actions are Reviewable

Plaintiffs have alleged that there is no real emergency as required by § 360bbb–3(b), that Defendants have willfully failed to satisfy the statutory criteria for issuing the Vaccine EUAs required by § 360bbb–3(c), and that Defendants have failed to create and maintain the conditions of authorization for the Vaccine EUAs required by § 360bbb–3(e) (Counts I, II, III and VI).

The Administrative Procedures Act ("APA") imposes four requirements that must be met before a federal court can review agency action: (1) the alleged injury must "arguably" be within the "zone of interests" protected or regulated by the statute in question, (2) no statute precludes judicial review, (3) the agency action is "final" and (4) the agency action is not "committed to agency discretion" by law.

i. Plaintiffs' Injuries are Within the Zone of Interests

The "zone of interests" test is "*not* 'especially demanding'" Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 130 (2014) (quoting Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak, 567 U.S. 209, 225 (2012)). The Supreme Court has "conspicuously included the word 'arguably' in the test to indicate that the benefit of any doubt goes to the plaintiff. " Id. The test "'forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that' Congress authorized that plaintiff sue." Collins v. Mnuchin, 938 F.3d 553, 574 (5th Cir. 2019) (quoting Lexmark, 572 U.S. at 130.). The Vaccine injuries and death, and the violations of the constitutionally protected right to bodily integrity and personal autonomy that Plaintiffs assert in the Complaint, are within the zone of interests protected by these statutory provisions, the purpose of which is to tightly limit the circumstances in which

potentially harmful medical products can be placed in the stream of commerce and used by the American public prior to their full approval by the FDA.

ii. No Statutory Preclusion

Plaintiffs can locate no valid statute purporting to preclude judicial review of this agency action, either categorically, or prior to the exhaustion of administrative remedies.

Defendants may cite to 42 U.S.C. § 247d-6d(b)(7), a provision of the Public Readiness and Emergency Preparedness Act ("PREP Act"), which states: "No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." However, a "strong presumption in favor of judicial review of administrative action" governs the construction of potentially jurisdiction-stripping provisions like § 247d-6d(b)(7). INS v. St. Cyr, 533 U.S. 289, 298 (2001). "Even when the ultimate result is to limit judicial review, the Court cautions that as a matter of the interpretive enterprise itself, the narrower construction of a jurisdiction-stripping provision is favored over the broader one." ANA Int'l Inc. v. Way, 393 F.3d 886, 891 (2004) (citing to Reno v. American-Arab Anti-Discrimination Committee, 525 U.S. 471, 480-482 (1999)); see also Patel v. United States AG, 917 F.3d 1319, Fn. 4 (11th Cir. 2019) ("We are also mindful that there is a strong presumption in favor of interpreting statutes to allow judicial review of administrative actions; consequently, jurisdiction stripping is construed narrowly."), (citing to Kucana v. Holder, 558 U.S. 233, 251-252 (2010).

Thus the prohibition on judicial review in § 247d-6d(b)(7) must be construed narrowly so as to apply exclusively and specifically to declarations conferring the PREP Act "immunity" described in § 247d-6d(a), which are the only declarations made by the Secretary under "this subsection." Section 247d-6d(b)(1) refers to the Secretary's having first and beforehand made a declaration that a public health emergency exists (a declaration that is made under an entirely

different statute, 21 U.S.C. § 360bbb–3(b)), and states that if such a public health emergency declaration has been made, then the Secretary may confer PREP Act immunity by publishing a notice of same in the Federal Register.

Any broader interpretation of § 247d -6d(b)(7) — and in particular, any broader interpretation that purports to categorically eliminate judicial review of actions taken under § 360bbb–3 — is an unconstitutional delegation of legislative power by Congress to the executive branch. It is unconstitutional for three reasons. First, it is unconstitutional because it is devoid of any "'intelligible principle' on which to judge the conformity of agency action to the congressional grant of power." Florida v. Becerra, 2021 U.S. Dist. LEXIS 114297 (M.D. Fl. 2021) (quoting J.W. Hampton, Jr., & Co. v. Unitd States, 276 U.S. 394, 409 (1928)). Further, it purports to categorically exclude, rather than merely limiting, all judicial review. Finally, it is unconstitutional because it purports to eliminate judicial review in that most constitutionally perilous of situations, a state of emergency unilaterally declared and sustained by an executive branch official.

In Home Building and Loan Association v. Blaisdell, 290 U.S. 398 (1934), the U.S. Supreme Court stated: "Whether an emergency exists upon which the continued operation of the law depends is always open to judicial inquiry." 290 U.S. at 442, citing Chastleton Corp. v. Sinclair, 264 U.S. 543 (1924). In Sinclair, the Supreme Court stated: "A law depending upon the existence of emergency or other certain state of facts to uphold it may cease to operate if the emergency ceases or the facts change." 264 U.S. at 547. Both Blaisdell and Sinclair are clear authority that an emergency and the rules promulgated thereunder must end when the facts of the situation no longer support the continuation of the emergency. They also forbid this Court to merely assume the existence of a "public health crisis" based on the pronouncements of the Executive Defendants. They are clear authority that it is the duty of the court of first instance to

grapple with this question and conduct an inquiry. "[A] Court is not at liberty to shut its eyes to an obvious mistake when the validity of the law depends upon the truth of what is declared." Id. The Sinclair court instructed lower court's to inquire into the factual predicate underlying a declaration of emergency, where there appears to have been a change of circumstances: "the facts should be gathered and weighed by the court of first instance and the evidence preserved for consideration by this Court if necessary." 264 U.S. at 549.

In Sterling v. Constantin. 287 U.S. 378 (1932), the Supreme Court reviewed the actions of the Texas Governor in declaring martial law and interfering with oil well production in a manner that impaired private drilling rights. In holding that the question whether an emergency existed justifying such interference with the plaintiffs' property rights was subject to judicial inquiry and determination, the Court stated:

> *If this extreme position could be deemed to be well taken, it is manifest that the fiat of a state governor, and not the Constitution of the United States, would be the supreme law of the land; that the restrictions of the federal Constitution upon the exercise of state power would be but impotent phrases, the futility of which the state may at any time disclose by the simple process of transferring powers of legislation to the Governor to be exercised by him, beyond control, upon his assertion of necessity. Under our system of government, such a conclusion is obviously untenable. There is no such avenue of escape from the paramount authority of the federal Constitution. When there is a substantial showing that the exertion of state power has overridden private rights secured by that Constitution, the subject is necessarily one for judicial inquiry in an appropriate proceeding directed against the individuals charged with the transgression.*

287 U.S. at 397-98.

Similarly, the actions of the Secretary must be subject to judicial review. Under 21 U.S.C. § 355(q)(1)(A), the DHHS Secretary

> *shall not delay approval of a pending application [ ] because of any request to take any form of action relating to the application, either before or during consideration of the request, unless — (i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations . . .*

21 C.F.R. § 10.30 in turn provides for so called "citizen petitions" which are a form of administrative redress. However, a close reading of the statutory language and due consideration of the underlying policies compel the conclusion that Congress did not intend to preclude judicial review of this particular agency action.

Section 355(q) could easily state that interested parties "shall not pursue" (or the equivalent) lawsuits prior to the completion of the citizen petition process. It does not. Instead, the only mandatory language in § 355(q) is directed at the Secretary, not at citizens, and it states that the Secretary "shall not delay". This language is intended to target the predominant, anti-competitive mischief marring the FDA approval process at the time the statute was enacted. Entrenched market participants abused the citizen petition process by soliciting citizenry to file petitions for the improper purpose of delaying applications for new drug approval submitted by new market entrants.[46] Senator Edward Kennedy explained: "The citizen petition provision is designed to address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health."[47] The statutory language should be read narrowly in accordance with that purpose, to apply only to the "approval of a pending application" which should not be delayed.

Plaintiffs here are seeking first and foremost the **revocation** or **termination** of the declared emergency and existing Vaccine EUAs, and not for anti-competitive purposes, but in order to respond to unlawful agency action driven by financial conflicts of interest, political pressure and fear, the substantial risk of widespread personal injury and death, and constitutional infractions.

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[46] See *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 252 (2012) ("The study finds that brand drug companies file 68% of petitions, far more than generic firms or other parties such as universities, doctors or hospitals. Of the petitions by brand firms, more than 75% target generic entrants.").
[47] 153 Cong. Rec. 25,047 (2007).

Further, neither 21 U.S.C. § 355 nor 21 C.F.R. § 10.30 expressly references § 360bbb–3, the statute pursuant to which the emergency has been declared and the Vaccines released to the public. Conversely, § 360bbb–3 does not expressly refer to 21 U.S.C. § 355 nor 21 C.F.R. § 10.30. If Congress had intended for the citizen petition process — designed to address the specific mischief of anti-competitive behavior — to apply to the very particular and very different circumstances of an emergency use authorization of highly experimental and potentially dangerous medical interventions with the potential to rapidly injure or kill large swathes of the American populace, surely it would have said so. Plaintiffs are the current and future Vaccine-injured in a time of purported emergency, complaining of gross agency malfeasance and conflicts of interest, not profit-seeking market participants.

Neither should the judicial doctrine of "exhaustion of administrative remedies" bar judicial review. "[J]udicially created exhaustion requirements are 'subject to numerous exceptions.'" Georgia v. United States, 398 F.Supp. 1330, 1343 (S.D. Ga. 2019) (quoting Kentucky v. United States ex rel. Hagel, 759 F.3d 588, 599 (6th Cir. 2014)). In their discretion, the district courts

> *"…have recognized at least three prudential exceptions to exhaustion requirements. [ ] Exhaustion may be excused if a litigant can show: (1) that requiring exhaustion will result in irreparable harm; (2) that the administrative remedy is wholly inadequate; or (3) that the administrative body is biased, making recourse to the agency futile."*

Id. (quoting Kansas Dept. for Children and Families v. SourceAmerica, 874 F.3d 1226, 1250 (10th Cir. 2017) ("We permit district courts to excuse a failure to exhaust where '(1) the plaintiff asserts a colorable constitutional claim that is collateral to the substantive issues of the administrative proceedings, (2) exhaustion would result in irreparable harm, and (3) exhaustion would be futile.'")).

Courts have recognized exceptions to the requirement of administrative exhaustion in the specific context of the FDCA and 21 C.F.R. § 10.30. *See, e.g.*, Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1378 (9th Cir. 1983) ("Biotics and Seroyal admit failing to take advantage of this available administrative remedy, but argue that the administrative remedy is 'inadequate and not efficacious' and that its pursuit would have been a 'futile gesture.' **Although we recognize an exception to the exhaustion requirement in these circumstances**, there is nothing in the record to indicate that a citizens petition to the Commissioner would have been ineffective or futile." (emphasis added)) (citing to AMP Inc. v. Gardiner, 275 F.Supp. 410 (S.D.N.Y. 1967), aff'd, 389 F.2d 825 (2d Cir. 1968), cert. denied, 393 U.S. 825 (1968); Premo Pharmaceutical Laboratories, Inc. v. United States, 629 F.2d 795, 801 (2d Cir. 1980), Natick Paperboard Corp. v. Weinberger, 498 F.2d 125, 128-29 (1st Cir. 1974).

The record in this case contains abundant evidence that the citizen petition process is both "inadequate and not efficacious". First and most importantly, the FDA need not respond to a citizen petition for 5 months, and in fact as a practical matter the "deadline" is more honored in the breach than the observance. When the FDA does respond, its response may be indeterminate. The chart below constructed from VAERS data shows that the American public cannot afford to wait for 5 months, while physical injuries and deaths due to the Vaccine skyrocket. Jane Doe's expert testimony that the true number of deaths caused by the Vaccine is in excess of 45,000 (*see* Declaration at Ex. D) renders the Defendants' likely argument that Plaintiffs must muddle through the citizen petition process before bringing this litigation not just legally absurd, but inhumane.

VAERS DATA		
APRIL 23, 2021	**JULY 2, 2021**	**% INCREASE**
118,902 ADVERSE EVENTS	438,441 ADVERSE EVENTS	72.88%
3,544 DEATHS	9,048 DEATHS	60.83%
12,619 INJURIES	41,015 INJURIES	69.23%

Plaintiff AFLDS' experience with the citizen petition process to date substantiates the argument. The Complaint alleges that Defendants are suppressing information regarding the availability of safe and effective alternative prophylaxis and treatments for COVID-19, including for example hydroxychloroquine (ECF 10, ¶¶ 219-228). Plaintiff AFLDS filed a citizen petition regarding hydroxychloroquine on October 12, 2020, requesting that the FDA exempt hydroxychloroquine-based drugs from prescription-dispensing requirements and make them available to the public over-the counter (*see* Citizen Petition at Exhibit E). The FDA acknowledged receipt of the petition on October 13, 2020. (*see* FDA Acknowledgment Letter at Exhibit F). Then on April 8, 2021, the FDA wrote to AFLDS to say that it "has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." (*see* FDA Delay Letter at Exhibit G). As recently as June 21, 2021 the FDA has confirmed by email that it has no substantive response to the Citizen's Petition, responding to AFLDS' request for an update by referring back to the FDA's April 8 delay letter! The issues raised in the Complaint and in this Motion would almost certainly be claimed to be equally or more complex, and there is no reason whatsoever to believe that the FDA will respond substantively to them within the statutory deadline, or in any amount of time shorter than the 10 months that have passed since the hydroxychloroquine petition was filed. All of this is becomes

even more relevant in light of the fact that while a response to a citizen's petition is put off for many months, the vaccines were approved with no delay.

Not only is the citizen petition process fatally slow, the FDA is ultimately powerless to award civil money damages for the physical injury and death that have invaded Plaintiffs' constitutional right to personal autonomy and bodily integrity. These are irreparable injuries. Winck v. England, 327 F.3d 1296, 1304 (11th Cir. 2003) ((“[exhaustion] is not required where no genuine opportunity for adequate relief exists, **irreparable injury** will result if the complaining party is compelled to pursue administrative remedies, or an administrative appeal would be futile”) (emphasis added)).

The pursuit of a citizen petition is also a “futile gesture” since the FDA will not grant the relief requested by Plaintiffs. An empirical study has shown that the mean and median citizen petition grant rates fluctuated between 0% and 16% in the eight years from 2003 through 2010, and the mean and median denial rates were both 92%.[48] The real and substantial financial conflicts of interest compromising the Defendants and their key officials involved in the § 360bbb–3 process (*see* Complaint, ECF 10, ¶¶ 250-256), combined with the immense pressure[49] placed on the FDA by industry and politicians to fast track the approval process, and Jane Doe's revelation that the Defendants have intentionally concealed from the public that the true number of deaths caused by the Vaccines is at least 45,000 not the approximately 9,000 reported by VAERS (*see* Declaration at Ex. D), destroy any pretense that the FDA could adjudicate such a citizen petition with fairness and impartiality.

The policy justification traditionally cited by those courts that have required compliance with the citizen petition process do not apply here. *See, e.g.*, Garlic v. United States Food &

[48] *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. at 275.
[49] Gardner, L., “Calls Mount on FDA to Formally Endorse COVID Vaccines as Delta Surges” (July 8, 2021). *See* https://news.yahoo.com/calls-mount-fda-formally-endorse-182622109.html (last visited July 12, 2021).

