Scientific Lay Summary to Support the Letter of Concern to Prime Ministers and Governing Bodies of the Nordic and Baltic Countries and the United Kingdom.

Prepared by the NORTH Group (info@northgroup.info):

Our letter of concern, co-signed by physicians, scientists, politicians, and other qualified professionals calls for the immediate suspension of COVID-19 modified mRNA vaccines and an investigation into the presence of excessive levels of residual DNA in multiple vials, which is a serious, unquantified risk to human health.

This lay summary explains the background to these concerns.

1. The mRNA vaccines do not stop the transmission of COVID-19

The European Medicines Agency (EMA) stated in an official response (EMA/451828/2023) to eight Members of the European Parliament that "COVID-19 vaccines have not been authorized for preventing transmission from one person to another." In addition, "EMA´s assessment reports on the authorization of the vaccines note the lack of data on transmissibility."[1]

During the height of the pandemic citizens were compelled to accept Pfizer and Moderna's mRNA products to protect others from COVID-19[2]. This was a lie and despite serious side effects being evident in clinical trial data[3], lamentable safety and efficacy profiles, extreme pharmacovigilance safety signals reported worldwide, and thousands of peer-reviewed articles documenting harms associated with mRNA vaccines, these products continue to be recommended and administered.

In addition, proven prevention strategies were ignored, ineffective practices were promoted, and alternative treatment modalities for COVID-19 were suppressed. This led to billions of people worldwide, including children not at risk of COVID-19, being administered with mRNA products unnecessarily.

Considering that residual DNA has now been discovered in five independent labs around the world, and at levels greatly exceeding the threshold deemed safe by medical product regulatory agencies, regulators under the direction of governments have an opportunity to recall these products from the market and complete an investigation into their contents. Potential harms to unsuspecting and uninformed recipients of these products must be limited.

The risks highlighted in the sections below support a call for the immediate withdrawal of mRNA-based products. In addition, the use and development of all products based on the mRNA technology should be halted until the results of a fully independent and transparent forensic investigation have been made public and these products have been shown to be free from risks, including damage to human DNA (genotoxicity).

2. COVID-19 modified mRNA vaccines resulted in an unprecedented level of reported side effects and deaths.

Real-world data collected by national competent authorities and distributed to EMA shows the presence of statistically significant safety signals including a high degree of variability in reported side effects for different batches of COVID-19 modified mRNA vaccines[4-6]. These signals were consistent between countries and were particularly evident in the first few months of vaccine roll out, even though EMA suppressed this information by keeping statutory periodic safety reports (PSURs) confidential until 2023[7].

Published, peer-reviewed research on adverse event reporting data from Denmark[4], Sweden[5], and the USA[6] has revealed batch-dependent side effects associated with Pfizer's COVID-19 mRNA vaccines. Data from the Czech Republic[8] has shown the same pattern of variable batch-dependent side effects for both Pfizer and Moderna's products. Pfizer informed the EMA in August 2021 about the same batch dependency of side effects[9]. This clearly suggests that the products were not manufactured to a consistent standard and that some individuals were exposed to a far greater risk of vaccine-associated side effects than others.

Usually, the sheer number of cases of reported side effects and the entirely atypical cases of deaths occurring in temporal proximity to vaccine administration[10-13] would have led to immediate withdrawal of the products from the market. However, this did not occur and points towards a systematic and collusive failure to recognize COVID-19 vaccine harms. Since the regulatory authorities charged with pharmacovigilance are also those responsible for the approval process, they are conflicted. This makes a clear case as to why independent scrutinization of the regulator's role in this process is essential.

3. COVID-19 modified mRNA vaccines are contaminated with high and variable levels of artificial bacterially derived DNA.

On September 20th, 2024, Australian Member of Parliament (MP) Russell Broadbent, wrote to the Australian Prime Minister Anthony Albanese describing compelling evidence of excessive levels of residual plasmid DNA in vials of Moderna and Pfizer's mRNA vaccines distributed in Australia.

The letter, co-signed by a group of 26 doctors, scientists, and other qualified professionals from Australia[14] pointed to the risk of residual DNA impurities being contained in lipid nanoparticles (LNPs), which creates a serious but unquantified risk for damage to human DNA, genetic instability, hereditary changes, cancer, and immune system disorders etc. Mr. Broadbent called on Prime Minister Anthony Albanese to initiate an immediate and urgent investigation and suspension of Pfizer and Moderna's COVID-19 modified mRNA vaccines, until the broader implications of these findings had been determined.

Mr. Broadbent further highlighted the responsibility of both the Australian Therapeutic Goods Administration (TGA) and the Department of Health in having ignored repeated warnings by experts and continuing to distribute these products despite the undetermined risks to the public. This also applies to Europe and the Nordic and Baltic regions and the UK.

