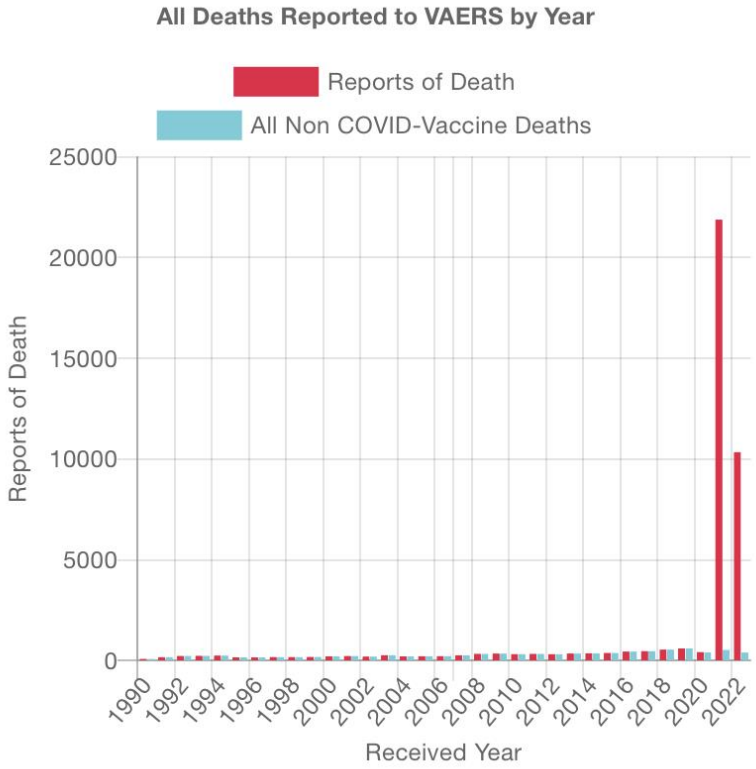
COVID GENETIC VACCINES DO NOT MEET GOOD MANUFACTURING PRACTICE COMPLIANCE (cGMP) GUIDELINES STIPULATED FOR THEIR AUTHORIZED USE RESULTING IN LOT TO LOT VARIABILITY AND MEASURABLE LOT TO LOT VARIATIONS IN ADVERSE EFFECTS AND DEATHS AND THEREFORE MUST BE RECALLED FOR PUBLIC SAFTEY UNTIL COMPLIANCE IS ASSURED

The CDC VAERS Reporting System is Showing Death Numbers from the COVID Genetic Vaccines which are Many Times Above those Seen from Past Vaccine Campaigns

The Vaccine Adverse Event Reporting System (VAERS) was designed to alert the CDC to safety signals in the public from newly released vaccine formulations. In the past, 53 deaths from Gillian Barre Syndrome associated with the Swine Flu vaccine of 1976 and 15 cases of bowel obstruction in infants caused by the RotaShield vaccine, resulted the recall of the vaccines that caused these deaths and adverse effects.[1][2] A rapidly growing body of data indicates that the new COVID genetic vaccines are resulting in severe adverse effects and deaths in numbers that far exceed all other past vaccines **combined** since 1990. As of September 30, 2022, there are over 31,000 deaths suspected of being related to these vaccines that have been reported into the (VAERS) system since the genetic vaccine rollout in December of 2020.[3]

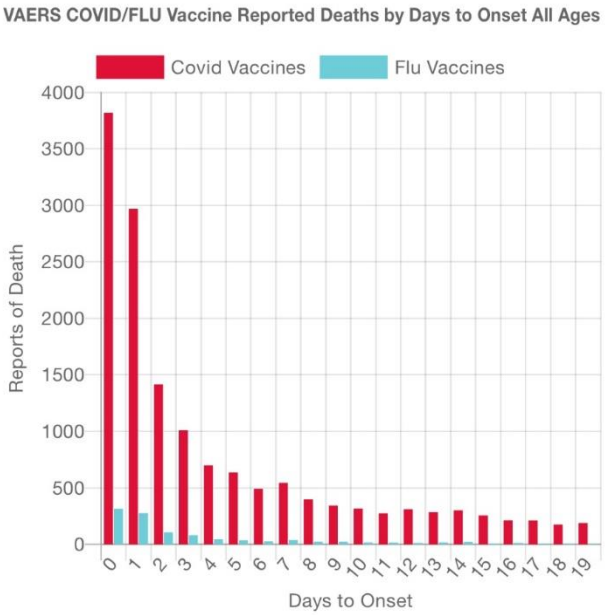


[1] Centers for Disease Control CDC Suspension of rotavirus vaccine after reports of intussusception—United States 1999. MMWR Sep. 3 2004 53(34);786-89 https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5334a3.htm

