COVID-19 mRNA vaccines for pregnant women? The contradictory advice between the regulatory and health authorities

Sonia Elijah

Author at Trial Site News | Investigative journalist and broadcaster

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Opinion Article

This is a follow-up to my in-depth investigative report for Trial Site News entitled, 'On what basis are pregnant women being encouraged to take the Pfizer vaccine?' My May report revealed alarming data buried in the court-ordered release of Pfizer's trove of documents, which the FDA relied on to grant emergency use authorization of the Pfizer-BioNTech Covid-19 vaccine on December 11, 2020.

An extract from Pfizer's post-authorization safety

report (which was disclosed around December 2021 thanks to FOIA request) reads as follows, '*Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each).* ***No outcome was provided for 238 pregnancies.***'

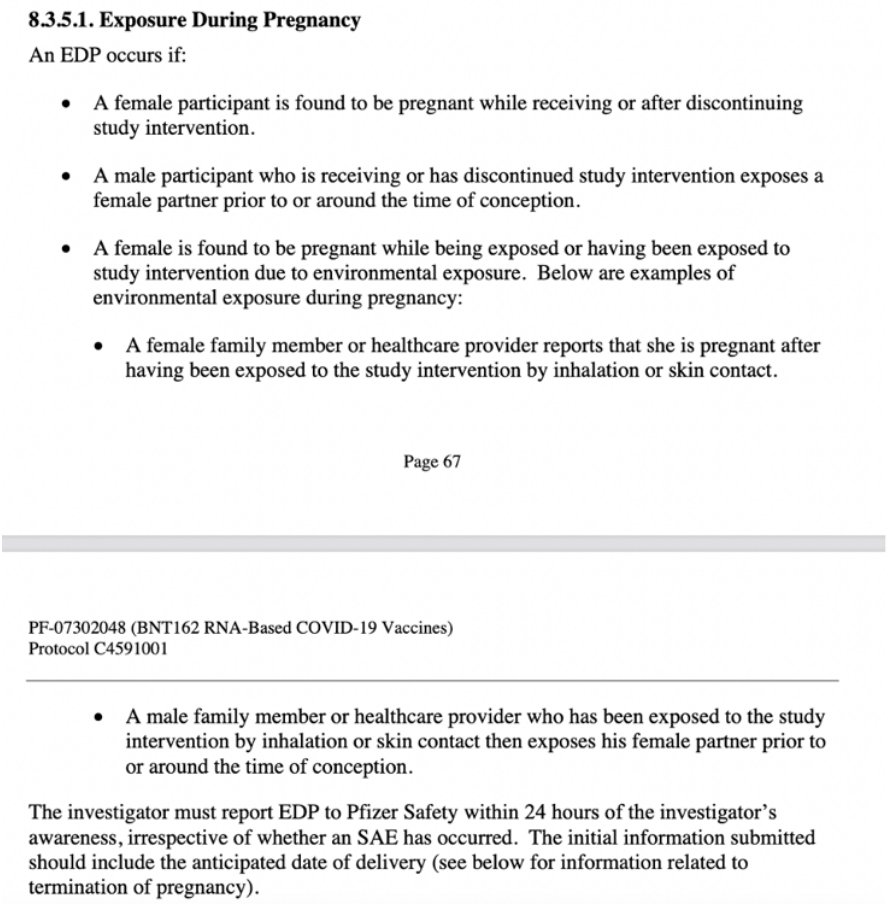
In the Spring of 2021, Health authorities such as the CDC and the NHS in the UK gave the green light for pregnant and lactating women to be administered the Covid-19 vaccine, despite the fact that phase1/2/3 of Pfizer's clinical trials excluded pregnant and lactating women.

Vaccine shedding

In Pfizer's own clinical protocol, the criteria for exposure during pregnancy (EDP) is described in great detail on page 67-68, implying that exposure of pregnant women to the study intervention (vaccine) was something Pfizer and BioNTech were concerned about. Given that no reproductive toxicity or genotoxicity reports were ever done, perhaps there was something of concern on their radar. What is shocking is that the intramuscular injection of the study intervention was not the only form of exposure which

concerned them but the possibility of vaccine shedding, too.

(See screenshot below)



8.3.5.1. Exposure During Pregnancy

An EDP occurs if:

- A female participant is found to be pregnant while receiving or after discontinuing study intervention.
- A male participant who is receiving or has discontinued study intervention exposes a female partner prior to or around the time of conception.
- A female is found to be pregnant while being exposed or having been exposed to study intervention due to environmental exposure. Below are examples of environmental exposure during pregnancy:
  - A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention by inhalation or skin contact.

