

The FDA Committee's Review of Pfizer-BioNTech COVID-19 Vaccine: Unscientific, False and Deceitful

Saeed A. Qureshi, Ph.D. (principal@pharmacomechanics.com)

On December 10th, 2020, the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC or the Committee) held a meeting to evaluate the Pfizer-BioNTech vaccine for COVID-19.

This article provides a critical review of the underlying scientific aspect of the evaluation process and its outcome. The Committee's judgment is considered biased, lacking scientific vigor - including for chemistry and manufacturing, and misleading for describing efficacy and safety assessment for the vaccine use.

COVID-19 has recently been declared a highly contagious infectious disease based on a newly discovered virus labeled as SARS-CoV-2. Before considering the Committee's evaluation of the vaccine's safety and efficacy, it is crucial to understand the background of how the new virus came into existence and became a "killer bug."

The existence of COVID-19 and SARS-CoV-2 was generally described by multiple news stories based on reports from authorities such as the CDC and WHO stating that a new disease is causing illness and deaths in an area of China.

For unknown reasons, from the beginning, it was assumed that it is a viral disease, and the virus belongs to the class known as coronavirus. It is not clear why and how the virology experts took charge of the disease and its spread. It was believed that the virus is highly contagious, spreading worldwide, and had reached the USA.

The only solution suggested to mitigate its deadly effect is by isolating and limiting people's close interactions – hence the (partial or full) lockdowns and closing of businesses worldwide, including the USA and Canada, were implemented.

It is critical to note that no confirmed identification of the virus was available in the USA and Canada until that time. Everything was based on the presumptions and proclamations by the virology and infectious diseases experts. However, the public was firmly convinced that it is a viral disease.

The CDC, the USA organization, later published a study describing the "isolation and identification" of the virus from an "infected" person who arrived from China, hence "confirming" its existence. The virus was supposedly extracted, isolated, and identified under the guidance of mostly virologists and medical experts [1].

A virus is a particle that comprises various chemical components (DNA/RNA, proteins, lipids, etc.). To establish its physical existence, the virus's isolation and characterization falls in the science of chemicals, i.e., chemistry.

However, the virologist and medical experts who are neither trained nor have working experience with the subject claimed that they have isolated and characterized the virus. Their ignorance and incompetency on this matter are so blatantly evident that they considered a mixture or soup of unknown ingredients and composition (called

BIOANALYTICX

Everything about pharmaceutical testing



"isolate") as a confirmed and pure virus (SARS-CoV-2) [2].

It is such a ridiculous claim that would put modern medics at a higher level than snake-oil merchants. The point being there is no actual scientific evidence provided to indicate that, indeed the virus exists. However, the medical community declared that a virus exists, which will be called SARS-CoV-2.

This imaginary virus was then promoted as causing the new deadly disease called COVID-19 without providing any verifiable link to new or unique symptoms or markers. No scientific evidence has been provided to show that the virus causes the disease.

The public has been compelled to accept the official (medical) narrative that the disease exists and the SARS-CoV-2 causing it. Also, it has been decided that as the infection is viral; therefore, a vaccine would only be an appropriate treatment, so it needs to be developed urgently.

Simultaneously, the testing was introduced to monitor the virus's or disease's spread, not only for the patients but, surprisingly, also for everyone, including those without any symptoms.

The most commonly used test for this purpose is known as a PCR test. It should be clear that this test is not for the virus. In reality, it is a chemical test to monitor a chemical component of a virus – non-specific to the virus (SARS-CoV-2).

A must requirement for any test is that it first be validated against the analyte it intends to quantify. As the virus has never been isolated, the PCR test cannot be validated for it or its components. Therefore, the PCR test cannot

detect or quantify the virus with any degree of certainty [3]. The use of the non-validated method, or its requirement, is a violation of scientific principles and standard regulatory requirements.

No one should, therefore, claim that a valid virus test is available at present. All claims based on the PCR test for the virus (SARS-CoV-2) must be considered false and rejected.

Authorities should have considered withdrawing the test and testing. Unfortunately, virologists and medics do not recognize this deficiency, as this is not part of their training and knowledge base, and continue to promote the narrative of the false pandemic.

Promoters of the pandemic convinced the higher-level authorities that the virus and COVID-19 pandemic exist, and the only solution to deal with this pandemic is to develop a vaccine.

This understanding led to a collaborative effort between industry and the authorities, including the FDA, to develop a vaccine. No external opinions other than the medical subject experts were sought when, in reality, the development of drug products, including vaccines, falls almost in its entirety within the domain of chemical sciences.

If the underlying scientific aspect is to consider, it would be evident that such trials fall in the category of relatively simple and straightforward science of testing [4]. Such trials could be conducted by administering the vaccine, documenting the symptoms and adverse effects, and analyzing swab or blood samples using some valid tests.

BIOANALYTICX

Everything about pharmaceutical testing



Indeed, the physicians' monitoring of volunteers would be essential for vaccine dose administration and to document and treat adverse effects if they occur.

