Comment for the January 26, 2023 VRBPAC
Interest Of Justice's comment is also the FDA Citizens Petition
Comment for Docket Number is FDA-2022-N-2810

Amended Citizen Petition #FDA-2022-P-2411. The public is also invited to comment on the Interest Of Justice Citizen Petition.

Wednesday January 25, 2023

Robert M. Califf, M.D. Commissioner of Food and Drugs Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993

Submitted electronically (21 C.F.R. § 10.30(b)(l))

Re: Amended Citizen's petition regarding the FDA's ethical duty to prevent the use of the harmful unproven emergency intervention mRNA or viral vector outside clinical trials and issue an indefinite moratorium on the experimental covid-19 non vaccine gene therapy under the WHO MEURI ethical framework and HANDBOOK FOR GOOD CLINICAL RESEARCH PRACTICE (GCP) **GUIDANCE FOR IMPLEMENTATION on HHS website**.

Dear Dr. Califf:

Interest of Justice is presenting this citizens petition on behalf of our organization, the international community and other concerned vulnerable medical, legal experts, journalists, health workers, military and citizens regarding the Food and Drug Administration's original and continuing authorization of the product called COVID-19 vaccines made by Pfizer and Moderna with no human testing and insufficient animal testing that fails to meet the unequivocal rules of science.

The authorization is PROHIBITED as unethical, even if legal, which is outlined below.

Pursuant to 21 C.F.R. § 10.30 et seq. and section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3 et seq., and as per international norms, MEURI ethical framework and the common law we DEMAND that you revoke or suspend the FDA's emergency use authorization of the COVID-19 bivalent and original vaccines for children and adults.

The FDA has an obligation to apply the precautionary principle pending FDA's obligation to meet the burden of proof of science and trial safety data.

The evidence required by FDA to meet their burden of proof under jus cogens norms begins with the exact methodology to justify the FDA's determination of more benefit to risk, and is not fulfilled until due process is provided in the contentious matter in which FDA is obliged to hold a scientific debate with dissenting experts, including Paul Offit from VBRPAC. So far FDA is in breach of duty to provide adequate scientific debate required for FDA to meet their burden of proof. All in all, many expert scientists will testify the EUA does not appear to be supported by the totality of facts available.

Interest of Justice requires the bivalent and original vaccines revoked:

- FDA is not in compliance with international peremptory norms, including the MEURI ethical framework.

- FDA has failed to properly consider the potential and known risks and lack of benefit in injecting children and adults with these unproven emergency use interventions outside clinical trials which are experimental gene therapies mislabelled as vaccines.

About the Interested Parties

Our international organization is an interested party in the authorization process and spoke about the risks of the original and bivalent scheme. IOJ's membership is comprising of many thousands of non conflicted and "uniquely qualified" civil society and human rights organizations, scientists, journalists and experts, including Dr. Mike Yeadon, former VP of Pfizer. It is worth mentioning that Interest of Justice has many “uniquely qualified” experts as members who are far more qualified than the VBRPAC committee members that FDA chose with conflicts of interest to authorize the unproven emergency use interventions outside clinical trials. Our truly uniquely qualified expert members have relevant knowledge to share and no conflicts of interest, which the FDA has thus far failed to consider and even censored when the FDA spuriously provided waivers of conflicts of interest to members of the VERPAC committee June 28, 2022, who voted on this same act we require is revoked. We are forced to speak again January 26, 2023 because FDA is stubborn as a mule, refusing to be reasonable and revoke the EUA’s. It is not true the committee who voted was unbiased or uniquely qualified. Interest of Justice firmly rebuts the false presumption that conflicts can be managed in the committee, especially considering the importance of the vote by such a small number of people affecting such a large population that rely on the purity of and full consideration and scientific validation of each vote. FDA did not rebut this presumption in the original petition, and unless it is rebutted, it stands as true the FDA gave waivers of conflicts of interest for VBRPAC members under the false presumption they are “uniquely qualified”, when in fact in the last petition we alerted FDA to this problem and the solution of

using our experts such as Dr. Yeadon, who are indeed uniquely qualified. Let the record show FDA was offered non conflicted uniquely qualified world class experts, refused the reasonable offer of using non conflicted VBRPAC members for this January 26, 2023 meeting, and once again unethically allowed VBRPAC members with major conflicts of interest. *Our organization finds it worth mentioning that public trust is waning in FDA like the so called vaccines that don't work!*

A. Action Requested

This petition is a continuance of the prior discussion with FDA regarding the Original and August 31, 2022, FDA amendment the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination. see: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use (last visited September 23, 2022)

Specifically, and according to the FDA's own August 31, 2022 press release: "Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination. The bivalent vaccines, which we will also refer to as "updated boosters," contain two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2."

The FDA is currently discussing the future regimen of **unproven emergency use interventions outside clinical trials called** covid-19 vaccines. This petition demands that FDA revoke all EUA's for mRNA and viral vector unproven emergency use interventions outside clinical trials and issue a moratorium, or at minimum, IMMEDIATELY suspend all EUA's.

Whilst it may possibly be true that inferior national Federal legislation can legally allow FDA to issue statutory exceptions, statutory ethical loopholes or statutory terms of art to introduce these covid-19 vaccines, or other mRNA/viral vector gene therapy unproven emergency use interventions outside clinical trials, FDA knows or should know, that the unequivocal international norms and legal limits PROHIBIT any use of the covid-19 [non]vaccines outside clinical trials under the circumstances outlined in this amended citizen petition/notice and demand. The ethical omissions to abide by the MEURI ethical framework is triggering the FDA's duty of revoking the EUA. Upon review of the MEURI framework, it is apparent the FDA is obliged by ethical duty to ensure the IMMEDIATE annulment of all FDA authorizations that allow for mass use of the covid-19 [non]vaccine unproven emergency use interventions outside clinical trials.

Granting this petition is mandatory by HHS and WHO MEURI ethical framework standards. FDA was not granted discretion to ignore and omit application of the MEURI ethical framework or Nuremberg Code.

