Commentary on Preliminary Findings of mRNA Covid Vaccine Safety in Pregnant Persons as Reported by the Center for Disease Control and the Food and Drug Administration, June, 17, 2021, New England Journal of Medicine

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I. Context:

This article was undertaken as part of a widespread review of Pfizer documents concerning their experimental lipid nanoparticle + messenger ribonucleic acid gene (LNP/mRNA) therapy drug, BNT162b2.

The document release was ordered by Judge Mark T. Pittman of the United States District Court in the Northern District of Texas on January 6, 2022.[1] The Food and Drug Administration requested these documents be sealed for 75 years.

Pfizer completed Phase 3 trials of BNT162b2 in fall of 2020 and submitted its application for an Emergency Use Authorization (EUA) to the Food and Drug Administration on November 20, 2020.

On December 11, 2020 the FDA issued an Emergency Use Authorization. Widespread distribution and mass inoculation began shortly afterward.[2] Moderna received approval for their product, mRNA-1273) along a similar time line.[3]

The New England Journal of Medicine published a research article, Shimabukuro, et. al., on June 17, 2021 (online publication) authored by 21 affiliates of the Center for Disease Control (CDC) and Food and Drug Administration (FDA) on behalf of the 47 member CDC/FDA Pregnancy Registry Team entitled "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons".[4]

This study reported results of 35,691 pregnant women entered into the **V-safe Registry** maintained by the CDC who received at least one dose of either the Pfizer/BioNTech or Moderna Covid-19 drug during the ten-week period from December 14, 2020 through February 28, 2021.

Results from the **Vaccine Adverse Event Reporting System** or VAERS were also queried and results are presented.

Shimabukuro, et. al. identify the then and now current CDC policy regarding use of new SARS-CoV-2 Spike encoding genetic products from Pfizer and Moderna in pregnant women,

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[1] https://www.sirillp.com/wp-content/uploads/2022/01/ORDER_2022_01_06_9e24e298ae561d16d68a3950ab57077b.pdf

[2] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

[3] https://en.wikipedia.org/wiki/Moderna

4 https://www.nejm.org/doi/full/10.1056/NEJMoa2104983 This article was published on April 21, 2021, and updated on September 8, 2021. The April and September versions are not available online.

> The Centers for Disease Control and Prevention (CDC) and ACIP, in collaboration with the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, have issued guidance indicating that **Covid-19 vaccines *should not be withheld*** from pregnant persons. p. 2274. *Bold Italics added.*

The basis of this recommendation in light of the CDC/FDA documentation presented in Shimabukuro, et. al. is the focus of this article.

II. Registry Data and Data Mining

A registry is one of the scientifically weakest clinical research tools we have and ranks far below the gold standard randomized, double blinded tightly controlled study of at least two years duration or a prospective tightly controlled matched subject study.

SAS, the well-regarded maker of the statistical package used by the CDC/FDA on this project, notes the following about data mining:

> With masses of new data, there are also masses of incomplete, incorrect, misleading, fraudulent, damaged, or just plain useless data. The tools can help sort this all out, but the users must be continually aware of the source of the data and its credibility and reliability.[5]

Sometimes, not always, this process is referred to as GIGO or garbage in garbage out. A registry can be used to detect signals but they do not generate robust high quality scientific data.

III. Methodology

Two databases were queried for the study samples reported in the Shimabukuro, et. al. report.

#1: The V-safe Surveillance System and **Pregnancy Registry** is a voluntary smartphone-based surveillance system maintained by the CDC. Participants agree to receive periodic emails to which they respond.

One estimate puts the rate of participation in V-safe at about 5% of all those given the drug.[6]

From V-safe, participants were contacted and entered into a second registry, the Pregnancy Registry, from which data for this report were drawn. The Registry was to collect data for 12 months.

[5] https://www.sap.com/insights/what-is-data-mining.html

[6] V-safe COVID-19 vaccine pregnancy registry. Atlanta: Centers for Disease Control and Prevention. May 3, 2021 (https://www.cdc.gov/coronavirus/2019 - ncov/vaccines/safety/vsafepregnancyregistry.html).

#2: The second registry was the **Vaccine Adverse Event Reporting System (VAERS)**, a voluntary reporting system maintained by the CDC and FDA established to monitor side effects of vaccines 30 years ago.[7] This registry is voluntary and entries are verified by the CDC.

Speculation as to what percentage of actual AEs the VAERS reporting comprises varies widely from a single digit Under Reporting Factor or URF of 4 to 5 to upwards of 40. Overreporting is less likely given the verification process. The reader should keep this URF range of 4-40 in mind for any VAERS data.

