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UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

DAN ROBERT et. al.,
Plaintiffs,
vs.
LLOYD AUSTIN et. al.,
Defendants.

Case No.: 1:21-cv-02228-RM-STV

AMICUS CURIAE BRIEF OF PRITISH VORA, Pro Se

Hon. Judge Raymond P. Moore

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 Dan Robert ("Robert"), Hollie Mulvihill ("Mulvihill"), and the 200,000 others in the Armed Forces 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.").

[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 that do not use a live or attenuated virus to stimulate an immune response. They are considered "biological products" and/or "drugs."

Amicus provides information to this Court from publicly available sources found on the following sites, including, but not limited to, FDA.gov, CDC.gov, HHS.gov, SENATE.gov, 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 hysteria. Indeed, as Amicus types this brief, the country is now in Day 624 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 three distinct parts for the purpose of this brief and shall provide the Court with supporting references for each:

1. COMINARTY is not interchangeable with the Pfizer-BioNTech Covid-19 vaccine.

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

3. "DEATH" is a listed serious adverse event following administration of the Covid-19 vaccine in the emergency use authorization ("EUA") fact sheet provided to healthcare providers (i.e., vaccine providers). "DEATH" is not listed as a side effect in the fact sheet provided to the **recipients** (i.e., those who are receiving the Covid-19 vaccine). (Emphasis added).

I. "COMINARTY" is not interchangeable with Pfizer-BioNTech Covid-19 vaccine.

The mainstream media, whipped into a frenzy over an FDA press release on August 23, 2021, proffered a false reality that has permeated into the minds of the masses as well as the Federal District Courts regarding an "FDA approved" COMINARTY Covid-19 vaccine, when no such FDA approved vaccine was readily available to U.S. consumers.

[2] Defendants requested the Court to take judicial notice of factual information available on government websites, citing Tellabs, Inc. v Makor Issues & Rts., Ltd., 551 U.S., 308, 322-23 (2007). (See Def. Op., Doc 36 at 3, n.1). Amicus therefore requests the same.

During the early part of the litigation, when the facts were not yet fully developed, the Court issued an ORDER denying the TRO filed by Plaintiffs. The Court stated as follows: *"Moreover, as is now common knowledge, the Food and Drug Administration has now **fully approved** a COVID-19 vaccine, likely rendering moot Plaintiffs' underdeveloped arguments concerning the emergency use authorization for the vaccines currently available."* (See Doc 12, ORDER at 8). (Emphasis supplied).

Plaintiffs have since briefed extensively regarding the *two* letters sent by FDA to Pfizer on August 23, 2021. The first letter granted the approval of the BLA (biologics license application) to BioNTech in Mainz, Germany to produce, label, and market "COMINARTY," subject to specific terms and conditions. The second letter extended the current EUA for the Pfizer-BioNTech unapproved mRNA Covid-19 vaccine for those 12 years of age and older. (See Docs 26-2 and 26-3, respectively).

Amicus respectfully requests the Court to take judicial notice of two letters sent by Senator Ron Johnson (R-WI) [3] ("Sen. Johnson") to the FDA, one on August 26, 2021,[4] and a follow up letter on October 7, 2021, seeking answers to questions regarding the "*de facto endorsement of an EUA vaccine to support mandates,*" and the availability of COMINARTY.[5] According to Sen. Johnson, despite requesting an expeditious response, acting commissioner Janet Woodcock **failed to respond**. (Emphasis added).

Amicus informs the Court that Sen. Johnson *also* held a hearing on November 2, 2021, which included sworn testimony from Lt. Col. Theresa Long, MD, MPH, FS, Brigade Surgeon for the 1st Aviation Brigade, US ARMY.[6] (See also Doc 30-2, Exhibit 18, affidavit of Dr. Theresa Long). It is worthy to note that the letter to Pfizer extending the EUA dated August 23,

[3] Senator Johnson served as the Chairman of the Homeland Security and Governmental Affairs Committee from 2015-2021 and now is the ranking member for the Permanent Subcommittee on Investigations.

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

[5] https://www.ronjohnson.senate.gov/2021/10/sen-johnson-continues-to-press-the-fda-pfizer-biontech-on-transparency-and-politicization-of-vaccine-approval-process (last visited Dec. 1, 2021)

[6] https://www.bitchute.com/video/DoZnwZ0iXr5X/ (last visited Dec. 1, 2021)

2021, has been "purged" from the FDA.gov search results. Sen. Johnson, in his follow-up letter to the FDA dated October 7, 2021, states in a footnote that the August 23, 2021 letter appears to have been *"removed."* Fortunately, it was filed in this docket, and is available for free download on CourtListener.com via its RECAP archive.[7]

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 use in individuals 12 years of age and older."* (See Doc 26-3, pages 11 and 12 of letter, marked as pages 12 and 13 in filed document). (Emphasis added)

Amicus informs the Court of the following additional facts that warrant judicial notice. CDC.gov states as follows: *"**COMINARTY products are not orderable at this time**. NDCs are listed as per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in the CDC Vaccine Set Files at this time."* [8] (Emphasis added).

