

My Affidavit on Different Formulations in Pfizer Vaccine Lots



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Evidence of a De-Facto Adulterated Product?

I was recently asked to provide a witness statement in regard to extensive variability of manufactured lots for Pfizer's BNT162b2 injection products. The variability is inconsistent with that expected of compendial pharmaceutical products. It can be deemed as a de-facto adulterated product. My affidavit is as follows:

The following statements are based on my review of documentation that has been publicly disclosed from Pfizer, European Medicines Agency (EMA) and Food and Drug Administration (FDA) and relates to the Chemistry, Manufacturing and Controls (CMC) sections of Pfizer's BNT162 dossier. Documents used in my review are provided in the Attachment. The documents were released due to a cyberattack on the EMA. The EMA acknowledged the release of the documents and did not dispute their authenticity. Furthermore, the British Medical Journal confirmed the contents of these documents with respect to the issues of integrity of the active ingredient discussed herein through correspondence with the EMA, MHRA, FDA, Health Canada and Pfizer.[\[1\]](#)

The rates of adverse events and deaths per manufacturing batch number are derived from CDC VAERS database.

My affidavit attests to the following facts identified in the documents, with evidence information provided below:

1. The modified RNA (mRNA) which is the active substance of Pfizer's vaccine BNT162b2 is allowed to vary in its integrity by up to 50% in the finished product.
2. Product impurities in the form of truncated mRNA, untranslated DNA and other unknown nucleic acid constructs have been allowed in the finished product in unspecified quantities.
3. As a result of the reckless widening of quality acceptance criteria for the integrity of active ingredient in manufacturing batches, there is a great variation in resulting formulations of final product as dispensed in vials. Furthermore, 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.
4. There is an excessive variation in the rates of adverse events and deaths observed post-vaccination for different manufacturing batches which far exceeds expected batch-to-batch variations for compendial pharmaceutical products, such as for example seasonal flu vaccines.

Evidence from EMA and Pfizer Documents:

Lack of mRNA integrity and product impurities (fragmented nucleic acid chains) were found in Pfizer's product days before it was authorized for market:

mRNA integrity, and conversely, its instability, is one of the most important variables relevant to all mRNA vaccines. Pfizer and BioNTech repeatedly stated that the efficacy of the product is highly dependent on the quantity of the sufficiently intact mRNA molecule. Even a minor degradation reaction, anywhere along a mRNA strand, can severely slow or stop proper translation performance of that strand and thus result in the incomplete expression of the target antigen.

Pfizer made several major changes to its manufacturing process going from small clinical scale manufacturing (Process 1) to commercial scale (Process 2) as described in the “Rapporteurs Rolling Review Report”, p. 57 (full document in Attachment).

“Process 1

[..]two changes were made within Process 1 between nonclinical toxicology and Phase 1/2/3 process: the scale of the reaction and the site. The increase in scale was required to make sufficient material for clinical trials. The location changed from a non-GMP lab into GMP facilities. This process was based on BioNTech platform knowledge from other mRNA therapeutic programs.

Process 2

[..]The DNA template changed from a PCR template to linearized plasmid DNA in order to meet commercial demands. Additionally, the magnetic bead purification was replaced with proteinase K digestion and UFDF steps. The magnetic bead purification method was not scalable, but removed small molecule

impurities (e.g. spermidine, DTT), residual DNA, and enzyme impurities (e.g. T7 polymerase, DNase I). [...]"

These changes were performed without re-validation of the manufacturing process or re-running the preclinical and clinical studies to confirm comparability on safety and efficacy characteristics of the product. Importantly, these changes resulted in a substantial drop in the integrity of key active ingredient – mRNA molecule as measured by the %mRNA integrity and % of fragments (Late Migrating Species, LMC) in each manufactured batch. This was identified by the regulatory reviewers at EMA and FDA, and EMA specifically recorded this as a Major Objection #2, i.e. a regulatory flag that required a resolution prior to the product approval. The discussions around this issue are recorded in numerous documents that were released from EMA, at the end of November 2020, including email exchanges between EMA staff and management (see Emails in Attachment). For example, a PowerPoint document from the meeting on November 26, 2020 between EMA and Pfizer/BioNTech describes the issue of mRNA integrity (see 20201126_BNT162b2_EMAMEETING14.pdf in Attachment).

In this meeting it was discussed that the batches manufactured with Process 2 had a much lower range of % intact mRNA and higher % of impurities – fragmented nucleic acid chains of various length and type (DNA and RNA). Specifically, p. 20 lists final product batches manufactured with both processes, ranging in mRNA integrity from 55% to 85% with the

remaining % of volume occupied by uncharacterized fragments.

EMA regulatory concern with lack of mRNA integrity in Pfizer's product was evident. Specifically, on p. 4 the document states that:

“Significant differences between batches manufactured by DS Process 1 and 2 are observed for the CQA [*critical quality attribute*] mRNA integrity. In addition, the characterisation of BNT162b2 DS [*drug substance*] is currently not found acceptable in relation to this quality attribute. This is especially important considering that the current DS and DP [*drug product*] acceptance criteria allows (sic) for up to 50% fragmented species.”

Further, on p. 5 the reviewers discussed the presence of uncharacterized fragmented nucleic chains, some long enough to translate into unknown proteins, and deemed them product impurities that required further characterization:

“Truncated and modified RNA species should be regarded as product-related impurities. Even though two methods, namely agarose gel electrophoresis and capillary gel electrophoresis (CGE), have been applied to determine RNA integrity of BNT162b2 DS [*drug substance*], no characterisation (sic) data on truncated forms is presented. “

As a result of the manufacturing inconsistency, the clinical trial data collected using the Process 1 material was not deemed applicable to the material manufactured in Process 2. Several EMA reviewers wanted to understand the potential impact on safety

and efficacy via bridging clinical studies (see Emails in Attachment). No such comparisons were done. Pfizer provided comparison of some chemical analyses from various batches, but no further characterization of the fragments of RNA and DNA or study of impact of these impurities on safety and efficacy of patients was provided.