Drug Administration, 783 F.Supp. 4, 5 (D. D.C. 1992) ("Allowing 'interested parties' to bypass the administrative remedies would undermine the entire regulatory process. Drug manufacturers could circumvent the FDA's procedures by soliciting private citizens to sue for judicial approval new medications."). Plaintiffs are not attempting to circumvent the substantive provisions of § 360bbb–3 in order to force the approval and release of a new experimental drug, rather they are trying to force the FDA, its officials riddled with serious conflicts of interests, to comply with these provisions in order prevent widespread personal injury and death and egregious violations of the constitutionally protected rights to personal autonomy and bodily integrity.

Count VI of the Complaint seeks mandamus, since there is "'practically no ot her remedy.'" Collin v. Berryhill, 2017 U.S. Dist. LEXIS 78222 at *9 (quoting Helstoski v. Meanor, 442 U.S. 500, 505 (1979). Courts have held that the perceived medical urgencies created by COVID-19 itself, and also those created by the decisions, orders and actions of authorities responding to COVID-19, can make it impractical and inappropriate to force a plaintiff seeking *mandamus* to wait for alternative processes to run their course:

> *Moreover, given the broader context of the COVID-19 pandemic, we agree with the Fifth Circuit that "[i]n mill-run cases, it might be a sufficient remedy to simply wait for the expiration of the TRO, and then appeal an adverse preliminary injunction. In other cases, a surety bond may ensure that a party wrongfully enjoined can be compensated for any injury caused. Those methods would be woefully inadequate here."*

In re Rutledge, 956 F.3d 1018, 1026 (8th Cir. 2020), quoting In re Abbott, 2020 U.S. App. LEXIS 10893 at *14.[50]

[50] The Supreme Court subsequently vacated the judgment in In re Abbott, and remanded to the Fifth Circuit with instructions to dismiss the case as moot, following the Texas Governor's relaxation of his order restricting abortion as a non-essential surgical procedure, however the decision did not turn on an analysis of mandamus. *See*, Planned Parenthood Ctr. for Choice v. Abbott, 2021 U.S. LEXIS 647.

iii. The Emergency Declaration and the EUAs are "Final" Agency Action

In order to be deemed "final", an agency action (1) "must mark the consummation of the agency's decision-making process — it must not be of a merely tentative or interlocutory nature" and (2) "must be one by which rights or obligations have been determined, or from which legal consequences will flow." United States Corps of Eng'rs v. Hawkes Co., 136 S.Ct. 1807, 1813 (2016) (quoting Bennett v. Spear, 520 U.S. 154, 177-178 (1997)).

After fact-finding and consultation, the DHHS Secretary declared, under § 360bbb–3(b), that there is an emergency. Once issued, his declaration remained valid for a period of time and was serially renewed. The declaration is not merely "advisory in nature." Id. It represents the "consummation of the decision-making process" with respect to whether or not an emergency exists. The declaration also gives rise to "'direct and appreciable legal consequences.'" Id. at 1814. The declaration paved the way for Pfizer, Moderna and Janssen to apply for EUAs for their experimental Vaccines, for the DHHS Secretary and his designee the FDA Commissioner to adjudicate and approve their EUA applications, and for the Vaccines to be released into interstate commerce and injected into millions of Americans.

The FDA Commissioner engaged in fact-finding and made vital determinations that the statutory criteria for issuing the Vaccine EUAs required by § 360bbb–3(c) were met, and that the conditions of authorization for the Vaccine EUAs required by § 360bbb–3(e) were also met. On that basis, the Vaccine EUAs were issued. The issuance of the Vaccine EUAs represents the "consummation of the decision-making process" with respect to whether or not EUAs will be granted, and also gave rise to "'direct and appreciable legal consequences'" since millions of people have been injected with these experimental Vaccines while their manufacturers have made billions of dollars in revenues under an immunity shield.

iv. Not "Committed to Agency Discretion"

The emergency declaration is not committed to agency discretion by law. Section 360bbb–3(b)(1) states that the DHHS Secretary "may" make a declaration, but then proceeds to enumerate in detail the limited bases upon which the declaration may be made, at least three of which prohibit unilateral declarations by the Secretary by requiring consultation with or the prior decisions of other cabinet-level executive branch officials. Section 360bbb–3(b)(3) prohibits the Secretary from unilaterally terminating the declaration. This is not a broad grant of discretion, but even if it were, "[t]he fact that a statute grants broad discretion to an agency does not render the agency's decisions completely unreviewable unless the statutory scheme, taken together with other relevant materials, provides absolutely no guidance to how that discretion is to be exercised." Louisiana v. Biden, 2021 U.S. Dist. LEXIS 112316 * 40-41 (W. D. La. 2021).

Section 360bbb–3(b)(1)(c) is the sole ground for an emergency that does not seem to require consultation with or the prior decisions of other cabinet-level executive branch officials, and it provides guidance to the Secretary by requiring him to make a 4-pronged finding that (parsing the statute): (i) there is a "public health emergency" (ii) that "affects, or has a significant potential to affect" (iii) (a) "national security" or (b) "the health and security United States citizens living abroad", and (iv) that "involves" (a) "a biological, chemical, radiological, or nuclear agent or agents" or (b) "a disease or condition that may be attributable to such agent or agents."

Similarly, the EUAs are not committed to agency discretion by law. Under § 360bbb–3(c), the Secretary "may issue an authorization" but "only if" after consultation with three other executive branch officials, he is able to make at least four different findings. Under § 360bbb–3(e), the Secretary "shall" ensure that certain "required conditions" of authorization, set forth in detail in the statute, are met. Since the Secretary does not have unfettered discretion to issue

EUAs, he must follow detailed guidance as to how any discretion granted to him by the statute is exercised. Id.

In addition to their Counts seeking judicial review of agency action and mandamus, Plaintiffs have also alleged physical injury, death and loss of employment proximately caused, aided and abetted by Defendants' actions, justifying an award of civil money damages under Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics, 403 U.S. 388 (1971) (Count VII). By issuing and maintaining the EUAs in these circumstances, the Defendants are enabling the shipment of the Vaccines in interstate commerce, and their use by third parties who actually administer them to the public. Defendants, as joint tortfeasors, are purposefully aiding and abetting the infliction of physical injury and death on Plaintiffs and countless other Americans, all in violation of their constitutionally protected right to personal autonomy and bodily integrity.

Guertin v. Michigan, 912 F.3d 907 (6th Cir. 2019) is a case arising out of the infamous Flint Water Crisis. 912 F.3d at 907-915. The City of Flint Michigan instituted cost-saving measures, and used outdated equipment to treat water before delivering it to residents. Id. Residents consumed the water, now contaminated with lead and *e coli* bacteria. Id. Their hair fell out and they developed rashes. Id. Some died from an associated spike in Legionnaire's disease. Id. Children tested positive for dangerously high blood levels. Id.

The 6th Circuit Court of Appeals upheld the district court's denial of defendants' motion to dismiss 42 U.S.C. § 1983 substantive due process claims based on qualified immunity, because plaintiffs had plead a plausible Fourteenth Amendment violation of their right to bodily integrity, where the City's knowing decision to use outdated equipment and mislead the public about the safety of its water shocked the conscience. Id. The Court admonished:

> ***[K]nowing the Flint River water was unsafe for public use, distributing it without taking steps to counter its problems, and assuring the public in the meantime that it was safe*** *"is conduct that would alert a reasonable person to the likelihood of liability." [ ] [T]aking affirmative steps to systematically contaminate a community through its public water supply with deliberate indifference is a government invasion of the highest magnitude. Any reasonable official should have known that doing so constitutes conscience-shocking conduct prohibited by the substantive due process clause. These "actions violate the heartland of the constitutional guarantee" to the right of bodily integrity…*

Id. at 933 (emphasis added).

The language of this decision ought to send a chill through each of the individually named Defendants, for their conduct — albeit distributing dangerous experimental Vaccines, rather than contaminated water — is effectively a mirror image. This is indisputably so with respect to the under-18 age category, and those previously infected with SARS-CoV-2. Since SARS-CoV-2 / COVID-19 present no statistically significant threat to these subpopulations, the Vaccines can have no therapeutic benefits for them. At the same time, the experimental Vaccines, which have known, dangerous side effects and in some cases are even fatal, expose them to unnecessary and dangerous risks.

B. Irreparable Injury

The test does not require that harm actually occur, or that it be certain to occur. *See* Whitaker v. Kinosha Unified School District, 858 F.3d 1034, 1044 (7th Cir. 2017). Rather, "[w]e have indicated that the injury suffered by a plaintiff is 'irreparable only if it cannot be undone through monetary remedies.'" Siegel v. LePore, 234 F.3d 1163, 1191 at Fn. 4 (11th Cir. 2000), quoting Cunningham v. Adams, 808 F.2d 815, 821 (11th Cir. 1987).

The actual or threatened violation of core constitutional rights is presumed irreparable. Id., citing *inter alia* Deerfield Med. Ctr. v. City of Deerfield Beach, 661 F.2d 328 (5th Cir. 1981) (irreparable injury presumed based on threats to access to abortion services implicating the 14th Amendment right to privacy); Robinson v. Attorney General, 957 F.3d 1171, 1177 (11th Cir.

2020) (denying motion for stay of preliminary injunction enjoining public health order issued in response to COVID-19 pandemic because it invaded constitutionally protected 14th Amendment rights); Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) ("In any event, it is the alleged violation of a constitutional right that triggers a finding of irreparable harm."); Mitchell v. Cuomo, 748 F.2d 804, 806 (2d Cir. 1984) ("'When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.'").

In Planned Parenthood v. Casey, 505 U.S. 833, 857 (1992), the U.S. Supreme Court stated:

> *Roe, however, may be seen not only as an exemplar of Griswold liberty, but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection. If so, our cases since Roe accord with Roe's view that a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 278, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990); cf., e. g., Riggins v. Nevada, 504 U.S. 127, 135, 118 L. Ed. 2d 479, 112 S. Ct. 1810 (1992); Washington v. Harper, 494 U.S. 210, 108 L. Ed. 2d 178, 110 S. Ct. 1028 (1990); see also, e. g., Rochin v. California, 342 U.S. 165, 96 L. Ed. 183, 72 S. Ct. 205 (1952); Jacobson v. Massachusetts, 197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905).*

To reiterate: "a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims." *See also* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) ("the 'liberty' protected by the Due Process Clause [of the Fourteenth Amendment] includes the right[] . . . to bodily integrity"); Shillingford v. Holmes, 634 F.2d 263, 265 (5th Cir.1981) ("the right to be free of state-occasioned damage to a person's bodily integrity is protected by the fourteenth amendment guarantee of due process."); Doe v. Moore, 410 F.3d 1337, 1343 (11th Cir. 2005) ("The Supreme Court has recognized that fundamental rights include those guaranteed by the Bill of Rights as well as certain 'liberty' and privacy interests implicit in the due process clause and the penumbra of constitutional rights. These special

'liberty' interests include 'the rights to marry, to have children, to direct the education and upbringing of one's children, to marital privacy, to use contraception, to bodily integrity, and to abortion.'").

Further, the Supreme Court has stated that the protected liberty claims inherent in personal autonomy and bodily integrity include both the right *to be free from* unwanted medical intervention, and the right *to obtain* medical intervention:

> *As the joint opinion acknowledges, ante, 505 U.S. at 857, this Court has recognized the vital liberty interest of persons in refusing unwanted medical treatment. Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990). Just as the Due Process Clause protects the deeply personal decision of the individual to refuse medical treatment, it also must protect the deeply personal decision to obtain medical treatment, including a woman's decision to terminate a pregnancy.*

Casey, 505 U.S. at 927.

In the Supreme Court's seminal "right to die" case, Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990), it addressed whether an individual in a persistent vegetative state could require a hospital to withdraw life-sustaining medical care based on her right to bodily integrity. 479 U.S. at 265-69. Chief Justice Rehnquist noted that "[b]efore the turn of this century, [the Supreme Court] observed that 'no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.'" Id. at 269 (quoting Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891). He continued: "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment," Id. at 269, "generally encompass[es] the right of a competent individual to refuse medical treatment," Id. at 277, and is a right that "may be inferred from [the Court's] prior decisions." Id. at 278-79 (citing Jacobson v. Massachusetts, 197 U.S. 11 (1905); Breithaupt v. Abram, 352 U.S. 432 (1957);

Washington v. Harper, 494 U.S. 210 (1990); Vitek v. Jones, 445 U.S. 480 (1980); Parham v. J.R., 442 U.S. 584 (1979).).

In Deerfield, the case relied upon by the 11th Circuit in Siegel, a medical group attempted to establish a medical facility to provide abortion services. 661 F.2d at 330-332. The city denied their application for an occupational license on various grounds. Id. The medical group sued the city alleging that the city's actions violated the "right to privacy" in the due process clause of the 14th Amendment by depriving women of access to abortion services, even though any potential constitutional violation was minimized by the presence of other abortion facilities operating in the area. Id. The medical group moved for a preliminary injunction, and the district court denied the motion. Id.

The 5th Circuit reversed, adopting an aggressive, prophylactic approach to the protection of the constitutional right to privacy. "[T]he right of privacy must be carefully guarded for once an infringement has occurred it cannot be undone by monetary relief." Id. at 338, citing to Kennan v. Nichol, 326 F. Supp. 613, 616 (W.D.Wis.1971), aff'd mem., 404 U.S. 1055, 92 S. Ct. 735, 30 L. Ed. 2d 743 (1972) ("to withhold a temporary restraining order is to permit the (constitutional right of privacy) to be lost irreparably with respect to the physician and those women for whom he would otherwise perform the operation in the meantime."). It continued: "We have already determined that the constitutional right of privacy is 'either **threatened** or in fact being impaired', and **this conclusion mandates a finding of irreparable injury**" (emphasis added). Id. at 338, citing to Elrod v. Burns, 427 U.S. 347, 373 (1976).

The Defendants are both violating, and threatening the violation of, the core constitutional right to personal autonomy and bodily integrity held by Plaintiffs and all Americans. Plaintiffs Brittany Galvin (*see* Declaration of Brittany Galvin at Exhibit J), Aubrey Boone, Snow Mills, Angelia Deselle (*see* Declaration of Angelia Deselle at Exhibit H), Kristi

Simmonds, Vidiella A/K/A Shawn Skelton (*see* Declaration of Shawn Skelton at Exhibit I) and the Estate of Dovi Sanders Kennedy have alleged that their rights to personal autonomy and bodily integrity were violated when they were subjected to Vaccines without first having given voluntary, informed consent. Plaintiffs have also attached the Declaration of Diana Hallmark, a resident of Blount County, Alabama, containing the same allegations (*see* Declaration of Diana Hallmark at Exhibit K).[51] These victims testify under penalty of perjury to their physical injuries caused by the Vaccines, and to facts and circumstances that establish that they did not give, and could not possibly have given, their voluntary, informed consent. By way of example, Plaintiff Deselle states (Ex. H):

> *No one ever provided me with any information regarding possible adverse reactions, nor did they provide me with any information regarding alternative treatments. I did not understand this was gene therapy rather than a traditional vaccine. Again, I also did not understand that the Vaccines were not "approved" by the FDA. No one told me, and I did not understand that the Vaccines were not determined to be "safe and effective" by anyone — only that it was "reasonable to believe" that they were.*

In addition to constitutional infringements, physical injury and death may constitute irreparable harm justifying preliminary injunctive relief. *See* Chastain v. Northwest Ga. Hous. Auth., 2011 U .S. Dist. LEXIS 135712 (N.D. Ga. 2011) (possibility of worsening health following eviction from public housing); Garcia v. Google, Inc., 766 F .3d 929, (9th Cir. 2014), aff'd on rehearing en banc, 786 F .3d 733 (9th Cir. 2015) ("[I]t is not irrelevant that the harm Garcia complains of is death or serious bodily harm, which the dissent fails to mention. Death is an 'irremediable and unfathomable' harm, and bodily injury is not far behind. To the extent the irreparable harm inquiry is at all a close question, we think it best to err on the side of life."); Seniors Civil Liberties Ass'n v. Kemp, 761 F .Supp. 1528, 1537 (M.D. Fla. 1991) (possibility of

[51] Plaintiffs anticipate amending the Complaint for the purpose of *inter alia* adding Diana Hallmark to it as a named Plaintiff.

physical injury or death arising from police chokeholds). Plaintiffs Brittany Galvin (Ex. J), Aubrey Boone, Snow Mills, Angelia Deselle (Ex. H), Kristi Simmonds, Vidiella A/K/A Shawn Skelton (Ex. I) and the Estate of Dovi Sanders Kennedy have alleged that the Vaccines have caused them grave physical injury and, in the case of Dovi Sanders, also death. Diana Hallmark has made the same allegations (Ex. K).

