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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

BENJAMIN COKER, et. al., Plaintiffs, vs. LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, et. al., Defendants.	Case No.: 3:21-cv-1211-AW-HTC **AMICUS CURIAE BRIEF OF PRITISH VORA, Pro Se** **Hon. Judge Allen Winsor**

COMES NOW, Pritish Vora, Amicus Curiae, by way of Pro Se, files with the Honorable Court his amicus curiae brief in the above referenced matter, and states as follows:

INTEREST OF THE AMICUS CURIAE

Amicus Curiae ("Amicus"), submits this informational brief in support of the Plaintiffs BENJAMIN COKER, JOSEPH CONNELL, KALEM COSSETTE, SEAN COTHRAN, SAMUEL CRAYMER, KACY DIXON, JORDAN KARR,

NICHOLAS HARWOOD, ERIC KALTRIDER, NICKOLAS KUPPER, BLAKE MORGAN, TAYLOR ROBERTS, SAMUEL SIGOLOFF, ANDREW SNOW, BRIAN STERMER, and MICHAEL THOMPSON, (collectively, "Plaintiffs"), who are facing the order from the Secretary of the Department of Defense ("DoD") to become fully vaccinated with the Pfizer-BioNTech Covid-19 mRNA vaccine[1] or face disciplinary action. (Hereinafter for simplicity the order referred to as "the DoD mandate.").

Amicus provides information to this Court from publicly available sources found on the following sites, including, but not limited to, FDA.gov, CDC.gov, SENATE.gov, CLINICALTRIALS.gov, HEALTH.mil, and publicly available court filings on CourtListener.com via its RECAP archive, which are also available on PACER.gov, of facts that warrant judicial notice,[2] and of facts that may escape the Court's consideration.

This brief was not authored in whole or in part by counsel representing any party in this case. Amicus can observe objectively the pandemic that has grappled the nation over what now has transgressed into the Covid-19 vaccine mandate

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[1] Amicus uses the word "vaccine" for convenience, but wholly rejects the notion of the Covid-19 injections being "vaccines." They are not. These are novel gene therapies using mRNA technology (e.g., Pfizer-BioNTech, Moderna) that do not use a live or attenuated virus to stimulate an immune response. They are considered "biological products" and/or "drugs."

[2] See US v. Jones, 29 F.3d 1549, 1553 (11th Cir. 1994). See also Fed.R.Evid. 201(b).

hysteria. Indeed, as Amicus types this brief, the country is now approaching two full years of the pandemic and is on Day 675 of "15 days to slow the spread" announced on March 16, 2020. Amicus has not received any monetary compensation to file this brief from any source, and does so at his own time, effort and expense.

Amicus shall focus on five distinct parts for the purpose of this brief and shall provide the Court with supporting references for each:

1. The COMIRNATY Covid-19 vaccine is not available and thus the DoD mandate for the Armed Forces is unjustified.

2. The COMIRNATY Covid-19 vaccine is not "interchangeable" with the Pfizer-BioNTech Covid-19 vaccine (i.e., BNT162b2).

3. The Centers for Disease Control and Prevention ("CDC") tracks and lists "Deaths **with** confirmed or **presumed** COVID-19," thereby making the total amount of deaths **"from"** COVID-19 unquantifiable. (Emphasis added).

4. "DEATH" is a listed serious adverse event following administration of the Pfizer-BioNTech Covid-19 vaccine, as stated in the emergency use authorization ("EUA") fact sheet for vaccine providers (i.e., the ones *administering* the vaccine). DEATH is **not** listed as a side effect in the EUA fact sheet provided **to recipients** (i.e., the ones actually *getting* the vaccine). (Emphasis added).

5. The Public Readiness and Emergency Preparedness Act ("PREP Act")

provides immunity from liability to "qualified persons" (e.g., vaccine companies).

1. COMIRNATY IS NOT AVAILABLE

The mainstream media, whipped into a frenzy over an FDA press release on August 23, 2021,[3] proffered a false reality that has permeated into the minds of the masses as well as Federal District Courts (and some Appellate Courts). The ploy sold to the public to boost their confidence and "get vaccinated" was quite simple: the Pfizer-BioNTech Covid-19 vaccine was claimed as "FDA approved" and would be marketed as the new tradename COMIRNATY® Covid-19 vaccine, even if no such FDA approved vaccine was readily available for U.S. consumers.

