Children's Health Defense EUROPE

To the
European Commission
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BELGIUM

- in the person of the **President**
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- in the person of the **Commissioner for Health**
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To the
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➢ To the
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To the
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To the
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- in the person of the **Director General**
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URGENT OSTENSION / F.O.I.A.
according to article 15 TFEU, article 41 and 42 EU Charter of Fundamental Rights, article 22 and subsequent Law 241/1990 and Legislative Decree (D.Lgs.) no. 33/2013

In my capacity as a member of the Executive Board of Children's Health Defense Europe, based in Belgium, 1348 Louvain-la Neuve 55/307 Grand Rue, and with respective proxy conferred by the Executive Board (see attachment 1), as well as in my capacity as an Italian/European lawyer admitted also to the Supreme Courts and with seat in I-39100 Bolzano viale Stazione 7 (see attachment 2), who defends Italian health care workers against the imposition of treatment with the so-called Covid-19-"vaccines" (for example before the Administrative Tribunal (TAR) Lazio-Rome in the legal proceeding pending with register number 5114/2022) and parents against the treatment (requested by the other parent) of minors with the so-called Covid-19-"vaccines" (for example before the Court of Appeal in Bolzano in the legal proceeding with register number R.G. 15/2022) and who has sworn on the respect and protection of the Constitution of the Italian Republic (and, therefore, of the Charter of Fundamental Rights and Freedoms of the EU as well as the European Convention on Human Rights and every supra-national law guarantor of Human Rights), and finally in my quality of an over 50-years-old Italian citizen and mother born on 10th September 1966 (HLZRNT66P50A952M – see attachment 4), and therefore in my quality of an Italian/European citizen personally subjected according to article 4-quater D.L. n. 44/2021 to the imposition of the treatment with the so-called Covid-19-"vaccines" and, therefore, recipient of sanction under article 4-sexies D.L. n. 44/2021

WHEREAS

- Our organization Children's Health Defense, chaired worldwide by Robert Kennedy jr., is committed to the protection of children's health also in Europe/Italy.
- The European Commission by decisions of 21.12.2020 and 06.01.2021 respectively has conditionally authorized the placing on the market of the two so-called mRNA "vaccines" against Covid-19, Comirnaty by Pfizer/BioNTech and Spikevax by Moderna, first for adults and later also for minors. Currently the two mRNA vaccines are conditionally authorized for inoculation in minors from the age of 5 years (Comirnaty by Pfizer/BioNTech) and 6 years (Spikevax by Moderna) upwards, respectively.
- The respective conditional marketing authorization refer to Commission Regulation (EC) No. 507/2006 of 29 March 2006 on the conditional marketing authorization of medicinal products for human use as well as to the Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorization and supervision of medicinal products for human use and

establishing the European Medicines Agency, and expressly mention that **the two substances conditionally authorized for placing on the market contain mRNA (modified nucleoside level)**.

- **The two so-called Covid-19 "vaccines", Pfizer-BioNTech's Comirnaty and Moderna's Spikevax, contain a molecule called messenger RNA (mRNA) with instructions to produce a protein coded by SARS-CoV-2, the virus responsible for Covid-19** (see AIFA's website https://www.aifa.gov.it/comirnaty https://www.aifa.gov.it/moderna).

- **As shown below, there is plausible and experimental evidence that the mRNA contained in Pfizer/BioNTech's substance Comirnaty can retrotranscribe into DNA and can insert itself into the human genome. Given that Moderna's substance Spikevax is very similar to Pfizer/BioNTech's Comirnaty, it is assumed that what has already been shown in scientific studies regarding Comirnaty also applies to Spikevax.**

- Nucleosides form the basis of RNA. RNA is a nucleic acid and is essential for protein synthesis. The construction plans for proteins in the human body are stored in the genome, in the DNA in the nucleus of the cell, where they are transcribed into mRNA. Once the mRNA is formed with the construction plan/model for the protein, the mRNA leaves the cell nucleus. Outside the cell nucleus, ribosomes read this construction plan and build the respective protein. There are more than a hundred thousand mRNA molecules simultaneously in a human cell. The ribosomes are only able to read the information during a restricted period, as mRNAs are usually rapidly degraded.