The court may consider the harm to the public in assessing whether irreparable injury would result from the denial of an injunction. In Hornbeck Offshore Servs., LLC v. Salazar, 696 F.Supp. 2d 627 (E.D. La. 2010) the court granted a motion for preliminary injunction enjoining a federal agency decision to suspend drilling operations in the Gulf of Mexico, finding irreparable harm based on the harm to the public generally:

> *The defendants trivialize [Plaintiffs' losses] by characterizing them as merely a small percentage of the drilling rigs affected [ ] [C]ourts have held that in making the determination of irreparable harm, "both harm to the parties and to the public may be considered. The effect on employment, jobs, loss of domestic energy supplies caused by the moratorium as the plaintiffs (and other suppliers, and the rigs themselves) lose business, and the movement of the rigs to other sits around the world will clearly ripple throughout the economy in this region.*

696 F.Supp. 2d at 638-639 (internal citations omitted).

In In re Northwest Airlines Corp., 349 B.R. 338, 384 (S.D.N.Y. 2006), aff'd, 483 F.3d 160 (2d Cir. 2007), the court granted a motion for preliminary injunction enjoining a flight attendants' union from carrying out threats to engage in a labor strike, finding irreparable harm based on the harm to the public generally:

> *"[I]n making the determination of irreparable harm, both harm to the parties and to the public may be considered."* * * Here, the record also demonstrates that the public will be harmed: as the Bankruptcy Court found, Northwest carries 130,000 passengers per day, has 1,200 departures per day, is the one carrier for 23 cities in the country, and provides half all airline services to another 20 cities.*

349 B.R. at 384 (quoting Long Island R. Co. v. Int'l Ass'n of Machinists, 874 F.2d 901, 910 (2d Cir. 1989)).

Like Plaintiffs Brittany Galvin (Ex. J), Aubrey Boone, Snow Mills, Angelia Deselle (Ex. H), Kristi Simmonds, Vidiella A/K/A Shawn Skelton (Ex. I), and the Estate of Dovi Sanders Kennedy, and like Diane Hallmark (Ex. K), millions of Americans have already suffered an outrageous violation of their constitutionally protected right to personal autonomy and bodily integrity, and millions more are vulnerable. According to the VAERS data, there have been 438,441 reported adverse events following injection with the Vaccines, including 9,048 deaths and 41,015 serious injuries, between December 14, 2020 and July 2, 2021. The evidence suggests the VAERS system reports only between 0.8% and 2% of all Vaccine adverse events. Plaintiffs' expert and whistleblower Jane Doe has testified that the true number of deaths caused by the Vaccines is at least 45,000 not the approximately 9,000 reported by VAERS (*see* Declaration at Ex. D). By contrast, the Swine Flu vaccine was removed from the market even though it caused only 53 deaths.

C. Balance of Equities (Hardships) and Public Interest

In each case involving a request for pretrial injunctive relief, the court "must consider the effect on each party of the granting or withholding of the requested relief." Winter, 555 U.S. at 24. The plaintiff "must establish . . . that the balance of hardships tips in his favor." Id. at 20.

"'[W]here the government is the party opposing the preliminary injunction, its interest and harm merge with the public interest.' Thus the Court proceeds with analyzing whether the threatened injury to Plaintiffs outweighs the harm that the preliminary injunction would cause Defendants and the public." Brown v. Azar, 497 F. Supp. 3d 1270, 1298 (N.D. Ga. 2020), quoting Swain v. Junior, 958 F.3d 1081, 1091 (11th Cir. 2020).

"[I]t is always in the public interest to prevent the violation of a party's constitutional rights." G & V Lounge, Inc. v. Mich. Liquor Control Comm'n, 23 F.3d 1071, 1079 (6th Cir. 1994). "The vindication of constitutional rights and the enforcement of a federal statute serve the public interest almost by definition." League of Women Voters of Fla. v. Browning, 863 F. Supp. 2d 1155, 1167 (N.D. Fla. 2012). On the other hand, "[t]here is generally no public interest in the perpetuation of unlawful agency action." League of Women Voters v. Newby, 838 F.3d 1, 12 (D.C. Cir. 2016).

Defendants themselves suffer no conceivable harm from the grant of the requested injunctions. A disease that has an overall survivability rate exceeding 99% — comparable to the seasonal flu and countless other ailments — does not create a public health emergency within the meaning of § 360bbb–3. SARS-CoV-2 and COVID-19 do not give rise to any countervailing public interest that justifies overriding the constitutionally protected right to personal autonomy and bodily integrity. This is so with respect to the entire American public, but even more acutely with respect to the under-18 age category and those previously infected with SARS-CoV-2.

IV. CONCLUSION

Accordingly, and for all of the foregoing reasons, Plaintiffs move under Rule 65, Fed.R.Civ.P., for a preliminary injunction against Defendants enjoining them from continuing to authorize the emergency use of the so-called "Pfizer-BioNTech COVID-19 Vaccine," "Moderna COVID-19 Vaccine" and the "Johnson & Johnson (Janssen) COVID-19 Vaccine" pursuant to their respective EUAs, and from granting full FDA approval of the Vaccines:

(i) for the under-18 age category;

(ii) for those, regardless of age, who have been infected with SARS-CoV-2 prior to vaccination; and

(iii) until such time as the Defendants have complied with their obligation to create and maintain the requisite "conditions of authorization" under Section 546 of the Food, Drugs and Cosmetics Act, 21 U.S.C. § 360bbb–

3(e), thereby enabling Vaccine candidates to give truly voluntary, informed consent.

Dated: July 19, 2021.

RESPECTFULLY SUBMITTED BY:

ATTORNEYS FOR PLAINTIFFS:

/s/ *Lowell H. Becraft, Jr.*
LOWELL H. BECRAFT, JR.
Attorney for Plaintiffs
ASB 5005-F66L
403C Andrew Jackson Way
Huntsville, AL 35801
(256) 533-2535
becraft@hiwaay.net
Attorneys for Plaintiffs

/s/ *Thomas Renz*
THOMAS RENZ
(Ohio Bar ID: 98645)
1907 W. State St. #162
Fremont, OH 43420
(419) 351-4248
renzlawllc@gmail.com
(*Pro Hac Vice*)

/s/ *F.R. Jenkins*
F. R. JENKINS
(Maine Bar No. 004667)
Meridian 361 International Law Group, PLLC
97A Exchange Street, Ste 202
Portland, ME 04101
(866) 338-7087
jenkins@meridian361.com
Attorney for Plaintiffs
(*Pro Hac Vice*)

/s/ *Michael A. Hamilton*
MICHAEL A. HAMILTON
(KY Bar No. 89471)
CORNERSTONE ATTORNEY
1067 N. Main St, PMB 224
Nicholasville, KY 40356
(859) 655-5455
michael@cornerstoneattorney.com
(*Pro Hac Vice*)

/s/ *Robert J. Gargasz*
ROBERT J. GARGASZ
(Ohio Bar ID: 0007136)
1670 Cooper Foster Park Rd. Lorain, Ohio 44053
(440) 960-1670
rjgargasz@gmail.com
(*Pro Hac Vice*)

/s/ *N. Ana Garner*
N. ANA GARNER
Garner Law Firm
1000 Cordova Place #644
Santa Fe, NM 87505
(505) 930-5170
garnerlaw@yahoo.com
(*Pro Hac Vice*)

/s/ *Jonathan Diener*
JONATHAN DIENER
P.O. Box 27
Mule Creek, NM 88051
(575) 388-1754
jonmdiener@gmail.com
(Admission Pending Pro Hac Vice)

/s/ *Joseph S. Gilbert*
JOSEPH S. GILBERT
(Nevada Bar No. 9033)
Joey Gilbert & Associates
D/B/A Joey Gilbert Law
405 Marsh Avenue
Reno, Nevada 89509
(775) 284-7700
joey@joeygilbertlaw.com
(*Pro Hac Vice*)

CERTIFICATE OF SERVICE

I hereby certify that on this date, July 19, 2021, I electronically transmitted this pleading to the Clerk of the Court using the CM/ECF system for filing, which will send notification of such filing to the following counsel for the Defendants:

Hon. Don B. Long, III
Assistant United States Attorney United States Attorney's Office
Northern District of Alabama
1801 Fourth Avenue North
Birmingham, Alabama 35203

Hon. James W. Harlow
Trial Attorney, Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386

/s/ *Lowell H. Becraft, Jr.*
Lowell H. Becraft, Jr.

MANUFACTURING AND SUPPLY AGREEMENT

BY AND AMONG

PFIZER EXPORT B.V.,

ALBANIA MINISTRY OF HEALTH AND SOCIAL PROTECTION

MINISTER OF STATE FOR RECONSTRUCTION

AND

INSTITUTE OF PUBLIC HEALTH

GOGO.al

EXHIBIT3

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MANUFACTURING AND SUPPLY AGREEMENT

THIS MANUFACTURING AND SUPPLY AGREEMENT effective as of the date of the last signature below (the "**Effective Date**") is made by and among **Pfizer Export B.V.**, a company established under the laws of the Netherlands with its registered office at Rivium Westlaan 142, 2909LD Capelle aan den Ijssel, the Netherlands (hereinafter "**Pfizer**") and Albania Ministry of Health and Social Protection, acting on its own behalf and on behalf of the Republic of Albania with offices at Kavaja St 25, Tirana 1001 ("**MOH**"), Albanian Minister of State for Reconstruction,acting on its own behalf and on behalf of the Republic of Albania with offices at Boulevard "Dëshmorët e Kombit", Tirana 1001 (MOR) and Institute of Public Health, acting on its own behalf and on behalf of the Republic of Albania with offices at Rr. Aleksander Moisiu, nr. 80, Tirana, 1001 ("**IPH**") (MOH,MORand IPH, individually and collectively referred to hereinafter as "**Purchaser**"). Purchaser and Pfizer may be referred to herein individually as a "**Party**" or collectively as the "**Parties**".

WHEREAS, Pfizer Inc. ("**Pfizer US**") and BioNTech SE, a company organized and existing under the laws of Germany ("**BioNTech**"), are collaborating to develop a vaccine to address the global COVID-19 pandemic;

WHEREAS, subject to clinical success, Pfizer US and BioNTech shall be responsible for all requirements of the processes of approval of the clinical trials and the marketing authorization of the Product;

WHEREAS, Purchaser desires to purchase the Product for use in Albania, and subject to clinical success and regulatory approval, Pfizer desires to manufacture and supply such Product to Purchaser; and

WHEREAS, the Parties are willing to carry out the foregoing pursuant to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of these premises and the covenants and agreements set forth herein, the sufficiency of which is hereby acknowledged and agreed, and intending to be legally bound thereby, the Parties hereby agree as follows:

1. **DEFINITIONS**.

As used in this Agreement, the following terms shall have the meanings set forth below.

1.1 "**Adjusted Delivery Schedule**" shall have the meaning set forth in Section 2.4(e).

1.2 "**Advance Payment**" shall have the meaning set forth in Section 3.2(a).

1.3 "**Affiliate(s)**" means, with respect to each Party or, if applicable, BioNTech, any corporation, firm, partnership or other entity or Person which directly or indirectly controls or is controlled by or is under common control with the named Party, including without limitation Pfizer US, or, if applicable, BioNTech. For purposes of this definition, "control" (including, with correlative meaning, the terms "controlled by" and "under common

control with") shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors of such corporate entity or any direct or indirect parent of such corporate entity, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.4 "**Agreement**" means this Manufacturing and Supply Agreement and all Attachments hereto as the same may be amended, amended and restated, supplemented or otherwise replaced from time to time.

1.5 "**Allocation**" shall have the meaning set forth in Section 2.5(a).

1.6 "**Authorization**" means the Conditional Approval or Marketing Authorization.

1.7 "**BioNTech**" shall have the meaning set forth in the recitals.

1.8 "**Business Day**" means any day other than Saturday, Sunday or a public holiday in New York, New York or Tirana, Albania.

1.9 "**Commercially Reasonable Efforts**" means with respect to the efforts to be expended by Pfizer to achieve the relevant objective, the activities and degree of effort that a similarly situated party (with respect to size, resources and assets) in the pharmaceutical industry would use to accomplish a similar objective in its own commercial interests under similar circumstances and considering the relevant risks, uncertainties, limitations and challenges of the development, manufacture, commercialization and distribution of a novel COVID-19 vaccine product, taking into account the following factors: actual and potential issues of safety and efficacy, novelty, product profile, the proprietary position, the then current competitive environment for such Product, the likely timing of the Product's entry into the market, the regulatory environment and status of the Product, compliance with Laws, past performance of the Product and other similar products, the ability to produce or obtain adequate supply of the Product or any components or materials used in the manufacture of the Product and other relevant scientific, technical, operational and commercial factors, in each case as measured by the facts and circumstances at the time such efforts are due.

1.10 "**Conditional Approval**" means a conditional marketing authorization ("**CMA**") or emergency use authorization ("**EUA**") for the Product granted (a) by (i) the United States Food and Drug Administration (the federal agency of the United States Department of Health and Human Services) ("**FDA**") (in the case of an EUA) or (ii) the European Commission (in the case of a CMA) and (b) via an appropriate regulatory mechanism by the (i) National Agency of Medicines and Medical Equipment (**"NAM"**) or (ii) the Minister of Health and Social Protection that allows the Product to be placed on the market in Albania ("**Albanian Conditional Approval**").

1.11 "**Confidential Information**" means all confidential or proprietary information, other than Exempt Information, in any form, directly or indirectly disclosed to Recipient or its

Representatives by or on behalf of the Disclosing Party pursuant to this Agreement, regardless of the manner in which such information is disclosed, delivered, furnished, learned, or observed, either marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure. Confidential Information includes, without limitation, the terms and conditions of this Agreement. Failure to mark Confidential Information disclosed in writing hereunder as "Confidential" shall not cause the information to be considered non-confidential, with the burden on the Disclosing Party to prove such information clearly should have been known by a reasonable person with expertise on the subject matter, based on the nature of the information and the circumstances of its disclosure, to be Confidential Information, provided that the Disclosing Party has otherwise made good faith efforts to clearly mark Confidential Information as such.

