December 18, 2022

EXHIBIT 1

Evidence of cGMP/cGxP Non-Compliance in Manufacture and Distribution of the Biological Materials Marketed as "Covid-19 Vaccines."

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Executive Summary:

- **The fundamental reasons for pharmaceutical industry regulations include the assurance of product safety, purity, potency, traceability, consistency, and precise labeling.**
- **A substantial body of evidence exists demonstrating lack of cGMP compliance for Covid-19 vaccines. Lack of cGMP compliance means that no assurances can be made by the manufacturers or the regulators that the products contain specific ingredients in specific amounts in the units dispensed to the patients (dose units).**
- **Therefore, neither the manufacturers nor the regulators can verify that the ingredients in vaccine doses as dispensed are present in the quantities specified.**
- **It is possible that large percentage of the US population received sham covid vaccinations, or doses that were lacking key ingredients, and equally possible that a very large number of people were injured by overdoses and/or dangerous process-related contaminants in these shots.**
- **Use of Emergency Use Authorization, "covered countermeasures" under Public Health Emergencies cannot constitute a clinical investigation, therefore these countermeasures could not be tested for safety and efficacy in accordance with US law (21 CFR 312 and 21 CFR 601), nor could compliance with current Good Manufacturing Practices (cGMP) or Good Distribution Practices (GxP in general) be enforced by the Food and Drug Administration (FDA).**
- **This legal fact was known to high-level FDA officials, to officials working within the US Department of Defense and Biomedical Advanced Research and Development Authority (BARDA) and to the pharmaceutical companies signing these contracts.**
- **This fact was not known to the public, clinical investigators, clinical trial subjects, as well as most of the lower-level employees of the pharmaceutical companies and the US Government.**

Pharmaceutical Industry Regulations – Background

The reasons behind the pharmaceutical industry regulations include the assurance of product safety, purity, potency, traceability, consistency, and precise labeling.[1]

Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law a quarter-century in the making that prohibited interstate commerce in adulterated and misbranded food and drugs.

Numerous food and drug bills preceded the formation of the FDA. The Biologics Control Act was passed in 1902 to ensure purity and safety of serums, vaccines, and similar products used to prevent or treat diseases in humans. In 1912 Mrs. Winslow's Soothing Syrup for teething and colicky babies, unlabeled yet laced with morphine, killed many infants. In 1913, the Gould Amendment required that food package contents be "plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count."

[1] Information in this section is copied from the FDA website.

In 1924 in *U.S. v. 95 Barrels Alleged Apple Cider Vinegar*, the Supreme Court ruled that the Food and Drugs Act condemns every statement, design, or device on a product's label that may mislead or deceive, even if technically true.

In 1937, Elixir of Sulfanilamide, containing the poisonous solvent diethylene glycol, killed 107 people, many of whom were children, dramatizing the need to establish drug safety before marketing and to enact the pending food and drug law.

The Federal Food, Drug, and Cosmetic (FDC) Act of 1938 passed by Congress, included new provisions:

- Requiring new drugs to be shown safe before marketing, starting a new system of drug regulation.
- Eliminating the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases.
- Authorizing factory inspections.
- Adding the remedy of court injunctions to the previous penalties of seizures and prosecutions.

A consumer or a healthcare provider usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work, and therefore safety testing and assurance processes are needed.

Adherence to the current Good Manufacturing Practices (cGMP) regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems; obtaining appropriate quality raw materials; establishing robust operating procedures; detecting and investigating product quality deviations; and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

While cGMPs require testing, testing alone is not adequate to ensure quality. In most instances testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used for patients rather than destroyed by testing. Therefore, it is important that drugs are manufactured under conditions and practices required by the cGMP regulations to assure that quality is built into the design and manufacturing process at every step. Facilities that are in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes that are reliable and reproducible, are a few examples of how cGMP requirements help to assure the safety and efficacy of drug products.

If a company is not complying with cGMP regulations, any drug it makes is considered “adulterated” under the law. The majority of product recalls are voluntary by the manufacturers; however, the FDA has power to enforce cGMP compliance and force recalls, product seizure and a variety of other regulatory actions to ensure compliance.

Evidence of noncompliance with cGMP for Covid "Vaccines"

A substantial body of evidence exists demonstrating lack of cGMP compliance for Covid-19 vaccine countermeasures.

