VIA ELECTRONIC FILING

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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE ACTION REGARDING CONFIRMATION OF EFFICACY END POINTS OF THE PHASE III CLINICAL TRIALS OF COVID-19 VACCINES	**:**	**Docket No. FDA-2020-P-2225**

ADMINISTRATIVE STAY OF ACTION

This petition for a stay of action is submitted on behalf of Dr. Sin Hang Lee ("**Petitioner**") pursuant to 21 C.F.R. § 10.35 and related and relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request the Commissioner of Food and Drugs (the "**Commissioner**") stay the Phase III trials of BNT162b (NCT04368728) to conform with the requests in the "Action Requested" section below.

Because of the compelling need to ensure the safety and efficacy of any COVID-19 vaccine licensed by the FDA, and to allow Petitioner the opportunity to seek emergency judicial relief should the Commissioner deny its Petition, **Petitioner respectfully requests that FDA act on the instant Petition by December 11, 2020.**

A. DECISION INVOLVED

1. Approval of trial design for Phase III trial of BNT162 (NCT04368728)[1]

[1] NCT04368728 available at https://www.clinicaltrials.gov/ct2/show/NCT04368728 (last visited November 3, 2020).

B. ACTION REQUESTED

2. Stay the Phase III trial of BNT162 (NCT04368728) until its study design is amended to provide that:

> 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.[2]
>
> All RT-qPCR-positive test results used to categorize patient as "COVID-19 cases" and used to qualify the trial's endpoints should be verified by Sanger sequencing to confirm that the tested samples in fact contain a unique SARS-CoV-2 genomic RNA. Congruent with FDA requirements for a confirmed diagnosis of human papillomavirus (HPV) using PCR, the sequencing electropherogram must show a minimum of 100 contiguous bases matching the reference sequence with an Expected Value (E Value) $<10^{-30}$ for the specific SARS-CoV-2 gene sequence based on a BLAST search of the GenBank database (aka NCBI Nucleotide database).

C. STATEMENT OF GROUNDS

3. As detailed herein, (i) without the requested stay, the Petitioner will suffer irreparable harm, (ii) the request is not frivolous and is being pursued in good faith, (iii) the request demonstrates sound public policy, and (iv) the public interest favors granting a stay. [3]

4. The current study designs for the Phase II/III trials of BNT162b ("**the Pfizer Vaccine**") are inadequate to accurately assess efficacy.

5. 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

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[2] *See* New York Times. Your Coronavirus Test Is Positive. Maybe It Shouldn't Be. By Apoorva Mandavilli. Published Aug. 29, 2020 and updated Sept. 17, 2020, available at https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html.

[3] The Petitioner hereby incorporates by reference as if fully set forth herein the Statement of Grounds from its Citizen's Petition, dated November 23, 2020, available at, https://beta.regulations.gov/document/FDA-2020-P-2225 (last visited November 25, 2020).

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.

6. 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…"[4] 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.

7. Furthermore, if the vaccine is approved without an appropriate and accurate review of efficacy, then any potential acceptance or mandate of these vaccines is likely to be based on inaccurate evidence regarding the vaccine, namely that it will stop transmission of the virus from the vaccine recipient to others and/or that it will reduce severe COVID-19 disease and deaths. The Pfizer trial protocol is currently not designed to determine whether either of those objectives can be met; and even if it was, if cases cannot be reliably identified, neither objective could be reliably met.

8. The public interest also weighs strongly in favor of the requested relief because improving the accurate determination of primary endpoints (i) will comport with the best scientific practices, (ii) increase public confidence in the efficacy of a product likely to be mandated or intended for widespread use, and (iii) not doing so will have the opposite result and create uncertainties regarding the efficacy of and need for the COVID-19 vaccines.

