Should Children Receive mRNA Injectable Products known as COVID-19 Vaccinations?

I. The Purpose of this Correspondence

This paper is written to suggest that COVID-19 injections should not be given to normal children. This paper will argue that for normal children, these products are not needed, are not effective, and are not safe. Multiple countries (England, Sweeden, Italy, France, Germany, Denmark, Portugal, New Zeeland) recommend against the use of these products except in older or higher risk groups [Prasad, 12/18/2023]. The European CDC, and European Countries do not recommend these products for healthy children [European CDC, 2023]. And yet, in the United States these products are now enshrined into the CDC pediatrics vaccine schedule even though, in the Omicron variant era, these products increase the risk of disease acquisition and transmission. Ironically, the FDA and CDC recently recommended these products for young children while at the same time acknowledging that the Pfizer data showed no efficacy [Vaccines and Related Biological Products Advisory Committee, June 14, 2022] [a]. In addition, the mRNA platform technology will likely be deployed in the creation of other vaccines, making yet another reason why the evaluation of this technology is of ongoing significance.

The nature of scientific inquiry requires open and thoughtful debate as well as a measure of humility as new data present themselves. If you are convinced these products should be given to children, this paper invites you to show the supporting data. This paper welcomes disagreement and revision and asks that criticism be directed at the methods and analysis of the data presented, and not at the character or motives of the authors promoting either point of view.

II. Background

A. Classic Vaccine Technologies

Vaccines technologies used for wide-spread human distribution have **classically** been developed using live-attenuated (weakened) viruses; inactivated (killed) viruses; subunit vaccines that contain pieces of a pathogen; or inactivated bacterial toxins. These **classic** vaccines typically remain at the injection site, produce a discrete immune response, and often provide lasting immunity (exception influenza vaccine that does not promote lasting immunity) [b].

B. mRNA Technologies are not Vaccines.

In contrast, the COVID-19 messenger RNA (mRNA) injectable products are built using synthetically manufactured mRNA that is enclosed within a lipid nanoparticle. After fusing with the host cell membrane, the mRNA highjacks the cells' normal protein synthesis machinery to produce the spike protein. Unlike what happens with a classic vaccine, this spike protein does not stay at the injection site but circulates throughout the body for at least 6 months [Brogna, et al 2023]. More than 1,000 papers have been published describing the toxicity of the spike

protein [Alibayov, 2022]. This toxicity is further enhanced by modifications made in the vaccine mRNA that retard its degradation, allowing the mRNA to persist in a molecularly active form for more than 2 months [Roltgen et al, 2022] [c.] The immune benefit from these products is not enduring but rapidly declines to very low levels within 5 months. “Efficacy has been inconsistent with the traditional sense of ‘vaccine,’ and failure to prevent infection or transmission of the COVID-19 variants eventually led the US Centers for Disease Control and Prevention (CDC) to reinvent their definition for ‘vaccine’ [Rhodes, 2024].

These products “also meet FDA’s definition of gene therapy products: (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.”” [Wiseman et al, Docket No. FDA-2021-N-0965, 2021] [Weisman, 2021] C. Moderna, in their 2020 SEC filing identifies their mRNA product as gene therapy [Hammond, 2023].

Messenger RNA technologies have been investigated for decades, primarily as tools for gene or cancer therapy, but when used in animal models for the prevention of viral infections virus prevention they have never been shown to be safe [d]. The biologic complexity of mRNA injectable products should humble anyone claiming equivalence of these products with classic vaccines. These products should be identified as gene therapy or pro-drugs with complex pharmacology and should be recognized as novel and experimental [Rhodes, 2024]. On the other hand, by calling these products “vaccines,” the public comes to view them as classical vaccines, and by inference believes in their safety. (For and extensive discussion on the pharmacology of these injectable products showing why they should not be classified as conventional vaccines see the paper by [Cosentino, et al, 2022]).

C. The Omicron Variant Era

Unlike the legacy COVID-19 variants (Wild, Alpha, Delta) that could result in severe lower respiratory/pneumonia type illness, the Omicron variant that appeared in late 2021 produces primarily an upper-respiratory illness. Although the Omicron variant is more contagious than the legacy variants, it is far less lethal [Lewnard et al, 2022], [Hani et al, 2023]. Currently the Centers for Disease Control (CDC) estimates that 220 to 350 million Americans (67% to 92% of the total population) have been exposed to one of the COVID-19 variants. This percentage qualifies as herd immunity by some epidemiologists and most agree that we are no longer in a pandemic but will be dealing indefinitely with an endemic virus that will remain in the environment. Because the virus lives in multiple animal reservoirs, it can never be eradicated [e].

Many expert immunologists, vaccinologists, and virologists warn that further global efforts to vaccinate against COVID-19 variants may result in the creation of escape mutants that might be more lethal than the Omicron variant [Malone, 2021]. This concern is amplified by the observation that repeated immunization may result in degradation of the innate immune system, making it more likely for vaccinated individuals to acquire and spread the disease (see later discussion on safety).

D. Vaccines and the Pandemic Reversal

Some researchers have attributed the downturn in COVID-19 cases in early 2021 to be the result of the vaccine campaign. This is not true, however, as COVID-19 cases and deaths from the Alpha variant peaked in mid-January 2021 and began to decline on January 14, 2021, when only 4.3% of Americans had been vaccinated. In addition, by February 20, 2021, COVID-19 cases had decreased by 73% with only 5.4% of Americans vaccinated at that time [Our World in Data, 2022] [f].

E. COVID-19 Origins

Gain of Function research is defined as research designed to increase the transmission, pathogenicity, immune evasion, or vaccine evasion of a pathogen. This research comprises <0.1% of all research but has by far the greatest existential threat. There is no civilian value to this, as creating a vaccine to a virus that does not exist can only happen by first created the lethal virus. From 2007 to 2020 over 61 million dollars in funding from a variety of federal agencies, including the Department of Defense (DOD) and the NIH, to conduct research on coronavirus and other viruses including gain of function research [Fleming, 2021]. A brief history of COVID shows gain of function research beginning as early as 1998 [Zelenko, 2023]:

1998/1999: Dr Ralph Baric perfects cross-species transmissibility [Baric, et al, 1999]

2002: Dr. Baric patents a method of how to take a bat coronavirus and make it lethal to human lung tissue

2014-17: Obama places a moratorium on gain-of-function research. Gain of function was outlawed in the US, so it was outsourced to Wuhan China where Baric and Zhengli completed the job.

In October, 2014, then NIH director Francis Collins announced "NIH will not provide new funding for any projects involving these experiments and encourages those currently conducting this type of work — whether federally funded or not — to voluntarily pause their research while the government determines how to proceed" [Collins, 2014]. However, according to Baric his chimeric coronavirus research "began before the moratorium was announced, and the NIH allowed it to proceed during a review process, which eventually led to the conclusion that the work did not fall under the new restrictions" [Akst, 2015].

2015: Dr. Baric and Dr Shi Zhengli (Wuhan Institute of Virology) (WIV) collaborate and perfected the technique of making a bat coronavirus infectious to human beings [Nature Medicine, [Menachery, et al, 2015].

2016: Moderna files to patent the Furin cleavage site sequence and applies for a vaccine patent for COVID but the patent office rejects the application saying that the product is not a vaccine but gene therapy.

2017: Moratorium lifted, but future gain of function research must show risk/benefit and be reviewed in committee by NIH.

2018: Peter Daszak (president of EcoHealth Alliance) applies to the Defense Advanced Research Projects Agency (DARPA) for funding for insertion of furin cleavage site [Paul, 2022]. He was refused but was able to launder money from the NIH to WIV. NIH fails to flag the research and fails to insist on committee review.

2019, March: Moderna obtains COVID Vaccine Patent. Evidence of pre-pandemic vaccine development at Pfizer's collaborator, is also found in a "BioNTech study report released in response to an FOIA request shows that the company had already in fact begun preclinical (animal) testing on January 14, 2020" [Kogon, 2023]. Contrary to the view that COVID-19 appeared in 2020 as a "novel" virus, there are actually 73 patents that were filed from 2008-2019 on genetic sequence elements of SARS-COV2, recognizing "innovations" for 12 years prior to 2020. [Martin, 2021].

Some may argue that this was not an engineered virus but that argument false short when we examine several biological "innovations" found in COVID-19 [Quay, et al 2021], [Quay, et al, 2022].

1) Optimization of Receptor Binding Domain: Specific alterations to the Spike protein were done to optimize binding to human ACE-2 receptors, which was needed to support a pandemic.
2) Creation of a 19-nucleotide genetic sequence to create a FURIN cleavage site, which enhances viral entry and therefore infectivity. [US Patent # 9,587,003 filed by Moderna, Feb 4, 2016; approved Mar 7, 2017], [Boyd, 2022].
3) Insertion of a genetic sequence to create the ORF 8 protein which suppresses interferon release, thereby suppressing immune signaling.
4) The genetic code for a glyco-protein called gp120 was inserted into the virus to enhance its ability to infect certain immune cells. These immune cells, called dendritic cells and macrophages, have proteins called lectins that bind gp120 and when this happens the virus is better able to infect these cells, thereby weakening the immune response to the virus [Syed, 2022].

In their paper "MSH3 Homology and Potential Recombination Link to SARS-CoV-2 Furin Cleavage Site" Ambati, et al, shows how a 19 nucleotide genetic sequence in SARS-CoV-2 coding for the contageon enhancing furin clevage site matches the sequence described in the Moderna patent. "Conventional biostatistical analysis indicates that the probability of this sequence randomly being present in a 30,000-nucleotide viral genome is 3.21×10^{-11} "(i.e. 3.21/100,000,000,000) [Ambati, et al, 2022] [g].

When researchers engineer a virus there are stitching sites, called restriction sites, that can serve as a fingerprint of synthetic assembly. In their paper "Endonuclease fingerprint indicates a synthetic origin of SARS-CoV-2" Bruttel, et. al, show a synthetic fingerprint common in lab-assembled viruses' providing additional evidence that SARS-CoV-2 was engineered [Bruttel, et al, 2022]

John Ratcliffe, former United States Director of National Intelligence has stated that "The most likely origin of COVID-19, of the Wuhan virus… was a lab leak at the Wuhan Institute of Virology". Dr "Robert Kadlec, who at the time was the Assistant Secretary of Health and Human Services (Preparedness and Response) and technically Dr Fauci's superior, told Sharri [Markson, of Sky News] he had discussions with Dr Fauci and they deliberately decided to downplay the lab leak theory" [Hannaford, 2023] [Malone, 2023]. The FBI and the Department of Energy also acknowledged that gain of function research created the virus.

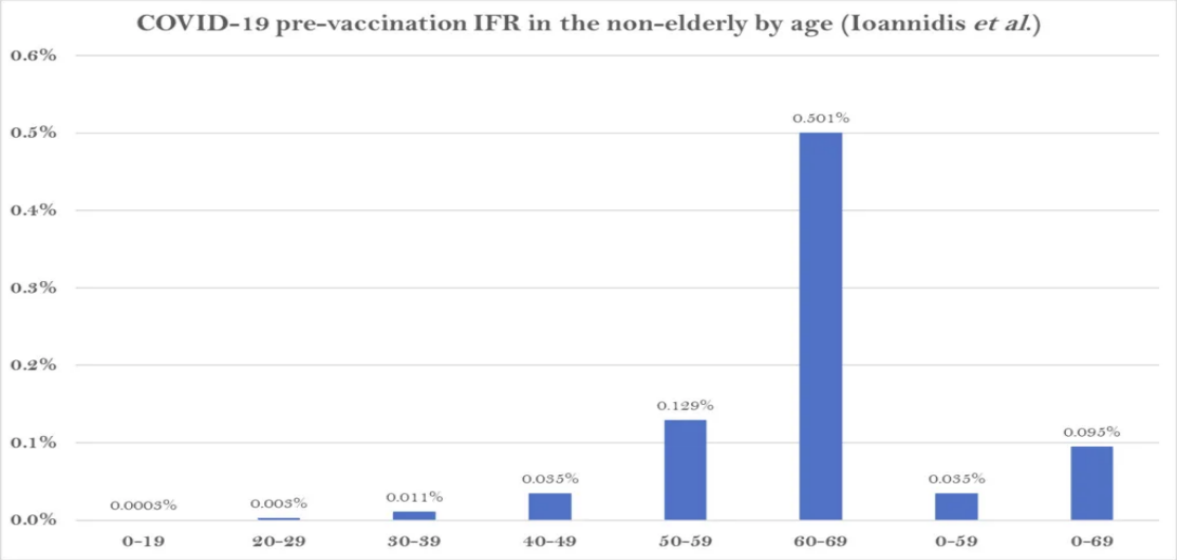
III. Thesis

Summary: My claim is that COVID-19 risk, vaccine efficacy, and vaccine safety do not support the use of these injectable biologic products for normal children to protect them against the Omicron variant.

A. COVID-19 Risk/Need for COVID-19 Injections

1. Infection Fatality Rate

The mortality rate of COVID-19 in healthy children is statistically zero. Because the Omicron variant is primarily an upper respiratory illness, there are very few cases of pneumonia. Current studies on Omicron variant mortality place adult mortality at 1/50,000 with risk for severe disease at 1/10,000 [Lewnard et al, 2022]. For children, the risk of severe disease or death is far less [Wang et al, 2022]. In fact, even with the more virulent Alpha and Delta strains, the mortality for normal children was statistically zero. The FAIR Health study, done by epidemiologist Marty Makary MD, MPH at the Johns Hopkins School of Public Health, examined data on "48,000 children under 18 diagnosed with Covid in health-insurance data from April to August 2020…and **found a mortality rate of zero among children without a pre-existing medical condition**" (Makary, July 2021). Of 3105 deaths from all causes among the 12 million children aged less than 18 years in England between March 2020 and February 2021, only 25 were attributable to COVID-19 — a rate of about 2 for every million people in this age range [Smith et al, 2021]. These data are further corroborated by a study examining the pre-vaccine infection fatality ratio (IFR) that showed a rate of **only 3/1,000,000** deaths for people aged less than 20 years (see graph below) [Pezzullo et al, 2022]. Moreover, since the pre-vaccine variants were more virulent the actual infection fatality rate for children with Omicron is even lower than 3/1,000,000 [Hani, et al, 2023].



The data represented on this graph was assembled from 31 seroprevalence studies, and shows an Infection Fatality Rate (IFR) of .0003% or 3/1,000,000 in 0–19-year-olds [Jones, 2022], [Pezzullo et al, 2022] [h].

2. Natural Immunity

More than 88% of all children have natural immunity and this is superior to vaccine immunity. Because the Omicron strain is extremely contagious and has a rapid replication rate, it has infected most of the pediatric population, conferring natural immunity. This group of children, therefore, does not need to be vaccinated. A systematic review and meta-analysis of 65 studies from 19 different countries published in 2023 in Lancet showed protection against severe disease remained high for all variants, with 90·2% (69·7–97·5) for ancestral, alpha, and delta variants, and 88·9% (84·7–90·9) for omicron BA.1 at 40 weeks" [Stein, 2023].

The CDC finally acknowledged the importance of natural immunity 6 months after initial studies in Israeli [CDC, MMWR January 19, 2022]. In January 2022, the CDC released data "which demonstrated natural immunity was 2.8 times as effective in preventing hospitalization and 3.3 to 4.7 times as effective in preventing Covid infection compared with vaccination", and this immunity is enduring [Leon, 2022]. In more recent studies looking at the relative value of natural immunity versus the efficacy of COVID-19 vaccines against the Omicron variant, natural immunity remained at 50% at 10 months while 2-shot vaccine immunity dropped to negative numbers after 9 months [Altarawneh et al, 2022]. The efficacy of natural immunity likely persists beyond 10 months as this was the length of the study, while negative immunity conferred by the vaccine at 9 months means that vaccinated individuals were more likely to be infected with the Omicron variant than unvaccinated individuals (i.e., they were harmed by the vaccine). In another study from Israel, unvaccinated individuals with natural immunity had half the risk of reinfection compared to 2-dose vaccinated patients [Goldberg et al, 2022]. Exposure to the common cold coronavirus, which is the cause of 20% of all upper respiratory infections, also confers some protection against SARS-COV-2 [Adhikari, 2023] [Humbert, et al, 2023].

In the Pfizer study reported at the VRBPAC (Vaccine and Related Biological Products Advisory Committee) October 26, 2021, meeting [Sahly, 2021] "No cases of Covid were observed in either the vaccine group or the placebo group in participants with evidence of prior SARS-CoV-2 infection". "That's consistent with the largest population-based study [Gazit et al, 2021] on the topic, which found that natural immunity was 27 times as effective as vaccinated immunity in preventing symptomatic Covid. Natural immunity is likely even more robust in children, given their stronger immune systems" [Makary and Saphier, 2021]. More than one hundred studies suggest natural immunity equivalent or superior to vaccine induced immunity [Alexander, 2022].

3. Risk of Transmission

The CDC has long recognized that children are not forward drivers of COVID-19 because their superior immune systems drastically limit viral shedding. No studies show that these mRNA products limit transmission among any age group. The best way to protect others from infected children remains to quarantine symptomatic children until they are well, as the risk of asymptomatic transmission by people of any age has been shown to be <0.7%. Even if it were the case that vaccination did reduce the spread of disease, putting children at risk (no long-term safety data on genetic or fertility or teratogenicity risk are available) for the sake of the elderly goes against any commonly held medical ethic.

Based on current levels of natural immunity in children, the low pathogenicity of the Omicron strain, the low risk of transmission among asymptomatic children, and the lack of data showing severe virulence in normal children even with the more pathogenic legacy variants [Makary, July 2022], there is no need for these products in normal children.

B. EFFICACY

1. CDC/FDA Review:

In the June 2022 meeting of the ACIP (Advisory Committee on Immunization Practices), Dr Fink (FDA) stated that the efficacy estimates for the Pfizer vaccine for children aged less than 5 years are "preliminary, imprecise, and potentially unstable." Dr Long, Dr Fink, and Dr Daily all acknowledged that there was ***no efficacy***, yet they were all comfortable with the immune-bridging data [Vaccines and Related Biological Products Advisory Committee, June 14, 2022]. This stance was strange as FDA's Dr Fink indicated Immuno-bridging, "may not be scientifically established" [Fink, 2022]. In the VRBPAC meeting, Dr Levy acknowledged the same. It is not possible to directly correlate these immune markers with clinical outcomes. Neutralizing antibody measurements are proxy outcomes, and the immune correlate of protection (ICOP) has not been established.

The clinical trial data that Pfizer presented to the FDA on efficacy of the COVID-19 products in children aged 6months to 4 years showed that compared to the unvaccinated 2.6 times more vaccinated children developed COVID-19, and more vaccinated children developed severe COVID-19 or were hospitalized [Craig, 2022].

The following data tables graphically illustrate very low and negative efficacy in most scenarios. For the 6- to 23-month-old age group, efficacy was only 14.5% seven days after the second

dose, with a Confidence Interval (CI) as low as -24.9; and after the third dose, the CI is as low as -370, making both these results statistically insignificant [Prasad, June 2022].

FDA presentation, Dr. Susan Wollersheim[5] June 15

Post hoc efficacy, from Dose 1
2-4 Years (Data accrued through April 29, 2022)

FDA

First COVID-19 Occurrence After Dose 1, Blinded Follow Up Period
Participants 2-4 Years of Age, All-Available Efficacy Population

Efficacy Endpoint	BNT162b2 3 µg (N=1178) Cases, n1/n2 Surveillance Time	Placebo (N=598) Cases, n1/n2 Surveillance Time	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence after Dose 1	127/1673 0.661	92/834 0.323	32.6 (10.8, 48.8)
Dose 1 to before Dose 2	21/1673 0.100	8/834 0.050	-32.1 (-244.8, 43.8)
Dose 2 to <7 days after Dose 2	4/1639 0.031	5/819 0.016	60.1 (-85.6, 92.1)
≥7 Days after Dose 2 to before Dose 3	100/1630 0.464	74/814 0.228	33.6 (9.1, 51.3)
Dose 3 to <7 days after Dose 3	0/553 0.010	0/222 0.004	NE
≥7 Days after Dose 3	2/481 0.056	5/209 0.025	82.3 (-8.0, 98.3)

Abbreviations: NE=not estimable; VE=Vaccine Efficacy; UND=Undefined.
N = number of participants in the specified group.
n1 = Number of participants meeting the endpoint definition.
Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period for the overall row and from start to the end of range stated for each interval.
n2 = Number of participants at risk for the endpoint.

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Post hoc efficacy, from Dose 1
6-23 Months (Data accrued through April 29, 2022)

FDA

First COVID-19 Occurrence After Dose 1, Blinded Follow-Up Period
Participants 6 -23 Months, All-Available Efficacy Population

Efficacy Endpoint	BNT162b2 3 µg (N=1178) Cases, n1/n2 Surveillance Time	Placebo (N=598) Cases, n1/n2 Surveillance Time	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence after Dose 1	98/1027 0.456	58/524 0.232, (524)	14.0 (-21.2, 38.4)
Dose 1 to before Dose 2	13/1027 0.063	5/524 0.032	-29.7 (-364.7, 56.6)
Dose 2 to <7 days after Dose 2	3/1002 0.019	3/517 0.010	48.4 (-285.0, 93.1)
≥7 Days after Dose 2 to before Dose 3	80/998 0.338	48/512 0.173	14.5 (-24.9, 41.0)
Dose 3 to <7 days after Dose 3	1/336 0.006	0/147 0.003	UND (NA, NA)
≥7 Days after Dose 3	1/277 0.030	2/139 0.015	75.5 (-370.1, 99.6)

Abbreviations: NA=not applicable; VE=Vaccine Efficacy; UND=Undefined.
N = number of participants in the specified group.
n1 = Number of participants meeting the endpoint definition.
Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period for the overall row and from start to the end of range stated for each interval.
n2 = Number of participants at risk for the endpoint.