[2] Reflections on the 1976 Swine Flu Vaccination Program - Volume 12, Number 1—January 2006 - Emerging Infectious Diseases journal – CDC https://wwwnc.cdc.gov/eid/article/12/1/05-1007_article

[3] www.openvaers.com

Roughly 30% of these deaths happened within 3 days of receiving the COVID vaccine establishing the necessary temporal relationship to apply causality.



It is well known and acknowledged by the CDC that the VAERS system is grossly underreported into holding only 1-13% of all AE's estimated to be present. A Harvard study in 2007 reported the following: [4]

"Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."

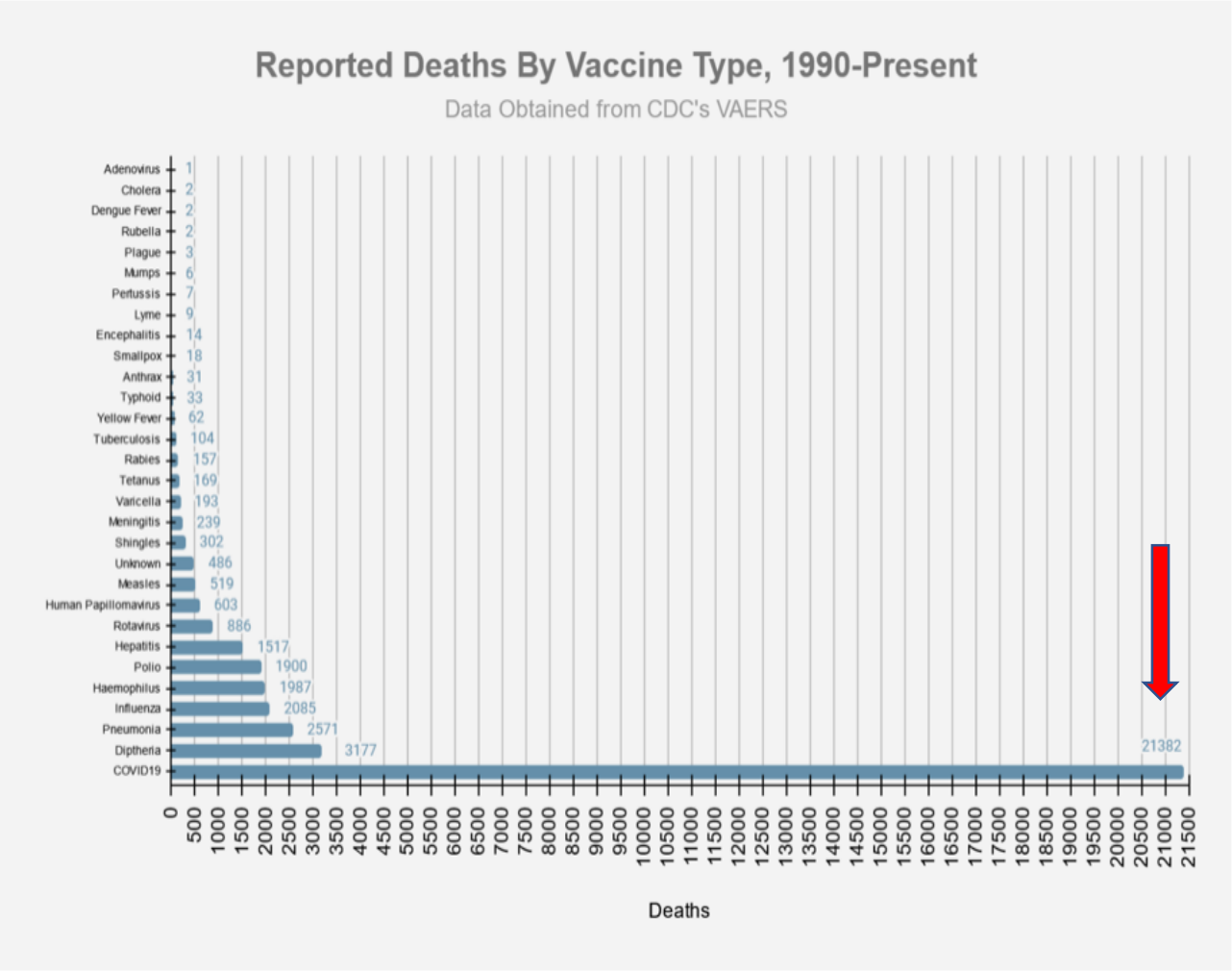
The typical average death reports per year for the past 30 years averaged less than 200 and did not exceed 600 per year for all vaccines combined. Therefore, there is a clear and robust "safety signal" with respect to this new technology, the cause of which, must be addressed.