The National Institutes of Health ("NIH"), on NIH.gov, also states as follows, 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 (COMINARTY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMINARTY... ". "At present, **Pfizer 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**."* [9] (Emphasis added).

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[7] https://www.courtlistener.com/docket/60219585/robert-v-austin/ (last visited November 30, 2021)

[8] https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html (last visited November 30, 2021)

[9] https://dailymed.nlm.nih.gov/dailymed/ (last visited November 30, 2021)

The American Medical Association ("AMA") has an online resource tool to track each specific Covid-19 vaccine for immunization purposes.[10] Pfizer-BioNTech, Moderna, and Janssen are listed, with their respective "boosters." COMINARTY is not listed; it does not exist.

The Pfizer-BioNTech Covid-19 vaccine had its EUA issued on December 11, 2020, then reissued multiple times, starting on December 23, 2020, then February 25, May 10, June 25, August 12, August 23, September 22, and October 20, 2021, respectively, meaning ALL the vaccine providers who are administering the EUA products are *still* administering the EUA products. The FDA letter makes it abundantly clear that an EUA means "unapproved."

Amicus informs the Court of the BLA product insert for COMINARTY, a publicly available document found on FDA.gov.[11] On page 5, under the section titled "**2.3 Vaccination Schedule**," it states as follows: *"COMINARTY is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.* ***There are no data available on the interchangeability of COMINARTY with other COVID-19 vaccines to complete the vaccination series****. Individuals who have received 1 dose of COMINARTY should receive a second dose of COMINARTY to complete the vaccination series."* (Emphasis added).

Plaintiffs attached the search results from the FDA Purple Book to their motion for preliminary injunction, also found on FDA.gov.[12] (See Doc 30-1, Exhibit 17). See also, in general, F.R.Civ.P. 10(c). Any person with a laptop or iPad, an Internet connection, and can type "COMINARTY" in the search field will come to the same results: there is NO biosimilar and NO interchangeable data to compare with COMINARTY.

In their opposition to Plaintiff's motion, Defendants state the following: *"Plaintiffs do not dispute that the licensed vaccine and the EUA vaccine are medically interchangeable."* (See Def. Op. at 21, citing Plaintiffs Mot 9-12). Defendants are playing a clever sleight-of-hand, and the Court should not be persuaded. As Amicus will show, Plaintiffs have said no such thing.

By way of example, in paragraph 32 of Plaintiff's motion, Plaintiffs state as follows:

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[10] https://www.ama-assn.org/find-covid-19-vaccine-codes (last visited November 30, 2021)

[11] https://www.fda.gov/media/151707/download (last visited November 30, 2021)

[12] https://purplebooksearch.fda.gov/ (last visited November 30, 2021)

"Pfizer BNT FACT SHEET (Exh. 12 to Amended Complaint, ECF #29) also attempts to confuse recipients by stating that the two different vaccines "have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series[.]" (emphasis added)." (See Doc 30 Plaintiff's motion, ¶ 32 at 10). Plaintiffs did NOT concede whatsoever that the products were interchangeable. Instead, Plaintiffs quoted verbatim from what was written in the Pfizer-BioNTech fact sheet and claimed the FACT SHEET "***attempts to confuse recipients***." (Emphasis added). Each of the follow-up paragraphs in Plaintiff's motion cited by Defendants speaks for itself. (See Doc 30, at 10-12).

Defendants claim that the DoD has "*received hundreds of thousands of BLA-manufactured, EUA-labeled vaccine doses, and is using them.*" (See Def. Op. at 21). In the next sentence, Defendants then claim, *"Plaintiffs do not plausibly allege any facts to the contrary."* However, there has been no discovery as to what Defendants may or may not have in their possession. It appears that Defendants want the Court to adopt the FDA's "bait and switch."

Amicus informs the Court that the CDC stores files for Covid-19 lot numbers from vaccine manufacturers which are available to registered users only, such as healthcare and pharmacy organizations. **The lots are not for licensed Covid-19 vaccines**. (Emphasis added). By way of example, according to CDC.gov, *"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."* [13] Indeed, the CDC makes a clear distinction between licensed vaccines and those authorized under an EUA. The CDC has no such files for licensed Covid-19 vaccines because none exist.

The FDA Purple Book, FDA letters to Pfizer, COMINARTY product insert, Sen. Johnson letters to the FDA, and the Pfizer-BioNTech fact sheet are all inextricably intertwined. A reasonable trier-of-fact may eventually conclude post discovery that these documents, along with certain facts on CDC.gov, doom the Defendant's thesis of "interchangeability."

