

# COVID-19: Restoring Public Trust During A Global Health Crisis

March 23, 2021

An Evidence-Based Position Paper to Ensure Ethical Conduct



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# Preface

## **A Statement from Lead Author Dr. Henry Ealy**

*Our COVID Research Team has dedicated more than 20,000 hours into investigating all aspects of COVID-19 and producing this work. The authors feel that it is a seminal manuscript that will empower elected officials, attorneys, professional organizations, and the public to take action on behalf of good people throughout the world.*

*Our aim is to provide our readers with information pointing toward acts of willful misconduct, based largely upon what we believe is the withholding of evidence-based treatments, clear violations of federal law, unproven theories of asymptomatic transmission, fatal flaws in PCR testing, significant problems with projection models, and unethical practices that have created the possibility of poorly conceived experimental biologics being touted as the only solution to the global crisis we all face.*

*We are grateful for this opportunity to serve humanity. Our hope is that this position paper sparks actionable ideas and meaningful conversations that bring people hope and a more detailed understanding of what is truly going on, which the mainstream media has failed to properly investigate in open and honest journalism.*

- Dr. Henry L. Ealy

## **Helpful Information**

To assist readers in orienting themselves to the wide scope of information in this manuscript, our Research Team created an Executive Summary for each major topic as well as a clear table of contents. The position paper is intended to be expandable with new information as it emerges and has been carefully evaluated. Please note that four Appendix documents are also included.

## **Reprint Authorization Guidelines**

Thank you for sharing this peer-reviewed position paper. Reprint of this paper in full, or part, is authorized provided that you reference its source and include a backlink to the companion action campaign (cited in the URL below) calling for a formal investigation into the Centers and Disease Control and Prevention. This grassroots campaign, hosted by Stand for Health Freedom, can be found here: <https://standforhealthfreedom.com/action/investigate-the-cdc/>

Additionally, your organization should include an original source attribution link to the full position paper here: <https://www.greenmedinfo.com/blog/covid-19-restoring-public-trust-during-global-health-crisis>

# Table of Contents

'This Is Not Okay' – A COVID Story.....	3
Letter from the Authors .....	4
Acknowledgements.....	5
Executive Summary – Asymptomatic Transmission .....	6
Executive Summary – PCR Testing .....	7
Executive Summary – Effective Treatments.....	8
Executive Summary – Violations of Federal Law .....	10
Executive Summary – Projection Models.....	12
Executive Summary – Violations of Medical Ethics .....	14
Executive Summary – Clinical Trials and Adverse Events .....	15
An Argument in Favor of Personal Injury Civil Litigation .....	17
An Argument in Opposition to Mandates .....	18
An Argument that an Emergency No Longer Exists .....	19
Introduction.....	20
Topic 1 - Asymptomatic Transmission Never Proven .....	22
Topic 2 – PCR Testing Problems .....	38
Topic 3 – Effective Treatments For COVID .....	55
Proposal for Safe and Effective Nutritional Guidance .....	80
Topic References.....	82
Topic 4 – Violations of Federal Law and Data Quality .....	90
Topic 5 – Projection Models Lead Us Astray .....	100
Topic 6 – History of Medical Ethics .....	130
Topic 7 – Violations of Medical Ethics During COVID .....	151
Topic 8 – Formal Grand Jury Petition.....	171
Formal Citizen Petition Overview <sup>1-8</sup> .....	172
Summary of Primary Concerns .....	173

<b>Relevant Federal Agencies .....</b>	<b>174</b>
<b>Office of Management and Budget (OMB) .....</b>	<b>174</b>
<b>Office of Information and Regulatory Affairs (OIRA).....</b>	<b>174</b>
<b>Department of Health and Human Services (HHS) .....</b>	<b>174</b>
<b>Centers for Disease Control and Prevention (CDC).....</b>	<b>174</b>
<b>National Center for Health Statistics (NCHS).....</b>	<b>175</b>
<b>National Vital Statics Service (NVSS) .....</b>	<b>175</b>
<b>Relevant Law .....</b>	<b>175</b>
<b>Administrative Procedures Act (APA) .....</b>	<b>175</b>
<b>Paperwork Reduction Act (PRA) .....</b>	<b>175</b>
<b>Creation of the Office of Information of Regulatory Affairs (OIRA) .....</b>	<b>175</b>
<b>Information Quality Act (IQA) .....</b>	<b>175</b>
<b>Additional Exhibits .....</b>	<b>179</b>
<b>Additional Considerations Regarding the APA .....</b>	<b>181</b>
<b>Disclaimer .....</b>	<b>184</b>
<b>Authors and Reviewers .....</b>	<b>185</b>
<b>Appendix .....</b>	<b>186</b>
<b>Dr. Lee’s Petition to FDA For Stay of Phase 2/3 Pfizer Clinical Trial</b>	
<b>FDA Response to Dr. Lee’s Petition</b>	
<b>Dr. Lee’s Reply to FDA’s Response</b>	
<b>Allegheny County v. The Cracked Egg</b>	

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# 'This Is Not Okay' – A COVID Story

Last year, the fear of God was put in my 80-year-old mother's mind.

She was babysitting for my brother and had a routine doctor's visit during which she was told that she needs to stop babysitting immediately. "I don't think you understand. If you get this virus, you die," said her doctor. My mother called me crying, and I was so disheartened and angry.

My parents immediately removed themselves from our lives, stopped regular visits, and have since done only outdoor visits from a distance. Back in March 2020, my oldest brother in Brooklyn told me, "I'll see you in 2021!" My kids were baffled, and all of us were devastated that he told us he'd see us so many months from now. It seemed so far away and yet he stood by his word!

My entire family has been separated for a year—no 80th birthday celebration for my mother, no Hanukkah or family meals, no graduations, dozens of missed grandkids' birthdays ... everything!

I've sent my mom literature about protecting herself by supporting her immune system and about the stats suggesting a very high success rate for surviving COVID and thought she might be listening.

So, when my 11-year-old daughter whispered in my ear, "Mom, do you think it would be okay if I put a mask on and sanitize my hands and ask grandma if I could give her a hug at the waist?" I replied, "Yes, ask her."

Worried about the reply, she asked me to do it.

So, standing in my mother's garage in the freezing cold for our visit, and still standing 6 feet away, I asked my mom, "Elliana wants to know whether or not she can hug you at the waist with a mask on and sanitized hands?"

My mother replied, "Elliana, I'm so sorry; maybe this thing will be done by March when it's your birthday." My daughter turned away devastated; but always a pleaser, she didn't want my mom to see how upset she truly was. She buried her head in my armpit to hide her face and leaned into me.

I think we were both so shocked. And, as my mom tried to talk to her in a lighthearted manner to make it better, my daughter was quickly overwhelmed with emotion, devastated by the rejection of her request to hug her grandmother.

In that moment, it became crystal clear that what is going on is not okay.

My daughter was speechless, and while she was trying not to hurt her grandma's feelings, she also could not bring herself to tell her grandma that, "it's ok."

Never in my life have I witnessed a child being turned away by a loving, selfless grandmother who lives for her grandchildren. This was THE moment that it became even more apparent all the pain and hurt that this pandemic has truly inflicted upon us all.

# Letter from the Authors

During our investigation into the variety of topics this manuscript covers, a theme began to stand out as a consistent concern. Safe and effective treatments for COVID-19 are inexplicably being withheld.

As you read this position paper, you will encounter many similar examples of what appears to be willful misconduct on the part of government agencies supplying inaccurate information to elected officials and the public at large.

While incessant arguments persist regarding the accuracy of polymerase chain reaction (PCR) testing, asymptomatic transmission, dubious projection models, and alleged violations of federal law, the issue that is still inexplicably unresolved is the withholding of safe and effective treatments from millions of people most in need.

The sad reality is that loved ones are still dying alone. Children are still being isolated from their in-person classrooms, dear friends, and other systems of support. Experimental COVID biologics (vaccines) are being tested on millions of individuals, with scant short-term data and no long-term data to ensure safety. All the while, significant nutrient deficiencies that adversely impact the natural adaptive immune response (vitamins A, C, D, E, and the mineral zinc) have yet to be resolved.

Imagine how many lives could have been, and still could be, saved if public health departments widely promoted the use of evidence-based nutritional therapies. Yet, these evidence-based treatments (also effective at prevention) continue to be ignored by major health organizations such as the CDC, WHO, and NIH in spite of their ease of use and cost-effectiveness.

We ask, *“Is it ethical to withhold evidence-based treatments, proven to be safe and effective, from people in need?”* Historically, this question has been answered with a resounding “no.” Yet this is where we find ourselves again: once again, more embroiled in an age-old struggle to an ethical question we have already repeatedly answered correctly. **A common ground we must all be able to reach is that it is unethical to withhold evidence-based treatments proven to be safe and effective from people in need.**

When we fail to remember our history, inevitably our history repeats itself. To ensure that life, liberty, and the pursuit of happiness are preserved for future generations, people must be presented with accurate scientific data and evidence-based options to make their own informed decisions with regard to their health.

Ethically, no one should be vaccinated with experimental biologics while those biologics are still in clinical trial, especially when safer and more effective treatments already exist.

Perhaps the question that matters most is, *“Does a government, employer, airline, school or other entity have the right to mandate the use of an experimental product with limited safety data—and that is still in an ongoing clinical trial?”*

When living in a free and collective society, this may be the most important question we need to answer.

We believe that governments, employers, airlines, and schools do not have the right to mandate the use of products still in clinical trial. This position paper substantiates our point of view with respect to medical ethics, civil liberties, and individual bodily sovereignty. Our findings call into question numerous scientific and ethical problems surrounding the COVID-19 global crisis response and raise questions of willful misconduct.

Thank you for considering our findings objectively.

# Acknowledgements

## People Worthy of Our Remembrance

Throughout this position paper, at the end of each topic, you will see our heartfelt attempt to honor people that have been lost during this crisis. We acknowledge the potential sensitivity of adding this to a science-driven position paper. Please allow us to share our intention for your consideration.

We are all on edge as we get bombarded with numbers, numbers, and more numbers. It is our position that the constant promotion of cases, hospitalizations, and deaths has promoted a loss of humanity. By acknowledging individuals who have passed away, we recognize that humans are not just numbers and statistics.

Throughout this unprecedented time, the fact that we all still have feelings has not changed, and many of us are hurting for a variety of completely valid reasons. Much of the suffering we have endured could have been prevented had obvious solutions not been ignored and openly attacked by the FDA and mainstream media. As human beings, we are more than an aggregate of mathematical calculations.

The inspiration for this section was a realization that weighs heavily on the hearts of all good people: *“Why are we only talking about numbers? Why are we not talking about the people that make up those numbers?”*

To the family members of the people we are honoring, we sincerely hope our position paper respectfully voices the love you have for your departed. By using your published quotes, the story of your loved ones can be heard in your words. As tears stream down my face, I say to you on behalf of my team and my family, we feel your pain ... we have lost loved ones too. I very much want to give each of you a hug, so I hope my words reach your heart in the spirit in which they are composed. We are fighting to make this right. We hope that in doing so, we are honoring your loved ones.

– Dr. Henry Lee Ealy

## The Intention of Our Position Paper

The intention of our position paper is to honor our departed and everyone who has sacrificed so much so that we all might live free. In our opinion, discriminate censorship of genuine attempts to help this crisis is a major problem, as has been the repeated suppression of effective treatments for COVID-19.

Censorship of science at any time is a direct attack upon everything we hold dear. It is a direct insult to the sacrifices made throughout this crisis by billions of well-intentioned people whose lives have been forever changed. This is why we are calling for a special grand jury investigation and formal congressional hearing into the alleged acts of willful misconduct that led to violations of federal law, medical ethics, and our constitutional rights. The agencies entrusted with protecting the citizens of our nation must be held accountable to ensure that incidents of this magnitude never happen again.

Detailed empirical evidence matters. This position paper is our effort to provide that detailed empirical evidence for your consideration. Difficult conversations remain, and difficult conversations require the most accurate information available.



# Executive Summary – Asymptomatic Transmission

- The theory of asymptomatic transmission as a driver of infective spread and fatalities is overstated at best and fatally flawed at worst.
- **Wuhan Participant Study** - 9,898,828 enrolled participants were tested using qualitative COVID RT-qPCR testing. Only 300 possible asymptomatic carrier candidates were identified. Of the 300 possible asymptomatic carriers, all were tested using live cell cultures to determine if their PCR samples could produce replication-competent virus. All 300 live cell cultures were negative for being able to produce replication-competent virus, indicating that none of the 300 people identified as potential asymptomatic carriers from the 9,898,828 people tested were infectious. Therefore 0.00% of COVID transmissions were asymptomatic.
- **U.S. Projection Study** - Zero participants were enrolled, yet the study was still sanctioned by the CDC. This published manuscript is a mathematical projection model estimating the percentage of people that tested positive and were presumed asymptomatic based upon a number of dubious assumptions. It asserts that 59% of COVID transmissions in the United States were asymptomatic.