- In the case of "mRNA vaccines", however, the mRNA is synthetically constructed in the laboratory. According to what has been known for many months now, **contrary to what was officially declared to the population by the institutions responsible for the "vaccination" campaign, this synthetic mRNA does not remain in the muscle of the arm where inoculation takes place, but can be dispersed throughout the body, even crossing the blood-brain barrier** (*Nature Neuroscience*, *The S1 protein of SARS-CoV-2 crosses the blood-brain barrier in mice, Elizabeth M. Rhea et al*) and has been found in the bodies of people treated with these substances even months after inoculation. After some particles have been absorbed and spike protein has been produced by them, this spike protein may facilitate the passage of other "vaccine" particles into the brain (*A Case Report: Multifocal Necrotizing Encephalitis and Myocarditis after BNT162b2 mRNA Vaccination against Covid-19* https://www.preprints.org/manuscript/202206.0308/v1).

- **There is now not only great concern, but also evidence that inoculated synthetic mRNA can be back transcribed into DNA, and that these DNA copies can insert themselves into the chromosomal DNA of human cells. Therefore, genetic information from RNA can contaminate and alter the human genome** (*Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b" in vitro in human liver cell line, Markus Alden et al*).

- The scientific opinion of two microbiologists and a pulmonologist (Dr. Michael Palmer, Prof. Dr.med. Sucharit Bhakdi and Dr.med. Wolfgang Wodarg; attachment 3), shows that **reverse transcription from RNA into DNA is a mechanism that has been known for many decades! So, nothing new and, above all, nothing that can be ruled out. On the contrary! The risk of reverse transcription, of course, increases with each additional inoculation.**
- **In its respective determination to extend the application of these two investigational substances also to minors aged 5 years and over (for Comirnaty of Pfizer/BioNTech) and 6 years and over (for Spikevax of Moderna) respectively, AIFA expressly refers to Regulation (EC) no. 1394/2007 on advanced therapy medicinal products as well as to the favorable opinion of the Technical and Scientific Committee issued at its extraordinary meeting of 31 May 2021 (for Comirnaty of Pfizer/BioNTech) and of 26 July 2021 (for Spikevax of Moderna).**
- The two mRNA substances Comirnaty and Spikevax have been formally "categorized" as "vaccines" - even though, as the facts show, they do not fulfil the function of a vaccine. And evidently they are substances which, on the basis of a **labelling of mere convenience**, have been formally categorized as "vaccines", irrespective of their real nature, without having such a function.
- Apart from the obvious mislabelling, **these two substances should, in any case, have been tested for genotoxicity, carcinogenicity and mutagenicity**, for the following reasons.
- Although "vaccines against infectious diseases" have been excluded from the definition of "gene therapy medicinal products", in consideration of the real nature and function of the two substances Comirnaty and Spikevax (which, as set out above and documented here, can lead to an alteration of the human genome, with retro-transcription of mRNA modified at the level of nucleosides), and having noted, therefore, the erroneous "labelling" of the substances Comirnaty and Spikevax, it is absolutely necessary to take into consideration what the European legislator has provided for gene therapy medicinal products.
- For the purpose of **defining gene therapy medicinal products**, **article 2 Regulation (EC) n. 1394/2007** refers to **Part IV of Annex I of Directive 2001/83/EC of the European Parliament and of the Council on the community code relating to medicinal products for human use**

  Pursuant to point 2 of Annex I Part IV of Directive 2001/1983 (definitions 2.1)