[13] https://vaccinecodeset.cdc.gov/LotNumber (last visited Dec. 1, 2021)

II. THE CDC LISTS "DEATHS WITH COVID-19" AS CONFIRMED OR PRESUMED

Amicus informs the Court that the CDC.gov reports Weekly Updates by demographics regarding death counts for COVID-19.[14] Defendants state the following: *"...more than 770,000 have died from COVID-19."* (See Def. Op. at 3). *"As of November 17, 2021, there have been 252,658 cases of Coronavirus Disease 2019 (COVID-19) in service members across DoD, of which 2,280 have required hospitalizations and led to 76 deaths...none were fully vaccinated."* (See Decl. of Major Scott Stanley, Doc 37-13 at ¶ 3). ("Stanley Decl."). *"As a result of COVID-19, there have been 20 deaths among Service members, contractors, Department of Army civilians, and family members at Fort Rucker. In addition, there have been more than 3,000 reported cases of COVID-19 across that population as of November 19, 2021."* (See Decl. of Col. Whitney B. Gardner, Doc. 37-19 at ¶ 3). ("Gardner Decl.").

Amicus does not undermine any person's death, especially that of a member of the Armed Forces, however, Amicus simply informs the Court that the DoD mandate pursuant to the "public health emergency" is not supported by the data.

By way of example, pursuant to the Stanley Decl., 76 deaths among 252,658 cases represents a percentage infection fatality rate of .0003%, or three ten thousandths of one percent. By way of example, pursuant to the Gardner Decl., 20 deaths among 3,000 cases represents a percentage infection fatality rate of .0066%, or approximately seven thousandths of a percent. Effectively, the risk of a Service Member dying from Covid-19 is/was statistically ZERO. Putting it differently, the case survival rate is well over 99%.

Besides, the Stanley Decl. claims *"none were fully vaccinated,"* which means some *may* have been partially vaccinated, thus suffering an adverse event from the Covid-19 vaccine, or were given Remdesivir, which has well documented side-effects. The Gardner Decl. does not state whether any of the 20 deaths were partially vaccinated, or any information whatsoever as to the specifics that led to their respective hospitalization and eventual death.

Furthermore, the Stanley Decl. makes somewhat of a bizarre claim to explain why MORE vaccinated people are getting breakthrough cases. According to Stanley, *"if every service*

[14] https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm (last visited Dec. 1, 2021)

member were vaccinated, only vaccinated individuals would have infections or be hospitalized." (See Stanley Decl. ¶ 18). Of course, being hospitalized **post-vaccination** defeats the purpose of getting the Covid-19 vaccine. (Emphasis added).

The CDC also includes footnotes in their Weekly Tracker data in the same link. (See n.14). The footnote marked as [1] is for Covid-19 deaths, and it states as follows, *"Deaths with confirmed or **presumed** COVID-19, coded to ICD-10 U07.1"* (Emphasis added). This ICD code is used for reimbursement purposes, with or without a laboratory confirmed Covid-19 test.

Amicus informs the Court that if any of the Covid-19 cases and/or deaths are "presumed," then the number of actual cases or deaths "with Covid-19" are inappropriately exaggerated, as it does not take into consideration a person's co-morbidities or treatments provided once hospitalized. Indeed, the CDC does not specify how many deaths listed in the Weekly Tracker are "confirmed" versus "presumed," and neither have Defendants.

According to the CDC, *"those at highest 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."* [15]

According to the CDC, the survival rate for Covid-19 is 99.8% for the 20-49 age group, thus most likely covering ALL the Services Members facing the DoD mandate. The DoD mandate disregards natural immunity or immunity from a prior infection, preferring to rely on "CDC recommendations." Amicus 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.[16]

The Court may eventually conclude post-discovery that the DoD mandate relies on presumptions, is unjustified, and therefore **"ultra vires," (i.e., VOID)**. (Emphasis added).

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[15] https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/ (last visited Dec. 1, 2021)

[16] https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/ (last visited Dec. 1, 2021)

III. DEATH IS AN ADVERSE EVENT OF THE COVID-19 VACCINE

Time and time again, in District Court upon District Court, the defendants supporting Covid-19 vaccine mandates, (including the Defendants in *this* case), will often parrot the rhetoric spewed by various politicians, mainstream media pundits, 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 department of Health and Human Services ("HHS"), which tracks the Vaccine Adverse Events Reporting System ("VAERS").[17] There are other databases that extrapolate the data from HHS, such as OpenVaers.com,[18] MedAlerts.org,[19] and VaersAnalysis.info.[20]

Amicus informs the Court that CDC.gov makes a clear distinction between EUA Fact Sheets and Vaccine Information Sheets ("VIS"), **which are only used for licensed vaccines**. (Emphasis added). According to the CDC, *"There is no VIS for COVID-19 vaccines authorized under an EUA. Instead, the FDA-issued EUA Fact Sheet for Recipients and Caregivers for each Covid-19 vaccine must be used."* [21] Indeed, the CDC clearly states the following: *"Thus far, the codes and URL links to access the EUA Fact Sheet documents have been developed for the following current and potential COVID-19 EUA vaccines."* (See n.21). There is no VIS, because **no such licensed Covid-19 vaccine is listed**. (Emphasis added).