7. According to the trial protocol, "8.1. Efficacy and/or Immunogenicity Assessments," the trial's primary endpoint is prevention of symptomatic disease in vaccine recipients. In order to evaluate that endpoint, the trial will track recorded COVID-19 disease. The definition of confirmed COVID-19 is:

> presence of at least 1 of the following symptoms and SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period, either at the central laboratory or at a local testing facility (using an acceptable test):
>
> • Fever;
> • New or increased cough;
> • New or increased shortness of breath;
> • Chills;
> • New or increased muscle pain;
> • New loss of taste or smell;
> • Sore throat;
> • Diarrhea;
> • Vomiting.

[4] https://nysba.org/app/uploads/2020/06/2b-REV-6-12-20-FINAL-HOD-RESOLUTIONS-1-through-4.pdf.

8. As a result, if a participant has a positive reverse transcription-quantitative polymerase chain reaction ("**RT-qPCR**") test along with a cough or sore throat, that participant would be considered as a "confirmed COVID-19 case" and would be counted as an endpoint. Once a trial reaches a certain number of "endpoints", the trial is closer to seeking FDA approval or licensure by demonstrating that the vaccine is "effective" (in that the vaccine group had lower incidence of endpoints than the control group).

9. This effectively means that the efficacy of the vaccine will be determined based on only symptoms of non-specific disease in conjunction with a PCR positive laboratory test.

10. According to the trial protocol, "8.1 Efficacy and/or Immunogenicity Assessments," efficacy will be assessed throughout a participant's involvement in the study through surveillance for potential cases of COVID-19. If, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study he or she will be considered to potentially have COVID-19 illness. In this circumstance, the participant should contact the site, an in-person or telehealth visit should occur, and assessments should be conducted as specified in the SoA. The assessments will include a nasal (midturbinate) swab, which will be tested at a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (ie, NAAT), to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests (as detailed in Section 8.13) will be assessed. The central laboratory NAAT result will be used for the case definition, unless no result is available from the central laboratory, in which case a local NAAT result may be used if it was obtained using 1 of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2
- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001)

11. These test kits referred to in the trial protocol, namely the Cepheid Xpert Xpress SARS-CoV-2, the Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), and the Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001), are very unreliable tools when they are used to determine whether the nasal swab sample collected from a symptomatic participant contains SARS-CoV-2 or not. These real-time RT-PCR or RT-quantitative PCR tests should be referred to as rRT-PCR or RT-qPCR tests to be distinguished from conventional RT-PCR. The very short RT-qPCR product (amplicon) cannot be analyzed by automated Sanger sequencing as the products of conventional PCR can. And DNA sequencing for validation of the PCR products is needed to correctly determine if the presumptive RT-qPCR-positive SARS-CoV-2 test result is a true positive or a false positive. The reasoning is further outlined as follows:

a. Nowadays DNA sequencing of the PCR amplicon of the genomic nucleic acid of the pathogen is a universally accepted technology for detection and for confirmation of infectious agents, especially pathogenic viruses, in clinical specimens. On January 10,

2020, the first SARS-CoV-2 genome sequence was released online. On the same day, a group of American scientists, most from the CDC, immediately designed 2 complementary panels of primers to amplify the virus genome for sequencing. The PCR amplicons averaged 550 bp in size in their research.[5]

b. The World Health Organization (WHO) guidance titled "WHO Laboratory testing for coronavirus disease (COVID-19) in suspected human cases-Interim guidance dated 19 March 2020" advised "Routine confirmation of cases of COVID-19 is based on detection of unique sequences of virus RNA by NAAT such as real-time reverse transcription-polymerase chain reaction (rRT-PCR) with confirmation by nucleic acid sequencing when necessary."[6]

c. The FDA also recognizes the inherent inaccuracy of the RT-qPCR tests. In its letter issued on February 4, 2020 authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV, renamed as SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel, the FDA specifically stated that the test panel is "for the ***presumptive*** qualitative detection of nucleic acid from the 2019-nCoV (sic) in upper and lower respiratory specimens."[7]

d. In addition to false-negative results, these RT-qPCR test kits under EUA also generate false-positive test results. For example, 77 positive SARS-CoV-2 test results on a group of football players all turned out to be false positives on repeat tests.[8]

e. The FDA has officially alerted clinical laboratory staff and health care providers of an increased risk of false-positive results with some of these commercial test kits permitted to be used under EUA.[9]

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[5] Paden CR, Tao Y, Queen K, Zhang J, Li Y, Uehara A, Tong S. Rapid, Sensitive, Full-Genome Sequencing of Severe Acute Respiratory Syndrome Coronavirus 2. Emerg Infect Dis. 2020 Oct;26(10):2401-2405. doi: 10.3201/eid2610.201800. Epub 2020 Jul 1. PMID: 32610037; PMCID: PMC7510745.