1.12 "**Contracted Doses**" shall have the meaning set forth in Section 2.3(a).

1.13 "**Current Good Manufacturing Practices**" or "**cGMP**" means applicable Good Manufacturing Practices as specified in the United States Code of Federal Regulations and/or the EU Good Manufacturing Guidelines, and any successor legislation from time to time, prevailing at the time of the manufacture of the Product.

1.14 "**Delivery Price**" shall have the meaning set forth in Section 3.2(b).

1.15 "**Delivery Schedule**" shall have the meaning set forth in Section 2.4(d).

1.16 "**Delivery Specifications**" shall have the meaning set forth in Section 2.4(d).

1.17 "**Disclosing Party**" means the Party or any of its Affiliates that discloses, or causes to be disclosed, Confidential Information to the other Party or any of its Affiliates.

1.18 "**Effective Date**" shall have the meaning set forth in the preamble.

1.19 "**Exempt Information**" means information that: (a) the Recipient or any of its Representatives lawfully possessed, as demonstrated by competent proof, before the Disclosing Party disclosed such information under this Agreement; or (b) was already generally available and in the public domain at the time of disclosure, or becomes public (other than as a result of breach of this Agreement by the Recipient or its Representatives); (c) the Recipient or any of its Representatives lawfully obtains from a Person not in breach of any confidentiality obligation (or other prohibition from disclosing the information) to the Disclosing Party with respect to such information (and Recipient has made reasonable enquiry with respect thereto); or (d) the Recipient evidences to the reasonable satisfaction of the Disclosing Party is independently developed by or on behalf of the Recipient or its Representatives without the use of, reference to, aid from, or reliance on, the Confidential Information. In clarification of the foregoing, a general disclosure in the public domain will not cause more specific (but related) information to be deemed Exempt Information under one of the above exceptions; similarly, a combination of several pieces of information, which individually would be deemed Exempt Information, will not be deemed Exempt Information unless the combination itself is in the public domain, independently

developed by the Recipient or its Representatives or otherwise lawfully in the possession of the Recipient or any of its Representatives.

1.20 "**Facilities**" means Pfizer's manufacturing sites in Kalamazoo (Michigan) and Puurs, Belgium and BioNTech's two manufacturing sites, in Mainz and Idar Oberstein in Germany or such other manufacturing site used in connection with the manufacture of the Product supplied by Pfizer hereunder.

1.21 "**Force Majeure Event**" shall have the meaning set forth in Section 12.9.

1.22 "**Forms**" shall have the meaning set forth in Section 12.13.

1.23 "**Government**" means all levels and subdivisions of government (i.e., local, regional, national, provincial, federal, administrative, legislative, or executive) of Albania.

1.24 "**ICC**" shall have the meaning set forth in Section 12.2.

1.25 "**Indemnified Claims**" shall have the meaning set forth in Section 8.2.

1.26 "**Indemnitees**" shall have the meaning set forth in Section 8.1.

1.27 "**Intellectual Property**" means (a) any processes, trade secrets, inventions, industrial models, designs, methodologies, drawings, discoveries, result, materials, formulae, procedures, techniques, clinical data or technical or other information or data, manufacturing, engineering and technical drawings, including proprietary rights in any of the foregoing, and (b) registered trademarks, trade mark applications, unregistered marks, trade dress, copyrights, know-how, patents, patent applications, and any and all provisionals, divisions, continuations, continuations in part, extensions, substitutions, renewals, registrations, revalidations, reissues or additions, including certificates of supplementary protection, of or to any of the aforesaid patents and patent applications, and all foreign counterparts of any, or to any, of the aforesaid patents and patent applications.

1.28 "**Labelling and Packaging Specifications**" shall have the meaning set forth in Section 2.4(e).

1.29 "**Latent Defect**" means a defect causing the Product to not conform to the applicable Specifications that Purchaser can show was present at the time of Pfizer's delivery of the Product to Purchaser and which could not have been detected by Purchaser, its designee, or their Personnel at delivery through diligent inspection.

1.30 "**Law/s**" means, collectively, all applicable national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law.

1.31 "**Losses**" shall have the meaning set forth in Section 8.1.

1.32 "**Marketing Authorization**" means the marketing authorization, or such other permission having similar effect, in respect of the Product granted by both (a) (i) the FDA, or (ii)

European Commission, and (b) (i) NAM or (ii) the Minister of Health and Social Protection from time to time, that allows the Product to be placed on the market in such country or territory according to Law.

1.33 "**Non-Complying Product**" shall have the meaning set forth in Section 4.4(a).

1.34 "**Party**" or "**Parties**" shall have the meaning set forth in the preamble.

1.35 "**Person**" means any natural person, entity, corporation, general partnership, limited partnership, limited liability partnership, joint venture or similar entity or organization, joint stock company, proprietorship, other business organization, trust, union, association or Government.

1.36 "**Personnel**" means all Affiliates, subcontractors, or other third parties, and employees and agents of each of them, used by a Party in the performance of services or obligations or in connection with this Agreement.

1.37 "**Pfizer**" shall have the meaning set forth in the preamble.

1.38 "**Pfizer US**" shall have the meaning set forth in the preamble.

1.39 "**Point of Delivery**" shall have the meaning set forth in Section 2.8(a).

1.40 "**Price**" shall have the meaning set forth in Section 3.1.

1.41 "**Privileges and Immunities**" means any privileges, immunities, or legislation in Albania, including, without limitation, no-fault vaccine compensation programs, pandemic insurance programs, immunities from suit or liability, or any protections, defenses, or limitations-of-liability (whether statutory, regulatory, common law or otherwise), existing or future, that may separately protect Indemnitees from Losses.

1.42 "**Product**" means all vaccines manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or BioNTech or any of their Affiliates pursuant to this Agreement that are intended for the prevention of the human disease COVID-19 or any other human disease, in each case which is caused by any of the virus SARS-CoV-2, and/or any or all related strains, mutations, modifications or derivatives of the foregoing.

1.43 "**Product Materials**" means all packaging materials and components needed for delivery of the Product.

1.44 "**Purchase Order**" means a written or electronic order form submitted by Purchaser to Pfizer in accordance with the terms of this Agreement authorizing the manufacture and supply of the Product, in substantially the form attached as Attachment G (as may be updated from time to time by Pfizer upon notice to Purchaser).

1.45 "**Purchaser**" shall have the meaning set forth in the preamble.

1.46 "**Recipient**" means the Party who receives Confidential Information from the other Party.

1.47 "**Records**" means books, documents, and other data, of all matters relating to performance of obligations under this Agreement.

1.48 "**Representatives**" means, with respect to Recipient, its Affiliates and its and their respective directors, officers, and employees, agents, contractors, consultants, advisors and representatives who (a) are subject to an obligation of confidentiality protecting the Confidential Information on terms no less restrictive than those contained in this Agreement; and (b) have a need to know the Confidential Information in connection with this Agreement.

1.49 "**Specifications**" means the material specifications for the manufacture, processing, packaging, labeling, testing and testing procedures, shipping, storage and supply of the Product as will be set out in Attachment A following the Effective Date (and in any event before supply in accordance with the agreed Delivery Schedule), and as such specifications may be amended, supplemented or otherwise modified by Pfizer and communicated to Purchaser.

1.50 "**Taxes**" shall have the meaning set forth in Section 3.4.

1.51 "**Term**", with respect to this Agreement, shall have the meaning set forth in Section 6.1.

1.52 "**Third Party Beneficiary**" or "**Third Party Beneficiaries**" shall have the meaning set forth in Section 12.6(a).

1.53 "**USD**" means the lawful currency of the United States of America.

1.54 "**Vaccine**" shall include (a) all vaccines manufactured, in whole or in part, or supplied, directly or indirectly, by or on behalf of Pfizer or BioNTech or any of their Affiliates pursuant to this Agreement that are intended for the prevention of the human disease COVID-19 or any other human disease, in each case which is caused by any of the virus SARS-CoV-2, and/or any or all related strains, mutations, modifications or derivatives of the foregoing, (b) any device, technology, or product used in the administration of or to enhance the use or effect of, such vaccine, or (c) any component or constituent material of (a) or (b).

1.55 "**VAT**" means Value Added Tax.

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors

and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Attachments shall be construed to refer to Sections or Attachments of this Agreement, and references to this Agreement include all Attachments hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof and (j) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or".

2. **SUPPLY OF PRODUCT**.

2.1 Agreement to Supply.

(a) During the Term, Pfizer shall use Commercially Reasonable Efforts to supply or have supplied the Product to Purchaser, and Purchaser shall purchase the Product, subject to and in accordance with the terms and conditions of this Agreement.

(b) Purchaser acknowledges and agrees that (i) Pfizer's efforts to develop and manufacture the Product are aspirational in nature and subject to significant risks and uncertainties, and (ii) the fact that any other drug or vaccine to prevent, treat or cure COVID-19 infection is successfully developed or granted authorization earlier than the granting of Authorization for the Product shall not change the current situation of urgent needs for prevention of the spread of the COVID-19 infection that poses serious threats to and harmful effects on the lives and health of the general public.

(c) Notwithstanding the efforts and any estimated dates set forth in the Delivery Schedule, the Parties recognize that the Product has completed Phase 2b/3 clinical trials and that, despite the efforts of Pfizer in research, and development and manufacturing, the Product may not be successful due to technical, clinical, regulatory, manufacturing, shipping, storage, or other challenges or failures.

(d) Accordingly, Pfizer and its Affiliates shall have no liability for any failure by Pfizer or its Affiliates to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement. Even if the Product is successfully developed and obtains Authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with any estimated delivery dates set forth herein (other than as expressly set out in this Agreement), nor shall any such failure give Purchaser any right to cancel orders for any quantities of Product.

(e) Pfizer shall keep Purchaser apprised of the progress of the material development of the Product and shall provide Purchaser with such information regarding that development as Purchaser reasonably requests.

2.2 Capacity.

Pfizer shall use Commercially Reasonable Efforts to build or obtain manufacturing capacity to be capable of manufacturing and supplying the Product to Purchaser in accordance with the provisions of this Agreement.

2.3 Purchase Orders.

(a) Upon receipt of Approval set forth in Section 9.6, Purchaser shall submit to Pfizer a legally binding and irrevocable Purchase Order(s) for four hundred ninety-nine thousand five hundred ninety (499,590) doses ("**Contracted Doses**") of the Product.

(b) The Purchase Order shall be provided together with Purchaser's order number, VAT number, and invoice address. Pfizer shall accept the Purchase Order conforming to the terms set forth in this Agreement in writing, and the confirmed Purchase Order shall be binding upon the Parties and subject to the terms and conditions set out in this Agreement.

2.4 Delivery Schedule.

(a) Pfizer shall deliver the Product Carriage and Insurance Paid ("**CIP**") Incoterms 2020.

(b) The Parties shall reasonably agree, in writing, to the location(s) (including number of locations) for delivery of shipments of Product ("**Place(s) of Destination**") as soon as reasonably practicable following the Effective Date; provided that: (i) each Place of Destination meets the requirements set forth in Attachment D, (ii) all agreed upon Place(s) of Destination shall be agreed in writing by the Parties at least eight (8) weeks prior to shipment of the Product, (iii) the Place(s) of Destination are serviced by a contracted transportation carrier of Pfizer ("**Shipping Agent**"), and (iv) each Place of Destination is an authorized location to receive the Product, evidence of which shall be presented to Pfizer on Purchaser's official letterhead, or other official format acceptable to Pfizer, and Purchaser shall provide any additional information, as requested by Pfizer in advance of delivery, to verify such authorization. In case the Parties do not agree on the Place(s) of Destination within the abovementioned timeline, Pfizer shall have the right to revise the Delivery Schedule. Pfizer shall have the ability, acting reasonably, to restrict the number of Places of Destination where shipments of Product shall be delivered. However, the Parties agree that: (a) title to the Products and risk of loss or damage shall pass to Purchaser at the Point of Delivery as defined under Section 2.8(a) of this Agreement, and (b) Purchaser shall have full liability and responsibility for any further transportation and distribution following delivery to Place(s) of Destination that is not a point of use of the Product, including but not limited to ensuring compliance with Attachment D.

(c) Each shipment of Product shall have a minimum volume of 195 vials.

(d) Pfizer may deliver the Product by separate installments and shall use Commercially Reasonable Efforts to meet the delivery schedule set out in Attachment B (the "**Delivery Schedule**"), provided that no Product shall be shipped until Authorization is received and Purchaser is compliant with, to Pfizer's satisfaction, the conditions set forth in Section 9.5. All deliveries shall be accompanied by the documentation specified in Attachment C (which may be updated from time to time by Pfizer upon notice to Purchaser), and shall be in accordance with, and subject to, the delivery specifications to be set forth in Attachment D (which shall be populated following the Effective Date, but in any event before supply in line with the agreed Delivery Schedule, and as may be updated from time to time by Pfizer upon notice to Purchaser) ("**Delivery Specifications**").

(e) The Product shall be labelled and packaged in accordance with the packaging specifications to be set forth in Attachment E (which shall be populated following the Effective Date, but in any event before supply in line with the agreed Delivery Schedule, and as may be updated from time to time by Pfizer upon notice to Purchaser) ("**Labelling and Packaging Specifications**"). For clarity, Purchaser shall be solely liable for compliance with local labelling requirements, including without limitation, any local language translation requirements.

(f) If an Authorization is granted after March 31, 2021 but before June 30, 2021, then the Delivery Schedule will be revised to add the period of time between March 31, 2021 and the date of the Authorization ("**Adjusted Delivery Schedule**"). In the event that the Authorization is granted prior to March 31, 2021, Pfizer has no obligation to accelerate shipment of Product.

(g) If Authorization is received by March 31, 2021, but Pfizer is unable to deliver any Contracted Doses for technical or other reasons from the Facilities intended to produce the Contracted Doses under this Agreement, Pfizer agrees to use Commercially Reasonable Efforts to obtain supply of the Product from another location, subject to availability of supply.

(h) If Authorization is received by March 31, 2021, but by September 30, 2021, Pfizer is unable to manufacture or deliver any Contracted Doses for technical or other reasons from any Facilities, Pfizer will have no obligation to deliver against the Delivery Schedule, Adjusted Delivery Schedule or a Purchase Order.

2.5 Product Shortages.

(a) If Authorization is received but there is insufficient supply to deliver the full number of Contracted Doses on the Delivery Schedule (including the Adjusted Delivery Schedule), including to the extent any shortage is due to a requirement of Pfizer to divert available supply of the Product to another market, Pfizer shall work collaboratively to provide notice (and manage any communications associated with any Product shortages). Following receipt of such notification, Purchaser shall

execute any instructions set out in the notice in a timely fashion (and in no event longer than 24 hours). Subject to the foregoing, including any requirement by Pfizer to divert Product to another market, Pfizer shall decide on necessary adjustments to the number of Contracted Doses and Delivery Schedule due to the Purchaser to reflect such shortages based on principles to be determined by Pfizer under the then existing circumstances ("**Allocation**") which shall be set out in such notice. Purchaser shall be deemed to agree to any revision.

(b) Purchaser hereby waives all rights and remedies that it may have at Law, in equity or otherwise, arising from or relating to: (i) any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement; or (ii) any failure by Pfizer to deliver the Contracted Doses in accordance with the Delivery Schedule. In the event of an inconsistency between the provisions of this Section 2.5 (Product Shortages) and those of other sections of this Agreement, the provisions of this Section 2.5 (Product Shortages) shall control and supersede over those of other sections of this Agreement to the extent of such inconsistency.