Plaintiffs have since briefed extensively regarding the *two* letters sent by FDA to Pfizer on August 23, 2021 (the same day of the FDA press release) and one day prior to the DoD mandate. (See, in general, Sec. Amend. Compl. Doc 56). The first letter granted the approval of the BLA (biologics license application) to BioNTech in Mainz, Germany to produce, label and market "COMIRNATY," subject to specific terms and conditions, including safety data studies that span until the year 2025 for various groups. (See Exhibit 3, BLA approval letter with listed safety study completion dates). The second letter extended the current EUA for the Pfizer-BioNTech unapproved mRNA Covid-19 vaccine for those 12 years

[3] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Jan. 18, 2022).

of age and older. (See Exhibit 5, letter from FDA to Elisa Harkins at Pfizer).

The August 23, 2021 letter addressed to Elisa Harkins at Pfizer from Denise Hinton at FDA, states as follows: *"All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 vaccine clearly and conspicuously shall state that: "**This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an EUA** to prevent Coronavirus Disease 2019 (COVID-19) for individuals 12 years of age and older."* (See Exhibit 5 at pages 11 and 12, respectively). (Emphasis added). Applying a logical perspective, "printed matter" would include the labeling of vials and cartons. Consequently, any label on a vial or carton would thus indicate that the product is neither approved nor licensed.

Amicus respectfully requests the Court to take judicial notice of two letters sent by Senator Ron Johnson (R-WI) [4] ("Sen. Johnson") to the FDA, one dated August 26, 2021,[5] and a follow up letter dated October 7, 2021, seeking answers to questions regarding the *"de facto endorsing of vaccine mandates utilizing EUA vaccines."* Sen. Johnson specifically asked about the availability of COMIRNATY and how COMIRNATY and Pfizer-BioNTech vaccines were "legally distinct."

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[4] Senator Johnson served as the Chairman of the Homeland Security and Governmental Affairs Committee from 2015-2021 and now is a ranking member for the Permanent Subcommittee on Investigations. https://www.ronjohnson.senate.gov/ (last visited Jan. 18, 2022).

[5] https://www.ronjohnson.senate.gov/services/files/50503B93-EB6A-49C3-ADAA-4B93200D32D5

According to Sen. Johnson, despite requesting an expeditious response, acting commissioner Janet Woodcock (one of the defendants in this case) **failed** to respond. (Emphasis added). Interestingly, the letter to Pfizer extending the EUA dated August 23, 2021, has since been removed from FDA.gov search results.

Amicus informs the Court of the following facts that warrant judicial notice. CDC.gov states as follows, quoted verbatim:

"COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels:" [6] (Emphasis added).

The National Institutes of Health ("NIH"), on NIH.gov, also states as follows, quoting the same statement by Pfizer as found on CDC.gov, placing in doubt to any reasonable factfinder as to why a product would be "approved" and yet still not be available: *"Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. At present,* ***Pfizer***

[6] https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html (last visited Jan. 18, 2022).

does not plan to produce any product *with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes* ***until Pfizer has determined when the product will be produced with the BLA labels***." [7] (Emphasis added).

"NDCs" stand for National Drug Codes found on the drug's outer packaging on each carton of vials. Indeed, the NIH includes the sample photos of the cartons that contain the vials. [8] (See n.8, "View Package Photos"). The labels of the Pfizer-BioNTech Covid-19 vaccine clearly are marked with the following disclosure: **"For use under Emergency Use Authorization."** (Emphasis added).

The American Medical Association ("AMA") has an online resource tool to track each specific Covid-19 vaccine administration code and determine which dose in the regimen is being administered for immunization purposes.[9] The AMA lists each Covid-19 vaccine available, including Pfizer-BioNTech, Moderna, and Janssen, with a vaccine code for each respective "booster" dose. The AMA does not list COMIRNATY at all; it does not exist.

Pursuant to the "Authorization & Regulatory Guidance" of the U.S. Army

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[7] https://dailymed.nlm.nih.gov/dailymed/ (last visited Jan. 18, 2022).

[8] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=908ecbe7-2f1b-42dd-94bf-f917ec3c5af8

[9] https://www.ama-assn.org/find-covid-19-vaccine-codes (last visited Jan. 18, 2022).

Medical Materiel Development Activity,[10] its authority derives from: Department of Defense Instruction 6200.02, Army Regulation 40-7, and the FDA. On the site ARMY.mil, it clearly states as follows: **"The DOD is mandated to use FDA-approved products."** (Emphasis added).