This article will also make reference to a third database maintained by Pfizer as reported in **Confidential Document 5.3.6**.[8]

A. V-safe/Pregnancy Registry Data

Outcomes were assessed in terms of comparison of **reactogenicity** in pregnant and non-pregnant women aged 16-54 years as well as **pregnancy outcomes**.

Reactogenicity is a concept applied to vaccines and includes early reaction to drug products such as pain at the injection site, fever, other short-term signs and symptoms as differentiated from Adverse Events (AEs) and Adverse Events of Special Interest (AESI) that focus on specific categories of events and specific diagnoses by function and or organ system.

Pregnancy outcomes were assessed in a subset of completed pregnancies in terms of spontaneous abortion (loss of fetus in the first 20 weeks also called miscarriage), stillbirth (loss of fetus after 20 weeks), pre-term birth, congenital anomalies, small size for gestational age and neonatal death.

Loss of fetus is caused by multiple factors and occurs decreasingly as a function of duration of gestation. The miscarriage rate is highest in the first six weeks and most fetal loss occurs in the first trimester.

Data are entered and database queries return results from the system. Each query can return data from different subjects. It must be understood that the numbers returned from each query likely represent a unique set of subjects **making comparisons across queries problematic.**

Contrast this process with a cohort study that produces a complete data set for all or most of those enrolled in the study. Data from this more robust type of study are very limited.

B. VAERS Data

> VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might

[7] https://vaers.hhs.gov/
[8] https://robertchandler.substack.com/p/pfizer-document-536-cumulative-analysis

indicate a possible safety problem with a vaccine. This way, VAERS can provide CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern.[9]

Analysis of VAERS reporting included Adverse Events (AEs) that are both pregnancy and non-pregnancy related.

IV. Outcomes:

There were 35,691 pregnant women entered into the CDC V-safe COVID-19 Pregnancy Registry system during the first $2^{1/2}$ months after the EUA. Remember that these almost 36,000 pregnant women may be just 5% of the total as of February 28, 2021 or **720,000**.

Of the 35,691 cases 5,230 were contacted and offered enrollment in the Pregnancy Registry and a total of 3,958 agreed and qualified for further study.

Table 1: V-Safe Data Set

As of 3/30/2021 for data 12/14/2020 thru 2/28/2021	
From Table 1, Shimabukuro, et. al.[3]	
mRNA + Pregnancy Cases	35691
Pregnant at time of Injection	30887
+ Pregnancy test after injection	4804

Table 2 gives the summary statistics for the Pregnancy Registry.

Table 2: Pregnancy Registry

Pregnant at or shortly after Injection	5230
Unreachable	912
Declined	86
Did not meet inclusion criteria	274
Eliminated	1272
Net	**3958**

These 3,958 pregnant women were the subject of further analysis but here is where the caution from SAS applies. The numbers reported in each category may refer to results of a data query rather than unique individuals followed through various cuts. This is important in coming to an understanding of what exactly is being reported in Shimabukuro, et. al.

A. Spontaneous Abortion Rate (SABR)

Spontaneous abortion does not include medically induced loss of fetus or stillbirths.[10]

[9] https://vaers.hhs.gov/about.html

Of the **3,958** pregnant women entered into the V-safe Pregnancy database, 1,132 cases received LNP/mRNA drugs during their first trimester and another 1,714 in their second trimester totaling 2,846 subjects injected during the first 24 weeks after conception according to Table 3, page 2279.

There were 2,846 combined first and second trimester subjects representing 72% of those receiving LNP/mRNA during pregnancy who were entered into the Pregnancy Registry and 7% of the entire sample of 35,691 pregnant women receiving LNP/BNT162b2. From authors' Table 3, page 2279:

Timing of first eligible dose			
Periconception: within 30 days before last menstrual period	55 (2.6)	37 (2.0)	92 (2.3)
First trimester: <14 wk	615 (28.8)	517 (28.4)	1132 (28.6)
Second trimester: ≥14 and <28 wk	932 (43.6)	782 (42.9)	1714 (43.3)
Third trimester: ≥28 wk	533 (25.0)	486 (26.7)	1019 (25.7)
Missing data	1 (<0.1)	0	1 (<0.1)

Only 827 subjects out of the **3,958** cases enrolled in the Pregnancy Registry **completed pregnancy** during the study period. Random selection cannot be assumed based on information provided.

This represents **21%** of the group entered into the pregnancy registry and **2.3%** of the initial group of 35,691 pregnant women drawn from the total pool**. 827 represents about 0.1% of the estimated total number of pregnant women injected with LNP/mRNA in the first 10 weeks following the EUA.**

The most profound change to the fetus occurs in the first trimester and spontaneous abortion rates are much higher during this phase.