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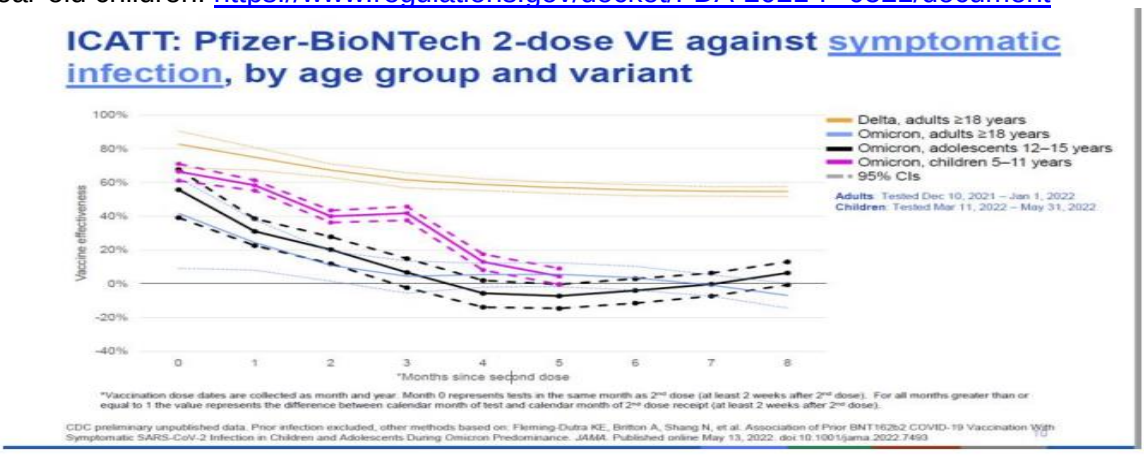
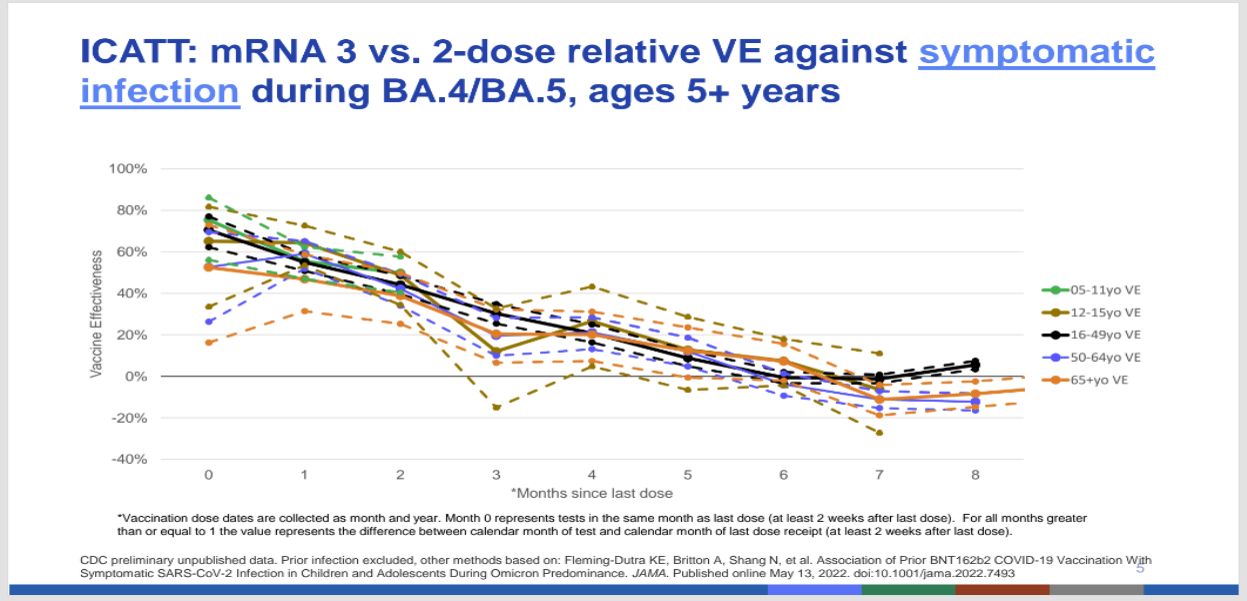
Also, over time the efficacy wanes rapidly (see below) such that by 3 months, the vaccine efficacy was no longer statistically significant, and by month 4, efficacy is negative for the 12 to 15-year-old children. https://www.regulations.gov/docket/FDA-2021-P-0521/document



Efficacy rapidly declines for children against the Omicron variant with a reduction in efficacy to only 12% for children aged 5 to 11 years by 28 to 34 days [Dorabawila et al, 2022] and negative efficacy by day 35 [Lyons-Weiler, June 11 and June 16, 2022] over time, meaning that those vaccinated against COVID-19 have a greater risk of being infected by the Omicron variant than

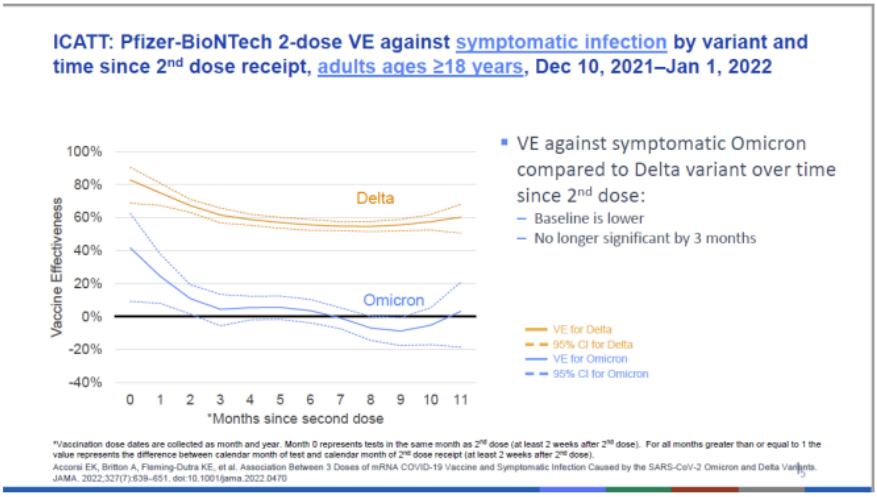
those who are not vaccinated [Lyngse et al, 2021], [Alexander, 2022], [Vaccine and Related Biological Products Advisory Committee, June 14, 2022].

Data from the CDC's "Increasing Community Access to Testing" program showed that booster efficacy compared to the 2- shot series against symptomatic infection decreased within 2 months to <50%, and at 6 months, the efficacy turned negative [Link-Gelles, 2022].



This slide, also by Gelles, shows negative efficacy against Omicron for adults.

Slide 5 presented by Dr. Ruth Link-Gelles at VRBPAC Meeting of June 14 2022[8]



2. Cleveland Clinic Data: More data on negative efficacy

A study using data from 51,017 working-aged Cleveland Clinic employees, showed COVID-19 cases increased with progressive COVID-19 vaccination [Shrestha, 2023], thus showing not only confirmation of no efficacy but in fact confirmation of the development of negative efficacy.

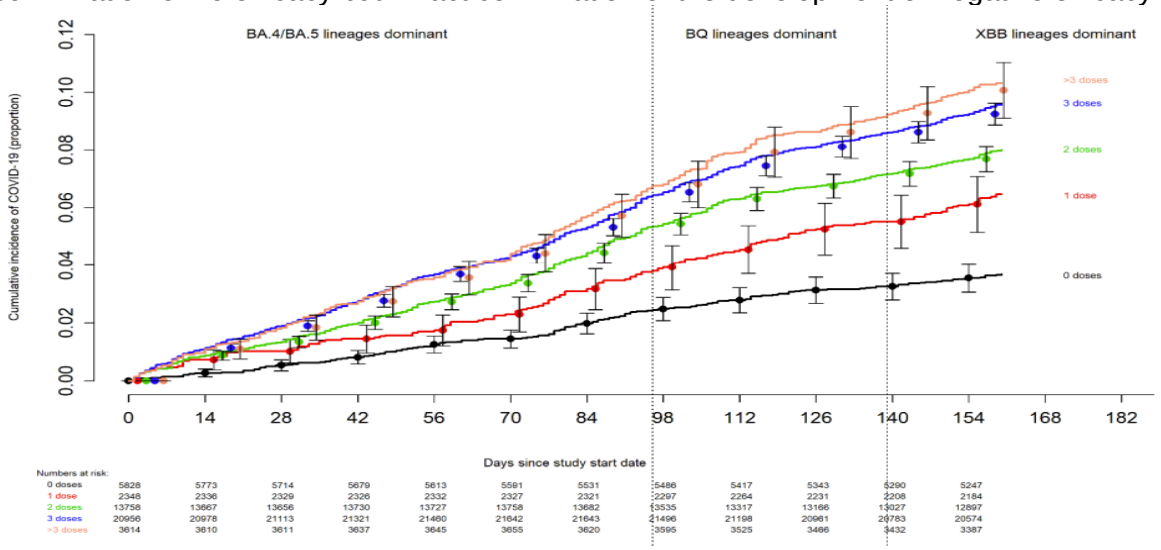


Figure 2. Simon-Makuch plot comparing the cumulative incidence of COVID-19 for subjects stratified by the number of COVID-19 vaccine doses previously received. Day zero was 12 September 2022, the day the bivalent vaccine began to be offered to employees. Point estimates and 95% confidence intervals are jittered along the x-axis to improve visibility.

3. Dagan Study

In the largest observational trial in Israel where 600,000 people were immunized, those aged less than 40 years without 3 co-morbid conditions who received 2 injections showed no benefit from the vaccine in terms of death reduction, disease severity reduction, or hospitalization (See Supplemental Table S-6, page 42, [Dagan et al, 2021] shown below). Therefore, it appears no direct benefit to children who are without pre-existing risk factors. In this study no discussion is given about adverse events related to the COVID-19 injections.

Ages 16-39										
0 - 20	21% (16%-27%)	3.22 (2.36-4.31)	29% (23%-36%)	2.42 (1.80-3.08)	49% (-65%-92%)	0.04 (-0.02-0.13)	NA	NA	NA	NA
0 - 27	32% (27%-36%)	6.54 (5.35-7.78)	38% (32%-44%)	4.03 (3.30-4.79)	33% (-104%-78%)	0.04 (-0.06-0.14)	NA	NA	NA	NA
0 - End of follow-up	50% (44%-55%)	15.09 (12.49-18.22)	56% (49%-61%)	8.34 (6.74-10.01)	50% (-85%-85%)	0.08 (-0.06-0.22)	NA	NA	NA	NA
14 - 20	49% (41%-57%)	2.29 (1.74-2.88)	57% (46%-68%)	1.38 (0.99-1.80)	74% (-46%-100%)	0.04 (-0.01-0.09)	NA	NA	NA	NA
21 - 27	64% (54%-72%)	2.80 (2.20-3.48)	67% (52%-78%)	1.27 (0.89-1.73)	NA	NA	NA	NA	NA	NA
2nd - 2nd+6	72% (64%-80%)	3.19 (2.53-3.91)	79% (68%-88%)	1.44 (1.04-1.86)	NA	NA	NA	NA	NA	NA
2nd+7 - end of follow-up	94% (87%-97%)	8.72 (5.72-12.69)	99% (96%-100%)	4.06 (2.76-5.66)	NA	NA	NA	NA	NA	NA

Table S6 – Full Analysis Results

Period	Documented Infection		Symptomatic Infection		Hospitalization		Severe Disease		Death	
	1-RR	RD	1-RR	RD	1-RR	RD	1-RR	RD	1-RR	RD

4. Pfizer Randomized Controlled Trial

In the only randomized controlled trial of COVID-19 injectable products done by Pfizer [Polack, et al, 2020], Pfizer claimed 100% efficacy in reducing death, but this claim was based on a difference in deaths in individuals who were vaccinated (1/22,000) compared with deaths of individuals who were unvaccinated (2/22,000) of only ONE in 22,000. This meager benefit is cancelled out by a 3.7-fold increase in cardiac arrests or congestive heart failure in the vaccinated group compared with the unvaccinated group (see table S4) [Thomas et al, 2021]. As a randomized controlled trial, this study on efficacy should be regarded as the highest level of evidence. When all-cause mortality and severe, non-Covid illness are used as endpoints, this table appears to show no apparent difference in all-cause mortality exists between the vaccinated and unvaccinated groups, with 15 deaths in the vaccinated group compared with 14 deaths in the unvaccinated group. Further forensic analysis of this data, however, revealed 21 deaths in the vaccinated group and 17 in the placebo group [Michels, et al, 2023]. It turns out that “79% of relevant deaths were not recorded in time to be included in Pfizer’s regulatory paperwork. By not including relevant subject deaths in the case report, Pfizer obscured cardiac adverse event signal, allowing the EUA to proceed unchallenged.” [DePalma, 2023].
It should also be noted that a Texas “regional director who was employed at the research organization Vestavia Research Group has told *The BMJ* [British Medical Journal] that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer’s pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding” [Thacker].

Reported Cause of Death[a]	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

This data has also been analyzed by viral immunologist Byram W. Bridle, PhD., et. al showing greater severe adverse events and death in the vaccinated population in the trial.

Customized Table by Dr. Byram W. Bridle and **Ten Co-Authors**:

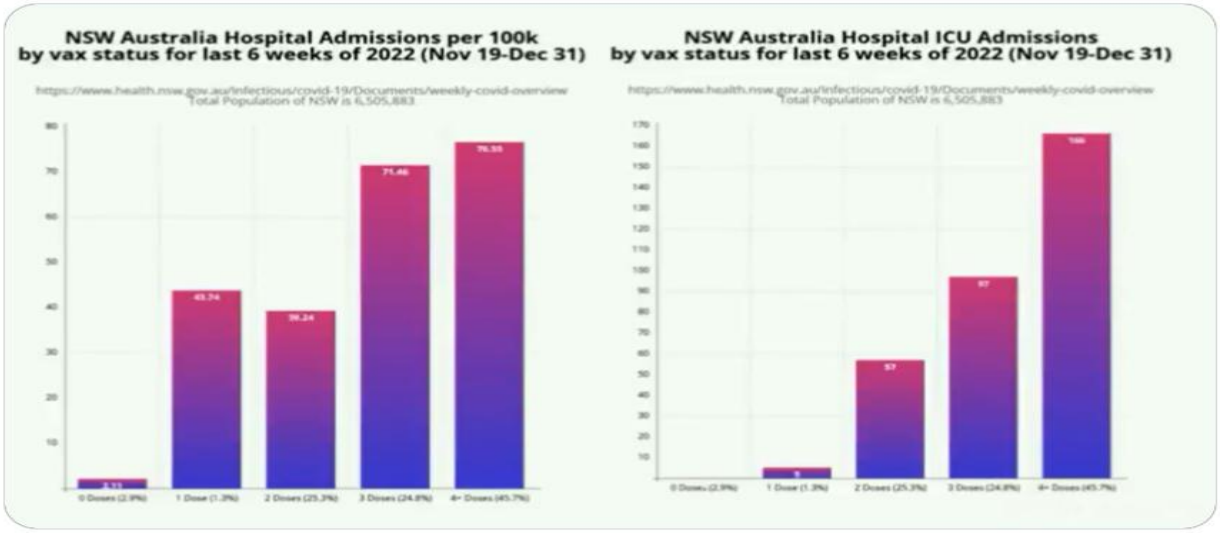
Differences in the Number of Efficacy and Safety Events in Eligible Populations Reported in the Six-Month Update of the BNT162b2 mRNA COVID-19 Vaccine

Event	BNT162b2 (*n*)	Placebo (*n*)	Absolute Difference (*p*-value)	Absolute Risk Change (%)	Relative Risk Change (%)
Cases Adults and Adolescents 7 days after 2nd dose	77	850	-773 (*p*<0.00001)	-3.7	-90.9
Any Unsolicited Treatment-Related Adverse Event Adults	5,241	1,311	+3,930 (*p*<0.00001)	+17.9	+299.7
Any Severe Event Adults/	390	289	+101 (*p*=0.0001)	+0.5	+34.9
Severe Cases in Adults 7 days after 2nd dose	1	23	-22 (*p*<0.00001)	-0.1	-95.7
Unsolicited Severe Adverse Events Adults Prevents daily routine activity or requires intervention or worse	262	150	+112 (*p*<0.00001)	+0.5	+74.6
Serious Adverse Event Adults Requires hospitalization or results in permanent injury or death	127	116	+11 (*p*=0.5)	+0.05	+9.5
Deaths during placebo-controlled period [additional deaths during open-label period in vaccine recipients or placebo-only]	15 [+5]	14 [+0]	+1 [+5] (*p*=0.9)	+0.005	+7.1
Deaths due to cardiovascular events	9	5	+4		

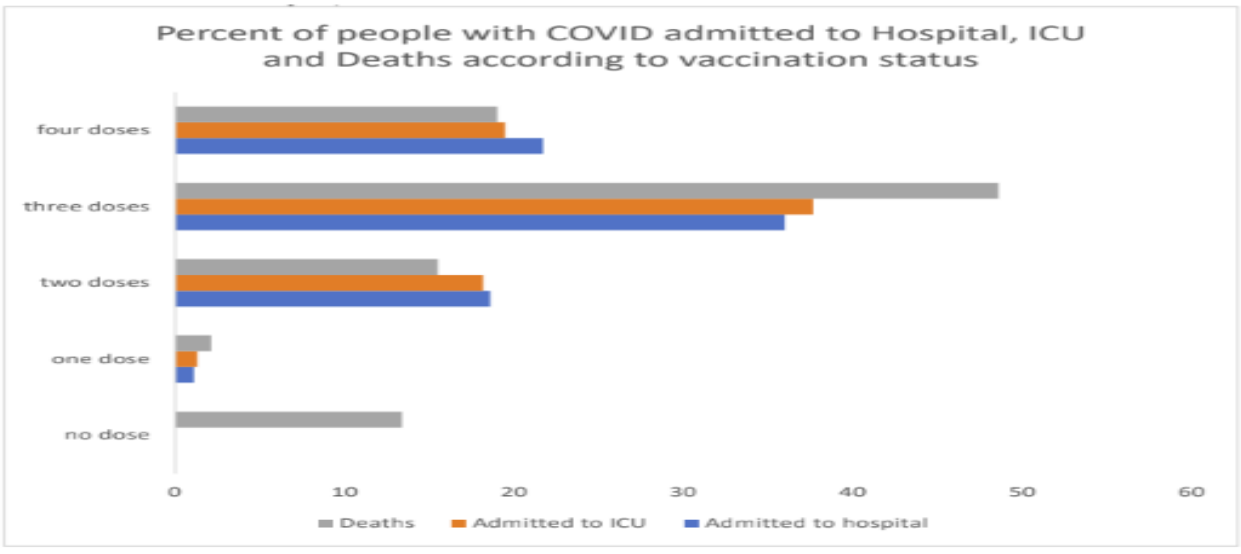
Figure 1. This shows that Pfizer's own data shows that the vaccine increased your risk of severe adverse events, hospitalization, and death. This is the best case since the vaccine matched the variant.

5. Australian Data:

November 19-December 31, 2022, data from Australia also shows that progressive increase in doses of the bivalent C-19 products result in a progressive increase in hospitalizations and ICU admissions as illustrated below:



According to the Health NSW [Australia] site the data obtained in 14 days until 16th of July 2022 continues to show the trend of worsening effects after the booster shots. The figure below shows the hospitalization, the ICU admission and deaths sorted by vaccination status with a total of 806, 77 and 142 respectively (shown as a percentage of the total number infected), as provided by NSW Health Department [Turni, 2022]:



C. SAFETY: IMMEDIATE RISK

A recent national survey done by Rasmussen finds that 24% of American adults say they know someone personally who died from side effects of the COVID-19 vaccine. Forty-two percent (42%) say that if there was a major class-action lawsuit against pharmaceutical companies for vaccine side effects, they would likely join. This study was shown to have an error rate of +/- 3% and was not biased by socio-political demographics [Rasmussen, 2023]. While this in no way proves causality it does provide a strong observational opinion, one which is supported by over 3,580 peer reviewed papers describing COVID-19 vaccine related injuries [Covidvaccineinjuries, 2022], [React 19, 2023]. In addition, the U.S. Countermeasure Injury Compensation Program, which covers vaccines and treatments used during public-health emergencies, has received 9393 claims alleging injury/death from the COVID-19 Vaccines as of November 1, 2023 [CICP DATA, 2023].

To better understand the issue of causality, that is are the COVID-19 injectable products causally related to the injuries described, we will begin with discussion about the molecular aspects of these products to demonstrate mechanistic plausibility and will also discuss toxicities related to their component parts and the contaminants introduced by poor manufacturing practices (1-4). Next, we will discuss specific adverse events and diseases caused by these products (5-9). Then (10-15) we will show in several data sets evidence of adverse events including an increase in all-cause mortality, and later provide additional risk/benefit analysis (16). While the analysis of any one data set might be considered by some to be only a partial story, a review of multiple data sets shows concurrence that these products are not safe.

1. Molecular Mechanistic Evidence of Biological Toxicity:

Spike Protein Toxicity: In 2021, the Salk Institute demonstrated that the spike protein produced by the virus causes COVID-disease by damaging vascular endothelial cells and impairing mitochondrial function [Lei, et al, 2021]. Pharmaco-distribution studies have shown that the spike protein from the vaccine circulates for up to 6 months [Brogna, et al, 2023] [Mercola, September 2023] and can cross the blood/brain barrier. Recent in vitro studies have also shown that the mRNA vaccine produced spike protein might impair DNA repair mechanisms [Jiang and Mei, 2021], increasing the risk of DNA mutations and cancer. It also has homology at over 30 locations with native proteins that might explain the occurrence of certain autoimmune conditions after infection with COVID-19. In addition, a segment of the protein is partially identical to the highly toxic *S aureus* endotoxin B protein. Dr Bruce Patterson has shown that residual spike protein, contained but not degraded by atypical monocytes, is one cause of long-haul COVID-19, and appears to create through immune dysregulation the same vasculitis and micro thrombosis found in COVID-19 disease [Patterson, 2022]. For a more extensive review of spike protein pathology see [Parry, 2023] and [Palmer, 2023]. Discussion in the literature as far back as 2005 warns against the use of the spike protein as a template for vaccine development due to the known “harmful immune or inflammatory responses” [He and Jiang, 2005].

***Lipid Nanoparticle (LPN) Toxicity*:** PEG-conjugated and cationic lipids are the two synthetic lipid species known to be potentially toxic. The PEG-conjugated lipids can create, in some, a severe allergic reaction mediated as a drug type allergy in patients with PEG allergy. "In contrast, the cationic lipids account for almost half of the total lipid in the vaccine LNPs, and they can exert toxicity outright, without any "help" from the adaptive immune system" [Palmer, et al, 2023]. Biodistribution studies on the lipid nanoparticle show circulation in the first day throughout the body with concentration in the ovaries and bone marrow [Demasi, 2022] [Syed, 2023] [i]. Studies as far back as 2012 had shown the risk of potential nano-toxicity to ovaries [Schadlich, 2012].

mRNA Toxicity: While originally thought to have a short half-life, the vaccine mRNA has been found to remain for at least 2 months [Roltgen et al, 2022]. This longevity is likely because pseudo-uridine is used in its synthesis, and human cells lack the ability to quickly degrade this un-natural molecule. Because this synthetic mRNA has such a long half-life, it is possible that substantial amounts of spike protein might be synthesized well beyond the desired immune response, leading to subsequent immune dysregulation. mRNA may epigenetically downregulate the innate immune system's ability to detect cancer cells, foreign molecules, and pathogens [Cole, 2022]. The use of pseudo-uridine modified mRNA has been shown to cause frameshift mutations [Mulroney, 2023] which generate frightening mutated proteins that are radically different from native proteins and are potentially carcinogenic.