[6] WHO Laboratory testing for coronavirus disease (COVID-19) in suspected human cases-Interim guidance 19 March 2020. Available from: https://www.who.int/publications/i/item/10665-331501.

[7] FDA letter dated February 4, 2020 authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV, renamed as SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel. See Open letter from FDA to Robert R. Redfield, MD, Director, Centers for Disease Control and Prevention. March 15, 2020. https://www.fda.gov/media/134919/download.

[8] Kevin Patra. Around the NFL- All 77 false-positive COVID-19 tests come back negative upon reruns. Aug 24, 2020. Available from: https://www.nfl.com/news/all-77-false-positive-covid-19-tests-come-back-negative-upon-reruns.

[9] FDA. False Positive Results with BD SARS-CoV-2 Reagents for the BD Max System - Letter to Clinical Laboratory Staff and Health Care Providers. Available from: https://www.fda.gov/medical-devices/letters-health-care-providers/false-positive-results-bd-sars-cov-2-reagents-bd-max-system-letter-clinical-laboratory-staff-and Accessed November 2, 2020; *see also* FDA. Risk of Inaccurate Results with Thermo Fisher Scientific TaqPath COVID-19 Combo Kit - Letter to Clinical Laboratory Staff and Health Care Providers. Available from: https://www.fda.gov/medical-devices/letters-health-care-providers/risk-inaccurate-results-thermo-fisher-scientific-taqpath-covid-19-combo-kit-letter-clinical?utm_campaign=2020-08-17%20Risk%20of%20Inaccurate%20Results%20with%20Thermo%20Fisher%20Scientific%20TaqPath&utm_medium=email&utm_source=Eloqua.

f. To resolve the problems caused by these inherently inaccurate tests, the FDA's position is that false results can be investigated using an additional EUA RT-qPCR assay, and/or Sanger sequencing.[10] Since an additional EUA RT-qPCR test result may also generate a false result, Sanger sequencing is the *de facto* gold standard for confirmation of presumptive qualitative detection of nucleic acid from the SARS-CoV-2 and for excluding false-positive cases.

g. According to the FDA guidance on molecular diagnosis of viral infection caused by human papillomavirus (HPV), a conventional PCR detection of genomic DNA followed by Sanger sequencing on both strands of the PCR amplicon (bi-directional sequencing) that contains a minimum of 100 contiguous bases is acceptable as valid diagnostics for HPV infection provided the sequence matches the reference or consensus sequence, e.g. with an Expected Value (E Value) $<10^{-30}$ for the specific HPV DNA target based on a BLAST search of the GenBank (NCBI Nucleotide) database.[11] Following this FDA guidance, and showing the feasibility of implementing the FDA guidance for accurate diagnosis of COVID-19, a protocol using the nested PCR cDNA amplicon of a 398-base highly conserved SARS-CoV-2 N gene segment as the template for Sanger sequencing was developed for confirmatory detection of SARS-CoV-2 in clinical samples.[12]

h. DNA sequencing verification is necessary for confirmation of the presumptive SARS-CoV-2-positive cases in the Pfizer vaccine's Phase II/III clinical trial because, according to its Protocol, the specimens collected from the symptomatic trial subjects were sent to a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under EUA), or other equivalent nucleic acid amplification–based test (i.e., NAAT), to detect SARS-CoV-2.

   In order to raise the detection sensitivity, the mean Ct value of the Cepheid system is set as high as 42.9 for the N2 target, and as high as 44.9 for the E target, as shown in Table 4 of Instructions for Users (Cepheid 302-3562, Rev. E September 2020).[13]

[10] FDA. Molecular Diagnostic Template for Laboratories. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Available from: https://www.fda.gov/media/135659/download .