Category	Wuhan Study	US Study
Location	Wuhan, China	None
Publishing Journal	Nature	JAMA
Publishing Date	11/20/2020	1/7/2021
Peer-Reviewed	Yes	No
Enrolled Participants	9,898,828	0
Methods	PCR, Antibody, Viral Culture	Math Assumptions Only
Suspected Asymptomatic Carriers	300 Total	NA
Actual Asymptomatic Carriers	29 Possible	NA
Asymptomatic Contacts	1,174	None
Asymptomatic Contacts Infected	0	NA
Asymptomatics w/ Replication Competent Virus	0	NA
% Asymptomatic Carriers	0.00029%	Not Stated
% Asymptomatic Transmitters	0.00000%	59%

Wuhan Study - <https://www.nature.com/articles/s41467-020-19802-w>  
 US Study - <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707>

- The theory of asymptomatic transmission is yet to be definitively proven. There are 5 gold-standards of medical investigation: (1) Confirmed absence of clinical symptoms; (2) Confirmed serologic presence of viral antigen load; (3) Confirmed serologic absence of IgM and IgG antibodies; (4) Confirmed ability of nasal sample to produce replication-competent virus in live human cell culture; and (5) Confirmed infective spread to a susceptible host. For a person to be infectious, including persons assumed to be asymptomatic without definitive laboratory evidence, their nasal or serologic sample must be able to produce replication-competent virus in a live human cell culture.
- Until evidence exists regarding replication-competent virus in human cell cultures, the theory of asymptomatic transmission should not be used as a basis for public health policies for otherwise healthy individuals.



# Executive Summary – PCR Testing

- RT-qPCR tests are quantitative tests. However, it appears PCR testing is intentionally being used qualitatively. To use a test not calibrated to be used diagnostically, as the primary diagnostic tool is a poor decision and brings forward questions of willful misconduct.
- Current Qualitative COVID RT-PCR testing is not calibrated to be used diagnostically. Yet, according to a meta-analysis by Jefferson, attempts to calibrate it to determine infectiousness are being made.

PROPOSAL FOR CALIBRATING COVID RT-qPCR TESTING BASED UPON VIRAL REPLICATION-COMPETENCE		
DIAGNOSTIC INTERPRETATION	CYCLE THRESHOLD	PROPOSED ACTION
Infectious	< 25.00	Quarantine/Isolation Until No Longer Symptomatic + 2 Days. Administration Of Evidence-Based Nutritional Guidance. Retest Serologic Antibodies To Confirm (+ IgG, - IgM).
Possibly Infectious	25.00 - 33.99	Confirmatory Lab Testing. Serologic Antigen Or Live Human Cell Culture. Quarantine/Isolation Until Confirmed. Administration Of Evidence-Based Nutritional Guidance As Precaution.
Not Infectious	≥ 34.00	Recommendation Of Evidence-Based Nutritional Guidance As Precaution.

Oxford Academic (Jefferson) - <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217>  
 NEJM Hospital Study - <https://www.nejm.org/doi/full/10.1056/NEJMc2027040>  
 Caco-2 Cell Human Cell Line Infectiveness - <https://pubmed.ncbi.nlm.nih.gov/32966582/>  
 VERO Monkey, HU7 D Human, 293T Human Cell Line Infectiveness - [https://wwwnc.cdc.gov/eid/article/26/6/20-0516\\_article](https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article)

- According to CDC, current testing continues to detect traces of past SARS-CoV-2 infections for as many as 12 weeks after the end of the infectious period.
- According to PhD Molecular Geneticist Dr. Pieter Borger and former Pfizer Chief Scientist Dr. Michael Yeadon, there are 10 major problems with the current version of qualitative COVID RT-PCR testing. They stated this **“renders the SARS-CoV-2 PCR test useless”** because of the increased likelihood of false positive results and the inability to determine infectiousness.
- Current Qualitative COVID RT-PCR testing **“cannot discriminate between the whole virus and viral fragments. Therefore, the test cannot be used as a diagnostic for intact (infectious) viruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus and make inferences about the presence of an infection.”**
- Current Qualitative COVID RT-PCR testing cannot determine an infectious individual compared to a non-infectious individual. Therefore, the current testing invalidates all studies that have used it as the sole diagnostic laboratory method of evaluation. This includes the Pfizer/BioNTech Phase 2/3 experimental biologic clinical trials.
- Doctors and nurses working on the front line deserve to have the most accurate diagnostic tools to determine a definitive diagnosis and help mitigate the spread of the infection. Before consenting, people deserve to know the limitations of PCR testing.
- Clinical trials for experimental COVID biologics (vaccines) should be required to use accurate diagnostic tools ensuring that the safety and efficacy of the biologic can be assessed. The use of a single test that is not calibrated to be used diagnostically opens the door for inaccurate data collection and analysis. A formal legal petition by Dr. Sin Hang Lee on November 25, 2020 explained this issue to the FDA, but the FDA dismissed his concerns as lacking “scientific merit,” despite Dr. Lee’s obvious credentials as an expert in the field.

# Executive Summary – Effective Treatments

- **“Science is being suppressed for political and financial gain. Covid-19 has unleashed state corruption on a grand scale, and it is harmful to public health...When good science is suppressed by the medical-political complex, people die.”** - Kamran Abbasi, executive editor of the British Medical Journal  
<https://www.bmj.com/content/371/bmj.m4425>
- The overwhelming evidence obtained through the analysis of federally funded and published National Health and Nutrition Examination Survey (NHANES) data indicates that a significant percentage of the U.S. population is clinically deficient in essential micronutrients—vitamins A, C, D, E, and zinc. NHANES data should not be ignored and excluded from clinical application during a national health crisis.

Nutrient	RDA/EAR/ODI	Adults 2005-2016	Nutritional Deficit For Minimum Requirements	% US Population Deficient*
Vitamin A	2,333-3,000 IU	2,130 IU	870 IU	35-45%
Vitamin C	75-200 mg	83 mg	117 mg	37-46%
Vitamin D	600-800 IU	188 IU	612 IU	65-95%
Vitamin E	22-200 IU	13 IU	187 IU	60-84%
Zinc	8-30 mg	12 mg	18 mg	11-15%

Data Source: NVSS Published By CDC - <https://www.cdc.gov/nchs/nhanes/index.htm>  
 \*Low End Of Range Adjusted For Supplemental Nutrient Intake Plus Dietary Intake - Reider, C. A., Chung, R.-Y., Devyarshi, P. P., Grant, B. W., & Hazlet's Mitmesser, S. (2020). Inadequacy of Immune Health Nutrients: Intakes in US Adults, the 2005–2016 NHANES. *Nutrients*, 12(6), 1735. doi:10.3390/nu12061735

- An overwhelming body of evidence-based studies exists to support the use of foundational nutritional guidelines that drastically reduce hospital burden and disease severity while enhancing and expediting recovery from COVID-19.
- One study used vitamin A (100,000 IU/day), vitamin C (1,000mg/hour during waking), vitamin D (50,000 IU/day), and Lugol’s Iodine (25mg). **One hundred seven out of 107 patients fully recovered within seven days of treatment.**
- A Chinese hospital treated 50 cases of moderate to severe COVID-19 infection with intravenous ascorbic acid (IVAA). The dose strategy was 100% effective at successful management of cytokine storms. There were no side effects reported from any patients in the IVAA group. Although COVID-19 patients had a 30-day hospital stay on average, COVID-19 patients who received IVAA had a hospital stay that was three to five days shorter compared to the non IVAA treated patients. **All 50 patients who received IVAA recovered, and no mortality was reported in the IVAA group.**
- Vitamin D3 has been shown to significantly reduce ICU admission rates as well as reduce the severity of COVID-19 disease. Of the 50 total patients who received vitamin D3, one was admitted to the ICU (2%). Of the 26 patients who were not administered vitamin D3, 13 were admitted to the ICU (50%). **Of the 50 patients treated with vitamin D3, zero deaths occurred, and all 50 patients were discharged without complications.**
- Vitamin D deficiency was associated with increased hospitalizations (OR = 1.81, 95% CI = 1.41–2.21), and increased mortality (OR = 1.82, 95% CI = 1.06–2.58). Individuals with severe cases of COVID-19 were 64% more likely to be vitamin D deficient than those with mild cases of COVID-19 (OR = 1.64; 95% CI = 1.30–2.09). Among critically ill populations, **vitamin D deficiency is associated with higher infection rates, increased incidence of sepsis, and increased mortality risk.**

- In another study, 57% of COVID-19 patients were zinc deficient. These patients had **“higher rates of complications ( $p = 0.009$ ), acute respiratory distress syndrome (18.5% vs 0%,  $p = 0.06$ ), corticosteroid therapy ( $p = 0.02$ ), prolonged hospital stay ( $p = 0.05$ ), and increased mortality (18.5% vs 0%,  $p = 0.06$ ).”**
- Ivermectin – **“Viral clearance was treatment dose- and duration-dependent. In six randomized trials of moderate or severe infection, there was a 75% reduction in mortality (Relative Risk=0.25 [95%CI 0.12-0.52];  $p=0.0002$ ); 14/650 (2.1%) deaths on ivermectin; 57/597 (9.5%) deaths in controls) with favorable clinical recovery and reduced hospitalization.”**
- **Hydroxychloroquine (HCQ)** – A meta-analysis of 192 studies concluded that HCQ is effective when used early. Early treatment is most successful, with 100% of studies reporting a positive effect and an estimated reduction of 67% in the effect measured (e.g., death, hospitalization, etc.) using a random effects meta-analysis (RR 0.33 [0.25-0.43]).
- The inclusion of evidence-based nutritional research must become an integral component of modern medical practice. **Effective natural and pharmaceutical treatments for COVID-19 exist and have been withheld from people in need throughout this crisis, which raises the question of willful misconduct.**

## Our Proposal for Safe and Effective Nutritional Guidance

### Seniors, Adults, and Teens

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,500-2,167 IU
VITAMIN C	3000-5000 mg	65-125 mg
VITAMIN D3	10,000 IU (14-Days) 5,000 IU (After)	600-800 IU
VITAMIN E	200-600 IU	22-28 IU
ZINC	25-40 mg (min 30mg for High-Risk)	8-11 mg

### Children Ages 5 to 12

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,000-2,000 IU
VITAMIN C	2,000-4,000 mg	25-45 mg
VITAMIN D3	5,000 IU (14-Days) 2,000 IU (After)	200 IU
VITAMIN E	100 IU	10-17 IU
ZINC	25 mg	8 mg

### Children Ages 1 to 4

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	2,000 IU	1,000-1,500 IU
VITAMIN C	500-1,000 mg	15-50 mg
VITAMIN D3	1,000-2,000 IU	200 IU
VITAMIN E	50 IU	6-9 IU
ZINC	10 mg	3 mg



# Executive Summary – Violations of Federal Law

Accurate and verifiable data is essential to public health policy development. However, our research revealed that the CDC significantly compromised data quality during a time of public crisis.

- Data quality was irreparably compromised by the CDC’s implementation of the National Vital Statistics System (an inter-governmental data sharing system) COVID Alert No. 2 document on March 24, 2020, which significantly altered death certificate reporting. It was also compromised by the CDC’s adoption of the April 15, 2020 Council of State and Territorial Epidemiologists’ position paper, which defined the criteria for COVID cases—but without safeguards in place to ensure the same person could not be counted multiple times. Both practices have significantly affected data aggregation and interpretation, and both adoptions were in violation of the Administrative Procedures Act, the Paperwork Reduction Act, and the Information Quality Act at minimum.
- For the previous 17 years, pre-existing/comorbid conditions were reported in Part I, not Part II, of death certificates. By reporting in Part II rather than Part I, the role of comorbidities as cause of death has been deemphasized. This change impacts statistical aggregation according to Certified Death Reporting Clerks we interviewed. The point of contention with the 2020 change is that it was made without official notification in the Federal Register to initiate federal oversight and invite mandatory public comment.

A 77-year-old male with a 10-year history of hypertension and chronic obstructive pulmonary disease (COPD) presented to a local emergency department complaining of 4 days of fever, cough, and increasing shortness of breath. He reported recent exposure to a neighbor with flu-like symptoms. He stated that his wheezing was not improving with his usual bronchodilator therapy. Upon examination, he was febrile, hypoxic, and in

**Comment:** In this case, the acute respiratory acidosis was the immediate cause of death, so it was reported on line a. Acute respiratory acidosis was precipitated by the COVID-19 infection, which was reported below it on line b. in Part I. The COPD and hypertension were contributing causes but were not a part of the causal sequence in Part I, so those conditions were reported in Part II.