Genome Integration: Evidence suggests that within 6 hours of exposure to the mRNA vaccines, cells can convert (by the reverse transcriptase enzymes) the mRNA into DNA, thus creating the potential for DNA integration [Alden et al, 2022]. Also, researchers from MIT and Harvard published a disturbing paper in 2021, where they provided strong evidence that the SARS-CoV-2 RNA can be reverse transcribed into DNA and integrated into human DNA [Zhang et al, 2021]. As will be stated later, if similar genetic transfer occurs in the germ cells (ovary or sperm) germ cell mutations could occur and then be propagated to multiple generations, corrupting the human genome [Lindsay, 2023]. (For an extensive review of mRNA vaccine molecular biology, please see Seneff and Nigh, 2021). Further discussion of this problem can be found in this paper in the section on cancer mechanism, as well as in Michael Palmer's book "mRNA Toxicity" [Palmer, et al, 2023].

Mechanism of Vascular Injury and Thrombosis: A helpful summary of mechanisms for vascular injury, thrombosis, and immune dysregulations has been summarized by Sucharit Bhakdi [Bhakdi, 2022]. Genetic material for the spike protein in the form of mRNA is delivered to cells by way of a lipid nanoparticle. Because cells are not designed to produce foreign proteins the production of such proteins causes the immune system to destroy the cells that are producing these proteins.

Foreign proteins (non-self) are broken down intracellularly, and their fragments are presented on the cell surface, giving rise to T-cell activation (Figure 1). This is what happens when spike protein is generated.

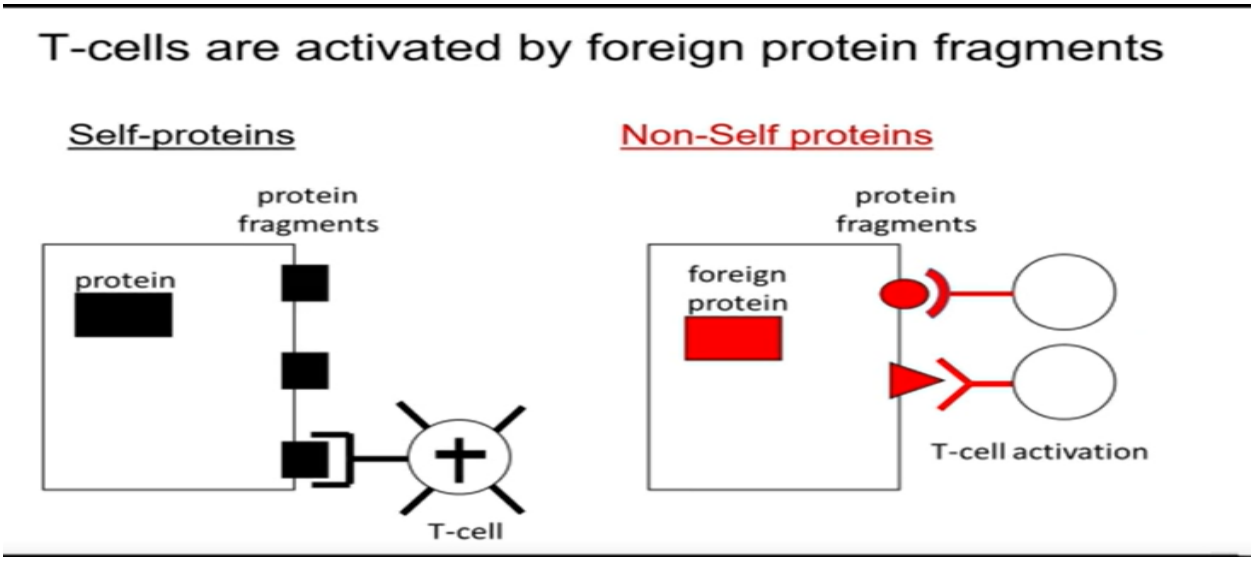


Figure 1 [Bhakdi, 2022]

Activated T cells then destroy the cells directly or activate B cells that make antibodies which activate the complement system. The complement system, once activated, then results in cell destruction. Antibodies generate in this manner are only created in the blood and not the nasopharynx and therefore they do not protect against viral entry (Figure 2).

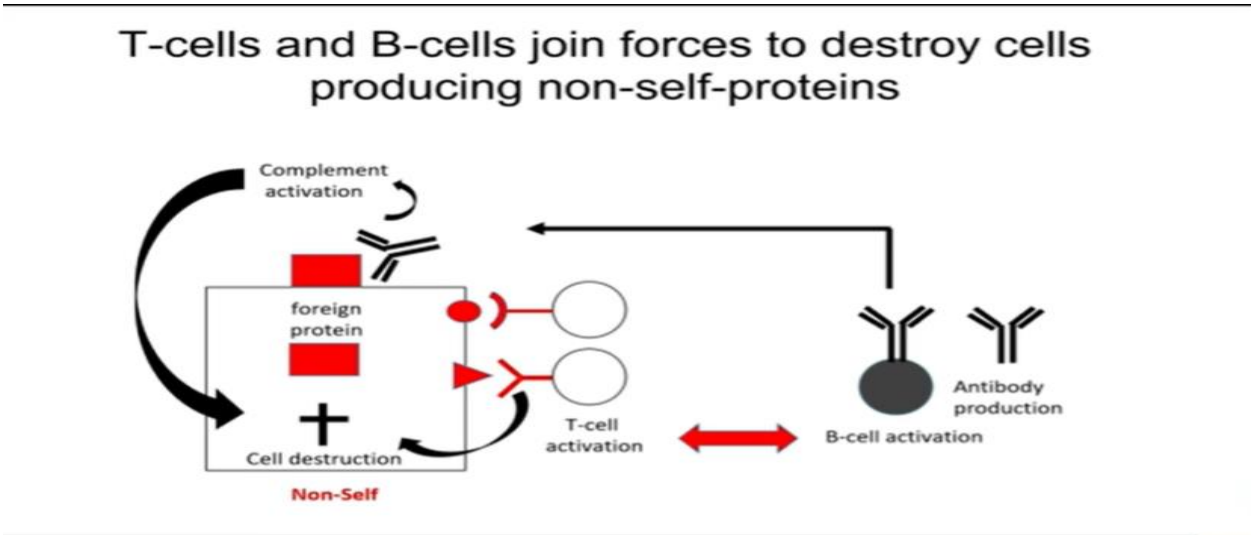


Figure 2 [Bhakdi, 2022]

Figure 3 below illustrates the progressive inflammatory/destructive/thrombotic process that ensues with entry of mRNA into the cell. The figure is a cross sectional depiction of a blood vessel. (1) is a normal endothelial cell that lines the artery or vein; (2) mRNA enters the cell via lipid nanoparticle delivery; (3) resulting in production of the spike protein; (4,5) which is then transported to the cell membrane which then triggers both a cellular and humoral/antibody immune attack; (6) resulting in endothelial damage; (7) release into adjacent tissues or into the deeper vascular layers and exposure of deeper vascular layers ; and (8) platelet aggregation and clotting and in some cases vascular dissection.

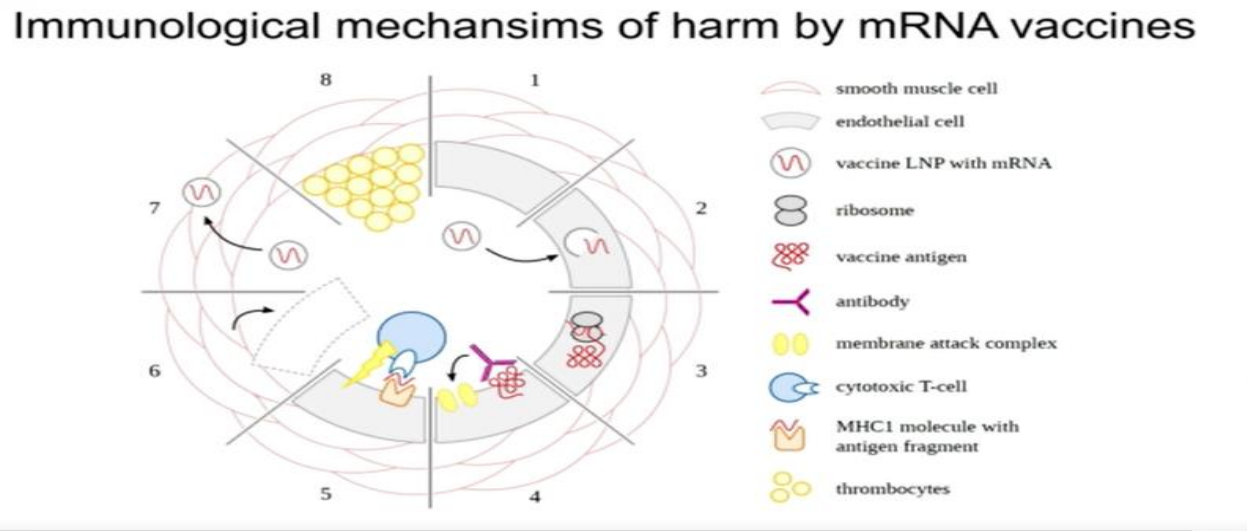


Figure 3 [Bhakti, 2022]

2. Pathologic Evidence of Spike Protein Damage

Because the spike protein can remain in circulation for up to or greater than 6 months, and because it can cross the blood brain barrier, evidence of multisystem involvement has been shown at autopsy in patients who have died suddenly. Precipitous death may occur because of fatal stroke, myocardial infarction, pulmonary embolus, extreme thrombocytopenia, or cardiac arrythmias.

Hulscher, et al, 2024 did a systematic review of autopsy and necropsy reports relating to COVID-19 vaccination up to May 18, 2023, and found that “a total of 240 deaths (73.9%) were independently adjudicated as directly due to or significantly contributed to by COVID-19 vaccination. Of these 53% were cardiovascular, 17% hematologic, 8% respiratory and 7% multiorgan, with a high likelihood of a causal link between COVID-19 vaccines and death in most cases. Appendix IV shows a variety of tissues containing spike protein demonstrating the horrific way in which spike protein can be generated in multiple organ systems, including heart, liver, testis, placenta, and endometrium. When these tissues are simultaneously stained for viral proteins (e.g., the nuclear capsid protein) and the spike protein, only the spike protein shows stain uptake, indicating that these pathologic findings are the result of the COVID-19 injection and not the COVID-19 virus. The cardiac muscle illustrations show intensive inflammatory infiltrations which then result in irreversible scar formation and can serve as a nidus for malignant cardiac arrythmias. The gross pathology specimens of post-mortem harvested clots illustrated in Appendix IV are structurally unlike clots formed by normal clotting and form due to a different process than natural clotting post death [Cole, 2022], [Campbell, 2023], [Burkhardt, 2022].

3. Batch Lot Variability and Product Integrity

Products approved by the FDA must meet exact standards of purity. A good comparator is the influenza vaccine. When 22,000 influenza vaccine lots were examined, almost all of them

produced 5 or fewer adverse reactions per lot, and only 2 lots exceeded this number. In contrast, analysis of COVID-19 mRNA products has shown high batch-to-batch variability with 90% or more of all vaccine adverse events occurring in only 4.2% of the lots. The variation could be due to variation in mRNA degradation, or to adulteration of product. This degree of variation does not meet the original expectations by FDA for quality, and normally would negate EUA authorization as well as carry significant legal penalties [Paardekooper, 2021]. In another study by [Schmeling, et al, 2023] substantially different rates of SAEs (serious adverse events) were shown in "different BNT162b2 vaccine batches administered in Denmark (population 5.8 million) from 27 December 2020 to 11 January 2022".

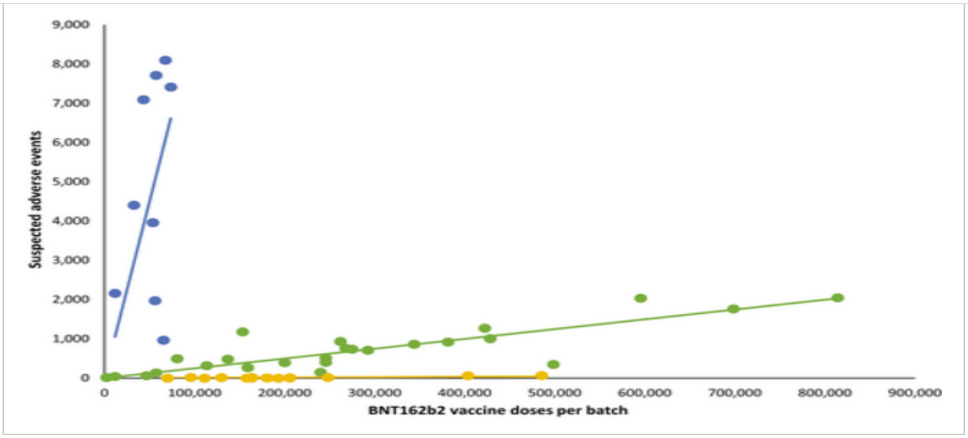


FIGURE 1 Open in figure viewer | PowerPoint

Numbers of suspected adverse events (SAEs) after BNT612b2 mRNA vaccination in Denmark (27 December 2020–11 January 2022) according to the number of doses per vaccine batch. Each dot represents a single vaccine batch. Trendlines are linear regression lines. Blue: $R^2 = 0.78$, β = 0.0898 (95% confidence interval [CI] 0.0514–0.1281), green: $R^2 = 0.89$, β = 0.0025 (95% CI 0.0021–0.0029), yellow: $R^2 = 0.68$, β = 0.000087 (95% CI 0.000056–0.000118). Vaccine batches representing the blue, green and yellow trendlines comprised 4.22%, 63.69% and 32.09% of all vaccine doses, respectively, with 70.78%, 27.49% and 47.15% (blue trendline), 28.84%, 71.50% and 51.99% (green trendline), and 0.38%, 1.01%, and 0.86% (yellow trendline) of all SAEs, serious SAEs, and SAE-related deaths, respectively.

In March 2022, retired Australian lawyer Julian Gillespie [Gillespie, 2022] testified at a panel called *Covid Under Question*, a "cross-party inquiry into the Australian government's response to Covid." He said "[For example] Pfizer's clinical trial was said to have been run with mRNA integrity of 72% … after they got approval and went to commercial operations … they could not get stability on the mRNA integrity … In a rush to get this stuff out the door and approved, all of a sudden, the regulatory agencies, the FDA together with the [*European Medicines Agency of the European Union]* together with the English equivalent, the [*Medicines and Healthcare products Regulatory Agency of the UK]*, all of a sudden dropped the mRNA integrity requirement, to 50% … there were no clinical trials done with respect to any vaccine, which was only putting forward an mRNA integrity of 50%. So, there is no safety data with respect to the lower mRNA integrity, and there's no efficacy data with respect to the lower mRNA efficacy." He adds: "We've never seen such instability in drugs."

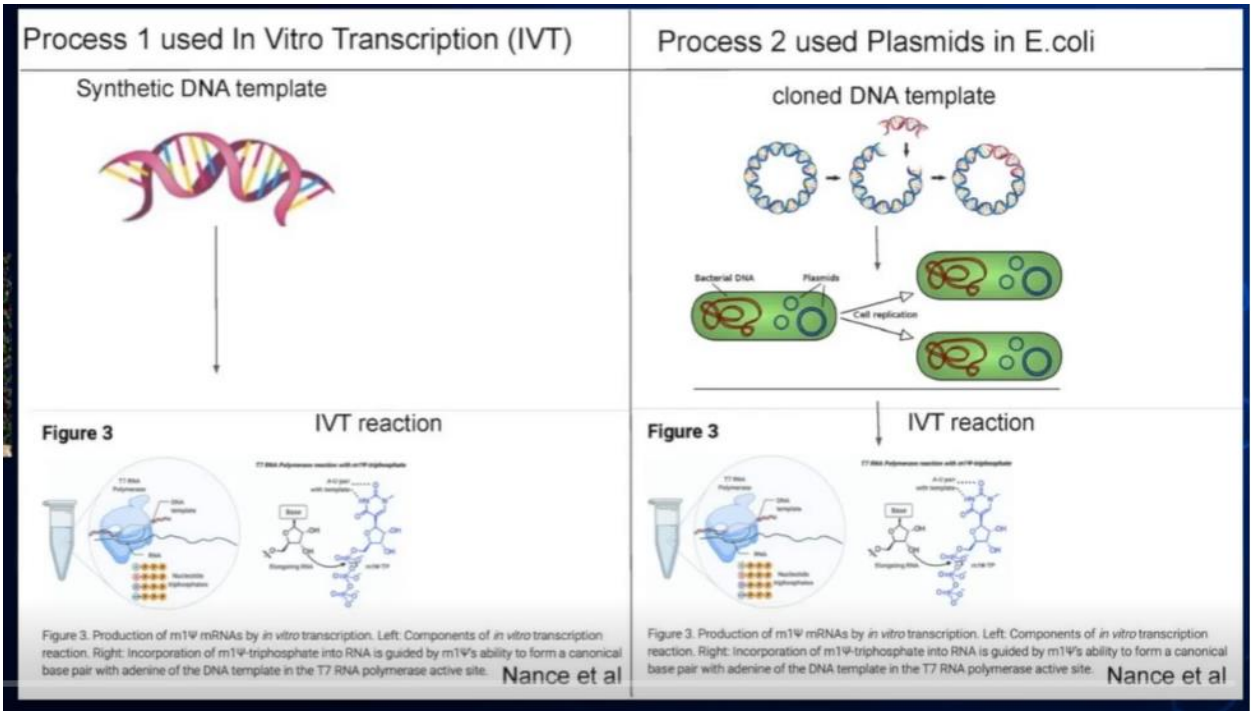
4. Product Adulteration and Contamination

Because the FDA has chosen not to list the ingredients of the mRNA vials, or the testing methodology to verify contents, a comprehensive assessment of product integrity is difficult to do [Gortler, 2023]. However, there is now convincing evidence of severe product contamination and adulteration.

Manufacturing Process for Mass Production was not the same as the Manufacturing Process for the Clinical Trial [Pain, 2023]:

The original process used to generate mRNA in the Pfizer clinical trials relied on Polymerase Chain Reaction (PCR) technology using a DNA template. This was a relatively clean process, which can be called PROCESS 1.

The process used to mass produce the mRNA for the COVID-19 injectable products, which can be called PROCESS 2, however, relied upon a DNA plasmid molecule (a circular DNA) inserted into E. coli bacteria. This is a more cost effective and scalable solution whereby both the plasmid and the E.coli multiply creating large numbers of plasmid copies which are then used to make large numbers of mRNA copies. After this, the residual DNA and bacterial remnants need to be removed. It has now been shown by multiple labs that this purification process was not done well, leaving instead, a substantial amount of DNA (which can be mutagenic) and bacterial cell wall contamination (which includes endotoxin/lipopolysacharide, which is highly toxic) in the vials. We know from Pfizers own documents that endotoxin was present in the PROCESS 2 vials [Campbell/ Guetzkow interview, October 4, 2023], [Guetzkow, et al July 2022].



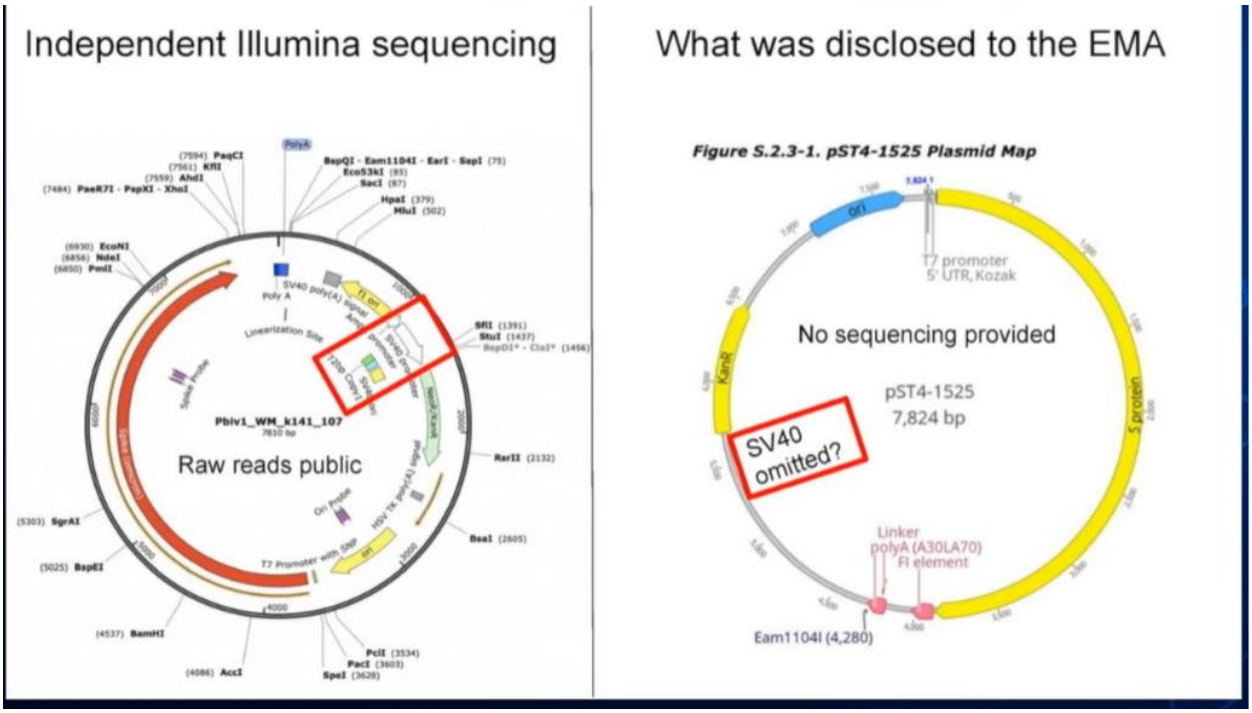
[McKernan, 2023]

Process 2 batches fail to pass prior mRNA integrety standards and have worse outcome data:

With any biopharmaceutical “the process is the product”. Because PROCESS 2 was different from PROCESS 1 the EMA asked for a new assessment, in January 2021, of product integrety and found that consistency in mRNA size and purity was only 50-60%. Rather than insisting on the same standard used in PROCESS 1, which showed 70-80 % consistency, the EMA compromised its position and settled for a 50-60% standard. This is disturbing as we know that variable mRNA size would mean that microRNAs might also be present and these are known immune-suppressors. Product produced by PROCESS 2 should have been clinically trialed, but was instead tested on only 252 patients, and the MHRA (UK regulator) accepted that. A review of the clinical results on the 252 that received the PROCESS 2 vials revealed that only 4 of the 252 patients were tested to see if they had an antibody response and of these 1 of the 4 had no response. In addition only 16-22 year olds were tested. Also, analysis of PROCESS 2 batches showed a substantially greater number of adverse events than did PROCESS 1 batches [Campbell/ Guetzkow interview, October 2023], [Guetzkow, et al July 2022].