Evidence of mass deaths and injury worldwide[2]

Since the mass deployment of the Covid-19 vaccine countermeasures began in early 2021, unprecedented increases in the adverse events and deaths have been recorded by various passive reporting systems[3],[4],[5]. Astonishingly high reports of the adverse events and deaths from the pharmaceutical companies' own pharmacovigilance[6] systems have become available through the US Freedom of Information Act (FOIA). Autopsy findings[7] in vaccinated post-mortem have demonstrated the mechanisms of mRNA technology damage in histopathologic evaluations.

On the other hand, many who have received the injections report no adverse effects.

This unprecedented variability of outcomes in what is supposed to be a tightly controlled, predictable pharmaceutical product is a clear indicator of lack of formulation control.

Direct evidence of non-compliance with cGMP

Evidence includes the European Medicines Agency (EMA) "rolling review" of Pfizer's Chemistry and Manufacturing Controls (CMC) documentation.[8] The discussions around this issue are recorded in numerous documents that were leaked from EMA[9] at the end of November 2020, including email exchanges between EMA staff and management. Authenticity of the documents and emails was independently verified by the British Medical Journal.[10]

The EMA reviewers noted lack of cGMP compliance as "Major Objection #1," in addition to more than 100 additional Major Objections and Critical Observations.

Further direct evidence includes Forms 483 issued by the FDA to Catalent and Rentschler – key contract manufacturers for Moderna and Pfizer, respectively in 2021 and 2022[11]. The audit findings include numerous severe violations of cGMP practices as well as basic security and

[2] See "Evidence of harm from countermeasures" in Attachment folder
[3] https://openvaers.com/
[4] https://vaersanalysis.info/
[5] https://icandecide.org/v-safe-data/
[6] https://github.com/ndconline/Pfizer-document/blob/main/5.3.6-postmarketing-experience.pdf
[7] https://pathologie-konferenz.de/en/
[8] See "COVID-19 mRNA Vaccine BioNTec24" in Regulatory Review Documents folder in Attachment folder
[9] See EMA Leaked emails in Attachment folder
[10] https://www.bmj.com/content/372/bmj.n627
[11] See "FDA audit forms 483" in Attachment folder

sanitation norms. Finding a key supplier along the manufacturing chain to be non-compliant, renders the entire product volume that went through that chain non-compliant.

Evidence from independent worldwide testing of substances in the vials of Covid-19 "Vaccines"

Despite the prohibition[12] of any independent vial testing (highly unusual for an FDA-approved product in interstate commerce and internationally), covert random testing of the mRNA vials has been ongoing worldwide. Thousands of vials have been obtained and tested by dozens of research groups working independently of each other. The quality of these studies varies and depends on the conditions of the samples acquired, access to the lab equipment and the experience of the investigators.

However, of all the vials tested to date, not one has been found to be in full conformance to the manufacturer's label. An extensive review[13] of these independent testing efforts has been peer reviewed and published recently. Another high-quality report summarizes experiences testing vials from various manufacturers in Germany.[14] These studies use different techniques ranging from optical to electron microscopy, spectroscopy, as well as isolation of genetic and protein components and in some cases sequencing of the RNA.

Some vials contain RNA as well as high concentrations of DNA and protein impurities in quantities far exceeding allowed limits specified by the manufacturer.[15] When RNA was sequenced, the sequences did not fully match the specified BNT162b2 sequence,[16] and a large quantity of RNA fragments was found. In other instances, vials have been found apparently without[17] RNA or DNA in them (evidently absent nitrogen and phosphorus). These results could depend on the methods used and more thorough testing may be needed.

Nevertheless, it was possible to confirm that the apparent "blank" vials from at least one researcher came from batches of Pfizer and Moderna that had almost no adverse events reports in the US Vaccine Adverse Event Reporting System (VAERS): two batch numbers had one report each and one batch number had no reports. This should be contrasted with some batch numbers of Pfizer and Moderna products associated with more than 5000 adverse event reports in VAERS, and an average of ~1,500 adverse event reports including ~700 serious reports and deaths across all CDC-verified batch numbers.