  "Gene therapy medicinal product means a biological medicinal product which has the following characteristics:

a) it contains an active substance which contains or consists of a ***recombinant nucleic acid used in or administered to human beings with a view to regulating,*** *repairing, replacing,* ***adding*** *or deleting* ***a genetic sequence[1];***

b) its *therapeutic,* ***prophylactic*** *or diagnostic* ***effect relates to the recombinant nucleic acid sequence it contains or to the product of the genetic expression of this sequence'.***

- **Given that the two substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna contain recombinant nucleic acid (RNA) and this can re-transcribe into DNA with modification of the human genome** (see above), **it is clear that these two substances can develop a genetic function that in fact falls within the definition of gene therapy drugs.**
- As regards the specific requirements for gene therapy products, the EU legislator also provides in Annex I Part IV Directive 2001/83 that

"4.2.1.... the duration of the nucleic acid sequence function and the proposed dosing regimen in the clinical studies shall be provided

4.2.2. Pharmokinetics:

a) Biodistribution studies shall include investigation on persistence, clearance and mobilization. Biodistribution studies shall additionally address the risk of germline transmission.

b) Investigation of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment...

4.2.3. Toxicology

(a) Toxicity of the finished gene therapy medicinal product shall be assessed... ... the in vivo effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated...

c) Repeated dose toxicity studies shall be provided when multiple dosing of humen subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies, depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided.

d) Genotoxicity shall be studied...

e) Carcinogenicity shall be studied...

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[1] With the injection of the so-called Covid-19-"vaccines", Comirnaty and Spikevax, a genetic sequence is added and the product's effect relates to the genetic expression induced by the recombinant nucleic acid sequence it contains.

f) Reproductive and developmental toxicity. Studies on the effects on fertility and general reproductive function shall be provided. Embryo-fetal and perinatal toxicity studies and germ line transmission studies shall be provided....

-g) Additional toxicity studies

- Integration studies: integration studies shall be provided for any gene therapy medicinal product ... For gene therapy medicinal products not expected to be performed[2], if biodistribution data indicate a risk for germline transmission.

- Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied. "

In section 5.1. Specific requirements for all advanced therapy medicinal products is provided for:

"5.1.7 A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan. "

In section 5.2. Specific requirements for gene therapy medicinal products is provided for:

"5.2.1. Human pharmacokinetic studies

Human pharmacokinetic studies shall include the following aspects:

a) Shedding studies to address the excretion of the gene therapy medicinal products;

b) Biodistribution studies;

c) Pharmacokinetic studies of the medicinal product and the gene expression moieties (i.e. expressed proteins or genomic signatures).

5.2.2. Human pharmacodynamic studies

Human pharmacodynamic studies shall address the expression and function of nucleic acid sequence following administration of the gene therapy medicinal product.

5.2.3. Safety studies

Safety studies shall address the following aspects: ...

d) neoplastic proliferation due to insertional mutagenicity. "

- **<u>The function of the so-called "Covid-19 vaccines" is exactly as described by the EU legislator for the definition of gene therapy medicinal products</u>.**

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[2] There is no reason which could exclude for this kind of products, without doing any studies, the insertion in the human DNA.