**Scenario 1**

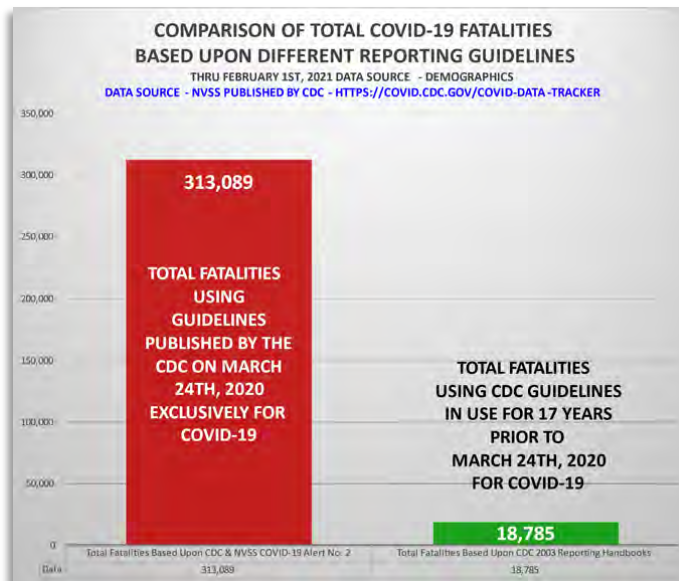
CAUSE OF DEATH (See instructions and examples)		Approximate interval: Onset to death
32. <b>PART I.</b> Enter the <u>chain of events</u> —diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.		
IMMEDIATE CAUSE (Final disease or condition resulting in death)	a. Acute respiratory acidosis Due to (or as a consequence of):	3 days
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the <b>UNDERLYING CAUSE</b> (disease or injury that initiated the events resulting in death) <b>LAST</b> .	b. COVID-19 Due to (or as a consequence of):	1 week
	c. _____ Due to (or as a consequence of):	
	d. _____ Due to (or as a consequence of):	
<b>PART II.</b> Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I		
Chronic obstructive pulmonary disease, hypertension		
33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No		
35. DID TOBACCO USE CONTRIBUTE TO DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> Probably <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year <input type="checkbox"/> Pregnant at time of death <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined

**77-Year-old male death certificate for COVID-19 based upon March 24, 2020 COVID Alert No. 2.**

CAUSE OF DEATH (See instructions and examples)		Approximate interval: Onset to death
32. PART I. Enter the <u>chain of events</u> —diseases, injuries, or complications—that directly caused the death. DO NOT enter terminal events such as cardiac arrest, respiratory arrest, or ventricular fibrillation without showing the etiology. DO NOT ABBREVIATE. Enter only one cause on a line. Add additional lines if necessary.		
IMMEDIATE CAUSE (Final disease or condition resulting in death)	a. Cardiac Arrest Resulting From Acute Respiratory Acidosis <small>Due to (or as a consequence of):</small>	3 days
Sequentially list conditions, if any, leading to the cause listed on line a. Enter the <b>UNDERLYING CAUSE</b> (disease or injury that initiated the events resulting in death) <b>LAST</b>	b. Influenza H1N1 <small>Due to (or as a consequence of):</small>	1 week
	c. Hypertension <small>Due to (or as a consequence of):</small>	10 years
	d. Chronic Obstructive Pulmonary Disease (COPD)	10 years
PART II. Enter other significant conditions contributing to death but not resulting in the underlying cause given in PART I		
Fever & Hypoxia		
33. WAS AN AUTOPSY PERFORMED? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
34. WERE AUTOPSY FINDINGS AVAILABLE TO COMPLETE THE CAUSE OF DEATH? <input type="checkbox"/> Yes <input type="checkbox"/> No		
35. DID TOBACCO USE CONTRIBUTE TO DEATH?  <input type="checkbox"/> Yes <input type="checkbox"/> Probably  <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown	36. IF FEMALE: <input type="checkbox"/> Not pregnant within past year  <input type="checkbox"/> Pregnant at time of death  <input type="checkbox"/> Not pregnant, but pregnant within 42 days of death  <input type="checkbox"/> Not pregnant, but pregnant 43 days to 1 year before death  <input type="checkbox"/> Unknown if pregnant within the past year	37. MANNER OF DEATH  <input checked="" type="checkbox"/> Natural <input type="checkbox"/> Homicide  <input type="checkbox"/> Accident <input type="checkbox"/> Pending Investigation  <input type="checkbox"/> Suicide <input type="checkbox"/> Could not be determined

**The 77-year-old male's death certificate for H1N1 flu based upon CDC handbooks used for 17 years.**

- To have accurate mortality metrics, we must openly advocate for an independent expert panel of medical examiners, coroners, and physicians with death reporting experience to audit all death certificates associated with COVID-19.
- Each fatality with a confirmed PCR test is required to have a record at the conducting lab for the date of the test and the cycle threshold (Ct) value associated with the positive lab result. If we were able to have the date of the death certificate, the date of the positive PCR, the Ct value at which a signal was detected on the individual's PCR, and a basic knowledge of pre-existing/comorbid conditions from medical records, then the death count could be audited for a better understanding of the number of people who died from COVID, how many died with COVID, and how many died but were previously mis-categorized as COVID fatalities.
- The correction of death counts is anticipated to be significant but may be as large as the graphic below:**



# Executive Summary – Projection Models

- ***“The death rate is a fact; anything beyond this is an inference.”*** – Dr. William Farr

Unfortunately, with respect to COVID-19 and the NVSS COVID Alert No. 2 document issued on March 24, 2020, this brilliant observation is no longer applicable.

- From the start, computer projection models were widely adopted as a means to manage the COVID-19 health emergency. People around the world were concerned about the harm associated with COVID-19 long before it was possible to know any of the potential repercussions of the virus.
- All computer projection models make assumptions and require inputs. Understanding these aspects of the model is crucial to understanding model outputs. Unfortunately, vast uncertainty surrounds most inputs, especially at the start of a public health crisis.
- One assumption, central to all current COVID-19 models, is that the spread of germs is the main factor in disease transmission, even though susceptibility to infection is the main factor. Many models assume everyone is equally susceptible. Susceptibility depends on variables such as available nutrient status, pre-existing conditions, age, genetic predispositions, socioeconomic factors, individual mental outlook, stress exposure, restorative sleep, bioaccumulation of chemical pollution, environmental exposure, place of residence, and multiple other factors unique to the individual.
- Many COVID-19 projection models presume the frequency of asymptomatic transmission. The underlying assumption is that such infection *is possible*. This assumption, though widespread, is contradicted by the extensive study of nearly 10 million people carried out in Wuhan, China.
- A 2018 modeling study noted, ***“In practice, incorporating asymptomatic carriers into models is challenging due to the sparsity of direct evidence.”***
- Stochastic models, such as the Institute for Health Metrics and Evaluation (IHME) model, must manipulate data to obtain useful inputs. This may involve using means, using medians as proxies, using moving averages, imputing values to fill in missing data, dropping numbers that seem too large, and using Gaussian regression to smooth the resulting smorgasbord of adjustments. Each input becomes its own model within a model.
- One of the early attractions of the IHME model was its “ability” to forecast hospital demand. For New York State, as of April 4, 2020, the IHME model projected a need for 65,400 hospital beds. 15,905 beds were actually used, and new hospitalizations continued to decline. For that same date, the IHME model projected a need for 12,000 ICU beds but only 4,100 were used.
- Another attraction of the early IHME model was that its projected numbers in bands narrower than rival models, suggesting its estimations were more precise. Considering data is so scarce and unreliable at the start of an epidemic, narrow estimation bands cannot be legitimate and should be assumed to misrepresent the accuracy of the projections.
- In general, there is no way for officials to evaluate how exactly a disease projection model’s inputs and assumptions affect its output. Nor is there a practical way for officials to verify that a model’s code and data are secure, or that the model works as advertised. Officials choose to rely on a model, *not* because of the accuracy of the model, but for reasons that are often undisclosed.

- **The Imperial College COVID Model caused international panic by using a model that predicted a vast number of deaths from COVID-19.** When the model’s programming was finally made public, it was learned by an independent investigation that the team, led by epidemiologist Neil Ferguson, had cleaned up the code with the assistance of Microsoft. This raises additional questions of the presence of willful misconduct.
- Insurance companies might be a better choice than academic institutions to develop projection models. ***“Insurers employ modelers and data scientists, but also employ managers whose job is to decide whether a model is accurate enough for real world usage and professional software engineers to ensure model software is properly tested, understandable and so on. Academic efforts don’t have these people, and the results speak for themselves.”***
- Early diagnostic models were as inaccurate as early projection models. In the beginning of April 2020, just a few months after the first cases of COVID-19 appeared in the United States, over 4,900 studies analyzing diagnostic models had already been conducted and published. A meta-analysis concluded, ***“...proposed [diagnostic] models are poorly reported, at high risk of bias, and their reported performance is probably optimistic. Hence, we do not recommend any of these reported prediction models for use in current practice.”***
- Regardless of how impressive the model is, or how well it fits the past, the future is always unpredictable.



# Executive Summary – Violations of Medical Ethics

- For more than 2,000 years, the first fundamental law governing the safe and effective practice of medicine has been exceedingly clear ... 'Do No Harm.' It is a powerful statement that establishes the primary responsibility each practitioner has with respect to his or her patients and forms the foundation for the key concepts shaping virtually all ethics for medical conduct.
- Withholding evidence-based treatment from 399 American men during the Tuskegee Experiment was evidence of willful misconduct and the impetus for our current medical ethics laws. From 1943 to 1972, evidence-based treatment for syphilis was willfully withheld from 399 participants enrolled in the Tuskegee Experiment. **With this understanding, would the withholding of evidence-based treatments from 332 MILLION Americans during COVID-19 also be considered willful misconduct?**
- More than 12 months since the first confirmed case of COVID-19 in the United States, the FDA and CDC have not approved any affordable evidence-based treatments currently being used in other countries with great success. **How many lives could have been saved if the FDA authorized the use of intravenous ascorbic acid (IVAA), oral nutritional therapies (vitamins D, C, A, E, and zinc), ivermectin, and hydroxychloroquine during the summer of 2020 instead of politicizing and attempting to invalidate these treatments proven to be safe and effective?**
- Informed consent laws codified as 45 CFR 46 came into existence to protect human participants in clinical trials and any medical/scientific experiments following the Nuremberg Military Tribunal and Tuskegee Experiment.
- 45 CFR 46.116(b)(8) explicitly protects a person's right to decline participation in any clinical trial: ***"A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;"***
- Since the **Moderna/NIH clinical trial does not end until October 27, 2022**, and the **Pfizer/BioNTech clinical trial does not end until January 31, 2023**, the experimental COVID biologics (vaccines) are considered to be under investigation for safety and efficacy until the trials conclude. With this in mind, every person has the right to decline the use of an experimental product still in clinical trial. On this point, we must stand resolute in protecting the individual civil rights each person has over their own bodily sovereignty that is protected by existing informed consent laws.

# Executive Summary – Clinical Trials and Adverse Events

## Author's Note Regarding Use of the Words 'Vaccine' and 'Biologic'

Our investigation has raised legitimate concerns whether the current new medical technologies developed by the Pfizer/BioNTech and Moderna/National Institutes of Health (NIH) partnerships meet the legal criteria for categorization as vaccines or as gene therapies. Until a legal ruling is made, we respectfully decline to refer to the new mRNA technologies as vaccines or gene therapies. Throughout this position paper, we will refer to the new technologies as **experimental COVID biologics**, which is intended to be both scientifically neutral and legally accurate.

- According to the federal Vaccine Adverse Events Reporting System (VAERS), **1,739 people have died** and **38,444 people have experienced adverse events** after receiving experimental COVID biologics for records reported from December 13, 2020, to March 12, 2021.
- As stipulated by the emergency use authorization (EUA) regarding experimental COVID biologics, all healthcare providers are **REQUIRED**, for the first time in U.S. history, to report all known adverse events to VAERS.
- Moderna/NIH clinical trial is ongoing until **October 27, 2022**.
- Pfizer/BioNTech clinical trial is ongoing until **January 31, 2023**.
- Pfizer/BioNTech Phase 1 clinical trial enrolled **45 participants**.
- Pfizer/BioNTech Phase 1 clinical trial lasted **six months**.
- Pfizer/BioNTech Phase 2/3 clinical trial enrolled **43,998 participants**.
- Pfizer/BioNTech Phase 2/3 clinical trial did not prescreen for serologic IgM or IgG antibodies, qualitative COVID RT-PCR positive participants, or any other laboratory tests to ensure that enrolling participants were free from prior SARS-CoV-2 infection.
- Pfizer/BioNTech Phase 2/3 clinical trial adverse event measurement for the preliminary phase of the trial was extended by six months **for the first 360 participants only**.
- **Animal testing was not completed** on any of the experimental COVID biologics before human participants were enrolled into Phase 1 or Phase 2/3 of the clinical studies **as is required by informed consent laws**.
- The Pfizer/BioNTech clinical trial design measured serologic antibody production post vaccine administration in Phase 1 only and **in fewer than 25 enrolled participants total**. Establishing serologic antibody production is the key to determining the efficacy of the experimental COVID biologic. Considering this was not done in Phase 2/3 constitutes a major design flaw of the clinical trial because the trials cannot demonstrate that the biologic actually provides immunity.
- In the Pfizer/BioNTech Phase 2/3 clinical trial, **43,448 of the 43,998 enrolled participants received 162BNTb2 experimental COVID biologic inoculation or placebo**. The reason that 550 participants did not receive inoculations could not be located within the New England Journal of Medicine (NEJM) peer-reviewed publication.