A second letter co-signed by 52 international doctors, scientists, and other qualified professionals[14] was sent by Mr. Broadbent to Prime Minister Albanese on 25th September 2024 highlighting multiple attempts by prominent scientists to warn the TGA of the risks, which have been disregarded since early 2021. Attention was also drawn to possible relevance of the Biosecurity Act 2015, with a recommendation that the Minister for Agriculture initiate a Biosecurity Import Risk Analysis, potentially leading to the suspension of these products due to the risks they pose to human health. The same type of risk analysis needs to be carried out in all countries.

Action by a local council

On October 11th, 2024, the local government of Port Hedland, Western Australia voted to suspend Moderna's and Pfizer's COVID-19 vaccines until they have been tested for excessive levels of foreign DNA. They also decided to distribute information to all general practitioners in the Port Hedland area, urging them to share this information with patients who wish to receive the mRNA vaccines in question, Furthermore, the council voted to inform the other 537 local councils in Australia about the evidence for prohibitive levels of DNA impurities in the modified mRNA products.

Nature of the DNA contamination

The basis for Mr. Broadbent's letter to the Prime Minister was an independent investigation conducted by Dr. David Speicher, an independent researcher from the University of Guelph, Canada, who measured the amount of DNA in three vials of COVID-19 modified mRNA products retrieved from cold storage facilities of registered Australian health practitioners (see Appendix A).

Dr. Speicher found that all vials contained measurable levels of residual plasmid DNA and exceeded the regulatory limit of 10 ng/dose set by the TGA and WHO[15] by 7.8-145 times.

The DNA identified in the vials is artificial and foreign genetic material, copied and expanded in *E. coli* bacteria and used as a template to produce the mRNA coding for the Spike protein. However, this DNA should have been degraded and effectively removed from the mRNA component prior to the encapsulation of purified mRNA into LNPs. Critically, the artificial plasmid DNA contains sequences that allow it to replicate in both bacteria, and in the case of Pfizer's vaccine; in human cells, thereby posing a significant but entirely unnecessary health risk [Appendix A, 16-17].

Alarming presence of undeclared, high-risk sequences in the residual plasmid DNA.

Crucially, Dr. Speicher also confirmed the presence of a specific DNA sequence derived from Simian Virus 40 (SV40) in the Pfizer vaccine. This piece of DNA (known as the SV40 promoter-enhancer) was not declared to the regulatory authorities as being part of the vaccine manufacturing process[18-19]. Had Pfizer declared this component in their manufacturing process, it is likely that this would have led to greater scrutiny, since the SV40 virus is associated with cancer[20-22] and the SV40 promoter-enhancer itself has potent biological activity. Hence, the presence of this sequence in the Pfizer product presents a much more serious risk than the presence of only excessive DNA.

This SV40 promoter-enhancer is typically used in applications such as genetic engineering or gene therapy to control how much of an mRNA and the protein that is made from the mRNA is 'turned on'. However, once this DNA crosses the cell membrane, as would happen within an LNP, this SV40 enhancer sequence can target the associated DNA to the cell nucleus, where may cause changes to human DNA[23-24].

The SV40 enhancer can facilitate the integration of associated sequences into human DNA within cells of the human body and the SV40 sequence would augment the likelihood of such an integration event[20-21, 25].

Dr. Speicher's findings confirm multiple studies that also identified the SV40 promoter-enhancer sequence in DNA within Pfizer's products[16-17, 26-27]. The risks raised by these undeclared components of the COVID-19 modified mRNA products have not been investigated and have not been declared to recipients. This is inexcusable.

Risk of integration into the human genome.

LNPs are known to be taken up by all organs of the body including the brain, heart, liver, ovaries, and testes and therefore can transfer their contents to the cells of these organs[28-29]. Hence, the injected material does not necessarily remain at the site of intramuscular injection as was widely claimed.

Kevin McKernan and Professor Ulrike Kämmerer have provided preliminary findings that addition of Pfizer's COVID-19 vaccine to a human ovarian cell line (OvCar3) can result in integration of the residual plasmid DNA into human DNA[30]. Furthermore, Dr. Phillip Buckhaults, Dr. Wafik El-Diery, Dr. Jessica Rose, and Kevin McKernan have all expressed their concern that residual plasmid DNA could trigger serious side effects, autoimmune diseases, and cancer[31].

It is not a question of if residual plasmid DNA present in LNPs integrates into the DNA of human cells but how often does it occur and how bad are the effects. It must be noted that DNA integration is not necessary to induce cancer-associated pathways[32]. The genetic risks to people who have received these products, as well as their offspring, are uncharted. Scientific investigation is urgently required to determine the risks of gene-based mRNA therapeutics to humans.

Regulatory authorities on the possibility of integration.