Therefore, pregnant women receiving LNP/mRNA during their first trimester are of special interest in terms of spontaneous abortion, prematurity, small size for gestational age, congenital anomalies, and neonatal death.

Caution: Multiple attempts have been made to calculate rates of spontaneous abortion from these data.

Four determinations of the rate of spontaneous abortion after LNP/mRNA treatment in pregnant women will be illustrated. A fifth, referred to as an MSU Analysis[11], will be addressed in a subsequent article.

1. V-safe Analysis 1:

Shimabukuro, et. al. reported on spontaneous abortions as follows:

[10] https://www.emedicinehealth.com/what_are_abortion_and_miscarriage/article_em.htm
[11] MSU = Make Stuff Up.

> Among **827 participants** who had a completed pregnancy, the pregnancy resulted in a live birth in 712 (86.1%), in a **spontaneous abortion in 104 (12.6%),** in stillbirth in 1 (0.1%), and in other outcomes (induced abortion and ectopic pregnancy) in 10 (1.2%). A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation (Table 4), and **700 of 712 pregnancies that resulted in a live birth (98.3%) were among persons who received their first eligible vaccine dose in the third trimester.** P. 2276

Here the authors' calculated a 12.6% rate of spontaneous abortion using 104 as the numerator and 827 as the denominator.

However, **this is a gross error** as spontaneous abortion refers to loss of the fetus during the first 20 weeks and the **827** included **700 third trimester pregnancy cases** so using 827 as a denominator is **erroneous and misleading**.

Later attempts were made to retroactively change this number but it remains in the 6/17/2021 online version. A 9/8/2021 editorial effort successfully deleted the calculation from Table 4 of the 6/17/2021version as acknowledged in the NEJM on 10/14/2021 but the 12.6% figure remains in the text.[12]

Additionally, **only 127 participants received LNP/mRNA** products during the **first and second** trimesters. Why lump first and second trimester cases together? The risk for SABs is almost all in the first trimester.

2. V-safe Analysis 2:

Some have attempted to pull the first trimester cases out of the data to match these cases with the 20-week abortion group. Why not match the 20-week group with the 20-week SABs? Great question.

Here is how Analysis 2 goes.

Authors' Table 4 reports 104 spontaneous abortions during the first 20 weeks. P. 2280.

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17] ‡	Not applicable	104
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§

[12] https://www.nejm.org/doi/full/10.1056/NEJMc2113516

Table 2 below summarizes the data regarding the numbers of total pregnant women in V-safe, the number entered into the Pregnancy Registry and the number who complete their pregnancy.

Given as well is the number of spontaneous abortions in the first 20 weeks.

Table 2: CDC Spontaneous Abortions[13]

	N	%
Pregnant women (PW) injected 12/14/2020-2/28/2021	35691	
PW Enrolled in Pregnancy Registry	3958	11.1%
PW Completing Pregnancy (CP)	827	2.3%
PW CP Inoculated during first two trimesters 24 wks. or less	127	
Spontaneous abortions < 20 weeks	**104**	**82%**

A SABR of 82% appears to be impossibly high compared with published rates of 10-20%.[14]

Keep in mind that the 104 mothers with spontaneous abortions are probably not from the same query pool as the 127 making this calculation erroneous as well.

If the actual data were made available, we could check these assumptions but they have not been released as noted below from NEJM.com. Remember, this paper was published 14 months ago and the data still has not been released.

Data Sharing Statement

Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. N Engl J Med. DOI: 10.1056/NEJMoa2104983.

Question	Authors' Response
Will the data collected for your study be made available to others?	No
Would you like to offer context for your decision?	Our goal is to make deidentified data publicly available, but the process is still under development. Data are not available to others at the time of publication.

3. V-safe Analysis 3:

This analysis begins with the completed pregnancies as the rest of the figures above this line are unchanged.

[13] See Dr. James Thorp, MD's calculations in the comment section of https://pierrekory.substack.com/p/massive-miscarriage-rates-among-vaccinated

[14] https://www.mayoclinic.org/diseases-conditions/pregnancy-loss-miscarriage/symptoms-causes/syc-20354298

Completed pregnancies	827
Live births	712
1st and 2nd Trimester	12
3rd Trimester	700
Spontaneous abortions + Stillbirth	115
Spontaneous abortions before 13 weeks gestational age	96
PW injected within 30 days before the first day of the last menstrual period or in the first trimester the first day	1224
No follow up through 20 weeks	905
Follow up through 20 weeks	319
Spontaneous abortions @<20 weeks	104
Spontaneous abortions @<20 weeks	**33%**

Unfortunately, this approach falls victim to the same flaw as in Analysis 2, multiple unique groups.

