

"Stay of Action" Filed Against FDA to Stop Approval of COVID Vaccine for Using Faulty PCR Tests in Trials

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An <u>ADMINISTRATIVE STAY OF ACTION</u> has been filed with the Department of Health and Human Services and Food and Drug Administration (FDA) for the new Pfizer COVID vaccine that has been submitted for "emergency use authorization" (EUA).

It is widely expected that the FDA is going to grant EUA fast-track approval to Pfizer's experimental COVID vaccine within days.

The STAY OF ACTION is a <u>Petition for Administrative Action Regarding Confirmation of Efficacy End Points of Phase III Clinical Trials of COVID19 Vaccines.</u>

The <u>STAY OF ACTION</u> is based upon the faulty PCR tests that were used in the vaccine trials:

Before an EUA or unrestricted license is issued for the Pfizer vaccine, or for other vaccines for which PCR results are the primary evidence of infection, all "endpoints" or COVID-19 cases used to determine vaccine efficacy in the Phase 3 or 2/3 trials should have their infection status confirmed by Sanger sequencing, given the high cycle thresholds used in some trials. High cycle thresholds, or Ct values, in RT-qPCR test results have been widely acknowledged to lead to false positives.

The Petitioner of this <u>ADMINISTRATIVE STAY OF ACTION</u> is **Dr. Sin Hang Lee**, a pathologist and founder of <u>Milford Molecular Diagnostics</u>, a CLIA-certified diagnostic laboratory in Milford, Connecticut.

Dr. Lee is a world-renowned expert on DNA sequencing-based diagnostics. He has trained and taught in some of the world's most prestigious institutions and has published scores of scientific articles in peer-reviewed journals.

He recognized very early on that the PCR tests and other tests fast-tracked by the FDA were not accurate in identifying SARSCoV-2 RNA, and even <u>sent a letter</u>, back in March, to Dr. Margaret Harris and Dr. Eduardo Guerrero of the World Health Organization, and Dr. Anthony Fauci at the National Institute of Allergies and Infectious Diseases of the National Institutes of Health (NIH), explaining why the tests to detect SARS-CoV-2 RNA were generating false positives and negatives.

You can read his <u>March 22, 2020 letter here</u>. He explained that a two-phased test would "guarantee no-false positive results" based on his research and published work from Japan.

According to <u>Attorney Mary Holland of Children's Health Defense</u>, he never received a reply from the WHO or the NIH. To this day, they continue to use faulty tests to identify COVID.

So here we are now at the end of November, 2020, and the FDA appears to be ready to grant EUA fast-track approval to COVID vaccines that have gone through Phase I, II, and III vaccine trials, all using these faulty COVID tests.

In Dr. Lee's <u>ADMINISTRATIVE STAY OF ACTION</u>, he recognizes the great risk for harm on the American public if the vaccine trials are approved based on these faulty tests.

Petitioner and the public will suffer irreparable harm if the actions requested herein are not granted, because once the FDA licenses this COVID-19 vaccine, both governments and employers may make this product mandatory (in general, or for airline or international travel) or may recommend it for widespread use.

If the assignment of cases and non-cases during the course of the trial is not accurate, the vaccine will not have been properly tested. If the vaccine is not properly tested, important public policy decisions regarding its use will be based on misleading evidence. The medical and economic consequences to the nation could hardly be higher.

The New York State Bar Association has already issued a report on COVID-19 recommending that, "a vaccine subject to scientific evidence of safety and efficacy be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required..."

Thus, it is reasonable to suspect that COVID-19 vaccines, including the Pfizer vaccine, could become mandatory. Without the FDA assuring proper efficacy trials of the vaccine now, the Petitioner and the public may not have the opportunity to object to receiving the vaccine, which was approved based on currently deficient and unreliable clinical trial data.

How likely is it that HHS and the FDA will grant this stay and deal with the PCR testing deficiencies before issuing emergency use fast-track approval to the Pfizer vaccine?

Not very likely at all, unless the public puts pressure on them to be more transparent and deal with these testing deficiencies, that top scientists all around the world now are speaking out against. See: <u>"Pandemic is Over" - Former Pfizer Chief Science Officer Says</u> "Second Wave" Faked On False-Positive COVID Tests

German Lawsuit Against "FactCheckers" Will Force Them To Prove Legitimacy of COVID Tests

Dr. Peter Marks is the head of the FDA's Center for Biologics Evaluation and Research, and will be the main person to make the decision of whether or not to issue an EUA for the Pfizer COVID vaccine. He recently told the press that "Americans can expect a very open process" in their evaluation of the experimental vaccine. (Source.)

We need thousands if not tens of thousands of Americans to contact Dr. Peter Marks and let him know the public is watching, and that we want the FDA to consider Dr. Lee's <u>ADMINISTRATIVE STAY OF ACTION</u> and respond to it.

Here is Dr. Marks' public contact info:

Dr. Peter Marks - email: Peter.Marks@fda.hhs.gov - Phone: 240-402-8116

Here is FDA Director Dr. Stephen Hahn's contact info:

Dr. Stephen Hahn – email: <u>Stephen.Hahn@fda.hhs.gov</u> – Phone (Main FDA #): 1-888-463-6332 – Twitter account: <u>@SteveFDA</u>

A Strong Warning to the U.S. Military about Operation Warp Speed

If you are a member of the military who will soon be called upon to participate in Operation Warp Speed and help distribute the new experimental COVID vaccine, be careful that you do not end up on the wrong side of history!

Just claiming to be "following orders" if massive deaths and injuries result from this experimental vaccine may not save you!

That is what many of the Nazi doctors in Germany who served under Hitler tried to claim, but during the Nuremberg trials, and specifically the "Doctors Trial" in 1946-1947, twenty of the twenty-three defendants were medical doctors, and were accused of having been involved in Nazi human experimentation and mass murder.

Of the 23 defendants, seven were acquitted and seven received death sentences; the remainder received prison sentences ranging from 10 years to life imprisonment.

What they did under German law, or maybe "emergency orders" during war time, was probably perfectly "legal" at the time, but after the Hitler regime was overthrown those who committed these "legal" actions that resulted in murder and crimes against humanity, were brought to justice after the war.

Dr. Peter Marks and Dr. Stephen Hahn would also do well to just not blindly excuse Dr. Lee's <u>ADMINISTRATIVE STAY OF ACTION</u>, because Dr. Lee appears to have close ties to **Attorney Mary Holland**, currently the Counsel for Children's Health Defense and former Professor of Law at NYU, and one of the nation's top attorneys when it comes to vaccines.

Mary Holland works now for **Attorney Robert F. Kennedy, Jr.,** who himself has become one the top attorneys in the world taking on Big Pharma.

He currently has <u>4 lawsuits filed against pharmaceutical giant Merck</u>, for their approval of the HPV vaccine, Gardasil, which has destroyed the lives of so many young people due to being fast-tracked into the market.

The work of Dr. Sin Hang Lee and his DNA sequencing-based diagnostic testing on the HPV Gardasil vaccine found DNA fragments in the vaccine, something that Merck and the FDA had denied. See: Fighting Academic Censorship on Gardasil Vaccine Research, Dr. Sin Hang Lee Challenges Medical and Scientific Community to Debate in Open Forum

His work in identifying these problems with the Gardasil vaccine <u>led Japan to stop</u> recommending the vaccine as part of their national vaccination program.

Here is a warning from a former Military Commander regarding current Commanders taking part of Operation Warp Speed, and the legal risks of doing so, published at Children's Health

Defense.

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