Friday, September 30, 2022

This is a Citizens Petition to revoke FDA Authorization for Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose, and revoke all other authorization for mRNA Gene Therapies misbranded as vaccines which do not confer immunity because FDA January 2020 guidance: "Long Term Follow-Up After Administration of Human Gene Therapy Products Guidance for Industry", states the use of these experimental products affects DNA with an unreasonable risk to use in more than a few people at a time. Also, the act is absolutely null for exceeding statutory jurisdiction and violating international norms.

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

July 1, 2022
Submitted electronically (21 C.F.R. § 10.30(b)(l))

**Re: Citizen's petition regarding the FDA 's emergency use authorization o/COVID-19 vaccines for bivalent

Dear Dr. Califf:

We are presenting this citizens petition on behalf of our organization Interest of Justice, the international community and other concerned medical and legal experts regarding the Food and Drug Administration's August 31, 2022 authorization of the product called COVID-19 vaccines made by Pfizer and Modema using FDA's "future framework" to allow bivalent and other gene vaccines with no human testing.

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 and the common law we DEMAND that you revoke or suspend the FDA's emergency use authorization of the COVID-19

bivalent vaccines for these young children pending FDA's obligation to meet the burden of proof of science and trial safety data, which so far FDA is in breach of duty to provide.

Interest of Justice requires the bivalent vaccines revoked, or at minimum suspended/stayed so the regulatory agency can meet their obligation to show they are in compliance with international peremptory norms, and so the FDA can reverse their reckless course to finally properly re-consider the potential and known risks and rewards in injecting young kids with these experimental gene therapies mislabelled as vaccines.

IOJ's membership is comprising of many thousands of non conflicted and "uniquely qualified" scientists, journalists and experts, including Dr. Mike Yeadon, ex VP of Pfizer respiratory. Our uniquely qualified experts are more qualified than the VERPAC committee members that FDA chose with conflicts of interest. It is not true the committee who voted was unbiased or uniquely qualified and Interest of Justice firmly rebuts the false presumption that conflicts can be .

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.

Essentially, we were all censored about the risks of the bivalent scheme, and to protect the public interest and actually consider the actual "totality of evidence" FDA failed to consider thus far we need due process to be heard on the facts that the FDA failed to consider. Furthermore, new facts came out since the FDA authorized these products which shows a 44% increased risk of transmission, auto immune like reactions and that there is 92% more risk than benefit.

The product is a failure, doomed to fail and could never be reasonably believed to have prevent transmission. 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"

A. Action Requested

On August 31, 2022, the FDA 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. 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."

This petition DEMANDS that you revoke this authorization, or at minimum, IMMEDIATELY suspend it so the FDA can properly meet their State obligations to international law which requires a public hearing for FDA to meet the burden of proof of trial safety data, how 8 mice that died is sufficient, to explain why this gene therapy not pose an unreasonable risk like the FTA previously said in 2018, as well as to hear our expert evidence that was not taken into consideration and re-consider the potential risks and rewards in injecting young kids with these experimental pharmaceuticals.

B. Statement of Grounds

During the time gene therapy began until today FDA learned there would be unreasonable risk if administered to more than a few people at a time. Petitioners refer the Commissioner to our slides we presented to VERPAC, which quotes FDA guidance recommendations based on FDA's knowledge of the inherent risks of gene therapy.

FDA's 2018 gene therapy guidance recommendations (which FDA says is their "current thinking on the matter") says "there is an unreasonable risk" in widespread use of this gene therapy which they say can affect DNA and cause cancers, auto immune like disorders and long term adverse effects.

It is not yet proven safe, effective because it is investigational.

Its irrational and illogical for FDA to say the investigational shots are safe and effective to give to masses when the FDA also has a truthful (and contradictory) website stating the opposite: https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs This FDA website states:

*"An investigational drug can also be called an experimental drug and is being studied to see if your disease or medical condition improves while taking it. Scientists are trying to prove in clinical trials:

*- If the drug is safe and effective.

- How the drug might be used in that disease.