Page 67

PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines)
Protocol C4591001

- A male family member or healthcare provider who has been exposed to the study intervention by inhalation or skin contact then exposes his female partner prior to or around the time of conception.

The investigator must report EDP to Pfizer Safety within 24 hours of the investigator's awareness, irrespective of whether an SAE has occurred. The initial information submitted should include the anticipated date of delivery (see below for information related to termination of pregnancy).

'A female family member or healthcare provider reports that she is pregnant after having been exposed to the study intervention (the Pfizer-BioNTech mRNA vaccine) by ***inhalation or skin contact****.'*

'A male family member or healthcare provider who has been exposed to the study intervention ***by inhalation or skin contact then exposes his female partner***

prior to or around the time of conception.'

These specifications reveal that the trial sponsor (BioNTech) and the company conducting the trial (Pfizer) were very much aware of the possibility of vaccine shedding and considered it to be a serious adverse event (SAE) with the need of the immediate reporting of it by a trial investigator to *'Pfizer Safety within 24 hours of the investigator's awareness.'*

In contrast, we have the mainstream media and platforms such as *Wikipedia* branding vaccine shedding as a wild conspiracy theory .

The skewed retrospective study of pregnant women

CDC based their recommendation of the COVID-19 vaccines for pregnant women on a limited retrospective study of roughly 10,000 pregnant women, with over 60% vaccinated during their third trimester (only 1% were in their first trimester) undeniably this could have led to bias in the results. The results of this study paved the way for health authorities around the world to say that the Covid-19 vaccines (Moderna, Pfizer, Janssen) were safe for pregnant women.

Conflicts of interest

The lead authors of a report analysing this study stated, '*COVID-19 vaccination during pregnancy was not associated with preterm birth or small-for-gestational-age at birth overall, stratified by trimester of vaccination, or number of vaccine doses received during pregnancy, compared with unvaccinated pregnant women*' had received institutional research funding from Pfizer and Johnson & Johnson (the makers of the Janssen Covid-19 vaccine).

The contradictory advice between the governmental regulatory bodies and the health authorities

Buried within the FDA package insert for COMIRNATY (marketing name for the Pfizer-BioNTech mRNA vaccine) states, ***'Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.'***

Below is a screenshot of the Long Version (Full EUA Prescribing Information) which was last revised on 31 August 2022.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (modRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on 4 occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

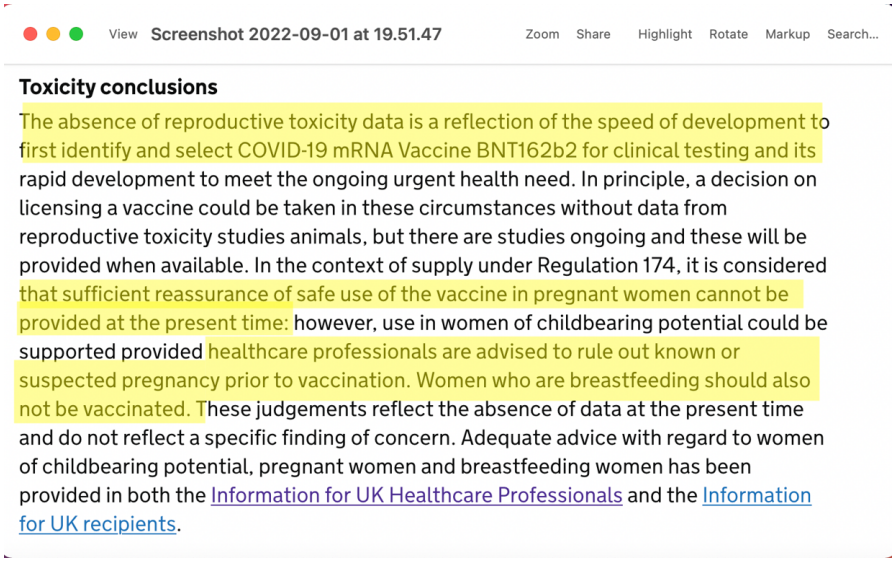
Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

Not only is the fact, *'available data on Pfizer-BioNTech COVID-19 vaccine administered to pregnant women are **insufficient** to inform vaccine-associated risks in pregnancy'*, there's **none** available *'to assess the effects of Pfizer-BioNTech COVID-19 vaccine on the breastfed infant or on milk production/excretion.'*

Yet, this did not appear to bother health authorities around the world like the NHS in the UK and the CDC in the US, which have strongly encouraged pregnant and lactating women to have the COVID-19 vaccines, stating they are 'safe and effective'- even when those countries' governmental regulatory bodies (the US FDA and the UK's MHRA) have not apparently authorised their use in those specific populations.

