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C-19 Injections: Massive Regulatory and Manufacturing Fraud

Analysis by Tessa Lena | November 22, 2022

STORY AT-A-GLANCE

- Alexandra Latypova is an ex-pharmaceutical industry and biotech executive with a lot of experience in the areas of drug safety and clinical trials
- Early on, she discovered that, based on the number of reported deaths and adverse events per lot, there was unprecedented variability in the toxicity of the product
- According to Alexandra, the mRNA shots do not conform to their label specifications, and "in practice, both 'blank' and 'lethal' vials and anything in between is produced"
- Having analyzed massive amounts of publicly available data, as well as documents that became available as a result of FOIA requests and other sources, she has found strong evidence of manufacturing and regulatory fraud

I recently had the pleasure of interviewing Alexandra Latypova, an ex-pharmaceutical industry and biotech executive, who has been investigating and exposing manufacturing and regulatory fraud related to COVID injections.

We talked about the industry standards that were not adhered to during the clinical trials and the manufacturing of those injections, about the vial content quality testing procedures that had not been put in place, about the "hot batches" and their geographical distribution, about signs of fraud at every stage of testing and manufacturing the product, and about the general condition of living in a world run by a mob.

The latter was the lightest part of our conversation — evoking a lot of dark Eastern European humor — since both of us are Soviet expats, and in 2020, neither of us required a whole lot of imagination to embrace the existential possibility of living in a world run by a mob. We had seen it in the past without a disguise — and when something looks like a duck, walks like a duck, and quacks like a duck, maybe it's just a duck!

Alexandra Latypova's Background

Alexandra grew up in Soviet Ukraine and immigrated to America in the late 1990s. She received her MBA from Dartmouth College and the spent about twenty five years in pharmaceutical industry and biotech (including in the areas of drug safety and clinical trials).

Alexandra has had a very gratifying entrepreneurial career. She has founded a number of successful startups, sold them — all before COVID — and retired, hoping to focus on enjoying her life and especially painting, which she does masterfully.

When 2020 knocked on the door with a whole bag of ugly and weird "new normal" treats, Sasha smelled the rat right away. Initially, she became alarmed by the abnormalities in "COVID response," including the very conspicuous campaign to prevent effective treatment of COVID.

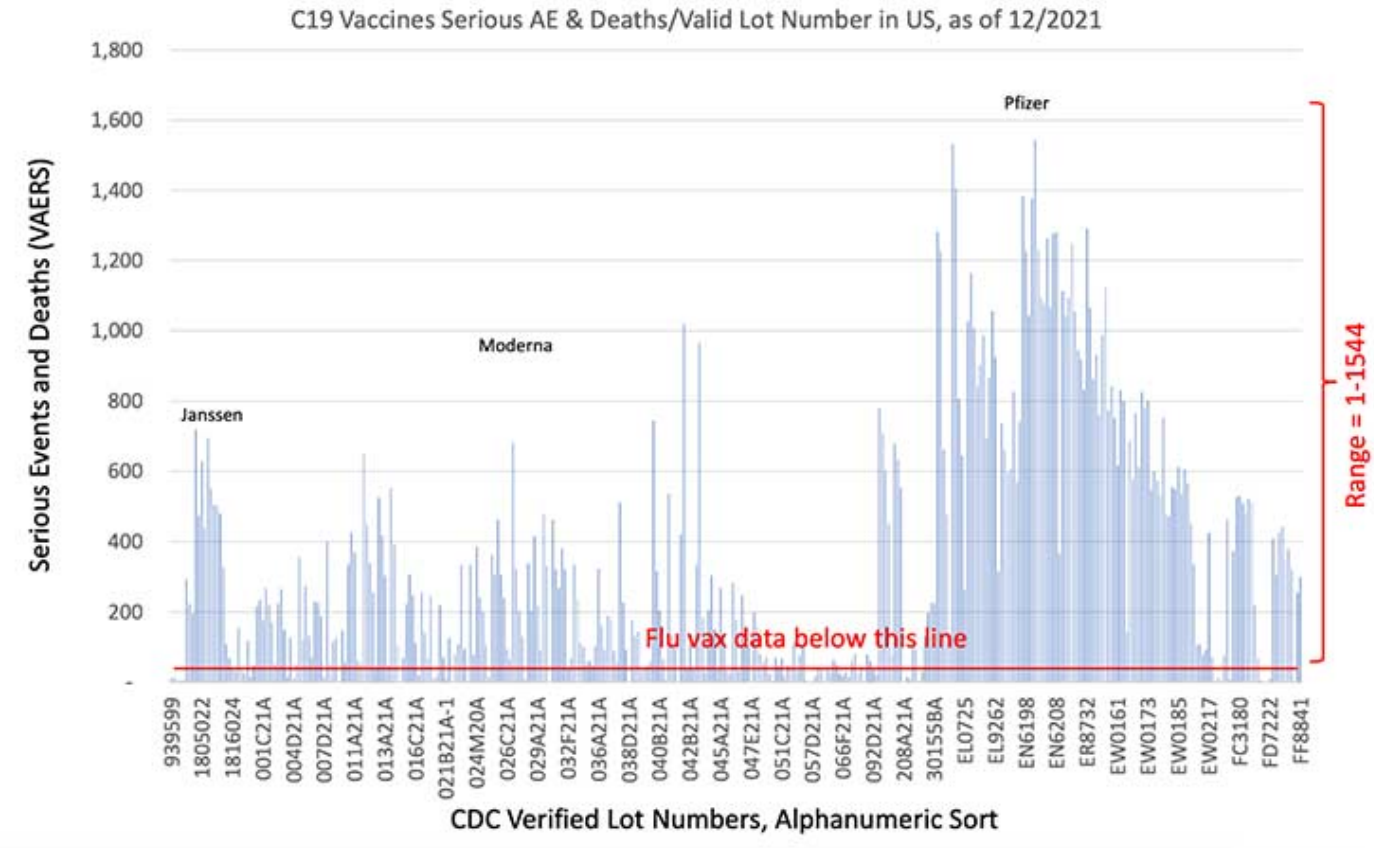
Compelled to understand what was going on, Alexandra got to work. She looked at VAERS and discovered huge discrepancies between the lots, where some batches had just a few reported severe adverse events, and some had over 1500 (she later learned from FOIA'ed documents that lot sizes were in a relatively similar range, and thus the discrepancies could not be explained by the lot size).