- *How much of the drug is needed.*

- *Information about the potential benefits and risks of taking the drug."*

Finally, remember that approved drugs have completed extensive testing in clinical trials and there is scientific proof that they are safe and effective for treating the particular disease or medical condition that has been studied.

FDA published serious risks and concerns about these same types of gene therapy products in 2018, but to approve these products today, the same FDA is now ignoring the risks and FDA guidance recommendations they published just 4 years ago!

The gene therapy products called vaccines are known by FDA to affect the DNA, causing cancers, long term delayed adverse effects and ADE destroying peoples immunity for life, KNOWINGLY at great detriment to their right to life and health, which is criminal recklessness at worst and gross negligence and best.

As a matter of strict accordance with law, the FDA's own guidance proves the FDA has no ethical choice but revocation at this time, because they, themselves are clear of the known unpredictable and long term risks. **These known risks are not revealed in the fact sheet** which prevents the marketing, unless the FDA wants to be in violation of FTA false advertising laws, as well as violations of Nuremberg Code and other human rights norms.

It violates much more than Federal law that the FDA is failing to inform the public about the risk of death which is a common effect in the fact sheets. For FDA to know a % of people will die yet continue to give the mRNA and gene products to people outside clinical trials without informing people death is listed as common in 1.1% of users is a violation of Nuremberg Code Article 1 and Siracusa Principles 69 (b). It means United States andFDA are violating peoples non derogable rights illegally.

We tried to explain in the meeting that when FDA violates the international norms it affects other countries that rely on FDA. For instance, Costa Rica is the first country in the world to mandate the bivalent vaccine 3 doses for 6months to 5 years, and is using FDA's authorization to do so in an expedited decree, even though the emergency was dropped. The product that FDA is exporting to the wrongdoer country is under EUA and the forced administration of the experimental immune damaging product is violating Nuremberg Code, Siracusa Principles 69 b and EUA laws of the United States.

We are desperately trying to inform FDA they are making a grave error which is causing USA to bear State responsibility (under Responsibility of States for Internationally Wrongful Acts) by aiding and abetting international crimes against humanity occurring locally and abroad.

This focus on the government's decision-making process means that a plaintiff in an administrative law case can show the government acted arbitrarily because it "ignored ... evidence altogether or provided reasons for its decisions that were contrary to the evidence presented." Innova Sols., Inc. v. Baran, 338 F. Supp. 3d 1009, 1024 (N.D. Cal. 2018) (discussing cases). We have concrete evidence of the FDA ignoring evidence altogether here, as well as clearly showing provided reasons for its decisions that were contrary to the evidence presented.

It's not true the decision was based on a totality of evidence because if the following list of evidence we provided were considered, the FDA would have restrained the agency from violating the laws we showed would be violated. If the evidence were truly considred by people without conflicts of interest they would only be one rational decision which is to not approve the investigational bivalent gene therapy [non]vaccines under an EUA for use in masses of healthy people and babies.

What FDA does affects the world. FDA says "we believe the federal decisions to convert Expanded access use to EUA preempts state law" and that is why the FDA is allowing waivers of informed consent (not allowed by State law) by operating only under Federal laws.

We have to be very clear. NO Federal law is allowed to preempt international human rights norms and that is exactly what is occurring under the commissioner of the FDA's watch.

We wrote to the FDA in regards to these bivalent vaccines to explain exactly which violations of international human rights and peremptory norms the FDA is in violation of. No one will respond and we even spoke with the FDA Commissioners Omsbudsman Laurie Linkle and she first promised to help us facilitate communication with FDA's VERPAC communication department. After reading our June 28, 2022 letter that was never taken into consideration when the bivalent vaccines were approved, naming Nuremberg and other violations with evidence we are right, she had decided that *she never said she would help us facilitate communication* and even though her only duty is to facilitate communication within FDA she refuses to pass VERPAC our information that was not considered in regards to the manifest illegalities of the use of the gene therapy outside clinical trials by converting EAU to EUA in an FDA precedent during covid. This conversion from only terminally ill who have no other option to widespread use of gene therapy treatments in healthy people exceeds authority of FDA and is criminally recklessly endangering peoples lives and health.