4. V-safe Analysis 4:

If you waited until the October 2021[15] update to read this paper you would have been rewarded with the final analysis as contained in this bizarre statement:

> **No denominator was available to calculate a risk estimate for spontaneous abortions**
>
> because at the time of this report, follow-up through 20 weeks **was not yet available for** 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester.
>
> **Spontaneous abortions @<20 weeks Unknown**

Bottom line: Computation of SABR from V-safe Registry data does not produce a reasonable estimate of the true rate of spontaneous abortion in women given LNP/mRNA products during pregnancy particularly during the critical first 12-14 weeks.

5. VAERS Registry SABR

Perhaps VAERS can help. Table 5 gives the results of the VAERS database query.

Table 5: VAERS

Pregnant women	221
Non pregnancy AEs	155
Pregnancy/Neonatal AEs	66

[15] https://www.nejm.org/doi/full/10.1056/NEJMx210016

Pregnancy related AEs	
Spontaneous abortions (SAs)	46
1st Trimester SAs	37
2nd Trimester SAs	2
Unknown	7
Stillbirth	3
Premature membrane rupture	3
Vaginal bleeding	3

The authors do not provide the logic or terminology used to query the VAERS database making verification of these numbers impossible.

Unfortunately, not much can be concluded from this tiny non-random sample of cases other than to note that the potential harms of LNP/mRNA in pregnant women and their babies.

6. Pfizer Registry Abortion Rate

For comparison with V-safe and VAERS there is Pfizer Document 5.3.6 that reports Adverse Events in its own registry collected during the same time period covered by the CDC data and reports on spontaneous abortions in 28 completed pregnancies.[16]

The trimester of the injection(s) was /were not given.

Altogether there were 270 pregnant women who received LNP/mRNA injections but outcome was not known in 238 and 5 were in progress.

Table 3: Pfizer Spontaneous Abortions

Pregnancies with outcomes out of 270 PW	28	
Spontaneous abortion	23	82%

With 88% of the pregnant women unaccounted for and no information provided about injection date as a function of gestational age no reasonable estimate of SABR can be made from these data.

Using the 720,000 estimate of the actual number of pregnant women receiving LNP/mRNA from the V-safe Registry in the first 10 weeks, these 28 cases represent a non-random sample of 0.004% of the estimated total number of pregnant women given experimental gene products during the period from 12/14/2020 to 2/28/2021.

B. Pre-Term, Small Size and Congenital Anomalies.

Of the 724 live-born infants in the V-safe registry there were 60 of 636 pre-Term births, 23 of 724 small for gestational period and 16 of 724 with major congenital anomalies.

[16] https://robertchandler.substack.com/p/why-do-females-have-more-adverse

Table 4: Pre-Term, Small size and congenital anomalies.

Pre-Term Cases	60/636	636 vax before 37 wks.
Small size for gestational period	23/724	8%
Major congenital anomalies	16/724	3%

This data is virtually meaningless since there is no trimester data, no data about age at conception, co-morbidities, number of prior pregnancies and births and so on.

C. Dose Related Reactogenicity

Shimabukuro, et. al. present the following reactogenicity data in their Table 2.

Table 2. Frequency of Local and Systemic Reactions Reported on the Day after mRNA Covid-19 Vaccination in Pregnant Persons.*

