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David Wiseman,[1] PhD, MRPharmS., Joshua Guetzkow PhD[2], Hervé Seligmann PhD. [3]

[1] Synechion Inc., Dallas, TX. david.wiseman@synechion.com
[2] Hebrew University, Jerusalem, Israel. joshua.guetzkow@mail.huji.ac.il
[3] varanuseremius@gmail.com

Summary

- Significant safety concerns need to be addressed for the Covid-19 vaccines as presently used, and with the use of booster doses.
- We show intense safety signals for the Covid-19 vaccines compared with influenza vaccines with 176 times the number of deaths/person vaccinated reported in VAERS.
- To account for any stimulated reporting, compared with H1N1 vaccines where stimulated reporting was suspected, this ratio is still high at 35.
- Although classical disproportionality analysis is inadequate and superseded by methods that normalize for actual doses administered or people vaccinated, we nonetheless detected strong age-dependent signals for deaths, serios events coagulopathy and myocardial infarction.
- We identified three separate pools of vaccine associated deaths, totaling 45,000-147,000 deaths.
  - Non C19 deaths under reported in VAERS 20,400-62,500
  - C19 deaths occulting in vaccinated 25,000-85,000
  - An unknown number of deaths in non-vaccinated contributed by transmission from vaccinated.
  - These figures should be placed in the context of the upper estimate of 140,000 lives saved due to the vaccines (to May 2021)(1)
  - The benefits of vaccination should be considered in light of resistant strains, waning immunity(2) and development of natural immunity(3).
  - Unresolved safety questions for pregnant and nursing mothers must be resolved.
- An appropriate control group must be established
- Products must be regulated as gene therapy products, with appropriate long term follow up for autoimmune diseases, cancers etc.
- Significant short and Long term health issues require the ***Recognition of short and long term vaccine -related effects as a major public health issue.*** To concretize recognition of, and to spur action to avert and confront this potential public health crisis, we propose the term:

Post Covid Vaccine Syndrome – pCoVS

A syndrome occurring after injection of antigen-inducing, gene therapy vaccines to SARS-Cov-2 virus. The syndrome is currently understood to manifest variously as cardiac, vascular, hematological, musculoskeletal, intestinal, respiratory or neurologic symptoms of unknown long-term significance, in addition to effects on gestation. Manifestations of the syndrome may be mediated by the spike protein antigen induced by the delivered nucleic acids, the nucleic acids themselves, or vaccine adjuvants. As more data become available, subsets and longer-term consequences of pCoVS may become apparent, requiring revision of this definition. Sub-categories may be designated by suffix for example:

- We propose the establishment of an ICD10 code for pCoVS, and an mechanism to fund research into pCoVS.

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1. Introduction: Safety of Covid-19 Vaccines

Globally[1] (8/29/21) around 5 billion doses of Covid-19 vaccines have been administered (8/20/21), mostly pursuant to Emergency Use Authorization (USA) or equivalent status. The purpose of this document is to contribute comments and questions for the discussion of safety of the Covid-19 vaccines as indicated in the draft agenda for the above referenced meeting.

2. Analysis of adverse events for Covid-19 vaccines using methods published by CDC

2.1. Insensitivity of Disproportionality Signal Analysis (DSA) used to detect safety signals

Several methods have been proposed to detect safety signals related to medical products, specifically from databases of spontaneous adverse event reports, such as VAERS. In general, these methods do not infer causality, merely they provide a signal for further investigation. To mitigate a number of statistical and informational challenges, methods involving Disproportionality Signal Analysis (DSA) have been devised, such as the use of the Proportional Reporting Ratio (PRR) or other Bayesian or data mining techniques. The VAERS team have indicated that these sorts of methods should be employed to detect safety signals for the Covid-19 vaccines.(4) Although DSA is a useful tool in pharmacovigilance (PhV) it has known limitations. A paper authored by scientists from Astra-Zeneca, Pfizer, as well as British and European regulators stated: *"Thus, the quantitative data in spontaneous reporting systems, while being useful in detecting new signals of drug-event associations, are not easily interpretable in terms of clinical impact" (5)* The authors further stated *"calculation of PRRs from spontaneous reporting databases should not replace nor delay the performance of formal epidemiological studies,"*

DSA uses the total number of reports reported for a particular drug as a surrogate denominator to estimate the incidence of a particular event in the population, to be compared with other drugs in the same class. Although methods exist to partially compensate for masking of a particular event by other events, as well as non-independence of events, the output from these techniques remains that of a signal which provides no estimate of **epidemiological or clinical impact.** This problem is compounded in the case of drugs where, even if the number of prescriptions written are known, detail as to actual usage, dose, length of treatment and so on may not be.