Across the pond in the UK, this significantly contradictory pattern of advice to pregnant women has been the same. The public assessment report of Pfizer-

BioNTech COVID-19 vaccine (BNT162B2) which was only recently updated as of 16 August 2022, includes the alarming toxicity conclusions on page 21 of the document.

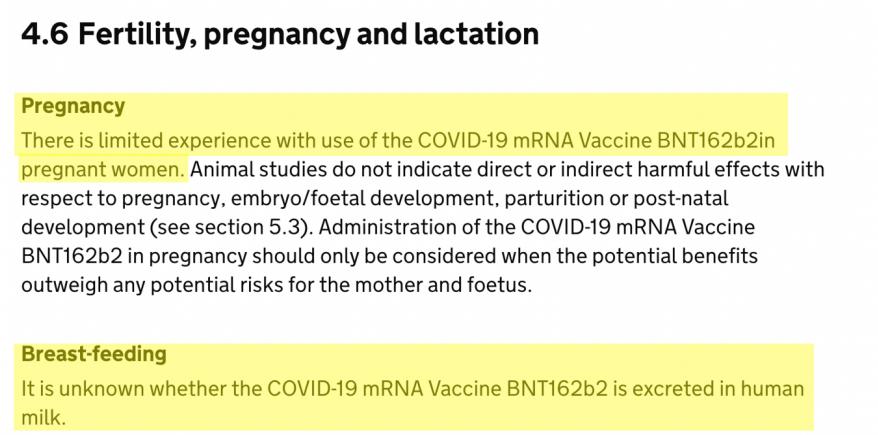

View Screenshot 2022-09-01 at 19.51.47 Zoom Share Highlight Rotate Markup Search...

Toxicity conclusions

The absence of reproductive toxicity data is a reflection of the speed of development to first identify and select COVID-19 mRNA Vaccine BNT162b2 for clinical testing and its rapid development to meet the ongoing urgent health need. In principle, a decision on licensing a vaccine could be taken in these circumstances without data from reproductive toxicity studies animals, but there are studies ongoing and these will be provided when available. In the context of supply under Regulation 174, it is considered that sufficient reassurance of safe use of the vaccine in pregnant women cannot be provided at the present time: however, use in women of childbearing potential could be supported provided healthcare professionals are advised to rule out known or suspected pregnancy prior to vaccination. Women who are breastfeeding should also not be vaccinated. These judgements reflect the absence of data at the present time and do not reflect a specific finding of concern. Adequate advice with regard to women of childbearing potential, pregnant women and breastfeeding women has been provided in both the Information for UK Healthcare Professionals and the Information for UK recipients.

Just like the FDA, the MHRA makes a similar conclusion of there being insufficient data to authorise the safe use of the vaccine in pregnant women. However, the MHRA goes even further by stating that ***'healthcare professionals are advised to rule out known or suspected pregnancy prior to vaccination. Women who are breastfeeding should also not be vaccinated.'***

In my earlier report, I included the document, Regulation 174 Information for UK healthcare professionals, which was also last updated 16 August 2022. The screenshot below is taken from that document.



4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited experience with use of the COVID-19 mRNA Vaccine BNT162b2in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development (see section 5.3). Administration of the COVID-19 mRNA Vaccine BNT162b2 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Breast-feeding