2.6 Delivery Delays.

Under no circumstances will Pfizer be subject to or liable for any late delivery penalties.

2.7 Product Handling.

(a) Pfizer shall use Commercially Reasonable Efforts to assure the Product is manufactured in accordance with material Specifications and cGMP.

(b) Upon delivery of Product to Purchaser at the Place(s) of Destination and, to the extent applicable, for any onward distribution and/or transportation to a Place of Destination that is not a point of use of the Product, Purchaser shall store and handle the Product in the manner set forth in the Specifications, instructions on Attachment D and the instructions provided by Pfizer to ensure stability and integrity of the Product.

(c) For the avoidance of doubt, Purchaser shall bear all expenses for use of the Product upon transfer from Pfizer at the Place(s) of Destination, including, but not limited to, those for storage of the Product and distribution and administration of the Product (if applicable) in Albania.

(d) Purchaser shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in Albania following delivery of the Product to Purchaser or its designee at the Place(s) of Destination. Without prejudice to the generality of the foregoing, Purchaser shall ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment F (which may be updated from time to time by Pfizer upon notice to Purchaser) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws

regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate. Attachment F provides the ability for Pfizer to charge Purchaser for the cost of such packaging components, without limiting any other remedies available to Pfizer, in the event that Purchaser fails to comply with the return requirement set forth in Attachment F.

(e) Purchaser shall be responsible for and shall ensure that any equipment used to deliver the Product, for example the shipper(s) and monitoring device(s), are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc). Within thirty (30) days of delivery of the Product at the Place(s) of Destination, subject to Section 4.4(b), Purchaser shall organize safe return of all such equipment, including the shipper and monitoring device, in accordance with Pfizer's instructions.

(f) Pfizer may provide Safety Data Sheets and other information to Purchaser to assist Purchaser to develop processes and procedures, including training, to handle the Product and Product Materials in a safe manner and in compliance with Laws, including occupational health and safety Laws. Purchaser represents and warrants that Purchaser has and shall ensure that all recipients of the Product and Product Materials have the requisite expertise to develop and implement appropriate procedures and training programs to enable proper handling of the Product and Product Materials in a safe and lawful manner.

2.8 Title to Product, Risk of Loss.

(a) Title to the Product, and risk of loss or damage shall pass to, Purchaser at the first point of entry in Albania at any airport in Albania, before customs clearance (the "**Point of Delivery**"). Pfizer reserves the right to change any supply or Point of Delivery by giving Purchaser adequate notice as acceptable under the Laws, taking into account to change the point of delivery in one of the neighboring states of the Republic of Albania. Prices are quoted on CIP Place(s) of Destination basis in effect at the time and Point of Delivery. For purposes of this Agreement, the terms CIP shall have the meaning ascribed thereto in INCOTERMS 2020 as published by the ICC, Paris, France.

(b) Purchaser shall be the sole importer of the Products in front of the relevant customs authorities in Albania ("**Importer of Record**") and shall be responsible to obtain, where applicable, at its own risk and expense, any import license or other official authorization and carry out all customs formalities for the import of the Products in Albania. Purchaser shall also be responsible to pay, where applicable, all duties, taxes and other charges, as well as the costs of carrying out customs formalities payable upon import of the Products. Given the nature of the Product, Purchaser undertakes to support the Shipping Agent to swiftly clear the Products from the relevant customs authorities **within one (1) Business Day** from the arrival of the Product at the Point of Delivery; any delay in such clearance process might affect the overall shelf-life of the Products. Subject to Pfizer's prior written approval, the

Purchaser can request and procure any such customs clearance services from the Shipping Agent. The Purchaser confirms that the required documents for customs clearance of the Products are indicated in Attachment H Part 1 of this Agreement.

(c) Without prejudice to the generality of the foregoing, following the transfer of title to and risk of the Product to Purchaser at the Point of Delivery as defined under Section 2.8(a), Purchaser shall be fully responsible for and liable in relation to any Product wastage, and for ensuring appropriate disposal in accordance with Sections 2.7(d) and 2.7(e). For absolute clarity, even though Pfizer will support in the transportation of the Product from the Point of Delivery to the Place(s) of Destination through the Shipping Agent, Pfizer will not be liable for any risks of loss or damage to the Product after the Point of Delivery, including without limitation, temperature excursions, theft, or damages of any kind to the Product.

(d) Without prejudice to Section 4.4, Purchaser acknowledges that Pfizer will not, in any circumstances, accept any returns of Product (or any dose). In particular, following receipt of the Product in accordance with this Section 2.8, no Product returns may take place under any circumstances (inclusive of future changes in stock, expired Products, changes in Product allocation, delivery, demand or new product launch).

3. PRICE AND PAYMENT.

3.1 Purchase Price.

Purchaser shall purchase the Product from Pfizer at the price per dose set out in Attachment B, excluding VAT (the "**Price**") and in accordance with the terms of this Agreement. The Price shall include all of Pfizer's internal costs associated with the manufacturing and delivery of the Product to the Place(s) of Destination in accordance with this Agreement. For clarity, the Price shall be exclusive of the costs described in Section 2.8(b). The Price shall be firm for the Term.

3.2 Invoices and Payment.

(a) In partial consideration of the Contracted Doses, Purchaser shall pay an upfront payment of $2,997,540 USD (calculated as $12.00USD/dose multiplied by 249,795 of the Contracted Doses) within thirty (30) days of receipt of an invoice from Pfizer issued upon Purchaser's receipt of Approval set forth in Section 9.6 (the "**Advance Payment**"); provided, however, that Pfizer shall have no obligation to ship or deliver Product until receipt of the Advance Payment. All amounts due hereunder shall be converted to EUR which shall be determined based on the exchange rate used by The Wall Street Journal, Eastern U.S. Edition, one (1) Business Day prior to the date of this Agreement.

(b) Pfizer shall invoice Purchaser for the Price for the remaining 249,795 of the Contracted Doses at least sixty (60) days in advance of each delivery pursuant to Section 2.4 (Delivery Schedule) (the "**Delivery Price**") payable in accordance with

the terms of Section 3.3(a). All such amounts shall be due prior to delivery of the volume of anticipated doses to be delivered in such delivery.

(c) Invoices shall be provided to ishp@shendetesia.gov.al, Institute of Public Health, Aleksander Moisiu, nr. 80, Tirana, Albania 1001. Pfizer shall include the following information on all invoices: the Purchase Order number and billing address; and shall also include, where applicable, the type description, part number (if any) and number of Contracted Doses delivered; the delivery date; the actual date of shipment; the Price; any applicable taxes or other charges provided for in the Purchase Order; and the ship-to destination.

3.3 Method of Payment.

(a) Purchaser shall pay all undisputed (in good faith) amounts due in EUR within thirty (30) days from the date of the invoice. Payment shall be remitted by wire transfer in immediately available funds to a bank and account designated by Pfizer. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day. Any dispute by Purchaser of an invoice shall be provided to Pfizer in writing (along with substantiating documentation and a reasonably detailed description of the dispute) within ten (10) days from the date of such invoice. Purchaser will be deemed to have accepted all invoices for which Pfizer does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Section 3.3(a). The Parties shall seek to resolve all such disputes expeditiously and in good faith.

(b) Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest, to the extent permitted by law, at the higher of (a) the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus five points (or such centralized bank reference rate set forth in the Vaccine Order Form) and (b) 2%. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent. In addition to all other remedies available under this Agreement or at Law, if Purchaser fails to pay any undisputed amounts when due under this Agreement, Pfizer may (i) suspend the delivery of the Product or (ii) terminate this Agreement.

(c) Purchaser shall not, and acknowledges that it will have no right, under this Agreement, any Purchase Order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to Pfizer, whether under this Agreement or otherwise, against any other amount owed (or to become due and owing) to it by Pfizer or a Pfizer Affiliate.

3.4 Taxes.

It is understood and agreed between the Parties that any payments made and other

consideration provided under this Agreement are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including, without limitation, custom duties, levies and charges and all local taxes) ("**Taxes**"), which shall be added thereon as applicable. Where Taxes are properly chargeable on a payment made or consideration provided under this Agreement, the Party making the payment or providing the consideration will pay the amount of Taxes in accordance with the laws and regulations of the country in which the Taxes are chargeable.

In the event any payments made pursuant to this Agreement become subject to withholding Taxes under the laws or regulation of any jurisdiction, the Party making such payment shall deduct and withhold the amount of such Taxes for the account of the payee to the extent required by Law and such amounts payable to the payee shall be reduced by the amount of Taxes deducted and withheld. Any such withholding Taxes required under Law to be paid or withheld shall be an expense of, and borne solely by, the payee.

4. **MANUFACTURING STANDARDS AND QUALITY ASSURANCE**.

4.1 Manufacturing Standards.

Pfizer shall manufacture and supply the Product in material accordance with the Specifications and cGMP. Such Specifications may be revised through written notification by Pfizer to Purchaser to conform to the Authorization or changes to the manufacturing or distribution of the Product.

4.2 Legal and Regulatory Filings and Requests.

(a) Pfizer shall (a) comply with all regulatory or government licenses and permits, and (b) comply with all cGMP with respect to its manufacturing and packaging processes, the Facilities or otherwise, to permit the performance of its obligations hereunder. Notwithstanding the foregoing, Pfizer shall use Commercially Reasonable Efforts to obtain the Authorization provided that the Purchaser shall waive, to the extent applicable, all the requirements set out in Attachment H Part 2 of this Agreement in respect of the issue of the Authorization.

(b) Pfizer shall ensure that all Product is properly labelled and packaged in accordance with the applicable Authorization, Specifications and material cGMP standards. For clarity, Purchaser shall be solely liable for compliance with local labelling requirements, including without limitation, any local language translation requirements.

(c) Prior to delivery, Pfizer shall comply with all conditions (in the relevant timescales) set out in the Authorization; provided, however, that Purchaser shall grant, or obtain on Pfizer's behalf, all exemptions, exceptions, and waivers of country specific requirements for the Product granted or permitted by the Government authority (including but not limited to serialization, applicable laboratory or quality testing and/or marketing information form submission and approval), which requirements,

absent an exemption, exception or waiver, would prevent Pfizer from supplying and releasing the Product in Albania upon receipt of the Authorization.

(d) In the event that a third party is the applicant or holder of the Authorization, any obligation on Pfizer under this Agreement shall be taken as a requirement on Pfizer to use Commercially Reasonable Efforts to procure the compliance of such third party Authorization applicant or holder with such obligations to the extent necessary to ensure the relevant obligation is fully met.

(e) Due to the current pandemic situation and the fact that any anticipated Authorization will be initially under an emergency use authorization, and the Parties agreement that Pfizer will only supply the Purchaser directly, the Purchaser agrees to the below conditions and, as a condition precedent to supply of the Product, will issue, or make any other Government authority to issue, any necessary approvals to ensure enforceability of the same:

(i) During the Term, Pfizer will not be required by the Purchaser or any other Government authority to appoint a local agent, distributor, or any responsible Person, including without limitation, for purposes of selling or supplying the Product or applying for the Albanian Conditional Approval, unless Pfizer decides otherwise at a later stage to appoint a local agent or distributor. For the avoidance of doubt, Purchaser also agrees that (i) Pfizer or any of its Affiliates will be the entity applying and submitting any regulatory files required for issuance of Albanian Conditional Approval, and (ii) Albanian Conditional Approval will be issued under Pfizer's or any of its Affiliates name.

(ii) During the Term, Pfizer will not be required by the Purchaser or any other Government authority to submit a price reference certificate for purposes of applying for Albanian Conditional Approval or otherwise.

4.3 Quality Tests and Checks.

Pfizer shall perform all bulk holding stability, manufacturing trials, validation (including, but not limited to, method, process and equipment cleaning validation), raw material, in-process, bulk finished product and stability (chemical or microbial) tests or checks required to assure the quality of the Product and tests or checks required by the Specifications and cGMP.

4.4 Rejection of Product; Disposal of Rejected Shipments.

(a) Purchaser may reject any Product that does not materially conform to Specifications or cGMP ("**Non-Complying Product**") by providing written notice of rejection to Pfizer and the delivery carrier and setting out detailed reasons for such rejection: (i) immediately (and in no event more than 24 hours) upon delivery at the Point of Delivery; (ii) immediately and in any event within 24 hours of delivery at the Place(s) of Destination of such Non-Complying Product to Purchaser; or (iii)

immediately and in no event more than 24 hours upon its first knowledge of a Latent Defect. In the event notice is not provided within 24 hours from delivery, the Product shall have been deemed accepted. Pfizer shall respond to any rejection and notice of Non-Complying Product from Purchaser in a timely manner. For clarity, Purchaser shall not be entitled to reject any Product based on service complaints unless a Product does not materially conform to Specifications or cGMP.

(b) Pfizer shall conduct an analysis of the causes of any such quality-related complaint, and shall report to Purchaser on any corrective action taken. If Pfizer's inspection and testing reveals, to Pfizer's reasonable satisfaction, that such items of the Product are Non-Complying Product and that any such non-conformity or defect has not been caused or contributed to by any abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer, Pfizer shall use Commercially Reasonable Efforts to replace such Non-Complying Product as soon as practicable at no additional charge to Purchaser. In such circumstances, Pfizer will further arrange for reverse logistics for Product collection and manage the destruction of the Non-Complying Product. Until collection, Purchaser shall store and maintain the relevant Non-Complying Product in appropriately secure locations and in accordance with the manufacturers' specifications. Notwithstanding any other provision of this Agreement, this Section 4.4(b) contains Purchaser's sole and exclusive remedy for Non-Complying Product. The provisions of this Section 4.4 (Rejection of Product; Disposal of Rejected Shipments) shall survive termination or expiration of this Agreement.

4.5 Maintenance and Retention of Records.

(a) Each Party shall maintain detailed Records with respect to its activities under this Agreement as required by Laws.

(b) Purchaser will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If Purchaser does not have a quality system for the activities defined, Pfizer may share details of a proposed quality system for Purchaser's compliance.

4.6 Diversion Issues.

All Product delivered to Purchaser shall be: (a) stored securely by Purchaser; and (b) distributed by Purchaser only in Albania in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) resale or export out of Albania, and to protect and preserve the integrity and efficacy of the Product. Purchaser shall promptly notify Pfizer by email[1] within 48 hours (with follow up in writing in line with the notice provisions of this Agreement) if at any time Purchaser believes that any of the Product has been stolen, diverted, tampered with, substituted, or otherwise

[1]**Note to Draft:** To include quality/diversion notice contact information.

subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Pfizer. The notice shall provide all information relating to the Product diversion, including, but not limited to, detailed information including the date, time, location, number, batch number(s), expiration date, circumstances, and contact person(s) information. Purchaser shall cooperate with Pfizer or its designee, upon Pfizer's request, to cooperate in connection with such Product diversion.

4.7 Recalls.

Purchaser shall be responsible for all costs of any recall or market withdrawal of the Product in Albania, including, without limitation, reasonable costs incurred by or on behalf of Pfizer and its Affiliates or BioNTech and its Affiliates, except to the extent that such recall or market withdrawal results from willful misconduct (being a wrongful act, willingly and knowingly committed without legal or factual justification, with the intent to cause the harmful effects) on the part of, Pfizer or any of its Affiliates or any of their respective Personnel, in which event Pfizer will be responsible solely for: (a) any reasonable and documented out of pocket expenses directly incurred by Purchaser to third parties in implementing such recall or market withdrawal; and (b) replacing, at Pfizer's expense, the Product which has to be recalled.