The Danish Medicines Agency, on behalf of the Minister of Health, has admitted that the DNA plasmid used in Pfizer's vaccine contains a very small “sample” of an SV40 virus. They claim that these sequences are unlikely to pose a risk in cancer development, nor be able to induce damage to human DNA. According to the Danish Medicines Agency there is no risk of inheritance to the next generation[19].

This response from the Danish Medicines Agency is almost identical to responses from other drug regulatory agencies around the world, including the response from the United States Food and Drug Administration (FDA) to Florida State Surgeon General Dr. Joseph Ladapo, who in January of this year demanded a halt to the use of modified mRNA vaccines until safety is proven, after the FDA failed to provide a satisfactory explanation for the DNA contamination[33].

This lack of concern is deeply worrying and the fact that authorities have not prosecuted the manufacturers due to their failure to disclose all sequences used in the production of their products casts a further, very dark shadow over the lack of impartiality of the regulatory authorities. Safe and effective vaccines cannot be produced if regulators fail to act in the public interest.

We believe that the level and variability of residual plasmid DNA impurities in mRNA vaccines, as well as the inclusion of the SV40 promoter-enhancer sequence in the process Pfizer used to manufacture its vaccines, could pose serious and undetermined risks to the human population, including cancer, and in particular to pregnant women and their unborn children, who continue to be urged to receive these products.

Unquantified risks associated with modified mRNA vaccines.

Modified mRNA coding for a biologically active spike protein, variable levels of residual plasmid DNA and the presence of the SV40 promoter-enhancer sequence, pose serious risks to human health including cardiovascular disease, cancer, immunological, autoimmune, skin and neurological disorders, particularly in the context of a highly efficient cell delivery system such as LNPs.

As detailed in the supplied scientific summary provided by Russel Broadbent MPs team [Appendix 2] and the peer reviewed literature provided therein, excessive residual plasmid DNA in the Pfizer and Moderna products, exacerbated by repeated doses, may result in:

a) Genomic insertion of the synthetic DNA into natural Human chromosomal DNA;

b) Genomic integration inducing malignant/cancerous diseases;

c) Inactivation of the p53 leading to the proliferation of tumours;

d) Presence of synthetic DNA in cytoplasm inducing malignant/cancerous diseases;

e) Transfection into Oocytes and sperm-producing cells leading to:

i. Altered transgenic offspring;

ii. Interference with early intrauterine development;

iii. Induction of miscarriages and malformations.

If contamination includes intact and integratable whole genes then further hazards arise, namely:

f) Spike protein production for an indefinite period, possibly years. Undesired production of spike protein for weeks or months may arise owing to the use of degradation resistant modified mRNA;

g) Promotion of antibiotic resistance within the Human host and throughout communities;

h) Replication of the synthetic (whole plasmid) DNA within the Human host.

Summary of the concerns associated with modified mRNA vaccines.

- COVID-19 modified mRNA vaccines pose inherent health risks that were not adequately studied before their conditional approval and subsequent roll-out, but which have become abundantly clear afterwards.
- LNPs do not necessarily remain at the injection site but may reach the bloodstream and thereby multiple organs.
- Any cell in the body that takes up an LNP may express both the native Spike protein, a foreign antigen, as well as range of aberrantly mistranslated and misfolded proteins[34], and thus be marked for attack and destruction by the immune system. If this happens to cells that line the blood vessels, it will cause vessel damage and blood clotting, leading to increased risk of stroke, heart attack, and other acute vascular diseases. Some of the aberrant proteins may lead to cross reacting immunity against normal human proteins and thereby autoimmune disease. All these conditions have been well documented in the medical literature and in pharmacovigilance reporting systems worldwide. Likewise, LNPs are inherently toxic and may affect the blood (hemagglutination induction)[35] and organs such as the brain, heart, lungs, kidneys etc. Cell destruction by the immune system can lead to conditions such as encephalitis, myocarditis, autoimmunity etc., which again have been amply documented.
- While the above risks are inherent in the COVID-19 modified mRNA vaccine technology, the additional and potentially grave risk to human health due to excessive levels of residual plasmid DNA must be investigated.
- The credibility of the regulatory bodies and the governments that coerced their citizens into taking these products – primarily to protect the vulnerable, which was deliberate misinformation, is under serious public scrutiny.

- Development of safe and effective medical products depends upon transparent and trustworthy regulatory oversight of the manufacturing process. This has been disregarded during the COVID-19 response and is a catastrophe of governance that will take years if not decades to repair.

Positive change begins with an acknowledgement of error and this process must begin immediately before more lives are lost carelessly and unnecessarily.

Appendices

A. Dr. David Speicher's report.

https://russellbroadbent.com.au/wp-content/uploads/David-Speicher-Report-2.pdf

B. Science summary. Consequences of Synthetic DNA Contamination.

https://russellbroadbent.com.au/wp-content/uploads/Science-Summary-Consequences-of-DNA.pdf

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