During the past two years, FDA has developed an unprecedented amount of scientific knowledge about COVID-19, mostly still hidden by FDA. What is revealed however, says a lot about absolute nullity. We have learned a fatal flaw about the Pfizer and Moderna COVID vaccines: they do not prevent people from becoming infected with, or transmitting COVID-19.

Gene Therapy or Vaccine as defined by the legislator? People have the right to know the truth.

The EUA was issued to prevent covid, its a fraud of law to continue under that prong of the EUA law, which of course makes the approval VOID ab inito because it was always known by FDA that it couldn't work as a preventative or to confer immunity.

The CDC and WHO defines vaccines more broadly, and FDA is biased towards the CDC and WHO, but let us remember, the FDA is not empowered by USA law to use or rely on the WHO's or CDC's definition. FDA can rely only upon the following definition (which is clearly violated, leaving FDA with **zero statutory authority** to authorize, falsely market or continue to mislabel the gene therapy product as a vaccine): [26 USC § 4132(a)(2)](https://www.law.cornell.edu/uscode/text/26/4132#a_2) vaccine (2) Vaccine The term

"vaccine" means any substance designed to be administered to a human being for the prevention of 1 or more diseases.

The legal problem that must be dealt with immediately by FDA is the EUA laws have 2 prongs:
1. to prevent infection, or

2. to treat an existing disease.

At this time no mRNA product has ever been found to be effective for the prevention or prophylactics of infectious diseases, only monocoloidial antibodies, so rationally the EUA for mRNA products cannot be under the EUA prong to prevent infection.

The only other prong and Congress narrow intent is that an EUA can also be issued to treat an existing disease. Congress never authorized any use of investigational products outside clinical trials in healthy masses of people, especially with no informed consent that death is a known common adverse effect.

It's illegal to give to healthy people mRNA at this time because FDA's EUA violates superior laws and other nations regulatory provisions who rely on FDA to harmonize laws to meet FDA's international duties.

FDA 2020 guidance says, **"an immune response to self antigens from gene therapy may introduce the risk for auto-immune like reactions"**, therefore, the new CDC and WHO definition of vaccine for gene therapy conflicts with Congress intent and is void.

It is not proper, scientific or legal to determine a vaccine is to "stimulate an immune response". It's arbitrary and capricious.

Moreover it's dangerous and recklessly endangering life by giving people Antibody Dependent Enhancement like AIDS.

Moderna says the bivalent vaccines create even more antibodies than the monovalent. This is absolutely unacceptable because the FDA said in 2018 the NMU response to self antigens from gene therapy may introduce the risk for autoimmune like reactions. Now the bivalents double the risk.

If you have more of an immune response stimulated by this bivalent product the FDA themselves has confessed that an increase in immune response to the self antigens introduces the risk for autoimmune like reactions. Petitioners did not make up this statement, this is a statement of the FDA in a guidance recommendation that was finalized in 2020 regarding gene therapy that the FDA is now in violation of by promoting the lie that a vaccine is to stimulate an immune response knowing that in immune response to this exact product creates autoimmune like reactions!

UK Government data and all kinds of data that has been censored by the FDA and their cohorts within the CDC and WHO absolutely show that these bivalent and gene therapy products that the FDA is authorizing are destroying peoples immune system causing antibody dependent enhancement that the FDA warned people about in 2020 but is now facilitating and causing with these reckless acts of approving a situation to stimulate immune response with gene therapy products in healthy masses of people.

FDA breached duty when they authorized these products with the facts sheet omitting a warning of the risk of autoimmune like reactions and death which is common according to FDA and CDC own phase 4 data.

We rebut the presumption of FDA that "state laws and common law governing the administration of investigational medical products such as informed consent laws are preempted by Federal law "because the laws that demand more requirements of FDA stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress and conflicts with the exercise of federal authority under 564".

In our opinion it is the opposite, because we presume the application of 564 to justify emergency use authorization for use in mass populations of healthy people is in reality thwarting the will of Congress, who wrote into that law the right of review of the circumstances that might warrant revocation of the EUA.
The EUA should be revoked and no composition changes allowed due to large numbers of credible reports of adverse events (number or severity) linked to, or suspected of being caused by, the EUA product.
Courts have stated that the Supremacy Clause of the U.S. Constitution can operate to nullify both state legislative requirements and state common-law duties, but FDA forgot that would require due process to prove in this case of experimenting on healthy babies and people.