The Plasmid sequence in the vials don’t match the map that was published to the EMA:

Kevin McKernan, former team leader of the human genome project, current CSO of Medicinal Genomics, analysed the contents of several COVID-19 injectable vials (Pfizer) and found substantial DNA contamination. DNA can be mutagenic if it enters the cell nucleus, can induce thrombosis [Gaitzsch, et al, 2017], and can integrate into host DNA [Sheng-Fowler, et al, 2009], and if it integrates near cancer-genes can promote cancer. The spike protien is also known to facilitate the uptake of DNA into the cell nucleus [Syed, 2023]. McKernan found that the plasmid genetic map from the Pfizer vials did not match the map that Pfizer had submitted to the EMA (European Medicines Agency). In particular, the plasmid in the Pfizer product had both an SV 40 promoter region (an area designed to enhance protien transcription) and an SV 40 enhancer. This is very problematic, not only as it constitutes fraudulent representation, but also because the SV 40 enhancer serves as a device to transport DNA into the cell nucleus [Lindsay, 2023], which can then lead to gene expression from foreign DNA. Thus, the COVID-19 injection places recipients at risk of becoming Genetically Modified Organisms (GMOs)! If similar genetic transfer occurs in the germ cells (ovary or sperm) germ cell mutations could occur and then be propagated to multiple generations, corrupting the human genome [Linday, 2023].



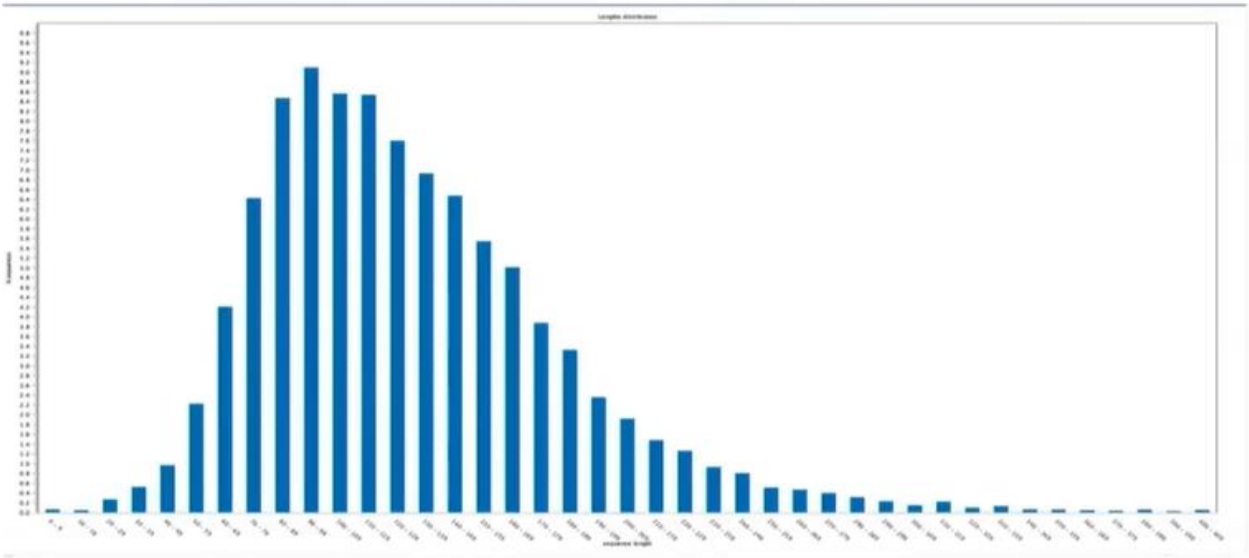
[McKernan, April, 2023]

The Lipid Nano Particle (LNP) can also package the DNA creating a trojan horse effect to allow entry of the DNA into the cell and possibly into the cell nucleus [Dean Lab]. In addition, there is a substantial risk of direct DNA integration into the cell nucleus, which may be as high as 10-20% [Lim, 2023]. Smaller DNA fragments in higher concentrations may be even more problematic. [McKernan, April, Oct 2023].

Supporting evidence of DNA contamination:

Dr Phillip Buckhaults, PhD Biochemistry and Molecular Biology, does research in cancer genomics at the University of South Carolina. In September 2023 he testified before the South Carolina Senate Medical Affairs Ad-Hoc Committee on DHEC and showed how he found multiple DNA fragments of varying sizes in the COVID-19 injectables (Pfizer) [Buckhaults, 2023].

Pieces of DNA in two batches of Pfizer vaccine.
These are the batches that were given out here in Columbia.



Endotoxin Contamination:

The Pfizer products were found to have endotoxin contamination. Endotoxin is a lipopolysaccharide found in the cell membranes of E. Coli bacteria. Like DNA contamination this contamination is a result of poor manufacturing/purification processes. Endotoxin can cause anaphylaxis, sepsis syndromes, toxic shock, and death [Rose, Oct 2023], and may be responsible for some of the Severe Adverse Events seen with the COVID-19 injectable products. The effects of endotoxin are also enhanced by the spike protein. [McKernan, April and October 2023], [Petruk, et al, 2020].

5. Myocarditis

The CDC claims that cases of myocarditis are mild and rare. This is not supported by the evidence. In a recent *New England Journal of Medicine* study published in Oct 2021 [Mevorach et al, 2021], the reported incidence of myocarditis for boys aged 16-19 was 1/6600 for Pfizer. Comparable results were presented in a recent analysis that showed a rate of 1/10,600 for 16- to 17-year-old male patients and 1/6200 for 12- to15-year-old male patients. This paper showed that the hospitalization rate due to vaccine-related myocarditis in children exceeds the hospitalization rate due to COVID-19 [Hoeg et al, 2022]. A study published in *JAMA Cardiology* in April 2022 showed myocarditis rates as high as 28/100,000 [Karlstad et al, 2022]. Another study published in JAMA reported comparable results [Oster et al, 2022]. Another study published in March 2022 in the *Journal of Pediatrics* showed that of the 16 children aged 12 to 17 years with mRNA vaccine-induced myocarditis, 100% of these children had late gadolinium enhancement (LGE) which, “in classical myocarditis, can be predictive of a poor outcome. ” The authors state that “little is known about the prognostic value or expected evolution of these cardiac MRI abnormalities associated with post–COVID-19 mRNA vaccine myopericarditis”. Although all patients showed rapid clinical improvement, many (69%) had persistent cardiac magnetic resonance imaging findings (LGE) at 3- to 8-month follow-up” [Schauer et al, 2022]. In

a study of 40 adolescent boys (average age 15) with MRI confirmed myocarditis from the COVID-19 vaccine, 73% were asymptomatic, 18% had evidence initially of reduced ejection fraction, and **56% had ongoing MRI confirmed evidence of cardiac damage one year after initial diagnosis** [Yu, 2023], dispelling the myth that cases of myocarditis are mild and rare.

At the June 23 ACIP meeting, Dr Shimabukuro and Dr Klein showed that myocarditis rates appear underreported in VAERS by a factor of 2 to 10 times. The rate for 16- to 17-year-old males reported from the Vaccine Safety Datalink was extremely high at 200/million [Shimabukuro, 2022]. In another study by Krug et al the incidence of myo/pericarditis was as high as 162 per million in boys aged 12015 [Krug, 2022]. Unfortunately, even these high numbers may be an underestimate. In the first ever prospective study published in August 2022 in the journal *Tropical Medicine and infectious Disease* **the combined rate of subclinical and clinical myocarditis in teenage boys was an astounding 3.5% (1 in 30 teenage boys)** [Mansanguan and Charunwatthana, 2022]. Another prospective study looking at the effects of mRNA vaccines presented by the University Hospital Basil, Switzerland showed similar results **with 3.7% of women and 0.8% of men demonstrating subclinical myocarditis** as measured by high sensitivity troponins [Buergin, 2023].

Since myocardial inflammation can result in irreversible scarring (as myocardial tissue does not regenerate), all forms of myocarditis in children should be regarded as very significant and not classified as “mild.” In the initial populations studied, 90% of the children required hospitalization and 25% of the cases had compromised ejection fractions [Rose and McCollough, 2021]. The incidence of peri/myocarditis is not rare as claimed by the CDC (9148 cases of myopericarditis for all ages combined, as of November 4, 2022, with the highest incidence in teenage boys).

6. Immune Suppression resulting in Increased Contagion Risk:

Interferons (IFN) are antiviral proteins. The 3 major types -- type I, II, and III -- are categorized based on the receptors to which each IFN binds. One of the most important IFN is type 1 IFN; IFN-alpha and IFN-beta are type 1 IFN; these molecules alert other cells to the presence of a virus or cancer, and stop infected and cancerous cells from proliferating, causing diseased cells to die. Research on the spike protein and mRNA vaccines suggests that IFN-alpha action may be impaired when exposed to the spike protein [Seneff et al, 2022]. As discussed earlier in this paper the spike protein incorporates an engineered genetic sequence coding for the ORF 8 protein which suppresses interferon release.

A study published in July 2021 in the *NEJM* shows that **those vaccinated were, at 10 days post infection, 5 times more likely (31% rate) to continue to carry live virus compared to the unvaccinated (6% rate)** [Boucau et al, 2022]. This increased risk in contagion can be explained by the immunosuppressive effect (impaired cellular immunity) of the vaccine. Evidence of negative efficacy as previously described in this paper might also be a results of immune suppression by the COVID-19 injectables. See also the discussion on cancer risk, showing various plausible mechanisms for immune suppression. It is also apparent that the COVID-19 injectable products “induce complex functional reprogramming of innate immune responses” and “reprograms both adaptive and innate immune responses” and “may contribute to a diminished innate immune response towards the 236 virus” [Fohse, 2023].

7. Cancer Risk

Recent observations by prominent oncologists, epidemiologists, and data scientists have shown an alarming increase in a variety of bizarrely behaving cancers in 15- to 45-year-olds appearing in 2021-2023. These malignancies have been called turbo cancers due to their rapid progression and resistance to traditional cancer therapies [Mercola, November 2023].

Several scientists have made these observations, including:

(1) Dr Harvey Risch, Professor Emeritus of Epidemiology, Department of Epidemiology and Public Health at the Yale School of Public Health and Yale School of Medicine. His research has focused extensively on the causes of cancer as well as prevention and early diagnosis…According to Risch "What clinicians have been seeing is very strange things: For example, 25-year-olds with colon cancer, who don't have family histories of the disease—that's basically impossible along the known paradigm for how colon cancer works—and other long-latency cancers that they're seeing in very young people." "Some of these cancers are so aggressive that between the time that they're first seen and when they come back for treatment after a few weeks, they've grown dramatically compared to what oncologists would have expected for the way cancer normally progresses," Dr. Risch says [Jakielec, 2023].

(2) Dr William Makis, a Canadian Oncologist/Nuclear Radiologist/Scientist who has also observed cancers presenting in young people 20-40 years-old already advanced to stage 3 or 4, that rapidly metastasize and are refractory to conventional chemotherapy.

(3) Dr Ryan Cole, Pathologist and Immunologist, Owner of Cole Diagnostics, began observing an increase in unusual cancers in his lab in 2021.

(4) Professor Angus Dalgleish, MD, FRCP, FRCPA, FRCPath, FMedSci, Clinical Consultant, has a published career of over 500 papers and focuses on melanoma in his research and clinical work. He recently noticed a recurrence of melanoma in his patients that had been in remission, following the COVID-19 booster. He measured T-cell activity and many of these patients had a decline in T-cell activity [Campbell, October 2023].

There are several sources of data that support this hypothesis:

(1) Data from the ONS (UK): A report from the data analytics firm Phinance Technologies has shown "a large increase in mortality due to malignant neoplasms that started in 2021 and accelerated substantially in 2022. The increase in excess deaths in 2022 is highly statistically significant (extreme event). The results indicate

that from late 2021 a novel phenomenon leading to increased malignant neoplasm deaths appears to be present in individuals aged 15 to 44 in the UK" [Alegria, 2023].

As noted in Figure 6 below - Excess adjusted deaths rates for diseases by malignant neoplasms versus excess death rates for all registered deaths in England and Wales. Left: Relative deviation from trend, percent. Right: Deviation from trend Z-Score. In Figure 6 (left) we can observe that the excess deaths rates from malignant neoplasms were close to zero in 2020, rose by about 13% in 2021 and about 43% in 2022. On the other hand, the excess mortality for all registered deaths was about 5% in 2020, 15% in 2021 and 10% in 2022. The drop in excess mortality for all registered deaths from 2021 to 2022 was not mirrored in a drop in malignant neoplasm deaths. The opposite occurred, with a sharp acceleration in excess deaths due to malignant neoplasms.

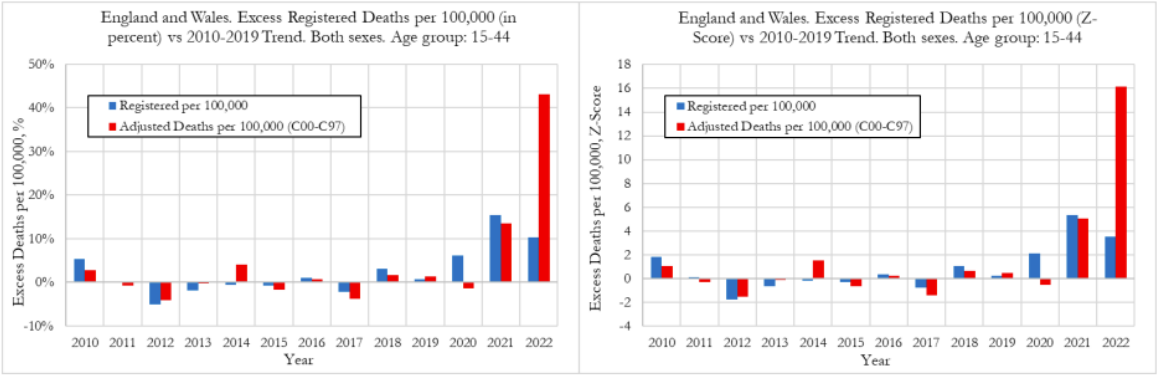
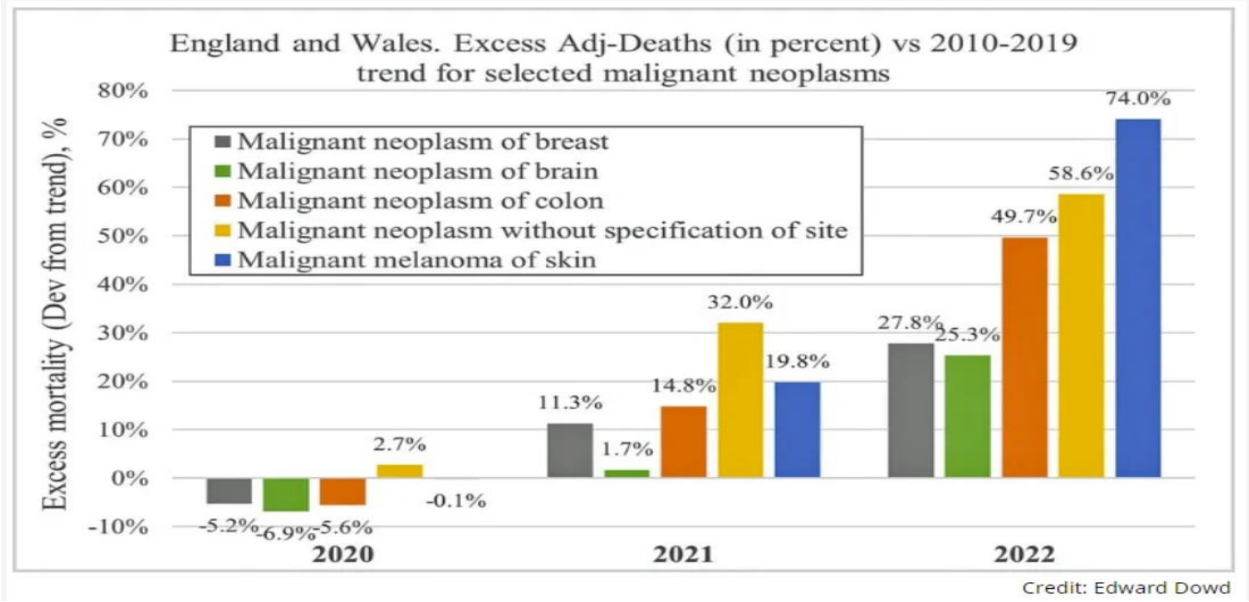


Figure 6 - Excess adjusted deaths rates for diseases by malignant neoplasms versus excess death rates for all registered deaths in England and Wales. Left: Relative deviation from trend, percent. Right: Deviation from trend Z-Score.

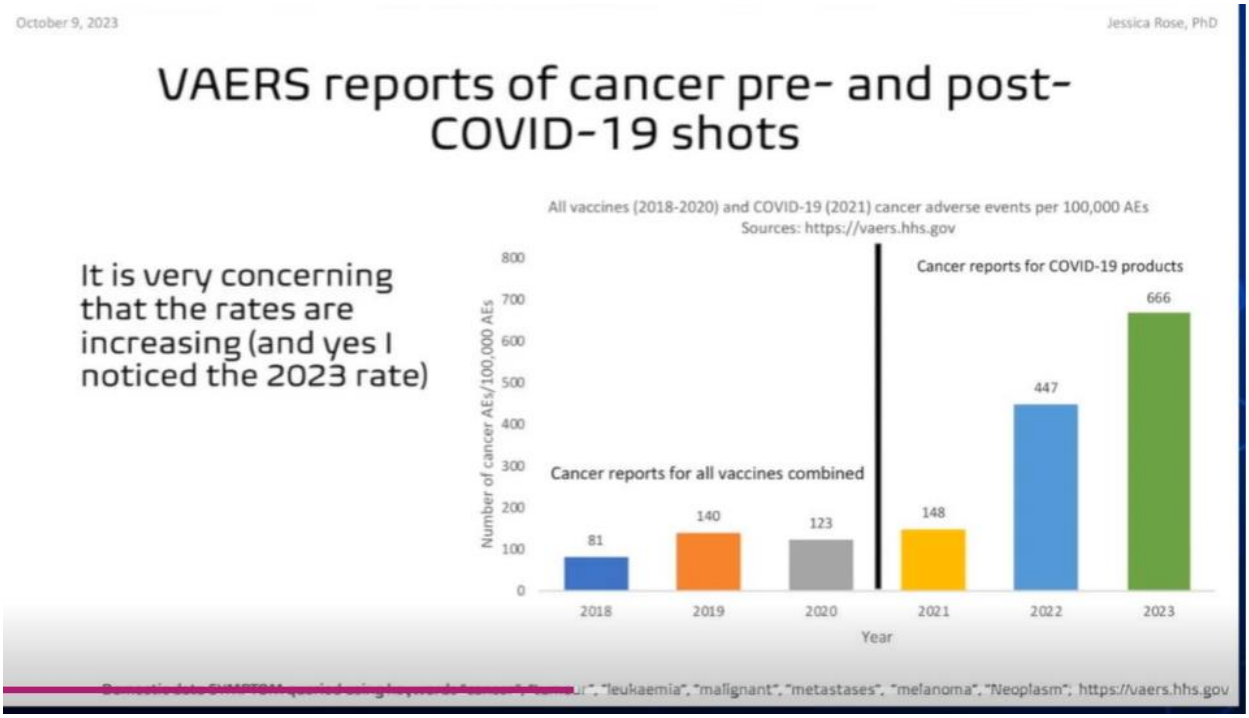
The Phinance Technologies analysis also showed a substantial increase in cancer deaths from historic norms for ages 15-44 in 2022, including a (a) 28% rise in breast cancer rates in women, (b) a 80% increase in pancreatic cancer deaths in women and a 60% increase in men, (c) a 55% increase among men in colon cancer deaths and a 41% increase in women, (d) a 120% increase in colon cancer deaths among men and a 41% increase in women, (e) and a 35% increase in fatal melanomas in women and 120% increase in men, (f) a 12% increase in brain cancer deaths in women and a 35% increase in men, and (g) a 55% increase in "non-site specific" cancer deaths in women and a 60% in men, as shown in the figure below [Makis, 2023], [Cappuzo, November 22, 2023].



(2) Data from VAERS

a. **"**David Wiseman**,** PhD**.,** research scientist in pharmacy, pharmacology, and experimental pathology, told The Epoch Times in an email that neither Comirnaty—Pfizer's fully approved version of its COVID-19 vaccine—nor Spikevax by Moderna has been evaluated for its potential to cause cancer. On March 30, 2023, Mr. Wiseman and four other experts submitted a 27-page document (Wiseman) to the National Academies Committee, an ad hoc committee tasked with reviewing relevant adverse events associated with COVID-19 vaccines. Using the Vaccine Adverse Event Reporting System (VAERS)—a database co-managed by the U.S. Centers for Disease Control and Prevention (CDC) and FDA used for reporting vaccine adverse events—Mr. Wiseman and his coauthors found an excess of cancer signals for COVID-19 vaccines from Dec. 14, 2020, to July 24, 2023, compared to all other vaccines for all years beginning in 1990" [Redshaw, August 1, 2023].

b. Jessica Rose, BS Applied Mathematics, MA Immunology, PhD, Computational Biology, Post-Doc Molecular Biology, Post-Doc Biochemistry, has also analyzed the VAERS data on cancer and noted the following trends:



[Rose, 2023]

(3) Data from the CDC

David Wiseman has stated: "The CDC's PRR report detected cancer signals for colon cancer, metastatic breast cancer, metastasis to the liver, bones, central nervous system, lymph nodes, breast masses, chronic lymphocytic leukemia, B-cell lymphoma, and follicular lymphoma." Mr. Wiseman said" it's clear from the FOIA documents that the CDC is aware of cancer reports and isn't being forthcoming" [Redshaw, 2023].