Safety Signals are Being Ignored

Here is another chart from December 2021, which breaks out the total deaths attributed to each of the other vaccines typically given in the US. If we look at a chart comparing the mortality from these COVID genetic vaccines as compared to all other vaccines used since 1990, it is more than apparent that there is a clear "safety signal" from these COVID vaccines. In the graph below all previous vaccine deaths from 1990 forward for each

[4] Grant Final Report. Grant ID: R18 HS 017045. Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

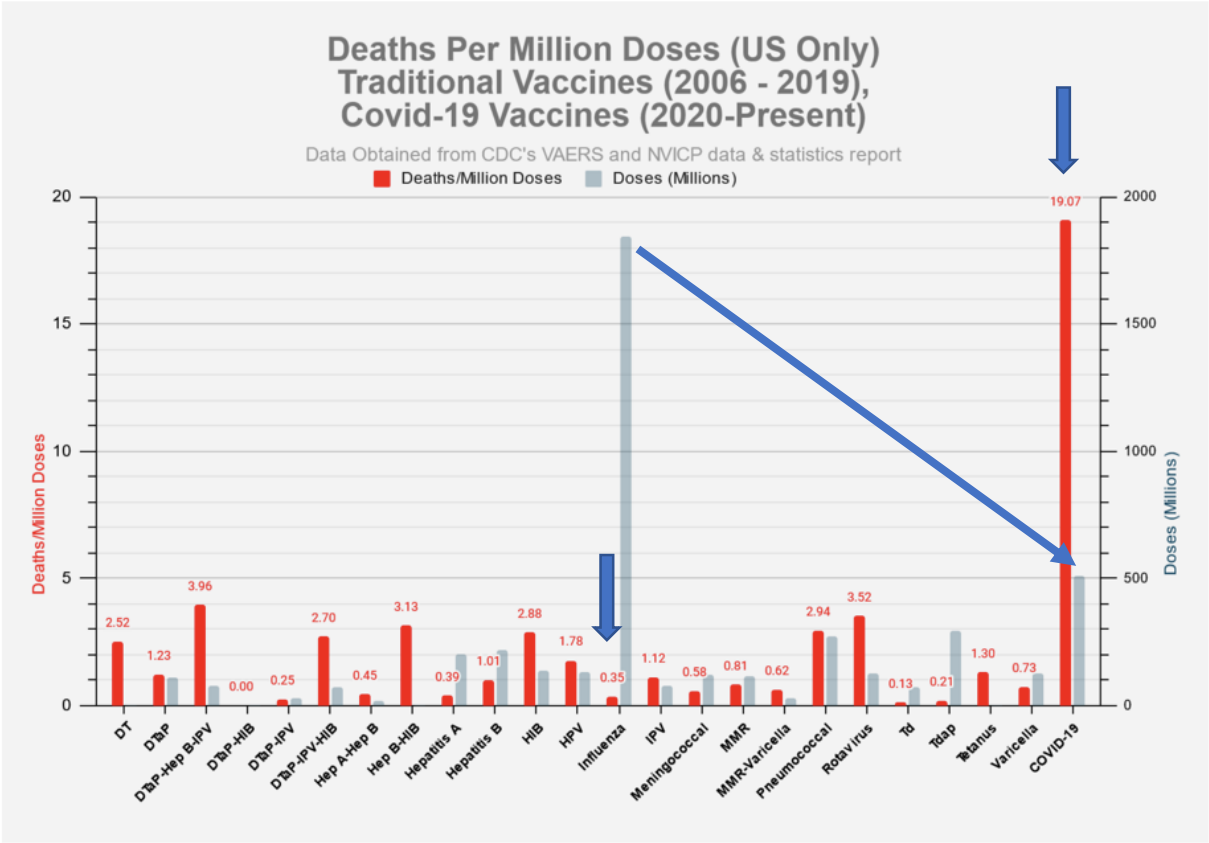
vaccine type cumulatively, are compared to COVID vaccine-related deaths through 12/31/2021.[5]