5. REPRESENTATIONS & WARRANTIES.

5.1 Mutual Representations and Warranties. Pfizer and Purchaser each represents and warrants to each other the following:

(a) Organization and Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, including, in the case of Purchaser, that all necessary authorizations and approvals have been obtained by Purchaser to authorize entering into this Agreement and its performance of all of its obligations contained herein, that Purchaser is entering into this Agreement pursuant to the Normative Act of the Albanian Council of Ministers no. 38 dated December 31, 2020 "On the approval of agreement for the manufacturing and supply by and between Pfizer Export B.V. and the Ministry of Health and Social Protection, Minister of State for Reconstruction and the Institute of Public Health, and the authorization of procedure for the anticovid-19 vaccination of the population", a true and correct copy of which is attached hereto as Appendix H (the "**Normative Act**"), that this Agreement is exempt from the application of all Albanian Public Procurement Laws and each of the terms and conditions of this Agreement are fully enforceable, that the budgetary allocation set forth in Article 4 of the Normative Act in no respect limits Purchaser's funding or other obligations under this Agreement, including the indemnification obligations set forth in Article 8, that Purchaser has the authority to bind the Republic of Albania and that Purchaser has exercised that authority to bind the Republic of Albania as to each of the provisions and terms and conditions set forth in this Agreement;

(b) No Conflicts or Violations. The execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (i) do not conflict with or violate any Laws existing as of the Effective Date, or upon date of Approval, and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such Party existing as of the Effective Date, or upon date of Approval; and

(c) Valid Execution. Such Party is duly authorized to execute and deliver this Agreement, and the Person executing this Agreement on behalf of such Party is duly authorized to execute and bind such Party to the terms set forth herein.

5.2 Warranties of Pfizer.

Pfizer warrants to Purchaser that:

(a) At the time of delivery, the Product (except for any non-compliance or failure to meet the relevant standard or requirement that could not be reasonably discovered given the state of medical, scientific or technical knowledge at the time when Pfizer delivered the Product):

(i) complies in a material manner with the relevant Specifications; and

(ii) has been manufactured in material accordance with current Good Manufacturing Practices.

(b) Subject to Pfizer's disclaimer of non-infringement of Intellectual Property rights of a third party (at Section 5.4(a) and (b) below), it has good title to the Product delivered to Purchaser pursuant to this Agreement and shall pass such title to Purchaser free and clear of any security interests, liens, or other encumbrances.

(c) The execution, delivery and performance of this Agreement by Pfizer will not violate any agreement or instrument to which Pfizer is a party.

5.3 Anti-Bribery/Anti-Corruption and Global Trade Controls.

(a) The Parties represent and warrant that, beyond the mutual consideration set forth in this Agreement, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from another Party or its agents to induce a Party to enter this Agreement or perform any part of this Agreement.

(b) Pfizer has not made, and will not make, in the performance of this Agreement directly or indirectly any payment, offer, promise, or authorization of payment of money or anything of value to a Government official, political party, candidate for political office, or any other Person, and has not sought and will not seek improperly or corruptly to influence any Government official, political party,

candidate for political office, or any other Person, in order to gain an improper business advantage.

(c) The Parties will comply with applicable economic sanctions, import, and export control laws, regulations, and orders in the performance of this Agreement.

(d) Activities performed under this Agreement will not involve Restricted Parties (defined as the list of sanctioned parties maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; and similar lists of restricted parties maintained by relevant governmental entities).

(e) Notwithstanding any other provision of this Agreement, Pfizer shall not be required to take or refrain from taking any action prohibited or penalized under the laws of the United States or any applicable non-United States jurisdiction, including, without limitation, the antiboycott laws administered by the U.S. Commerce and Treasury Departments.

5.4 No Other Warranty.

Except to the extent set out expressly in this Agreement, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Agreement (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Laws. Without prejudice to the general nature of the previous sentence, unless this Agreement specifically states otherwise and to the maximum extent permitted by Law, Pfizer expressly disclaims any representations or warranties with respect to the Product, including, but not limited to, any representation, warranties or undertaking as to (a) non-infringement of Intellectual Property rights of any third party, (b) that there is no requirement to obtain a license of third party Intellectual Property rights to enable the use or receipt of the Product, (c) merchantability, or (d) fitness for a particular purpose.

5.5 Purchaser Acknowledgement.

Purchaser acknowledges that the Vaccine and materials related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to Purchaser under this Agreement. Purchaser further acknowledges that the long-term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, Purchaser acknowledges that the Product shall not be serialized.

6. **TERM; TERMINATION**.

6.1 Term of Agreement.

This Agreement shall commence on the Effective Date and shall continue until delivery of the Contracted Doses of the Product under the accepted Purchase Order, unless extended or terminated pursuant to this Section 6 (Term; Termination), or the mutual written agreement of the Parties, or pursuant to Section 9.6 ("**Term**").

6.2 Termination for Cause.

a) Pfizer may terminate this Agreement immediately upon written notice to Purchaser in the event of a material breach by the Purchaser of any term of this Agreement, which breach remains uncured for thirty (30) days following written notice to Purchaser of such material breach.

b) Purchaser may terminate this Agreement immediately upon written notice to Pfizer in the event of a material breach by Pfizer of any term of this Agreement, which breach remains uncured for thirty (30) days following written notice to Pfizer of such material breach.

c) Notwithstanding the foregoing, if such material breach, by its nature, cannot be cured, the terminating Party may terminate this Agreement immediately upon written notice to the other Parties. In the event that this Agreement is terminated by Pfizer under this Section 6.2, Purchaser shall pay within thirty (30) days of the date of notice of termination of this Agreement the full Price for all Contracted Doses less amounts already paid to Pfizer as of such date.

6.3 Mutual Termination Rights.

(a) In the event: (i) the Product does not obtain Authorization by the EC by June 30, 2021, (ii) Pfizer has supplied to Purchaser no doses of Product by December 31, 2021, subject to the extensions set forth in Section 2.4 (Delivery Schedule), or (iii) Pfizer is unable to supply all of the Contracted Doses by December 31, 2022, then a Party may terminate this Agreement upon written notice to the other Parties. Purchaser may invoice Pfizer for a refund of fifty percent (50%) of the Advance Payment for the initial 249,795 Contracted Doses not delivered (as determined ratably for the doses not delivered) except for cases where the cause of the termination is mainly or solely attributable to Purchaser. In the event this Agreement is terminated pursuant to this Section 6.3(a), the return of fifty percent (50%) Advance Payment shall be Purchaser's sole and exclusive remedy for the failure to deliver any Contracted Doses.

(b) If the Authorization is received on or before June 30, 2021 but there is insufficient supply to deliver the full number of Contracted Doses by December 31, 2022, fifty percent (50%) of the Advance Payment for the initial 249,795 Contracted Doses not delivered (as determined ratably for the doses not delivered) will be refunded to Purchaser except for cases where such event is mainly or solely attributable to Purchaser. In such case and this Agreement is terminated, the return of Advance

Payment for amounts not delivered shall be Purchaser's sole and exclusive remedy for the Contracted Doses, or portion thereof, that were not delivered to Purchaser. For absolute clarity, there shall be no refund for the Contracted Doses delivered.

6.4 Termination in Event of Insolvency.

In the event that Pfizer: (a) becomes insolvent, or institutes or has instituted against it a petition for bankruptcy or is adjudicated bankrupt; or (b) executes a bill of sale, deed of trust, or a general assignment for the benefit of creditors; or (c) is dissolved or transfers a substantial portion of its assets to a third party (excluding any of Pfizer's Affiliates); or (d) has a receiver appointed for the benefit of its creditors, or has a receiver appointed on account of insolvency; then Pfizer shall immediately notify Purchaser of such event and Purchaser shall be entitled to terminate this Agreement.

6.5 Effect of Termination.

(a) Upon expiry or termination of this Agreement for any reason:

(i) Purchaser shall pay any sums owed to Pfizer pursuant to this Agreement within thirty (30) days of the date of invoice for the same; and

(ii) each Party shall use Commercially Reasonable Efforts to mitigate both (1) the damages that would otherwise be recoverable from the other pursuant to this Agreement, and (2) any costs, fees, expenses or losses that may be incurred by a Party, or for which a Party may be responsible, under this Agreement, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

(b) The termination or expiration of this Agreement shall not affect the survival and continuing validity of Sections 2.1(b)-(d), 2.5(b), 2.6, 2.7(b)-(e), 2.8, 3.1, 3.3, 3.4, 4.4, 4.5, 4.6, 4.7, 5.4, 5.5, 6.2 (last sentence), 6.5, 9.2, 9.3, 9.4, 9.5, 9.6, and Articles 1, 7, 8, 10, 11 and 12 or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.

(c) Expiry or termination of this Agreement for any reason shall be without prejudice to a Party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; provided that (i) Pfizer shall have no liability for any failure by Pfizer to develop or obtain Authorization of the Product in accordance with the estimated dates described in this Agreement and (ii) even if the Product is successfully developed and Pfizer obtains Authorization, Pfizer shall have no liability for any failure to deliver Contracted Doses in accordance with any estimated delivery dates set forth herein.

7. **INTELLECTUAL PROPERTY**.

Pfizer US will be the sole owner of all Intellectual Property it generates during the development, manufacture, and supply of the Product or otherwise related to the Product.

No Party will gain any rights of ownership to or use of any property or Intellectual Property owned by the other Parties (whether by virtue of this Agreement, by implication or otherwise).

8. **INDEMNIFICATION**.

8.1 Indemnification by Purchaser. Purchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, sub-contractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development, manufacture, distribution, commercialization or use of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing ("**Indemnitees**"), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of an investigation or litigation), whether sounding in contract, tort, intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise (collectively, "**Losses**") arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labeling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine.

8.2 Assumption of Defense by Purchaser. The Indemnitee(s) shall notify Purchaser of Losses for which it is seeking indemnification pursuant hereto ("**Indemnified Claims**"). Upon such notification, Purchaser shall promptly assume conduct and control of the defense of such Indemnified Claims on behalf of the Indemnitee with counsel acceptable to Indemnitee(s), whether or not the Indemnified Claim is rightfully brought; provided, however, that Purchaser shall provide advance notice in writing of any proposed compromise or settlement of any Indemnified Claim and in no event may Purchaser compromise or settle any Indemnified Claim without Indemnitee(s)'s prior written consent, such consent not to be unreasonably withheld. Indemnitee(s) shall reasonably cooperate with Purchaser in the defense of the Indemnified Claims.

8.3 Participation Rights. Each Indemnitee shall have the right to retain its own counsel and to participate in Purchaser's defense of any Indemnified Claim, at its own cost and expense except as set forth below. A failure by the Indemnitee(s) to give notice or timely notice or to offer to tender the defense of the action or suit pursuant to this Section 8.3 (Participation Rights) shall not limit the obligation of Purchaser under this Section 8 (Indemnification), except and only to the extent Purchaser is actually prejudiced thereby.

8.4 Assumption of Defense. Notwithstanding the foregoing and without prejudice to Section 12.6, Pfizer, directly or through any of its Affiliates or through BioNTech, may elect to assume control of the defense of an Indemnified Claim (a) within thirty (30) days of Indemnitee's notice to Purchaser of the Indemnified Claim or (b) at any time if, in Pfizer's sole discretion: (i) Purchaser fails to timely assume the defense of or reasonably defend

such Indemnified Claim(s) in good faith to the satisfaction of Pfizer (or Pfizer's Affiliates and BioNTech); or (ii) Pfizer believes (or any of Pfizer's Affiliates or BioNTech believe) in good faith that a bona fide conflict exists between Indemnitee(s) and Purchaser with respect to an Indemnified Claim hereunder. Upon written notice of such election, Pfizer shall have the right to assume control of such defense (directly or through either one of its Affiliates or BioNTech), and Purchaser shall pay (as incurred and on demand), all Losses, including, without limitation, the reasonable attorneys' fees and other expenses incurred by Indemnitee(s), in connection with the Indemnified Claim. In all events, Purchaser shall cooperate with Indemnitee(s) in the defense, settlement or compromise of the Indemnified Claim.

8.5 Privileges and Immunities. Purchaser acknowledges that its indemnification obligations under this Agreement are (a) expressly in addition to, and not limited by, any Privileges and Immunities, and (b) do not waive or relinquish Indemnitees' rights to any Privileges and Immunities.

8.6 Costs. Costs and expenses, including, without limitation, fees and disbursements of counsel, incurred by the Indemnitee(s) in connection with any Indemnified Claim shall be reimbursed on a quarterly basis by Purchaser, without prejudice to Purchaser's right to refund in the event that Purchaser is ultimately held in a final, non-appealable judgment or award to be not obligated to indemnify the Indemnitee(s).

9. INSURANCE AND LIABILITY.

9.1 Insurance.

During the Term, Pfizer or its Affiliates shall self-insure or procure and maintain such types and amounts of general liability insurance to cover liabilities related to its activities under this Agreement as is normal and customary in the pharmaceutical industry generally for companies that are similarly situated and providing similar manufacturing and supply services. For absolute clarity, this shall not include, nor constitute, product liability insurance to cover any third party/patients claims and such general liability insurance shall be without prejudice to Purchaser's indemnification obligation as set out in this Agreement.

9.2 Limits on Liability.

(a) Subject to the exclusions set forth in Section 9.3, in no circumstances shall (i) a Party be liable to the other Parties or its Affiliates, whether arising in tort (including, without limitation, negligence), contract or otherwise, for any indirect, special, consequential, incidental or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise arising out of or relating to this Agreement, the transactions contemplated therein or any breach thereof (whether or not reasonably foreseeable and even if the first Party had been advised of the possibility of another Party incurring such loss or type of loss), and (ii) in the case of Pfizer and its Affiliates, in no event shall Pfizer be liable to Purchaser for any direct damages except to the extent such direct damages were a result of a material breach of a representation or warranty by Pfizer under this Agreement that directly and

solely caused the damage. In no instance shall Pfizer and its Affiliates be liable to Purchaser (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) for any liabilities of Purchaser to any third party, including, without limitation, through contribution, indemnity, or for any claim for which Purchaser would have to indemnify Pfizer if that claim were brought directly against Pfizer.

(b) The aggregate liability of Pfizer and its Affiliates (whether arising in warranty, tort (including, without limitation, negligence), contract, strict liability or otherwise) arising out of, under or in connection with this Agreement shall not exceed a sum equivalent to one hundred percent (100%) of the total Price actually received by Pfizer under this Agreement for the Contracted Doses.

9.3 Excluded Liability.

Nothing in this Agreement excludes or limits the liability of a Party for:

(i) fraud or fraudulent misrepresentation;

(ii) any breach of Section 10 (Confidential Information);

(iii) in the case of Purchaser, the indemnity given by it under Section 8 (Indemnification); or

(iv) in the case of Purchaser, failure to pay the Price for the Product or any other sums properly owing to Pfizer under this Agreement.