And when it comes to VAERS, let's not forget the 2010 Harvard Pilgrim study showing that VAERS was severely underreported — NOT overreported — capturing less than 1% of adverse events.

"Hot Batches"

Early on, Alexandra discovered the existence of "hot batches." She is one of team members behind the famous "How Bad Is My Batch" webpage where people can look up the number of severe adverse events reported to VAERS associated with a COVID injection lot number. Other fearless members of the team are Dr Mike Yeadon, ex-head of Pfizer Respiratory Research, Jessica Rose, statistician, Craig Paardekooper, researcher, and Walter Wagner, lawyer.

The slide below show the unprecedented variability of serious adverse events and deaths in the U.S. per batch. Note the comparison to the variability of the flu vaccine lots.



In the interview, Alexandra also mentioned the uneven distribution of deaths per a hundred thousand doses from batch to batch in the U.S. The coasts did much better than some of the Midwestern states that showed a very high numbers of reported

deaths per a hundred thousand doses. The worst state is South Dakota (30+ reported deaths per 100,000 doses).

The areas that did even worse, according to Alexandra, were some of the U.S. territories with high percentage of indigenous population. (The latter data became available after the presentation was created, not reflected in the slide.)

"Garbage Soup": Non-Compliance With Good Manufacturing Practices

In the interview, Alexandra calls the COVID injections products "garbage soup," both due to the massive non-compliance of the vial content to the specifications (per multiple independently done tests) — as well as due to their non-compliance with Good Manufacturing Practices. Wait, are the manufacturers trolling us? Are telling us that they do not comply (but we must)?!

There are many theories about what's behind for such wild inconsistency between batches, from manufacturing defects to deliberate toxicity testing — and anything in-between. In her TrialSiteNews article, Alexandra tackles one important angle of the challenge that so many of us had to "explain" when talking to the friends of a more mainstream persuasion:

> *"Many of us are familiar with the following conundrum: on one hand, highly credentialed scientists and doctors have written numerous research papers explaining the dangerous mechanisms of action underlying mRNA/DNA*

*"platform" **technologies**. The papers are meticulously researched and depict, correctly in my opinion, many terrifying consequences of the technology that breaches the innate protective mechanisms of human cells."*

*"Furthermore, these theoretical papers are validated by the observed outcomes, such as for example, increases in all-cause mortality in high **correlation** with increases in rates of vaccination in a given territory, unprecedented increases in the adverse events and deaths recorded by various passive reporting **systems**, astonishingly high reports of the adverse events and deaths from the pharmas' own **pharmacovigilance** systems, and autopsy **findings** in vaccinated post-mortem showing the mechanisms of mRNA technology damage in histopathologic evaluations.*

On the other hand, many who have received the injections report no adverse effects and deem the points above a 'crazy conspiracy.'"