COVID Vaccine-Related Deaths are not an "Artifact" of the Increase in Vaccine Doses

An argument has been made by some that the increased number of COVID deaths is simply proportional to the amount of dosages given overall and has not exceeded the number of deaths from other well-known vaccine campaigns. This is actually not the case. As can be seen clearly from the graph below, the deaths are solely related to the toxicity of the genetic vaccines and not the number of doses given as compared to all other vaccines in the childhood schedule.[6] Take for example the flu vaccine. All deaths combined from 2006-2019 equaled 0.35 deaths per million doses over 1,800,000,000 doses given, while the COVID vaccine deaths total about 19.07 deaths per million doses for 500,000,000 doses given as of December 2021—a 54 fold or over **a 5,300 % increase**---a clear and resounding "safety signal".

[5] https://vaersanalysis.info/2022/01/07/vaers-summary-for-COVID-19-vaccines-through-12-31-2021/
[6] https://vaersanalysis.info/2022/01/07/vaers-summary-for-COVID-19-vaccines-through-12-31-2021/



There are many theories as to what precisely within the genetic vaccines is causing the huge increase in mortality and morbidity. These include:

- Direct toxicity of the Corona spike protein, encoded by the mRNA (ModeRNA and Pfizer) and Adenoviral vector (J and J) causing clotting and immune dyregulation;
- Direct toxicity of the lipid nanoparticle envelope causing oxidative stress and cell death;
- Direct toxicity of the spike protein inside the nucleus of the cell and potential DNA/spike interactions, as early submissions to the TGA and FDA from Pfizer showed, despite CDC contentions against this
- Retroposition and genomic integration of the genetic message and constitutive expression of the spike protein
- Retroposition and genomic integration and/or frame shift mutations resulting in excess DNA damage and aberrant expression of proteins;
- Toxicity of degraded and truncated mRNA and other contaminants such as bacterial DNA and double stranded RNA which have been noted by the manufacturers themselves and by regulatory agencies;
- Toxicity of undisclosed ingredients/contaminants as have been noted by vaccine vial analyses by laboratories around the globe

These possible causes are all under investigation by various scientific groups around the world but have not yet been openly investigated by our own safety and regulatory agencies nor by the manufacturers themselves. To the contrary, the manufacturers, the

CDC and FDA, while promising to be "completely transparent" prior to the genetic vaccine rollout due to the emergency use authorization and skipped safety trials of the brand new genetic technology, have since argued "trade secrets" and not wanting to induce "vaccine hesitancy" as excuse for not turning over the raw data that informed their assessment of "safe and effective". Shockingly, the FDA asked for these documents to be withheld from the public for 75 years when sued over failure to respond to freedom of information act requests for public documents.[7] Pfizer then asked to intervene in the suit ostensibly to make sure the FDA did not release "trade secrets".[8]

At the heart of it all are questions as to the integrity of the contents in the vials and the fact that the COVID genetic vaccines don't meet cGMP guidelines and have not been forced to do so.

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1. **cGMP Compliance is a Requirement of DOD/BARDA/HHS Contracts for Covid-19 Vaccines:**

Compliance with current Good Manufacturing Practices was a condition of the DOD/BARDA/HHS contracts awarded to the Covid-19 vaccine manufacturers, including Pfizer, Moderna, Emergent Biosolutions, Janssen (J&J), AstraZeneca, Merck, Sanofi, Protein Sciences, Novavax, GlaxoSmithKline, ICON (as a clinical research organization), Inovio, Ology Bioservices, Texas A&M and many others. Numerous references to compliance with cGMP for the vaccine manufacturing are included throughout these contracts, for example:

Pfizer's DOD-ATI Technical Direction Letter (July 21, 2020), p. 9 states that **"Consistent with the Government's objectives under Operation Warp Speed, Pfizer intends to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act (to the extent required for COVID-19 medical countermeasures, as defined by relevant FDA guidance), to manufacture and deliver vaccine."** On p.10, Section 2.0 "Applicable References" specifies **"Current Good Manufacturing Procedures, 21 CFR 210 and 211"** and no other regulations or references. On p.14, under Deliverable 4.18 Pfizer is obligated to **"describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code ("U.S.C." §351 (a) (2)(B)) regarding good manufacturing practices ("GMP").** This deliverable is specified as not being paid for by the Government contract