Several vaccines are required for Service Members regardless of where they are located globally, both prior to and during deployment. **However, a vaccine for Covid-19 is not listed as one of them**. (Emphasis added). By way of example, HEALTH.mil breaks down the list of vaccines by region, stated as follows: "U.S. Africa Command, U.S. Central Command, U.S. European Command, U.S. Indo-Pacific Command, U.S. Northern Command, and U.S. Southern Command." [11]

For the USNORTHCOM (i.e., U.S. Northern Command), the required vaccination list is as follows: Chickenpox, Hepatitis A, Seasonal Influenza, M-M-R, Polio and Tdap. (See n.11). For the USSOUTHCOM (i.e., U.S. Southern Command), the required vaccination list is as follows: Chickenpox, Hepatitis A, Hepatitis B, Seasonal Influenza, M-M-R, Polio, Tdap, Typhoid, Pneumococcal (required for high-risk conditions), Rabies (required for personnel at high-risk conditions), and Yellow Fever (required for countries where disease is endemic). For the USINDOPACOM (i.e., U.S. Indo-Pacific Command), the required

[10] https://www.usammda.army.mil/index.cfm/fhp/authorization (last visited Jan. 18, 2022).

[11] https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Recommendations/Vaccine-Recommendations-by-AOR (last visited Jan. 18, 2022).

vaccination list is as follows: Anthrax (required for 15 days or longer to Korea), Chickenpox, Hepatitis A, Hepatitis B, Influenza (Northern or Southern hemisphere), Japanese encephalitis (required for certain countries), M-M-R, Pneumococcal (required for high risk health conditions), Polio (required for settings of a polio outbreak), Rabies (required for personnel at high risk of exposure), Tdap, Typhoid (required for Korea), and Yellow Fever (required for entry into some countries as listed).

The site HEALTH.mil updated its page on September 2021, yet there is still NO LISTING for either Covid-19 as a disease or any requirement for a vaccine related to Covid-19. Since COMIRNATY is not available, the DoD is using other guidance documents in its attempt to enforce either an experimental vaccine or an investigational new drug without giving the Plaintiffs proper informed consent.

2. COMIRNATY IS NOT "INTERCHANGEABLE"

To test "interchangeability," FDA.gov has a searchable online database called the "Purple Book" that contains information about biological products, including biosimilar and interchangeable biological products licensed by the FDA.[12] See also, in general, 42 U.S.C. § 262(k)(4) (e.g., "interchangeable") and compare with 42 U.S.C. § 262(k)(7) (e.g., "biosimilar").[13] Any person with a

[12] https://purplebooksearch.fda.gov/ (last visited Jan. 20, 2022).

[13] https://www.law.cornell.edu/uscode/text/42/262 (last visited Jan. 20, 2022).

laptop or iPad, an Internet connection, and can type "COMIRNATY" in the search field of the FDA Purple Book will get the same results: There is NO biosimilar and NO interchangeable data to compare with COMIRNATY (e.g., this includes the alleged "BLA compliant" lots which the FDA claims are "interchangeable").

According to Defendants, the Pfizer-BioNTech Covid-19 vaccine is an EUA labeled product while at the same time an FDA approved product. That theory is spurious. Either the Pfizer-BioNTech EUA product is licensed, or it is not. Indeed, a woman is either pregnant, or she is not. A woman cannot be "half-pregnant."

Pfizer's Phase 3 clinical trials are still ongoing, despite the "FDA approval" of COMIRNATY. The clinical trial estimated study completion date is May 15, 2023, almost 18 months from now.[14] According to the referenced link (see n.14), it also states as follows: *"The study will evaluate the safety, tolerability, and immunogenicity of 3 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the efficacy of 1 candidate...The candidate selected for efficacy evaluation in Phase 2/3 is BNT162b2."* Additionally, the trials clearly indicate that BNT162b2 (i.e., the Pfizer-BioNTech Covid-19 mRNA vaccine being touted to the public as "FDA approved") is actually **"Experimental."** (Emphasis added).

CDC.gov provides registered users access to COVID-19 lot numbers and expiration dates provided to CDC by the vaccine manufacturers. According to

[14] https://clinicaltrials.gov/ct2/show/NCT04368728 (last visited Jan. 20, 2022).