*"The question from the uninjured seems to be – why don't we see MORE deaths if what you say about mRNA products is true? Setting aside ethical limitations of this question, here is a possible answer why: **The mRNA shots do not conform to their label specifications. In practice both "blank" and "lethal" vials and anything in between is produced** **[emphasis mine]."***

Like I wrote earlier on my Substack, "remarkably, some analyzed vials were reported to contain left over magnetic beads (magnetic beads are used in production of mRNA). Remember the "crazy" videos of some people developing magnetism in the place of injection? Now we have a new, 'non-conspiratorial' explanation for the 'conspiratorial' videos! Yay, following the science!"

According to Alexandra, vials of mRNA injections are not routinely tested by the manufacturers for conformity to the label. She notes that "the more they conform to the mRNA specification, the deadlier they seem."

The only vial-level tests specified, for instance, by Pfizer, in leaked Chemistry Manufacturing and Controls documents, are the vial weight at filling, manual inspection

for large visible particles, and some tests related to integrity such as vial capping.

The documents don't describe no routing vial or dose tests verifying the ingredients. Each Pfizer dose is supposed to contain 30 mcg of mRNA, as stated on the label, but there is no information about any testing done to verify that.

> *"The ingredient conformity tests described in 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. Per **contracts** with the US Government/DOD, the product is shipped to the DOD who retains the ownership of the vials until the product is injected into people."*

Alexandra notes that those contracts are very detailed and specify manufacturing data to be delivered to the DOD, however, she not find any descriptions of sampling of the vials for purposes of verification of their contents vs the label. "Furthermore, it is expressly forbidden by the international vaccine supply **contracts** to perform the vial tests for label conformity."

Evidence of Collusion

In the interview, as well as in this **article**, Alexandra talks about the evidence of collusion between the manufacturers, the global regulatory agencies, and the US Department of Defense.

Having analyzed various public data from CDC's VAERS database as well as various documents that have been obtained through FOIA releases and other source, she concluded that such collusion "led to the commercial release of the Covid-19 countermeasures that do not comply with the current Good Manufacturing Practices (cGMP)."

Evidence that Alexandra talks about includes Moderna's non-clinical study summaries, Pfizer's Chemistry Manufacturing and Controls documentation, and contracts between

pharma and the DOD for supply of the mRNA/DNA products. According to her, "it reveals disregard for established safety rules, regulations, and safety practices throughout the development, manufacture, and distribution of these products."

Moderna Red Flags

As reported by **Children's Health Defense**, Alexandra reviewed 700 pages of documents that Moderna submitted to the FDA as part of its application process and obtained via a Freedom of Information Act request.

And according to her, "out of nearly 700 pages, about 400 pages are irrelevant studies that Moderna repeated multiple times. Moderna also submitted three versions of a single module, she said. And one module contained only narrative summaries of Moderna's studies, but no actual study results." Alexandra's conclusion is that we are missing a large number of results, such as full reports that would support their narrative.

> *"The FDA 'obviously did not object' to any of this, she said. 'That's **evidence of collusion** to me with the manufacturer.'"*

Other "abnormalities" that Alexandra highlighted both in the interview and in the Children's Health Defense article, were Moderna's clinical trials timeline and the fact that their product has two — not one — Investigational New Drug (IND) number.

Normally, there is one IND application for one product. "In this case, however, there are two IND applications — one belonging to Moderna, and one belonging to the National Institutes of Health, which **partnered** with Moderna on its COVID-19 vaccine."

"The Investigational New Drug (IND) application meeting is supposed to occur with the FDA when the company initiates human clinical trials. Moderna and the FDA had a pre-IND meeting on Feb. 19, 2020, and the IND application was formally opened the next day. The global pandemic was declared on March 11, 2020."

In the words of Alexandra, "Somehow these visionaries could predict the future with such certainty that they opened a clinical trial for the vaccine, for which a pandemic was announced a month later."