[1] covid19.who.int/

In the case of the Covid-19 vaccines, the primary reasons for employing a surrogate denominator do not pertain: individual doses are usually fixed, the number of doses given is fixed, with mostly uniform dose intervals. Lastly, the number of doses administered as well as the number of persons receiving those doses, is known from CDC tracking systems.

2.2. Use of normalized event ratios for signal detection

We adopted the approach published (6) by scientists from FDA and CDC to normalize the number of events reported in VAERS for the number of people receiving a particular vaccine or doses administered. This figure can be divided by a similar ratio from a reference vaccine to obtain a normalized event ratio (NER).

We were particularly interested in the H1N1 data, as the paper published by CDC scientists (6) had stated that there had been active efforts to encourage people to use the VAERS system for H1N1 (see p7251 *"These findings, however, should be interpreted in light of the publicity around the 2009-H1N1 vaccine and efforts to increase reporting to VAERS"*).

Examining the data in VAERS (7/30/21) obtained using the WONDER portal, the per population- or per dose-normalized event ratios are very high, particularly for reports of death (177, 98 respectively) (Table 1).

Estimates of PPR are clearly highly muted, challenging their value and appropriateness. Nonetheless, the signal (5.2) for deaths was significant according to the Evans criteria.(7) To the extent that there was any sort of stimulated reporting, this was against a background of extensive campaigns promoting the safety of the C19 vaccines.

***Table 1:* Normalized Event Ratio (NER) or Proportional Reporting Ratio (PRR) for Covid-19 Vaccines Compared with Seasonal Flue or H1N1 Vaccines**

	NER or PPR				
	C19 vs Flu			C19 vs H1N1	
Event Category	NER people[a]	NER Doses[b]	PRR[c]	NER People[d]	PRR[e]
Death	176.7	97.5	5.2*	35.1	0.4
Life Threatening	58.9	32.5	1.7	13.2	1.1
Permanent Disability	29.6	16.3	0.9	19.5	0.7
Congenital Anomaly / Birth Defect *	47.0	26.0	1.4	0.0	0.0
Hospitalized	53.8	29.7	1.6	13.5	1.1
Existing Hospitalization Prolonged	44.3	24.5	1.3	1.3	11.3
Emergency Room * (note)	42.1	32.3	1.7	18.2	0.8
Office Visit * (note)	22.4	17.2	0.9	13.1	1.1
None of the above	37.8	20.9	1.1	15.7	0.9
Serious	51.4	28.3	1.5	14.8	0.97
Not serious	33.1	18.3	1.0	14.9	0.96

We used estimates from CDC for the number of doses delivered/ people vaccinated.[2] We used USAFACTS[3] for age-related population figures for various years, and CDC figures on numbers of people vaccinated [4]for seasonal flu or H1N1 vaccines. Original figures obtained from VAERS 7/30/21 using "USA Territories, unknown"" as the location filter.

[a] Normalized Event Ratio (NER) of number of events in each event category (denominator number of unique events) adjusted for number of people given at least one dose of C19 (all dates) or Flu vaccine for 2016/7, 17/18 or 18/19 seasons

[b] NER of number of events in each event category adjusted for number of doses given of C19 (all dates) or Flu vaccine for 2016/7, 17/18 or 18/19 seasons

[c] PRR, C19, vs. flu (using unique events as denominator)

[d] Ratio of number of events in each event category adjusted for number of people given at least one dose of C19 (all dates) or H1N1 vaccine for 2009/10 season

[e] PRR C19 vaccines vs. H1N1.

* p <0.00001. (chi squared test). Although other values for example for life-threatening or serious conditions do meet the Evans(7) criteria because they do not exceed 2, the chi-squared test nonetheless yields p<0.00001.