CDC, *"These files contain **all lots for COVID-19 vaccines made available under Emergency Use Authorization (EUA)** for distribution in the United States...The vials and cartons for COVID-19 vaccines authorized under EUAs are not 2D barcoded following the standards used for products licensed by the US Food and Drug Administration, so lot number and expiration dates may not be scanned into the system."*[15] (Emphasis added). Indeed, the CDC makes a clear distinction between lots that are pursuant to an EUA and lots that are licensed.

Where are these *"hundreds of thousands of BLA-compliant doses"* of the Pfizer-BioNTech Covid-19 EUA labeled vaccine that are in the possession of DoD? Despite having plenty of opportunity to do so, the DoD fails to identify even ONE specific military base that can affirmatively state that it has them and is actively using them. Instead, the Defendants are playing a clever sleight-of-hand regarding interchangeability, and the Court should not be persuaded.

By way of example, Defendants state as follows: *"**FDA's determination that the vaccines are medically interchangeable – a factual finding that Plaintiffs do not dispute** – is consistent with the vaccines being legally distinct, for example, with respect to labeling requirements."* (See Doc 65-1, Def. Op. at 46). (Emphasis added). As Amicus will show, Plaintiffs dispute REPEATEDLY the FDA's determination of "interchangeability" in the following paragraphs in the SAC:

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[15] https://vaccinecodeset.cdc.gov/LotNumber (last visited Jan. 20, 2022).

On page 10, at n.11; On page 26 at ¶ 50; On page 30 at ¶ 60 and n.33; On page 69 at ¶ 140; On page 70 at ¶ 141; and on page 70 at ¶ 142. Defendants appear to engage in their own self-aggrandizing *ipse dixit*. The Purple Book results regarding COMIRNATY and the ongoing clinical trials regarding BNT162b2 are inextricably intertwined. A reasonable trier-of-fact may conclude post discovery that it dooms the thesis of "interchangeability."

3. THE CDC LISTS DEATHS "WITH" COVID-19

CDC.gov reports Weekly Updates by demographics regarding death counts involving COVID-19.[16] Amicus does not undermine any person's death; however, Amicus will show that the DoD mandate pursuant to the ongoing "public health emergency" is not supported by the data.

By way of example, the CDC includes footnotes in their Weekly Tracker data at the bottom of Table 1 in the same link. (See n.16). The footnote marked as "[1]" in Table 1 states as follows: *"Deaths with confirmed or presumed COVID-19, coded to ICD-10 U07.1."* This ICD code is used for reimbursement purposes, with or without a laboratory confirmed Covid-19 test.

Obviously, if the cases and/or deaths are "presumed," then the number of actual cases or deaths **"from"** Covid-19 as claimed by Defendants and mainstream media (e.g., CNN), are inappropriately exaggerated, and thus unquantifiable.

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[16] https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm (last visited Jan. 20, 2022).

(Emphasis added). Black's Law defines "presume" as follows: *"a term that means to believe, accept as true or to assume."* [17]

Indeed, CDC.gov does not list ANY number of deaths *"from"* Covid-19. It only lists deaths *"with"* Covid-19. Of those deaths *"with"* Covid-19, it does not specify how many deaths listed in the Weekly Tracker are *"confirmed"* versus *"presumed,"* and neither have Defendants. Is this mere semantics? It is not. According to CDC, for Covid-19, *"those at high risk for severe disease and death include people aged over 60 years (especially those 85 years and older) and those with underlying conditions, including, but not limited to obesity, hypertension, diabetes, cardiovascular disease, chronic respiratory or kidney disease, immunosuppression for solid organ transplant, and sickle cell disease."* [18]

According to the CDC, the survival rate for Covid-19 is 99.8% for the 20-49 age group, thus most likely covering ALL of the Service Members facing the DoD mandate. Putting it differently, the infection fatality rate of Covid-19 for the Armed Forces is/was statistically ZERO. Defendants' own data confirm this fact. Also, the DoD mandate disregards natural immunity or immunity from a prior infection, preferring to rely on "CDC recommendations." The CDC only promotes the slogans to "get vaccinated" and now, "get boosted." Amicus respectfully

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[17] https://thelawdictionary.org/presume/ (last visited Jan. 20, 2022).