FDA has failed to meet their State obligations to international law by failing to provide informed consent in the fact sheets and community involvement.

see: EMERGENCY USE OF UNPROVEN CLINICAL INTERVENTIONS OUTSIDE CLINICAL TRIALS: ETHICAL CONSIDERATIONS pg 27: "*Physicians and other health-care workers may have their own opinions about whether a particular unproven clinical intervention*

is more likely to be beneficial or harmful. ***A consent process for use of unproven clinical interventions that does not explicitly recognize the scientific community's uncertainty about the risk–benefit ratio would not, however, be ethically appropriate.****"***

FDA's consent process is very coercive, deceitful and unethical as it turns out. The news is recently reporting public hearings that testify the WHO and HHS agencies have colluded with FB, twitter, social media, big tech, big media, the global intelligence apparatus and Pfizer to censor and persecute truth teller whistleblowers in the scientific community.

FDA has failed to consider published peer reviewed documents from our experts Dr. Yeadon and Dr. Mc Cullough on NIH website, among many others we are defending in their position of having been censored after testifying and courageously speaking out about the *the scientific community's uncertainty about the risk–benefit ratio* of the **unproven emergency use interventions outside clinical trials.** (a list of expert peer reviewed publicly available documents FDA failed to consider or put in the fact sheet about the *the scientific community's uncertainty about the risk–benefit ratio* is forthcoming and will be uploaded shortly)

FDA ****is committing a very, very serious breach of duty by authorizing a serious internationally wrongful act of using harmful unproven emergency use interventions outside clinical trials, which requires State obligations of cessation, satisfaction, restitution and non repetition met.

- FDA is obliged to include the scientific community's uncertainty about the risk–benefit ratio in the consent process (in this case a fact sheet). Because the FDA clearly failed this duty, the EUA is prohibited by current superior advisory MEURI ethical guidance of the WHO. This is not debatable or extendable. The prohibition is mandatory by law

(Nuremberg Code, Helsinki, Belmont Report, MEURI ethical framework) and of immediate effect upon receipt of this petition/demand.

- FDA is obliged to hold a public hearing when science is in dispute instead of censor and suppress public debate regarding the ***scientific community's uncertainty about the risk–benefit ratio of the covid-19 [non]vaccine*** **unproven emergency use interventions outside clinical trials.**
- FDA is obliged to disprove the Sweden study that shows Pfizer integrates into DNA in less than 6 hours, otherwise the FDA shall consider that Pfizers IND application was false in stating DNA is not affected because the vaccine is intended to have a different mechanism of action than gene therapy.
- Covid-19 mRNA and viral vector [non]vaccines are in reality a gene therapy by FDA definition and classification, which thus far FDA has conspicuously failed to dispute on the record, and therefore it is presumed true, unless properly rebutted by FDA under oath with analysis of the product definition compared to vaccine vs gene therapy definitions.
- FDA has failed to meet the burden of proof of trial safety data to ethically justify the mRNA and viral vector **unproven emergency use interventions outside clinical trials**
- FDA is required to re-consider the potential and known risks and rewards in injecting babies, children and adults with these experimental products using only the MEURI ethical framework, which must be applied immediately to protect the public health and safety. The MEURI framework, once applied, shows the unproven emergency use interventions outside clinical trials EUA's are prohibited due to the FDA's omissions of scientific and ethical duties. Its not debatable. The use is prohibited.

- FDA is required to prevent the mass experimentation on the human population, with unproven emergency use interventions outside clinical trials that killed 1223 people in the trials.

B. Statement of Grounds

Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3,1 authorizes the Food and Drug Administration ("FDA") to issue an "emergency use authorization" ("EUA") for a medical product, such as a vaccine, under certain emergency circumstances. This authorization permits the product to be introduced into interstate commerce and administered to individuals even when FDA has not approved the product for more general distribution pursuant to its standard review process. Section 564 directs FDA—"to the extent practicable" given the emergency circumstances and "as the [agency] finds necessary or appropriate to protect the public health"—to impose "[a]ppropriate" conditions on each EUA. FDCA § 564(e)(1)(A). Some of these conditions are designed to ensure that recipients of the product "are informed" of certain things, including "the option to accept or refuse administration of the [experimental] product." Id. § 564(e)(1)(A)(ii)(III).

Under an EUA, the FDA may allow the use of unapproved [experimental] medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious illnesses or conditions, or life-threatening, only when certain regulatory criteria have been met, including that there are no adequate, approved and available alternatives.

The Standard for Revocation of EUAs Is Met

1. The Criteria for the Issuance of the EUA No Longer Exists
2. Not A Serious or Life-Threatening Disease or Condition
3. No Real Evidence of Effectiveness
4. Upside Down Benefit-Risk Analysis
5. Alternatives To Vaccines Exist
6. Other Circumstances Make a Revision or Revocation Appropriate to Protect the Public Health or Safety

First, The Criteria for the Issuance of the EUA No Longer Exists

Circumstances Described under Section 564(b)(1) of the FD&C Act No Longer Exist

New facts have came to light since the FDA authorized these products which shows:

- a 44% increased risk of transmission, auto immune like reactions
- there is 92% more risk than benefit according to BMJ.
- Natural immunity is found to be far more robust and longer lasting with no risk
- HHS posted the December 2022 WHO HANDBOOK FOR GOOD CLINICAL RESEARCH PRACTICE (GCP) **GUIDANCE FOR IMPLEMENTATION which**

Second, Not A Serious or Life-Threatening Disease or Condition

Section 564(c)(1) of the FD&C Act requires that, for an EUA to be issued for a medical product, the "agent[s] referred to in [the HHS Secretary's EUA declaration] can cause a serious or life-

threatening disease or condition." FDA has unreasonably concluded that SARS-CoV-2, which is the subject of the EUA declaration, meets this standard.