We refined our analysis (Table 2) using VAERS data as of August 6 2021. We considered only reports from the 50 States plus Washington DC, excluding US territories and "unknown" locations to ensure that only AE's reported from the US were used when calculating rates based on vaccination coverage in the US. For the flu vaccines, data from the 2015/16, 2016/17, 2017/18, 2018/19 and 2019/20 were considered. The 2020/21 season was excluded to avoid confounding effects with Covid-19. For the Covid-19 vaccines, reports with an indication of SARS-CoV-2 infection or COVID-19 were not included in counts for COVID-19 vaccines. Because data availability in VAERS is ephemeral, we needed to repeat parts of our earlier analysis on what was the currently available dataset. In addition to deaths and serious events, we examined three categories of events noted to be of interest in the VAERS' Standard Operating Procedures for COVID-19:(4) Guillan-Barré Syndrome (GBS), coagulopathy, and acute myocardial infarction.

Table 2 shows strong signals for serious events, death, coagulopathy and myocardial infarction. The signals are more evident using the Normalized Event Ratio (by dose) than with the PRR. No major differences were evident if the PRR was calculated by number of unique events or by number of unique reports (i.e. symptoms). The

[2] cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html
[3] usafacts.org/data/topics/people-society/population-and-demographics/population-data/population/
[4] cdc.gov/flu/prevent/vaccine-supply-historical.htm

values for Normalized Event Ratios (by dose) for death and serious events were similar to those from our earlier analysis (Table 1).

For death and coagulopathy, the signals appear to increase with age. The reverse is true for myocardial infarction. For serious events an age-dependency is not evident. For Guillan-Barré syndrome, the signals appear weak and not detected at all using the DSA/ PRR method.

We conclude from this portion of our work that:

- There are strong safety signals evident for death, serious events, coagulopathy and myocardial infarction associated with the Covid-19 vaccines compared with the flu vaccines.
- Signals are age dependent for death and coagulopathy (increase with age) and myocardial infarction (decreases with age).
- Even after accounting for possible stimulated reporting, by comparison with H1N1 vaccines, strong safety signals are still evident.
- Using Normalized Event Ratios, consistent with CDC published methodology (6) appears a far more sensitive method of identifying signals than DSA/PRR methods.
- Further investigation is warranted to determine causality.
- Caution is warranted as booster doses are being considered.

***Table 2:* COVID-19 vs. Flu Vaccines: Normalized Event Ratio vs. Disproportionality Signal Analysis as Proportion of All Reports or events**

	SERIOUS EVENTS			DEATHS			GBS			COAGULOPATHY			Myocardial Infarction		
Ages	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report	NER dose	PRR event	PRR report
10-17	34	1.66	1.35	32	1.52	1.24	7	0.34	0.28	74	3.56	2.89	n.e.	n.e.	n.e.
18-49	25	0.87	0.99	64	2.22	2.52	3	0.09	0.1	226	7.78	8.82	403	13.92	15.78
50-64	26	1.23	1.45	85	4.01	4.74	3	0.12	0.14	239	11.19	13.22	121	5.68	6.71
65+	30	2.34	2.76	98	7.77	9.16	3	0.22	0.26	370	31.34	36.97	88	7.01	8.27
10+	28	1.31	1.52	91	4.24	4.93	3	0.13	0.15	276	12.77	14.84	126	5.83	6.78

Note: The PRR is the ratio of the proportion of a particular event or event type out of all reports (or events) for COVID-19 to the proportion of all reports (or events) for the combined 2015-2019 flu seasons. Orange shading indicates a statistically significant difference between the proportion of COVID-19 proportion of COVID-19 and flu reports for that age group and event type (chi squared test. Flu reporting rates represent the total reports to VAERS across the 2015/16-2019/20 flu seasons for each age group. Covid-19 reporting rates include all reports to VAERS for COVID-19 vaccines for each age group as of Aug. 6, 2021. The Normalized Event Ratio shown is calculated according to the number of doses given.

The "coagulopathy" category includes a set of 26 preferred terms (PT) for thromboembolic events (although the category does not include coagulopathy PT). The full list of PT's for GBS, coagulopathy and acute myocardial infarctions can be found in Table 4.6 of the VAERS SOP document.(4)

3. Estimate of under-reporting in VAERS using CDC published methods

CDC has acknowledged the many limitations inherent in the VAERS system, including that the system is prone to under-reporting for a variety of reasons. There is additional confusion given specific reporting requirements pursuant to the EUA. The CDC web site states[5] that under an EUA, health providers are required to report certain categories of events following vaccination including serious events, deaths and life-threatening events, regardless of if the report think the AE caused the event or not.

