

## **Rebuttal Letter to European Medicines Agency** (EMA) from Doctors for COVID Ethics

By Doctors for COVID Ethics Global Research, April 09, 2021 Doctors for COVID Ethics 1 April 2021 Region: <u>Europe</u> Theme: <u>Media Disinformation</u>, <u>Science and</u> <u>Medicine</u>

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From Doctors for Covid Ethics

Emer Cooke, Executive Director, European Medicines Agency, Amsterdam, The Netherlands

April 1st, 2021

Ladies and Gentlemen,

# FOR THE URGENT PERSONAL ATTENTION OF: EMER COOKE, EXECUTIVE DIRECTOR OF THE EUROPEAN MEDICINES AGENCY

We acknowledge receipt of your March 23 reply to our letter dated February 28, seeking reassurance that foreseeable risks of gene-based COVID-19 "vaccines" had been ruled out in animal trials prior to human use. Our concerns arise from multiple lines of evidence, including that the SARS-CoV-2 "spike protein" is not a passive docking protein, but its production is likely to initiate blood coagulation via multiple mechanisms.

Regrettably, your reply of March 23 is unconvincing and unacceptable. We are dismayed that you choose to respond to our request for crucially important information in a dismissive and unscientific manner. Such a cavalier approach to vaccine safety creates the unwelcome impression that the EMA is serving the interests of the very pharmaceutical companies whose products it is your pledged duty to evaluate. The evidence is clear that there are some serious adverse event risks & that a number of people, not at risk from SARS-CoV-2, have died following vaccination.

1. You concede that the "vaccines", which are more accurately described as investigational gene-based agents, enter the bloodstream but you can obviously provide no quantitative data. In the absence of the latter, any scientific assessment you purport to have undertaken lacks foundation.

2. Your statement that non-clinical studies do not indicate any detectable uptake of the vaccines into endothelial cells lacks credibility. We demand to see the scientific evidence. If not available, it must be assumed that

endothelial cells are targeted.

3. Auto-attack could not have been excluded in animals unless they had been immunologically primed beforehand. We demand evidence that such experiments had been performed. Similar experiments have been undertaken before with previous, unsuccessful candidate vaccines, and fatal, antibodydependent enhancement of disease was observed.

4. We requested scientific evidence, not a vague description of what was purportedly seen in non-valid animal experiments. Your cursory mention of laboratory findings in humans is cynical. In view of the plausible connection between production of spike protein and the emergence of thromboembolic serious adverse events (SAEs), we demand to see the results of D-dimer determinations. As you are aware, D-dimer is a very good test as an aid to diagnose thrombosis.

After delivery of our letter to you on March 1, events followed that debunk your response to our last three queries to an extent that can only be termed embarrassing. As we feared, severe and fatal coagulopathies occurred in young individuals following "vaccination", leading 15 countries to suspend their AZ-"vaccination" program. An official investigation by the EMA into the cases of afflicted younger individuals followed, the results of which were announced by the WHO on March 17, 2021, stating: "At this time, WHO considers that the benefits of the AstraZeneca vaccine outweigh its risks and recommends that vaccinations continue."

What was this decision based upon? The WHO is not a competent body for formally evaluating drug safety. That is explicitly the role of the agency you lead.

In your press release, you disclosed the following information to support your conclusion. You had scrutinized data on two mortally dangerous conditions that had followed within 14 days of "vaccination": DIC, disseminated intravascular coagulation; and CSVT, cerebral sinus vein thrombosis. 5 DIC and 18 CSVT were on record, with a total death toll of 9. Most cases were <55 year-old individuals. 5 DIC and 12 CSVT were under 50 years of age. None were reported as having had serious pre-existing illness.

You stated numbers that "normally" would be expected : DIC <1, CSVT 1.3.

Consequently, for these very rare conditions, a link to vaccination could not entirely be dismissed. However, given that 20 million individuals had been "vaccinated", the benefits were deemed to far outweigh the risks.

But in fact, your Press Release rendered it glaringly apparent that the AZ-"vaccine" does have the potential to trigger intravascular coagulation, that the true risks far outweigh any theoretical benefits, and that any authority with the slightest sense of responsibility must suspend its further use.