- Only 40,137 of 43,998 enrolled participants were included in final efficacy analysis. A reason for **3,861 enrolled participants not being included in final efficacy analysis** was unable to be located within the NEJM publication.
- Only 37,706 of 43,998 enrolled participants were included in the final safety analysis. A reason for **6,292 enrolled participants not being included in final safety analyses** was unable to be located within the NEJM publication.
- Did these unaccounted participants withdraw, or were they removed from the clinical trial? If removed, what was the reason?
- Qualitative COVID RT-PCR testing was used to determine efficacy without clear disclosure of the cycle threshold value utilized to delineate a positive result from a negative result. No other testing methods were used to determine efficacy despite other tests being authorized for use.
- The **95% efficacy headline** was based upon a comparative analysis between the placebo group and the experimental group measuring how many participants tested positive for SARS-CoV-2 upon follow-up Qualitative COVID RT-PCR testing. No confirmatory antibody testing or live cell viral cultures were performed to confirm the accuracy of the PCR results or individual participant infectiousness.
- If the goal of the experimental COVID biologic clinical trial is to prove efficacy, then the question must be asked: efficacy of what? Is it the efficacy of speculative protection or the efficacy of antibody production and the subsequent ability of biologic-induced antibodies to bind to the SARS-CoV-2 virus? The clinical design and analysis checked only for speculative efficacy rather than empirical efficacy and did so unreliably.
- The Pfizer/BioNTech clinical trial was flawed with respect to design and analysis, making it impossible to independently verify safety or efficacy.
- In cases where causation of injury or death can be proven based upon medical records reported to VAERS, a case can be made for private right of action in civil court. Rushing poorly tested experimental COVID biologics to market when evidence-based treatments exist, but are willingly withheld from people in need, creates the appearance of willful misconduct.
- Human beings should not be treated as guinea pigs.
- There must always be freedom of medical choice, especially when risk of injury is possible.
- ***“To make decisions about the care the physician recommends and to have those decisions respected, a patient who has decision-making capacity may accept or refuse any recommended medical intervention.”***  
- AMA Principles of Medical Ethics: I, IV, V, VIII, IX

#### Relevant News Reports:

##### **As serious issues mount from experimental biologics, European countries continue to suspend the use of the AstraZeneca vaccine**

<https://www.dw.com/en/coronavirus-digest-more-countries-suspend-use-of-astrazeneca-vaccine/a-56866786>

##### **India rejects Pfizer experimental COVID biologic**

<https://theprint.in/health/why-indias-expert-panel-rejected-emergency-use-nod-for-pfizer-vaccine/599529/>

# An Argument in Favor of Personal Injury Civil Litigation

## Key Questions

- Does the data support this crisis being considered an emergency?
- Does the Public Readiness and Emergency Preparedness (PREP) Act adequately protect people using an experimental COVID biologic?
- Do these experimental COVID biologics satisfy the legal definition of a vaccine?
- Does 45 CFR 46-116 and 46-117 define the sponsor of the experimental COVID biologic as the true liable party?

## Argument (See ‘Violations of Medical Ethics’ and ‘Effective Treatments for COVID-19’)

As of March 12, 2021, according to VAERS records, 1,739 people have died after receiving the experimental COVID biologics. Additionally, 38,444 people have been injured. Emergency Use Authorization (EUA) law requires the reporting of all adverse events for experimental COVID-19 biologics to VAERS.

The key to the argument may be that the experimental COVID biologics are still in ongoing clinical trials. The clinical trial for the Moderna/NIH biologic ends October 27, 2022. The clinical trial for the Pfizer/BioNTech biologic ends January 31, 2023.

Both experimental COVID biologics are still in clinical trials while evidence-based treatments exist. As such, anyone receiving either experimental biologic must be afforded the same legal protections under 45 CFR 46 as the enrolled participants. We are in unprecedented legal territory. Everyone who consents is now an unknowing participant in a global medical experiment.

Should the FDA have issued EUAs for experimental COVID biologics while safe and effective evidence-based treatments exist?

The experimental COVID biologics are still in clinical trial, which proves they are (1) experimental; (2) not FDA approved; and (3) should not be available to anyone outside of the clinical trial without their informed consent. Entry into the clinical trial is the lawful means for access to the experimental COVID biologics.

45 CFR 46-116(j) may make the sponsor of the trial and/or federal agencies liable for injuries resulting from the use of the experimental products. If withholding effective treatments rises to the level of willful misconduct, it may create a private right of action outside of the Public Readiness and Preparedness (PREP) Act.

## Key References

- PREP Declaration & Amendments - <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>
- Clinical Trials - <https://clinicaltrials.gov/ct2/show/study/NCT04368728> & <https://clinicaltrials.gov/ct2/show/NCT04470427>
- Civil Immunity - <https://www.law.cornell.edu/uscode/text/42/300aa-11> & <https://www.law.cornell.edu/uscode/text/42/300aa-22>
- Informed Consent Laws - [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)
- Informed Consent Laws - [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117)

# An Argument in Opposition to Mandates

## Key Questions

- Which populations were excluded from the experimental COVID clinical trials?
- Are the clinical trials complete?
- Under 45 CFR 46-116 and 46-117, does the federal government or any private business have the right to force a child or employee to use an experimental COVID biologic that remains in clinical trial status?

## Argument (See 'Effective Treatments for COVID-19' and 'Violations of Medical Ethics')

The Moderna/NIH clinical trials excluded all persons under 18 years of age, pregnant and breastfeeding mothers, persons with a history of anaphylaxis and similar hypersensitivity reactions, immunodeficient populations, blood donors, and those with a history of bleeding disorders. Everyone in these populations receiving access to this experimental COVID biologic is doing so with no clinical trial data to support its safety or efficacy. The clinical trial cannot receive FDA approval until the conclusion of the trial on October 27, 2022 only if the placebo group does not receive the biologic.

Despite listing the testing age for Phase 2/3 inclusion at 12 years of age and older, the Pfizer/BioNTech clinical trials in Europe excluded all persons under 18 noting that, “persons under 18 are not eligible to be enrolled in EU clinical trials.” Persons with a history of suicidal ideation or other psychiatric conditions, immunodeficiency, history of severe vaccine reactions, pregnant and breastfeeding mothers are additionally excluded from the clinical trials. In Phase 1, the only phase to measure the efficacy of antibody response to the biologic, the following conditions that individuals suffered from and thus excluded from the group of 45 total participants enrolled: hypertension, diabetes mellitus, chronic pulmonary disease, asthma, current vaping or smoking, history of smoking, or a BMI > 30 k/m<sup>2</sup>. Everyone in these populations receiving access to this experimental COVID biologic is doing so with no clinical trial data to support its safety or efficacy. The clinical trial cannot receive FDA approval until the conclusion of the trial on January 31, 2023 only if the placebo group does not receive the biologic.

According to Informed Consent Law (45 CFR 46) it is illegal to force, mandate, coerce, or incentivize participation into an ongoing clinical trial. Additionally, it is unethical to force children under 18 years of age to participate in a global experiment. Considering this virus, their recovery rates exceed 99.987% as of February 16, 2021.

Children need to be in school, and there are evidence-based, safe, and effective treatments that enable them and teachers to do so. People need to get back to work, and there are evidence-based, safe, and effective solutions that allow them to get back to work.

A person cannot be granted access to an experimental COVID biologic for which their demographic has not been tested or approved—and that is still in an ongoing clinical trial.

## Key References

- Clinical Trials – <https://clinicaltrials.gov/ct2/show/study/NCT04368728> & <https://clinicaltrials.gov/ct2/show/NCT04470427>
- Informed Consent Laws - [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)
- Informed Consent Laws - [https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117)

# An Argument that an Emergency No Longer Exists

## Key Questions

- Does current COVID data still warrant a state of emergency?
- How many Americans have recovered despite evidence-based treatments being withheld?
- What are the specific statistical criteria that define a pandemic and a public health emergency?

## Argument

While challenging executive authority has proven to be increasingly difficult, it is important to note that at the time of this publication, many Americans are currently living under executive authority for the longest period in our history that did not involve a World War.

Demographic	Cases	Fatalities	Fatality Rate	Est. Recovery Rate
Age 0 to 17	2,323,592	298	0.013%	99.987%
Age 18 to 49	11,015,803	15,547	0.141%	99.859%
Age 50 to 64	4,206,743	50,217	1.194%	98.806%
Total 0 to 64	17,546,138	66,062	0.377%	99.623%
Age 65 to 74	1,589,030	73,389	4.62%	95.38%
Age 75+	1,340,638	208,804	15.57%	84.43%
Total 65 & Over	2,929,668	282,193	9.63%	90.37%
Total	20,475,806	348,255	1.701%	98.30%

Data Source - NVSS Published By CDC - <https://covid.cdc.gov/covid-data-tracker>

As of February 16, 2021, more than 18 million Americans have recovered from a SARS-CoV-2 infection as defined by the CDC. The Oregon Health Authority has reported that less than 0.8% of infected persons will experience long-term effects that require more than 37 days to fully recover.

When evaluating case, fatality, and recovery data it is important to assess it based upon age demographics and pre-existing health conditions. Because data for pre-existing health conditions is sparse nationally, it forces analysis of data to be relegated to age demographics. (Note: the New York State Department of Health and several other state health departments have done an excellent job of reporting pre-existing health conditions)

When evaluating COVID case, fatality, and recovery data based upon age demographic distribution, it is clear that COVID does not constitute an emergency in people under 65 years of age. With fatalities in people 65 and older constituting 81% of total fatalities, and knowing that 36-42% of these fatalities have occurred in senior assisted living centers and similar venues, it creates the opportunity to clearly define in which populations, and at which venues, emergency situations still exist more than 12 months after this crisis began.

## Key References

- CDC Data Tracker – <https://covid.cdc.gov/covid-data-tracker/#demographics>
- Oregon Health Authority Weekly Report page 36 of 40 - <https://www.oregon.gov/oha/covid19/Documents/DataReports/COVID-19-Weekly-Report-2021-2-18-FINAL.pdf>
- AARP COVID Deaths in Nursing Homes - <https://www.aarp.org/caregiving/health/info-2021/nursing-homes-new-years-covid-deaths.html>

# Introduction

Throughout this crisis, life as we knew it changed without warning and without the input of billions of people around the world who bear the disproportionate burden of these changes every day.

What began in the United States as an ill-fated, two-week attempt to “flatten the curve” morphed into a seemingly never-ending extension of executive orders and restrictive public health policies based largely upon inaccurate projections, illegally compromised data, unproven theories of asymptomatic infective spread, and severely flawed PCR viral fragment testing.

At the time of this publication, the same mitigation strategies that have proven ineffective for more than a year now continue to be implemented and enforced under threat of law in many places.

What is done is done, but what has been done does not necessarily have to continue. We have the ability and evidence to re-evaluate executive orders and public health policies by taking objective approaches guided by accurate data and legitimate research now available throughout the world.

Some well-intentioned people have nobly sacrificed their basic human rights in good faith efforts. However, they have done so based upon fraudulent data and manipulated social narratives. These people have trusted that the institutions in place to protect the public health were promoting guidelines based upon sound scientific evidence in the best interests of life, liberty, and the pursuit of happiness. Yet, many of these people have been forced to conclude that they no longer know whom to trust. The guidelines they have followed have clearly been ineffective.

Other well-intentioned people have questioned whether this crisis qualifies as an emergency based upon the published data. These people have suffered unjustly, mourning the loss of loved ones who were forced to die alone and afraid. These people have suffered unjustly, watching their children spiral downward into depression, drug addiction, and suicide. These people have suffered unjustly, losing their jobs and businesses without any say in the matter despite being in good health and demographically at low risk for succumbing to the SARS-CoV-2 virus. These people become collateral damage and have lost more than a virus could ever take away.

**This position paper is a collection of seminal research, evidence-based science, legal arguments, and insights into potential solutions that can save lives. The information presented in this position paper is free from any financial or political conflicts of interest and published to provide information that can be independently verified.**

It is time to objectively re-evaluate all executive orders, public health policies, and guidance previously based upon fraudulently inaccurate data and soon-to-be disproven theories of transmission. We all must maintain our right to question, verify, and reform our opinions in the presence of new information because the right to do so is exactly why we live in a free society.

This position paper is written by a team of volunteer professionals with more than 20,000 collective hours of investigative research into the scientific, medical, legal and ethical aspects of COVID-19.



This position paper is written by the people, and for the people, so that we may engage in a productive, collaborative, solution-oriented dialogue. Science is not what we 'believe in,' as that is the basis for faith, and faith is wonderful in its own right.

Science is asking intelligent questions, seeking answers that can be proven, and independently verifying these answers to prove their substance. Science seeks fact and never relies upon faith.

Thankfully, science is never settled because there is no such thing as *the* science.

Science is the embodiment of diversity...diversity of intellects, curiosities, cultures, genders, perspectives, and thoughts. Science seeks to clarify and collaborate.

Our mission is to collaborate with decision makers to usher in new public health policies based upon verifiable science and accurate data to protect those of us most at risk without creating collateral damage in those least at risk.

This position paper provides key research that calls into question the many public health policy failures and proposes reasonable and logical solutions to the following topics:

- An Unproven Theory of Asymptomatic Transmission
- Fixing PCR Testing Problems
- Withholding of Effective Treatments
- Violations of Federal Law with Respect to Data Quality
- Inaccuracy of Projection Models for Public Health Policy Development
- Growing Violations of Medical Ethics

An egregious number of failures—failures that appear to constitute willful misconduct—have been made throughout this crisis that emphasize the essential need for accurate information, collaboration, oversight, and public participation in our own governance. We need accurate data for a multitude of reasons, including its significance in driving decisions; collaboration to ensure that all points of view factor into decision-making, oversight to ensure that opportunistic corruption is greatly minimized, if not outright eliminated; and public participation in our governance because all too often, people who bear the disproportionate burden of legislative decisions have the least say.