FDA cites 54 Johns Hopkins University School of Medicine, Coronavirus Resource Center, https://coronavirus.jhu.edu/map.html (accessed November 15, 2022) to back up the following presumption: *"The SARS-CoV-2 pandemic continues to present an extraordinary challenge to global health and, as of November 15, 2022, has caused more than 635 million cases of COVID-19 and claimed the lives of more than 6.61 million people worldwide.54 In the United States, as of November 15, 2022, more than 97 million cases and over 1 million deaths have been reported to the Centers for Disease Control and Prevention (CDC).55 On January 31, 2020, the Secretary of HHS declared a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS, and the U.S. President declared a national emergency in response to COVID-19 on March 13, 2020. Additional background information on the SARS-CoV-2 virus and COVID-19 pandemic may be found in FDA's EUA decision memoranda.56 As explained above, FDA has concluded that SARS-CoV-2 can cause a serious or life-threatening disease or condition. Petitioner has not provided any data, and FDA is not aware of any data, that change the conclusion that SARS-CoV-2 can cause a serious or life-threatening disease or condition."*

Petitioners note that as a matter of strict law serious disease or condition means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity like covid-19 will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. **Whether a disease or condition is serious is a matter of clinical judgment,** based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe

condition to a more serious one. https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources (21 CFR 312.300External Link Disclaimer)

The FDA, CDC and WHO all say the illness is symptomatic and mostly mild, except in the small group of vulnerable old and infirm. The mortality rate is what is serious, and our experts will testify that overall, covid-19 is not very serious to well over 99% of people. Mass use of these unproven emergency use interventions outside clinical trials subjects healthy people to unreasonable risk, far above the threat that covid-19 poses to them. Covid-19 does not pose an abnormally high risk above a bad influenza pandemic season, which makes it implausible to truly qualify as "can cause a serious or life-threatening disease or condition". Read liberally, nearly anything qualifies as "can cause a serious or life-threatening disease or condition", including mRNA and viral vector can cause a serious or life-threatening disease or condition or other adverse reactions that may become apparent with widespread use of the vaccine and with longer duration of follow-up, making it unethical to authorize these unproven emergency use interventions outside clinical trials as an alternative "solution" to covid-19 which is a mild illness for 99% of people!!!

FDA's judgment is severely lacking, to the point of malicious abuse of discretion, because the symptoms and mortality rate of covid are not of extraordinary magnitude.

*****Even Dr. Fauci from NIH is on record early on comparing covid's mortality rate to flu, and all studies show the mortality rate is akin to flu.

Whilst covid may pose a threat to a small minority vulnerable or old population as a serious or life threatening disease, just like the flu, it is not serious or life threatening to the vast majority, and not at all to children. Covid-19 does not qualify as "may cause a serious or life-threatening disease"

of the magnitude that would justify such a drastic measures unproven interventions outside clinical trials using mRNA or viral vector experiments in mass use.

- the mortality rate of covid-19 is akin to the flu.
- These are unnecessary experiments, other countries such as Denmark have advised to catch covid, get immune, get over it.
- HHS and FDA have grossly exaggerated the threat of covid may be causing a serious or life threatening disease
- Corman-Drosden Report showing PCR is 97-100% false. Not refuted by WHO, HHS OGA or NIH. On NIH website peer reviewed by 22 experts, it has been almost 2 years and not one scientific challenge from FDA or NIH or the WHO when directly asked to rebut the Petitioners expert evidence discrediting the PCR test results upon which the emergency was spuriously declared. Corman-Drosden Report must be rebutted to prove the HHS Secretary declaration of emergency is valid to support the EUA's. The report refutes the PCR test results as unscientific and void. The Petitioners evidence "Corman-Drosten Report" is of the scientific rigor FDA accepts, being on NIH website and peer reviewed, but never properly refuted with genuine evidence by WHO DG Tedros or HHS OGA. Dr. Yeadon will testify and his affidavits are attached to refute point by point if FDA disagrees with Dr. Yeadon and the 22 experts science that proves there was never an emergency to justify an EUA.
- false statistics
- "cases" definition is arbitrary and capricious, even absurdly including "cases" that are no longer infectious, or may be the flu, because the PCR test shows positive months after no longer infectious and cannot differentiate between flu and covid-19. See Dr. Yeadon

verified affidavits attached which must be rebutted point by point with genuine evidence under oath, or presumed true.

- see recent news that backs up the Petitioners evidence showing overcounted cases as true: https://www.washingtonpost.com/opinions/2023/01/13/covid-pandemic-deaths-hospitalizations-overcounting/

Third, No Real Evidence of Effectiveness - No Reasonable Belief May Be Effective

- The product is a failure, doomed to fail and could never be reasonably believed "may be effective to prevent a serious or life threatening disease". According to White House advisor covid response director Mrs. Birx: https://www.bitchute.com/video/3aA5L5Hl1bNG/ "I knew these vaccines were not going to work against infection and I think we overplayed the vaccines."
- **Former Chief Scientist W.H.O. Soumya Swaminathan confessed no reasonable belief may be effective to prevent covid-19 before resigning: *"**And the FDA has approved the one that has the BA four five Omicron variant whereas the UK and Europe have approved the BA one. So there are two different types of vaccines. Now what they've shown in lab studies is that these Bivalent vaccines help you to mount a slightly higher antibody response against Omicron.* ***But whether that's going to translate into any kind of clinical efficacy, we don't know because we don't really have those studies and so time will tell whether we need this type of Omicron specific vaccine****"* see: https://www.bitchute.com/video/ciNdr7vc8AKw/
- Albert Bourla Pfizer CEO - "*We know that the two doses of the vaccine offer very limited protection, if any*," said Pfizer CEO and chairman Albert Bourla in a Monday interview with Yahoo! Finance, to peddle and sell FDA and the public on accepting a third dose to

compensate for the waning immunity brought about by the product failure. https://www.bitchute.com/video/gqC8QOiNk8X6/

- FDA Denial of Citizens petition evidence states on pg 39 "Uncertain how the magnitude of the increase in antibody response in humans will translate into effectiveness against COVID-19 outcomes, including symptomatic and serious disease".

Petitioners emphatically point out that despite FDA's self serving conclusory statements and simple speculations, there is no real evidence proffered by FDA thus far to reasonably conclude the EUA mRNA or adenovirus viral vector unproven products outside clinical trials "may be effective to prevent covid-19".

Fourth, Upside Down Benefit-Risk Analysis - Far More Harm Than Benefit Clearly Shown In CDC Safety Signals

see: https://aaronsiri.substack.com/p/v-safe-part-5-the-fight-to-get-the V-Safe Part 5: The Fight to Get the V-Safe Data! Fifth part of an incredible story that shows just how broken our public "health" apparatus is: very, very broken. notice: this amended citizens petition's evidence packet will be updated seperate of the petition, to update FDA as evidence is revealed, such as the CDC V-Safe data mentioned above that sounds pretty damning.