Reported Reaction	Pfizer–BioNTech Vaccine		Moderna Vaccine		Total	
	Dose 1 (N=9052)	Dose 2 (N=6638)	Dose 1 (N=7930)	Dose 2 (N=5635)	Dose 1 (N=16,982)	Dose 2 (N=12,273)
	number (percent)					
Injection-site pain	7602 (84.0)	5886 (88.7)	7360 (92.8)	5388 (95.6)	14,962 (88.1)	11,274 (91.9)
Fatigue	2406 (26.6)	4231 (63.7)	2616 (33.0)	4541 (80.6)	5,022 (29.6)	8,772 (71.5)
Headache	1497 (16.5)	3138 (47.3)	1581 (19.9)	3662 (65.0)	3,078 (18.1)	6,800 (55.4)
Myalgia	795 (8.8)	2916 (43.9)	1167 (14.7)	3722 (66.1)	1,962 (11.6)	6,638 (54.1)
Chills	254 (2.8)	1747 (26.3)	442 (5.6)	2755 (48.9)	696 (4.1)	4,502 (36.7)
Fever or felt feverish	256 (2.8)	1648 (24.8)	453 (5.7)	2594 (46.0)	709 (4.2)	4,242 (34.6)
Measured temperature ≥38°C	30 (0.3)	315 (4.7)	62 (0.8)	664 (11.8)	92 (0.5)	979 (8.0)
Nausea	492 (5.4)	1356 (20.4)	638 (8.0)	1909 (33.9)	1,130 (6.7)	3,265 (26.6)
Joint pain	209 (2.3)	1267 (19.1)	342 (4.3)	1871 (33.2)	551 (3.2)	3,138 (25.6)
Injection-site swelling	318 (3.5)	411 (6.2)	739 (9.3)	1051 (18.7)	1,057 (6.2)	1,462 (11.9)
Abdominal pain	117 (1.3)	316 (4.8)	160 (2.0)	401 (7.1)	277 (1.6)	717 (5.8)
Injection-site redness	160 (1.8)	169 (2.5)	348 (4.4)	491 (8.7)	508 (3.0)	660 (5.4)
Diarrhea	178 (2.0)	277 (4.2)	189 (2.4)	332 (5.9)	367 (2.2)	609 (5.0)
Vomiting	82 (0.9)	201 (3.0)	77 (1.0)	357 (6.3)	159 (0.9)	558 (4.5)
Injection-site itching	103 (1.1)	109 (1.6)	157 (2.0)	193 (3.4)	260 (1.5)	302 (2.5)
Rash	20 (0.2)	18 (0.3)	22 (0.3)	18 (0.3)	42 (0.2)	36 (0.3)

* Shown are solicited reactions in v-safe participants 16 to 54 years of age who identified as pregnant and who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021.

There may to be four different data samples represented here which is a typical finding in a data mining project.

Tests of statistical significance were not performed on this data but there appears to be a dose related effect here that reinforces the observation from Pfizer pre-clinical and clinical trials that there is a dose related response to LNP/mRNA.[8]

Dose related adverse events are events that increase in frequency as the total amount of drug received increases and are of concern when considering the possible cumulative frequency and severity of AEs and AESI rates in a multiple booster program.

V. Omissions

The CDC authors neglected to mention the relevant omissions from the preclinical studies as reported in Pfizer Confidential Document 2.4. listed below[17]:

A. Pre-Clinical Studies:

1. **Safety pharmacology:** "No safety pharmacology studies were conducted with BNT162b2 as they are not considered necessary for the development of vaccines according to the WHO guideline (WHO, 2005)." P.14¶2

2. **Pharmacodynamic Drug Interactions:** "Nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted as they are not generally considered necessary to support development and licensure of vaccine products for infectious diseases (WHO, 2005)." P14¶3.

3. **No pharmacokinetic studies** were performed with BNT162b2 and "...are generally not considered necessary to support the development and licensure of vaccine products for infectious diseases (WHO, 2005, WHO, 2014)." P17¶1.

4. **"The protein encoded by the RNA in BNT162b2 is expected to be proteolytically degraded like other endogenous proteins.** RNA is degraded by cellular RNases and subjected to nucleic acid metabolism. Nucleotide metabolism occurs continuously within the cell, with the nucleoside being degraded to waste products and excreted or recycled for nucleotide synthesis. **Therefore, no RNA or protein metabolism or excretion studies will be conducted." P20¶3**

5. **Genotoxicity: "No genotoxicity studies are planned for BNT162b2** as the components of the vaccine construct are lipids and RNA are not expected to have genotoxic potential (WHO 2005)." P29 ¶3.

6. "**Carcinogenicity studies with BNT162b2 have not been conducted** as the components of the vaccine are lipids and RNA and are not expected to have carcinogenic or tumorigenic potential." P29 ¶4. (WHO 2005)

These omissions were not mentioned the Shimabukuro, et. al. paper which was and continues to be used as reference for medical professionals charged with informing patients about the risks,