A formal petition for a special grand jury investigation into the events surrounding this crisis exists for your consideration at the end of this position paper.

Let's create the world we all want to live in by working together with accurate information.

# Topic 1 - Asymptomatic Transmission Never Proven

**Topic Introduction** – Executive orders and most public health policies related to COVID-19 mitigation strategies are primarily based upon the theory of asymptomatic transmission first proposed in March and April of 2020 but remain unproven when held to medical gold-standards of investigation. The theory asserts that a person could be positive for SARS-Cov-2, completely absent of any symptoms, and therefore unknowingly transmit the virus to another susceptible host. Theories are educated guesses. However, has a person ever been definitively proven to be an asymptomatic carrier, or is the scientific community making too many assumptions relative to this topic?

Quarantining all healthy individuals was based heavily upon the theory of asymptomatic transmission. Many projection models for how deadly the SARS-CoV-2 infection might be were based heavily upon the theory of asymptomatic transmission. The pre-emptive closure of schools, small businesses, and places of worship around the world—still ongoing after 365-plus consecutive days—was based upon the theory of asymptomatic transmission. Social distancing and mask guidance were based upon the theory of asymptomatic transmission. Yet, a new, large-scale study published by the highly respected journal, *Nature*, raises legitimate concerns that the theory of asymptomatic transmission is proving to be more science fiction than scientific fact.

**For a patient to be definitively identified as an asymptomatic carrier, at a minimum, the following gold-standards of medical investigation would need to be satisfied:**

- (1) Complete absence of any clinical signs or symptoms associated with COVID-19
- (2) Confirmed serologic presence of a viral antigen load
- (3) Confirmed serologic *absence* of IgM and IgG antibodies

#### References

- Clinical Infectious Diseases vol. 31, Oxford Academic for Diagnostic Virology, Storch
- <https://microbiologynote.com/laboratory-diagnosis-of-viral-infections/>
- <https://microbeonline.com/laboratory-diagnosis-of-viral-diseases-five-common-approaches/>

The complete absence of clinical signs or symptoms associated with COVID-19 ensures that persons with mild symptoms are excluded from a controlled study, so as not to compromise the investigative goal of confirming that asymptomatic carriers exist.

The confirmed serologic presence of a viral antigen load ensures that the virus is present in the bloodstream, and therefore a person is potentially contagious if the sample can produce replication-competent virus in a human cell culture.

The confirmed serologic absence of IgM and IgG antibodies ensures that there is no immunological response in the study subject. Presence of an immunological response confirms that a subject could not be a carrier of the virus.

If all three standards are satisfied, a subject could be confirmed to be an asymptomatic carrier.

It is important to note, as we will discuss in the PCR topic section, that Qualitative COVID RT-PCR testing is not among the gold-standards of medical investigation because Qualitative COVID RT-PCR testing is not calibrated to be used diagnostically. While there are other COVID studies that have used Qualitative COVID RT-PCR testing exclusively as the sole diagnostic criteria to assert asymptomatic transmission, the fact that the current Qualitative COVID RT-PCR test is not calibrated to be used diagnostically immediately disqualifies those studies from scientific consideration.

**Once it is established that a person could be an asymptomatic carrier, the next objective is to confirm that the same person can transmit the virus to another susceptible person using these additional gold-standards of medical investigation:**

- (4) Ability to culture replication-competent virus in any human cell line
- (5) Ability to infect any close contact or household contact

If a suspected asymptomatic carrier, based upon the three gold-standard criteria, can produce replication-competent virus in a human cell culture (not a VERO monkey kidney or other animal cell culture), they are confirmed contagious.

If there is additional evidence that a close contact or household contact contracted the virus from the asymptomatic carrier, then this could be used as anecdotal evidence to substantiate that the theory of asymptomatic transmission is a scientifically verified fact.

However, without these five gold-standards being satisfied, particularly (1) thru (4), the theory of asymptomatic transmission, upon which COVID specific executive orders and most public health policies are based, cannot be definitively proven.

Should unproven scientific theories dictate the lives of billions of people globally? The investigation of this question begins by comparing two key studies published in highly respected peer-reviewed journals.

## **Comparison of the Wuhan Participant Study to the U.S. Projection Study**

### **Wuhan Study with Nearly 10 Million Participants**

<https://www.nature.com/articles/s41467-020-19802-w>

**Key Quote** – *“Virus cultures were negative for all asymptomatic positive and re-positive cases, indicating no ‘viable virus’ in positive cases detected in this study.*

*All asymptomatic positive cases, re-positive cases, and their close contacts were isolated for at least 2 weeks until the results of nucleic acid testing were negative. Zero positive cases or their close contacts became symptomatic or newly confirmed with COVID-19 during the isolation period.”*

**Summary** – 9,898,828 enrolled participants were tested using PCR viral fragment testing set to a cycle threshold of 37 and 40 in special circumstances. 300 possible asymptomatic carrier candidates were identified. Of the 300 candidates, 110 were considered false positives because of the absence of IgM and IgG antibodies and the inability to culture replication-competent virus via nasal sample. Of the remaining 190 candidates, 161 were deemed recovered due to the presence of IgG antibodies without IgM antibodies. Their positive PCR test was likely because patients can test positive for SARS-CoV-2 up to 12 weeks following the end of their contagious phase, according to a CDC cited study from South Korea. Of the remaining 29 candidates, all had IgM and IgG antibodies indicating their natural adaptive immunity development was in progress due to a recent infection. These 29 possible asymptomatic carriers make up 0.00029% of all people tested to assess how prevalent asymptomatic carriers might be in large populations.

Under strict scientific standards, these 29 possible asymptomatic participants would not be considered carriers because they are clearly demonstrating an immunological response to the infection (IgM and/or IgG antibody production). This violates gold-standard (3), and therefore they cannot be a carrier because their body is in process of destroying the SARS-CoV-2 antigen. This is *exactly* how the process of natural adaptive immunity responds to any and all viral infections for successful recovery from infection. For the purposes of this discussion, we will include these 29 as possible asymptomatic carriers to investigate whether or not they were contagious.

Of the 300 possible asymptomatic carriers, all were additionally tested using live cell culture to determine if their PCR samples could produce replication-competent virus. All 300 live cell cultures were negative for being able to produce replication-competent virus, indicating that none of the 300 people identified as potential asymptomatic carriers were infectious.

Additionally, the 300 possible asymptomatic carriers encountered 1,174 people who were forced to quarantine for 14 days. These 1,174 people were frequently tested using PCR tests and monitored for symptom development during their quarantine. All 1,174 contact traces tested negative during each PCR test and none developed symptoms of COVID-19.

This study, the largest infectious disease study ever conducted in a single year, confirms that if asymptomatic carriers exist, they make up an insignificant percentage of any population (0.00029%). This study confirms that asymptomatic carriers are unable to produce replication-competent virus or infect susceptible hosts.

As a result, this study satisfies medical gold-standards (1), (3), (4) and (5) for definitive evaluation of the existence of asymptomatic carriers and asymptomatic transmission.

**Position** – The results of the study suggest the theory of asymptomatic transmissions as a driver of infective spread and fatalities is severely overstated at best and fatally flawed at worst.

Asymptomatic transmission should no longer be a foundational theory for any emergency executive orders or public health policies until definitively proven in the United States in accordance with the five criteria for gold-standard medical investigation to ascertain infectiousness in asymptomatic individuals.

It is essential that the scientific and medical communities be able to definitively confirm the existence of asymptomatic carriers and, if they exist, confirm that they can transmit replication-competent virus. It is crucial that medical teams have the ability to easily distinguish asymptomatic carriers from non-symptomatic recoveries, who are therefore incapable of producing replication-competent virus. A person who has recovered is non-symptomatic because they have established natural adaptive immunity against the SARS-CoV-2 virus. This is exactly the outcome all medical professionals are seeking to create.

### U.S. Projection Study Endorsed and Authorized by the CDC

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707>

**Key Quote** – *“The Centers for Disease Control and Prevention determined that this decision analytical study, which involved no enrollment of human subjects, did not require institutional review board approval.”*

**Summary** – Zero participants were enrolled. This published manuscript is a mathematical model for estimating what percentage of people testing positive were asymptomatic based upon several assumptions. It asserts that 59% of SARS-CoV-2 transmissions in the United States were asymptomatic.

COMPARISON OF STUDIES REGARDING ASYMPTOMATIC TRANSMISSION		
Category	Wuhan Study	US Study
Location	Wuhan, China	None
Publishing Journal	Nature	JAMA
Publishing Date	11/20/2020	1/7/2021
Peer-Reviewed	Yes	No
Enrolled Participants	9,898,828	0
Methods	PCR, Antibody, Viral Culture	Math Assumptions Only
Suspected Asymptomatic Carriers	300 Total	NA
Actual Asymptomatic Carriers	29 Possible	NA
Asymptomatic Contacts	1,174	None
Asymptomatic Contacts Infected	0	NA
Asymptomatics w/ Replication Competent Virus	0	NA
% Asymptomatic Carriers	0.00029%	Not Stated
% Asymptomatic Transmitters	0.00000%	59%

Wuhan Study - <https://www.nature.com/articles/s41467-020-19802-w>  
 US Study - <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707>

**Position** – The U.S. published manuscript asserts, without clinical evidence, that 59% of all people testing positive contracted the virus from an asymptomatic carrier. This mathematical model significantly contrasts the findings of the Wuhan Participant Study, which provides substantial evidence that asymptomatic carriers are an insignificant percentage of the infected total and are not contagious.

Dr. Anthony Fauci is quoted in 2020 as saying, “The one thing historically that people need to realize is that even if there is some asymptomatic transmission, in all the history of respiratory-borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person. Even if there’s a rare asymptomatic person that might transmit, **an epidemic is not driven by asymptomatic carriers.**”

So, which study more closely satisfies the five gold-standards for medical investigation? A study with almost 10 million enrolled participants or a study with zero enrolled participants?

**The Wuhan Participant Study satisfied four of the five gold-standards for medical investigation.**

**The U.S. Projection Study satisfied zero of the five gold-standards for medical investigation.**

It is important to note that the U.S. Projection Study makes multiple assumptions to be used as baselines in the mathematical modeling, but the assumptions were not presented for independent evaluation. Obviously, this presents impediments to reproducibility. Additionally, the population used to model the projections is not evident. The following statement, “*SARS-CoV-2 spread faster than SARS-CoV, and accumulating evidence showed that SARS-CoV-2, unlike SARS-CoV, is transmitted from persons without symptoms*” is irresponsible given the gravity of the situation, presented with neither reference nor empirical evidence, and therefore lacks scientific credibility.

Further, the U.S. Projection Study did not reference the use of serology testing on human subjects in their modeling. It is not clear if PCR testing was the only testing used to develop the assumptions. The manuscript stated that “*No statistical testing was conducted, so no prespecified level of significance was set.*” To state that “these results lack quantitative precision” and then make direct claims stating that “59% of all transmission came from an asymptomatic carrier” is intellectually dishonest.

**Quantitative analysis cannot be made from qualitative assumptions.** As a result, there is no reasonable means to evaluate the error rate for this study. Using studies such as these to develop public health policy for COVID-19 invites inaccurate assumptions that lead to further collateral damage.

Considering this study was published in response to the Wuhan Participant Study and sanctioned by the CDC, it demonstrates potential evidence of willful misconduct and an attempt to mislead the American public regarding the theory of asymptomatic transmission.

Mathematical models potentially have their place in forecasting provided they are based upon accurate data rather than assumptions. Projections are not data; they are only numerical assumptions. **It is important for all public health agencies to re-evaluate their public health policies regarding COVID-19 to ensure they are based upon accurate data as opposed to theories and projections.** At this time, it would be prudent to explore replicating the Wuhan Participant Study on a smaller scale, but in a major metropolitan area to confirm the accuracy of its findings. Until definitive proof that asymptomatic carriers exist, and until they are proven to be capable of producing replication-competent virus in human cell cultures, the theory of asymptomatic transmission should not be used as a basis for public health policies for otherwise healthy individuals.

As such, and as will be further demonstrated throughout this position paper, the data suggests that all children and teens must return to in-person education without restriction. All small businesses must be encouraged to reopen without restriction. All families must be empowered to legally join their loved

ones in hospital settings as health advocates, just as they have always done throughout the world before this crisis.

All masking and social distancing for people not exhibiting symptoms should be immediately discontinued due to the lack of scientific justification for asymptomatic transmission.

If a person is exhibiting symptoms, they should stay home unless medical care is required. If they must leave their home during quarantine, they should do so wearing a N95 mask and maintain appropriate social distance.

Continued practice of excellent hygiene, clinical nutrition for optimized immune performance, and caution when in contact with high-risk individuals (people over 65 years of age with pre-existing conditions) can remain in place for all non-symptomatic people but should not prohibit them from interacting with anyone in the high-risk demographic.

All non-symptomatic persons should return to life as previously enjoyed before this crisis began, without social restriction, and without any requirements for proof of vaccination or recovery from prior SARS-CoV-2 infection.

#### **Additional Subtopic Reference**

- “Although replication-competent virus was not isolated 3 weeks after symptom onset, recovered patients can continue to have SARS-CoV-2 RNA detected in their upper respiratory specimens for up to 12 weeks.” (Korea CDC, 2020; Li et al., 2020; Xiao et al, 2020).