This graph shows CDC gathered trend data:

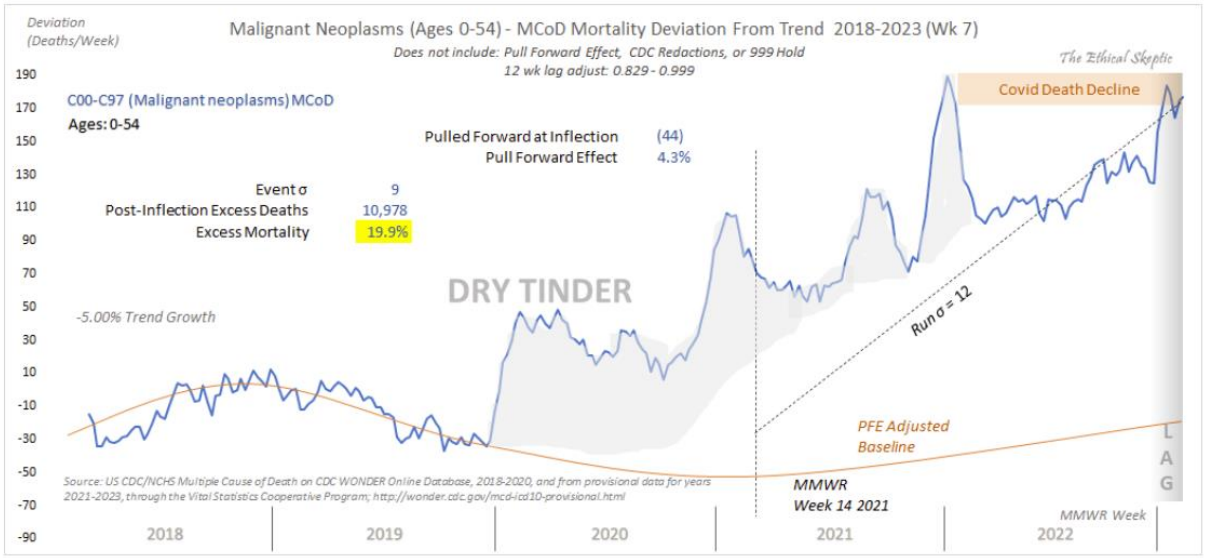
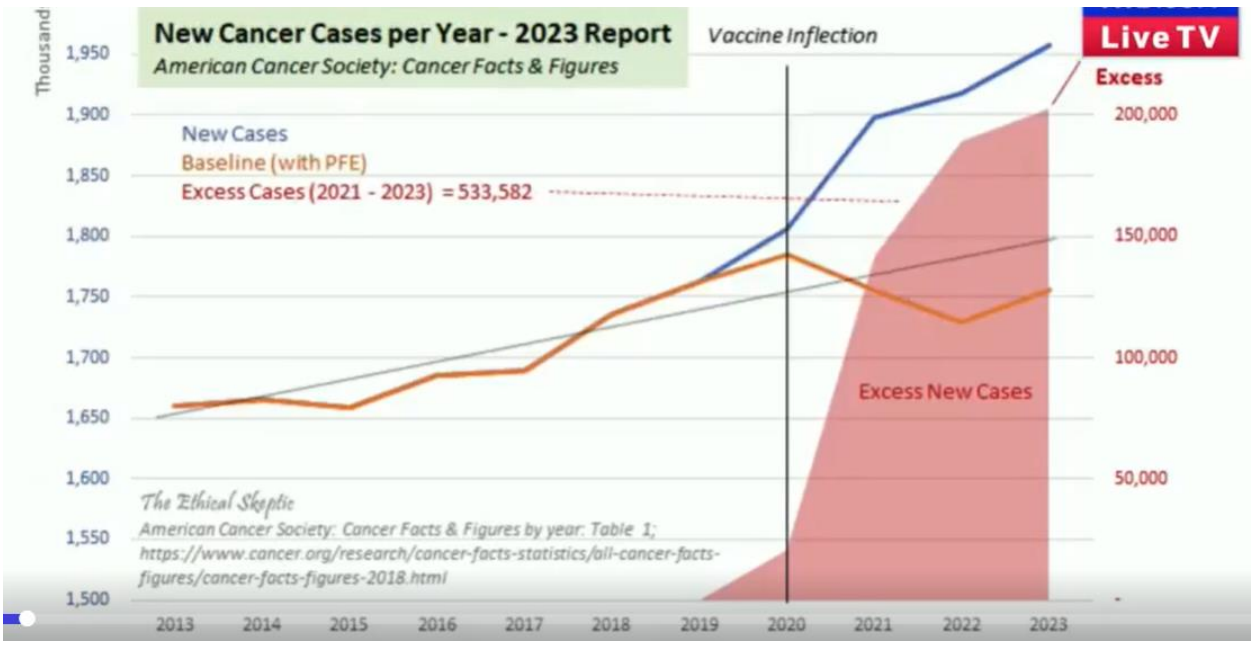


Exhibit C3 – Malignant neoplasms deviation from trend in age 0 – 54 age brackets through Week 7 of 2023. Take the early increases with a grain of salt, as those deaths constituted early capture of persons dying from cancer (dry tinder). That is a discrete and artificial peak, not a trend basis (hence the sudden rise in Feb 2020). What is significant is the robust trend which emerges once this dry tinder effect is no longer in play. This is a 12-sigma run in increase in younger person cancers. No, the stories people are telling across US society are not 'mere anecdote'.

[Skeptic, 2023]

(4) Data from the American Cancer Society:

This trend chart shows a dramatic uptick near the initiation of COVID-19 injections:



(5) **Data from Japan: "**No significant excess mortality was observed during the first year of the pandemic (2020). However, some excess cancer mortalities were observed in 2021 after mass vaccination with the first and second vaccine doses, and significant excess mortalities were observed for all cancers and some specific types of cancer (including ovarian cancer, leukemia, prostate cancer, lip/oral/pharyngeal cancer, pancreatic cancer, and breast cancer) after mass vaccination with the third dose in 2022. AMRs for the four cancers with the most deaths (lung, colorectal, stomach, and liver) showed a decreasing trend until the first year of the pandemic in 2020, but the rate of decrease slowed in 2021 and 2022. " [Miko, 2024]

Mechanisms for Cancer Formation

A variety of plausible mechanisms for cancer formation have been proposed based on lab and/or clinical observations [Angues, 2023]. Understanding these mechanisms is vitally important for devising prospective therapies as conventional treatments offer little or no benefit [Makis, 2023], [Redshaw, 2023].

A primary hypothesis put forward to explain turbo cancer is that the spike protein, and other elements of the vaccine product, weakens the immune system, which then allows precancerous cells (dormant or nascent) to proliferate [Hooker, 2023]. In addition, there may be molecular mechanisms induced by the vaccine product which promote cancer cell formation. When multiple mechanisms are engaged simultaneously (multi-hit hypothesis) carcinogenesis can outpace the immune system [McKernan, Oct 2023].

Mechanisms on how the vaccine can weaken the immune system include: (1) t-cell suppression [Campbell, October 7, 2023]; (2) impaired type I interferon response (a signaling molecule that activates T cells) [Seneff, 2022]; (3) creation of micro-RNAs that indirectly impair the cancer protective BRAC2 gene [Seneff, 2022]; (4) inhibition of P53 or BRAC1 genes or gene products, the guardians of the genome [Singh, et al, 2020]; (5) increase in IGG4 by the booster shot [Irrgang, et al, 2023] that confers immune evasion/tolerance at both humoral and cellular levels [Uversky, et al, 2023] [Rose, December, 2022], (for a more in-depth discussion of IGG4 mediated immune evasion/tolerance see Appendix III); (6) attenuation or alteration of key innate immune system proteins by the pseudo uridine-modified mRNA, impairing cancer surveillance. When activated, these key proteins, called toll-like receptors, can prevent tumors from forming and growing [Javaid, 2020].

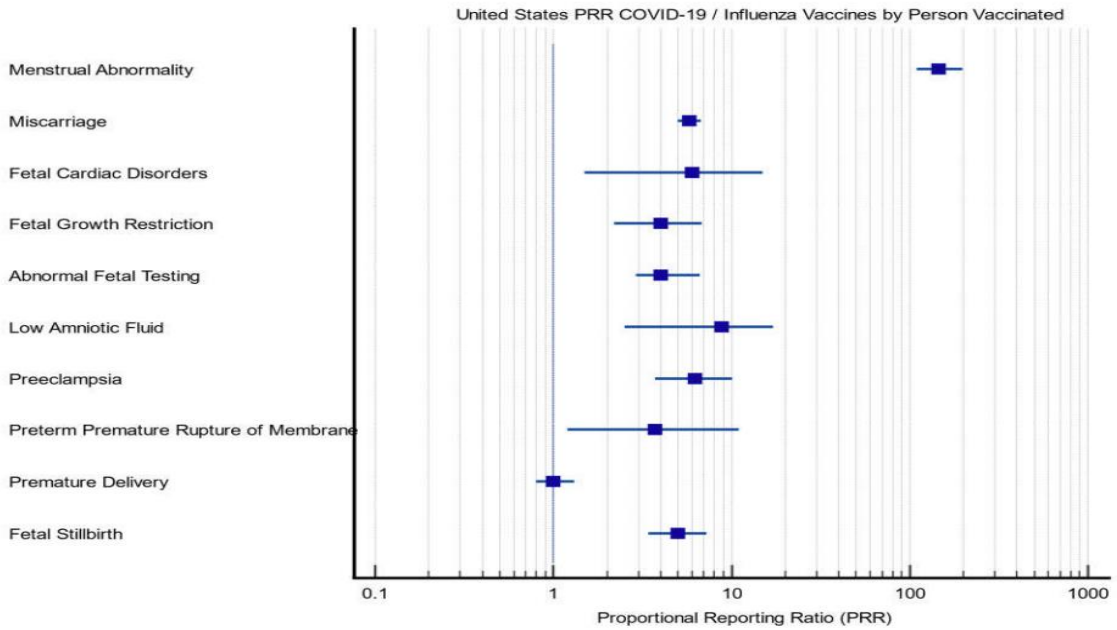
Ways the vaccine can increase mutagenesis include: "transfection of hematopoietic stem cells through mRNA and DNA contained in LPNs (lipid nano particles), mRNA reverse transcribed to DNA and integrating into the genome, enhanced endothelial leakiness by LPN's resulting in increased cancer spread, SV40 super promoters enhancing gene expression of oncogenes, SV40 enhancer regions transporting DNA to the nucleus (DNA in this context is mutagenic), plasmid DNA and double stranded DNA entering the cell nucleus, insertional mutagenesis causing frameshift mutations leading to aberrant proteins which lead to cancer, mRNA reverse transcribed to DNA and integrating into the genome (which causes cancers)" [Lindsay, 2023], "the spike protein may interfere with important tumor suppressor proteins—P53, BRCA 1, which are involved in cancer surveillance [Singh, et al, 2020], the spike protein has a segment homologous to human Galectin-3, which is a known tumor promoter [Doorless Carp, 2023], and the spike protein may interfere with DNA repair mechanisms" [Jiang, et al, 2021] [Redshaw, 2023].

8. Fetal Demise

The Nuremberg code requires that medical experiments on humans be preceded by animal studies to assess safety. Animal studies by Moderna submitted to the European regulators before the vaccine rollout showed evidence of birth defects, and neuro-muscular side effects [European Medicines Agency, 2021]. No clinical trials were done on pregnant women before the release of these products.

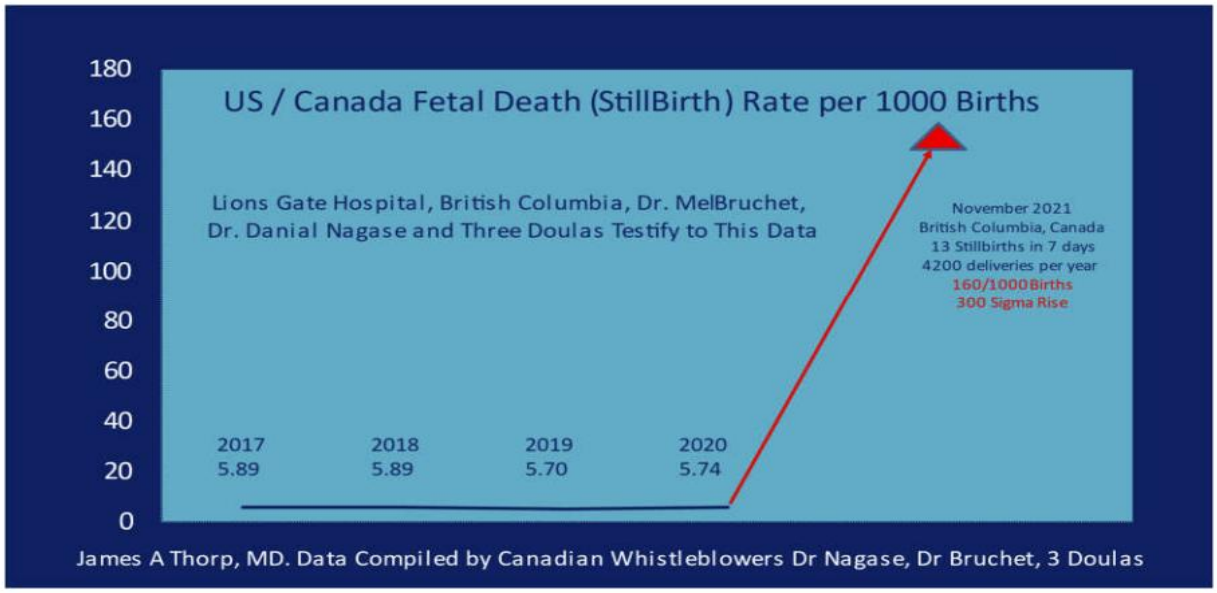
In April 2021, a study appeared in the *NEJM* claiming no increased risk in miscarriage rates for pregnant women receiving the COVID-19 vaccine [Shimabukuro et al, 2021]. “Here the authors’ calculated a 12.6% rate of spontaneous abortion using 104 as the numerator and 827 as the denominator. However, *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*. 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 was not collected. Later attempts were made to retroactively change this number, but the 12.6% figure remains in the text” …. “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.” [Chandler, 2023], [Anon, 2021].

The protocol agreed to by the CDC to evaluate adverse COVID-19 vaccination events relies on the proportional reporting ratio (PRR) which is the ratio of COVID-19 adverse events / Influenza vaccine adverse events by person vaccinated.



“A value greater than 1 implies that the AE (adverse event) is reported more frequently after the COVID-19 vaccines than after the Influenza vaccines. Note the log scale spanning multiple orders of magnitude, indicating a large effect across many different AE - all substantially greater than 1. Data are reported as PRR with 95% confidence interval. Abnormal Menses 145, (CI 109-197); Miscarriage 6, (CI 5.0- 6.7), Fetal Malformation 2, (CI 0-5) (PRR cannot be calculated with zero); Fetal Cardiac Disorders 6, (CI 1.5- 15); Fetal Growth Restriction 4, (CI 2.2-6.8); Abnormal Fetal Testing 4, (CI 2.9-6.6); Low Amniotic Fluid Volume 8.8, (CI 2.5-17); Preeclampsia 6.2, (CI 3.7-10); and Stillbirth 5, (CI 3.4-7.2)” [Thorp, 2023].

At Lions Gate Hospital, coincident to the onset of the use of mRNA vaccines in pregnancy there has been an astronomical 27-fold increase in stillbirths:



“The US baseline rate of fetal death is 5.84 per 1000 births and has minimal variance. The US stillbirth rate dropped from the 2017-2019 aggregate of 5.83 to 5.74 in 2020 despite the COVID-19 caseload; COVID-19 infection clearly did not increase the rate of stillbirth in the US. Depicted here is the Whistleblower data taken directly from five healthcare workers (2 physicians and 3 doulas). Lions Gate Hospital in British Columbia, Canada experienced 13 stillbirths in just one 24-hour period. Because the rate was literally “off the charts” for one day, we used one week. Obviously, this underestimated the observed stillbirth rate at the Lions Gate Hospital at 160/1000 births. Assuming a similar standard deviation of about 0.5 stillbirth/1000 births, this observed surge is unfathomable at over 300 standard deviations (sigma) above baseline”. [Thorp, 2023].

“Recent documents from the UK government state “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.” The World Council of Health has also called for a ban on the COVID-19 vaccines in pregnancy and lactation. Producers of the COVID-19 vaccines themselves report significant AE post-COVID-19 vaccination including 1,223 deaths in the first 90 days of the COVID-19 vaccine

rollout (page 7). Specifically, 46% (124/270) of pregnant women in the first 90 days of rollout experienced AE and 81% (26/32) experienced miscarriage (page 12) [Pfizer, 2021]. Additional data from Pfizer also recorded biodistribution of the vaccine contents into the bloodstream within hours, crossing all physiologic barriers including the maternal placental-fetal barrier and the blood-brain barriers in both the mother and the fetus. This data, along with Schädlich et al. from 2012, documents a significant concentration of lipid nanoparticles in ovaries" [Thorp, 2023]. The risk of germ cell mutations described earlier in this paper creates the possible risk of chimeric progeny and corruption of the human genome [Lindsay, 2023].

The American Academy of Family Practice and the American College of Obstetrics and Gynecology recommend COVID-19 injections in pregnancy [Ramirez,2023], but from the data presented above it is clear that these products are abortifacients and that "an IMMEDIATE cessation of the use of mRNA/LNP vaccines in pregnant women is mandatory until further research proves beyond doubt that they are safe to give to pregnant women" [Chandler, 2022].

9. Seizures in Children

A potential seizure signal of concern because of COVID-19 vaccination in children aged 2-4/5 years-old has emerged [Lloyd, et al, 2023]. Vinay Prasad, MD, is a Hematologist-Oncologist, professor of Epidemiology and Biostatistics at the University of California, San Francisco, and expert in regulatory science. He notes: "The authors [Lioyd, et al] find the safety signal of seizures for 2 different products in comparable ages in kids, which lends clearance to the fact it is real… I am far more concerned the real signal is higher in magnitude (it is reported as 1 in 12k, but perhaps double? triple?)". ... We have no data showing us the absolute risk reduction for severe disease or death at the time it was debut. The virus had already evolved towards less lethality (it was always less than flu level risk for healthy kids). The few studies we do have on VE (vaccine effectiveness) in kids are confounded.'… Given the absolutely low risks of Covid to healthy kids in this age group… I would be concerned that vaccinating kids of this age group might represent a net harm" [Prasad, 2023].

10. The Vaccine Adverse Event Reporting System (VAERS)

The limitations of VAERS as a reporting system are well known: (1) it is a *passive* reporting system; and (2) it does not readily allow for an assessment of causality.

Passive reporting systems create a problem of under-reporting: Miller et al. state in their 2020 article published in the journal *Vaccine*, that "underreporting is a common limitation of passive surveillance systems". A prospective study in 2010 on vaccine adverse events (Harvard Pilgrim study) showed significant underreporting [Lazarus, 2010]. While anyone can report to VAERS, approximately 72% of VAERS reports are generated by healthcare workers. Healthcare workers are mandated reporters subject to Federal crime for false reporting, but they are not required to report if they do not believe the adverse event is related to the vaccine, and the process itself is onerous, requiring up to an hour to complete. Current studies now estimate that VAERS under-reports by at least a factor of 5 to 20 [Rose and Crawford, 2021]. There is also evidence that thousands of adverse events have been deleted from VAERS [Mercola, 2022].

Concerning the issue of Causality: While the FDA promised Americans that the COVID 19 vaccines would be safe, they did not develop a robust *active* surveillance system to better established causality, despite billions of emergency funds made available. During the FDA hearings before the Emergency Use Authorization was granted for the COVID-19 injections, Dr Nancy Messonier, who was then the director of the National Center for Immunization and Respiratory Diseases at the CDC, promised that if an epidemiological-based signal of concern were generated, the federal Federal government would probe the 11 databases that are available to them to investigate the safety issues. These promises have not been fulfilled, rather, the death and injury reports have completely overwhelmed the government's ability to respond, and we now know that the CDC has NEVER sufficiently evaluated the VAERs safety signals (see "regulatory collapse" below).

A visit to the **"OPENVAERS"** website https://www.openvaers.com/covid-data shows the staggeringly scary 'safety signal' of domestic events as of November 3, 2023:

18,382 deaths;
88,472 hospitalizations;
117,818 urgent care visits;
9,171 myocardial infarctions;
5,097 cases of myo/pericarditis:
17,647 permanent neurologic disabilities; and
14,838 life-threatening events

The WHO has recognized Brandon-Hill's rules of causality as a valid tool to assess causality. In fact, it was by using Brandon-Hill's rules that the US Surgeon General established a causal link between smoking and lung cancer in 1964. By applying all 10 criteria to the VAERS data (Strength, Consistency, Specificity, Temporality, Biological Gradient, Plausibility, Coherence, Experimental, Analogy, Reversibility) a **causal** relationship between vaccination and death, hospital admissions, urgent care visits, cardiovascular events, and severe neurologic (permanent disability) events has been established [Rose, February 2022]. APPENDIX I includes a full discussion of these 10 points, one of which is Temporality, which shows the association in time with the vaccination and the adverse event (Figures 8.1, 8.2, 8.3, 9.1 and 9.2. all from VAERS database.)