Court ordered documents show the unproven emergency use interventions outside clinical trials called covid-19 vaccines is indeed iatrogenic and harmful!

Comparatively speaking the data is upside down, showing covid poses zero risk to babies, however, the unproven emergency use interventions outside clinical trials updated on CDC vaccine safety shows 2% serious injuries to babies up to 5 and 5.7% serious injuries up to 12 (defined as

death and hospitalization). The **Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum Application #** EUA 27034, Amendment 617 As of August 3, 2022, VAERS cumulatively received 826,382 reports (404,482 U.S. reports) following vaccination with the original Pfizer-BioNTech COVID-19 Vaccine among all ages, including 67,147 reports (45,816 U.S.) following a 3rd, 4th, or 5th dose (i.e., booster dose) among individuals ≥12 years of age. The majority of U.S. VAERS reports for the original Pfizer-BioNTech COVID-19 Vaccine were non-serious (82.2% for any dose among all ages, and 78.6% for booster doses among those aged ≥12 years). The top ten most frequently reported MedDRA PTs (U.S. and foreign) include: Most frequent PTs among all ages and all doses: SARS-CoV-2 test, COVID-19, headache, fatigue, pyrexia, dizziness, pain, nausea, pain in extremity, **vaccination failure.**

FDA's purportedly "complete discussion of the data for the EUA" is in only one document:

FDA's denial letter states: "*89 Id. at 12. FDA interprets Petitioner's reference to "a single observational study of 8 mice" as referring to nonclinical data discussed by Pfizer during the June 28, 2022 Vaccines and Related Biological Products Advisory Committee Meeting (Vaccines and Related Biological Products Advisory Committee June 28, 2022 Meeting Presentation-Pfizer/BioNTech COVID-19 Omicron-Modified Vaccine Options, https://www.fda.gov/media/159496/download). For a complete discussion of the data evaluated by FDA to support the emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, see FDA, Pfizer-BioNTech COVID-19 Vaccine EUA Amendment Decision Memorandum for Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) in Individuals 12 Years of Age and Older (Aug. 31, 2022), https://www.fda.gov/media/161595/download; FDA, Pfizer-BioNTech COVID-19 Vaccine EUA*

Amendment Decision Memorandum for Authorization of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) in Individuals 5 through 11 Years of Age (Oct. 11, 2022), https://www.fda.gov/media/162410/download.

It is important to note that FDA's purportedly complete discussion of the data evaluated by FDA to support the emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, says on **pg 39: ***"Uncertain how the magnitude of the increase in antibody response in humans will translate into effectiveness against COVID-19 outcomes, including symptomatic and serious disease" see:* https://www.fda.gov/media/161595/download

Because FDA unequivocally states the "complete discussion of the data to support authorization of the EUA" reveals FDA is actually ***"uncertain how the magnitude of the increase in antibody response in humans will translate into effectiveness against COVID-19 outcomes, including symptomatic and serious disease".*** Petitioners take it to mean there is, in reality, no real possibility for FDA to hold a truly reasonable belief that the product may prevent covid-19, and as a result, the basis for the EUA is no longer met (and was always spurious ab initio). It is beyond absurd for FDA to state they are ***"uncertain how the magnitude of the increase in antibody response in humans will translate into effectiveness against COVID-19 outcomes, including symptomatic and serious disease"*** and also irrationally and illogically claim the EUA is *"to prevent covid-19",* based on a reasonable belief it may actually work to prevent covid-19.

None of this makes sense to our organization, or to the skeptical scientific community we represent who want answers.

Based on the FDA's one flimsy piece of hearsay evidence, that relies entirely on FDA's own self serving mere conclusory statements of interpretation of the data with no underlying datasets to

review, there is a vice or defect in the motivation or reasoning that justifies the administration's decisions underlying the choice of unlicensed harmful (covid-19 [non]vaccine) over natural immunity, over safe licensed ivermectin essential medicine (a human right to prescribe, use and have) or other early treatments off shelf, being insufficient the sole citation of legal norms, simple facts, arithmetic data or generic transcripts of judgments or administrative resolutions, without the foregoing being accompanied albeit succinctly, an analysis aimed at justifying a particular decision.

The FDA's evidence of the complete discussion of the data is also outlined in a separate document found by Petitioners: see: EUA Review Memorandum EUA 27034, Amendment 617, which states on page 40, **"The nonclinical study is still ongoing;** additional time points at 1-month post boost and following a 2-dose primary series of the monovalent (Omicron BA.4/BA.5) **and bivalent (Original and Omicron BA.4/BA.5) vaccines will be evaluated as samples become available."**

Based on the foregoing, FDA had a complete discussion about the data, but without complete data to discuss! The non clinical study is a fancy way of saying human experimentation using unproven interventions outside a clinical trial. This invokes responsibility for FDA to adhere to ethical guidelines.

Requirement *for a qualified ethics committee*. A research ethics committee (REC) or an equivalent qualified committee that meets local norms and has the capacity of evaluation for the type of proposed unproven intervention must review the protocol of monitored emergency use. While emergency use does not constitute research [this is highly contentious Orwellian doublespeak] but rather access to an unproven intervention outside clinical trials for the benefit of its recipients or the population, it should be guided by the ethical principles that govern the use of unproven

interventions. Its similarity to and relation with research justifies use of the research regulatory and review system *(16, 22, 63)*. (See section 3.3.) **3.3 Operational recommendations**

Scientific basis and qualified scientific committee: A scientific committee must have recommended the proposed intervention under monitored emergency use **on the basis of the latest evidence**. The committee may be local or international, such as a board of scientific societies that provides advice during a public health emergency. In the case of a PHEIC, recommendations issued by WHO can also be used for this purpose*.*

FDA is not up to speed on the latest evidence showing safety signals of harm.

What are the challenges that relevant authorities in Member States should consider when allowing emergency use of unproven interventions outside clinical trials? As recognized by PAHO *(22)*, **a key challenge to ethically using unproven interventions outside of clinical trials during the COVID-19 pandemic is lack of or limited adherence to the MEURI ethics framework**, for a number of reasons: first, unfamiliarity with the MEURI ethical framework, which was devised for the outbreak of EVD in 2014; and, secondly, **the complex correlation of the MEURI ethical framework with different regulatory frameworks** and pre-approval access designations (e.g. "off-label" use, expanded access, compassionate use, emergency use authorization), which are not globally harmonized and may not exist in some jurisdictions.