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

## **Comparison of Symptomatic Versus Asymptomatic Household Transmission**

### **JAMA Meta-Analysis**

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102>

**Key Quote** – *“Estimated mean household secondary attack rate from symptomatic index cases (18.0%; 95% CI, 14.2%-22.1%) was significantly higher than from asymptomatic or presymptomatic index cases (0.7%; 95% CI, 0%-4.9%;  $P < .001$ ), although there were few studies in the latter group. These findings are consistent with other household studies reporting asymptomatic index cases as having limited role in household transmission.”*

**Summary** – A meta-analysis of 54 studies that included 77,758 participants confirms a common sense understanding of transmissibility for infective spread. The most likely location of transmission is in extended close contact settings such as households. Symptomatic persons in these households drive infective spread and are 25 times more likely to infect a susceptible person in the same household as compared to asymptomatic and pre-symptomatic persons.



**Position** – This study suggests that household transmission from symptomatic persons is the most likely driver of SARS-CoV-2 infective spread, as is common in most infectious respiratory diseases.

This study lends credence to several commonsense ideas regarding COVID. First, the most likely location for transmission is in the household due to prolonged contact. Second, the person most likely to be infectious is the person exhibiting symptoms. Third, asymptomatic persons, if they exist based upon gold-standards for medical investigation, are not able to transmit SARS-CoV-2 with any level of significant concern relative to symptomatic persons in the locations of highest transmissibility. This study confirms that the driver of infectious spread are symptomatic persons in household settings.

## Study Basing Asymptomatic Transmission Heavily Upon PCR Testing

**Annals of Internal Medicine**

<https://www.acpjournals.org/doi/10.7326/M20-6976#t2-M206976>

**Key Quotes** – *“Primary Funding Source: National Institutes of Health.*

*Limitation: For PCR-based studies, data are limited to distinguish presymptomatic from asymptomatic infection. Heterogeneity precluded formal quantitative syntheses.*

*Sixty-one eligible studies and reports were identified, of which 43 used polymerase chain reaction (PCR) testing of nasopharyngeal swabs to detect current SARS-CoV-2 infection and 18 used antibody testing to detect current or prior infection. In the 14 studies with longitudinal data that reported information on the evolution of symptomatic status, nearly three quarters of persons who tested positive but had no symptoms at the time of testing remained asymptomatic. The highest-quality evidence comes from nationwide, representative serosurveys of England (n = 365,104) and Spain (n = 61,075), which suggest that at least one third of SARS-CoV-2 infections are asymptomatic.*

*We know for certain who is asymptomatic only in retrospect.*

*Infection without symptoms, whether presymptomatic or asymptomatic, is important because infected persons can transmit the virus to others even if they have no symptoms (8, 9).*

*Current data suggest that infected persons without symptoms—including both presymptomatic and asymptomatic persons—account for more than 40% of all SARS-CoV-2 transmission (75–77).”*

**Summary** – This is a meta-analysis of 61 studies (43 using PCR exclusively, 18 using antibody testing exclusively). Not all studies collected in this group of 61 studies were assessing the potential role of asymptomatic transmission. For instance, reference 55, *‘Declining prevalence of antibody positivity to SARS-CoV-2: a community study of 365,000 adults’* was conducted in England and makes no mention of symptomatic versus asymptomatic spread of infection. The authors cite this reference as their most definitive proof of asymptomatic transmission.

Additionally, reference 8, which is the evidence for the author’s baseless definitive statement, *“Infection without symptoms, whether presymptomatic or asymptomatic, is important because infected*

*persons can transmit the virus to others even if they have no symptoms”* is a research study by Furukawa that uses anecdotal, unconfirmed reports from China of exactly three possible asymptomatic transmissions based upon PCR testing alone published in March and April of 2020.

**Position** – There are many flaws with this meta-analysis. Immediately, the use of references that make no mention of asymptomatic versus symptomatic or pre-symptomatic subjects is disingenuous and provides a reason why references should always be verified when assessing the credibility of a research study submitted for peer-review. The English study that included 365,000 participants measured IgG antibodies only to determine how many people likely had immunity to the SARS-CoV-2 virus. From a medical perspective, people with IgG antibodies do not qualify as asymptomatic carriers or transmitters. Instead, they are correctly classified as non-symptomatic recoveries.

Additionally, any medical assertion that the only way to know if someone was truly asymptomatic is retrospectively to pretend that the five gold-standards for medical investigation of viral infection do not exist. The assertion is either ill-informed or completely disingenuous.

As previously mentioned, any studies relying exclusively upon uncalibrated Qualitative COVID PCR testing to be used diagnostically immediately disqualifies such studies from consideration. This is clearly demonstrated by the Korean CDC study that confirmed subjects can test positive for SARS-CoV-2 viral fragments using PCR testing for up to 12 weeks following the end of their infectious period. As a result, 43 of the 61 studies used in this meta-analysis are disqualified.

For the remaining 18 that used antibody testing, all prove that an immunological response was present and therefore call into question the ability of the subject to (1) produce replication-competent virus in a human cell culture and (2) be able to transmit the virus to a susceptible host.

None of the 61 studies cited, or the references provided as substantive evidence, provided proof that even one subject was simultaneously (1) asymptomatic, (2) had a viral antigen load, (3) did not produce antibodies, and (4) produced a sample that could be cultured for replication-competent virus.

The author’s decision to group asymptomatic and pre-symptomatic cases into one group negates the reported purpose of proving asymptomatic transmission. The fact that the authors attempt to quantify transmission in this joint group by assigning a speculative percentage of 40% without mathematical proof or empirical evidence is disingenuous. Manuscripts such as these should not survive peer review.

Of interesting note is this comment left by a reader, Ali Bangash, Shifa College of Medicine, ***“With great interest, the manuscript of the research article 'The Proportion of SARS-CoV-2 Infections That Are Asymptomatic: A Systematic Review' was critically evaluated. After expressing commendation for the serious effort by authors to explore the prevalence of asymptomatic SARS-CoV-2 infections, the commenter wishes to direct the attention of the Editor towards the fact that data from preprints which have not yet been peer-reviewed have been included in the synthesis of conclusions.”***

Obviously, Mr. Bangash checks the references as well.

This study was funded by the National Institutes of Health, which has a vested financial interest in the experimental Moderna biologic. Publishing a study such as this is a potential conflict of interest and therefore potential evidence of misleading the scientific community and willful misconduct.

## Uncalibrated PCR Tests Alone Cannot Determine If a Person Is Infectious

### Oxford Academic Clinical Infectious Disease Meta-Analysis

<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217>

**Key Quotes** – *“Complete live viruses are necessary for transmission, not the fragments identified by PCR. Prospective routine testing of reference and culture specimens and their relationship to symptoms, signs and patient co-factors should be used to define the reliability of PCR for assessing infectious potential. **Those with high cycle threshold are unlikely to have infectious potential.**”*

*The estimated probability of recovery of virus from specimens with Ct > 35 was 8.3% (95% CI: 2.8% to 18.4%). All donors above the Ct threshold of 35 (n=5) producing live culture were symptomatic.*

*There is evidence of a positive relationship between lower cycle count threshold, likelihood of positive viral culture and date of symptom onset.*

*In one COVID-19 (former) case, viral RNA was detectable until day 78 from symptoms onset with a very high Ct 18 but no culture growth, implying a lack of infectious potential.*

*The results of our review agree with the scoping review by Byrne and colleagues on infectious potential periods 26 and those of the living review by Cevick and colleagues. The authors reviewed 79 studies on the dynamics, load and RNA detection for SARS CoV-1, MERS and SARS CoV-2 from symptoms onset. They concluded that although SARS-CoV-2 RNA identification in respiratory (up to 83 days) and stool (35 days) can be prolonged, duration of viable virus is relatively short-lived (up to a maximum of 8 days from symptoms onset).*

*The importance of symptom onset and reported PCR threshold is shown in a study that collected test data during a prospective household transmission study. The authors found that Ct values were lowest soon after symptom onset and correlated with time elapsed since symptom onset (within 7 days after symptom onset, the median Ct value was 26.5 compared with a median of 35.0 21 days after onset). Ct values were significantly higher among those participants reporting no symptoms, and lower in those reporting upper respiratory symptoms at the time of specimen collection.*

*The evidence is increasingly pointing to the probability of culturing live virus being related to the amount of viral RNA in the specimen and, therefore, inversely related to the cycle threshold. **Thus, detection of viral RNA per se cannot be used to infer infectiousness.**”*

**Summary** – This is a meta-analysis of 29 studies attempting to correlate Qualitative COVID RT-PCR cycle thresholds (Ct) with proof of infectiousness via live cell culture of available samples. Qualitative COVID RT-PCR viral fragment tests are experimental for COVID-19 and have never been officially calibrated to establish at which Ct value replication-competent virus is no longer viable for live cell

culture. Doing so is instrumental if Qualitative COVID RT-PCR viral fragment testing is to be used in a diagnostic capacity with any level of confidence for accuracy.

**Position** – This meta-analysis confirms that Qualitative COVID RT-PCR viral fragment testing, as currently used around the world, cannot be used diagnostically without additional confirmatory lab tests. This meta-analysis suggests that symptom presentation is key to properly calibrating PCR viral fragment tests to be used diagnostically, because persons designated as asymptomatic typically have Ct values well above the 25 to 28 range where live culture of replication-competent virus has not proven to be possible for patients deemed asymptomatic.

There are significant flaws in both the design and implementation of current Qualitative COVID RT-PCR testing for COVID-19, as will be addressed in detail following the conclusion of this topic on asymptomatic transmission.

One of the most pressing concerns is the lack of Qualitative COVID RT-PCR calibration against live virus cultures using human cell lines (Caco-2, HUH7.0, or 293T). This would be instrumental in scientifically calibrating cycle threshold values for existing PCR tests with the ability to culture replication-competent virus in viable human cell lines, such as Caco-2 human cardiomyocytes where cytopathic effects have been observed. Currently, most researchers are using VERO monkey cell lines (E6, CCL-81), which have proven to have a much higher susceptibility for infectiousness than human cell lines and therefore could be statistically misleading for such a Qualitative COVID RT-PCR calibration.

For a person to be infectious, including persons assumed to be asymptomatic without definitive laboratory evidence, their nasal or serologic sample must be able to produce replication-competent virus in a live human cell culture. Without this calibration between cycle threshold and live virus human cell culture, there is no definitive way to extrapolate that a person is indeed infectious based upon existing Qualitative COVID RT-PCR viral fragment testing alone, even though that is exactly what is being done all throughout the world.

This realization proves very troubling for all studies utilizing existing Qualitative COVID RT-PCR viral fragment testing diagnostically, including both the Pfizer/BioNTech and Moderna/NIH clinical trials for their respective experimental COVID biologics. Our concern is that both clinical trials are significantly compromised due to the clinical trial reliance upon uncalibrated PCR viral fragment testing in Phases 2 and 3 and provide potential evidence of willful misconduct.

### **Additional Subtopic References**

- “In another study, the Nevada Department of Public Health found an average Ct value of 23.4 in people who died from Covid-19, compared with 27.5 in those who survived their illnesses. People who were asymptomatic had an average value of 29.6, suggesting they carried much less virus than the other two groups.” (New York Times, Dec. 2020, Mandavilli)

<https://www.nytimes.com/2020/12/29/health/coronavirus-viral-load.html>

- “Two strains of SARS-CoV-2 infected human induced pluripotent stem cell-derived cardiomyocytes as demonstrated by detection of intracellular double-stranded viral RNA and viral spike glycoprotein expression. Increasing concentrations of viral RNA are detected in supernatants of infected

cardiomyocytes, which induced infections in Caco-2 cell lines, documenting productive infections. SARS-CoV-2 infection and induced cytotoxic and proapoptotic effects associated with it abolished cardiomyocyte beating.” (Cardiovascular Research, Dec. 2020; Bojkova et al).

<https://pubmed.ncbi.nlm.nih.gov/32966582/>

- “We passaged virus isolate 2 more times in Vero CCL-81 cells and titrated by determining the 50% tissue culture infectious dose (TCID<sub>50</sub>). Titers were  $8.65 \times 10^6$  TCID<sub>50</sub>/mL for the third passage and  $7.65 \times 10^6$  TCID<sub>50</sub>/mL for the fourth passage...In contrast, HUH7.0 and 293T cells showed only modest viral replication, and A549 cells were incompatible with SARS-CoV-2 infection. These results are consistent with previous susceptibility findings for SARS-CoV and suggest other common culture systems, including MDCK, HeLa, HEP-2, MRC-5 cells, and embryonated eggs, are unlikely to support SARS-CoV-2 replication... In brief, we infected Vero CCL-81 and HUH7.0 cells with SARS-CoV-2 at a low multiplicity of infection (0.1) and evaluated viral replication every 6 h for 72 h postinoculation, with separate harvests in the cell-associated and supernatant compartments (Figure 4). Similar to SARS-CoV, SARS-CoV-2 replicated rapidly in Vero cells after an initial eclipse phase, achieving  $10^5$  TCID<sub>50</sub>/mL by 24 h postinfection and peaking at  $>10^6$  TCID<sub>50</sub>/mL... Replication in HUH7.0 cells also increased quickly after an initial eclipse phase but plateaued by 24 h postinoculation in the intracellular compartment at  $2 \times 10^3$  TCID<sub>50</sub>/mL and decreased after 66 h postinoculation.” (U.S. CDC, Jun. 2020; Harcourt et al).