Based on an agreed-upon study design with the FDA, the industry proceeded to develop a vaccine.

Many companies have announced that they have developed vaccines. Pfizer-BioNTech is the first one that has requested regulatory approval of its vaccine from the FDA on an Emergency Use Authorization or EUA basis.

As a part of the approval process, FDA seeks input and advice from external scientists and experts to provide their view on the company's submitted data demonstrating the safety and efficacy of the proposed vaccine.

The following provides a review of the Committee's deliberations for the vaccine approval. The discussion below is based on the provided documents at the FDA site and watching live presentations and discussions broadcasted by the FDA on December 10th, 2020 [5].

VRBPAC Membership Expertise – Limited and Biased

Almost all members have expertise in the medicine area (the majority with an M.D. degree). There is no doubt that they all have impressive medical credentials, mostly in virology and infectious diseases. Their expertise and experiences are appropriate for diagnosis, dosing regimens, efficacy assessment, and potential side effects monitoring and treating.

On the other hand, the drug or vaccine development part starts with identifying a

therapeutic agent through in vitro assessments based on basic science considerations. Once its efficacy potential is recognized, a therapeutic is then synthesized chemically or extracted with chemicals/solvents from natural sources, purified, and identified - first at a lab or bench level and then at a larger or commercial scale.

Selected chemical entities (medicines) are tested in vitro and in animals at every stage to establish their efficacy and safety and to understand their mechanisms of action. Then they are appropriately formulated for human testing. It is important to note that testing for medicines and their product is done before a test drug reaches human studies.

No such details of non-human studies, commonly known as a pre-clinical assessment, were submitted or available to assess. It is impossible to tell if the suggested vaccine has any scientific merit for clinical trials or human use.

Human studies come way after and may only be considered as final confirmatory testing. Conducting a valid clinical trial requires a clear disease endpoint or its well-established marker, along with a scientifically validated test method to monitor the drug and disease.

Without knowing about the pre-clinical details, in reality, the clinical trial outcomes equate to remedies sold by street healers. They sell their products on survey-based assessments stating how many of their clients/patients were happy, or not, with their products. They do not know or depend on their products' scientific investigations.

Similarly, assessing data in isolation or without sufficient pre-clinical information, as considered

BIOANALYTICX

Everything about pharmaceutical testing



by the Committee, does not provide needed confidence in the vaccine's safety and efficacy.

Lack of scientific vigor

If one carefully analyzes what was presented to the Committee and how it is assessed. It would be evident immediately that the provided data is from a survey exercise, not a scientific endeavor. The Committee was provided with the details of the doses, the number of subjects who participated in the study with breakdowns of demographic information, the outcome (i.e., the number of observed ill people presumed COVID-19 positive), and the number of volunteers who showed adverse effects.

One wonders how such a study could be considered scientific. How is it different from a product evaluation of a potential new variety of burgers from MacDonald's? McDonald's restaurants' supply free burgers to volunteers to obtain their demographic details with feedback on the burger quality to market a new and different variety of burgers. This vaccine ("clinical") assessment appears to fall in a typical marketing survey exercise!

From a scientific perspective, one would like to know the vaccine's (chemical) nature, the reason for selecting a particular vaccine molecule, the vaccine target site, details of the mechanism of action, and then quantifiable markers of the disease. All these assessments should have based on some scientifically valid tests and associated reports. Nothing of this sort was available in the submission or the literature.

The closest thing to science mentioned is the generic (not specific) description of the vaccine molecule. It is a "nucleoside-modified messenger

RNA (modRNA) encoding the viral spike glycoprotein" non-technical translation - a chemical molecule or compound (RNA) to produce another type of chemical molecule or compound (protein) in the body.

No information is provided regarding whether the vaccine produces the expected protein and kills or neutralizes the SARS-CoV-2 virus in the body. Such information is essential in establishing the vaccine's authenticity as treatment or usefulness.

The reason for missing information could be that an actual physical sample of the virus and disease cannot be monitored. After all, the virus has never been isolated. Therefore the claim of developing a vaccine against the SARS-CoV-2 virus becomes suspicious.

Lack of appropriate CMC details and discussion

Manufacturing, chemistry, and controls (CMC) data were not part of the Committee's review documentation. The FDA representative provided clarification and justification that the company met the FDA's CMC requirements. The details of which could not be submitted because of the propriety nature of the vaccine. Therefore, the Advisory Committee suggested its recommendation without knowing the vaccine's physical, chemical characteristics, manufacturing processes, and their controls.

No information is available to judge the vaccine's nature, stability, presence of impurities, reproducibility of manufacturing, quality control testing, and batch-to-batch consistency standards. These are all standard requirements for any drug product development and manufacturing but were missing.



The information that the vaccine requires storing at -65 to -80C is unusual and should be a cause of concern. One could only speculate on the instability of the vaccine requiring low-temperature storage. Is it because the vaccine's 3-dimensional structure unstable? In that case, it may become necessary to test the vaccine just before injecting it into humans to confirm the vaccine's integrity.