FDA's failure to adhere to the MEURI ethical framework or its appropriate implementation has raised serious ethical concerns, which can be categorized according to the MEURI ethical categories, such as:

***Inadequate justification*:**

- The EUA allows for use of unproven clinical interventions, such as those known to be toxic (e.g. mRNA, viral vector), that is not justified by the available evidence and risk–benefit ratio and are thus expected to be more harmful than beneficial; and
- The EUA allows for excessive assignment of limited resources to unproven clinical interventions with unknown risk–benefit profiles.
- FDA has *Inadequate ethical and regulatory oversight*:
- FDA gives waivers for conflicts of interest, allowing for undue interference with clinical trials or other necessary research activities;
- **negligent or intentional mischaracterization by** health-care workers, **health authorities such as FDA, ethics committees and other stakeholders of emergency use outside clinical trials**, including "off-label" use, as activities (e.g. "observational research", "compassionate use", "quality improvement") that evade or do not satisfy the justification, oversight, consent and monitoring established in the MEURI ethical framework;
- FDA has shown a lack of appropriate coordination of use of covid-19 vaccine unproven interventions within and outside clinical trials;
- Petitioners are concerned about undisclosed conflicts of interest of Member States' authorities, prescribers and manufacturers;
- FDA appears to be hiding large numbers of deaths for Pfizer according to confidential court ordered documents FDA begged the court to keep secret for 75 years that showed 1223 deaths early on. Based on the foregoing it is reasonable and logical that petitioners and many in the scientific community believe that FDA is authorizing misuse of unproven interventions outside clinical trials for commercial gain;
- The risks were known to FDA in the slide #16 from October 23, 2020 showing stroke, death, myocarditis, etc; and therefore Petitioners believe FDA is engaging in exploitation

of desperate individuals willing to try any intervention offered, regardless of the expected risks or lack of benefits.

- FDA failed to do a shedding study, presuming incorrectly the product does not act as a gene therapy. There is the potentiality of environmental or other harm to third parties due to use of unregulated or underregulated, unproven interventions.

Inadequate consent process:

- invalid or no individual informed consent process when it is required;
- undue promotion of unproven clinical interventions outside clinical trials that interferes with appropriate consent; and
- ***irresponsible overstatement of the benefits and understatement of the risks and uncertainties*** of unproven clinical interventions by national authorities, health-care workers and the media working in collusion, ***that interferes with the consent process.*** See: Mrs. Birx: https://www.bitchute.com/video/3aA5L5Hl1bNG/ "I knew these vaccines were not going to work against infection and I think we overplayed the vaccines."

Inadequate contribution to the generation of evidence:

- failure to use unproven interventions outside clinical trials such as ivermectin and other safe approved alternatives to the vaccines in a manner that contributes to the generation of evidence and would end the state of emergency.

What considerations should be made in evaluating monitored emergency use of preventive unproven clinical interventions outside clinical trials?

According to FDA's advisory opinion from WHO, particular care must be exercised in using preventive interventions, as they are usually given to healthy or at-risk groups. Evidence levels of safety and benefit are therefore more important than for therapeutic interventions. *Widespread use of unproven interventions outside clinical trials for preventive interventions should therefore be discouraged, as all harm related to the intervention will be iatrogenic. Possible exceptions include use of chemoprophylaxis in* ***situations in which the probability of harm is exceptionally high****, such as known exposure to an infectious agent. It is preferable, however, that clinical trials be organized in these circumstances to generate reliable information.* ***The Working Group considered that ethical guidelines for mass emergency use of novel vaccines for a disease or condition associated with a public health emergency (e.g. novel vaccines for COVID-19) should be addressed in a separate document or documents, given its distinct impact on public health and well-being.*** *The MEURI ethical framework may prove useful for emergency use of such interventions, but it should be adapted to the relevant ethical and regulatory considerations (41–45).*

Petitioners are not aware of how to find the unnamed secret "**ethical guidelines for mass emergency use of novel vaccines for a disease or condition associated with a public health emergency (e.g. novel vaccines for COVID-19)"** because its not revealed, if created at all. What is clear however, is that the covid-19 vaccines are so unusually far out on a limb ethically speaking, that they require an entire separate document or documents given its distinct impact on public health and well-being. Immediately before explaining the covid-19 vaccines require a separate ethical guidance, the WHO states very clearly "**Widespread use of unproven interventions outside clinical trials for preventive interventions should therefore be discouraged, as all harm related to the intervention will be iatrogenic."**

iatrogenic means Induced unintentionally in a patient by a physician. Used especially of an infection or other complication of treatment. Induced by the words or actions of the physician. **Induced by a physician's words or therapy (used especially of a complication resulting from treatment)** The American Heritage® Dictionary of the English Language, 5th Edition.

Data from CDC vax safety shows upside down benefit to risk ratio. WHO and FDA say covid is generally mild in children. Statistically zero are seriously injured by covid, but the latest CDC vaccine safety data says 5.7% are hospitalized or dead from the unproven interventions outside clinical trials for preventive interventions. FDA cannot continue the charade that the benefit outweighs the risk, its absurd squared at this point. It seems critical to Petitioners to bring attention to the enormous and serious known risk of enhanced disease not mentioned in the fact sheets, denying informed consent for the very risky experiment. FDA Denial of Citizens petition evidence states on pg 35 https://www.fda.gov/media/161595/download • **Important Potential Risks: Vaccine-associated enhanced disease, including vaccine associated enhanced respiratory disease.** The risk is known to FDA, identified as an "important potential risk", but not adequately monitored, which makes the FDA responsible for the unethical omission of failing to ask people if they want to risk auto immune disorder to protect themselves from a threat no greater than a bad flu.

Petitioners allege there is a vice or defect in the FDA's motivation or reasoning that justifies the administration's decisions underlying the choice of w**idespread use of unproven interventions outside clinical trials for preventive interventions which should be discouraged, as all harm related to the intervention will be iatrogenic,** being insufficient the sole citation of legal norms, simple facts, arithmetic data or generic transcripts of judgments or administrative resolutions,

without the foregoing being accompanied albeit succinctly, an analysis aimed at justifying a particular decision.

