cGMP Fraud by Covid-19 Injection Manufacturers Must Be Stopped and Investigated. Summary of Evidence.

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Opinion Article

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Vaccine and therapeutic manufacturers have benefited greatly during this pandemic operating under near complete immunity from any liability under the Public Readiness and Emergency Preparedness (PREP) Act. Pfizer and Moderna generated historic revenues in just a couple years as the federal government mandated use of their novel mRNA-based vaccine products. Yet how can we be certain the consumer is protected from the rapidly developed medical products known as "Countermeasures" during these emergency conditions? The answer to a great extent: Strict adherence to Current Good Clinical Manufacturing Practices (cGMP). Compliance with cGMP is a Requirement of DOD/BARDA/HHS Contracts for the procurement of Covid-19 Vaccines and therapeutics: Compliance with current Good Manufacturing Practices was, and remains 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 are included throughout the government COVID-19 vaccine procurement contracts establishing the responsibilities. But what if despite heretfore unheard of publically-funded revenues to the vaccine producers—coupled with near universal liability protection-- based on 100% adherence to cGMP--the vaccine production value chain continues to exhibit disturbing examples of deviation from cGMPs? Wouldn't this represent a gross breach of contractual terms. What's the associated accountability? What are the implications for the state health agencies that import these products for distribution and administration to their populations?

Before delving into some examples of cGMP breaches, examples of contracts demonstrate the criticality for adherence to these incredibly important quality standards.

1. 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 (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).

2. 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.
3. BARDA's 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 CoronaVirus {COVID-19), under CUN 1801A, cGMP Vaccine Master and Working Seed Lot Vaccine Research Lot(s)."

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 questionable evidence today that the manufacturers are consistently 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 the participating pharmaceutical companies and their suppliers and contractors, including the following evidence:

Excessive Batch Variability:

An area of concern has been the need for batch consistency, which has been lacking. This author has reported on 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 batch numbers 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 consistently observed for Pfizer, Moderna, and Janssen vaccines. See the following analyses:

- On the issue of "hot lots"
- More about "hot lots" independent of the lot sizes
- Unexplained large differences in mortality across the United States
- Lack of mRNA integrity that was "solved" by lowering acceptance standards and allowing for MORE broken mRNA

Neither the regulators nor the manufacturers have ever explained these glaring issues despite numerous requests for answers from the public and lawmakers.

Documented Manufacturers' Non-Compliance with cGMP:

On more than one occasion regulators found mRNA/DNA vaccine manufacturers and their subcontractors 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—from distributor to provider to consumer -- 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 material extraneous impurities.

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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. A US FDA Form 483 has revealed visible foreign particles in certain batches of drug product at Catalent's Bloomington, Indiana facility. 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 cGMP compliance was noted as a Major Objection #1 by the European Medicines Agency in November 2020. At the end of November 2020, 28 million doses of Pfizer product had been already manufactured (out of cGMP compliance). These doses (batches) were shipped commercially, and to 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". This is the Form 483. Rentschler Biopharma SE is the plant that produces the key ingredient in Pfizer's product – the 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. 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 shocking violations of cGMP regulations as well as basic sanitary norms.

Lack of Unit Dose Serialization – No Traceability:

Covid-19 vaccines are shipped in multi-dose vials. The contents of the vials are cut by hand into multiple doses by what have been reported at least at times untrained and unsupervised vaccinators who are working outside of the Good Manufacturing Practice compliance while performing the final step of manufacturing – unit dose preparation. *TrialSite* recently reported 77 on a mass overdosing of 77 prisoners due in part to this problem [the prisoners lost the lawsuit in Iowa].

This is a glaring violation of cGMP rules. The product is not serialized at the unit dose as dispensed to the patient and thus open to both adulteration and falsification. Serialization at the unit dose level (barcoding of unit

doses) is the only way to ensure traceability and security

throughout the supply chain. See analysis by drug and vaccine manufacturing supply chain expert Hedley Rees

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's label says each vial must contain 225 mcg of BNT162b2, and each prepared dose must contain 30 mcg, but based on this author's research there are no tests that verify this anywhere in the vaccine value chain workflow.

This appears to be the same for all the vaccine and therapeutic manufacturers during COVID-19. Review of Pfizer's Chemistry Manufacturing and Controls (CMC) documents leaked from EMA revealed that the vials are only tested for filled weight and visually inspected for any visible particles. To date, no vial- or dose-levels for testing ingredient conformity to the label have been specified: CMC documentation specifies only batch level testing. Batches are bulk products in upstream manufacturing, and batch tests are not a substitute for the unit dose test.

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

Independent research with these products is prohibited by the US Government contracts with vaccinators and by the

supply agreements abroad. The predatory clauses in Pfizer contracts have been recently subject to the MEP scrutiny by the European Parliament, and an investigation by the Public Prosecutor's office is currently ongoing in EU.

This conspicuous lack of transparency does not help to build the 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 a variety of methods. While no systematic peer reviewed output is available, this author has been able to review the work of dozens of independent investigations. These reports reveal numerous impurities; and in some cases what could be considered dangerous contaminants have been found in vaccine vials by these independent 3rd party analyses. See examples of numerous studies summarized here.

Conclusion

In conclusion, as a pharmaceutical industry professional, I am shocked and deeply disturbed by blatant disregard for established quality control rules, safety norms, and other safeguards we use to rely on as both participants of the industry and consumers of the industry products. Consider the context: an emergency law is triggered where all liability is waved (but for the extremely difficult-

to-prove fraud case) while the contracts between the vaccine producers and consuming nation-states look more

like adhesion contracts—see this media's summary on "Pfizer's Power" thanks to Public Citizen demonstrating a disturbing lack of transparency and other outrageous legal terms during the pandemic.

To date this author has uncovered rampant, disturbing cGMP violations while a worldwide review of product sampling (albeit not organized into peer-reviewed publication) doesn't bode well for quality assurance. Based on these findings to date, this author's vanished trust in these vaccines all but ensure family avoidance of these products-- and no number of threats and coercion from the government will change this position. Likewise, friends and colleagues grow ever more alarmed and equally skeptical of these products. This is reflected by the steep decline in the willingness of the public to get additional doses of these products despite in the aggregate tens of millions spent on advertising, overreaching mandates, and continued fear-mongering by the mainstream press. There is a surging tsunami of public mistrust that a government-pharma-medical industrial complex will have to reckon with in the coming years.