9.4 Waiver of Sovereign Immunity. Purchaser, on behalf of itself and the Republic of Albania, expressly and irrevocably waives any right of immunity which either it or its assets may have or acquire in the future (whether characterized as sovereign immunity or any other type of immunity) in respect of any arbitration pursuant to Section 12.2 (Arbitration) or any other legal procedure initiated to confirm or enforce any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 (Arbitration), whether in Albania or any other foreign jurisdiction, including but not limited to immunity against service of process, immunity of jurisdiction, or immunity against any judgment rendered by a court or tribunal, immunity against order to enforce the judgment, and immunity against precautionary seizure of any of its assets. Purchaser expressly and irrevocably submits to the jurisdiction of the courts of New York, or any other court of competent jurisdiction, for the purposes of enforcing any arbitral decision, order or award, or any settlement in connection with any arbitration pursuant to Section 12.2 and represents and warrants that the person signing this Agreement on its behalf has actual authority to submit to such jurisdiction. Purchaser also expressly and irrevocably waives the application of any Law in any jurisdiction that may otherwise limit or cap its obligation to pay damages arising from or in connection with any Indemnified Claims and represents and warrants that this Agreement and any Indemnified Claims arising hereunder are not subject to the Albanian Public Procurement Laws. Purchaser represents and warrants that the person signing this Agreement on its behalf has actual authority to waive such immunity and bind

Purchaser and the Republic of Albania to the limitations of liability and liability waivers set forth herein.

9.5 Conditions Precedent to Supply.

Purchaser represents that it has and will continue to have adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations and provide adequate protection to Pfizer and all Indemnitees from liability for claims and all Losses arising out of or in connection with the Vaccine or its use. Purchaser hereby covenants and acknowledges and agrees that a condition precedent for the supply of the Product hereunder requires that Purchaser shall implement and maintain in effect such statutory or regulatory requirements or funding appropriation sufficient to meet its obligations in this Agreement prior to supply of the Product by Pfizer and thereafter shall maintain such statutory and regulatory requirement and funding appropriation, each as applicable, for so long as necessary to meet all of Purchaser's obligations under this Agreement, including, without limitation, any such obligations that, pursuant to Section 6.5, survive expiration or termination of this Agreement. For clarity, the sufficiency of such statutory or regulatory requirements or funding appropriation shall be in Pfizer's sole discretion. Purchaser acknowledges that Pfizer's supply of Product hereunder is in reliance (without any duty of investigation or confirmation by or on behalf of Pfizer or its Affiliates), *inter alia*, on Purchaser's representations and covenants under this Section 9.5, Purchaser implementing and maintaining in effect the requirements and funding appropriation described in this Section 9.5 and the other representations and warranties made by Purchaser under this Agreement.

9.6 Condition Precedent. Purchaser further covenants and acknowledges and agrees that a condition precedent to the effectiveness of this Agreement requires that the Normative Act, and the entry into this Agreement thereunder, be ratified by a law of the Albanian parliament in accordance with Albanian law within ten (10) days of the Effective Date (the "**Approval**"). Purchaser shall notify Pfizer immediately upon issuance of such Approval and provide a copy of such Approval to Pfizer. A true and correct copy of such Approval shall be attached hereto as Attachment J. Purchaser acknowledges that such Approval is a material term of this Agreement and that Pfizer is entering into this Agreement in reliance thereon. In the event that such Approval is not obtained within the time period prescribed above, this Agreement shall automatically terminate. In such event, Pfizer shall have no liability to Purchaser, and Pfizer shall have no obligation to amend, restate, modify or enter into a new agreement with Purchaser for supply of the Product. For clarity, the provisions of Section 6.5 shall apply upon termination of this Agreement pursuant to this Section 9.6.

10. **CONFIDENTIAL INFORMATION**.

10.1 Non-Use and Non-Disclosure.

Each Recipient shall, and shall cause its Representatives which have access to the Disclosing Party's Confidential Information to, maintain in strict confidence, and shall not disclose to any third party, all Confidential Information observed by or disclosed to it by or on behalf of the Disclosing Party pursuant to this Agreement. In particular, the

Purchaser shall protect any Confidential Information pursuant to this Agreement on the bases of applicable provisions of public procurement and/or information right Laws in Albania for the protection of confidential information, trade secrets, industrial property rights. Each Recipient shall not use or disclose such Confidential Information except as permitted by this Agreement. Each Recipient shall safeguard the confidential and proprietary nature of the Disclosing Party's Confidential Information with at least the same degree of care as it holds its own confidential or proprietary information of like kind, which shall be no less than a reasonable degree of care. The Recipient and its Representatives may use, copy, and make extracts of the Disclosing Party's Confidential Information only in connection with fulfilling its obligations under this Agreement and, without limiting the foregoing, shall not use the Confidential Information for the benefit of the Recipient or any of its Representatives, or for the benefit of any other Person. In the event that Recipient becomes aware of any breach of the obligations contained in this Section 10 (Confidential Information) by it or its Representatives, Recipient shall promptly notify the Disclosing Party in writing of such breach and all facts known to Recipient regarding same. In addition, if Recipient is required to disclose the Disclosing Party's Confidential Information in connection with any court order, statute or Government directive or requirement under any Law, Recipient shall give the Disclosing Party notice of such request, as soon as practicable, before such Confidential Information is disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the Disclosing Party seeks a protective order or other remedy, Recipient shall promptly cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) in such efforts. If the Disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, Recipient shall disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose. Neither this Agreement nor the performance by a Party hereunder shall transfer to the Recipient any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including, but not limited to, any Intellectual Property rights subsisting therein) or be construed as granting a license in its Confidential Information. Notwithstanding the foregoing, in all cases, (a) Purchaser may not disclose any of the financial or indemnification provisions contained in this Agreement, including, without limitation, the price per dose of Product or refundability of the Advance Payment or any information that could reasonably ascertain the price per dose of Product, without the prior written consent of Pfizer, and (b) Pfizer may disclose (i) Confidential Information to its Affiliates and BioNTech without prior written consent of Purchaser, and (ii) upon foreign government request, financial information relating to this Agreement, including cost per dose.

10.2 Recipient Precautions.

In order to comply with the obligations contained in this Section 10 (Confidential Information), Recipient shall take at least the following precautions: (a) Recipient shall exercise all reasonable efforts to prevent unauthorized employees and unauthorized third parties from gaining access to Confidential Information (and in no event less than reasonable care); (b) Recipient shall disclose Confidential Information only to such of its Representatives who have a need to know such Confidential Information to fulfill its

obligations under this Agreement; provided, however, before any disclosure of Confidential Information, Recipient shall bind its Representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement; and (c) prior to any disclosure, Recipient shall instruct its Representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. Recipient shall be responsible for all actions of its Representatives, including, without limitation, any breach of the terms hereof, regardless of whether or not such Representatives remain employed or in contractual privity with the Recipient.

10.3 Return of Confidential Information.

Upon the written request of the Disclosing Party, Recipient shall promptly return or, at the Recipient's option, delete or destroy all Confidential Information of the Disclosing Party (including, without limitation, all copies in whatever medium provided to, or made by, such recipient); provided, however, that, subject to the terms of this Agreement, (i) Recipient shall be entitled to retain one archival copy of such Confidential Information for purposes of determining its obligations under this Agreement; and (ii) Recipient shall not be required to destroy any computer files stored securely by the Recipients or its Affiliates that are created during automatic system back up, or retained for legal purposes by the legal division of the Recipient and its Affiliates, provided that such retained Confidential Information shall remain subject to the terms of this Agreement. Notwithstanding Recipient's return or destruction of Confidential Information, Recipient shall continue to be bound by its obligation of confidentiality and non-use under this Agreement.

10.4 Survival.

The provisions of this Section 10 (Confidential Information) shall survive the termination or expiration of the this Agreement for a period of ten (10) years, except with respect to any information that constitutes a trade secret (as defined under Law), in which case the Recipient of such information will continue to be bound by its obligations under this Section 10 (Confidential Information) for so long as such information continues to constitute a trade secret, but in no event for a period of less than the ten (10)-year period specified above.

11. **NOTICES**.

Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently given, (a) when delivered in person, (b) on the next Business Day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (c) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) Business Day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and parties to this Agreement.

If to Purchaser:
Institute of Public Health
Aleksander Moisiu, nr. 80

Tirana, Albania 1001
Email: ishp@shendetesia.gov.al

If to MOH:
[**Insert Purchaser notice information**]
If to MOR
Insert Purchaser notice information

If to Pfizer:

PFIZER EXPORT B.V.
Rivium Westlaan 142, 2909LD
Capelle aan den Ijssel,
The Netherlands
Attn: Andrew Richmond
Email: Andrew.Richmond@Pfizer.com

With a copy (which shall not constitute notice) to:
Pfizer SRB d.o.o.
Tresnjinog cveta 1/VI
11070 Novi Beograd
Serbia
Attn: Mila Zrnic
Email: Mila.Zrnic@Pfizer.com

With a copy (which shall not constitute notice) to:
Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: General Counsel
LegalNotice@Pfizer.com

A Party may, by notice to the other Parties, change the addresses and names given above.

12. **MISCELLANEOUS**.

12.1 Negotiations of Dispute.

Prior to commencing any arbitration with respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement, a Party shall provide written notice to the other Parties of the existence of such dispute. The Parties shall for a period of thirty (30) days following such notice enter into good faith discussions and negotiations in an attempt to resolve such dispute. If, by the end of such thirty (30) day period, unless such period is extended by mutual written agreement of the Parties, the Parties have been unable to resolve such dispute, a Party may initiate arbitration in accordance with the procedures set forth in Section 12.2 (Arbitration). The procedures specified in this Section 12.1 (Negotiations of Dispute) are a precondition to the initiation of arbitration by a Party, in connection with disputes between the Parties arising from or related to this Agreement or a Purchase Order; provided, however, that a Party may seek a preliminary injunction or other preliminary judicial relief, without attempting to resolve such dispute as provided in this Section 12.1 (Negotiations of Dispute), if in its judgment such action is necessary to avoid irreparable harm. The Parties expressly and irrevocably submit to the jurisdiction of the courts of New York, New York, U.S.A., for any such injunctive relief. Further, the requirement to attempt to resolve a dispute in accordance with this Section 12.1 (Negotiations of Dispute) does not affect a Party's right to terminate this Agreement as

provided in Section 6 hereof, and a Party shall not be required to follow these procedures prior to terminating the Agreement. The failure of a Party to participate in good faith discussions and negotiations in an attempt to resolve such dispute shall not delay the date by which another Party may initiate arbitration under this Section 12.1 (Negotiations of Dispute).

12.2 Arbitration.

Any dispute, controversy, or claim arising out of, relating to, or in connection with this Agreement, including with respect to the formation, applicability, breach, termination, validity or enforceability thereof, or relating to arbitrability or the scope and application of this Section 12.2 (Arbitration), shall be finally resolved by arbitration. The arbitration shall be conducted by three arbitrators, in accordance with the Rules of Arbitration of the International Chamber of Commerce ("**ICC**"). The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30) days of the receipt of the request for arbitration. The two (2) arbitrators nominated by the Parties shall nominate a third arbitrator, in consultation with the Parties, within thirty (30) days after the confirmation of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three (3) arbitrators are not nominated within the time prescribed above, then the ICC shall appoint the arbitrator(s). The seat of the arbitration shall be New York, New York, U.S.A. and it shall be conducted in the English language. . The Parties undertake to maintain confidentiality as to the existence of the arbitration proceedings and as to all submissions, correspondence and evidence relating to the arbitration proceedings. This provision shall survive the termination of the arbitral proceedings. The costs of the arbitration, including, without limitation, the Parties' reasonable legal fees, shall be borne by the unsuccessful Party or Parties. However, the arbitral tribunal may apportion such costs between the Parties if it determines that apportionment is reasonable, taking into account the circumstances of the case. The arbitration award shall be final and binding on the Parties, and the parties undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant party or its assets.

12.3 Purchasers Obligations.

MOH, MOR and IPH are defined collectively herein as Purchaser; *provided, however*, that any references herein to "Purchaser", or similar references, shall be construed as a reference to each MOH, MOR and IPH. MOH, MOR and IPH shall be jointly and severally liable for all of the obligations of Purchaser under this Agreement. Each of MOH, MOR and IPH, individually, hereby acknowledge and agree that all of the representations, warranties, covenants, obligations, conditions, agreements and other terms contained in this Agreement shall be applicable to and shall be binding upon and measured and enforceable individually against each of MOH,MOR and IPH.

12.4 Publicity.

A Party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other Parties in publicity releases, advertising or any other publication, without the other Parties' prior written consent in each instance.

12.5 Governing Law.

All disputes shall be governed by the Laws of the State of New York, USA, without regard to conflict of Law principles other than Section 5-1401 of the New York General Obligations Law, except that any dispute regarding the arbitrability or the scope and application of this Section shall be governed by the Federal Arbitration Act of the United States.

12.6 Third Party Rights.

(a) Purchaser agrees the applicable rights granted or provided to Pfizer under this Agreement are also granted or provided to Pfizer's Affiliates or to BioNTech to the extent that those rights relate to such Affiliates or BioNTech, including but not limited to the indemnification in Section 8(a) (each a "**Third Party Beneficiary**" and together the "**Third Party Beneficiaries**"). Each Third Party Beneficiary shall be entitled to enforce the terms of this Agreement; provided that, to the extent permissible by Law and where reasonably practicable, any claims, demands or actions from any Third Party Beneficiary shall be brought by Pfizer itself on behalf of the relevant Third Party Beneficiary.

(b) Any Losses suffered by a Third Party Beneficiary will not be treated as being indirect solely because it has been suffered by a Third Party Beneficiary and not by Pfizer directly.

12.7 Relationship of the Parties.

The relationship hereby established between Purchaser and Pfizer is solely that of independent contractors. No Party has authority to act or make any agreements or representations on behalf of the other Parties. This Agreement is not intended to create, and shall not be construed as creating, between Pfizer and Purchaser, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

12.8 Assignment; Binding Effect.

Neither Purchaser nor Pfizer shall assign any of its rights or delegate or subcontract any of its duties and obligations under this Agreement without the prior written consent of the other Parties, which may be withheld at such Party's discretion, provided that Pfizer, without Purchaser's consent, may assign, delegate or subcontract any of its duties and obligations under this Agreement to an Affiliate of Pfizer, BioNTech or an Affiliate of BioNTech. Any such attempted assignment of rights or delegation or subcontracting of duties without the required prior written consent of the other Parties shall be void and ineffective. Any such assignment, delegation or subcontracting consented to by a Party in writing shall not relieve the other Parties of their responsibilities and liabilities hereunder and such assigning Party shall remain liable to other Parties for the conduct and performance of each permitted assignee, delegate and subcontractor hereunder. This Agreement shall apply to, inure to the benefit of and be binding upon the Parties hereto and

their respective successors and permitted assigns. The Parties agree that this Agreement is not intended by a Party to give any benefits, rights, privileges, actions or remedies to any Person or entity, partnership, firm or corporation as a Third Party Beneficiary or otherwise under any theory of Law.

12.9 Force Majeure.

Each Party shall not be liable for any failure to perform or any delays in performance, and each Party shall not be deemed to be in breach or default of its obligations set forth in this Agreement, if, to the extent and for so long as, such failure or delay is due to any causes that are beyond its reasonable control and not to its acts or omissions, including, without limitation, such causes as acts of God, natural disasters, flood, severe storm, earthquake, civil disturbance, lockout, riot, embargo, acts of Government (other than Purchaser), war (whether or not declared), acts of terrorism, the impact on a Party of an outbreak of any disease or an epidemic or pandemic or other similar causes ("**Force Majeure Event**"). Failure or inability to pay shall not be a basis for a Force Majeure Event under this Agreement. In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly give notice to the other Parties and shall use Commercially Reasonable Efforts to avoid or minimize the delay.