Figure 8.1 Time series plot — Percentage of reported deaths by time elapsed between the injection date and the reported adverse event

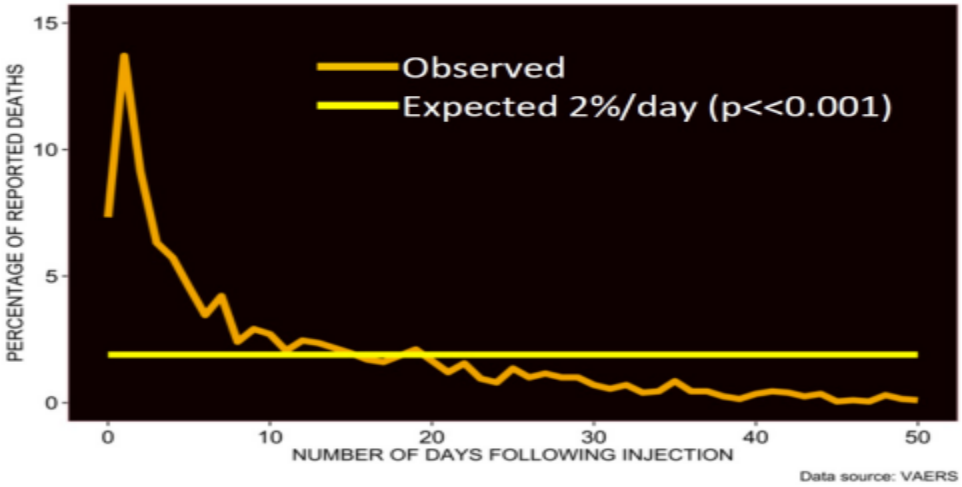


Figure 8.2 Time series plot — Percentage of reported hospitalizations by time elapsed between injection date and adverse event

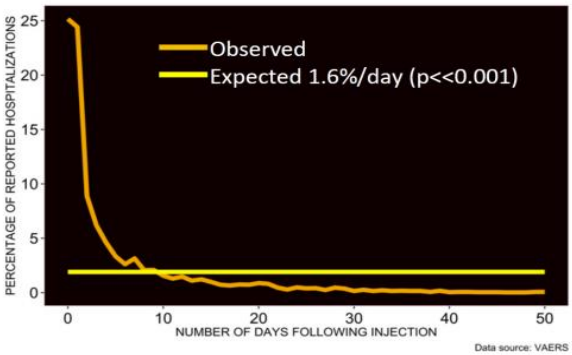


Figure 8.3 Time series plot — Percentage of reported emergency doctor visits by time elapsed between injection and adverse event

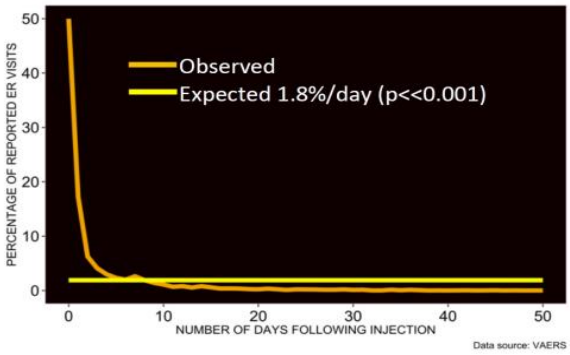


Figure 9.1 Time series plot — Percentage of reported cardiovascular AEs by time elapsed between injection date and adverse event

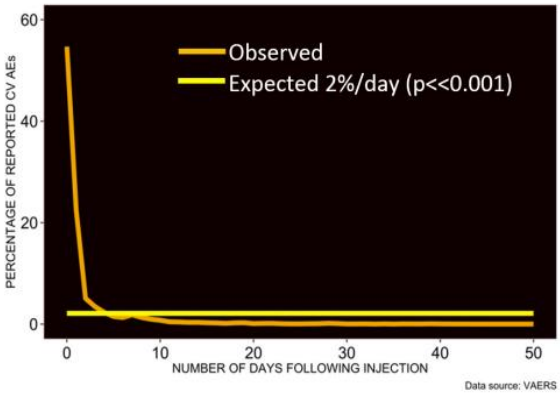
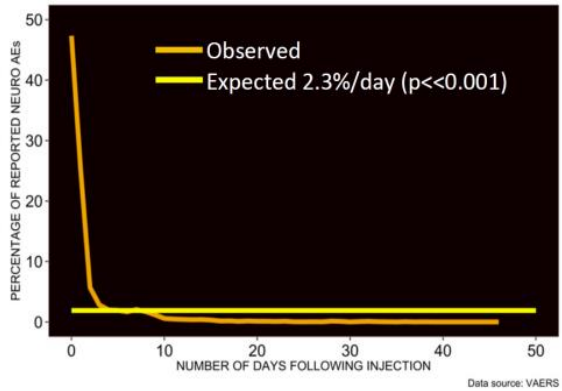
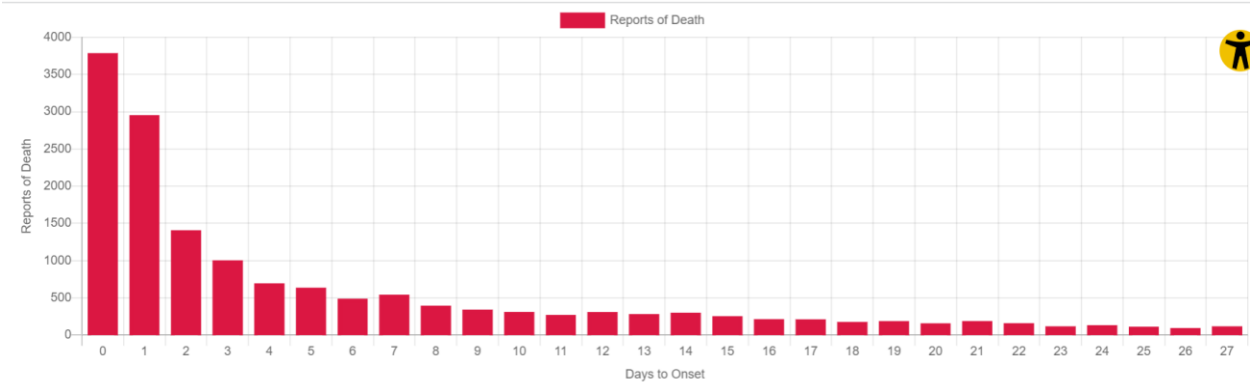


Figure 9.2 Time series plot — Percentage of reported neurological AEs by time elapsed between injection date and adverse event



Another way to illustrate temporality is found on the OPENVAERS website which shows 80% of all deaths occurring within the first week after vaccination: (https://openvaers.com/covid-data)

11



Scott McLachlan (University of London, 2021) has also shown in his analysis of the VAERS data that 86% of the deaths had no explanation other than the vaccine.[McLachlan, 2021].

11. Defense Medical Epidemiology Database (DMED

On February 1, 2022, US Senator Ron Johnson sent a letter to Secretary of Defense Lloyd Austin highlighting the dramatic rise in adverse events reported in the Defense Medical Epidemiology Database (DMED) after the vaccines were rolled out to the military. The letter was based on data submitted by three military whistle blowers that had data mined DMED data, which were represented by Thomas Renz, JD.

This data showed a dramatic increase from 2020 to 2021 of serious medical conditions including: Hypertension – 2,181% increase • Diseases of the nervous system – 1,048% increase • Malignant neoplasms of esophagus – 894% increase • Multiple sclerosis – 680% increase • Malignant neoplasms of digestive organs – 624% increase • Guillain-Barre syndrome – 551% increase • Breast cancer – 487% increase • Demyelinating – 487% increase • Malignant neoplasms of thyroid and other endocrine glands – 474% increase • Female infertility – 472% increase • Pulmonary embolism – 468% increase • Migraines – 452% increase • Ovarian dysfunction – 437% increase • Testicular cancer – 369% increase • Tachycardia – 302% increase [Kirsh, 2023].

12. CDC Data analysis (David Wiseman) using NER

David Wiseman is an experimental pathologist with a background in pharmacy, pharmacology and immunology. In his report to the National Academies Committee on Review of Relevant Literature Regarding Adverse Events Associated with Vaccines March 30, 2023, he presents his analysis of the COVID-19 vaccines using the CDC's vaccination coverage statistics. To do this he uses a method called the Normalized Event Ratio (NER). FDA and CDC scientists have used this method to "normalize the number of events reported in VAERS for the number of people receiving a particular vaccine or doses administered. The figure can be divided by a similar ration for the refence vaccine (either flu or H1N1) to obtain a normalized event ratio

(NER)…According to Wiseman, “The NER appears far more sensitive than the PRR, shown below.”

	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.[14] We used USAFACTS[15] for age-related population figures for various years, and CDC figures on numbers of people vaccinated [16]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

“We find NER value up to 7 for GBS, up to 34 for serious events, up to 370 for coagulopathies, up to 98 for deaths and up to 403 for myocardial infarction. In most cases these values correspond to a statistically significant PRR value”

*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.(21)

[Wiseman, 2023]

Wiseman also notes that at the 1-26-24 VRBPAC meeting VSD data suggested a possible ischemic stroke signal was found in those over 65 and may have been associated with the flu vaccine being given on the same day as the COVID-19 injection.

The Wiseman NER data analysis is very significant, as it, like the DMED data, confirms the validity of the VAERS signal.

13. SAE Requiring Ambulance or Hospital Admission

Serious Adverse Events (SAE) after COVID-19 injection are unfortunately common in children. A retrospective, multi-institution German/Swiss study examined 7806 children under age 5 for 91.4 days after at least on dose of the Pfizer injection was given and found that “1 in every 99 children aged 5 and under required emergency care (ambulatory) or hospitalization (inpatient) following Covid-19 vaccination” [Toepfner, et al, 2022].

14. Vaccine Damage Project: Estimating the Human Cost

Using data from the US Dept of Labor Statistics analysts at Phinance Technologies have attempted to “estimate the direct impact from the mass COVID-19 inoculations on individuals at a population level”.

In their study they “investigated the human cost in relatively young and healthy age groups as these are the most representative for the productive population (workforce). For absences, we estimated the injured pool of individuals by using the full-time workers aged 25-54, while for disabilities we use the employed workers aged 16-64 and for excess deaths we use the population aged 25-64”.

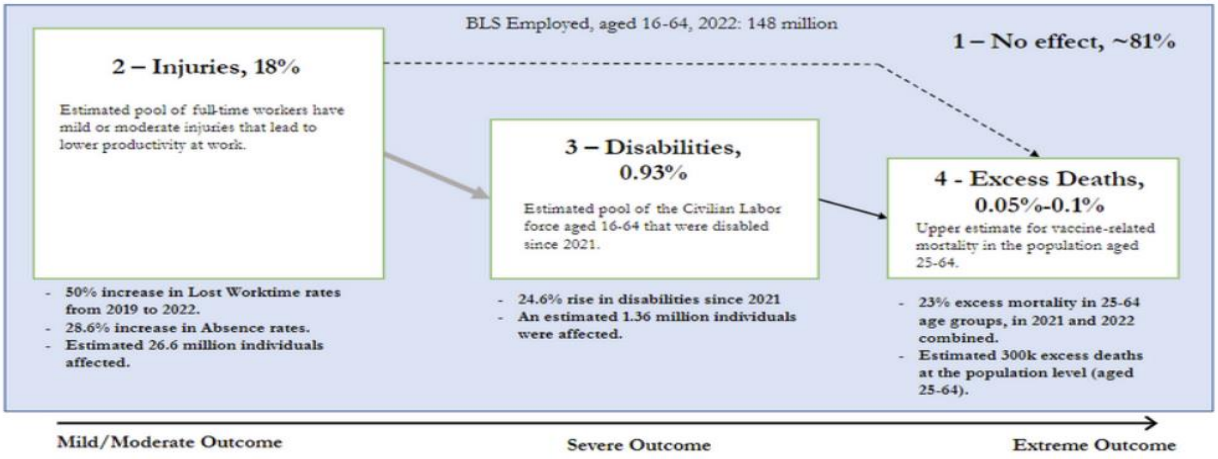
They identify four groups:

“Group 1: - No effect or asymptomatic This group of individuals comprises those individuals who did not experience adverse events following the COVID-19 inoculations. We estimate that the number to be about 80% of the population.

Group 2: With mild to moderate damage (injuries): About 18% of the Employed Labor Force aged 16-64 is estimated to have suffered injuries due to the COVID-19 vaccine rollout program that started in 2021. In absolute numbers, an estimated 26.6 million individuals have been injured by the inoculations. This corresponded to a 28.6% rise in absence rates in 2022 relative to 2019, and a 50% rise in lost worktime rates.

Group 3: With severe damage (disabilities): The rise in disabilities in the Civilian Labor Force population since the start of 2021 was about 0.93%, corresponding to a 24.6% rise. In absolute numbers, an estimated 1.36 million individuals aged 16-64 that are actively engaged in the labor market, became disabled.

Group 4: The most extreme damage (death): Excess deaths are estimated to have occurred at an absolute rate of about 0.1% of the 25-64 population for 2021 and 2022 combined (upper limit). This represents about 23% excess mortality for 2021 and 2022, relative to the expected baseline. In absolute numbers, this represents about 310,000 excess deaths. “



[Humanities Projects, 2023]

15. All-Cause Mortality and Sudden Death

Multiple Sources Show Increased All-Cause Mortality

To know the net benefit of any therapeutic, all-cause mortality and severe disease need to be measured as end points.

(a) Denis Rancourt: "COVID-19 Vaccine – Associated Mortality in the Southern Hemisphere" [Rancourt, et al, 2023]

In a paper entitled "COVID-19 Vaccine – Associated Mortality in the Southern Hemisphere" published in CORRELATION, September 2023, Denis Rancourt, PhD, establishes a causal link between vaccination and all-cause mortality (ACM). He also quantifies the degree of ACM related to the COVID-19 vaccination.

Excerpts from the paper are as follows:

"Seventeen equatorial and Southern-Hemisphere countries spanning 4 continent were studied, showing no benefit in all-cause mortality (ACM) and COVID-19 vaccination. Nine of the 17 countries have no detectable excess ACM in the period of approximately one year after a pandemic was declared until the vaccines are rolled out".

"Unprecedented peaks in ACM occur in the summer (January-February) of 2022 in the Southern Hemisphere, and in equatorial-latitude countries, which are synchronous with or immediately preceded by rapid COVID-19-vaccine-booster-dose rollouts (3rd or 4th doses). This phenomenon is present in every case with sufficient mortality data (15 countries). Two of the countries studied have insufficient mortality data in January-February 2022".

“Synchronicity between the many peaks in ACM (in 17 countries, on 4 continents, in all elderly age groups, at different times) and associated rapid booster rollouts allows this firm conclusion regarding causality, and accurate quantification of COVID-19-vaccine toxicity”.

“The all-ages vaccine-dose fatality rate (vDFR), which is the ratio of inferred vaccine-induced deaths to vaccine doses delivered in a population, is quantified for the January-February 2022 ACM peak to fall in the range 0.02 % (New Zealand) to 0.20 % (Uruguay). In Chile and Peru, the vDFR increases exponentially with age (doubling approximately every 4 years of age), and is largest for the latest booster doses, reaching approximately 5 % in the 90+ years age groups (1 death per 20 injections of dose 4). Comparable results occur for the Northern Hemisphere, as found in previous articles (India, Israel, USA).”

“We quantify the overall all-ages vDFR for the 17 countries to be (0.126 ± 0.004) %, which would imply 17.0 ± 0.5 million COVID-19 vaccine deaths worldwide, from 13.50 billion injections up to 2 September 2023. This would correspond to a mass iatrogenic event that killed 0.213 ± 0.006 % of the world population (1 death per 470 living persons, in less than 3 years), and did not measurably prevent any deaths.”

“The scientific tests for causality are amply satisfied, as extensively demonstrated in these sections of the present paper: (1) COVID-19 vaccines can cause death; (2) Absence of excess mortality until the COVID-19 vaccines are rolled out; (3) The COVID-19 vaccines did not save lives and appear to be lethal toxic agents; (4) Strong evidence for a causal association and vaccine lethal toxicity; (5) Causality in excess mortality is amply demonstrated; (6) Assessing other interpretations of the cause of the excess mortality; (7) Implications regarding age-dependence of fatal toxicity of COVID-19 vaccines” [Rancourt, et al, 2023].

(b) Pfizer Data

As mentioned earlier, in the only Randomized Controlled Trial of the COVID-19 products, when all-cause mortality and severe, non-COVID-19 illness are used as endpoints we see that total deaths in the vaccinated group exceeded (21 deaths) those in the unvaccinated group (17 deaths) showing an increase in all-cause mortality [Covid Care Alliance 2021], [Michels, et al, 2023].

Pfizer, together with the FDA tried to delay the release of the clinical data related to the roll out for 55 years, but fortunately a FOIA request prevailed, and we now know that 1223 people died within the first 90 days of the roll out.

The largest observational trial claiming vaccine efficacy [Dagan et al, 2021] failed to report any adverse events. In fact, Pfizer and authorities in Israel nefariously agreed to not report any adverse events in this study for 8 years.

(c) UK Data (ONS) on Vaccinated vs Unvaccinated All-Cause Mortality

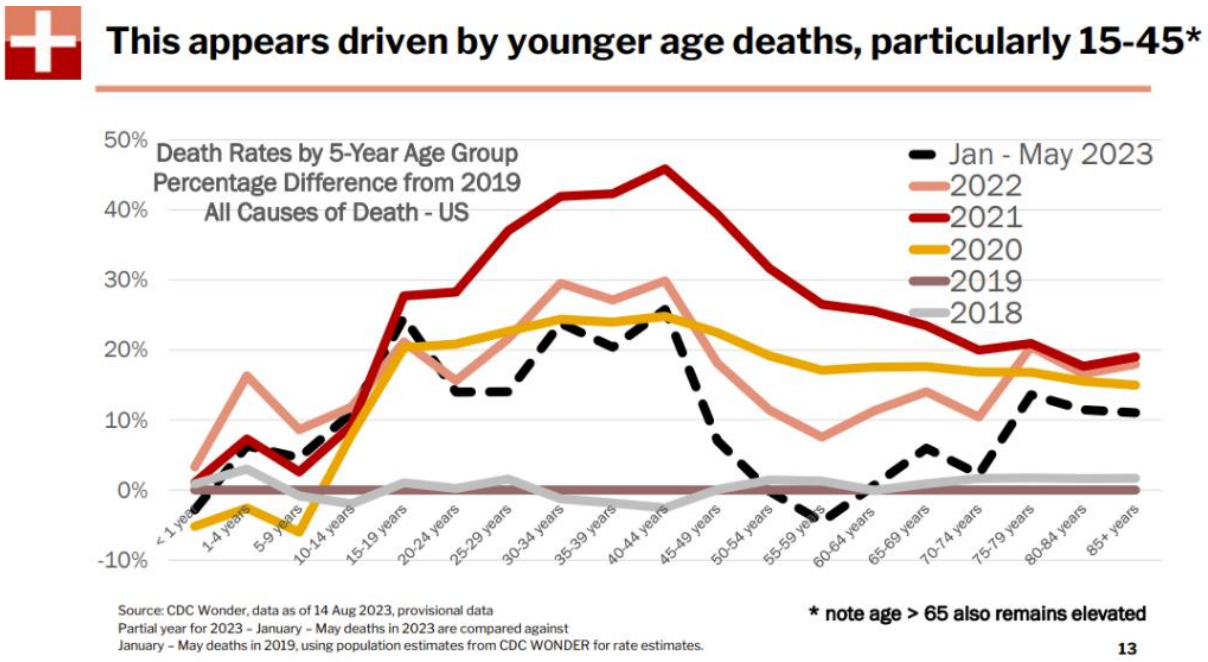
Data gathered from the Office of National Statistics (ONS) for England from January to May 2022 shows that **for all age groups singly and doubly vaccinated had greater all-cause mortality than unvaccinated** for all months, and triply vaccinate had greater mortality than

unvaccinated for 22 of the 30 age-month groupings [Expose, August 9, 2022] (see Appendix II). See also [Berenson, 2021].

“Data derived from the ONS and compiled by “The Expose News” show that 70,000 people died within 28 days of receiving the COVID-19 jab in the UK; nearly 180,000 died after 60 days. Children who received the jab had an increase of all-cause mortality between 8,100 percent and 30,200 percent” [Tenpenny, 2022].

(d) Actuarial and CDC Death Data

As would be expected all-cause mortality in 2020 increased compared to baseline numbers of previous years due to Covid. However, for the 15–45-year-old group, this increase has persisted well beyond a period explained by Covid alone.



[Bailey, 2023] [Stirling, 2023]

Some have attributed this pattern to other persistent issues that were COVID-19 related, or to lock down related issues or delays in care, increased suicide rates, and increased drug overdose. However, “CDC data reported in August [2023] showed that Americans in the period January-May 2023 were still dying at abnormally high rates with the pandemic long over. Mortality rates were 25% higher than normal among 15- to 19-year-olds and 20% higher among 45-year-olds considered in the prime of life” [Cappuzo, November 6, 2023].

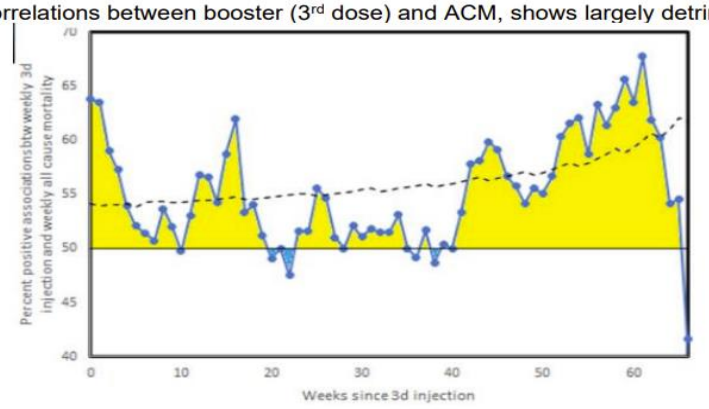
Edward Doud, former Black Rock Managing Director, and many others believe this is a result of the coincident roll out of vaccines. In his book “Cause Unknown: The Epidemic of Sudden deaths in 2021 and 2022”, Doud sites data that corroborate CDC data from the

Society of Actuaries, showing a 15% increase in Group Life insurance related mortality for 25–64-year-olds from 2020 to 2021, with a dramatic uptick in Quarter 3 of 2021 coincident with the timing of vaccine mandates. He also notes that the group life population, which is a generally healthier population than the overall US population, had "a massive 8% higher mortality rate than the overall US population [IN 2021, and] ….the only thing that changed was a mandated vaccination where continued employment was contingent upon compliance with no exceptions" [Doud, 2023]. See also [Alegria, 2023, UK Cause of Death Project] and [Nevradakis, 2023].

(e) Wiseman All-Cause Mortality and Vaccination Analysis

"We have found from European and CDC data, correlations between vaccination coverage and all-cause mortality…. Rather than take static snapshots in time common in other analyses, this analysis constructs correlations across 23 European countries using Euromomo data for every lag in time (by week) between vaccination and an estimate of ACM. The most recent version of this analysis (3/25/23) is shown here (courtesy Dr. H. Seligmann). Yellow and blue areas indicate detrimental and beneficial associations between vaccination coverage and ACM. The dotted lines indicate significance boundaries, outside of which denotes statistical significance. They are wider for the longer lag times, where there are fewer data points. The analysis aggregates time lags of the same length regardless of the calendar data when vaccination occurred" [Wiseman, 2023]

The following analysis of correlations between booster (3rd dose) and ACM, shows largely detrimental associations.



[Wiseman, 2023].

(f) All-Cause Mortality Germany

This graph shows the increase in excess mortality (as a percentage) in Germany in 2021 and 2022 coincident with the onset of COVID-19 vaccinations.

Figure 1 illustrates that the deviation of the observed mortality from the expected mortality is not uniform over the different age groups and that the pattern across the age groups changes from 2020 to 2021 and 2022.