EMA reviewers and Pfizer “resolved” this Major Objection by arbitrarily lowering the acceptance criteria for %mRNA integrity (see p.4):

“In addition, we are revising the RNA integrity specification for drug substance to $\geq 60\%$, drug product release to $\geq 55\%$, and drug product shelf life to $\geq 50\%$. “

An extremely wide variation of the integrity of the active substance in bulk material (batch) of the product and abundant presence of uncharacterized impurities means that batches of different formulation - and thus different potency and safety profiles - are being produced. This variation is further amplified when the bulk material is filled in small quantities into vials. Each batch of Pfizer product contains approximately 300,000 vials filled with 0.45ml of drug product which may get varying quantities of intact and broken mRNA molecules. In addition, at the final step of administration, this variability is further exacerbated by dose preparation in a non-GMP environment by untrained and unsupervised staff at the vaccination centers.

Both the regulators and Pfizer to date have not disclosed the acceptable ranges for the key ingredients of the vaccine product, neither in bulk product nor in

a vial (as dispensed), and claim “commercial secrets” that prevent them from doing so.

Evidence from adverse event reports (in VAERS database) analyzed by manufacturing lot number.

Manufacturing of pharmaceutical products is regulated by laws that are established to control within tight ranges acceptable criteria for the identity, quantity, quality, purity, potency and other characteristics of the product ingredients to ensure safety and conformity to the approved product labeling. It is expected that the product lot-to-lot, or batch-to-batch, is essentially the same. Therefore, when outcomes data such as rates of adverse events reported for each manufacturing lot is examined, it is expected that only minor variations from lot-to-lot may be observed. This is true for conventional pharmaceutical products and for traditional vaccines such as seasonal flu vaccines.

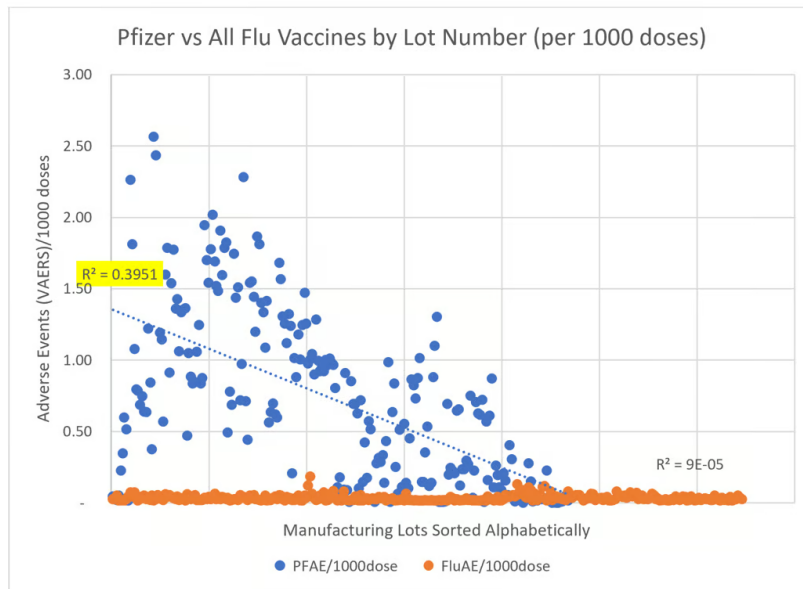
There is an excessive variation in the rates of adverse events and deaths observed post-vaccination for different manufacturing batches which far exceeds expected batch-to-batch variations for compendial pharmaceutical products, such as for example seasonal flu vaccines.

The graph below shows a comparison between the manufacturing lots of Pfizer’s BNT162b2 product and manufacturing lots of all seasonal flu vaccines released in 2019-2020. The lot numbers for Pfizer were verified with CDC and dates of manufacture and expiration were obtained. The flu vaccine lot numbers were obtained by downloading data from VAERS.

Rates of adverse events reported for each lot are plotted against the lot number (not shown on X-axis for clarity), sorted alphabetically. Finally, the adverse event rates are expressed in “per 1000 doses” to normalize for the lot size.

As evident from this analysis, there is an excessive variability in the toxicity (rates of adverse events) for Pfizer product. The flu vaccine lots in comparison look very similar to each other and have overall a very low rate of adverse events. There is a large correlation between the adverse even rates for Pfizer lots with the lot number ($R^2=0.4$). This should not happen. There should be no difference in the safety (toxicity) of a product depending on how its manufacturing lot is numbered. This does not exist for the flu vaccine lot numbers. Overall, the rate of adverse events per lot/dose adjusted is extremely high as can be visualized on the graph below.

The difference between the two sets of products is stark and cannot be explained by normal demographic variations such as age or underlying health status of the recipient. Flu vaccines are administered to approximately 50% of population, including to old and frail people with compromised health status as well.



In conclusion, the evidence presented in my statement shows that Pfizer’s manufacturing quality acceptance criteria permit for an extremely large variation of the key ingredient (up to 50%) and allow for a substantial presence of uncharacterized impurities. This can be deemed as product adulteration with de-facto different formulations produced in different batches. This leads to overall large rates of toxicities, reported adverse events and to extreme variations of product safety (toxicity) parameters in different manufactured lots.

Comments (10)

What do you think?

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D danieloconnor

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Serious insight from this author