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[12] In the US the vials are the US Government property until the product is injected and any independent access to vials is prohibited by the CDC contracts with vaccination centers. Outside of the US, it is prohibited to test vials for conformity of the ingredients by the vaccine purchase contracts.
[13] https://www.ijvtpr.com/index.php/IJVTPR/article/view/52/83
[14] https://www.documentcloud.org/documents/22140176-report-from-working-group-of-vaccine-analysis-in-germany
[15] DNA impurity was found in quantities 1000x higher than acceptable threshold. See "2021-Nov Analyse 2_Neu" in Attachment folder.
[16] See "Dr. Schmidt-Kruger summary" document and "alignment biontech" spreadsheet in Attachment folder.
[17] https://stevekirsch.substack.com/p/want-to-know-whats-inside-the-vaccine

Almost all vials examined contain high contamination levels of various metals and chemical elements that are toxic to human body. Examples include cesium, potassium, calcium, barium, cobalt, iron, chromium, titanium, cerium, gadolinium, aluminum, silicon, sulfur, thulium, antimony (Moderna). This finding is consistent across all groups and methodologies, and therefore should be deemed more conclusive. There is no explanation of the origin or purpose of these materials according to the known manufacturing processes.

Additional findings include various forms of carbon, including, potentially graphene oxide which is a known toxin. Finally, almost all vials examined contain a variety nano- and micro-particulate contaminants – another conclusive finding with plenty of photo and video documentation. These appear consistently under optical microscope examinations as large shapes and structures of various sizes and include characteristic ribbons, fibers, and crystals. Several published reports by qualified and credentialed microscopy experts have excluded the possibility of environmental dirt on the microscope slides. Sometimes a process of movement and what can be described as "self-assembly" is visible and has been documented in a single take video. The researchers also take steps to maintain the chain of custody, examine unexpired product and keep the vials frozen per manufacturer's instructions. The sizes of these structures alone are highly problematic due to the blood clotting risk.

33 Commercial Pfizer Batches Manufactured Prior to EUA/CMA Approvals

Pfizer manufactured 33 commercial batches of product before any regulatory authorizations were issued in the US, EU or UK. Despite numerous violations and objections raised in regulatory review as of November 30, 2020, these batches were shipped and deployed commercially in the US on December 13, 2020, and abroad (EU/UK) starting on December 3, 2020. These batches are associated with at least 1,065 deaths in the VAERS database.

Active drug substance was shipped and exported-imported between US and EU, in both directions from Andover MA and BioNTech/Rentschler, Germany plants during the manufacture of these batches between August and November of 2020. It is likely that international import-export regulations have been violated. This requires further investigation.

Records released by the EMA data leak contain some manufacturing and testing details for 33 commercial scale batches made by Pfizer between July and late November 2020, accounting for up to 6 million vials and up to 28.3 million doses. Specifically, these batches were listed in the document titled: "COVID-19 Vaccine (BNT162, PF-07302048) BB-IND 19736 Response to CBER Comments Received on 20 November 2020 Regarding Overall CMC Information."[18] The document is dated November 25, 2020.

[18] See "M1 20 Nov2020 FDA QueryRes19" in Attachment folder

Recent investigation of five of the 33 batches that were shipped to Sweden revealed that these batches were illegally imported due to non-compliance with cGMP and lack of importation compliance.[19]

Of these 33 batches, 26 batches have adverse event reports associated with them in VAERS database. The following number of reports was found around October 2021:

- Total Adverse Event (AE) Reports: 41,193
- Permanent Disability Reports (included in the total AE Reports): 1,614
- Life Threatening conditions Reports (included in the total AE Reports): 747
- Death Reports (included in the total AE Reports): 1,065

The table below provides details about these batches as well as the numbers of adverse events and deaths found in VAERS. It should be noted that since these batches were distributed to many regions, including US, Europe and other locations, parts of the batches or whole batches may have been sent to locations that do not submit adverse event reports to VAERS system.

In addition, VAERS system is known to under-represent the true adverse event rate by 10-100 times.

[19] https://www.epochtimes.se/Allvarliga-fel-i-vaccinproduktion---Lakemedelsverket-blundar-568601

Table 1.