[11] FDA. Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses. Available from: https://www.fda.gov/media/92930/download.

[12] Lee SH. Testing for SARS-CoV-2 in cellular components by routine nested RT-PCR followed by DNA sequencing. International Journal of Geriatrics and Rehabilitation. 2020; 2:69-96. Available from: http://www.int-soc-clin-geriat.com/info/wpcontent/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf.

[13] Cepheid. GeneXpert. Instructions for Users. XPRSARS-COV2-10. 302-3562, Rev. E September 2020 https://www.cepheid.com/Package%20Insert%20Files/Xpress-SARS-CoV-2/Xpert%20Xpress%20SARS-CoV-2%20Assay%20ENGLISH%20Package%20Insert%20302-3562-GX%20Rev.%20E.pdf.

Table 4. LoD Determination using USA-WA1/2020 Strain

Strain	Concentration (PFU/mL)	Total Valid Results	Hit Rate (%)	Hit Rate (%)	Mean Ct	Mean Ct
			N2 Target	E Target	N2 Target	E Target
SARS-CoV-2 virus (USA_WA1/2020)	0.0200	20	100	95.0	38.3	36.4
	0.0050	22	95.5	68.2	40.5	39.1
	0.0025	22	90.9	36.4	41.5	39.6
	0.0010	22	50.0	18.2	42.0	42.0
	0.0005	22	45.5	18.2	41.7	41.5
	0.0003	22	18.2	4.5	42.1	44.9
	0.0001	22	9.1	0	42.9	N/A
	0	0	0	0	N/A	N/A

At Ct values between 36.0 and 44.9, many RT-qPCR positive test results are false positives.

i. The results of the 3 RT-qPCR test kits used in the trial protocol are not comparable. A sample identified as negative by the Abbott kit can be classified as positive by the Cepheid kit. According to an FDA survey, the limit of detection by the Cepheid Xpert Xpress SARS-CoV-2 test kit and the limit of detection by Abbott RealTime SARS-CoV-2 assay kit are found to be identical, namely both being at 5400 NAAT Detectable Units/ mL, as shown in the comparative data extracted from an FDA reference panel.[14]

5400	Cepheid	Xpert Xpress SARS-CoV-2 test
5400	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay

However, due to the designation of higher cycle threshold test results as positives, the Cepheid Xpert kits have classified many Abbott kit negative cases as positives in a head-to-head comparative study as shown in the following "Table 2" extracted from a report by Basu et al.[15]

[14] FDA. SARS-CoV-2 Reference Panel Comparative Data. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative- data.

[15] *See* bioRxiv preprint doi: https://doi.org/10.1101/2020.05.11.089896; Basu A, Zinger T, Inglima K, Woo KM, Atie O, Yurasits L, See B, Aguero-Rosenfeld ME. Performance of Abbott ID Now COVID-19 Rapid Nucleic Acid Amplification Test Using Nasopharyngeal Swabs Transported in Viral Transport Media and Dry Nasal Swabs in a New York City Academic Institution. J Clin Microbiol. 2020 Jul 23;58(8):e01136-20. doi: 10.1128/JCM.01136-20. PMID: 32471894; PMCID: PMC7383552.

Table 2. Results of sequential nasopharyngeal specimens submitted in VTM from the Emergency Department tested on both Abbot ID NOW and Cepheid GeneXpert for SARS CoV-2 RNA