With about 2/3 of the US population vaccinated, we would expect about 5000 per deaths to occur every day from non-Covid-19 causes. Using a conservative 30-day follow up, we would expect to see 150,000 deaths reported in VAERS. As of 8/29/21, 6128 deaths (USA, territories and unknown) have been reported in connection with Covid-19 vaccines (4805 deaths 50 States and Washington DC). The system does not appear to be functioning as designed.

[5] www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html

Awaiting clarity from CDC as to the circumstances under which AEs are being reported to VAERS, we will assume that the requirement to do so is clearly not well known and that most reports are being made without knowledge of EUA requirements.

CDC scientists published (8) a method to estimate the degree of under-reporting in VAERS, by comparing the rates of AEs published in clinical trials, with rates normalized for population found in VAERS.

We used the 3 deaths classified as adverse events in Table S3 of the 6 month follow up study for the Pfizer vaccine (9). Conservatively, we did not use the 15 deaths in Table S4 there. Note the discrepancy between total deaths in the Thomas paper (18 vs 19 deaths in vaccine vs. placebo) and in the Summary Basis for Regulatory Action(10) where the total number of deaths reported are 21 and 17 for the vaccine and placebo groups respectively

Using these conservative data, we estimated the numbers of deaths tentatively associated with the Pfizer vaccine may be 4.9-15 times higher than reported. Applied to all vaccines, using the figure of 4805 deaths (50 states. DC) but subtracting deaths where Covid-19 or SARS is mentioned (639) this may represent a true report rate of between 20,400-62,500 deaths. The number of life-threatening events may be 24-64 times higher than reported. Noe that this estimate does not infer causality.

4. Estimate of number of deaths possibly associated with Covid-19 vaccines

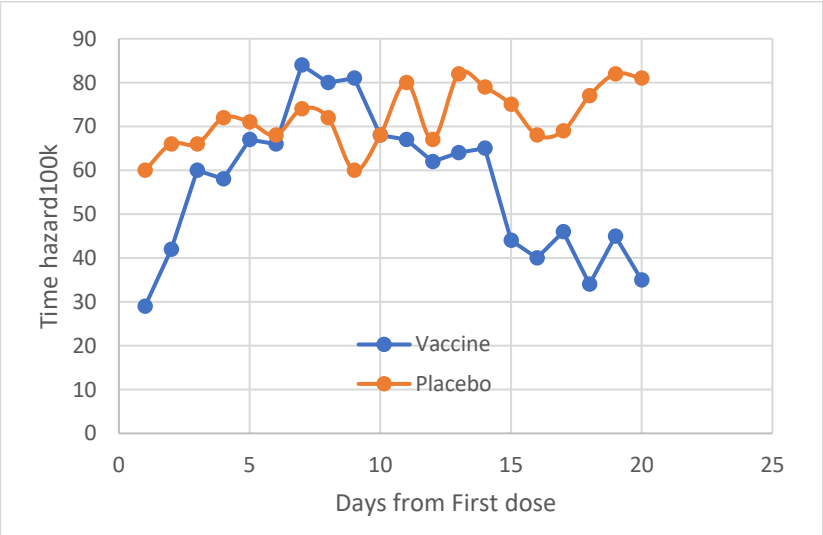
We have so far estimated 20,400-62,500 deaths unrelated to Covid-19, that we might have expected to find in VAERS (50 States+DC). We now estimate deaths related to Covid-19 subsequent to vaccination.

4.1. Post-vaccination deaths estimated from Israeli Ministry of Health and Clalit data.

Increased numbers of Covid-19 related deaths associated with vaccination

In an analysis of the data from the initial use (first 44 days) in 596,000 subjects of the Pfizer vaccine in Israel reported by Dagan et al. in NEJM (11), one of us (HS) observed an early (<7 days) uptick in Covid-19 cases following vaccination.

Figure 1: Covid-19 cases following vaccination in Dagan et al.