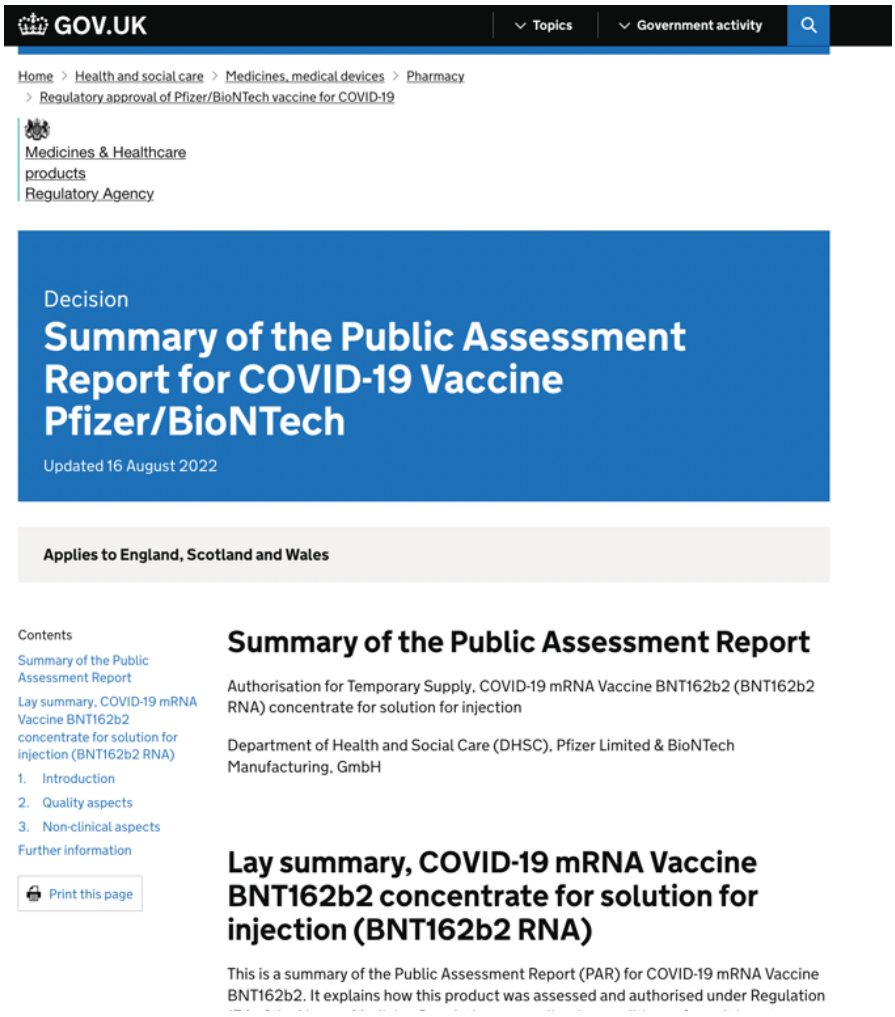
It is unknown whether the COVID-19 mRNA Vaccine BNT162b2 is excreted in human milk.

The acknowledgement of the 'limited experience' and 'unknowns' does not promote certainty in the safety of the mRNA vaccines for pregnant women or for breast-fed babies either.

The MHRA appears to side-step to quell a social media storm

Now, on or around Friday September 2, the MHRA slapped on a notice to its public assessment report of the Pfizer-BioNTech COVID-19 vaccine.

This is how it appeared before Friday September 2 on the UK government website, as you can see it was last updated 16 August 2022.



GOV.UK Topics Government activity

Home > Health and social care > Medicines, medical devices > Pharmacy > Regulatory approval of Pfizer/BioNTech vaccine for COVID-19

Medicines & Healthcare products Regulatory Agency

Decision

Summary of the Public Assessment Report for COVID-19 Vaccine Pfizer/BioNTech

Updated 16 August 2022

Applies to England, Scotland and Wales

Contents

Summary of the Public Assessment Report

Lay summary, COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection (BNT162b2 RNA)

1. Introduction
2. Quality aspects
3. Non-clinical aspects

Further information

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Summary of the Public Assessment Report