[https://wwwnc.cdc.gov/eid/article/26/6/20-0516\\_article](https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article)

## Symptom-Based Testing Strategies Adopted

### Centers for Disease Control and Prevention

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html>

**Key Quote – “As of July 20, 2020 a test-based strategy is no longer recommended to determine when to discontinue home isolation, except in certain circumstances. Symptom-based criteria were modified as follows:**

- *Changed from “at least 72 hours” to “at least 24 hours” have passed since last fever without the use of fever-reducing medications.*
- *Changed from “improvement in respiratory symptoms” to “improvement in symptoms” to address expanding list of symptoms associated with COVID-19.*

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

**Key Quote – “As of October 19, 2020 accumulating evidence supports ending isolation and precautions for persons with COVID-19 using a symptom-based strategy.**

*Although replication-competent virus was not isolated 3 weeks after symptom onset, recovered patients can continue to have SARS-CoV-2 RNA detected in their upper respiratory specimens for up to 12 weeks (Korea CDC, 2020; Li et al., 2020; Xiao et al, 2020). Investigation of 285 “persistently positive” persons, which included 126 persons who had developed recurrent symptoms, found no secondary*

*infections among 790 contacts attributable to contact with these case patients. Efforts to isolate replication-competent virus from 108 of these case patients were unsuccessful (Korea CDC, 2020).*

**Available data indicate that persons with mild to moderate COVID-19 remain infectious no longer than 10 days after symptom onset.**

*Role of viral diagnostic testing (PCR or antigen) to discontinue isolation or precautions*

- *For persons who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious diseases experts.*
- **For all others, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier than would occur under the strategy outlined in Part 1, above.”**

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html>

**Key Quote – “December 30, 2020 Testing, Isolation, and Quarantine for School-Aged Children**

*Pediatric healthcare providers should be prepared to answer questions from families about testing and when it is safe for children who have had, or were exposed to, COVID-19 to return to school or be with people outside the household. Review CDC’s information for school administrators on symptom screening and testing for children in school as well as CDC’s Community Mitigation Framework.*

*School-aged children should be prioritized for viral testing **if they have:***

*Signs or symptoms of COVID-19 **and***

- *close contact (within six feet of someone for a total of 15 minutes or more) with a person with laboratory-confirmed or probable SARS-CoV-2 infection **or***
- *increased likelihood for exposure (which includes living in or traveling to a community with substantial transmission as defined by the local public health department and described in CDC’s Community Mitigation Framework).”*

**Summary** – As of July 2020 and repeatedly confirmed throughout the remainder of the year, asymptomatic testing is no longer recommended by the CDC based on scientific evidence supporting that it is a useless endeavor. Non-symptomatic persons should not be tested because a positive result is FAR more likely a false positive (or proof of recovery from a previous infection up to 12 weeks prior) than it is of an asymptomatic carrier capable of transmitting the virus to a susceptible host.

#### **Additional Subtopic References**

- “A molecular test (test code 39448) is available **to test symptomatic patients** for COVID-19. Through qualitative multi-target molecular diagnostics, this testing option helps to detect the presence of SARS-CoV-2.
- Quest processes four different molecular tests—the FDA Emergency Use Authorized Quest Diagnostics lab-developed test (LDT), the FDA Emergency Use Authorized Roche Diagnostics test,



the FDA Emergency Use Authorized Hologic Panther Fusion test, and the FDA Emergency Use Authorized Hologic Panther Covid-19 molecular assay.”

<http://www.questdiagnostics.com/home/Covid-19/HCP/NAAT/>

## Asymptomatic Transmission Position

One of the foundations for public health policy development has been the presumption that not only is asymptomatic transmission occurring in mass scale but, without social distancing and masking of non-symptomatic persons, asymptomatic transmission is the major driver of infective spread.

While the Wuhan study challenges the credibility of the theory of asymptomatic transmission, it stands to reason that common ground still exists on the topic of global responses and mitigation strategies for COVID-19. The following is presented as important common ground ideals after removing asymptomatic transmission as a variable:

- **No loved one should be forced to die alone.** Family members play an instrumental role as advocates between patients and medical professionals. It is unrealistic to expect incapacitated patients to make important medical decisions without the assistance of loved ones nearby. Family members must be able to sign any waivers of liability and agree to a self-imposed quarantine or testing to confirm they are not infectious so they can be present with their loved ones in hospital, congregate care, and hospice settings.

In 2020, hundreds of thousands of people died alone, forcefully separated from their loved ones because of the excessively restrictive public health policies regarding COVID-19. This is not normal and never should be.

- **In-person education must resume in earnest.** In January 2021, due to a surge in teenage suicides, depression, anxiety, and substance abuse throughout Clark County, the Nevada Department of Education was compelled to accelerate plans for reopening in-person education. It is unconscionable that in an age demographic with a 99.987% estimated recovery rate from SARS-CoV-2, school-age children and teens have been forced into isolation for more than 300 consecutive days in most school districts throughout the country. Evidence-based nutritional guidelines for the safe return to school exist and will be presented in detail later in this position paper as a separate topic. Parents should not have to fight to have their children in school.



**COVID-19 US Fatality Rates By Age - Thru February 16, 2021**

Demographic	Cases	Fatalities	Fatality Rate	Est. Recovery Rate
Age 0 to 17	2,323,592	298	0.013%	99.987%
Age 18 to 49	11,015,803	15,547	0.141%	99.859%
Age 50 to 64	4,206,743	50,217	1.194%	98.806%
<b>Total 0 to 64</b>	<b>17,546,138</b>	<b>66,062</b>	<b>0.377%</b>	<b>99.623%</b>
Age 65 to 74	1,589,030	73,389	4.62%	95.38%
Age 75+	1,340,638	208,804	15.57%	84.43%
<b>Total 65 &amp; Over</b>	<b>2,929,668</b>	<b>282,193</b>	<b>9.63%</b>	<b>90.37%</b>
<b>Total</b>	<b>20,475,806</b>	<b>348,255</b>	<b>1.701%</b>	<b>98.30%</b>

Data Source - NVSS Published By CDC - <https://covid.cdc.gov/covid-data-tracker>

- Small businesses must reopen in earnest.** Healthy citizens should never lose their job or be forced to close their businesses without definitive proof that their job or places of business are sources of significant infective spread. When nationwide chains are permitted to be open for business, but ‘mom and pop’ shops are told they must close or risk being fined, there is obvious inequity that challenges reason and credibility. What has been sorely lacking throughout the public health and executive response to COVID-19 has been opportunity for public comment, logic, compassion, and definitive proof to justify the decisions being made.
- Quarantining the symptomatic during unprecedented times with little known in the beginning makes logical sense.** However, with so much known now, quarantining otherwise healthy people has the potential to create more collateral damage than the SARS-CoV-2 infection does. At least as early as March 9, 2020, the CDC knew that persons 65 and older with pre-existing health conditions were most at risk for severe reactions to the virus based upon verifiable data from South Korea and Italy. To invoke extended one-size-fits-all public health policies invites disaster into society.
- Using an unproven theory to dictate public health policy raises the question of willful misconduct during a crisis.** Social distancing of healthy, non-symptomatic persons is based upon the unproven theory of asymptomatic transmission. Masking of healthy, non-symptomatic persons is based upon the unproven theory of asymptomatic transmission. Closures of small businesses, schools, places of worship, etc. were all based upon the unproven theory of asymptomatic transmission. Promoting an unproven theory as medical fact is an attempt at obfuscation. Funding and sanctioning projection model-based studies filled with assumptions and without any enrolled participants has biased the scientific conversation. Simultaneously, disregarding a study with almost 10 million enrolled participants that disproves the theory of asymptomatic transmission, rather than attempting to replicate the study on a smaller scale, is scientifically irresponsible. If studies were funded to support the unproven theory of asymptomatic transmission and intentionally or unintentionally prolonged this crisis, while effective treatments are censored and suppressed, then it stands to reason that willful misconduct must be investigated.

## Mental Health and Collateral Damage

- Surge of Student Suicides Pushes Las Vegas Schools to Reopen  
<https://www.nytimes.com/2021/01/24/us/politics/student-suicides-nevada-coronavirus.html>
- 25% of Young Adults in the U.S. Have Contemplated Suicide During the Pandemic, CDC Says  
<https://foreverymom.com/health-fitness/suicide/cdc-reports-one-quarter-of-young-adults-contemplated-suicide-pandemic/>
- Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic  
<https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm>
- The loneliness experience of the dying and of those who care for them.  
<https://pubmed.ncbi.nlm.nih.gov/17578066/>
- "Who would want to die like that?" Perspectives on dying alone in a long-term care setting.  
[https://www.researchgate.net/publication/327607601\\_Who\\_would\\_want\\_to\\_die\\_like\\_that\\_Perspectives\\_on\\_dying\\_alone\\_in\\_a\\_long-term\\_care\\_setting](https://www.researchgate.net/publication/327607601_Who_would_want_to_die_like_that_Perspectives_on_dying_alone_in_a_long-term_care_setting)
- Dear Therapist: I Can't Accept My Father's Death From COVID-19, "I was not there for his last breaths. I was not there for his last words. I'm trying to combat my guilt."  
<https://www.theatlantic.com/family/archive/2020/12/dear-therapist-covid-19-took-my-father-i-am-so-angry/617516/>
- Coronavirus: How to grieve a loved one when you can't say goodbye  
<https://www.bbc.com/news/uk-52142660>
- "How could I mourn my mom's cancer death when coronavirus robbed us of closure?"  
<https://www.latimes.com/lifestyle/story/2020-08-07/how-could-i-mourn-my-moms-cancer-death-when-coronavirus-robbed-us-of-closure>

## People Worthy of Our Remembrance



### **Jo'Vianni Smith, 15, Died by Suicide**

Jo'Vianni was described as an outgoing teenager who excelled at softball, basketball, and music while attending Bear Creek High School in Stockton, California. Her mother said she seemed happy and was active on social media.

Danielle Hunt, who lives in Stockton, told local station KTXL that her 15-year-old daughter Jo'Vianni Smith showed no signs that she would take her own life by hanging herself but may have had difficulty dealing with the state's stay-at-home order, as it led to increased stress and feelings of isolation.

<https://www.bet.com/news/national/2020/04/13/karl-anthony-mother-dies-coronavirus.html>

## Topic 2 – PCR Testing Problems

**Topic Introduction** – Throughout the COVID-19 global crisis, there has been a rush to get products to market by repeatedly skipping essential developmental steps for verifying the accuracy of the products. In each case, a “rush to market” has led to significant inaccuracies in data collection, proof of infectiousness, objective situational assessment, and safety. One of the topics where this has been very injurious to the lives of billions of people has undoubtedly been PCR testing.

Polymerase Chain Reaction (PCR) testing has several synonyms such as (1) Molecular testing and (2) Nucleic-acid Amplification Testing (NAAT). However, what is most confusing about PCR testing regarding SARS-CoV-2 is that it is quantitative, yet it is being used qualitatively.

Quantitative laboratory testing for any type of test yields an objective numerical result that can assist doctors in the important process of reaching definitive diagnoses. Comparatively, qualitative laboratory testing is subjective and does not provide the same level of clinical detail or accuracy.

Reverse Transcriptase-Quantitative Polymerase Chain Reaction (RT-qPCR) for COVID-19 was hurriedly developed with the promise of providing clinicians and public health officials the fastest way to diagnose infectious persons during the outset of this crisis. Curiously, however, a decision was made globally to use the quantitative PCR tests qualitatively.

Essentially, the RT-qPCR is capable of providing crucial numerical data regarding the amplification cycle at which a positive signal is detected. This numerical data is available with every test performed and has been available since the beginning, but it was never published. However, rather than publishing this data, the RT-qPCR test has been reduced from a quantitative test to a qualitative “either-or” test.

Either a sample is deemed positive or a sample is deemed negative.

The delineation line between the subjective assessment of a positive test result from a negative test result is an arbitrary value known as cycle threshold (Ct). Ct values have been set by the FDA and CDC to be 40.00 amplifications despite global scientific agreement that a Ct of 40.00 is far too high, invites an exponential increase of false positive results, and does not correlate to infectiousness.

The RT-qPCR COVID test could be calibrated to be used diagnostically. However, it has not been calibrated to be used diagnostically in over 12 months of use, but continues to be used as if it is a diagnostic test when in fact it is not. This is yet another example of potential willful misconduct.

Why public health officials would fast-track the approval of a quantitative test, purposely reduce it to a qualitative test, and then make the qualitative test the primary testing method for a global infectious crisis does not make scientific sense if the goal is to mitigate infective spread.

As has been confirmed by the Korean CDC, patients are proven to test positive using the RT-qPCR test for up to 12 weeks after they are no longer infectious. Additionally, RT-qPCR test kits explicitly state that the test cannot diagnose whether a person is currently infectious. Therefore, this proves that the RT-qPCR cannot be used diagnostically, even though that is what it has been used for.

As it stands, RT-qPCR testing is intended to be a fast way to tell the clinician whether a patient has ever been infected with the SARS-CoV-2 virus. However, the test cannot tell the clinician if the patient is currently infectious. As Dr. Lee's reply to FDA notes, RT-qPCR testing cannot identify past infections reliably at high cycle thresholds because primers get mixed in with cellular sample material not specifically associated with SARS-COV-2 virus.