A letter to NEJM (March 11) was rejected but described in an article in France Soir – May 5.[6] There, the incidences of Covid-19 tripled from day 1 to 7 among the vaccinated,[7] and decreased to their initial rate 20 days after 1st injection, remaining at that level until day 28.The letter continues: "*This suggests a weakened immunity of the vaccinees which causes other, unreported, short-term (non-COVID-19) adverse effects, including some deaths. This analysis should have influenced decisions about who to vaccinate and when. Long-term risks can be expected with age and sex factors."*

Combining data in Dagan et al., with statistics from the Israeli Ministry of Health, an increase in the number of deaths in vaccinated subjects could be found following vaccination. These Israeli data are particularly informative because by the cut-off date, 54% of adult Israelis had been vaccinated, mitigating to some degree biases due to early vaccination of those most at risk. Further, by combining these data sources, we can see what is happening **among vaccinated patients**. There are a number of limitations as to causality and potential time biases, but this analysis suggests that there may be 121-413 excess deaths/million associated with vaccination, in those vaccinated (>= 1 dose), equating to about 25,000-85,000 deaths in the USA. Again, we cannot ascribe cause, merely association. The recent finding from a large Israeli cohort of and increased risk of Herpes zoster infection(12) may indicate immunosuppression related to vaccination in some subjects. In one study naïve vaccinees had a 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection with the Delta variant compared to those previously infected.(3)

4.2. Deaths in the unvaccinated population resulting from transmission by the vaccinated

There is a third pool of deaths and Covid-19 cases that must be considered in assessing the risk and benefits of the Covid-19 vaccines. Contrary to initial hopes, vaccines may not reduce transmission.(13), thus Covid-19 may have been unwittingly transmitted by vaccinees to the non-vaccinated.(14,15) Modeling and other types of studies may provide an estimate of these cases.

5. Unresolved pregnancy related safety issues

The COMIRNATY package insert(16) provides little guidance for pregnant or nursing mothers:

> *"Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."*
> *"It is not known whether COMIRNATY is excreted in human milk."*

Instead, the prescribing info says: *"There is a pregnancy exposure registry for COMIRNATY. Encourage individuals exposed to COMIRNATY around the time of conception or during pregnancy to register by visiting https://mothertobaby.org/ongoingstudy/covid19-vaccines/."*

FDA has required the conduct of a post-marketing pregnancy/neonatal study with a four-year term. Other biologics have been required to conduct longer studies. For example, a Janssen (J&J) product requires a 7-year[8] study that includes examining effects on the child and early development.

> *A prospective, registry-based observational exposure cohort study that compares the maternal, fetal, and infant outcomes of women exposed to guselkumab during pregnancy to an unexposed control population. The registry will detect and record major and minor congenital malformations, spontaneous abortions, stillbirths, elective terminations, small for gestational age, and any other adverse pregnancy outcomes. These outcomes will be assessed throughout pregnancy. Infant outcomes, including neonatal deaths, infections in the first 6 months of life, and effects on postnatal growth and development, will be assessed through at least the first year of life.*

A recently approved (2021) Astra-Zeneca biologic product[9] required a NINE year study:

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[6] francesoir.fr/societe-sante/le-new-england-journal-medecine-refuse-une-lettre-davertissement-du-dr-seligman-sur
[7] The imbalance between the two groups on initiation poses a separate problem as to the matching of the two groups.
[8] www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/761061Orig1s000ltr.pdf
[9] www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/761123Orig1s000ltr.pdf

Conduct a prospective pregnancy registry to evaluate the effects of Saphnelo (anifrolumab-fnia) on pregnancy and maternal and fetal/neonatal outcomes. This pregnancy registry study may be conducted as part of a multiple-product or disease-based pregnancy registry.

6. Vaccines or Gene Therapy Products? Regulatory and Safety Consequences

Although these Covid-19 agents fall under FDA's definition of vaccines and vaccine-associated products,[10]

> *"products, regardless of their composition or method of manufacture, intended to induce or enhance a specific immune response to prevent or treat a disease or condition, or to enhance the activity of other therapeutic interventions."*

they differ significantly from the classical vaccine consisting of an inactivated or attenuated pathogen in two major respects. Firstly, rather than an immune response being elicited by injected antigen, it is elicited by antigen (the SARS-Cov2 spike protein), whose within-subject biosynthesis is induced by mRNA or DNA deployed by the vaccine.