[18] https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/ (last visited Jan. 20, 2022).

requests the Court to take judicial notice of the Brownstone Institute, which aggregates published worldwide studies affirming naturally acquired immunity versus vaccine induced immunity to Covid-19, with links and documents for each.[19]

The Secretary of HHS (a defendant in this case) keeps renewing his determination every 90 days that a continued so-called "public health emergency" exists nationwide as a consequence of the pandemic.[20] The most recent renewal was on January 14, 2022, after *"consultation with public health officials."* (See n.20). Of course, these "public health officials" are not named in each of the renewals. See also Public Health Service Act, ("PHSA"), 42 U.S.C. § 247d(a)(2).[21] Pursuant to the PHSA, the Secretary of HHS may ONLY renew ***"on the basis of same or additional facts."*** (Emphasis added).

Amicus respectfully requests the Court that whether or not a continued emergency exists should be a matter of judicial inquiry. Indeed, what "same" facts are there now as the onset of the pandemic? What "additional facts" warrant the continuation of the renewal? The Court may eventually conclude post-discovery

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[19] https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/ (last visited Jan. 20, 2022).

[20] https://aspr.hhs.gov/legal/PHE/Pages/COVID19-14Jan2022.aspx (last visited Jan. 20, 2022).

[21] https://www.law.cornell.edu/uscode/text/42/247d (last visited Jan. 20, 2022).

that the DoD mandate utilizes incessant fearmongering over facts, ignores the law, and is therefore **"ultra vires," (i.e., VOID)**. (Emphasis added).

4. DEATH IS A LISTED ADVERSE EVENT OF THE COVID-19 VACCINE

Time and again, in District Court upon District Court, the defendants supporting a "one-size-fits-all" Covid-19 vaccine mandate, (including the Defendants in *this* case), will often parrot the rhetoric spewed by various politicians, mainstream media pundits, CDC Director Dr. Rochelle Walensky and Dr. Fauci himself, that the Covid-19 vaccines are "safe and effective."

As Amicus will show, these statements are not supported by the warnings on the EUA fact sheets, or in the publicly held databases of the Vaccine Adverse Event Reporting System ("VAERS").[22] There are other databases that extrapolate the data from VAERS, such as OpenVaers.com,[23] MedAlerts.org,[24] and VaersAnalysis.info.[25] Amicus respectfully requests the Court to take judicial notice of another letter sent by Sen. Johnson to the FDA dated December 29, 2021 with twelve fact-finding questions to explain the disturbing trend of adverse events following vaccination attributable ***to specific lots*** of the Pfizer-BioNTech Covid-19

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[22] https://vaers.hhs.gov/ (last visited Jan. 20, 2022).

[23] https://openvaers.com/covid-data (last visited Jan. 20, 2022).

[24] https://medalerts.org/ (last visited Jan. 20, 2022).

[25] https://vaersanalysis.info/ (last visited Jan. 20, 2022).

vaccine.[26] Once again, according to Sen. Johnson, the FDA **failed** to respond. (Emphasis added).

Plaintiffs filed the Pfizer-BioNTech EUA fact sheet for vaccine providers on the docket. (See Doc 1-2, Exhibit 13).[27] See also, in general, F.R.Civ.P. 10(c). Although not filed on the docket, Amicus informs the Court of the EUA fact sheet for recipients.[28] The discrepancies between the two fact sheets are as follows:

The EUA fact sheet for vaccine providers has the following disclosures that contradict any logical basis for the alleged licensure of a Covid-19 vaccine:" [29]

"The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death ***following administration*** *of the Pfizer-BioNTech COVID-19 vaccine to recipients."* (See n.29 at page 15). (Emphasis added). Obviously, the phrase *"following administration"* means AFTER giving the shot to the recipient.

Regarding VAERS, the EUA fact sheet for vaccine providers also states as follows: *"It is* ***MANDATORY*** *for vaccination providers to report to the Vaccine*

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[26] https://www.ronjohnson.senate.gov/2022/1/sen-johnson-presses-fda-and-cdc-for-information-on-adverse-events-linked-to-covid-19-vaccine-lots (last visited Jan. 20, 2022).

[27] https://www.courtlistener.com/docket/60630202/coker-v-austin/ (last visited Jan. 20, 2022).

[28] https://www.fda.gov/media/153716/download (last visited Jan. 20, 2022).

[29] https://www.fda.gov/media/153713/download (last visited Jan. 23, 2022).

