

DECLARATION OF MIKE YEADON, Ph.D.

Pursuant to 28 U.S.C. §1746, I, Mike Yeadon, Ph.D., declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

I am fully competent to make this declaration and make this statement voluntarily, based on my personal knowledge, education, facts or data, and experience, and under penalty of perjury of the laws of the United States of America

I am competent to testify as an expert to the facts and matters set forth herein. A true and accurate copy of my curriculum vitae is attached hereto as **Exhibit A** and a copy of my bibliography is attached as **Exhibit B**.

I am an independent life sciences researcher, with high-level expertise in multiple disciplines essential to new drug discovery and clinical development, particularly immunology, inflammation, and airway pharmacology. I am internationally recognized as a leading expert in allergic, inflammatory, and immunological disease processes in the lungs and skin.

I founded and led a biotechnology company as CEO, creating over \$300M value over 5 years. My company, Ziarco, was acquired by Novartis, then the world's largest pharmaceutical company, in 2017. Over the last decade, I have advised 30 start-up biotechnology companies including one (Apellis Pharmaceuticals) which now has a marketed product and a \$5B market capitalization. Many other venture-financed clients are advancing compounds through the R&D phase.

Previously, I spent 23 years in the pharmaceutical corporate sector, reaching Vice President at Pfizer, where I headed worldwide respiratory research as their Chief Scientific Officer. I led project teams seeking new pharmacological treatments for asthma and COPD. My work while at Pfizer was instrumental in the formation of the Pfizer/ Boehringer 'Spiriva Alliance', a product that became the world's leading treatment for chronic obstructive pulmonary disease. I also championed inhalation technologies at Pfizer, from which emerged a commercial inhaler device marketed by Mylan, Inc. A substantial portfolio of experimental medicines flowed from the laboratories I supervised including the candidate later advanced within Ziarco.

I obtained a research-based Ph.D. in respiratory pharmacology and have a 1st class joint honors degree in biochemistry & toxicology, which he finished as leader in my year. I have had Government security clearance and worked placements at top-secret facilities at Porton Down (Chemical Defence Establishment) and Aldermaston (Forensic Science Service HQ).

I have over 40 peer-reviewed journal articles and have presented over 60 times at international research meetings. I have also contributed chapters to textbooks and edited a major textbook on new drugs for asthma.

Concerning Information Related to Covid-19 Vaccination and Fertility

Covid-19 vaccines are unlike any previous vaccine & have been inadequately studied:

The medicinal agents which are being called vaccines against covid-19 all utilize new technology. Traditional vaccines comprise a small amount of the pathogen (disease-causing agent) mixed with a material called an adjuvant, which is a substance that induces mild inflammation and thereby alerts the immune system to the presence of a foreign protein. The small amount of pathogen is traditionally 'killed'

by heating or by chemical treatment so that it cannot cause the disease against which immunity is sought. Alternatively, the pathogen is grown on by repeatedly infecting one cell culture after another, during which process the lethality of the virus reduces. This is called attenuation and some vaccines use so-called 'live attenuated' material to bring about immunization. Vaccines of these basic designs cover almost every vaccine ever developed and in use in the population today.

A gross failure of medicines safety regulation has occurred secondary to product misclassification:

The covid-19 vaccines work in an entirely different way and what that means is that it is wholly inappropriate to treat them like other vaccines. However, that is exactly what has happened. The manufacturers have been asked only to comply with the requirements set out in the regulatory standard worldwide. These standards are not to be thought of as low in any way. They are just suited to the type of medical entity with which we have decades of experience.

Traditional vaccines, like any product, can occasionally malfunction, and recognizing this, regulatory authorities around the world usually maintain a public record of adverse events noted after vaccination, without necessarily attributing causation to the noted

adverse event. However, the collection of event types and their frequency, coupled with a description of the alleged injured party, taken together with the relationship in time after vaccination that the adverse event is alleged to have occurred does permit linkages sometimes to be made.

For example, the swine flu vaccine marketed in 2009-10 was eventually withdrawn because the Swedish regulatory authorities noted a striking incidence in young people of a neurological condition, narcolepsy, which was reported in almost 1000 citizens.