- **According to recital (10) of Regulation (EC) No 1394/2007, *'The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field'.***
- **In recital (10) of Regulation (EC) No 1394/2007, the Community legislator provided also that *'In addition, the Committee for Advanced Therapies should be consulted for the evaluation of any other medicinal product, which requires expertise falling within its area of competence'***
- **It should be pointed out that the recitals of the Regulation (EC) no 1394/2007, obviously, although they incomprehensibly don't appear on the current consolidated version, are still in force, because they never were abolished or modified by the EC regulations which partially modified the Regulation (EC) No. 1394/2007 (Regulation UE n. 1235/2010 and Regulation UE 2019/1243), and because, obviously, these recitals are the basic considerations of the European Legislator (Parliament and Council) regarding the medicinal products for advanced terapies.**
- **Given that the so-called mRNA "Covid-19vaccines" (Pfizer/BioNTech's Comirnaty and Moderna's Spikevax) have exactly the function of a gene therapy drug (the inoculated mRNA is intended to cause the body-cell to produce the spike protein and thus trigger cellular expression), and apart from the fact that they should have been subject in their entirety to the more restrictive provisions for advanced therapy products (since they do not actually have the function of traditional vaccines for the prevention of infectious diseases), they should (as provided for in recital 10 of Reg. EC No 1394/2007) in any case have been submitted for evaluation to the Committee for Advanced Therapies, since only that Committee, within the EMA, guarantees, or at least should guarantee, that specific competence which is necessary to evaluate substances that affect cell physiology because they have a genetic function.**
- Irrespective of the necessity of submitting Pfizer/BioNTech's Comirnaty and Moderna's Spikevax, although inappropriately referred to as "Covid-19-vaccines", to the Committee for Advanced Therapy Products for evaluation, it must be considered that under ***Directive 2001/83/EC Annex I (Analytical, Toxico-pharmacological and Clinical Standards and Protocols in respect of the testing of medicinal products) Part 3 (toxicological and pharmacological tests)*** the Community legislator has provided for the following:

  "I. Introduction. The information and documents to be submitted with the application for authorisation ... shall be provided in accordance with the following requirements. ***Member States shall ensure that safety tests are carried out in accordance with the principles of good laboratory practice laid down in Council Directives 87/18/EEC and 88/320/EEC.***

  Toxicological and pharmacological tests must show:

a) *The limits of the product's toxicity, its possible harmful or undesirable effects under the conditions of its intended use in humans,* ***effects that must be assessed according to the pathological state****;*

b) *The pharmacological properties of the product in relation to its prescribed use in humans in terms of dosage and pharmacological activity. All results must be reliable and suitable for generalisation. .....*

3. In the case of biological medicinal products such as immunological medicinal products ... the requirements of this Part shall be adapted, if necessary, to the individual products: for this purpose the applicant shall justify the test program performed.

The following elements will be taken into account when defining this program:

- *All tests for which repeated administration of the product is envisaged must take into account possible induction of or interference by antibodies;*
- *Consideration of reproductive function, embryo-fetal and perinatal toxicity, mutagenic and carcinogenic potential ...*

5. ***The toxicity and pharmokinetics of an ingredient used for the first time in pharmaceuticals must be examined.***

II. Performance of the tests A. Toxicity ... 2. Repeated dose toxicity ("subacute" and "chronic" toxicity)

Repeated-dose toxicity tests serve to highlight functional and/or anatomo-pathological changes following repeated administration of the substance .... Generally speaking, it is useful for two tests to be carried out: one medium-term ... and one long-term, the duration of which depends on the conditions of clinical application. ....

B. Examination of reproductive function

If the results of the other experiments carried out reveal evidence of harmful effects on offspring or alterations in male or female fertility, reproductive function must be adequately controlled. ...

D. Mutagenic power

The study of mutagenic potency serves to reveal the changes produced by a substance on the genetic material of individuals or cells with the effect of making their successors permanently or hereditarily different from their predecessors. This study is required for any new substance.

The number, types and evaluation criteria of the results will be determined taking into account the state of scientific knowledge at the time of submission."

- **From the scientific report signed by Michael Palmer, Sucharit Bhakdi and Wolfgang Wodarg (*Expertise on the genotoxic risks of the Pfizer Covid-19 vaccine* – attachment 3), it appears that there was very clear scientific data,**

already dating back decades, that should have led to the risk of the genotoxicity of the so-called mRNA Covid-19-"vaccines" (such as Pfizer/BioNTech's Comirnaty and Moderna's Spikevax) being taken seriously.

The scientific opinion of the experts states verbatim

"1. EMA dismissed the genotoxicity risks of the Pfizer COVID-19 vaccine based on outdated science

In the EMA assessment report on the Pfizer COVID-19 vaccine, we find the following succinct statement (1, p.50):

No genotoxicity studies have been provided. This is acceptable as the components of the vaccine formulation are lipids and RNA that are not expected to have genotoxic potential.