This EUA for mRNA and viral vector unproven emergency use interventions outside clinical trials is particularly egregious and unethical because the preliminary data FDA tried to hide from the public and court is already showing vaccine failure, confidential and proprietary piles of 1223 dead bodies in just the first 3 months and signals of enhanced disease in the Pfizer trial documents publicly released to date on the PHPMT website. https://phmpt.org/pfizers-documents/

The PHPMT court ordered documents and official data releases show the unproven emergency use interventions outside clinical trials is harming many peoples right to health and life. The trial results showed 1223 people died, critical information is held confidential and proprietary by FDA and Pfizer, which denies informed consent, therefore, ****under the MEURI ethical framework ****the FDA has an ethical, if not legal, duty to revoke the EUA's and issue a moratorium for all mRNA and viral vector harmful unproven emergency use interventions outside clinical trials, including but not limited to covid-19 vaccines.

Interest of Justice reminds FDA that 1223 dead bodies in a trial of 44,000 is wholly unethical to keep confidential and continue the experiment (Nuremberg Code 5 prohibits this exact conduct). Shut it down.

On Nov 4, 2023 CDC updated the vaccine safety page to show 5.7% of users ages 5-12 had serious reactions. On the same day, November 4, 2022 updated their site https://www.ehealthme.com/vs/pfizer-biontech-covid-vaccine/death/ based on the CDC data, to increase dead from 1.1% of Pfizer users with AE, to 1.29% of users with reported adverse reactions die.

FDA absurdly claims they cant confirm its really FDA and CDC data on eheathme.com, but they also do not deny it either. The presumption stands that ehealthme.com is telling the truth of the data from FDA and CDC, because if its false then Petitioners presume FDA has a duty to sue ehealthme.com for fabricating dangerous misinformation and falsely making FDA look grossly negligent, covering up that their own data shows death is common and death is now reported as the #6 adverse effect after 30 days of taking Pfizer BioNTech. https://www.ehealthme.com/vs/pfizer-biontech-covid-vaccine/death/ is clearly being updated precisely when CDC and FDA releases public data. Its serious enough that it may be true the official FDA/CDC data shows death is common, therefore, FDA has a duty to investigate the sites sources and firmly refute the sites claim that Phase 4 trial data shows death is a common reported effect of Pfizer BioNtech, as shown by FDA and CDC official data. Based on FDA behavior of trying to hide the trial data which showed 1223 people died in 3 months of a trial with only 44,000 people Petitioners are certain the statistics evidence is from official data and does indeed show death is common. Why would FDA presume the evidence of phase 4 data provided by Petitioners is possibly false without first checking if the data is indeed FDA's, and after the horrific trial results which clearly show death is common. The VAERS and aggregate data when checked by people, AI all show death is off the charts safety signal. Why is FDA wishing to hide this from the public for 75 years rather than shut it down?

FDA presumes the experiment does not affect DNA, however, based on peer reviewed data of the scientific rigor that FDA is obligated to accept the Pfizer BioNtech is proven to transcribe into DNA in less than 6 hours. Pfizer admits some of their vaccine candidates are considered gene therapy and due to the association with gene therapy it may never pass approval. Pfizer was either grossly negligent or intentionally defrauded FDA when they purported that, "the product is intended to have a different mechanism of action which does not affect DNA and therefore may

have less risks than those normally associated with gene therapy which does affect DNA." see: Sweden study is peer reviewed and it shows the product transcribes into DNA in less than 6 hours. FDA must refute Petitioners evidence with data and motivation for FDA's final conclusions, not mere conclusory statements, otherwise the precautionary principle and MEURI ethical framework must be applied to issue a full moratorium.

"It is commonly said that benefits and risks must be 'balanced' and shown to be 'in a favourable ratio.' ... Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit ... It should also be determined whether ... estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies." (The Belmont Report)

Regulators ****bear responsibility for allowing a protocol to proceed in accordance with applicable laws and regulations. This may include prospective review of the protocol, the investigator's brochure, and other relevant information to ensure that risk(s) and benefit(s) are accurately identified and justify allowing the protocol to proceed. The regulatory authority may require modification to a protocol as a condition to its proceeding and/or may suspend or terminate a protocol based on an unacceptable risk/benefit profile in accordance with applicable laws and regulations. In this case the act is prohibited as unethical. Terminating the EUA is mandatory.

Fifth, Alternatives To Vaccines Exist

Natural immunity was always an alternative. FDA has no right to ignore all alternatives to the widespread use of unproven [non]vaccine interventions outside clinical trials for preventive interventions which should be discouraged, as all harm related to the intervention will be

iatrogenic. FDA limits themselves to repeating in the fact sheet and in denying our petition that there are no alternative vaccines. THis is a glaring omission and breach of duty.

See: WHO therapeutics were inequitably not funded or researched, whilst there is an over investment in vaccine funding, research and promotion by FDA. It looks like FDA is biased and captured by Big Pharma that they refuse to consider all viable safer and more effective approved alternatives such as off shelf use of essential medicines and early treatments shown to be far more safe and effective than the widespread use of unproven interventions outside clinical trials for preventive interventions, which should be discouraged, as all harm related to the intervention will be iatrogenic.

Natural immunity and safe and effective ordinary therapeutics and early treatments are available, which are safer and more effective. If all approved alternatives were truly considered by FDA, it would require immediate revocation of the EUA's because the vaccines are not strictly required by the exigencies of the situation and not the least burdensome remedy for the situation. This is not debatable. FDA is grossly negligent and pretending the law means the FDA must only see if there are alternative vaccines, when FDA knows or should know the law means ALL adequate approved alternative treatments must be considered first and foremost to this unproven mRNA or viral vector prototype vaccine candidate that may never pass full approval for safety or efficacy.

- FDA has shown an inequitable focus, funding and approval of vaccines over therapeutics or natural immunity.
- WHO recently noted this is very problematic. WHY is the focus only on alternative vaccines as interpreted by FDA rather than focus on all available alternatives such as natural immunity or early treatments?