[7] https://www.brightworkresearch.com/if-the-covid-vaccines-are-safe-why-did-the-fda-and-drug-companies-ask-for-75-years-to-produce-documents-on-them/

[8] https://www.reuters.com/legal/government/pfizer-pushes-intervene-lawsuit-seeking-covid-vaccine-information-fda-2022-01-26

(in Section 1.1.2), however, it is a condition assumed to be implemented for the manufacturing of the doses shipped (and therefore paid for by the Government).

Lot consistency was specified as a deliverable under Moderna's contract with the US Government (Contract No. 75A50120C00034 Development of mRNA Vaccine for SARS-CoV-2), WBS 1.4.3.2.

The BARDA contract with Protein Sciences Corporation (a Sanofi company) in Section B.2, Contract Line Item Numbers (CLINs) and Pricing lists (p.3) lists deliverables **as "cGMP Vaccine Master and Working Seed Lot(s), cGMP Vaccine Investigational Lot(s), cGMP Vaccine Commercial Scale Bulk Lot(s)"**.

Protein Sciences Corporation was tasked by the HHS with production of the "virus bank" and therefore enabling the entire vaccine manufacturing supply chain: **"As part of HHS preparedness and response activities, HHS has requested PSC to submit a Proposal to produce a Working Virus Bank derived from 2019-CoV and a Vaccine Research Lot in preparation for possible CoV vaccine production".** Further: "BARDA Requirement HHS requires: **"Working Virus Bank (WVB) for 2019 Novel Corona Virus {COVID-19), under CUN 1801A, cGMP Vaccine Master and Working Seed Lot Vaccine Research Lot(s)"**

2. Evidence of Ongoing Non-Compliance with cGMP and Possible Product Adulteration:

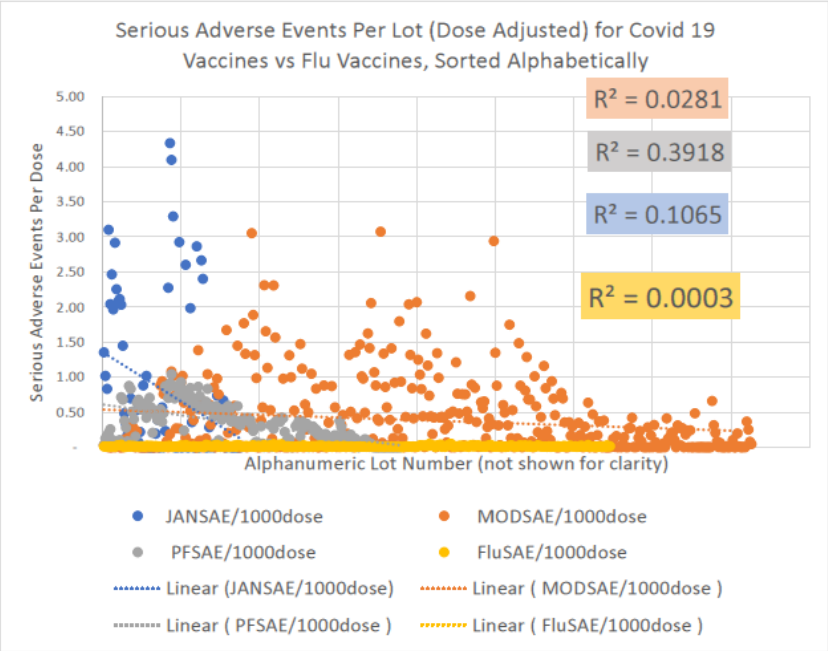
The manufacturers of mRNA/DNA products have scaled up and scaled out at an unprecedented speed, and the quality of the product coming out of these plants has been plagued with problems. There is no evidence today that the manufacturers are following the current Good Manufacturing Practices as they are required by law. There are numerous examples throughout the industry demonstrating lack of cGMP compliance from big pharmas and their suppliers and contractors.