Lot (batch)	# Vials	Drug Substance	Date manuf	LMS	RNA Integr	All AE	Deaths
EE8492	67,665	Pfizer Andover	5-Aug-20		55%	666	2
EE8493	68,445	Pfizer Andover	5-Aug-20		55%	608	2
EG5411	201,258	Pfizer Andover	3-Sep-20			-	-
EH9978	304,869	Pfizer Andover	23-Sep-20			-	-
EJ0553	164,580	Pfizer Andover	25-Sep-20	<QLc	68%	426	15
EJ0701	200,265	Pfizer Andover	26-Sep-20	17%	52%	-	-
EJ0724	39,195	BioNTech/ Rentc	29-Sep-20	<QLc	71%	131	5
EJ1685	159,315	BioNTech/ Rentc	5-Oct-20	9%	66%	2,776	45
EH9899	179,400	Pfizer Andover	7-Oct-20	<QLc	59%	3,470	25
EJ1686	147,615	BioNTech/ Rentc	7-Oct-20	6%	69%	1,696	64
EJ1688	150,345	BioNTech/ Rentc	12-Oct-20	10%	63%	510	31
EK4175	145,275	BioNTech/ Rentc	12-Oct-20	16%	58%	42	7
EK1768	141,960	Pfizer Andover	16-Oct-20	<QLc	60%	880	14
EK4176	131,625	BioNTech/ Rentc	16-Oct-20	10%	65%	1,344	30
EJ1691	133,575	BioNTech/ Rentc	16-Oct-20	24%	51%	-	-
EK2808	48,945	BioNTech/ Rentc	19-Oct-20			-	-
EK5730	191,295	Pfizer Andover	22-Oct-20	10%	62%	3,935	24
EL0141	156,195	BioNTech/ Rentc	29-Oct-20	5%	67%	498	13
EL0142	138,060	BioNTech/ Rentc	29-Oct-20	6%	69%	1,821	45
EL0140	155,610	BioNTech/ Rentc	29-Oct-20	6%	69%	1,865	70
EL0725	272,073	BioNTech/ Rentc	30-Oct-20	9%	63%	925	50
EL0739	294,239	BioNTech/ Rentc	3-Nov-20	6%	67%	1,051	19
EK9231	230,685	Pfizer Andover	4-Nov-20			3,827	51
EL1484	277,608	BioNTech/ Rentc	4-Nov-20			1,488	37
EK4244	*na*	BioNTech/ Rentc	5-Nov-20			606	3
EK4243	*na*	BioNTech/ Rentc	5-Nov-20			589	13
EK4237	140,985	BioNTech/ Rentc	5-Nov-20	9%	64%	125	2
EL1283	245,895	Pfizer Andover	11-Nov-20			2,578	69
EJ6795	282,645	Pfizer Andover	12-Nov-20			1,079	145
EJ6796	293,828	Pfizer Andover	13-Nov-20			1,070	117
EL1284	214,305	Pfizer Andover	17-Nov-20			2,775	47
EJ6797	293,526	Pfizer Andover	17-Nov-20			2,005	73
EL3246	204,360	Pfizer Andover	19-Nov-20			2,407	47
Total vials	**5,675,641**					**41,193**	**1,065**
Doses	**28,378,205**						

Excessive batch variability observed in VAERS database

The batch variability analyses are provided in detail in the Attachment folder.[20]

Overall, Covid-19 vaccines do not exhibit the lot-to-lot conformity and safety expected from approved pharmaceutical products. The variability of outcomes as measured by adverse events and death reports in VAERS database for Covid-19 vaccines is 100 to 1,000 times higher than that for the flu vaccines. Furthermore, the data when examined by lot number, time of manufacture or location of distribution exhibit unusual and alarming clustering patterns which should not exist for a consistently manufactured product under quality control.

There should not be a difference in toxicity of a product depending on when it was made, where it was shipped or how the lot was numbered.

Lot-to-lot consistency and very low variability of outcomes is demonstrated for a conventional vaccine product such as seasonal flu vaccines which are widely distributed in the United States every year. Therefore, Covid-19 vaccines are potentially dangerous, poorly manufactured, and possibly adulterated products.

Factors such as age, co-morbidities and demographics as well as distribution issues can affect variability of the lot-to-lot data. However, as we are comparing these data to the flu vaccines, these factors equally affect these products. Furthermore, if technical novelty of the Covid-19 vaccines precludes their lot-to-lot conformity due to these factors, then they should be removed from the market as products that cannot be distributed and administered safely under real-world conditions.