Secondly, these vaccines also meet FDA's definition of gene therapy products.[11]

> (emphasis added) *"Human gene therapy/gene transfer is **the administration of nucleic acids**, viruses, or genetically engineered microorganisms that mediate their effect by transcription and/or translation of the transferred genetic material, and/or by integrating into the host genome. Cells may be modified in these ways ex vivo for subsequent administration to the recipient, or **altered in vivo by gene therapy products administered directly to the recipient**."* A similar expanded definition is given in FDA's Guidance on Long Term Follow-Up After Administration of Human Gene Therapy Products.(17)

Moderna, Inc., the maker of one of the mRNA Covid-19 vaccines, acknowledged in their 2Q2020 SEC filing(18)[12] thus *"Currently, mRNA is considered a gene therapy product by the FDA."* Despite being excluded under European law(19) from the definition of Gene Therapy Products, these vaccines must therefore be described as "Gene Therapy Vaccines" (GTV).

Consistent with the FDA June 2020 guidance(20) on the development of vaccines for Covid-19, Pfizer,[13] Moderna[14] and Johnson & Johnson,[15] declared their intent in their requests for EUA status to follow study subjects for up to 36 months. Of particular concern is the unblinding of at least some of the clinical trials, thus preventing full assessment of safety issues.(21)

Even this follow period is inadequate for two reasons. Firstly, although the sorts of events anticipated by FDA and CDC are of relatively early onset, the duration or prognosis for a number of them is unknown. Secondly, since these agents are also Gene Therapy products, much longer surveillance is warranted for delayed malignant, neurologic, autoimmune, hematologic, other disorders or effects on the genome or gene expression, as advised in FDA in its guidance document "Long Term Follow-up After Administration of Human Gene Therapy (GT) products."(17) The length of monitoring advised by FDA may be (emphasis added) "***as long as 15 years*** *following exposure to the investigational GT product, specifying that the LTFU observation should include a*

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[10] www.fda.gov/combination-products/jurisdictional-information/transfer-therapeutic-biological-products-center-drug-evaluation-and-research

[11] *www.fda.gov/combination-products/jurisdictional-information/transfer-therapeutic-biological-products-center-drug-evaluation-and-research*

[12] Moderna's 2Q2020 SEC filing is dated August 6 2020, and states that the phase 1 study began March 16, 2020, with the phase 2 study being fully enrolled by July 8, 2020. Enrollment for the phase 3 study began July 27, 2020, as also reflected in for clinicaltrials.gov. Each phase would have been cleared by FDA. The start date given in clinicaltrials.gov for Pfizer's trial was April 29 2020 and for J&J Sept 7 2020.

[13] https://www.fda.gov/media/144245/download

[14] https://www.fda.gov/media/144434/download

[15] https://www.fda.gov/media/146219/download

minimum of five years of annual examinations, followed by ten years of annual queries of study subjects, either in person or by questionnaire."

Accordingly, the designation of these vaccines as Gene Therapy products is not merely a semantic nicety; rather it has regulatory consequences in terms of long term follow up manufacturers should be required to conduct. No reference to these FDA guidance documents on long term follow up for gene therapy products (17) was made in FDA's guidance on development of Covid-19 vaccines(20), nor in the EUA briefing documents provided by Pfizer, Moderna and Johnson & Johnson.

Understanding the concerns that this distinction reveals has significant long-term consequences. Given that these Gene Therapy Vaccines (GTV) have been used on what may fairly be termed an experimental basis, **every** GTV recipient may be subject to, or even entitled to long-term monitoring, as well as early intervention of delayed events. Assuming, conservatively, an annual cost of $500 per person, and based on an estimated (8/29/21) 204 million of Americans having received at least one GTV dose, this amounts to an annual cost of some $102 billion, just for the USA. This figure is comparable to the 2020 budgets or revenues of NIH ($42b), Pfizer ($42b), Johnson & Johnson ($83b) or Facebook ($86b) and eclipses estimates of between $25 billion and $35 billion for the global Covid-19 vaccine market. Considering the approximately 4.5 billion GTV recipients around the world, this annual global cost, before any treatment or indirect costs, will approach trillions of dollars. Who will absorb this cost? Government? Medicare? Medicaid? The manufacturers of AI-GTVs? Private insurers? Recipients of the GTVs?

An explanation is therefore required as to why the provisions relating to Gene Therapy products have not been incorporated into the risk-benefit analysis of these vaccines.

Will FDA and CDC collect other long-term data on autoimmune disease, cancer and other disorders as contemplated in the FDA Gene Therapy Guidance document?(17) The package insert(16) states that *"COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility*." Neither in the in the BLA Approval letter,(22) or Summary Basis for Regulatory Approval(10) is there a POST MARKETING REQUIREMENT to conduct carcinogenicity, genotoxicity or male fertility.