Excessive Batch Variability:

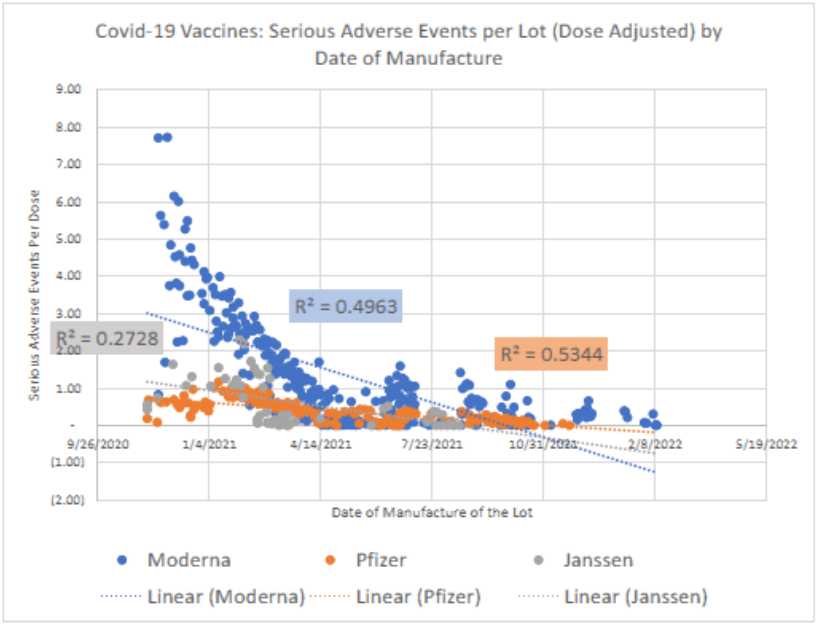
There is an excessive variation in the rates of adverse events and deaths observed post-vaccination for different manufacturing batches based on VAERS data (the only public database that tracks both adverse events and vaccine batches associated with them. This variation far exceeds expected batch-to-batch variations for regulated approved pharmaceutical products manufactured in compliance with cGMP, such as for example seasonal flu vaccines. This has been observed for Pfizer, Moderna and Janssen vaccines.

An excessive lot-to-lot variation in Serious Adverse Events and Deaths per manufacturing lot (adjusted per 1000 doses) for COVID-19 vaccines compared to seasonal flu vaccines puts in question whether the manufacturing process for COVID 19 vaccines conforms to the Current Good Manufacturing Practice (CGMP) requirements. It is expected that a product manufactured in compliance with Good Manufacturing practices will look approximately like the flu vaccine data on this graph below: all manufacturing lots (dark-yellow dots) look approximately the same and all would be very close to zero. In contrast, the COVID19 vaccine per lot data exhibit extreme variability in both the range of adverse

events and lot-to-lot differences. This data pattern is inconsistent with a product in compliance with Current Good Manufacturing Practice (CGMP) requirements.



There is an even stronger statistical relationship between all COVID-19 vaccine lot numbers and the date of manufacture of these lots. This relationship should not exist. See the chart below:



The R^2 values from linear regression models for each date of manufacture for a lot number vs rates of adverse events are as follows: Moderna $R^2 = 0.5$, Pfizer $R^2 = 0.5$, Janssen $R^2 = 0.3$.

The regression analysis as well as visual examination of the data show that the lots manufactured later in the time series are substantially less toxic than the earlier ones.

For a full review of the lot variability data please see following analyses:

https://www.trialsitenews.com/a/hot-lots-of-covid-19-vaccines-evidence-of-different-formulations-5bcedabb

https://www.trialsitenews.com/a/pfizer-vaccine-lot-sizes-do-not-explain-the-abnormal-lot-to-lot-variability-in-adverse-events-and-deaths-32e126eb

https://www.trialsitenews.com/a/broken-bioweapon-is-safer.-815e591b

https://www.trialsitenews.com/a/dying-fast-and-slow-part-2.-patterns-of-immediate-and-delayed-mortality-after-covid-19-vaccinations-across-the-united-states.-1f26b093

Well-Documented Non-Compliance with cGMP

There were no FDA physical audits of manufacturing facilities conducted in 2020, and this no Pre-Authorization Audits happened before the product was mass shipped world-wide. In 2021 the physical inspections restarted and the regulators (FDA and EMA) repeatedly found mRNA/DNA vaccine manufacturers and their subcontractors non-compliant with cGMP. FDA found vaccine manufacturing contractors (Emergent Biosolutions and Catalent) non-compliant with cGMP.