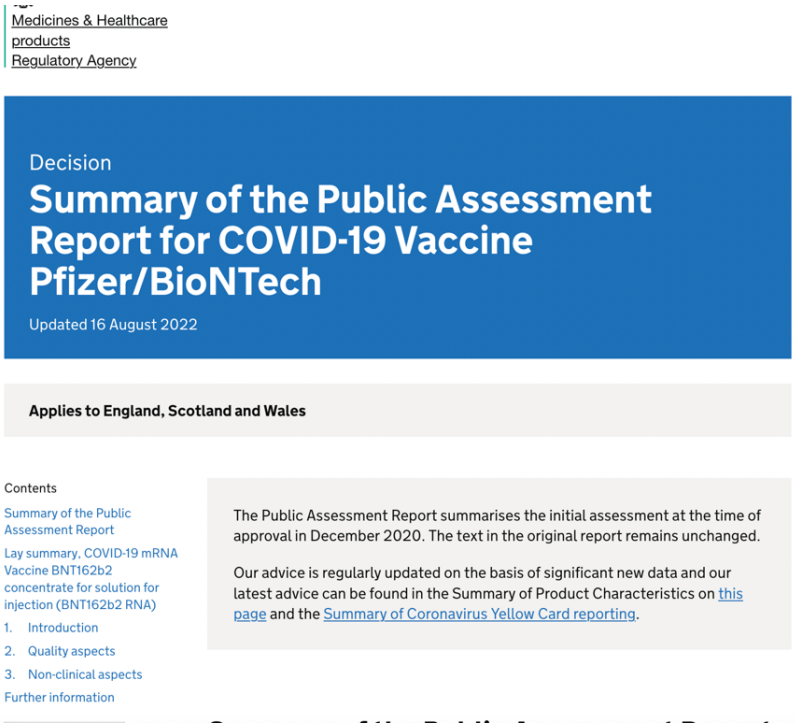
Authorisation for Temporary Supply, COVID-19 mRNA Vaccine BNT162b2 (BNT162b2 RNA) concentrate for solution for injection

Department of Health and Social Care (DHSC), Pfizer Limited & BioNTech Manufacturing, GmbH

Lay summary, COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection (BNT162b2 RNA)

This is a summary of the Public Assessment Report (PAR) for COVID-19 mRNA Vaccine BNT162b2. It explains how this product was assessed and authorised under Regulation

This is what it looks like now.



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Further information

The Public Assessment Report summarises the initial assessment at the time of approval in December 2020. The text in the original report remains unchanged.

Our advice is regularly updated on the basis of significant new data and our latest advice can be found in the Summary of Product Characteristics on this page and the Summary of Coronavirus Yellow Card reporting.

As you can see, there is a notice stating that the assessment report *'summarises the initial assessment at the time of approval in December 2020.'* It is unusual that the MHRA inserted a notice around September 2, when it only updated the document on 16 August 2022. Could it be because of the social media storm created after this post below went viral, highlighting the contradictory advice between the NHS and the UK government's MHRA?

The post here is not accurate when they state the *'UK government quietly removes approval'*- the document's toxicity conclusions has always been there from the beginning.

The fact that the NHS was 'strongly recommending' pregnant and breast-feeding women to have the COVID-19 vaccines against the authorisation of the MHRA for that specific population, is nothing but scandalous.

This story was picked up by Prof Norman Fenton and Dr John Campbell who has over 2 million subscribers and made a YouTube video about it. Following the

posting of that video, Campbell was issued with a strike against his YouTube channel.

It does appear that the MHRA, since September 2, has included this notice to their report to quell the social media storm and the attention it was getting from the UK mainstream media. The Independent ran the headline, *'Pregnant people targeted with false vaccine claims on social media.'*

It went on to state:

'Inaccurate vaccine claims on social media about the safety of Covid vaccines for pregnant people have been discredited by UK health agencies.

False messages shared by thousands alleged that people who are pregnant or breastfeeding were advised against taking the vaccine.'

It's also worth noting that in the MHRA's Public Assessment report for the Pfizer-BioNTech COVID-19 vaccine it states that two of the four lipids that the vaccine contains are ***'novel in that they have not been used in an authorised medicinal product in the UK.'***