As a result of the new-technology products called covid-19 vaccines working quite differently from prior products, appropriately termed vaccines, it is my considered opinion that the regulatory standard has fallen woefully short of the tests required to adequately assess and assure safety.

Recognizing that there was an ongoing failure of the regulatory standard, given the technical novelty of the covid-19 vaccines, a petition of concern was drawn up by the present author and one other and lodged with the European Medicines Regulator (EMA) on December 1, 2020 (<https://dryburgh.com/wp->

[content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_signed_with_Exhibits_geschwarzt.pdf](https://www.fda.gov/oc/ohrt/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01DEC2020_signed_with_Exhibits_geschwarzt.pdf)).

The covid-19 vaccines work entirely differently to conventional vaccines and therefore have a radically different set of potential safety concerns:

The covid-19 vaccines currently subject to emergency use authorizations all share a common and novel feature: they are gene- based products. Instead of containing a small amount of killed or live-attenuated pathogen, they instead comprise genetic code, instructions as it were to manufacture in our own cells a part of the pathogen. In some products, the genetic code is of DNA & uses a weakened respiratory virus to ensure delivery to our cells, or of messenger RNA (the intermediate between the DNA of our genes and the protein product thereby manufactured).

There is a further commonality: they cause the recipient's cells to manufacture a portion of the SARS-CoV-2 virus called the spike protein. This is the spike projecting outwards from the spherical object that contains the virus itself. As detailed elsewhere in this packet of information, coronavirus spike proteins are biologically active and they initiate the blood coagulation cascade among other properties. It is alleged that it is the induction of blood coagulation in various locations

in the body which is responsible for a high proportion of the serious adverse events including deaths which are being reported to the Vaccine Adverse Event Reporting System (VAERS) in the USA and analogous databases elsewhere. The rate of fatal outcomes following covid-19 vaccination, usually from clotting or bleeding disorders, is extraordinary and exceeds that from any previous vaccine by a very large amount, which this reviewer estimates is of the order of 60-fold.

That this astonishingly high rate of adverse events after vaccination is a consequence of two factors: 1. The manufacturers were simply not required to study the way the product moves around the body after injection and 2. They were not required to study the functional effects of the genetic code within the product after administration.

There are no products on the mass market which operate in this way. It is my expert opinion that **this is the greatest failure of medicinal product regulation in relation to reproductive health since thalidomide** and is very much greater in terms of societal impact. It is imperative that all these products be suspended until improved safety testing can

determine whether there are any groups in whom the benefits outweigh the risks.

The shadow of Thalidomide and changes to drug safety regulation in pregnancy:

The drug name 'Thalidomide' is, particularly in Europe, indelibly associated in the public mind with birth defects. Intended to treat nausea associated with early pregnancy, it was prescribed in 46 countries, but not the USA, between 1957 and 1962, when it was withdrawn, having been identified as the causative agent in 10,000 birth malformations involving reduced or absent limbs. Thalidomide is one of the most infamous cases of failed drug safety evaluation.

By contrast with regulators in dozens of other countries, the US drug regulatory agency, the Food & Drug Administration, did not approve thalidomide because the reviewer was not satisfied by the available information. Drug safety was substantially reformed worldwide in the aftermath of this event, notably to require manufacturers to conduct what is broadly termed 'reproductive toxicology' and also almost always to include rabbits as a test species, because it was later discovered that thalidomide did cause birth defects in rabbits but far less obvious in rodents.

There was a realization the concept that the fetus was somehow protected from harm by being in the womb was completely mistaken. On the contrary, the intricacies of embryo-fetal development started to be recognized as a period of extreme vulnerability. Perhaps the most striking cultural change was that women became extremely wary of taking any pharmaceuticals during pregnancy.

Covid-19 vaccines have not been taken through reproductive toxicology tests:

It is essential to lay out the backdrop to the current position with clinical use of covid-19 vaccines, for one reason: we have NEVER, since thalidomide, exposed women of childbearing potential (WOCBP) and ESPECIALLY NEVER pregnant women to ANY novel, an experimental pharmaceutical product without that product first having completed a full battery of reproductive toxicology tests. Even after this crucial step, pilot studies are always conducted in a small number of pregnant women to minimise risk to the developing fetus. Neither of these essential steps have been undertaken.