1. Regard your incidence numbers for <50 year old individuals in the "vaccinated" versus "normal" population:

CSVT : 12 versus 1.3.

A 9-fold increase is beyond the range of coincidence.

DIC : 5 versus <1.

As we hope you know, DIC neveroccurs out of the blue in healthy individuals. The incidence should not be stated as <1 when in reality it is ZERO.

ACCORDINGLY, THE DIC CASES REPRESENT CONCLUSIVEEVIDENCE THAT THE AZ-VACCINE ALONE CAN TRIGGER INTRAVASCULAR COAGULATION .

2. Assume that 10 million recipients of the "vaccine" were < 60 yrs and this was followed by 9 deaths due to DIC and SVCT. The death toll upon 60 million "vaccinations" would be extrapolatable to 54.

The pandemic hit around 60 million individuals < 60 yrs in Germany.

During the first 6 months it reportedly claimed 52 lives of individuals without pre-existing illness (See <u>this</u>)

Because of the unreliability of PCR testing and because of the completely novel way that deaths 'with covid19' are determined, the value of 52 is an overestimate of the real burden of disease, further weakening your alreadyinadequate claim for risk-benefit.

How, then, can you declare that the benefits of vaccination far outweigh the risks? We demand your reply supported by facts and figures that we will convey to the public.

3. Further considerations expose the truly frightful dimensions of your irresponsible assertion.

CSVT, cerebral venous thrombosis, is always a life-threatening condition that demands immediate medical attention. The number of cases you conceded had occurred can represent just the tip of a huge iceberg. As you must know, the most common symptoms of CSVT are piercing headache, blurred vision, nausea and vomiting. In severe cases, stroke-like symptoms occur including impairment of speech, vision and hearing, body numbness, weakness, decreased alertness and loss of motoric control.

Surely, you are not oblivious to the fact that countless individuals suffered from precisely such symptoms directly following "vaccinations" with all the experimental gene-based agents.

Clot formation in deep leg veins can lead to lethal pulmonary embolisms. Surely you must know that peripheral venous thromboses have repeatedly been reported following "vaccinations" with all the experimental gene-based agents

Microthromboses in the lung vasculature can lead to misdiagnosis of pneumonia. In combination with false-positive PCR (with high cycle thresholds), these will then be registered as COVID 19 cases. Surely you must know that this scenario has probably repeatedly taken place following "vaccinations" with all the experimental gene- based agents.

In all events, extensive thrombi formation can lead to consumption of platelets and coagulation factors, resulting in hemorrhagic diathesis and bleeding at all possible locations. Surely you must know that profuse skin bleedings have repeatedly been observed following "vaccinations" with all the experimental gene-based agents.

Given that there is a mechanistically plausible explanation for these thromboembolic

adverse drug reactions (TE ADRs), namely that the gene-based products induce human cells to manufacture potentially pro-thrombotic spike protein, the reasoned & responsible assumption must now be that this may be a class effect. In other words, the dangers must be ruled out for all emergency-authorised gene-based vaccines, not merely the AZ product.

We urge you to adopt this stance unless and until there is data providing high clinical confidence to the contrary. We are very willing to liaise with the Agency in order to help craft a focussed pharmacovigilance plan to accomplish this goal. With the above in mind, we hope you are aware that all thrombotic events can be rapidly diagnosed by measurement of D-Dimers in blood. And that good medical practice imperatively demands that attempts are undertaken to diagnose CSVT in any and every patient, young or old, presenting with the typical signs and symptoms following "vaccination".

Given the potential for adverse effects, potentially fatal ones, it is completely inappropriate and unacceptable that EMA permits these products, which hold only emergency use authorisations, to be administered to younger (<60y) people who are healthy, as they are at unmeasurable risks from SARS-CoV-2.

Not to make this explicit is, in our view, a reckless stance to have taken in the first place and doubly so now.

Of equal importance, you are bound by duty to investigate whether reasons exist for the waves of deaths that have occurred following "vaccination" of elderly residents in care and senior homes. Or are you asserting that dangers of "vaccine"-derived thrombotic events are limited to younger individuals? If not, restricting their use solely in one age group — as decided upon in Germany — equates with nothing less than monstrous, condoned genocide of the other.