Sample ID	Abbott IDNOW Result*	Cepheid Result	N2 Ct	E Ct
1	Negative	Positive	43.1	0.0
2	Negative	Positive	40.7	37.0
3	Positive	Positive	32.4	29.0
4	Positive	Positive	32.3	30.3
5	Positive	Positive	18.2	16.2
6	Positive	Positive	31.6	28.5
7	Positive	Positive	35.1	31.3
8	Negative	Positive	44.1	0.0
9	Negative	Positive	44.3	0.0
10	Positive	Positive	29.7	27.1
11	Positive	Positive	27.6	26.2
12	Positive	Positive	19.7	17.5
13	Positive	Positive	18.6	16.2
14	Negative	Positive	36.3	33.3
15	Positive	Positive	23.7	26.5

j. One of the Cepheid Xpert kit users has put out an alert, stating "The instruments are presently set by the manufacturer to interpret a single target positive with very poor amplification efficiency (high Cycle Threshold [Ct] and/or atypical curve) as 'DETECTED.' None of these to date have confirmed positive when tested on other systems using similar targets, and may be a false positive due to background noise."[16]

k. Another group of users also found that some tested samples classified as positives by the Cepheid test kits cannot be confirmed with other test kits. These authors published a report, stating: "We found that the sensitivity of the Xpert Xpress SARS-CoV-2 assay was 100% (20 of 20) and the specificity was 80% (16 of 20). When looking at the cycle threshold (Ct) values from the GeneXpert assay we observed that specimens with no amplification of the *E* gene (ie, Ct=0) and Ct values for the *N2* gene greater than 40 cycles were considered as positives, whereas they were negative using the other RT-PCR system (Da An Gene)."[17]

[16] Diagnostic Laboratory Services Inc. Technical Alert. Cepheid GeneXpert and BD Max Instruments may be Reporting False Positives. https://dlslab.com/documents/bulletins/2020/tech-memo-sars-cov-2-pcr-possible-false-positive-6-19-2020.pdf.

[17] Rakotosamimanana N, Randrianirina F, Randremanana R, Raherison MS, Rasolofo V, Solofomalala GD, Spiegel A, Heraud JM. GeneXpert for the diagnosis of COVID-19 in LMICs. Lancet Glob Health. 2020 Oct 19:S2214-109X(20)30428-9. doi: 10.1016/S2214-109X(20)30428-9. Epub ahead of print. PMID: 33091372; PMCID: PMC7572106.

12. DNA sequencing verification of the RT-qPCR positive test results is absolutely necessary in this placebo-controlled randomized clinical trial because *de facto* unblinding has occurred among the participants. According to the trial protocol Section 8.13. COVID-19 Surveillance (All Participants), "If a participant experiences any of the following (irrespective of perceived etiology or clinical significance), he or she is instructed to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible." This contact would trigger an automatic NAAT test by a Cepheid RT-qPCR assay at the central laboratory or at a local laboratory by any similar acceptable methods.

At the time of enrollment, the participants were informed that each of them would be injected with a vaccine to protect against COVID-19 infection or a saline placebo without disclosing which one of the two was injected into the participant. However, all participants were also informed that the vaccine may cause the following reactions:

- Fever ≥39.0°C (≥102.1°F).
- Redness or swelling at the injection site measuring greater than 10 cm (>20 measuring device units).
- Severe pain at the injection site.
- Any severe systemic event.

It is commonly known to the general public and especially to the informed clinical trial participants that intramuscular injection of a very small amount of sterile normal saline will not cause fever, local redness and swelling, and severe pain, or systemic reactions. The participants receiving placebo would intuitively or reasonably know that they were not injected with a vaccine and were not protected against COVID-19 disease due to the lack of any vaccine reaction after the injection. As a result, more participants receiving placebo than those receiving vaccine would report to the "site" manager when they developed any minor symptoms, such as a sore throat or a new cough for the fear of coming down with COVID-19. The site manager must investigate the symptoms reported, including ordering a RT-qPCR test by Cepheid assay to be performed at the Central Laboratory according to Protocol. The more severe cases might be tested locally by Abbott kits or Roche kits because they might have to be tested in the hospital after admission, and because many hospitals are aware of the high false positive rates generated by the Cepheid kits. The results generated by these test kits are not comparable since the Cepheid test kits using a very high Ct value up to 44.9 for "detection of SARS-CoV-2 genomic RNA" **tend to generate many more false positives than the other test kits**. A higher number of false-positive test results in the participants receiving placebo will artificially raise the efficacy of the vaccine, unless the RT-qPCR test results are verified by nucleotide sequencing to eliminate all false-positive test results.