Supply-demand factors can affect the ultimate size of the manufactured lot as it can be used fully or only partially. These factors exist equally for the flu vaccines, however, the demand for Covid-19 vaccines exhibited very large swings during 2021. There was very large demand in early part of the year with a peak in late April 2021, then a few secondary but much lower peaks occurred in the summer, with substantial decline toward the end of the year. Even so, this pattern did not fully coincide with the observed relative decline in toxicity lot-to-lot for the Covid-19 vaccines for which toxicity per lot was extremely high before March 2021 (not April) and then declined very quickly after. In parallel, the sizes of manufactured lots increased from approximately 1 million doses per lot to 3-4 million doses per lot, and some of the lots were even larger. If the lot-to-lot variation for Covid-19 vaccines ultimately is explained by the lower usage of later manufactured lots, than the true picture is even more alarming.

This would mean the two most likely reasons that later manufactured lots inflicted less relative damage are that:

1. the inherently toxic product was being diluted into larger volumes, and
2. the public began to reject these injections.

[20] See “Batch variability analysis” in Attachment folder

Lack of mRNA integrity and high amount of genetic material impurities

Lack of mRNA integrity, and substantial genetic material impurities (fragmented nucleic acid chains) were found in Pfizer's product at the end of November 2020 - days before it was authorized for market.[21] mRNA integrity, and conversely, its instability, is one of the most important variables relevant to all mRNA vaccines. The efficacy of the product is highly dependent on the quantity of sufficiently intact mRNA molecule which constitutes the active substance (or Drug Substance, DS) in the finished Drug Product (DP). Even a minor degradation anywhere along a mRNA strand, and/or breakage of the mRNA molecule into smaller strands, can severely slow or stop proper translation performance of that strand and thus result in the incomplete expression of the target antigen, and in unpredictable off-target effects with potential consequences to the safety of the product.[22]

At the time of the regulatory review, the integrity of the key active ingredient – mRNA molecules as measured by the percent mRNA integrity (%mRNA integrity) and RNA fragments called Late Migrating Species (LMS) in each manufactured batch is highly and unacceptably variable. The EMA noted that a decrease in RNA integrity, which is a critical quality attribute, was observed such that RNA integrity of Process 1 (78.1-82.8%) used to manufacture clinical trial materials was much higher than the commercial scaled up Process 2 (59.7%).

Furthermore, it was not possible to determine if the differences in RNA integrity were qualitative, quantitative, or both. This was identified by the regulatory reviewers at the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), and the EMA reviewers raised this issue as the "Major Objection #2." The apparent "solution" to this issue negotiated between the EMA reviewers and Pfizer/BioNTech at that time was to lower the acceptance standard for the %mRNA integrity in the active substance for shelf live to just >50%, down from the previously used standard of >70%.[23] In other words, up to 50% of the nucleic acid chains and other genetic material impurities can be present in the active substance, not characterized, not listed on the label, and the product is still deemed "acceptable."

When mRNA degrades due to various factors in manufacturing, it is possible that truncated mRNA may affect translational efficacy or modify the immunostimulatory profile. Even if these truncated mRNA are not translated, they are considered genetic impurities and should be minimized or eliminated as much as possible so that the same amount of intact pure mRNA is present in each batch. Micro-RNAs (miRNA) are known to have interference mechanisms in cellular genetic processes and thus can pose danger of genotoxicity and carcinogenicity on their own.[24]

At the time of the Conditional Marketing Approval in EU it was not known what proteins were coded for, if any, and their clinical effect was unknown. It could not be excluded that proteins

[21] See EMA's "Interim Opinion" document in Attachment, p.21 section "Impurities" in Attachment.
[22] Kirchner B, Paul V, Riedmaier I, Pfaffl MW. mRNA and microRNA purity and integrity: the key to success in expression profiling. Methods Mol Biol. 2014;1160:43-53. doi: 10.1007/978-1-4939-0733-5_5. PMID: 24740220.
[23] See Powerpoint presentation from EMA-Pfizer meeting on Nov 26, 2020 in Attachment.
[24] Gulyaeva, L.F., Kushlinskiy, N.E. Regulatory mechanisms of microRNA expression. *J Transl Med* **14**, 143 (2016). https://doi.org/10.1186/s12967-016-0893-x.

different from the intact full-length spike would be expressed. Furthermore, the Pfizer vaccine-induced spike protein was substantially different by total molecular weight from the Wuhan spike protein (180+kDa vs 141kDa, respectively) and the difference was never properly elucidated.