12.10 Severability.

If and solely to the extent that any court or tribunal of competent jurisdiction holds any provision of this Agreement to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken and the remainder of this Agreement shall not be affected thereby. In such event, the Parties shall in good faith attempt to replace any unenforceable provision of this Agreement with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision.

12.11 Non-Waiver; Remedies.

A waiver by any Party of any term or condition of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this Agreement shall be cumulative and in addition to any other remedies provided at Law or in equity.

12.12 Further Documents.

Each Party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this Agreement.

12.13 Forms.

The Parties recognize that, during the Term, a Purchase Order acknowledgment form or similar routine document (collectively, "**Forms**") may be used to implement or administer provisions of this Agreement. The Parties agree that the terms of this Agreement shall prevail in the event of any conflict between terms of this Agreement and the terms of such

Forms, and any additional or different terms contained in such Forms shall not apply to this Agreement.

12.14 Headings.

Headings of Sections or other parts of this Agreement are included herein for convenience of reference only and shall not constitute a part of this Agreement or change the meaning of this Agreement.

12.15 Counterparts.

This Agreement may be executed in three or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement, and shall become effective when signed by all of the Parties hereto and delivered to the other Parties in accordance with the means set forth in Section 11 (Notices) or by reliable electronic means (with receipt electronically confirmed).

12.16 Electronic Delivery and Storage.

Delivery of a signed Agreement by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed Agreement. This Agreement may be stored by electronic means and either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights or obligations of the Parties to this Agreement.

12.17 Entire Agreement; Amendments.

This Agreement, together with any attachments and amendments (and as such attachments may be amended, amended and restated or replaced from time to time), which are hereby incorporated by reference, constitute the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto. Except as otherwise set out herein, no modification or alteration of this Agreement shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and specifically referring hereto or thereto.

12.18 Rule of Construction.

The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

12.19 English Language.

This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into

any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

12.20 Legal Costs.

Each Party will bear its own legal costs in preparing and concluding this Agreement.

[signature on following page]

GOGO .vf

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

PFIZER EXPORT B.V.

By:_____

Name:_____

Title:_____

Date:_____

ALBANIA MINISTRY OF HEALTH AND SOCIAL PROTECTION

By:_____

Name:_____

Title:_____

Date:_____

AGREED AND ACKNOWLEDGED by MINISTEROF STATE FOR RECONSTRUCTION

By:_____

Name: _____

Title: _____

Date:_____

INSTITUTE OF PUBLIC HEALTH

By:_____

Name: _____

Title: _____

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Attachment A - Specifications

[To be inserted following the Effective Date (and in any event before supply in line with the agreed Delivery Schedule)]

[Attachment B - Delivery Schedule and Price]

Supply Period	January 2021	February 2021	Q3 -Q4 2021		Total
Doses	10,530	30,420	458,640		499,590
Price per dose	USD 12	USD 12	USD 12		

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Attachment C- Delivery Documentation

Documentation and Delivery Notes

Thermal Shipper Documentation

It is currently envisaged that the following will be provided with each shipment of the Products:

1. Emergency Use Authorization (EUA) Fact Sheets/Leaflets – Five (5) fact sheets folded 3x2" in a plastic bag

2. Pfizer Brochure – One (1) per thermal shipper container containing product storage and handling information including:
   - Dry Ice Handling Insert
   - Safety Data Sheet (SDS) for Dry Ice
   - Return instructions for GPS loggers and thermal shipping system
   - A stand-alone SDS for Dry Ice
   - Blank label – purpose of the blank label: for carriers to mark out the dry ice label to indicate that the thermal shipper containers are empty (not containing dry ice)

3. Return Shipping Label – One (1)

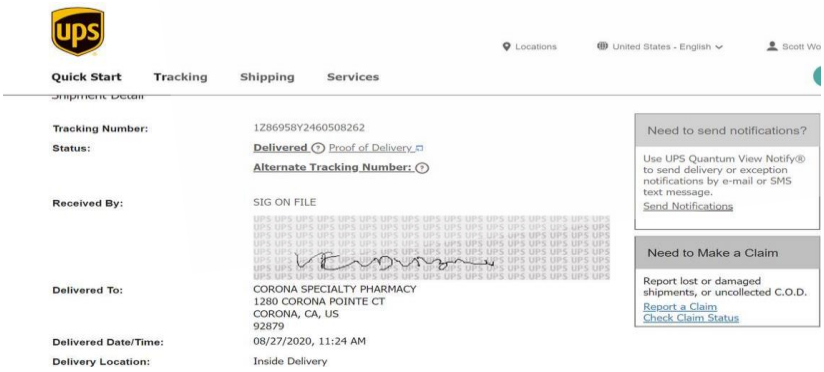
4. Outbound Shipping Label – One (1), standard label on thermal shipper

5. Contents Label – One (1) label on inside flap, picking label details how many carton trays are in thermal shipper

Proof of Delivery Documentation

Currently, Pfizer intends to use the carrier delivery signal as proof of delivery.

Proof of delivery document that can be accessed online based on track and trace number. See UPS example* below:



*The above proof of delivery image is an example only.

Attachment D – Delivery Specification

Product Delivery, Storage & Handling Specifications

Shipments will arrive in a long-distance thermal shipping container as provided by Pfizer in accordance with the Labelling and Packaging Specifications set forth in Attachment E ("**Thermal Shipper**"). At this time, the minimum package in any shipment shall be one (1) tray with 195 vials or 1170 doses of Product.

Purchaser ensures that at the expected time of arrival at the Place(s) of Destination, a dedicated person will be available to receive the Product, sign acceptance for delivery, and, immediately, no later than 24 hours of delivery, switch off the temperature logger located in the Thermal Shipper, and:

(a) transfer the Product to:
  (i) a -75 ºC (+/- 15 ºC) ultra-low temperature ("**ULT**") freezer; or
  (ii) a 2-8 ºC refrigerator; or

(b) maintain the Product with sufficient supply of dry ice in accordance with the protocols for re-icing set forth below with such initial re-icing to occur no later than 24 hours from signature of acceptance of delivery.

Purchaser acknowledges the following stability timelines as of the Effective Date:

- The Product has a shelf-life of up to 6 months when stored at a constant -75 ºC (+/- 15 ºC)
- The Thermal Shipper can be used as temporary storage for up to 30 days, as long as dry ice is replenished upon receipt and at least every five (5) days per Pfizer's guidelines.
- The Product has an effective life of up to 5 days when stored at refrigerator temperatures 2-8°C
- Once the Product is defrosted and reconstituted it can be retained for up to 6 hours at standard ambient room temperatures (19-25°C)

Any further shipment or distribution of the Product by Purchaser from the Place(s) of Destination shall be through a certified shipping service, or use of its own logistics system, that will ensure next day delivery from the Place(s) of Destination to point of use of the Product; and Purchaser shall be liable for ensuring continual compliance with the cold chain requirements for any further distribution following delivery to a Place of Destination that is not a point of use of the Product. In all cases, Purchaser shall ensure that all Product is transported in (a) the Thermal Shipper with re-icing performed in accordance with the Protocols for re-icing set forth below, or (b) an alternate shipper purchaser by Purchaser, in each case in a manner to maintain the temperature requirements set forth herein. All costs associated with receiving, handling, storing and further delivery of the Product shall be the responsibility of Purchaser, and Purchaser shall ensure that all locations where any Product is delivered by, or on behalf of Purchaser, shall comply with the requirements set forth in this Attachment D and shall meet the standards set forth herein.

Protocols for Unpacking Product and Re-icing: See Exhibits 1 and 2 of Attachment D

Requirements of Delivery Location:

1. EUA, Pre-approval, Post-approval vaccination points with -75 ºC (+/- 15 ºC) ULT freezer
2. EUA, Pre-approval, Post-approval vaccination points with sufficient access and supply of dry-ice
3. EUA, Pre-approval, Post-approval vaccination points with 2-8ºC refrigerator

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Attachment D – Delivery Specification
Exhibit 1 – Unpacking and Re-icing: Thermal Shipper A

Attachment D – Delivery Specification
Exhibit 2 – Unpacking and Re-icing: Thermal Shipper B

Vaccine Preparation & Administration Instructions

Removing the Vials to Thaw

- From storage, remove 1 vial for every 6 recipients according to planned vaccinations schedule.
- Vials may be stored in the refrigerator for 5 days (120 hours).

Diluting the Vaccine

- Obtain 0.9% Sodium Chloride Injection, for use as a diluent. Do not use any alternate diluents.
- Dilute the thawed vial by adding **1.8 mL of 0.9% Sodium Chloride Injection** into the vial.
- Ensure vial pressure is equalized by **withdrawing 1.8 mL air** into the empty diluent syringe before removing the needle from the vial.

Preparing the Dose

- **Draw up 0.3 mL of the diluted dosing solution** into a new sterile dosing syringe with a needle appropriate for intramuscular injection.
- For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.

Vaccine Administration

- Diluted vials must be used within 6 hours from the time of dilution and stored between 2-25 °C (35-77°F).
- A single 30 mcg/0.3 mL dose is followed by a second dose 21 days later.

Attachment E – Labelling and Packaging Specifications

Product Labelling Specifications

Product labels for primary, secondary and tertiary packaging will be shared closer to country regulatory filings.

It is currently envisaged that the following will be part of the initial product artwork:

Primary Packaging (Vial):

- Linear barcode: Scans as the Global Trade Item Number (GTIN) that includes the human-readable National Drug Code (NDC) number.

Secondary Packaging (Carton Tray):

- Linear barcode: Scans as the GTIN number that includes the human-readable NDC number.
- QR code: When scanned, this code links to a landing page where a copy of the Fact Sheets for the Healthcare Provider, patient/recipient, and Emergency Use Authorization Product Insert (i.e. e-leaflet) will be available.
- 2D GS1 DataMatrix: Scan of the 2D code will include the GTIN number, lot and expiry information.

Product Packaging Specifications

Primary Packaging

- 2 mL type 1 glass preservative free multi-dose vial (MDV)
- MDV has 0.45 mL frozen liquid drug product
- 6 doses per vial

Secondary Packaging "Single Tray"

- Single tray holds 195 vials
- 1170 doses per tray
- Tray (white box) dimensions: 229 X 229 x 40 mm

Tertiary Container: Thermal Shipper (Softbox)

- Minimum 1 tray (1170 doses) or up to 5 trays (max 5850) stacked in a payload area of the shipper
- Payload carton submerged in 23 Kg of dry ice pellets (9 mm – 16 mm pellets)
- Thermal shipper dimensions:
    - Internal Dimensions: 245mm X 245mm X 241mm
    - External Dimensions: 400mm X 400mm X 560mm

Attachment F – Return and Disposal of Product Materials

A. Return

"**Logistics Delivery Equipment**" refers to the long-distance thermal shipping container ("**Thermal Shipper**") used for shipping and the temperature data logger/monitoring device attached to such Thermal Shipper.

Once dry ice is no longer needed, open the **Logistics Delivery Equipment** and leave it at room temperature in a well-ventilated area. The dry ice will readily sublime from a solid to a gas. DO NOT leave dry ice unattended.

Store the empty **Logistics Delivery Equipment** until return in an appropriate clean and secure location to protect and maintain the functionality of the equipment (e.g., do not store outside under uncontrolled conditions, exposed to weather, exposed to pests, etc.).

Return of the **Logistics Delivery Equipment** to be undertaken within 30 days following delivery of the Product at the Place(s) of Destination. Instructions and logistics for return will be provided on the interior of the Thermal Shipper and will also be available on Pfizer's website. In the event that either: (a) the **Logistics Delivery Equipment** (or any part thereof), is not (i) delivered to the return carrier within 30 days following delivery of the Product or (ii) received by Pfizer within five (5) days following the date of Purchaser's return shipment of such Logistics Delivery Equipment; or (b) the **Logistics Delivery Equipment** (or any part thereof), is damaged in any way (determined in Pfizer's sole discretion), Pfizer shall be entitled to charge Purchaser $450 (exclusive of VAT) per Thermal Shipper and temperature data logger/monitoring device; which Purchaser shall pay within 30 days of the date of any invoice for such amount(s). Purchaser acknowledges that such amount represents a reasonable pre-estimate of replacement cost such Logistics Delivery Equipment as a result of Purchaser's default, act or omission.

B. Disposal

"**Primary Container Units**" refers to the vials that contain the Product.

Destruction of the **Primary Container Units** that have been opened or are unused must take place at a facility appropriately licensed to handle and destroy pharmaceutical waste, medical waste, and/or hazardous waste, and destruction must be by means of grinding or incineration.

"**Secondary Cartons**" refers to the immediate boxes that contain the vials of Product.

Secondary Cartons must be defaced and destroyed in accordance with local clinical dosing facility waste management services, and **Secondary Cartons** may not be disposed of in routine household waste collection or recycling centers.

Attachment G – Form of Purchase Order

[To be inserted following the Effective Date (and in any event before supply in line with the agreed Delivery Schedule)]

Attachment H- Customs Clearance Documentation and waivers

PART 1

SAMPLE

1. Shipping Document/Airway Bill "AWB"
2. Commercial Invoice
3. Packing List
4. Copy of the Certificate of Origin
5. Copy of the Certificate of Analysis "COA"
6. Copy of Export Declaration.

During the Term of the Agreement:

- Any other documents not included in the above-mentioned list of documents, including but not limited to import permits, will be waived by the Purchaser or any other Government authority.

- Any notarization, legalization and/or certification of the above-mentioned list of documents will be waived by the Purchaser or any other Government authority.

- Any required analysis to release any of the shipments upon arrival at the Point of Delivery will be waived by the Purchaser or any other Government authority.

PART II

- Any other documents not included in the global Pfizer dossier for Pfizer BioNTech Covid 19 Vaccine registration, will be waived by the Purchaser or any other Government authority.

- Any notarization, legalization and/or certification of the documents required for issuing the Marketing Authorization in Albania, will be waived by the Purchaser or any other relevant Government authority (e.g. GMPs, CPP, etc).

- Any required analysis to issue the Marketing Authorization in Albania, will be waived by the Purchaser or any other relevant Government authority (e.g. registration samples and reference standards).

Attachment I – Normative Act, dated 31.12.2020.

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Attachment J - Approval and Ratification of Agreement by Law of Parliament of Normative Act

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Jon Epstein[epstein@ecohealthalliance.org]
Sent: Fri 3/23/2018 6:54:18 PM (UTC-04:00)
Subject: dual use safety language

Hi Ralph,
DARPA wants a written section on communicating dual-use information. Do you have some written text you could send me:

A communication plan that addresses content, timing, and the extent of distribution of potentially sensitive dual-use information. The plan must also address how input from DARPA, other government, and community stakeholders will be taken into account in decisions regarding communication and publication of potentially sensitive dual-use information.

Cheers,
Jon

--

Jonathan H. Epstein DVM, MPH, PhD

Vice President for Science and Outreach

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

(direct)
(mobile)

web: ecohealthalliance.org

Twitter: @epsteinjon

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EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

EXHIBIT 4