[12]robertchandler.substack.com

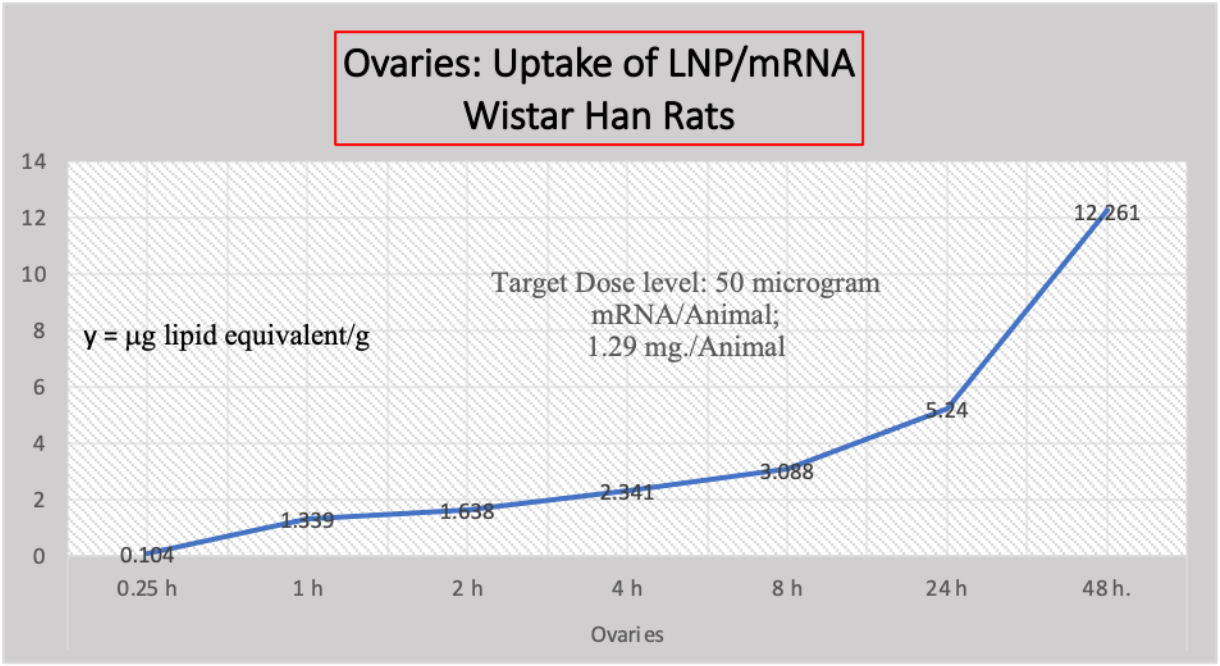
benefits, and alternatives to never before used experimental gene therapy drugs that have the potential for gene modification, carcinogenesis, autoimmunity and a host of other medical problems both known and unknown.

It is now known that Spike proteins, mRNA and lipid nanoparticles are present for weeks to months and possibly years in human tissues and the harms from these agents are being identified almost daily.

B. Biodistribution Data:

Another study **not mentioned** in the CDC document concerns the biodistribution of BNT162b2 that shows accelerating accumulation of LNP/mRNA in Wistar Han Rat ovaries, below Chart 4. **We have no such data in humans.**

Chart 4



Criticisms here have been that the dose may have not been suitable, that these biodistribution studies should have been run longer than 48 hours, and that animal studies can give misleading or erroneous results.

So, it's not possible to compress ten years of novel drug development into ten months? The simple answer is, exactly.

C. Phase 3 Clinical Trials:

What about the large Phase 3 clinical trial reported by Polack, et. al.?[18]

[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745181/pdf/NEJMoa2034577.pdf

> This **report does not address the prevention** of Covid-19 in other populations, such as younger adolescents, children, and **pregnant women**. Safety and immune response data from this trial after immunization of adolescents 12 to 15 years of age will be reported subsequently, and **additional studies are planned to evaluate BNT162b2 in pregnant women,** children younger than 12 years, and those in special risk groups, such as immunocompromised persons. P. 12.

Keep in mind that this was published 12/16/2020, mass inoculation began 12/14/2020 and by 2/28/2021 at least 35,691 pregnant women had been given LNP/mRNA gene therapy products and these pregnant women and their babies was largely lost to follow up.

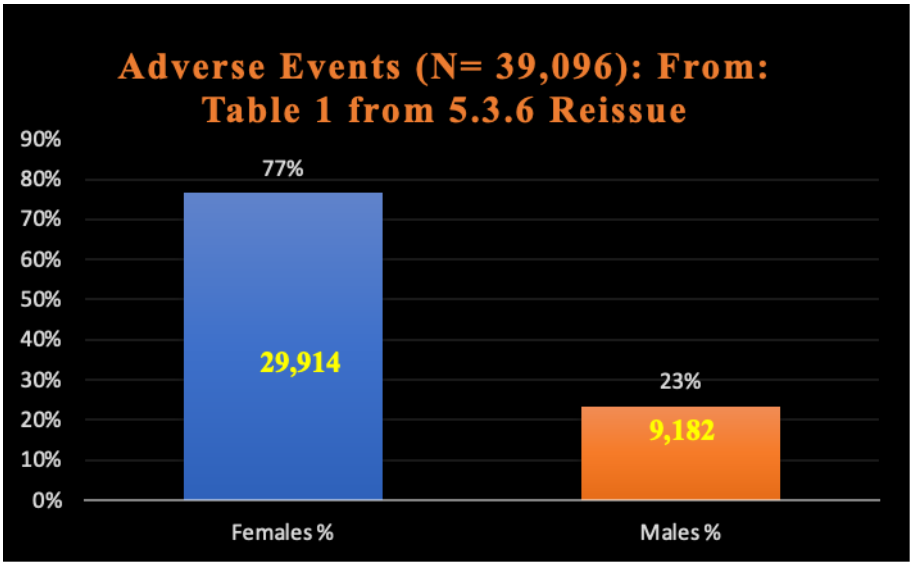
One more point about the Phase 3 trial subjects. Volunteers in the Placebo group were offered and many were given LNP/mRNA drugs t**hus ending the randomized, controlled study that should have lasted at least two years.**