Adverse Event Reporting System (VAERS) all vaccine administration errors, all ***serious adverse events****, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19* ***following vaccination*** *with the Pfizer-BioNTech COVID-19 Vaccine."* (See n.29 at page 27). (Emphasis added). Once again, the phrase *"following vaccination,"* similar to the phrase *"following administration,"* speaks for itself, and is indisputable.

The phrase "serious adverse events" is defined as: *"****Death****; A life threatening adverse event; Inpatient hospitalization or prolongation of existing hospitalization; A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; A congenital anomaly/birth defect; An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent 1 of the outcomes listed above."* (See n.29 at page 15). (Emphasis added).

What makes matters worse, the FDA held a "Vaccines and Related Biological Products Advisory Committee" meeting on October 22, 2020, less than two months prior to the issuance of the Pfizer-BioNTech EUA.[30]

On slide #17 of the meeting (see n.30), it shows a *"DRAFT Working list of possible adverse event outcomes."* These include, but are not limited to: Convulsions/Seizures, Stroke, Anaphylaxis, Myocarditis, Pericarditis, Vaccine

[30] https://www.fda.gov/media/143557/download (last visited Jan. 23, 2022).

Enhanced Disease, Multisystem Inflammatory Syndrome in Children, Pregnancy and birth outcomes, and Deaths.

Defendants know (or should know) these "possible adverse event outcomes" are now a reality as found in VAERS. Indeed, data as of January 24, 2022, reveals the following from all three EUA Covid-19 vaccines combined: Severe allergic reaction: 38,073; Heart attacks: 11,260; Myocarditis/Pericarditis: 27,674; Permanently disabled: 39,150; Shingles: 11,924; Miscarriages: 3,692; and DEATH: 22,193. As much as Defendants may try and "poo-poo" the VAERS data, these adverse events from the experimental Covid-19 vaccines are real, NOT rare.

By way of comparison, the Pfizer-BioNTech EUA fact sheet for recipients has an exhaustive list of milder short term side effects, including injection site pain, headache, tiredness, etc. (See n.28 at page 5). The EUA fact sheet also states, *"These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials."* Page 5 also has a heading, titled as follows: "WHAT SHOULD I DO ABOUT SIDE EFFECTS?" Recipients are instructed to *"call 9-1-1 or go to the nearest hospital."* There is NO mention of the serious adverse events in the recipient fact sheet as compared to the EUA fact sheet for healthcare providers, including, but not limited to, "*a substantial disruption of the ability to conduct normal life functions*," and "***DEATH***." (Emphasis added).

These discrepancies between the two EUA fact sheets are a monstrosity. It is evident that that Armed Forces are being deceived into taking an allegedly "safe and effective FDA approved" Covid-19 vaccine to support the DoD mandate. The **failure to disclose** all serious adverse events in the recipient fact sheet should "shock the contemporary conscience" of ANY District Court. (Emphasis added).

Amicus is fully aware that Defendants want to "bury" this case on procedural grounds for lack of subject matter jurisdiction, as they did in Colorado, where Amicus also filed a brief. See Robert v. Austin, No. 1:21-cv-02228-RM-STV (Dist. Colo. Jan. 11, 2022). Each case is unique in its own right, and although the ORDER in Colorado currently stands, Amicus of course respectfully disagrees with it. Besides, it is not binding to THIS Honorable Court.

The Supreme Court has ruled that for a Court to have subject matter jurisdiction, it only requires one of the Plaintiffs to have standing. See Horne v. Flores, 557 U.S. 433, 446 (2009). According to the Declaration by Plaintiff Jordan Karr ("Karr Decl."), it states as follows, in part: *"I was told to get the vaccine or pursue the religious exemption process by the deadline. I do not believe that I should be forced to pursue an exemption* ***since the only vaccines available are EUA****...I was worried because* ***I have a fertility disorder*** *and don't have children but want them...****I choose not to take the risk****."* (See Doc 52-3, Karr Decl. at ¶'s 7 and 8). (Emphasis added). The Summary Basis for Regulatory Action ("SBRA")

filed by Defendants actually *supports* Plaintiff Karr. By way of example, on page 25 of the SBRA, the "Pharmacovigilance Plan" for COMIRNATY includes the following important risks and missing information: *"Important potential risk: Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)."* Under **missing information**, it states: *"**Use in pregnancy and lactation**."* (See Doc 65-14, Marks Decl. Ex B, page 25). (Emphasis added). As stated, the EUA fact sheet for vaccine providers includes "Congenital anomaly/birth defect" as one of the serious adverse events.