No justification for taking risks with the health of unborn children:

Coming to the present, this expert reviewer is astonished at the current position. It is the height of recklessness to allow WOCBP to

receive covid-19 vaccines, which are of an entirely novel, gene-based technology for which there is no prior human safety experience in a large population. Worse, the active recommendation that these experimental agents should be administered to pregnant women is, in my opinion, criminally negligent. Furthermore, it is completely incomprehensible that these novel vaccines are recommended for use in pregnancy, most of which happen in women aged 40y or younger, since the dominant risk factor for poor outcomes from infection by SARS-CoV-2 is age.

The Pfizer / BioNTech covid-19 vaccine builds up in the ovaries of rodents:

A distributional study was undertaken for Pfizer in which various formulations of dummy versions of their vaccine candidate were administered to rodents and various tissues sampled over time. The tests did not include the mRNA 'payload' but as this is simply a study of where the container for the mRNA goes, that is irrelevant from a safety perspective. Note that this study does not classify as a reproductive toxicology test as the animals were not pregnant. Instead, the study might best be classified as a pharmacokinetic study, the discipline of understanding how drugs move around the body after administration

and the means and timing of its elimination. This study was not released by Pfizer into the public domain, even though this reviewer regards the findings as highly concerning. The information only came to light after a freedom of information inquiry was submitted to the Japanese medicines' regulator.

What this study shows is that the lipid nanoparticle shell of the Pfizer vaccine concentrates in the spleens and ovaries of rodents. It is not appropriate that this has happened. The intended induction of immunity definitely does NOT require the presence of vaccine components in reproductive tissue. Most commonly, the concentrations of drugs in any tissue in the body peak quickly after administration, after which they fall away gradually over time. In light of this, it is more troubling still that, instead of falling away gradually over time as expected, the tissue levels RISE over time, suggestive of an active process. The study was aborted 48 hours after administration of the test material, not unreasonably. After that much time, it would be normal to be expecting the peak of tissue concentrations to have passed. However, the highest concentrations were seen at the last time point, 48 hours post-dose, meaning it is not known when the peak time after

administration actually is or whether concentrations in the ovaries and spleen rise even higher at extended times (See part of the relevant datatable overleaf. The entire document is also attached).

Any experienced reviewer would call for a halt of use of this vaccine in non-menopausal women:

As a toxicologist, I say this: in the absence of evidence that says this is not a predictor for humans, this is what I expect is happening to every female administered this agent. It is to be expected that the consequences of this concentration in reproductive will be adverse. based on observations elsewhere in the body, where blood clots and bleeding have separately been reported. In my opinion, any reasonable reviewer would agree that these vaccines should not be administered to any female below menopause.

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [³H]-Labelled LN

Sample	Total Lipid concentration (µg lipid equivalent / g [or mL]) (males and females combined)							% of Administered Dose		
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	-	-	-
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	-	-	-
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	-	-	-
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001	0.009	0.008
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002
Salivary	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008

Women generate an autoimmune response to their placenta after vaccination:

As mentioned previously, all of the covid-19 vaccines currently subject to emergency use authorizations utilize novel, gene-based technology for which there are no mass-marketed products. What this means is immediately obvious to anyone experienced in the development of medical products: it is unsafe to make any assumptions at all about the safety profile, short or long, after administration to humans. We did not know, before the tragic lessons arising from thalidomide, that early in gestation the developing embryo is exquisitely vulnerable to the adverse effects of environmental agents, including pharmaceuticals. It is unreasonable to assume that because conventional vaccines are not generally considered to represent a safety

issue concerning fertility and pregnancy, that these novel, gene-based products will be safe in pregnancy.

On December 1, 2020, this expert reviewer together with experienced public health medical doctor Dr. Wolfgang Wodarg filed a petition of concern with the European Medicines Agency. The principal grounds of concern were the excessive speed of clinical development, together with a limited series of specific concerns (which were not claimed to be exhaustive):

1. Determination of covid-19 ‘cases’ relied on inadequately controlled PCR testing (it is very widely held by independent experts that the PCR tests used grossly over-estimate prevalence of truly infected ‘cases.’ (It is noteworthy that FDA has just announced that it is withdrawing approval from all PCR tests for detection of SARS-CoV-2 infection).