This was the best shot at understanding the possible harms of LNP/mRNA.

D. Sex Differences in Adverse Events and Adverse Events of Special Interest.

Another omission from the CDC report about safety using LNP/mRNA in pregnant women concerns the data from Pfizer summary report 5.3.6 that shows a strong signal of increased harms from the RNA drugs to women in general, Chart 5.

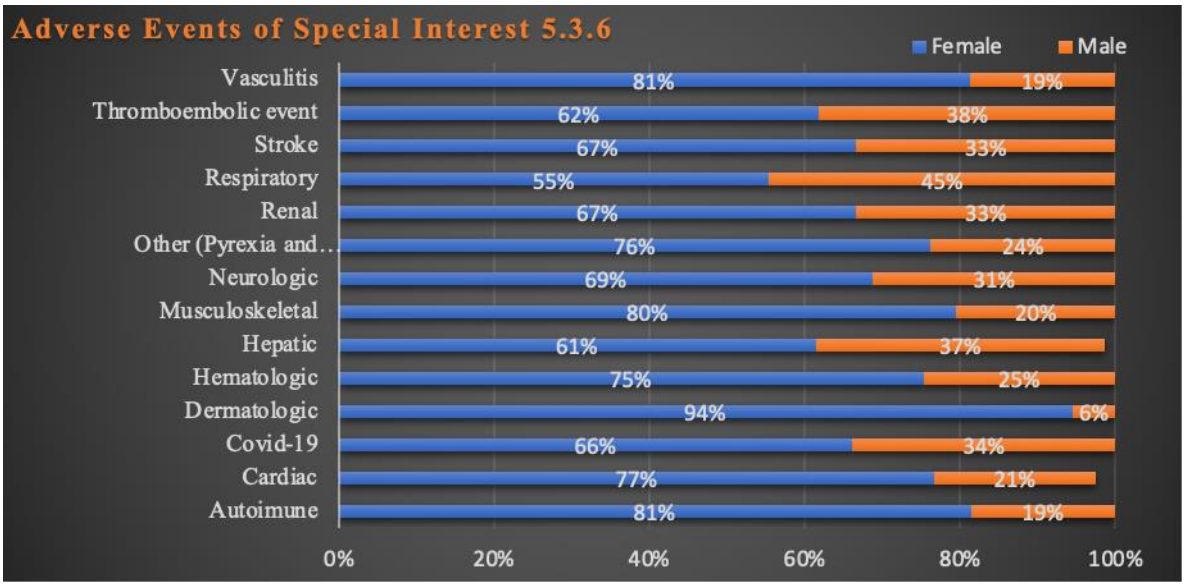
Chart 5: Sex Difference
Pfizer Adverse Events 5.3.6
2/28/2021



The chances this difference in reporting of adverse events between women and men is random is less than 0.001%.

The same findings apply to Adverse Events of Special Significance as shown in Chart 6.

Chart 6: AESI Sex Differences



These differences are also statistically significant at $p < 0.05$ in all but the following, Dermatologic, Hematologic, Renal, Vascular and "Other" categories by organ system.

A subsequent report confirmed the statistically significant differences in Reproductive System and Function AEs with strong predominance of harms to women's reproductive systems and functions compared with those of men.[19]

This data was collected during the same interval as that covered by Shimabukuro, et. al. and should have been known to the CDC/FDA doctors and scientists. This information was vital to provide proper informed consent to pregnant women specifically but applies to all women.