Lack of cGMP compliance noted by the regulators for one vendor renders the entire product supply going through that plant non-cGMP compliant. Without proper adherence to these requirements nobody can be assured that the final dose injected into a person contains specific ingredients in specific amounts stated on the approved labels and does not contain large extraneous impurities.

Form 483 issued in an FDA audit means that the site is not cGMP compliant and had not been prior to that date. Lack of cGMP compliance means the products are open to accidental or intentional adulteration. Some examples illustrate this issue below:

Catalent (Bloomington, Indiana), a fill-finish contractor to Moderna received a non-compliance warning from the FDA.[9] The Form 483 issued after the inspection is shocking and demonstrates many quality and safety violations of cGMP. Violations uncovered in the FDA audit are deep rooted and in "pre mRNA revolution" times would normally lead to the site closure while remediation activities take place. Specifically, the audit findings at the plant included the following Major Observation: **"OBSERVATION 1: Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed."**

Pfizer's lack of sGMP compliance was noted as a Major Objection #1 by the European Medicines Agency in November 2020. At the end of November 2020, approximately 33 batches accounting for 25 million doses of Pfizer product had been already manufactured (out of cGMP compliance). These doses (batches) were shipped commercially and to

[9] https://www.fiercepharma.com/manufacturing/fda-cites-catalent-issues-indiana-plant-which-caused-delay-moderna-booster

date are associated with approximately 40,000 injuries and 1000+ deaths as reported by VAERS (under-reporting in VAERS historically ranges from 10x to 100x).

Additionally, "Rentschler slapped with FDA Form 483 citing lax manufacturing procedures".[10]

This is the Form 483: https://www.fda.gov/media/159164/download.
Rentschler Biopharma SE is the plant that produces the key ingredient in Pfizer's product – mRNA molecule which is the active substance of BNT162b2 or COMIRNATY®.

Emergent Biosolutions, which was responsible for manufacturing both DNA vaccines – AstraZeneca and Janssen, was warned for conflating two different vaccine products. [11,12] FDA inspectors noted that Emergent did not thoroughly investigate several unexplained discrepancies, including cross-contamination of a viral vaccine drug substance batch. Form 483 issued to Emergent revealed numerous violations of cGMP regulations as well as basic sanitary norms.

Lack of Pre-Approval Inspections (PAIs) and Inspections for licensing of GMP Compliance – it was always unheard of for FDA for forego PAIs on all Drug Substance and Drug Product manufacturers prior to approval. Only distance (virtual) inspections have taken place and these are next to useless compared with a physical PAI. Manufacturers must be held to PAIs on the contract manufacturers. These include:

- Lonza and Catalent (Moderna)
- Wyeth BioPharma, Andover, US; BioNTech Manufactuing Mainz, Germany; and Rentschler, Laupeim, Germany; Pfizer Manufacturing, Puurs, Belgium
- Oxford Biomedica and Wockhardt (AstraZenneca)
- (not sure on Jannsen, but they seem to have drifted away)

Lack of FDA Inspection Report and Inspection History for these Genetic Vaccine Manufacturers

The individual formulations should already have been inspected during manufacture of the actual genetic product, and have that added to their GMP license before releasing anything for sale. Here are a few Inside Pharma Substacks that speak to the issues:

a. The SARS-CoV-2 injections require cold chain logistics—not something to be taken lightly
b. The neglected child in vax safety, now long forgotten—chemistry, manufacturing & controls.

[10] https://www.fiercepharma.com/manufacturing/rentschler-slapped-form-483-citing-lax-manufacturing-procedures.

[11] https://www.politico.com/newsletters/prescription-pulse/2022/08/16/emergent-biosolutions-discloses-fda-warning-letter-00051961

[12] https://www.politico.com/newsletters/prescription-pulse/2022/08/16/emergent-biosolutions-discloses-fda-warning-letter-00051961

Lack of Unit Dose Serialization – No Traceability:

Serialization is a mandatory requirement in the pharmaceutical industry. It was introduced in order to protect against counterfeit or other misbranded products entering the legitimate supply chain.[13]

"***The precondition for protection against counterfeit medicines is to produce a barcode (2d data matrix) that gives all production data (GTIN [Global Trade Item Number], expiration date, lot number) for one unit medicine. This distinctive marking ensures the authenticity and integrity of the medicine so that the manufacturer ensures that all the medicines are protected from intervention."***

The manufacturer must apply a 2D barcode to every unit of finished product produced and upload their manufacturing information to a central database. As the product moves through the distribution to patients, the barcode can be scanned and checked for authenticity.For Covid-19 vaccines, the product is not serialized (not barcoded and thus not traceable) at the unit-dose level and therefore open to both adulteration and falsification. The product comes unfinished. The contents of the vials are cut by hand into multiple doses by untrained and unsupervised vaccinators who are working outside of the Good Manufacturing Practice compliance while performing the final step of manufacturing – unit dose preparation. Specifically, Pfizer stated in the European Union purchasing contracts that the product will not be serialized.