Apparently, EMA's experts were assuming that RNA in general will not affect the integrity of the host cell genome. The first exception to this rule has been known since 1970, when oncogenic retroviruses were found to carry a reverse transcriptase activity that could copy the viral RNA genome into DNA, which could then insert into the host genome. The realisation that eukaryotic cells themselves have similar reverse transcriptase activities came one and a half decades later, but It could hardly be considered a novelty in 2020.

... 1.4 Summary. Even though this had not yet been experimentally demonstrated when EMA released its assessment report, there was ample precedent to suggest the strong possibility that DNA copies of the vaccine mRNA would be produced and inserted into the cellular genome. Rather than waving away this risk as it did, EMA should have obliged Pfizer to carry out the necessary studies for excluding the risk before green-lighting authorization.

1. ***The current state of the evidence***

As of this writing, substantial new evidence has accumulated regarding the genetic risks posed by the Pfizer COVID-19 vaccine.

1.1. DNA copies of the Pfizer COVID-19 vaccine mRNA are inserted into the host cell genome. Already in 2021, it was demonstrated that partial DNA copies of the genomic RNA of the SARS-CoV-2 virus can insert into the cellular DNA of infected cells. .... Of even greater and more immediate relevance is the recent demonstration that the mRNA contained in the Pfizer-COVID-19 vaccine itself can integrate into the cells of a human-derived liver cell line. ...

1.2. Long-term expression of the spike protein. While it had initially been assumed that expression of the spike protein after vaccination would be of short duration and largely limited to the injection site, it has since become clear that it is neither. A recent study by Röltgen et al. detected both the spike protein and mRNA encoding it within lymph nodes of vaccinated people at 60 days after the most recent injection. This surprisingly long persistence is difficult to reconcile with the notion

that the expression is only driven directly by the injected recombinant mRNA. ... We must therefore take the possibility very seriously that the gene encoding the spike protein is perpetuated and continuously expressed in vivo by way of DNA insertion. ....

2.4. Summary. The reverse transcription of the Pfizer COVID-19 vaccine mRNA into DNA and the integration of the DNA copy into the genome of host cells has been directly demonstrated in vitro, and the spike protein's documented long-term persistence in the bodies of vaccinated persons suggests that DNA integration may occur in vivo and perpetuate the expression of the spike protein. Moreover, the ovaries accumulate high levels of the vaccine, which implies that oocytes may be exposed to significant amounts of the recombinant mRNA.

3. Known and plausible risks that arise form the recently established genomic insertion of Pfizer Covid-19 vaccine

The results reported by Alden et al., even though preliminary in some respects, pose some very serious questions that can no longer be ignored by the EMA and other regulatory authorities...

3.3. Summary. Integration of the mRNA sequences into somatic cells is likely and implies a risk of cancer and of autoimmune disease. Moreover, the risk of germline integration, resulting in transgenic offspring, cannot be denied. These risks must urgently be addressed through in-depth animal studies. Meanwhile, the authorizations based on EMAS's demonstrably inadequate scientific assessment must urgently be revoked.

4. Genotoxic potential of lipid nanoparticles ...

4.2. Indications of genetic damage due to cationic lipids in Moderna's mRNA vaccine. According to the EMA assessment report on the Pfizer COVID-19 vaccine, this manufacturer did not provide any experimental data on the potential cytotoxicity of their lipid mixture (and the EMA committed a grave error in letting them get away with it). In contrast, Moderna, in its own application to the EMA, did supply some experimental data. ... In conclusion, while the data provided by Moderna are incomplete, they strongly suggest that their SM-102 lipid is indeed genotoxic. This agrees with prior observations of genotoxicity associated with similar cationic lipids in liposomes, reviewed for example by Inglut et al. Unless proof positive to the opposite is provided, it must be assumed that the same also applies to Pfizers's ALC-315 lipid. ....