13. Based on an MPR report published on November 8, 2020, there are only 180 confirmed cases of COVID-19 in this clinical trial series that have been analyzed to support the vaccine efficacy evaluation.[18] If the Sponsor (BioNTech/Pfizer) is unable to perform confirmatory Sanger sequencing tests on these 180 RNA extract residual samples, the Petitioner hereby offers

[18] Diana Ernst, RPh. Final Analysis Reveals COVID-19 Vaccine Candidate BNT162b2 95% Effective. MPR Report. November 18, 2020. https://www.empr.com/home/news/drugs-in-the-pipeline/pfizer-biontech-mrna-based-vaccine-bnt162b2-against-covid19-effective/.

to re-test them immediately with Sanger sequencing[19] and submit the laboratory data to support FDA's evaluation. Therefore, there is no excuse for the Sponsor to refuse using the gold standard Sanger sequencing technology for endpoint validation.

14. In summary, based on the scientific data available in the public domain and the FDA guidance, all RT-qPCR test results for detection of SARS-CoV-2 gene sequence must be considered presumptive. The Cepheid test kits for SARS-CoV-2 are known to generate more false-positive test results than other EUA assay kits.

15. The residues of the tested samples that were classified as positive for SARS-CoV-2 by the Cepheid GeneXpert assay, or equivalent as stated in the Pfizer Clinical Trial Protocol, must be re-tested by a Sanger sequencing method to confirm that the presumptive positive samples in fact contain a unique sequence of SARS-CoV-2 genome. Only then can the positive test results from the Cepheid GeneXpert test kits be accepted as an accurate component of the "endpoint." Only then can one nonspecific symptom plus laboratory positivity be accepted as a valid measure of confirmed COVID-19 cases or "endpoints."

Stay Urgently Required

16. Petitioner will suffer irreparable harm because once the FDA licenses this COVID-19 vaccine, states are expected to make this product mandatory, and hence without the FDA assuring proper safety trials of the vaccine *now*, the Petitioner will not have the opportunity to object to receiving the vaccine based on deficient clinical trials *later*.

17. For example, the New York State Bar Association recently passed a resolution recommending that "[s]hould the level of immunity be deemed insufficient by expert medical and scientific consensus to check the spread of COVID-19 and reduce morbidity and mortality, **a mandate and state action should be considered**."[20] Mandating administration of the vaccine, thereby eliminating the right to informed consent, makes acute the need to assure that the safety and efficacy of any COVID-19 vaccine is robustly studied in an adequate clinical trial monitoring for any potential adverse events.

18. Furthermore, if the vaccine is licensed without an appropriate efficacy review and without improving the accurate determination of primary endpoints, then any potential acceptance or mandate of these vaccines are likely to be based on inaccurate beliefs about the vaccine, namely that it will stop transmission of the virus from the vaccine recipient to others or that it will reduce severe COVID-19 disease and deaths. The trial protocols are not currently designed to determine whether either of those objectives can be met.

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[19] Lee SH. Testing for SARS-CoV-2 in cellular components by routine nested RT-PCR followed by DNA sequencing. International Journal of Geriatrics and Rehabilitation. 2020; 2:69-96. Available from: http://www.int-soc-clin-geriat.com/info/wpcontent/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf.

[20] https://nysba.org/app/uploads/2020/11/11.-Health-Law-Section-COVID-19-Report-September-20-2020-with-all-comments.pdf (emphasis added) (last visited November 10, 2020).

19. This request is also not frivolous and is being pursued in good faith as it seeks to increase the scientific integrity and reliability of the trials of the COVID-19 Vaccines.

20. Finally, the public interest also weighs strongly in favor of the requested relief because improving the accurate determination of primary endpoints (i) will comport with the best scientific practices, (ii) increase public confidence in the efficacy of a product expected to be mandated, and (iii) not doing so will have the opposite result in that it will create uncertainties regarding the efficacy of and need for the COVID-19 Vaccines.

21. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

Dr. Sin Hang Lee