An article which speaks to this is the following substack:
Pfizer refused to serialize its SARS-CoV-2 injections, even though it was a legal requirement

Lack of Unit Dose Testing for Conformity to Approved Label:

No quality/conformance/purity tests exist at the vial or unit dose level - this is a violation of cGMP: Product as dispensed to patients (unit dose) must conform to the label of the product. Pfizer label says each vial must contain 225 mcg of BNT162b2 and each prepared dose must contain 30 mcg, but there are no tests that verify this anywhere in the workflow. This is the same for all manufacturers. Vials are only tested for filled weight and visually inspected for any visible impurities or particles.

To date, no vial- or dose-levels for testing product conformity to the label have been specified: CMC documentation leaked from the EMA for Pfizer specifies only batch level testing (bulk product in upstream manufacturing). Recently, EMA confirmed this in an email correspondence with a TrialSite News journalist, stating that batches are tested (but providing no language describing vial or dose level testing for conformity with label, purity, consistency and other parameters at the unit dispensed level).

[13] https://www.drugtrackandtrace.com/serialization-in-pharmaceutical-industry/

Lack of Temperature Excursion Monitoring Resulting in Potentially Adulterated/Degraded Product:

These products require storage and transportation under extreme cold temperatures. The manufacturers never explained the scientific reason for extreme cold storage requirements, and highly confusing instructions are provided to vaccination centers requiring up to -130F temperature freezing for longer term storage, allowing normal refrigeration for medium term storage and room temperature conditions for up to 24 hours. These instructions vary by manufacturer[14],[15]. Hundreds of reports of vaccine administration with inappropriate temperature storage conditions have been submitted to VAERS database.

Dangerous Contaminants Found Consistently in Direct Vial Testing by Independent Parties:

The independent research with these products is prohibited by the US Government contracts with vaccinators and by the supply agreements abroad. This conspicuous lack of transparency does not help building public's trust in these products. On the contrary, lack of transparency only increases vaccine "hesitancy" not only for the novel mRNA injections but for the entire category of vaccines. Despite the prohibition by contracts, independent researchers worldwide have been able to obtain and test vials with variety of methods. Numerous impurities and dangerous contaminants have been found in vaccine vials by independent 3rd party analyses worldwide. See examples of findings summarized here: https://www.trialsitenews.com/a/failure-to-scale-covid-19-injection-vials-must-be-independently-tested-for-conformity-to-label.-9a77eba4

All in all, it is clear that there is a compelling argument that these COVID genetic vaccines are causing excess deaths and that these may be related to a failure to adhere to cGMP, resulting in "hot lots" presumably due to degradation and contamination of the vaccine vial contents. Regardless of whether the deaths are in fact related to the cGMP process or other aspects of the genetic vaccines and/or lipid carrier, failure to adhere to cGMP is a cause for recall according to the Emergency Use Authorization Contract pertaining to these products. Therefore, these products must be recalled until this cGMP failure is ameliorated and its potential contribution to the excess deaths is eliminated as a cause.

The American taxpayers who paid to fund these genetic vaccines, deserve products that are truly both safe and effective and legal representatives that help to protect their interests and safety, not protect the interests of the Pharmaceutical companies whom have made billions off these shots yet can't bother to ensure that their products meet basic manufacturing guidelines. Failure to even attempt to adhere to cGMP of these genetic biologics that are going into the bodies of infants, is not acceptable. We are strongly urging that the Attorney General take this case on to force an immediate recall of the genetic vaccines until an independent review of the vial contents as well as an independent review of the safety and efficacy claims regarding these genetic vaccines

[14] https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

[15] https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf

can be performed, as it is clear that our safety and regulatory agencies are not adhering to past safety practices with respect to these novel technologies and have clear conflicts of interests with the very companies they are tasked to regulate.

Sincerely,

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