Plaintiff Karr is obviously worried about the "imminent" injury of an experimental vaccine and chooses NOT to *"take the risk"* and harm herself. According to the 11th Circuit, *"Emotional distress can suffice for "injury.""* See Losch v. Nationstar Mortg., 995 F.3d 937, 943 (11th Cir. 2021). Not taking the Covid-19 vaccine is simply engaging in self-avoidance of imminent harm from what the 6th Circuit has called "an irreversible medical procedure."

5. THE PREP ACT PROVIDES IMMUNITY FROM LIABILITY

The PREP Act authorizes the Secretary of Health and Human Services ("HHS") to make a declaration that provides immunity from liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from the administration or use of covered countermeasures, including the Covid-19 vaccines. The Secretary of HHS must publish the PREP Act in the

Federal Register.[31] The current PREP Act declaration for Covid-19 was effective as of February 4, 2020, was published in the Federal Register on March 17, 2020, and is not set to expire **until October 1, 2024**. (See n.31). (Emphasis added).

Additionally, the Secretary of HHS continues to make amendments to the current PREP Act declaration (e.g., there are thus far TEN as of Jan. 2022).[32] The amendments keep expanding covered countermeasures, and the immunity shield available for covered persons (e.g., those involved in manufacturing and administering the Covid-19 vaccines). This also includes pharmacists who undoubtedly receive the vaccine provider fact sheet that lists the serious adverse events which are NOT disclosed to the recipients).

The Court pondered questions during oral arguments held on November 3, 2021 (where Amicus was a silent observer). Amicus shares the Court's concerns that having an approval of a product without it being available is meaningless. However, Defendants found a workaround: the alleged "BLA compliant" lots. Indeed, why make COMIRNATY when there are stockpiles of the EUA product still available? The FDA "bait and switch" works as long as one *believes* it is

[31] https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures (last visited Jan. 23, 2022).

[32] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx (last visited Jan. 23, 2022).

COMIRNATY. Besides, the FDA extended the expiry dates for each of the EUA vials by 90 days, where the last batch expires in May 2022. (See n.29 at page 4).

CONCLUSION

Based on the foregoing, the EUA fact sheet for recipients clearly states the following: *"You are being* offered ***either*** *COMIRNATY (COVID-19 Vaccine, mRNA)* ***or*** *the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2."* (See n.28 at page 1). (Emphasis added). The phrase "either/or" suggests there are TWO distinct products. However, in reality, there is only ONE: the Pfizer-BioNTech EUA Covid-19 vaccine. Nothing on the fact sheet states that it is a "BLA compliant" or a "BLA manufactured" vial of Pfizer-BioNTech. Plaintiffs do NOT concede those equate to COMIRNATY. Plaintiffs are challenging the terms and conditions of the DoD mandate by rejecting the *offer* to take the EUA product (save for Plaintiff LUND, who took the EUA Janssen vaccine). Simply stated, **Plaintiffs are refusing the offer to contract**, and demanding proof of claim. (Emphasis added).

Absent a revolution, if a Constitutional Republic has an Executive Branch that knowingly and willfully goes rogue by impinging upon the guaranteed freedoms of the people under the guise of *"safety and protection,"* then the last bastion of hope is **a strong-willed judiciary** to provide a remedy for those seeking justice to redress a grievance. (Emphasis added).

WHEREFORE, Amicus heeds to the Court's wisdom and respectfully requests the Court to find that it has jurisdiction so that Plaintiffs may be afforded discovery to pursue their respective causes of action, not only for the sake of equity and justice, but also for the benefit of public interest.

Respectfully submitted on this day of Jan. 27, 2022

By: Pritish Vora

Pritish Vora, Amicus Curiae, Pro Se

CERTIFICATE OF COMPLIANCE

I, Pritish Vora, Amicus Curiae, hereby certify that this Amicus Brief contains 4,656 words according to Microsoft Word in 14-point font, double-spaced, and is thus in compliance with Florida Northern District Court Local Rule 5.1(C) regarding format, and Rule 7.1(F) regarding 8,000 word count maximum.

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CERTIFICATE OF SERVICE

I, Pritish Vora, Amicus Curiae, hereby certify that I sent the Amicus Brief to the Clerk of the Court via FedEx on January 27, 2022, and a copy of same was sent via U.S. first class mail, postage prepaid, to each of the respective parties below.

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