- WHO publicly announced we have the tools to save lives, therefore, alternatives to EUA vaccines exist and no unproven emergency use interventions outside clinical trials emergency vaccine experiments are needed.

see Pfizer SEC filing pg 155: The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. **The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies**.

Even Pfizer concedes the FDA needs to compare the mRNA completely unproven unlicensed intervention with other available therapies. Alternatives exist but FDA has the tunnel vision of a dedicated vaccine peddler for Big Pharma who just so happens to pay 75% of FDA's funding, in an inherent conflict of interest and structural defect in the agency. Why would FDA look for other less profitable alternatives such as off shelf approved essential medicines such as ivermectin or natural immunity when their pharmaceutical funders request a least burdensome review for the EUA product to earn billions of dollars in revenue?

Approved safe alternatives to the completely unproven experiment have always existed as shown by the opinion of the scientific community.

The MEURI Ethical Framework is clear s**ection 3** provides general and operational recommendations, originally developed by PAHO during the COVID-19 pandemic, for policy makers, national regulatory authorities, health-care workers, ethics committees and others for implementing the framework. Section 3 has 2 sections which are required 1. Informed consent and 2. community engagement.

By failing to take the scientific communities ample repeated testimony into account FDA is in breach of duty to provide community engagement. A ministry of health or other relevant authority should establish appropriate policies for community engagement to prevent social practices that threaten the validity of an adequate consent process, such as overstatement of evidence and potential benefits, understatement of risk and uncertainties, undue promotion of unproven interventions, undue influence on the public and the medical community or exploitation of vulnerability.

Community engagement. In communications on emergency use outside clinical trials of both completely unproven or "off-label" interventions, national health authorities, health-care workers and others must refrain from overstating the evidence and potential benefits, understating the risks and uncertainties and exploiting the hope of populations for any reason, including political or economic gain *(74)*. National health authorities and health-care workers should provide information about the uncertainties, risks and potential benefits of interventions that have not been proven safe or efficacious and promote dialogue about monitored emergency use outside clinical trials in order to avoid false perceptions of risk-benefit profile and overstatement of evidence of unproven interventions. Community engagement is essential for meaningful consent, particularly in the context of a public health emergency *(22)*. All aspects of a public health emergency response should be supported by early, continuing engagement with the affected communities. Community engagement is essential not only because it is ethically important but also to establish and maintain trust and preserve social order12.

If FDA would come down to Earth with the rest of us and provide meaningful stakeholder engagement with the dissenting majority scientific community, they would be very aware of the concrete evidence proving alternatives have always existed to the completely unproven

interventions outside a clinical trial. The testimony stands as true that there are early treatments, until each peer reviewed study on early treatment and ivermectins efficacy to treat covid is properly refuted by FDA with genuine evidence.

Sixth, Other Circumstances Make a Revision or Revocation Appropriate to Protect the Public Health or Safety

- Numerous serious violations of the MEURI ethical framework
- Numerous serious violations of Siracusa Principles, including 69b violating non derogable right to be free of scientific and medical experimentation
- Numerous serious violations of Nuremberg Code 1, 3, 5, 7
- Numerous serious violations of Declaration of Helsinki
- Numerous serious violations of the Belmont Report
- **Petitioner presents new data regarding the effectiveness of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent or the Moderna COVID-19 Vaccine, Bivalent that is of the scientific rigor that FDA would rely on for scientific and regulatory decisions:**

To protect the public interest in health and safety our organization invokes our right to due process so we can be reasonably heard on the facts that the FDA failed to consider when authorizing the unproven emergency use interventions outside clinical trials, as well as bring forth new information previously unavailable to prove the inherent iatrogenic nature of the mRNA and viral vector intervention.

FDA failed to consider the slides about trial fraud or bioweapons.

FDA failed to consider the slide with the link to gene therapy https://www.fda.gov/media/106369/download. "When there is no previous human experience with a specific CGT product or related product, **treating several subjects simultaneously may represent an unreasonable risk.** To address this issue, most first-in-human trials of CGT products include staggered treatment to limit the number of subjects who might be exposed to an unanticipated safety risk."

FDA instead focused on a different document presented by Petitioners from 2020, claiming the document states it does not apply to immunotherapy product candidates. FDA's own guidance is in error when they failed to dispute all evidence to support Petitioners argument that the immunotherapy product candidates product is a gene therapy.

According to Pfizers SEC filing:

Our immunotherapy product candidates span four distinct drug classes:

- ***mRNA Therapeutics.*** *We have developed multiple proprietary formats and formulations of messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect.*
- ***Cell Therapies.*** *We are developing a range of cell therapies, including CAR-T cells, neoantigen-based T cell therapies and TCR therapies, in which the patient's T cells are modified or primed to target cancer-specific antigens.*
- ***Antibodies.*** *We are developing next-generation antibodies, including bispecifics, that are designed to target immune checkpoints and novel cancer antigens.*
- ***Small Molecule Immunomodulators.*** *We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation.*

On pg 12 ***Risks Associated with Our Business*** *• Data from our COVID-19 vaccine development program is not predictive of the safety or efficacy of any vaccine candidate*

• No mRNA immunotherapy has been approved, and none may ever be approved. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics. • Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. • Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business. • We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.

• We have entered into ***several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest****.*

Recently new information is in public record to support Petitioners concerns that gene therapy guidance must apply to these immunotherapy product candidates. see: https://www.bitchute.com/video/TKHh9YAs2wPB/ Senator Ron Johnson leads a hearing with global doctors and medical researchers in DC on the Covid-19 Vaccines on December 7, 2022.

Dr. Robert Malone testified, *"As I have said repeatedly, it came out of a gene therapy research program. These & the adenoviral vectors are absolutely gene therapy technology applied for the purpose of eliciting an immune response.*" also see: Sen. Ron Johnson Roundtable Discussion: Covid-19 Vaccines: What They Are, How They Work and Possible Causes of Injuries, Full video: https://thehighwire.com/watch/

The issue of the product being closely associated with gene therapy, showing the same unreasonable risks, must be addressed and ruled out completely due to the Sweden studies showing DNA is affected.