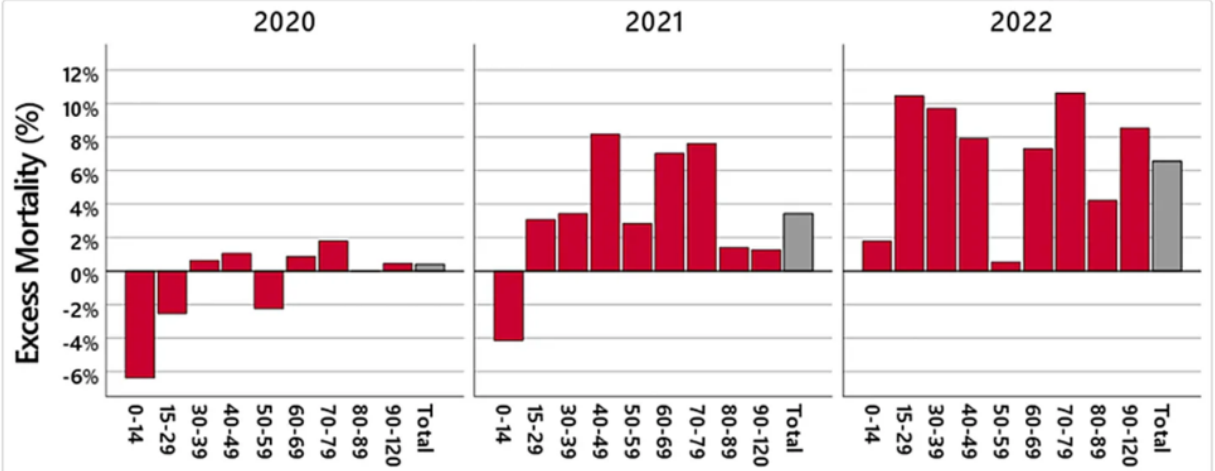
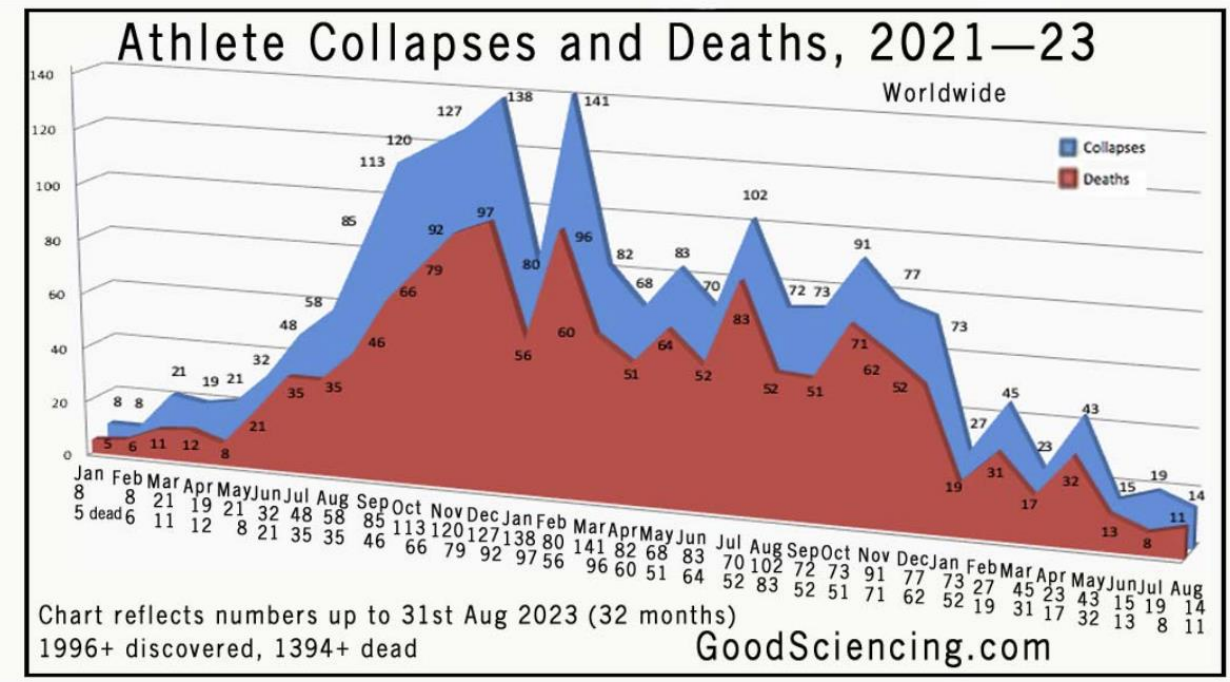


Figure 1: Yearly excess mortality.
The red bars show the excess mortality in 2020 (left panel), 2021 (middle panel), and 2022 (right panel) in different age groups. The gray bars are the total excess mortality.

[Chossudovsky, 2023]

(g) Data on Athletes and Young People Dying Suddenly

The current rate of sudden death among athletes is much higher than in previous years where the average was 29 per year [Bille et al, 2006]. Now according to the website Real Science, from January 2021 to August 2023 1996 athletes had a cardiac arrest and more than 1394 athletes have died and are listed by name [Anon, 2022].



Athlete collapses and deaths chart from 1st January 2021 to 31st August 2023. Good Sciencing.

In Ed Doud's book "Cause Unknown: The Epidemic of Sudden deaths in 2021 and 2022" [Doud, 2022], there is a compendium (not meant to be a comprehensive list) of 548 young people (age 5-45) who were confirmed to have died in 2021-22 suddenly. All those identified were confirmed to have had no obvious explanation for their death (e.g., suicide, homicide, drug overdose, accident, severe concurrent illness). As discussed earlier the sudden nature of these deaths is consistent with the VAERS showing that 80% of the now reported 30,000+ deaths occurred within 7 days of vaccination. Sudden death is also consistent with the know mechanisms of spike protein injury which include thrombosis with resultant stroke or pulmonary embolism, and spike related myocarditis with resultant cardiac infarction and/or malignant arrythmia.

"Dr Peter McCullough, one of the most highly published cardiologists in the world, pointed to a study of deaths after vaccination with detailed autopsies in Heidelberg, Germany. "Of 35 fatalities within 20 days of injection, 10 were ruled out as clearly not due to the vaccine (e.g. drug overdose). The remaining 25 (71%) had final diagnoses consistent with a vaccine injury syndrome including myocardial infarction, worsening heart failure, vascular aneurysm, pulmonary embolism, fatal stroke, and vaccine-induced thrombotic thrombocytopenia," McCullough wrote. [Schwab, et al, 2022], [Capuzzo, 11-6-23].

16. Risk Benefit Analysis

College Vaccine Mandates

In the paper "COVID-19 vaccine boosters for young adults: A risk-benefit assessment and 2 five ethical arguments against mandates at universities" "it was estimate that 22,000 - 30,000 previously uninfected adults aged 18-29 must be boosted with an mRNA vaccine to prevent one

COVID-19 hospitalization. Using CDC and sponsor-reported adverse event data, we find that booster mandates may cause a net expected harm: per COVID-19 hospitalization prevented in previously uninfected young adults, we anticipate 18 to 98 serious adverse events, including 1.7 to 3.0 booster-associated myocarditis cases in males, and 1373 to 3234 cases of grade ≥3 reactogenicity which interferes with daily activities. Given the high prevalence of post-infection immunity, this risk-benefit profile is even less favorable" [Bardosh et al, 2022].

Fraiman Paper

In September 2022 Fraiman, et. al., showed that "**the excess risk of serious adverse events caused by the vaccine… surpassed the benefit of reduced hospitalization"** by the Moderna or Pfizer products, and called for the release of higher lever datasets after pointing out the alarmingly high level of Serious Adverse Events (SAE) following mRNA COVID-19 vaccination of 1/800 (1/990 for Pfizer, 1/662 for Moderna) [Fraiman, 2022]. The definition of SAE in anything that results in death, life threatening events at the time of vaccination, in-patient hospitalization or hospital prolongation, significant disability, congenital anomaly of birth defect, or medically important events.

UK Health Security Agency (UKHSA) Data

On March 17, 2022, MP Mr. Andrew Bridgen gave testimony in the UK Parliament about the efficacy of the COVID-19 vaccinations [Bridgen, 2023]. In this presentation he cited United Kingdom data presented on January 25, 2023, by the UK Health Security Agency to the Joint Commission on Vaccines and Immunizations (JCVI), [UKHSA, 2022], which showed:

Number of Vaccinations Need to Prevent 1 Hospitalization

In the age **50-59** group, 43600 vaccinations were needed to prevent 1 hospitalization with a resultant number of 55 dying or having SAE from the jab. In the age **40-49** age group, 92,500 vaccinations were needed to prevent 1 hospitalization with a resultant number of 116 dying or having SAE from the jab. In the age **30-39** age group, 210,400 vaccinations were needed to prevent 1 hospitalization with a resultant number of 263 dying or having SAE from the jab.

Number of Vaccinations Need to Prevent 1 Severe Hospitalization

In the age **50-59** group, 256,400 vaccinations were needed to prevent 1 severe hospitalization (defined as hospitalization requiring oxygen or intubation) with a resultant number of 321 dying or having SAE from the jab. In the age **40-49** age group, 932,500 vaccinations were needed to prevent 1 severe hospitalization with a resultant number of 1165 dying or having SAE from the jab. In the age **30-39** age group, no one knows the number needed to prevent 1 severe hospitalization as there has never been a case of this age group being put into the ICU, and yet an average 1 in 800 will have had SAE from the booster.

In the highest risk group, the over 70 with comorbidity will need 800 vaccines to prevent 1 hospitalization. This amounts to swapping the risk of one COVID-19 hospitalization for the risk of one booster-induced hospitalization (and this does not consider the suffering noted in many people during the immediate post injection period of several days, suggesting that even here, we are not merely swapping one cause of death for another and so the impact is still overall a negative one). [Fraiman, 2022], [UKHSA, 2022].

Comments from Vinay Prasad

"The FDA and CDC have gambled with the health of young kids. They did not demand appropriately sized randomized data to demonstrate net benefit. They added these vaccines to the childhood schedule without these data. As time goes on, the FDA and CDC won't be able to hide the fact that boosting young men was harmful and that, very likely, vaccinating young kids was harmful. If that is conclusively proven, I suspect credibility in these agencies will go down further" [Prasad, November 2023].

D. SAFETY: LONG TERM AND ONGOING RISK

There is no long-term safety data to assess the safety of these products. In previous attempts to create a vaccine against SARS-1 using mRNA technology, the study animals either died or had severe autoimmune reactions due to pathogenic priming (this problem was known to Fauci and Collins in the Spring of 2020 prompting a paper where they warned of this potential problem) [Corey et al, 2020]. As stated earlier, animal studies by Moderna submitted to the European regulators showed evidence of fertility compromise, birth defects, and neuro-muscular side effects. There were either no, or insufficient toxicology packages submitted to the FDA to assess fertility, teratogenicity, or cancer risk. Peter Doshi, senior editor to the *British Medical Journal*, concurs and comments on current and future levels of harm to children in his testimony to the FDA [Doshi, 2021]. The long-term safety issues of these mRNA products will not be known for years and may be irreversible. Insertional mutagenesis is a real possibility, creating cancer risk, as well as alterations in the human genome if DNA insertions occur in the gametes. Therefore, these products cannot be promoted as safe. Most people have not been informed of this or of the fact that they are a part of a human experiment.

Add to this the reckless statement of the senior editor of the *NEJM*, Eric Rubin, MD about the use of these products in children: "But we're never going to learn about how safe this vaccine is unless we start giving it. That's just the way it goes." Whatever happened to the precautionary principle "first do no harm"? This recklessness is further affirmed by the fact the bi-valent product was only evaluated on eight mice prior to its release.

Although the pandemic is over, the risk of these products is ongoing. Because they have been enshrined into the pediatrics vaccination schedule, they pose an ongoing risk to children. In addition, the mRNA technology will serve as a platform for the development of future influenza and other vaccines, creating other venues for mRNA toxicity. The 'need' for these injections continues to be pushed relentlessly in advertisements run in the US media (and without any warnings regarding side-effects; warnings that are required of all other therapeutics when advertised). Recurrent vaccination with these products will amplify their risk and may create significant immune system suppression, increasing the risk of other infections and cancer.

Viral ecology and the Problem of Vaccinating into a Pandemic

Vaccinating against the Omicron variant will not only expose children to unnecessary risk but will also result in the production of escape mutants that may be more virulent. It is important, therefore, from both an individual patient perspective and a viral ecology perspective, to warn parents against future COVID-19 vaccination.

IV. Challenges to the Thesis of this Paper and Comments About Boosters

Expert Opinion

Many experts continue to recommend COVID-19 injectables, although there is no data to support the use of these products in children, and no data to support the use of boosters in adults [Prasad, 9-1-23]. An example of such an expert is Paul Offit, a prominent and very amicable vaccinologist with a wide following. In a recent podcast Offit promotes the use of these products for what he perceives as higher risk groups, namely 2-4/5-year-olds, pregnant women, immunosuppressed people, and the elderly [Offit, 2023]. However, data on efficacy, does not exist for these population groups and in fact shows negative efficacy and harm. While it would seem that elderly and immunosuppressed patients could benefit since, they are seen as higher risk groups, this paper has shown that the CODID-19 products are immunosuppressive [see section of cancer risk], pregnancy harmful [see section on fetal demise], and highly lethal especially in the elderly [see Rancourt paper]. It is important to remember, as stated before, that expert opinion is the lowest level of scientific evidence.

According to Vinay Prasad, MD, PhD, there are multiple reasons to recommend against COVID-19 boosters: (1) Peter Marks, MD, PHD, the FDA director of the Center for Biological Evaluation and Research (CBER), has stated that there is not sufficient evidence to recommend boosters outside of yet to be done large randomized controlled trials [Marks, 2022]; (2) The US is an outlier in its broad recommendation for boosters. Multiple countries (England, Sweeden, Italy, France, Germany, Denmark, Portugal, New Zeeland) recommend against the use of these products except in older or higher risk groups; (3) Experts from the European CDC told Euractiv that “No country currently recommends [Covid] immunization for healthy children”; (4) The testimony of expert FDA vaccine regulators (Dr Marion Gruber and Dr Philip Krause) who resigned over the data insufficient “boosters for all” campaign; (5) There is net harm, with insufficient risk of COVID-19 in children compared with the serious adverse events from the booster, such as a 28% rate of being out of work from the jab (CDC data), and high rates of myocarditis [Sharff, et al, 2022].; (6) The current FDA booster does not target the current variant; (7) There is no data supporting a true uptick in COVID-19 caused deaths with COVID-19 instead acting as a bystander [Trotter, et al, 2023]; (8) The poor and transient efficacy of the booster, with efficacy peaking at 30% at week 2 and declining to zero by week 16 [Lin, et al, 2023]. The vaccine does not protect against the spread of the disease [Prasad, December 18, 2023].

In an Austrian study by Chalupka, et al, 2024 there was no benefit for people who have had a fourth COVID-19 booster: “ we did not observe a significant rVE [vaccine effect] of a fourth vaccine dose for COVID-19 deaths during a time with already very low absolute risk for this outcome”, and “ no individual younger than 40 years died due to COVID-19” [Prazad, 2024].

Observational Trials

In “A Systematic Review of Coronavirus Disease 2019 Vaccine Efficacy and Effectiveness Against Severe Acute Respiratory Syndrome Coronavirus 2 Infection and Disease” [Higdon et al, 2022], the authors highlight several observational studies that show that the COVID-19 products reduce severe disease, hospitalization, and death for adults. This is sometimes cited as an endorsement for the use of these product in children and for the current use of the vaccines in adults. The Higdon paper reviewed observational trials of the COVID-19 products in adults, and as such this paper cannot be used to support efficacy in normal children against Omicron. Also, as stated earlier, in the largest observational trial [Dagan, et al, 2021], there was no benefit in people under 40 against severe disease and there was no analysis of long-term safety.

Observational studies showing supposed death benefit from COVID-19 vaccine also show death benefit for non-Covid categories, meaning that they are likely not adjusted for confounding. One likely confounder is that healthier people might have a higher vaccination rate and do better, not because of the vaccine, but because of their overall better health at baseline [Hoeg, et al, 2023]. This is called healthy vaccinee bias. There is also no sufficient data supporting the use of these products in adults given the benign nature of omicron [Prasad, 9-1-23].

Another paper often cited in support of pediatric COVID-19 vaccines is “BNT162b2 Protection against the Omicron Variant in Children and Adolescents” [Price et al, 2022]. This paper shows the odds of vaccination for children admitted for non-COVID-19 reasons are higher than the odds of vaccination for children admitted for COVID-19. The inference made by this paper is that the lower incidence of COVID-19 is due to the higher vaccination rate, but at least 2 other explanations are possible: (1) the group with the higher vaccination rate might be a more chronically ill population with a higher rate of hospital admission due to non-Covid chronic conditions, and with a higher vaccination rate due to proactive vaccination by providers concerned about this group’s higher risk status; or (2) it is also possible that the non-Covid group had a higher vaccination rate and lower COVID-19 rate due to socioeconomic characteristics (e.g., higher income, White or Asian race). Vinay Prasad, MD discusses the difficulties inherent with this case-control, test-negative research design, and how it is not possible to untangle the confounding issues, nor assign causality [Prasad, May 2022]. In other words, this commonly cited study cannot be used as support for COVID-19 products in children.

V. Regulatory Capture and Corruption

Both the FDA and the CDC have failed to provide proper oversight in the evaluation of mRNA products. Earlier in this paper, I described how FDA has given EUA for these products while at efficacy standard of 50% or better was not met and the FDA failed to insist that the manufacturers of these products provide definitive randomized controlled trials to establish efficacy. The FDA also dropped the product integrity standard to 50% with no supporting clinical trials. Perhaps some of this can be explained by conflicts of interest (so called regulatory capture) where, for example 75% of the 1.5-billion-dollar FDA budget, is financed by big pharma and there is a well-documented revolving door in leadership between regulators and corporate executives [Bien and Prasad, 2016]. Also, "Over the period of time from 2010 to 2016, 27,000 royalty payments were paid to 18,000 NIH employees” [Schemmel, 2022].

Why would Pfizer's agreement with the Israeli Minister of Health to delay the release of adverse outcomes for 8 years on the largest ever conducted vaccine trial go unnoticed by the FDA? Also, the FDA and Pfizer wanted to delay the full release of the 390,000 pages of Pfizer post-marketing data over a 75-year period. Thanks to a FOIA release, these data are being released over the next year. Preliminary review by a team of 800 scientists, analysists, and attorneys now shows that 1223 people died in the vaccinated group within the first 90 days of the vaccine roll out. [Pfizer, 2021] This data was not publicly disclosed by Pfizer, which constitutes fraud. This failure to report is a conspiracy, not a conspiracy theory and has prompted the *British Medical Journal* to demand the immediate release of all COVID-19 vaccine treatment data. [Doshi, et al, 2022].

As mentioned above, the CDC promised that if an epidemiological-based signal of concern were generated, the Federal government would probe the 11 databases that are available to them to investigate safety issues. A system to evaluate vaccine related adverse events is outlined in the "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19 (as of 29 January 2021)" Section 2.3.1 and Section 2.3.2. The protocol describes how the CDC is required to perform data mining on a weekly basis or as needed using a tool known as Proportional Reporting Ratio (PRR). The CDC has admitted under a FOIA request that "it didn't start performing the monitoring technique until 2022—more than one year after the Pfizer and Moderna vaccines were authorized" [Stieber, 2023], and at one point in June 2022 said "no PRR were conducted by CDC and data mining is outside the CDC's purview" [Guetzkow, June 2022]. It is incredible to see that despite repeated claims of safety, the CDC was not conducting timely evaluations of the VAERs safety signals. VAERS, as stated earlier, has provided an unprecedented signal (parenthetically VAERS also matches the British Yellow Card System) that demands evaluation. This negligence shows that the CDC does not care and does not want to see the evidence [Weinstein, 2022]. It is also shameful to realize that it has taken 18 months to produce the first prospective study on myocarditis risk. If regulators were doing their job such a study would have been done early in the vaccine rollout. On June 30, 2023, the CDC stopped collecting data on a system to collect COVID-19 vaccine adverse events through the app-based V-Safe program, "even after millions of Americans have reported such events" [Athrappully, 2023].

Pfizer did a bait and switch, by using an entirely different process to manufacture the shots use in the roll out as was used in the clinical trials. These products are contaminate with DNA fragments and may also contain endotoxin due to poor manufacturing processes. The addition of the SV 40 enhancer into the E. coli plasmids may promote transfer of DNA into the cell nucleus, enhancing the possibility of gene transfer and cancer. The presence of the SV 40 enhancer was deliberately not disclosed to the regulators. Process is product. Unfortunately, many large pharma companies have a poor track record when it comes to corporate integrity and data transparency as evidenced by the over 113 billion dollars in fines levied against major pharmaceutical companies since 2000, including fines to Johnson and Johnson totaling over 24.3 billion dollars, and to Pfizer totaling over 10.9 billion dollars [Rhodes, 2023].

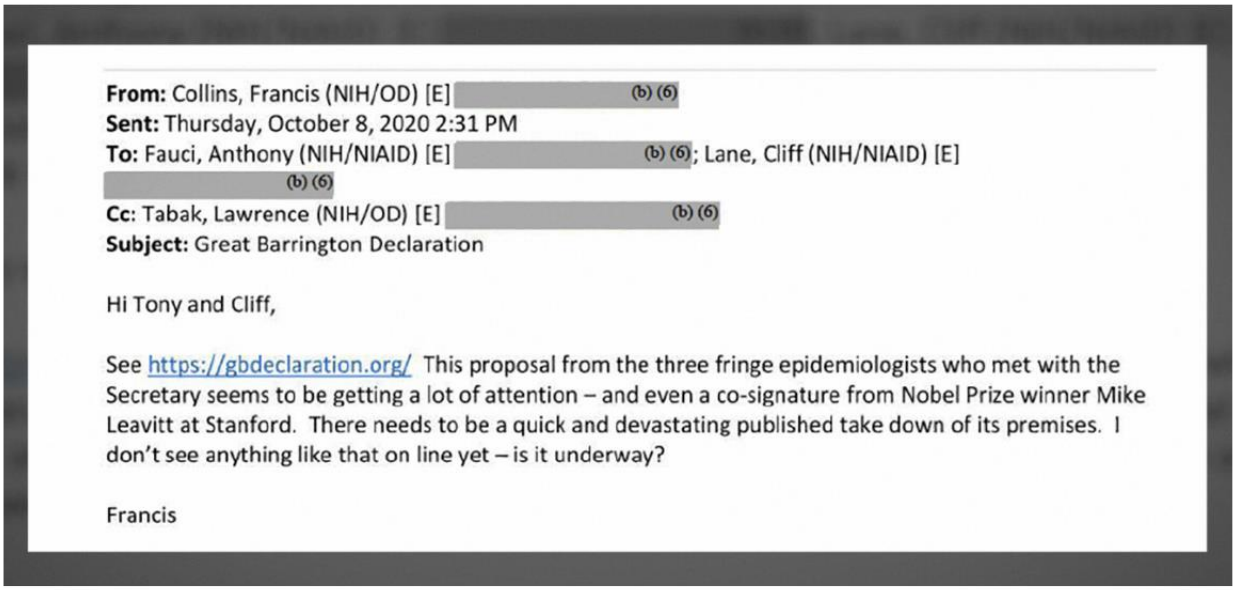
The response from the federal government to the needs of the vaccine-injured has been abysmal. Despite submission of 850 case reports and medical-journal articles related to severe adverse vaccine reactions by the advocacy group React-19 to the FDA, there has been little in the way of a meaningful response and virtually no awards have been given to those with vaccine injury [Finley, 2023]. The Federal Countermeasures Injury Compensation program, which was established to compensate citizens for vaccine and other Covid Countermeasure

injuries, has awarded only $36,945 to only 10 of the 9,921 applicants who have claimed an injury or death from the COVID-19 vaccine [CCIP, 2023].

The primary trial used to promote and qualify the Pfizer product resulted in more deaths in the vaccinated group compared to the placebo group. Forensic analysis of this data revealed 21 deaths in the vaccinated group and 17 in the placebo group [Michels, et al, 2023]. It turns out that "79% of relevant deaths were not recorded in time to be included in Pfizer's regulatory paperwork. By not including relevant subject deaths in the case report, Pfizer obscured cardiac adverse event signal, allowing the EUA to proceed unchallenged. [DePaulma, 2023].

"Both Pfizer and the medicine regulators who granted emergency authorization for the COVID-19 injections, knew that suitable animal studies had not been performed to determine the safety of the Pfizer vaccine during pregnancy but then falsely downgraded the risk [from pregnancy category B2 to B1]. They also knew the limited animal studies that had been performed displayed a risk of significant harm to the developing fetus, but they actively chose to remove this information from public documents." "Pregnancy Category B2, which was considered appropriate by the Module 4 evaluator, is given when – "Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage." Whereas Pregnancy Category B1, which was assigned in the publicly available official document, is given when – "Studies in animals have not shown evidence of an increased occurrence of fetal damage. [Expose, May 2022]. See also, Government regulatory documents from Australia (PM-2020-05461-1-2, Australian Government, Department of Health, Therapeutic Goods Administration) that show these products produced rib malformations in fetal rats.