Plaintiffs have attached the Pfizer-BioNTech EUA fact sheet for recipients (i.e., the one given to the public), which lists short term side effects, including injection site pain, headache, tiredness, etc. (See Doc 26-5 at 5). The EUA fact sheet states, *"These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur."* The EUA fact sheet for recipients fails to disclose EXACTLY what are these *"serious and unexpected side effects."*

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[17] https://vaers.hhs.gov/ (last visited Dec. 1, 2021)

[18] https://openvaers.com/covid-data (last visited Dec. 1, 2021)

[19] https://medalerts.org/ (last visited Dec. 1, 2021)

[20] https://vaersanalysis.info/ (last visited Dec. 1, 2021)

[21] https://www.cdc.gov/vaccines/covid-19/eua/index.html (last visited Dec. 1, 2021)

In contrast, the Pfizer-BioNTech EUA fact sheet on page 15 for vaccine providers [22](i.e., the one given to healthcare providers such as pharmacists, hospitals, doctors, clinicians, etc.) includes **DEATH as a reportable serious adverse event**, whereas the EUA fact sheet for recipients makes no mention of DEATH as a possible severe adverse event. (Emphasis added).

This discrepancy within the two fact sheets is a monstrosity, is evident that the Armed Forces are being deceived for an allegedly "FDA approved" Covid-19 vaccine to support a DoD mandate, and a failure to disclose that should "shock the contemporary conscience" of ANY District Court.

The EUA fact sheet for vaccine providers also makes another shocking revelation: *"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."* (Emphasis added). (See n.22 at page 15): Obviously, the phrase *"following administration"* means AFTER giving the shot to the recipient.

What makes matters worse, the FDA held a "Vaccines and Related Biological Products Advisory Committee" meeting on October 22, 2020, [23] two months prior to the issuance of the EUA. Slide 17 in that meeting shows a *"DRAFT Working list of possible adverse event outcomes, including, but not limited to, Guillain-Barre syndrome, Myocarditis/pericarditis, Anaphylaxis, Multisystem Inflammatory Syndrome in Children, Thrombocytopenia, and* ***DEATH****."* (Emphasis added).

It is no wonder that BOTH Robert and Mulvihill, along with 200,000 service members are choosing to opt-out of the DoD mandate. Pursuant to the EUA, the fact sheet clearly states that ***"it is your choice to receive or not receive the vaccine."*** (See Doc 26-5 at 6). (Emphasis added). It would be extremely disingenuous to tell the Plaintiffs, "Nobody is forcing you. If you don't want to take the Covid-19 vaccine, then go serve another country somewhere else."

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[22] https://www.fda.gov/media/153715/download

[23] https://www.fda.gov/media/143557/download

CONCLUSION

Based on the foregoing, COMINARTY is not "interchangeable" with ANY of the Covid-19 vaccines, including Pfizer-BioNTech. The CDC lists "deaths with COVID-19" as confirmed or presumed, thus making the total number of actual deaths unquantifiable. Finally, the Covid-19 vaccines are experimental biological products that fail to disclose "DEATH" as a severe adverse event for recipients. To ignore these facts is to engage in a blatant act of willful blindness.

The concept of "willful blindness," originating in a jury charge in 1982, is that one may not "close his eyes, when he pleases, **upon all sources of information**, and then excuse his ignorance by saying that he does not see anything." See Global-Tech Appliances, Inc. v. SEB S.A., 131 S.Ct. 2060, 2068-71 (2011). (Emphasis supplied).

WHEREFORE, Amicus heeds to the Court's wisdom to accept the factual references incorporated herein as warranted to make a final determination properly and fairly on the merits, not only for the sake of equity and justice, but also to preserve the benefit of public interest.

Respectfully submitted this day of: Dec. 2, 2021

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CERTIFICATE OF SERVICE

I, Pritish Vora, Amicus Curiae, hereby certify that I mailed the original of the Amicus Curiae brief in the above referenced matter to the Clerk of the Court on December 2, 2021, via USPS Express Mail, and a copy was sent to each of the parties' respective counsel below via USPS first class mail, postage prepaid.

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