FDA is aware that mRNA is an example of cell or gene therapy judging from Stephen Oelrich from Bayer at the World Health Summits confession, "*Ultimately the mRNA vaccines are an example for that cell and gene therapy (CGT). I always like to say if we has surveyed two years ago in the public would you be willing to take a gene or cell therapy and inject it into your body we would have probably had a 95% refusal rate."*

The fact that Big Pharma and FDA knows people would inherently refuse the experiment perhaps explains why the GCT product is mislabelled as a vaccine, to defraud people into taking an unreasonably risky unproven emergency use interventions outside clinical trials. The presumption stands as true at this point based on the evidence and FDA;s failure to dispute the argument that the product is not a vaccine, it is a gene therapy with far more risks than vaccines.

The document which FDA failed to consider https://www.fda.gov/media/106369/download explains the guidance for all cell or gene therapy (mRNA and viral vector included). Once again Petitioners forcefully reiterate the FDA is in breach of duty to follow their own proper guidance that states, "When there is no previous human experience with a specific CGT product or related

product, **treating several subjects simultaneously may represent an unreasonable risk.** To address this issue, most first-in-human trials of CGT products include staggered treatment to limit the number of subjects who might be exposed to an unanticipated safety risk."

FDA also failed to consider the testimony of 12 year old Pfizer trial victim of trial misconduct Maddy De Garay's mother, who testified Maddy was in the hospital with life altering injuries when the pediatric EUA was approved and FDA failed to consider her injuries, instead falsely claiming they were "abdominal pain". Maddie is wheelchair bound for life on a feeding tube, FDA failed to consider this or to warn the public, once again shielding Pfizers trial misconduct, in a great disservice to humanity. FDA truly failed to address this argument by Petitioners, which means the presumption stands that FDA knows of serious injuries in a trial with less that 1200 children and allowed the pediatric EUA very unethically.

CONCLUSION

Petitioners forcefully reject FDA's denial of our September 30th, 2022 Citizens Petition and kindly reiterate our position that the FDA is responsible for cessation of the internationally wrongful act of authorizing **unproven emergency use interventions outside clinical trials called** covid-19 vaccines EUA's.

Petitioners conclude that because the evidence from FDA, that is allegedly the "complete (totality of evidence) data analysis for the EUA approval", states essentially that there is no reason to believe the product may be effective. see: FDA evidence https://www.fda.gov/media/161595/download Denial of Citizens petition states on pg 39:

"Uncertain how the magnitude of the increase in antibody response in humans will translate into effectiveness against COVID-19 outcomes, including symptomatic and serious disease". Adding to the uncertainty and unethical nature of the EUA, the document further states, *"Risks that should be further evaluated include quantifying the rate of vaccine-associated myocarditis/pericarditis in this age group and* ***surveillance for other adverse reactions that may become apparent with widespread use of the vaccine*** *and with longer duration of follow-up."*

FDA's Orwellian doublespeak is intended to obfuscate and delay prompt justice to Petitioners in order to allow unethical covid-19 vaccines, or other mRNA/viral vector gene therapy unproven emergency use interventions outside clinical trials. The experiments are being unethically authorized by FDA as an **unproven emergency use interventions outside clinical trials,** whilst FDA unethically attempted to delay the release of the trial results for 75 years, presumably because the documents, once released under court order, show 1223 people died under the direction, control and care of FDA and Pfizer in the first 3 months of the Pfizer mRNA trial. The harmful nature of the unproven emergency use interventions outside clinical trials is on public display in a court ordered document (many in fact) with a footer saying "confidential and proprietary" and showing 1223 deaths and enhanced disease as an important potential risk in the first 3 months of use inside the clinical trial.

FDA's unethical conduct of withholding evidence of more actual risk than potential benefit is clearly intended to protect Pfizer, rather than the public that FDA is supposed to serve and protect. FDA was created to deal with the Thalidomide debacle and now they are causing an even worse public health crisis, failing their purpose for existence, losing public trust over the emergency authorization and mass use of mRNA and viral vector **unproven emergency use interventions outside clinical trials**.

The FDA is acting in excess of Statutorily granted authority by issuing the EUA's without all EUA elements being met, and also has a mandatory duty under the MEURI Ethical Framework to issue a moratorium on all mass emergency use of mRNA and adenovirus viral vector unproven emergency use interventions outside clinical trials.

Evidence:

January 2, 2023 - https://petermcculloughmd.substack.com/p/ivermectins-mechanism-of-action-against

January 25, 2023 - https://petermcculloughmd.substack.com/p/pfizer-fda-skullduggery-revealed

https://childrenshealthdefense.org/wp-content/uploads/2023-1-13-doc-86-decision-and-order.pdf

Dr. Yeadon affidavits which verify the truth of the Corman Drosden Report - Is a positive PCR sufficient to diagnose a case of Covid-19? It is in the US (CSTE, 4/5/20. CDC, National Covid-19 Case Surveillance, 8/28/20), yet the overwhelming majority of positive PCRs are found in individuals who harbor no live viruses. (https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/60...) A large group of international experts has demanded the retraction of a prominent article supporting the use of PCR for Covid-19 diagnosis, citing 10 fatal flaws. (Review report Corman-Drosten et al. Eurosurveillance 2020, submitted 27 November 2020)....PCR massively amplifies dead fragments of viral RNA; it is exquisitely sensitive and subject to contamination, leading to vast numbers of false positives, massive over-diagnosis of Covid-19 illness, and unnecessary quarantine of millions of healthy people. (Yeadon, et al)….Covid-19 is most contagious in the first 5 days after symptom onset, but beyond day 9 of the illness live viruses are not recovered. However, PCR tests remain positive for as long as 12 weeks

in respiratory secretions and 18 weeks in stool. (Cevik et al, Lancet Microbe 2020, Nov 19. BMJ 2020;371:m3862, Oct 23)

THIS IS WHAT WE NOW MUST DO: Open up society and focus protection on the truly vulnerable. Do not vaccinate healthy young and middle-aged individuals, but allow the gradual acquisition of lasting population immunity from an infection that is generally mild. Skip the flu shot. We are seeing very little influenza, and the vaccine increases the risk of illness from non-influenza respiratory viruses, probably including Covid-19. https://www.bmj.com/content/370/bmj.m3720/rr

The undersigned certifies, that, to our best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature

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