Pfizer Red Flags

As Alexandra notes in her article titled, "Did Pfizer Perform Adequate Safety Testing for its Covid-19 mRNA Vaccine in Preclinical Studies? Evidence of Scientific and Regulatory Fraud," "both the manufacturer and the regulators behaved in a highly dishonest manner and conspired to push an entirely novel technology and product on millions of people without carrying out a single well designed safety assessment."

For example, she points out that a review of clinical studies released by FOIA uncovered that at least 4 different variants of active ingredient were included in the single Investigational New Drug application by Pfizer IND#19736:

- BNT162a1 — Unmodified mRNA (uRNA; variant RBL063.3)
- BNT162b1 — Methylpseudouridine-modified mRNA (modRNA; variant RBP020.3)
- BNT162b2 — Methylpseudouridine-modified RNA (modRNA; variant RBP020.2)
- BNT162c2 — Self-amplifying unmodified mRNA (saRNA; variant RBS004.2)

Alexandra writes that while the use of multiple versions of a product in the early stages of development is often inevitable, each chemical or biological entity is nevertheless deemed legally distinct for the purpose of product approval.

"Therefore, studies conducted with versions of the product that don't conform to the exact specification of the final version may serve only as supporting information for the approval of the latter, but they should never be deemed definitive and sufficient tests for claims of safety or efficacy pertaining to the final product."

She further mentions that in September 2021, the FDA issued a draft guidance entitled "Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase

Clinical Trial," which states that each version of product requires a separate IND application.

However, stunningly, "a footnote in this guideline exempts 'vaccines intended to prevent infectious diseases' from this requirement. No explanation is given as to why this exemption is made, and no conceivable scientific or legal basis exists for this exemption, other than that the FDA had already arbitrarily allowed this unprecedented deviation from the regulatory standard and later needed to cover their tracks.

In fact, arguably this regulatory 'exception' does not even apply to Pfizer's COVID-19 'vaccine,' since the product does not prevent infection or transmission of the disease. Is intent to prevent illness alone a sufficient condition? After all, every new drug is intended to do something like preventing an illness, but only few successfully do so."

Alexandra's **article** is very detailed, and I highly recommend reading it in full. You can also find Alexandra on **TrialSiteNews** and on her **Bitchute channel.** To summarize her take on Pfizer, she make the following points:

- *Pfizer's program did not include a comprehensive end-to-end test of all components of the final approved product (the mRNA COVID-19 vaccine). Instead, the studies included in the document package submitted to the FDA employed several variants and analogues of the product, whose comparability to the actual COVID-19 vaccine was not demonstrated or evaluated.*

  Thus, no comprehensive assessment of product safety can be made on the basis of these studies.

- *A key determinant of a drug's toxicity is its distribution within the body. However, with the mRNA active ingredient of Pfizer's COVID-19 vaccine, this crucial aspect was never studied!*

- *Pfizer claimed absence of potential for "vaccine-elicited disease enhancement" based on studies of an animal species that does not get sick from SARS-CoV-2.*

- *The CDC, the FDA and Pfizer all lied about "vaccine staying at the injection site;" they knew all along that distribution of the vaccine throughout the body had to be expected.*
- *Pfizer skipped major categories of safety testing altogether.*
- *Pfizer used dishonest and self-serving interpretation of regulatory guidelines to justify the shortcuts it took in routine safety testing.*
- *Both FDA and Pfizer knew about major toxicities associated with gene-therapy medicines in general, and they therefore cannot claim lack of anticipatory knowledge of these risks with the particular gene therapy medicine that is Pfizer's COVID-19 vaccine. This points to intentional fraud and collusion between Pfizer and the regulators, who conspired to push this untested dangerous product on the market.*

Yes, They Are Trolling Us — But We Are Not Helpless

Even though it is rather disheartening to know we live in a world that run by a mob, the challenge is centuries old, and remembering it can bring us much needed perspective and balance. The novel and "sudden" part of the challenge is that is happening to us, here and now, in broad daylight. That's shocking! But throughout history, many of our ancestors had to deal with tyrants, and today, it is our turn to be brave. May our brave ancestors be our inspiration.

I would like to end this story with a short quote from my earlier **article** titled, "Is Our World Run Like a Mafia? So What Do We Do?:"

"Good news: As the mafia bosses do their predatory thing, something mysterious is happening the hearts of those of us who insist on love. Under pressure, we are forced to remember that we are not theirs." We are not theirs. It is true.

About the Author

To find more of Tessa Lena's work, be sure to check out her bio, **Tessa Fights Robots**.