THE BLA for COMIRNATY acknowledges LONG term myocardial issues with a 5 year follow up consistent with the lower range for LTFU for Gene Therapy Products. Is FDA quietly acknowledging the Gene Therapy classification?

7. Establishment of LTFU program: pCoVS

The growing list of short-term effects attributed to the Covid-19 vaccines, as well as unresolved long term concerns poses a major public health issue. To concretize recognition of, and to spur action to avert and confront this potential public health crisis, we propose the term:

Post Covid Vaccine Syndrome – pCoVS

A syndrome occurring after injection of antigen-inducing, gene therapy vaccines to SARS-Cov-2 virus. The syndrome is currently understood to manifest variously as cardiac, vascular, hematological, musculoskeletal, intestinal, respiratory or neurologic symptoms of unknown long-term significance, in addition to effects on gestation. Manifestations of the syndrome may be mediated by the spike protein antigen induced by the delivered nucleic acids, the nucleic acids themselves, or vaccine adjuvants. As more data become available, subsets and longer-term consequences of pCoVS may become apparent, requiring revision of this definition. Sub-categories may be designated by suffix for example:

- *-C Cardiac*
- *-N Neurologoc*
- *-H Hematologic*
- *-V Vascular*

We propose:

- Recognition by public health agencies, governments and professional societies of pCoVS.
- Assignment of ICD10 and related tracking or re-imbursement codes for pCoVS.
- Establishment of transparent systems to monitor and track for long-term and delayed pCoVS.
- Establishment of funding for research into the prevention and treatment of pCoVS.
- Regulation of the Pfizer, Moderna and Janssen vaccines (GTVs) as Gene Therapy products.
- Insistence on long term (15 years) pharmacovigilance by manufacturers of AI-GTVs for pCoVS consistent with FDA guidelines for gene therapy products.
- Legislation to prevent discrimination of patients based on vaccination[16] or actual or potential pCoVS status.
- Establishment of funding to determine what effects if any the GTVs have on the genome or gene expression, including their effects on toxicity and other disorders. Develop and implement methods to screen for, and treat the consequences of, such genetic changes.
- Comprehensive funding for the development of programs to prevent Covid-19 or reduce its impact by promoting good health practices, proper use of nutritional supplements and conduct of well-executed clinical trials to examine the effects of promising repurposed rugs.

The pCoVS Working Group is being established to include medical professionals and scientists from across the political spectrum who are not only proponents of classical type vaccines, but also proponents of gene therapy products that employ DNA or mRNA technologies to treat cancer and other heretofore incurable diseases. As with all new technologies, safety is paramount, and we assert that until proven otherwise, the risk-benefit balance demands a re-assessment of the justification for the continued use of these Gene Therapy Vaccines (GTVs), especially as booster doses are now being considered.

In addition to concerns related to the gene therapy nature of these products there are concerns about the toxicology of the spike protein antigen, the adjuvants themselves as well as downstream consequences at the gene or mRNA level. Importantly, inexpensive, safe and effective prevention and treatment based on repurposed drugs are readily available. (23)

The contentions that our motivations are rooted elsewhere or that allegedly politically motivated advocacy for use of repurposed drugs in Covid-19 has spewed misinformation fueling vaccine hesitancy is a perversion of the truth as such advocacy is subject to heavy censorship within social media, the peer reviewed scientific literature and in professional contexts. At a time when unity against Covid-19, and now pCoVS, is sorely needed, this demonization serves to increase divisiveness and political polarization. This demonization erodes patients' fundamental rights to choose whether or not to undergo any sort of medical treatment, and erodes physicians' freedom to practice medicine, by prescribing treatments they believe to be in the best interests of their patients.

Governments, public health agencies and the medical community must address pCoVS and at the same time make fundamental corrections to heretofore employed approaches to Covid-19 and the suppression of legitimate scientific debate.

Can CDC and this committee provide an assurance that it will do everything in its power to defuse the current toxic atmosphere that is stifling scientific discussion?

8. References

[16] According to one writer, those choosing to remain unvaccinated, rather than being demonzed, should be thanked for serving as a valuable control population enabling the effects of vaccines to be more fully evaluated.

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