There was no or minimal amount of data available for the vaccine's physical and chemical characteristics to provide confidence to assess the vaccine's safety and efficacy scientifically.

Lack of appropriate safety/toxicity assessment

In general, one of the critical aspects of drug or vaccine development would be to assess its safety or toxicity. These assessments are done at the molecular, cellular, tissue, and whole animal bodies levels. No data from toxicological studies is provided.

Toxicological assessments in humans are rarely done because of ethical reasons. One only evaluates the toxicity in non-human (chemical and pre-clinical) studies, rarely in humans.

Often pre-clinical part is the major time-consuming step for new drug development. It appears that expeditious vaccine development may be the result of skipping the needed toxicity assessments. Although repeatedly claims have been made in news media for not "cutting corners," however, not conducting such studies certainly falls in the category of "cutting corners." It should have been a cause of concern for the Committee.

During deliberation, it was repeatedly mentioned that such studies are in progress or need to be conducted. Hence, one can argue that an appropriate evaluation of safety assessment is lacking.

Weak support for the efficacy

Efficacy means how effective a vaccine is in treating the target illness. Therefore, the first and most important objective should be to establish specific and measurable symptoms of the disease, followed by a test/criteria to monitor it.

As noted previously, the most common symptoms described for COVID-19 are flu-like conditions (ache, cough, fever, etc.) with clinical evaluation based on the PCR test. They both (symptoms and the test) are vague and non-specific. The PCR test has never been validated to monitor SARS-CoV-2 or COVID-19. However, both indicators formed the basis of the disease assessment.

Moving along, one would expect that for the clinical trial, patients with symptoms will be selected and treated with the vaccine to monitor how many patients got healed from the sickness during the clinical trials.

However, the current trial has a problem with this approach because the SARS-CoV-2 infected or COVID-19 patients are not available. So how could the vaccine be tested for its efficacy? It cannot be!

It is not possible to develop a treatment without having a patient population. There should not be any clinical trial conducted for vaccine development until a sufficient number of the patient population is available. However, authorities and experts insisted on developing a vaccine for a non-existent disease or its patients.

BIOANALYTICX

Everything about pharmaceutical testing



They invented a trick to circumvent this "problem"; by administering the vaccine and placebo to a large number of healthy volunteers (divided into two groups), to observe how many would develop flu-like symptoms and positive PCR test results. It is important to note that observing illness will be purely an assumption because, as stated above, symptoms and tests are not reliable and valid indicators of COVID-19.

Based on this understanding, 8 and 162 volunteers in the treatment group and placebo, respectively, were found positive for COVID-19. The conclusion is drawn that as fewer infections were observed in the treatment group - the vaccine worked. The vaccine provided protection, and it protected from COVID-19 and pandemics.

Such studies and conclusions are not valid but laughable. They are not scientific but speculative inferences based. To view them as science or data-based evaluation is false and deceitful.

On top of that, the way the study outcome, i.e., vaccine efficacy, has been calculated is bizarre. The efficacy was calculated as follows; the number of infected people was counted in both groups (treated and placebo, about 20000 volunteers in each group) and found eight vs. 162. An assumption is made that as the treatment group has only eight infected subjects, not 162 as in the placebo, the vaccine treatment stopped 154 (162-8) people from getting infected. It leads to the vaccine's efficacy of 95% $\{(154/162)*100\}$. How about that!

Injecting a small amount of any powder, including dirt, might have provided similar results and conclusions because it is all based on chance. The

public has great trust in the scientists and experts, including at the FDA, which is lost.

Most would consider or understand that 95% efficacy means that about 19000 out of 20000 participants of the clinical trial in the treatment/infected group got protected. This would be incorrect.

Arguably, this is a deliberate exercise of twisting data interpretation to show the intended or desired outcome. Sad!

An argument could be made that there was no need to develop a vaccine if the required number of patients were not available.

In conclusion, the documentation submitted to the FDA's Committee regarding the Pfizer-BioNTech vaccine lacks appropriate scientific data to establish the vaccine's physical and chemical characterization. The safety and toxicology information was scarce. Efficacy data relied on irrelevant parameters and the invalid PCR test. Vaccine efficacy has been construed to the desired feel-good outcome, not to reflect the absence of the illness or vaccine effectiveness.

Unfortunately, most of the Committee members accepted and supported the conclusions as presented for the vaccine's regulatory approval on a EUA basis.

History will not judge the FDA and the Committee kindly!

References

1. https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article

BIOANALYTICX
Everything about pharmaceutical testing



2. <https://onlinelibrary.wiley.com/doi/full/10.5694/mja2.50569>

3. <https://bioanalyticx.com/what-does-a-positive-coronavirus-test-really-mean/>

4. <https://bioanalyticx.com/understanding-clinical-trials-and-their-outcomes-fake-science-at-its-best/>

5. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-december-10-2020-meeting-announcement>

BIOANALYTICX

Everything about pharmaceutical testing