Federal law does not supersede FDA's duties under international human rights

obligations. We invoke the right to demand the EUA for all mRNA products

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revoked today based on the phase 4 data in our slides showing death is common and illegally omitted in the fact sheets. Another possible option for consideration today is to review the phase 4 data and review the circumstances and appropriateness of an EUA, including circumstances that might warrant revocation of the EUA. FDA may revise or revoke an EUA if the circumstances justifying its issuance (under section 564(b)(1)) no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.58 Such circumstances may include significant adverse inspectional findings (e.g., when an inspection of the manufacturing site and processes has raised significant questions regarding the purity, potency, or safety of the EUA product that materially affect the risk/benefit assessment upon which the EUA was based); reports of adverse events (number or severity) linked to, or suspected of being caused by, the EUA product; product failure; product ineffectiveness (such as newly emerging data that may contribute to revision of the FDA's initial conclusion that the product "may be effective" against a particular CBRN agent)

FDA has a duty to determine that it is appropriate to protect the public health or safety to revoke all failing mRNA products Authorization rather than to try to prop up a failing product by skipping trials and having no data at all. The data we do have shows death. You CANNOT skip trials and be in compliance with international laws regarding investigational medicines, no matter what errors FDA believes.

We challenge the FDA’s authority and jurisdiction and accuse all members of misconduct now for hiding trial fraud and authorizing EUA’s with 12 year old Maddie De Garay in the hospital.

We presented data from any ongoing testing (e.g., longer term stability data) or other data or information that may change FDA's evaluation of the product's safety or effectiveness and that become available during the period of review or the term of the EUA. Such data should be submitted to FDA when such data become available, and you already had the data, its your own data that death is COMMON. The GAO says CDC and FDA are in violation due to political interference in scientific decision making. We agree, and accuse FDA and all people involved in

these decisions of willful misconduct and demand you cease and desist the experiments on healthy people.

We require your response within the legal limit and as urgently as possible. Please provide your evidence of the safety and efficacy of any mRNA product and proposed composition changes.

In particular we require your duty of substantiation and motivation to explain the necessity, legality, reasonableness and proportionality of the use of these gene therapy products outside clinical trials in health babies of 6 months old and up. The FDA is required by law to meet the burden of proof and once jurisdiction is
challenged.

There is no authority for FDA to proceed in this matter until our
presumptions are either agreed with or rebutted with evidence. Failure to rebut the presumptions and phase 4 evidence herein will result as a settled fact.

Thank you for your prompt assistance in this serious matter and appreciate all of your help working with us to correct FDA's errors.

Arbitrary and more Arbitrary:

"Not only must an agency's decreed result be **within the scope of its lawful authority** , but the process by which it reaches that result must be logical and rational." Allentown Mack Sales & Serv., Inc. v. NLRB, 522 U.S. 359,374 (1998).

NOT WITHIN LAWFUL AUTHORITY:

Further violations in excess of legal authority regarding this error of authorizing the bivalent in healthy masses and babies under EUA will be the Commissioners direct responsibility.

Criminal charges will be promptly filed in international law if the Commissioner continues to allow these criminal and grave errors of law and fact.

THE PROCESS WHICH REACHED THE RESULT WAS NOT LOGICAL OR RATIONAL:

Paul Offitt and another committee member wisely and ethically voted no and one no should have been enough, considering how many conflicted votes said yes, and considering these are baby experiments with DNA that is so risky FDA says its an unreasonable risk to test on more than a few people at once and 15 years of follow up is needed to know what will happen. Now FDA wants to give experiments to babies?

What happened? The Commissioner has a duty to explain if those facts changed and why this gene therapy bivalent is no longer posing an "unreasonable risk" in masses, when in 2018 the guidance was finalized. How is it no longer an unreasonable risk in 2022?