2. The potential for antibody-dependent enhancement, which process has caused the termination of all other prior vaccines against coronaviruses (it is being speculated that the high incidence of heart inflammation, called myocarditis, occurring with high frequency especially in young males).

3. The potential for precipitating acute allergic reactions upon administration of the lipid-encapsulated vaccines (Pfizer/BioNTech and Moderna products), which happened on the very first day of mass vaccination in the UK & the label was soon changed to avoid administration to persons suspected of having had allergic responses to injected products in the past.

4. The potential for cross-over immune responses to a protein essential to a successful pregnancy. It is this latter concern that the remainder of this note refers to.

As a comment, it is to be regretted that it appears the co-petitioners were correct in every particular in relation to their concerns, and deeply troubling for public confidence in drug safety regulation & trust in governments and the pharmaceutical industry that the reward for the public spirit in which they wrote was to be viciously smeared by major media organizations including Reuters and the BBC. ted products in the past).

Women administered the Pfizer/BioNTech vaccine rapidly develop antibodies to their placenta

I have previously outlined how these gene-based vaccines are expected to work. The part of the SARS-CoV-2 virus called the spike

protein is coded into these new technology products, such that they all induce the body of the recipient to manufacture that spike protein or a portion thereof.

It is conventional good practice to review the scientific literature around chosen targets for use in vaccines, in this case, spike protein, to ensure the potential for unwanted effects, when humans are caused to develop immune responses to it, is understood. Two outstanding findings were identified from this scientific literature search. First, spike proteins can initiate blood platelet aggregation and this triggers blood coagulation, which calls into serious doubt the wisdom of having selected spike protein in all the vaccines to date. Second, there is a weak, but obvious (to expert reviewers) similarity of the coronavirus spike protein and a family of human proteins called syncytins. It is wrong to decide the level of similarity solely by reference to the primary amino acid sequence of two proteins and important also to consider the similarity of their 3-dimensional structure.

The Syncytin family of proteins is considered critical for the formation and successful maintenance of the placenta. Therefore, no matter how weak the homology between spike protein and syncytins,

the concern arose that, upon making a strong immune response to spikeprotein, some women might generate an immune response to their own placental proteins. This concern would, in this reviewer's experience of over 30 years in the pharmaceutical industry, be met technically with a small series of studies to examine, hopefully, to rule out, this concern.

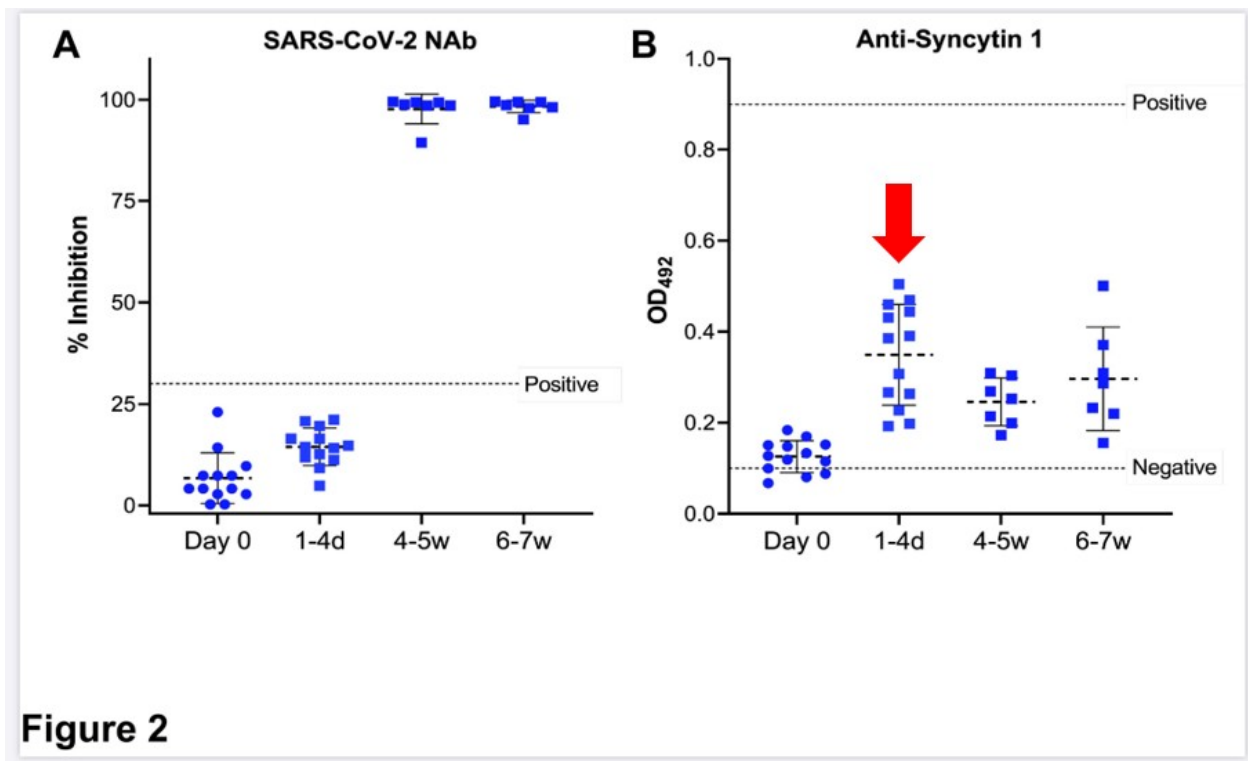
There are several ways in which this could be done. It is not difficult to devise a clinical study to evaluate whether or not women administered a covid-19 vaccine develop circulating antibodies to syncytin-1. Such a study has just been reported as a pre-print: (<https://www.medrxiv.org/content/10.1101/2021.05.23.21257686v1.full.pdf>)