The lack of characterization of the expressed spike protein by the vaccine was noted as a "severe deficiency" by the EMA reviewers and the proper characterization of the expressed spike protein was included as one of the conditions of the Conditional Market Approval (CMA). However, this condition was never fulfilled by the manufacturer and was abandoned by the regulators in 2022.

As result, an extremely wide variation of the integrity of the active substance in bulk material (batch) of the product and the abundant presence of uncharacterized nucleic acid impurities means that batches of different formulation - and thus different potency and safety profiles - are being produced. This variation is further amplified when a large volume of bulk material is filled in small 0.45 ml vials and subsequently manually divided into doses by untrained and unsupervised staff at the vaccination centers.

To date, neither the regulators nor Pfizer have disclosed the acceptable ranges, testing methods and results for the key ingredients of the vaccine products, for either bulk product nor per-vial product (as dispensed). They have claimed that "commercial secrets" prevent them from doing so.

Each vial of Pfizer product is labelled as containing exactly 225 mcg of mRNA total, and exactly 30 mcg of mRNA per dose. With variation of up to 50% in the mRNA active substance in bulk material, and further additional variation resulting from downstream manufacturing steps, filling, transportation, and manual preparation of the doses, it is not possible to assure that 30 mcg of mRNA will be present in every dose. Thus, many people receiving the vaccination can be receiving no or almost no mRNA, rendering vaccination with this product pointless, while some people may receive dangerously high amounts of mRNA, resulting in injury or even death as over-expression of spike protein would lead to major uncontrollable toxicities[25].

No tests for conformity to label at the unit dose level

Vials and doses of mRNA injections are not routinely tested by the manufacturers for conformity to the list and quantities of the ingredients on the approved product label. The vial-level tests specified by Pfizer in leaked Chemistry Manufacturing and Controls (CMC) documents are the vial weight at filling, manual inspection for large visible particles, and some tests related to integrity such as vial capping.

However, no vial or dose, i.e., "unit-level as dispensed" tests verifying the ingredients are described as routine. How is the public assured that each Pfizer dose contains 30 mcg of mRNA as stated on the label? What level of variability of this key ingredient and other ingredients is

[25] Seneff S, Nigh G, Kyriakopoulos AM, McCullough PA. Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs. Food Chem Toxicol. 2022 Jun;164:113008. doi: 10.1016/j.fct.2022.113008. Epub 2022 Apr 15. PMID: 35436552; PMCID: PMC9012513.

acceptable? The ingredient conformity tests described in the Pfizer CMC package are based on the bulk product batch testing – an upstream manufacturing process step. It is a regulatory requirement to retain samples of each batch produced, and these samples of vials should exist and be available for examination.

Lack of cGMP compliance means that no assurance can be made by the manufacturers or the regulators that the products contain specific ingredients in specific amounts in the units dispensed to the patients (dose units) and does not contain potentially dangerous impurities.

No serialization at the unit dose[26]

The products are not serialized (barcoded) at the unit-dose level as unit doses, and therefore not traceable through validated and regulatory-compliant supply chains. The unit doses – i.e., the final step of manufacturing, are made outside of the quality system and oversight of the manufacturer by untrained and unsupervised people. This makes the product open to falsification and mislabeling.

Product mislabeling attempts have been identified in the United States[27].

Conclusion

Neither the manufacturers nor the regulators can verify that the ingredients in vaccine doses as dispensed are present in the quantities specified. It is possible that a large percentage of the US population received sham vaccinations, or doses that were lacking key ingredients, and it is equally possible that a very large number of people were injured by overdoses and/or dangerous process related contaminants in these shots.

Use of EUA covered countermeasures under Public Health Emergency cannot constitute a clinical investigation (21 USC 360bbb-3(k)).

Therefore, these countermeasures could not be tested for safety and efficacy in accordance with US law (CFR 21), nor could compliance with current Good Manufacturing Practices (cGMP) or Good Distribution Practices (cGxP in general) be enforced by the FDA.

This legal fact was known to high-level FDA officials, to DOD and BARDA officials and to the pharmaceutical companies signing these contracts.

This fact was not known to the American public, clinical investigators, clinical trial subjects, or most of the lower-level employees of the pharmaceutical companies and the US Government.

[26] See "HRees Expert Report Supply Chain cGMP" in Attachment folder
[27] See "Brandon Johnson supplement Cocker v Austin" in Attachment folder