In closing, failure to inform "vaccine" recipients of the risks and negligible benefits outlined here represents serious violations of medical ethics and citizens' medical rights. Those violations are especially grave as all the risks we describe can be expected to increase with each re-vaccination, and each intervening coronavirus exposure. This renders both repeated vaccination and common coronaviruses dangerous to young and healthy age groups, for whom — in the absence of "vaccination" — COVID-19 poses no substantive risk.

Such is the real risk-benefit analysis of the COVID-19 "vaccines". Either the EMA lacks the subject-matter expertise to appreciate the molecular science of this reality, or it lacks the medical ethics to act accordingly.

At best, we regard the EMA's complacent stance on vaccine dangers to be symptomatic of the fact that, under the prevailing politico-medical response to COVID-19, medical ethics has migrated from the consulting room to a geopolitical stage. Faced with a medical problem, mass-medical intervention has seen the practice of medicine taken from doctors' hands.In this politicized context, corporate and political actors may consider themselves free from ethical constraints, operating unbound by a medical code of ethics, unlike medical doctors. All actors, however, are bound by the Nuremberg Code.

The Nuremberg Code prohibits human experimentation of the very kind being endorsed and defended by the EMA. Even under the terms of their own original FDA authorization, COVID-19 vaccines are deemed "investigational" and their recipients "human subjects", who are, by definition, entitled to informed consent. See <u>this</u>.

Misleading populations into accepting investigational agents such as the gene-based COVID-19 "vaccines", or coercing them through "vaccine passports", constitutes clear and egregious violations of the Nuremberg Code. The Nuremberg Code mandates voluntary informed consent "without the intervention of any element of force, fraud, deceit [or] duress". See <u>this</u>.

In other words, citizens have the right under the Nuremberg Code and related protections not to be subject involuntarily to medical experiments. It is clear that these experimental agents should be CONTRA-INDICATED in individuals not at elevated risk of serious illness & death if infected by SARS-CoV-2. Furthermore, the use of the experimental agents must also be withheld in the elderly population until a risk-benefit assessment has been properly conducted. In any event, the vaccine label must be revised to reflect the recently emerged serious adverse events addressed here.

We remind the EMA that Nuremberg violations constitute crimes against humanity under the Geneva Convention. Crimes against humanity are deemed "the worst atrocities known to mankind", and are prosecuted under the Rome Statute of the International Criminal Court. See <u>this</u>.

Given the hundreds of millions and eventually billions of people who may be coerced into accepting these agents, the EMA, in persistently shrinking from open debate and the truth, will be seen by lawyers and historians as having actively assisted in crimes against humanity, with the full weight of the implications to all involved. We demand thatyou engage openly with us to ensure that the public have an objective understanding of the clinical risk profile of these gene-based interventions.

You understand that coercive pressure is being placed on citizens to receive COVID-19 vaccines, which are experimental medical treatments. Your responsibility to those citizens includes ensuring that they are informed of the adverse event risks of every such treatment. To date you have failed to do so, and have instead misled the public on the reality of the "vaccines'" risk-benefit profile.

If you continue to conceal the truth, efforts will be made to bring this to light and to see that justice is done. For the sake of the injured and the dead, and to protect further lives from similar fates.

#### Notice

For the avoidance of doubt, if your regulatory body does not immediately suspend its "emergency" recommendation of potentially dangerous inadequately tested gene-based "vaccines", while the matters which we have highlighted to you are properly investigated, we hereby put the European Medicines Agency on notice of being complicit in medical experimentation, in violation of the Nuremberg Code, which thereby constitutes the commission of crimes against humanity.

Furthermore, it is your indirigible duty as a regulatory body to ensure that all doctors worldwide are advised that they are taking part in medical experimentation via "vaccination" programmes, whether wittingly or unwittingly, with all the legal and ethical obligations that such involvement entails.

This email is copied to the lawyer Reiner Fuellmich. It is also copied to Charles Michel,

President of the Council of Europe, and to Ursula von der Leyen, President of the European Commission.

Yours faithfully,

**Doctors for Covid Ethics** 

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