4.4. Summary. Apart from the mRNA, the cationic lipid contained in the Pfizer COVID-19 vaccine also poses risk of genotoxicity. The EMA erred in neglecting this risk and not insisting on its rigorous experimental assessment by the manufacturer.

5 EMA's evaluation of the Pfizer COVID-19 vaccine did not comply with EU regulations…

5.4. Summary. ***The EMA has failed in its duty to protect the EU population from the inherent genotoxic risks of the Pfizer COVID-19 vaccine. Even without understanding the relevant science at the depth we should expect of it, the EMA could easily have avoided this grave mistake by adhering to the letter of existing EU regulations on medicinal products in general and on "advanced therapies" in particular. "***

For all the above, the undersigned in her functions/qualifications as indicated above

ASKS

according to the article 15 TFEU, article 41 and 42 EU Charter of Fundamental Rights, article 22 and subsequent Law 241/1990 and Legislative Decree (D.Lgs.) no. 33/2013 to all addressees of this request, **the urgent disclosure with release of a copy of:**

1. **the documentation proving the involvement of the Committee for Advanced Therapies in the respective procedure of the conditional marketing authorization of the two mRNA substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna, as well as the opinion issued by the Committee for Advanced Therapies on the aspect of genotoxicity, the associated risk of carcinogenicity and mutagenicity of the two substances, and**
2. **the documentation proving the evaluation and respective outcome of the genotoxicity, carcinogenicity and mutagenicity of the two substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna.**

The addressed Italian institutions (Ministry of Health, Istituto Superiore della Sanità and AIFA), in addition to the above, are also asked to disclose with the release of a copy of:

3. **the opinion of the Italian Government's Technical and Scientific Commission on the genotoxicity, carcinogenicity and mutagenicity of the two mRNA substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna.**

Considering the enormous risk that the entire population, and primarily minors, run with the repeated inoculation of experimental substances that can potentially mutate the human genome, **it is with the utmost urgency necessary the absolute transparency** in point to the carried out (or not carried out) evaluation (by the EMA and the European Commission in general, and by the Scientific Technical Committee established by Decree of the Head of the Civil Protection Department 371 of 5.2.2020 as well as by the Italian Ministry of Health, the AIFA and the Istituto Superiore della Sanità) of the risk of genotoxicity, carcinogenicity and mutagenicity related to the (repeated) inoculation of the two mRNA-substances (Comirnaty by Pfizer/BioNTech and Spikevax by Moderna) for public health, i.e. Italian/European citizens.

In view of the very serious danger (periculum in mora) of an irreversible enormous damage to the public health a reply is requested with the utmost urgency.

Every further day that passes during which substances that can alter human DNA are administered, often even under duress (see Italy with the mandatory Covid-19 "vaccination" for health-care workers, for the over-50s under Decree Law 44/2021 and others and decisions taken by Italian judges against the will of the parents of minors), increases the very serious and totally unacceptable threat to public health and to the health of every single Italian/European citizen.

This request is submitted in both English and Italian versions. For the request directed to the European Commission and the EMA (and the respective persons responsible) in case of any inconsistencies the English version shall prevail, whereas for the request directed to the Italian authorities and the respective persons responsible the Italian version shall prevail.

Subject to any useful legal action.

Louvain-la-Neuve / Bolzano / Milan 22 July 2022

Avv.DDr. Renate Holzeisen

Digitally signed by: Renate Holzeisen
Date: 22/07/2022 10:14:31

Annexes:

1. Proxy given by CHD board;
2. Avv.DDr. Renate Holzeisen, lawyer's identity card;
3. Expertise on the genotoxic risks of the Pfizer Covid-19 vaccine, Dr.med. Michael Palmer, Prof.Dr.med. Sucharit Bhakdi, Dr.med. Wolfgang Wodarg;
4. Avv.DDr. Renate Holzeisen, identity card.