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# Pathologist Petitions FDA to Halt Pfizer Emergency Use Authorization Until Vaccine Efficacy Confirmed

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By Informed Consent Action Network
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*Connecticut pathologist **Dr. Sin Hang Lee** and Informed Consent Action Network (ICAN) have petitioned the U.S. Food and Drug Administration (FDA) to require accurate counts of COVID-19 cases in the Pfizer/BioNTech COVID-19 mRNA vaccine trial.*

> "Until an accurate count of COVID-19 cases in the vaccinated and placebo groups has been determined for vaccine efficacy evaluation, we are asking the FDA to stay its decision regarding the emergency use authorization for this vaccine," said Dr. Lee, director of Milford Molecular Diagnostics Laboratory.

The major reason for petitioning the FDA for a stay of action is that the Phase 2/3 clinical trial of the Pfizer vaccine used a presumptive RT-qPCR diagnostic test. This test is acknowledged by the medical science community to generate high rates of false-positive results among qualified trial participants from the placebo group with minor symptoms such as a sore throat or a new cough. This is especially evident when a de facto unblinding among the trial participants has taken place, according to the petition.

The Pfizer/BioNTech vaccine trial primarily uses an RT-qPCR test that employs cycle thresholds possibly up to 44.9 to identify COVID-19 "cases." Samples deemed positive that require high levels of amplification (cycle thresholds greater than 30 to 35) are usually false positives, said Dr. Lee.

A recent review of a COVID-19 PCR test, which was signed by 22 international scientists, emphatically stated:

> "To determine whether the amplified products are indeed SARS-CoV-2 genes, biomolecular validation of amplified PCR products is essential. For a diagnostic test, this validation is an absolute must. Validation of PCR products should be performed by either running the PCR product in a 1% agarose-EtBr gel together with a size indicator (DNA ruler or DNA ladder) so that the size of the product can be estimated. The size must correspond to the calculated size of the amplification product. But it is even better to sequence the amplification product. The latter will give 100% certainty about the identity of the amplification product. Without molecular validation one cannot be sure about the identity of the amplified PCR products..."

A recent petition to the European Medicines Agency to stay their COVID-19 vaccine trials used similar arguments regarding the inaccuracy of the PCR tests being used and the need for confirmatory sequencing.

On Dec. 1, Switzerland's medical regulator, Swissmedic, said it lacks the necessary information to approve three different coronavirus vaccines ordered by the government, including the Pfizer vaccine.

In a recent interview about the pending review of the Pfizer COVID-19 vaccine, FDA Commissioner Stephen Hahn has promised, "we will make a determination regarding safety and efficacy based upon our very stringent criteria."

As stated in the petition, if Pfizer is unable to perform the needed sequencing tests on the 180 RNA samples to confirm their stated vaccine efficacy rate of 95%, Dr. Lee has offered to re-test the residues of these samples in his laboratory.

Dr. Lee said his laboratory is located only one hour's driving distance from Connecticut-based Pfizer Inc., and he will submit all the testing data to the FDA to support its vaccine evaluation based upon "very stringent criteria," as promised by the FDA Commissioner.

Dr. Lee's Sanger sequencing-based method for molecular diagnosis of SARS-CoV-2 was published in International Journal of Geriatrics and Rehabilitation.

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