VI. Dr. Rubin, the NEJM, FDA and CDC

"But we're never gonna learn about how safe this vaccine is until we start giving it, that's just the way it goes. That's how we found out about-complications of other vaccines...And I do think that we should vote to approve it." said FDA Vaccines and Related Biological Products Advisory Committee panel member Dr. Eric Rubin, MD at a hearing on October 26, 2021 during an all-day session to consider use of BNT162b2 in children aged 5-11.[20,21]

[19] https://robertchandler.substack.com/p/why-do-females-have-more-adverse
[20] https://twitter.com/Techno_Fog/status/1453095851824459776
[21] https://townhall.com/tipsheet/scottmorefield/2021/10/26/fda-panel-member-were-never-gonna-learn-about-how-safe-the-vaccine-is-until-we-start-giving-it-n2598

It has been debated as to whether this remark was taken out of context or not but either way it remains a remarkable statement in the whole context of wide spread use of novel gene therapy products and is applicable to the subject of this paper.

Dr. Rubin is Editor-in-chief of the New England Journal of Medicine (NEJM), a once prestigious medical journal, and Adjunct Professor of Immunology and Infectious Diseases at Harvard's T.H. Chan School of Public Health. Dr. Rubin is also a member of the FDA's vaccine and biologics advisory panel.

"When politics and science meet, politics wins.". (Source unknown).[22]

During 2020 the NEJM published an article unrelated to the present work that used an obviously fraudulent data set that because of complaints from the medical community had to be retracted. In the context of this controversy Dr. Rubin wrote the following:

> Recently, substantive concerns have been raised about the quality of the information in that database. We have asked the authors to provide evidence that the data are reliable. In the interim and for the benefit of our readers, we are publishing this Expression of Concern about the reliability of their conclusions.[23,24,25]

It seems there was a precedent for faulty data sets in work published by the New England Journal of Medicine.

VII. Summary

The subject of the present article was the safety determination by the CDC and FDA of LNP/mRNA experimental gene products in pregnant women.

The article fell short of any reasonable expectation of providing useful information concerning the risks to pregnant women and their babies. Accurate and reliable scientific data were not collected.

Shortcomings of the Shimabukuro, et. al. report and the body of work it reports on are abundant.

Here are 10 of them.

1. The Pre-Clinical evaluation of the effects of LNP/mRNA on pregnancy was inadequate.

2. Phase 1-3 Clinical Trials by Pfizer did not include evaluation in pregnant women.

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[22] https://www.psychologytoday.com/us/blog/darwins-subterranean-world/202105/politics-and-science-losing-combination

[23] See: https://www.nejm.org/doi/full/10.1056/NEJMoa2007621 for an article published then retracted after numerous complaints about an obviously bogus data set was used. See for Expression of concern

[24] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7274164/pdf/NEJMc2021225.pdf

[25] https://www.nejm.org/doi/pdf/10.1056/NEJMe2020822?articleTools=true. Retraction

3. The control group from the Pfizer Phase 3 trial was compromised ending perhaps the most direct and powerful tool to understand the long-term effects of these drugs long before the required two years had elapsed.

4. The Pfizer registry summarizing the first two and a half months of widespread use of LNP/mRNA identified the statistically significant warning signal of increased adverse events and adverse events of special interest after LNP/mRNA therapy in women and this warning signal was not publicized.

5. The rates of spontaneous abortion, congenital anomalies, prematurity, and neonatal death were not determined with any degree of certainty.

6. 97% of the 35,691 pregnant women in the V-safe database and their babies who were injected with the experimental gene therapy drug had no outcomes recorded.

7. Candidates for LNP/mRNA products were not informed of AEs, AESI, and dose related harms associated with these products.

8. Absence of data from valid and reliable randomized controlled studies of pregnant women and their babies following treatment with LNP/mRNA products undermines a recommendation for these products in pregnant women.

9. Registry data is not appropriate for analysis of never before used gene therapy products.

10. The scientific integrity of this work was further compromised by multiple retrospective revisions of this work as revealed in the online publications June 17, 2021, September 8, 2021, and October, 14, 2021[26,27,28,29,30]

Conclusion:

Use of LNP/mRNA products in pregnant women must stop.

It is necessary now to FOIA the notes of the peer reviewers, the editorial staff of the New England Journal of Medicine, the FDA and CDC officials who raised no alarms when they saw that the vast majority of pregnant women in the CDC's 'VSafe' study- one that was invoked extensively as justification to inject millions of pregnant women with mRNA injections - were simply lost.

[26] https://www.nejm.org/doi/full/10.1056/NEJMx210016
[27] https://www.nejm.org/doi/full/10.1056/NEJMc2113891
[28] https://www.nejm.org/doi/full/10.1056/NEJMc2113516
[29] https://www.nejm.org/doi/full/10.1056/NEJMx210017
[30] https://www.nejm.org/doi/full/10.1056/NEJMe2107070