Military grade propaganda combined with efforts to censor opposing viewpoints were hallmarks of the government strategy to promote COVID-19 countermeasures. "CIA analysts were 'bribed to change position on COVID-19 origins as Fauci led an 'orchestrated' efforts to undermine the lab-leak origin theory" [Hannaford, 2023]. When the government proposed "lock down" measures to mitigate the spread of disease, esteemed scientists objected and issued the "Barrington Declaration." In response to this paper Francis Collins (former head NIH) authored the following email:



From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Thursday, October 8, 2020 2:31 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] (b) (6)
Subject: Great Barrington Declaration

Hi Tony and Cliff,

See https://gbdeclaration.org/ This proposal from the three fringe epidemiologists who met with the Secretary seems to be getting a lot of attention – and even a co-signature from Nobel Prize winner Mike Leavitt at Stanford. There needs to be a quick and devastating published take down of its premises. I don't see anything like that on line yet – is it underway?

Francis

"Collins's response to a memo signed by thousands of scientists should not have been to call for an immediate and devastating take down, but to use his pulpit as NIH director to hold a

series of public discussions and dialogues" [Prasad, December 2021]. In January 2022, a study from Johns Hopkins titled "A Literature Review and Meta-Analysis of the Effects of Lockdowns on COVID-19 Mortality" showed "that lockdowns have had little to no public health effects, they have imposed enormous economic and social costs where they have been adopted" [Herby, 2022].

Despite calls for caution, the risks of SARS-CoV-2 vaccination have been minimized or ignored by health organizations and government authorities [Bruno, 2021]. Unfortunately, objections to COVID-19 injections have been similarly discredited and met with an unwillingness by public health officials to critically examine the data, creating un-necessary social and political strife, and leading to the claim that those in disagreement with the governments promotional efforts are anti-science. Legacy and social media agencies, in collaboration with government agencies, have played a leading role in suppressing scientific debate, leading to damaged careers, and a decline in public health and trust (see also [Shir-Raz, et al, 2023]).

VI. Concluding Remarks:

In conclusion:

- For normal children, the legacy variant resulted in zero mortality, and since the Omicron variant is less virulent than either the Alpha or Delta variants, there is very low risk of severe disease and no risk of death for normal children;
- More than 88% of all children have natural immunity, which is better than vaccine immunity, and therefore do not need immunization;
- Studies now show that the COVID-19 products actually increase the risk of both disease acquisition and contagion, with negative efficacy occurring within 4 to 5 months, and 5 times the risk of contagion compared with unvaccinated persons;
- No studies show that vaccination reduces disease transmission, severity, hospitalization, or death in children against the Omicron variant. In addition, it is unlikely that a randomized controlled trial that is sufficiently powered (one million patients enrolled) would show statistical benefit given the extremely low risk of death and severe disease in normal children infected with the Omicron variant;
- These products are not safe and have had fundamental design flaws related to spike protein pathogenicity, mRNA toxicity, and lipid nanoparticle toxicity. More than 1000 studies suggest potential harm from these products [Compilation, 2022];
- Prospective studies now show an alarmingly high incidence of subclinical myocarditis; occurring at a rate of 3.7% in women, 0.8% in men, and 3.5% in teenage boys after receiving the COVID-19 injections;
- There is no longer a COVID-19 emergency state, and as such we should make every effort to investigate the development of classic vaccines that might be safe, as well as therapeutics that have been shown to be effective for those at risk of severe disease-outcomes (which does not include normal children).

- Ironically, even the FDA recognized recently that the Pfizer data do not show efficacy in children against COVID-19, yet the FDA continues for reasons that beggar the mind, to still recommend these injectable products.
- The US is an outlier in its broad recommendation for boosters. Multiple countries (England, Sweeden, Italy, France, Germany, Denmark, Portugal, New Zeeland) recommend against the use of these products except in older or higher risk groups [Prasad, 12/18/2023]. The European CDC, and European Countries do not recommend these products for healthy children [European CDC, 2023].
- Due to faulty manufacturing processes COVID-19 injectable products are contaminated and contain DNA fragments and molecules that increase DNA entry into the cell nucleus, allowing for the expression of foreign genes and increasing cancer risk. In addition, bacterial endotoxin (which can cause toxic shock and death) has been found in these vials.
- Although the pandemic is over, the risk of these products is ongoing. Because they have been enshrined into the pediatrics vaccination schedule, they pose an ongoing risk to children.
- The mRNA technology will serve as a platform for the development of future influenza and other vaccines, creating other venues for mRNA toxicity.
- The 'need' for these injections continues to be pushed relentlessly in advertisements run in the US media (and without any warnings regarding side-effects; warnings that are required of all other therapeutics when advertised).
- Recurrent vaccination with these products will amplify their risk and may create significant immune system suppression, increasing the risk of other infections and cancer.
- The COVID-19 injectable products should not be used for people of any age. This is the current recommendation of the Surgeon General of Florida [Florida Health Department, 2024].

The creation of the SARS-COV-2 virus occurred long before the pandemic [Nature Medicine, [Meanchey, et al, 2015] through gain of function methods funded by the DOD and the NIH. This research enhanced the infectivity and pathogenicity of the virus, using the modified pathogenic spike protein as the payload to be delivered by the remainder of the virus. US Patent Office documents show that in 2016 Moderna applied for both the patent for the nucleotide code that made the virus pandemic ready, as well as a patent for a covid "vaccine' [Martin, 2023]. And so, it would appear that the virus was created for the vaccine!!

Well before vaccination became the dominant strategy for COVID-19, good data were available on the effectiveness of a variety of medical therapeutics and the potential benefits to the immune system of Vitamin D. Vitamin D levels above 50 were associated with lower COVID-19 infection rates [Kaufman, et al, 2020][j] and disease severity (lower ICU admissions) [Angelidi, et al, 2021]. The preventive efficacy of vitamin D has now been shown in a Randomized Clinical Trial (RCT) [Villasis-Keever et al, 2022] and there are multiple RCTs showing efficacy with a variety of repurposed medications. This link **c19early.com** [COVID-19 Treatment, 2023] provides an analysis of more than 3699 studies addressing early treatment. Therapeutic early treatment protocols were published in 2020, but there was suppression of information on COVID-19 treatments [McCullough, 2020], [McCullough, 2021]. Countries that have adopted proactive protocols for treatment with nutrients and ivermectin for example, saw dramatic reduction in COVID-19 deaths, despite low vaccination rates [Junghaans, 2021]. The official stance of Federal agencies in simultaneously telling us how lethal a disease COVID-19 is, while

withdrawing therapies that have no financial profit, but work, speaks to a high level of indifference to human suffering [Weinstein, 2022].

We all have a special obligation to shed light on the truth and protect life. This paper does communicate a point of view, but this point of view is not based on preconceived notions or expert opinion (expert opinion is regarded as the lowest level of scientific evidence). Instead, this paper is heavily cited and includes peer reviewed articles published in scholarly journals by authors that are well published and respected in their fields of study. The nature of scientific inquiry requires open, and thoughtful debate as well as a measure of humility as new data present themselves. If you are convinced these products should be given to children, this paper invites you to show the supporting data. This paper welcomes disagreement and revision and asks that criticism be directed at the methods and analysis of the data presented, and not at the character or motives of the authors promoting either point of view.

Endnotes

a Unfortunately, the debate on COVID-19 vaccines has become far too politicized, relying instead on expert opinion which is considered the lowest level of scientific evidence.

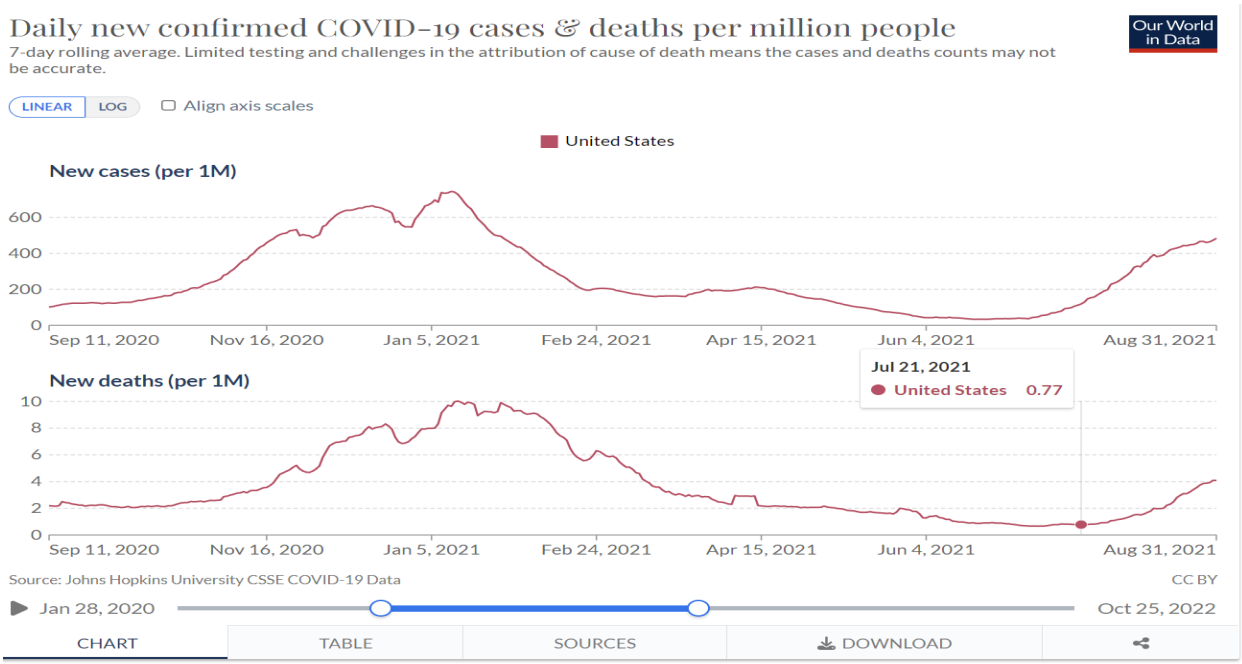
b Examples of live-attenuated are measles, mumps, and rubella (MMR) vaccine, varicella (chickenpox) vaccine; examples of inactivated are polio vaccine, influenza vaccine; subunit vaccines are Hemophilus influenzae type B (Hib) vaccine (conjugate), pneumococcal vaccine (polysaccharide or conjugate), shingles vaccine (recombinant protein), hepatitis B (recombinant protein), acellular pertussis, MenACWY (conjugate); examples of toxoid vaccines are tetanus vaccine, diphtheria vaccine

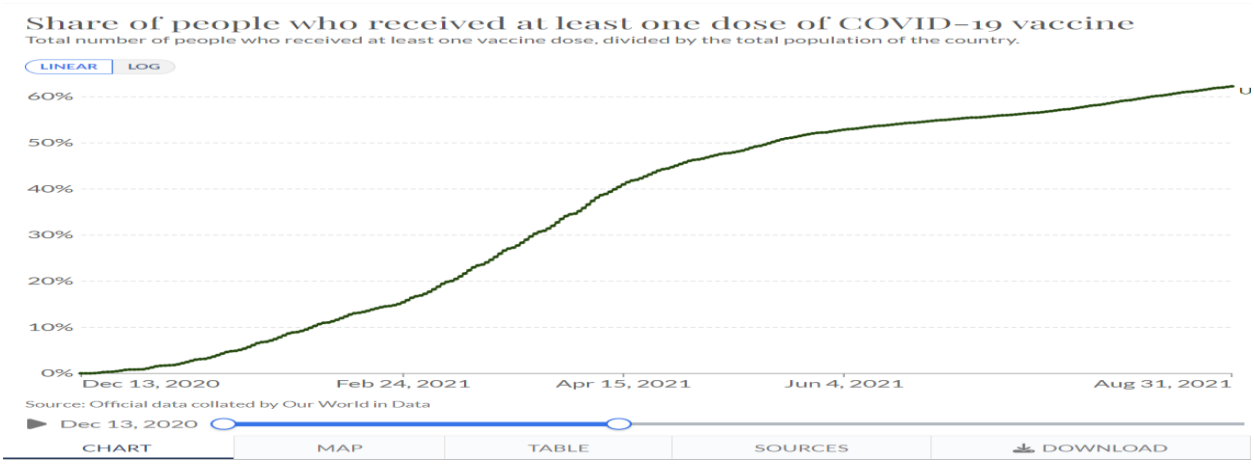
c Natural mRNA is usually made of 4 building blocks, called nucleotides (cytosine, guanine, adenine, and uridine. In contrast the mRNA contained in the vaccine is made with pseudo-uridine. Uridine is the normal biomolecule in the virus's genetic code. Pseudo-uridine is used for synthetic mRNA as it gives it greater resistance to degradation. As a result, the mRNA may remain in the body for months, resulting in extended spike protein production.

d Animals exposed to sarscov2 mRNA technology either died or developed severe autoimmune disease when later exposed to the wild virus.

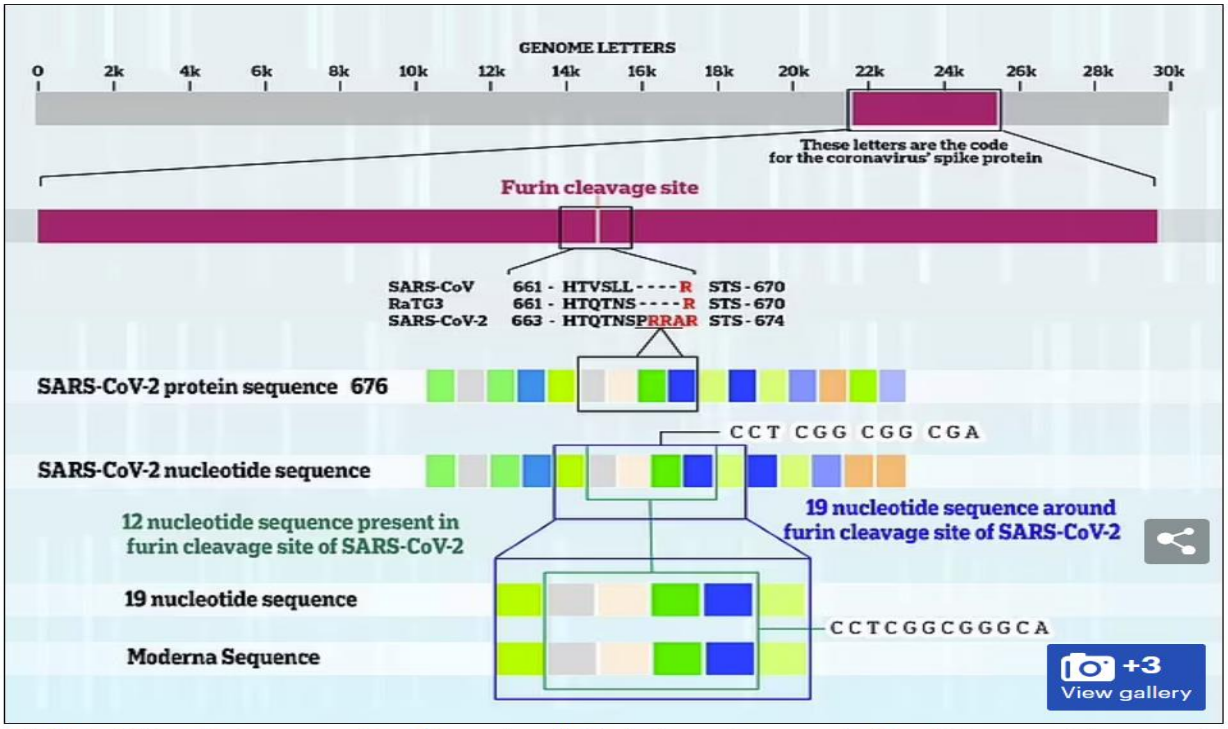
e An endemic virus is one that is consistently present but limited to a particular location. Many respiratory viruses are endemic in our community, including rhinovirus (common cold), RSV (respiratory syncytial virus), and influenza virus.

f These charts were generated from the website "Our World in Data" [Our World in Data, 2022] and show that after January 14, 2021, COVID-19 cases and deaths began to decline, but at that time only 4.32% of Americans had been vaccinated. By February 20, 2021, cases had decreased by 73% with only 5.4% of Americans vaccinated.


Daily new confirmed COVID-19 cases & deaths per million people
7-day rolling average. Limited testing and challenges in the attribution of cause of death means the cases and deaths counts may not be accurate.
Our World in Data
LINEAR
LOG
Align axis scales
United States
New cases (per 1M)
600
400
200
0
Sep 11, 2020
Nov 16, 2020
Jan 5, 2021
Feb 24, 2021
Apr 15, 2021
Jun 4, 2021
Aug 31, 2021
Jul 21, 2021
United States 0.77
New deaths (per 1M)
10
8
6
4
2
0
Source: Johns Hopkins University CSSE COVID-19 Data
CC BY
Jan 28, 2020
Oct 25, 2022
CHART
TABLE
SOURCES
DOWNLOAD


Share of people who received at least one dose of COVID-19 vaccine
Total number of people who received at least one vaccine dose, divided by the total population of the country.
LINEAR
LOG
60%
50%
40%
30%
20%
10%
0%
Dec 13, 2020
Feb 24, 2021
Apr 15, 2021
Jun 4, 2021
Aug 31, 2021
Source: Official data collated by Our World in Data
Dec 13, 2020
CHART
MAP
TABLE
SOURCES
DOWNLOAD

g Showing the sequence of the Sars-Cov-2 genome engineered by Moderna

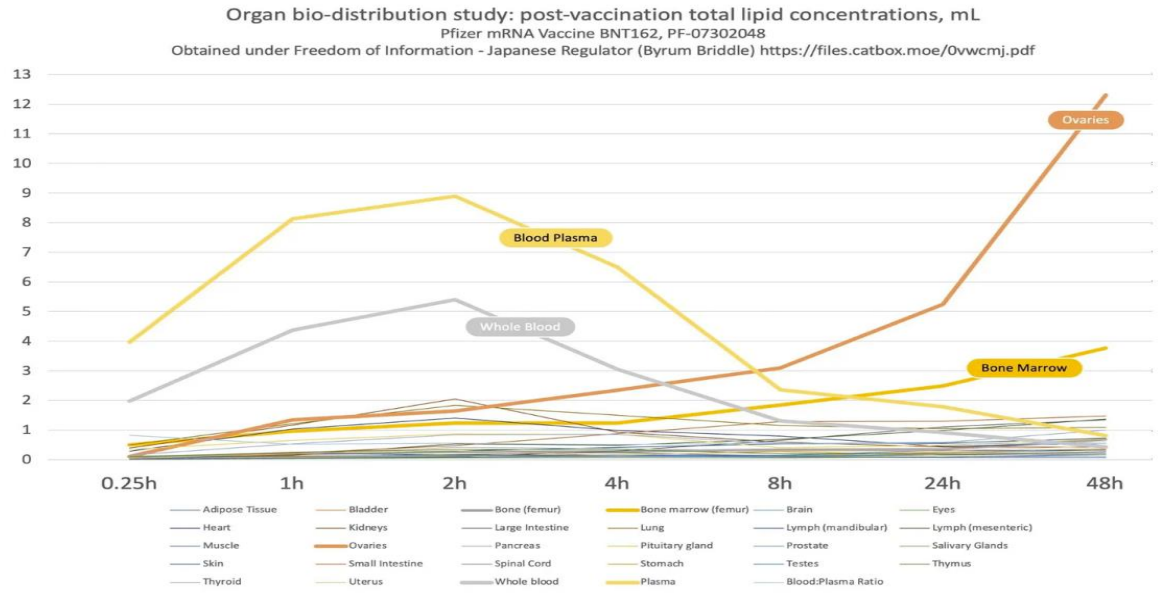


SARS-CoV-2, which causes Covid, carries all the information needed for it to spread in around 30,000 letters of genetic code, known as RNA. The virus shares a sequence of 19 specific letters with a genetic section owned by Moderna. Twelve of the shared letters make up the structure of Covid's furin cleavage site, with the rest being a match with nucleotides on a nearby part of the genome

[Ambati, et al, Frontiers in Virology, Feb 2022]

h “Across 31 systematically identified national seroprevalence studies in the pre-vaccination era, the median infection fatality rate of COVID-19 was estimated to be 0.035% for people aged 0-59 years people and 0.095% for those aged 0-69 years. The median IFR was 0.0003% at 0-19 years, 0.003% at 20-29 years, 0.011% at 30-39 years, 0.035% at 40-49 years, 0.129% at 50-59 years, and 0.501% at 60-69 years. At a global level, pre-vaccination IFR may have been as low as 0.03% and 0.07% for 0-59- and 0–69-year-old people, respectively. These IFR estimates in non-elderly populations are lower than previous calculations had suggested.” [Pezzullo et al, 2022].

i Bio-distribution of Lipid Nano Particles [Syed, 2023][Walters, 2021]



Graphical representation of LNP presence by tissue type and by time up to 48 hours
(in response to https://x.com/arkmedic/status/1398803725272043520?s=20)

j Associaton of Vitamin D levels and COVID-19 Positivity Rate

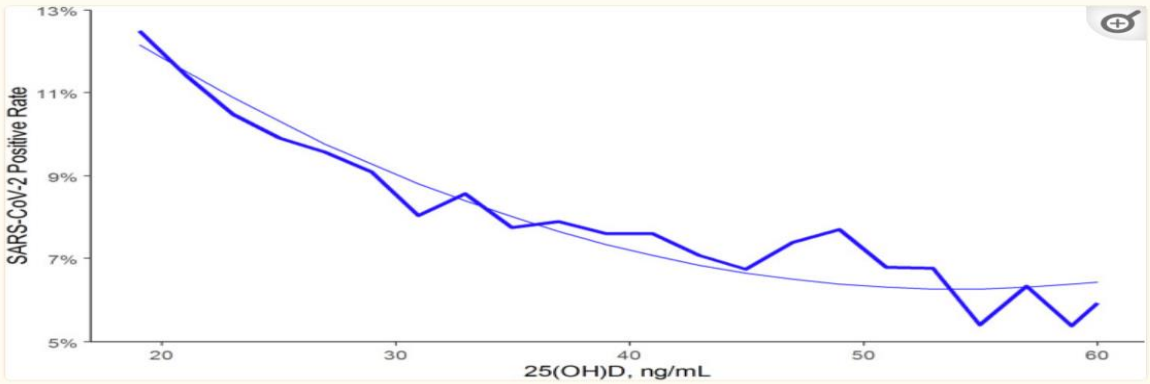


Fig 1

SARS-CoV-2 NAAT positivity rates and circulating 25(OH)D levels in the total population.

Smooth line represents the weighted second order polynomial regression fit to the data associating circulating 25(OH)D levels (x) and SARS-CoV-2 positivity rates (y) where: $y = 0.2029 - 0.0052*x + 4.8e\text{-}05*x^2$; $R^2 = 0.96$. SI conversion factor: 1 ng/mL = 0.400641 nmol/L.

[Kaufman, et al, 2020]