Even more illogical and irrational is that the FDA guidance (ignored in the June 28 2022 VERPSAC meeting) says that "an immune response to self antigens "

This highly contentious administrative act of authorizing the bivalent [non]vaccines is unconscionable, beyond reckless endangerment and violates the treaty on protecting the rights of the children.

FDA DENIED US DUE PROCESS AND BARRELED FORWARD

FDA said June 28, 2022 would be a very contentious meeting, however, despite knowing it was contentious they did not provide due process to go over or debate any facts. We were given 3 minutes to speak and its not enough time to review these types of extensive scientific or legally based facts in reality.

It appears that the FDA did not consider any of the comments it received about this matter as none were posted to Regulations.gov.

What is important to know:

Indeed, the FDA's rushed approval process is itself compelling evidence of arbitrariness. See United States v. NCR Corp., 911 F.Supp.2d 767, 773 (E.D. Wis. 2012) ("Capricious means [the agency] rushed through the process or made a sudden, knee-jerk decision without hearing enough evidence."); TOMAC v. Norton, 193 F. Supp. 2d 182, 195 (D.D.C. 2002) ("The fact that the Bureau made its decision in an apparently rushed fashion may be an indication of arbitrary and capricious action ....").

FDA'S AUTHORIZATION BASED ON "A TOTALITY OF EVIDENCE" IS A FRAUD. OUR EVIDENCE WAS NOT CONSIDERED.

The FDA stated in its press release that the Pfizer vaccine is safe and effective. There is no evidence to support this statement and evidence to the contrary was ignored by FDA. Ignoring the data is quintessentially arbitrary and capricious. See Union of Concerned Scientists v. Nat'! Highway Traffic Safety Comm 'n, No. 19- 1230) 2020 WL 3610284, at 64 (D.C. Cir. June 26, 2020) ("Ignoring evidence that undercuts the agency's judgment is quintessentially arbitrary and capricious") (cleaned up).

Due to the FDA's authorization being based on legal and factual inaccuracies, including those described above and more which are in the attachments, FDA has a duty to find it is appropriate to withdraw the FDA authorizations and approvals of all mRNA products and stay all future framework authorizations without human trials indefinitely.

The FDA Authorization of the gene therapy bivalent and original versions do not accurately reflect the Department's or FDA's thinking because it is inconsistent with the FD&C Act, FDA regulations, and judicial precedent, among other legal authorities, and is not supported by the facts. In addition, the FDA Authorization could result in significant harm to public health by suggesting that unsafe or ineffective drugs could circumvent the drug approval process. Additionally, the FDA Authorization is supported by flawed facts. It cites, for the proposition that the product is safe and effective, only a single observational study of 8 mice, which was unsuccessful, which could lead to an overestimation of the benefit of the experiments and an underestimation of potential and known harms.

The FDA Authorization also erroneously ties immune response to "protection" which is irrational and unscientific, as well as creates unreasonable risk in people who can develop auto immune like disorders according to FDA's current thinking in the gene therapy guidance documents. FDA's regulations on good guidance practices (§ 10.115 (21 CFR 10.115)). Under the APA, FDA may use guidance documents to ''advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.'' Accordingly, FDA's good guidance practice regulations define ''guidance documents'' to include ''documents that relate to . . . enforcement policies.'' (§ 10.115(b)(2)).

Another possible option for consideration today is to review the phase 4 data showing death, and review the circumstances and inappropriateness of this EUA, including circumstances of death and ADE in the trial data and serious trial fraud allegations in court now. Pfizer testified the government knows of trial fraud, all of which is willful misconduct obviously warranting revocation of the EUA.

FDA has a duty under human rights norms and law to revoke an EUA if the revocation is appropriate to protect the public health or safety, which CDC and FDA's own data and court ordered documents conclusively shows death in large numbers are known and maliciously withheld from the public, which is willful misconduct.

C. EnvironmentalImpact

Under 21 C.F.R. §§ 25.30(h) and 25.31 , no environmental impact statement is required.

D. EconomicImpact

There is no direct economic impact from revoking or suspending the amended emergency use authorization discussed in this petition. We can provide a further analysis if requested.

E. Certification

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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