Fifteen healthy young women were recruited to the study and were administered the Pfizer / BioNTech covid-19 vaccine. Blood was drawn at various times afterward and the relative amount of antibodies to the SARS-CoV-2 spike protein and syncytin-1 was measured.

In the first 1-4 days after vaccination, there was no measurable increase in antibodies to the spike protein. However, there was a striking (2 to 3-fold; marked by a vertical, red arrow) increase in antibody binding to syncytin-1.

It is the judgment of this reviewer that the increase in antibodies to syncytin-1 at that time is ‘statistically significant, that is, it is very unlikely to have occurred by chance. It is not possible to state what this extent of increase means, but it is consistent with an increased risk of first-trimester pregnancy loss. That the elevation of anti-syncytin-1 antibodies was absent by 4 weeks doesn’t diminish the potential for harm at early times after vaccination.

It is unaccountable that the authors state that there was “no humoral response to syncytin-1”. A figure in the paper is reproduced below. The authors have scribed a horizontal line perpendicular to the Y-axis, which they labelled “positive”. There is no information in the paper or in the literature which underwrites the positioning of this line. Absent that information, it is scientifically invalid to claim that the clear-cut increase in binding to syncytin-1 on days 1-4 is functionally irrelevant.



It is sobering to recall again the lessons from thalidomide. It turns out that if the mother, early in pregnancy, took her first dose of thalidomide on day 20 after conception, their baby was likely to be born with brain damage; If on day 21, blind; if on day 24, limbs were often shortened or missing; no damage occurred if taken after day 42 since conception.

The authors of this paper have no basis to claim that the amount of antibodies to syncytin-1 is too small to matter. They appear to be unaware of the thalidomide lessons, which show that periods of exquisite sensitivity exist during early development where the presence

of a toxin for periods of as little as two days can terminate development processes which are then never repaired.

This new data, which shows that women do raise antibodies to a component of their placenta after vaccination with the Pfizer/BioTech product, raises serious concerns for fetal safety. It is not safe to assume that this will not have adverse consequences on successful pregnancy. It is not safe to assume that the other vaccines will not have similar effects.

Again, as with the distributional study, a presumption of risk, potentially severe, arises from these clinical observations, and there isn't an aware person who wouldn't call a halt at this point.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on August 23 2021 . *Michael Yeadon*
Mike

[Michael Yeadon \(Aug 23, 2021 09:55 MDT\)](#)

Mike Yeadon, PhD






Declaration of Mike Yeadon PhD - fertility

Final Audit Report

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