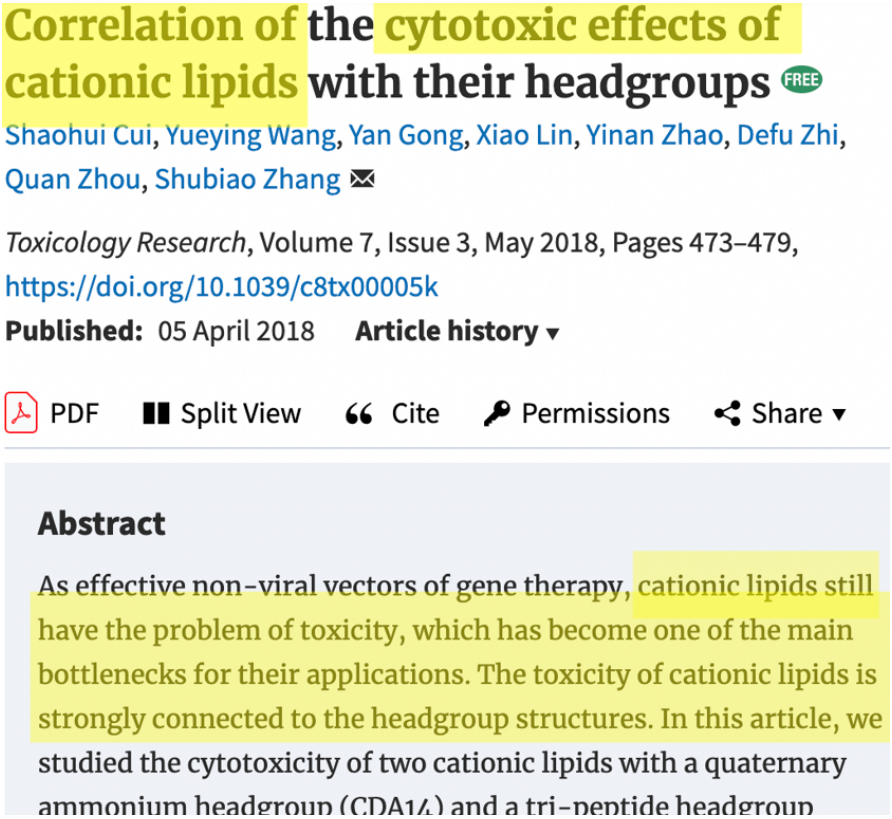
In addition to those excipients, the vaccine contains four lipids, of which two are used in approved medicinal products (cholesterol and 1,2-distearoyl-sn-glycero-3-phosphocholine, hereafter termed DSPC) and two are considered novel in that they have not been used in an authorised medicinal product in the UK:

ALC-0315 ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)) and ALC-0159 (2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide).

Not only have these two novel lipid nanoparticles never been used before in an authorised medicinal product, they are also known to be toxic.

ALC-0159 is a PEG/lipid conjugate (i.e. PEGylated lipid). PEG (polyethylene glycol) is known to trigger serious allergic reactions, including anaphylaxis, which is potentially life-threatening. An April 2021 study in the UK linked PEG found in both Pfizer and Moderna mRNA vaccines to be the cause of anaphylaxis. Just around the same time, health authorities were 'strongly encouraging' pregnant women to have the COVID-19 vaccines.

ALC-0315 is a cationic lipid. There's extensive scientific literature which states that this type of lipid is toxic, see screenshot below.



Correlation of the cytotoxic effects of cationic lipids with their headgroups FREE

Shaohui Cui, Yueying Wang, Yan Gong, Xiao Lin, Yinan Zhao, Defu Zhi, Quan Zhou, Shubiao Zhang

Toxicology Research, Volume 7, Issue 3, May 2018, Pages 473–479, https://doi.org/10.1039/c8tx00005k
Published: 05 April 2018 **Article history**

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Abstract

As effective non-viral vectors of gene therapy, cationic lipids still have the problem of toxicity, which has become one of the main bottlenecks for their applications. The toxicity of cationic lipids is strongly connected to the headgroup structures. In this article, we studied the cytotoxicity of two cationic lipids with a quaternary ammonium headgroup (CDA14) and a tri-peptide headgroup

An alarming study by Fraiman et al, including Dr Peter Doshi, has just recently been peer reviewed and published in the journal, *Vaccine*, entitled '*Serious adverse events of special interest following mRNA COVDI-19 vaccination in randomized trials in adults.*' The study showed that *'Pfizer and Moderna mRNA COVID-19 vaccines were associated* ***with an excess risk of serious adverse events of special interest.'*** *The Pfizer clinical trial produced a '****36% higher risk of these events in the vaccine group****.'* The authors concluded that *'The excess risk of serious adverse events found in our study points to the* ***need for formal harm-benefit analyses****, particularly those that are stratified according to risk of serious COVID-19*

outcomes. ***These analyses will require public release of participant level datasets.***'

If you look at OpenVaers, you can see that through to August 26, 2022 a staggering 4,992 miscarriages have been reported, along with 30,605 deaths, 9,979 anaphlaxis and 175,020 hospitalizations.

For the CDC, NHS and other health authorities around the world to say these novel mRNA vaccines are 'safe and effective' and to 'strongly recommend' them for pregnant women is reckless and harmful as the real-world data is sadly telling another story.

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vaccine?' My May report revealed alarming data buried in the court-ordered release of Pfizer's trove of documents, which the FDA relied on to grant emergency use authorization of the Pfizer-BioNTech Covid-19 vaccine on December 11, 2020.

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