This is a major problem and explains why RT-qPCR, as it is currently being used, cannot determine who should be in quarantine and who is safe to go to school, work, or recreational activities (e.g., concerts and sporting events).

Alone, RT-qPCR is essentially medically useless in helping to mitigate the spread of the virus through a community as has been observed over the previous year.

For the purposes of this topic, we will refer to qualitative interpretation of the RT-qPCR test as "Qualitative COVID RT-PCR" for SARS-CoV-2 testing and "RT-qPCR" in reference to the general medical technology.

## Corman-Drosten Review Report

<https://cormandrostenreview.com/report/>

The International Consortium of Scientists in Life Sciences (ICSLS) was one of the first research teams to thoroughly investigate the major flaws associated with the Qualitative COVID RT-PCR test. Led by PhD Molecular Geneticist Dr. Pieter Borger and former Pfizer Chief Scientist Dr. Michael Yeadon, the ICSLS team, comprised of 22 experts in their field, uncovered 10 major problems with the Qualitative COVID RT-PCR test including the two-day peer-review process that led to Christian Drosten's Qualitative COVID RT-PCR test's approval before any reasonable scientific review and comment could be registered.

In the ICSLS's exceptionally thorough seminal research published on November 27, 2020 and titled "*External peer review of the RT-PCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results,*" the ICSLS's research team uncovered 10 significant problems with Christian Drosten's Qualitative COVID RT-PCR test. Summaries of the issues are listed below.

### Key Quote

#### ***"SUMMARY CATALOGUE OF ERRORS FOUND IN THE PAPER***

*The Corman-Drosten paper contains the following specific errors:*

- 1. There exists no specified reason to use these extremely high concentrations of primers in this protocol. The described concentrations lead to increased nonspecific bindings and PCR product amplifications, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.*

2. Six unspecified wobbly positions will introduce an enormous variability in the real-world laboratory implementations of this test; the confusing nonspecific description in the Corman-Drosten paper is not suitable as a Standard Operational Protocol making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

3. **The test cannot discriminate between the whole virus and viral fragments. Therefore, the test cannot be used as a diagnostic for intact (infectious) viruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus and make inferences about the presence of an infection.**

4. A difference of 10° C with respect to the annealing temperature  $T_m$  for primer pair1 (RdRp\_SARSr\_F and RdRp\_SARSr\_R) also makes the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

5. **A severe error is the omission of a Ct value at which a sample is considered positive and negative.** This Ct value is also not found in follow-up submissions making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

6. **The PCR products have not been validated at the molecular level.** This fact makes the protocol useless as a specific diagnostic tool to identify the SARS-CoV-2 virus.

7. The PCR test contains neither a unique positive control to evaluate its specificity for SARS-CoV-2 nor a negative control to exclude the presence of other coronaviruses, making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

8. The test design in the Corman-Drosten paper is so vague and flawed that one can go in dozens of different directions; nothing is standardized and there is no SOP. This highly questions the scientific validity of the test and makes it unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.

9. **Most likely, the Corman-Drosten paper was not peer-reviewed making the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.**

10. We find **severe conflicts of interest for at least four authors**, in addition to the fact that two of the authors of the Corman-Drosten paper (Christian Drosten and Chantal Reusken) are members of the editorial board of Eurosurveillance. A conflict of interest was added on July 29, 2020 (Olfert Landt is CEO of TIB-Molbiol; Marco Kaiser is senior researcher at GenExpress and serves as scientific advisor for TIB-Molbiol), that was not declared in the original version (and still is missing in the PubMed version); TIB-Molbiol is the company which was “the first” to produce PCR kits (Light Mix) based on the protocol published in the Corman-Drosten manuscript, and according to their own words, they distributed these PCR-test kits before the publication was even submitted [20]; further, Victor Corman & Christian Drosten failed to mention their second affiliation: the commercial test laboratory “Labor Berlin”. Both are responsible for the virus diagnostics there [21] and the company operates in the realm of real time PCR-testing.

In light of our re-examination of the test protocol to identify SARS-CoV-2 described in the Corman-Drosten paper **we have identified concerning errors and inherent fallacies which render the SARS-CoV-2 PCR test useless.”**

**Summary** – One of the key published manuscripts used for the development of the Qualitative COVID RT-PCR test was the Corman-Drosten paper.

Upon the paper receiving a thorough peer-review by the ICSLS team, which did not happen before the paper was published and subsequently adopted, the following key findings were revealed:

1. Qualitative COVID RT-PCR tests are incapable of distinguishing between the virus and remnant viral fragments discarded by the immune system after successfully dispatching the virus.
2. Qualitative COVID RT-PCR tests cannot be used diagnostically to determine who is infectious and who is not.
3. Recommended Cycle Threshold (Ct) Values to determine a reasonable cut off point for who is likely infectious versus who is likely not infectious were curiously omitted.
4. The products for the Qualitative COVID RT-PCR Test were never validated at the molecular level.
5. The peer-review process for the Corman-Drosten paper lasted only two days. For reference, it is common practice for most published manuscripts to go through an extensive two-month (or longer) peer-review process.
6. The Corman-Drosten authors had significant financial conflicts of interest that they did not disclose during the warp speed peer-review process.

**Position** – This reveals that the test that is used globally—and that the entire world relies on to be accurate and calibrated to be used diagnostically to determine who is and who is not infectious—is severely inaccurate and not calibrated to be used diagnostically.

This revelation calls into question the accuracy of the data for every case, hospitalization, fatality, and recovery where Qualitative COVID RT-PCR was used as the exclusive diagnostic tool.

This also calls into question the necessity of global public health policies that have been based upon the accuracy and diagnostic prowess of the Qualitative COVID RT-PCR test.

A revelation such as this begs the question, *“With so much at stake, how was this able to happen?”*

With this in mind, several other researchers have been doing excellent work in bringing the scope of this problem to the public’s awareness.



# Qualitative COVID RT-PCR Significantly Inaccurate

## International Journal of Geriatrics and Rehabilitation

<http://www.int-soc-clin-geriat.com/info/wp-content/uploads/2020/03/Dr.-Lees-paper-on-testing-for-SARS-CoV-2.pdf>

**Key Quote** – *“In summary, the results of re-testing the cellular components of 20 reference samples of nasopharyngeal and oropharyngeal swab rinses by heminested RT-PCR amplification followed by nucleotide sequencing showed that SARS-CoV-2 was not found in 3 of the 10 (3/10) reference samples classified as positive by RT-qPCR, and that 2 of the 10 (2/10) reference samples classified as negative by RT-qPCR in fact contained SARS-CoV-2.”*

**Summary** – Dr. Sin Hang Lee is the internationally acclaimed Director of Milford Molecular Diagnostics Laboratory, which specializes in developing DNA sequencing-based diagnostic tests implementable in community hospital laboratories. Dr. Lee has over 40 years of clinical diagnostic experience and is a world-renowned expert with respect to RT-qPCR testing.

In a study published on July 17, 2020, Dr. Lee concluded that 30% of the positive Qualitative COVID RT-PCR samples he retested were indeed false positive when tested under more stringent protocols, and 20% of the negative Qualitative COVID RT-PCR samples he retested were indeed false negatives as well. This raised significant concerns regarding the accuracy of the Qualitative COVID RT-PCR Tests and their ability to accurately detect not only who was infectious, but who had really been infected at all.

The implications for this reached far beyond the public health crisis when Dr. Lee ultimately realized that the Qualitative COVID RT-PCR test was the sole diagnostic test being used during Phase 2/3 of the Pfizer/BioNTech clinical trials approved by the NIH. This raised concerns not only for accuracy of the clinical trial data, but for safety concerns for the enrolled participants.

On November 25, 2020, Dr. Lee filed a formal petition with the FDA (Docket No. FDA-2020-P-2225), “PETITION FOR ADMINISTRATIVE ACTION REGARDING CONFIRMATION OF EFFICACY END POINTS OF THE PHASE III CLINICAL TRIALS OF COVID-19 VACCINES” Dr. Lee filed a stay of action petition requesting that the FDA halt the Pfizer/BioNTech clinical trials until more accurate laboratory diagnostics could be used to determine clinical efficacy of the experimental COVID biologic. Dr. Lee also outlined potential replacements and solutions to ensure the accuracy of the diagnostic tests used in the clinical trial were accurate.

On December 11, 2020, the FDA responded to Dr. Lee’s formal petition, stating, *“We have determined there is not scientific merit in requiring the Phase 3 trial for BNT162 or other COVID-19 vaccine candidates to qualify a PCR diagnosis of COVID-19 with Sanger sequencing. Testing used to support the detection of SARS-CoV-2 infection should be sensitive and accurate, and PCR assays can be sufficiently sensitive and accurate without the need for Sanger sequencing.”*

The FDA also concluded, *“It would not be sound public policy to require testing protocols that lack scientific merit. Requiring scientifically-unjustified protocols would add unnecessary costs to the clinical trial process, which could disincentivize important medical research.”*

Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research, denied the petition in its entirety.

Two days later, on December 13, 2020, the Pfizer/BioNTech experimental COVID biologic was approved under emergency use authorization (EUA) for public distribution even though the clinical trial is ongoing through January 31, 2023.

On February 10, 2021, Dr. Lee filed a reply to Dr. Marks' response.

**Position** – Clinical trials for experimental COVID biologics should be required to use diagnostic tools that are accurate for definitively assessing the efficacy and safety of the biologic. Such a decided lack of redundancy with respect to diagnostic tools opens the door for inaccurate data collection and inaccurate analysis and is a potential indication of willful misconduct.

Discussed in the “Violations of Medical Ethics” topic later in this position statement, there were significant flaws in the design and analysis of the trials as well as a clear conflict of financial interest in the clinical trials.

No vaccine has made it to market for public distribution in less than four years, and most require eight to 10 years of development. For new experimental technology that progressed without preliminary animal trials ever being completed and that went from conception to production in only seven months, safety must be at the forefront of all considerations.

Dr. Lee's concerns are legally reasonable, scientifically valid, and demonstrate the type of compassion essential for the safety enrolled human participants within ongoing clinical trials. Interestingly, the Pfizer/BioNTech clinical trials report 3,861 participants who either withdrew or were withdrawn prior to completion of their preliminary phase. As a result, published analysis excludes these participants, and no published data on their outcomes is currently available.

### **Additional Subtopic References**

- Dr. Lee is widely regarded as an international expert in Sanger sequencing, which is considered the gold-standard for accuracy in nucleic acid amplification testing. The National Cancer Institute has stated, **“Sanger sequencing is the gold standard for sequencing technology in that it provides a high degree of accuracy, long-read capabilities, and the flexibility to support a diverse range of applications.”**

<https://genomics.ccr.cancer.gov/technologies/sanger-sequencing/>

- Dr. Lee's full petition to the FDA can be found in the Appendix.
- Dr. Marks' response to Dr. Lee's petition can be found in the Appendix.
- Dr. Lee's reply to Dr. Mark's response can be found in the Appendix.
- The case transcript of Allegheny County v. The Cracked Egg 20-9808 can be found in the Appendix.
- Page 72 line 8 to Page 73 line 10 (in a Q&A format):

“Q. So we have heard that this PCR test is called the gold standard and previously, you weren't here on Wednesday, but **Dr. Brink had testified that false positives in her opinion can only occur in the situation of a mishandling of the samples at a lab.** Do you agree that false positives can only occur through human error or mishandling of the samples when doing the testing?

A. Can I address the premise of the question? You said that the gold standard is the PCR?

Q. That was the term used by Dr. Brink based on — I guess that the CDC calls it the gold standard.

A. You are confusing two things with that statement. The first thing is that the CDC required— considers the presence of a virus the gold standard. If you can prove the virus is present in any way, the CDC would accept the presence of the virus. **There are other techniques that can be used other than PCR.** So, CDC actually says that the presence of the virus — and it accepts PCR as one of the levels of evidence. **The actual gold standard for clinical diagnostic testing using nucleic acid technology such as PCR, sorry if I am speaking fast, the actual gold standard acknowledged by the FDA is Sanger sequencing, sequencing of the nucleotide itself.”**

## The Importance of Cycle Threshold (Ct) Values

### FDA and CDC – Real-Time RT-PCR Diagnostic Panel

<https://www.fda.gov/media/134922/download>

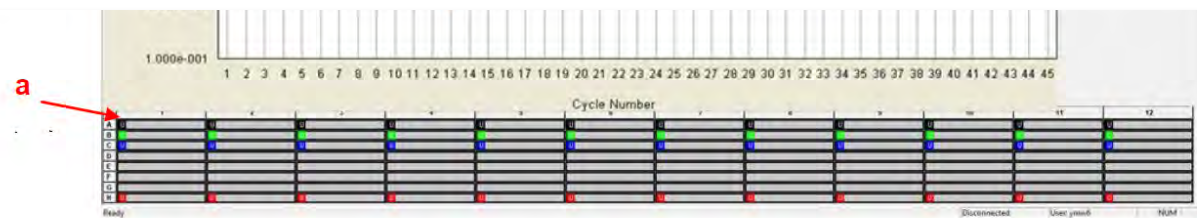
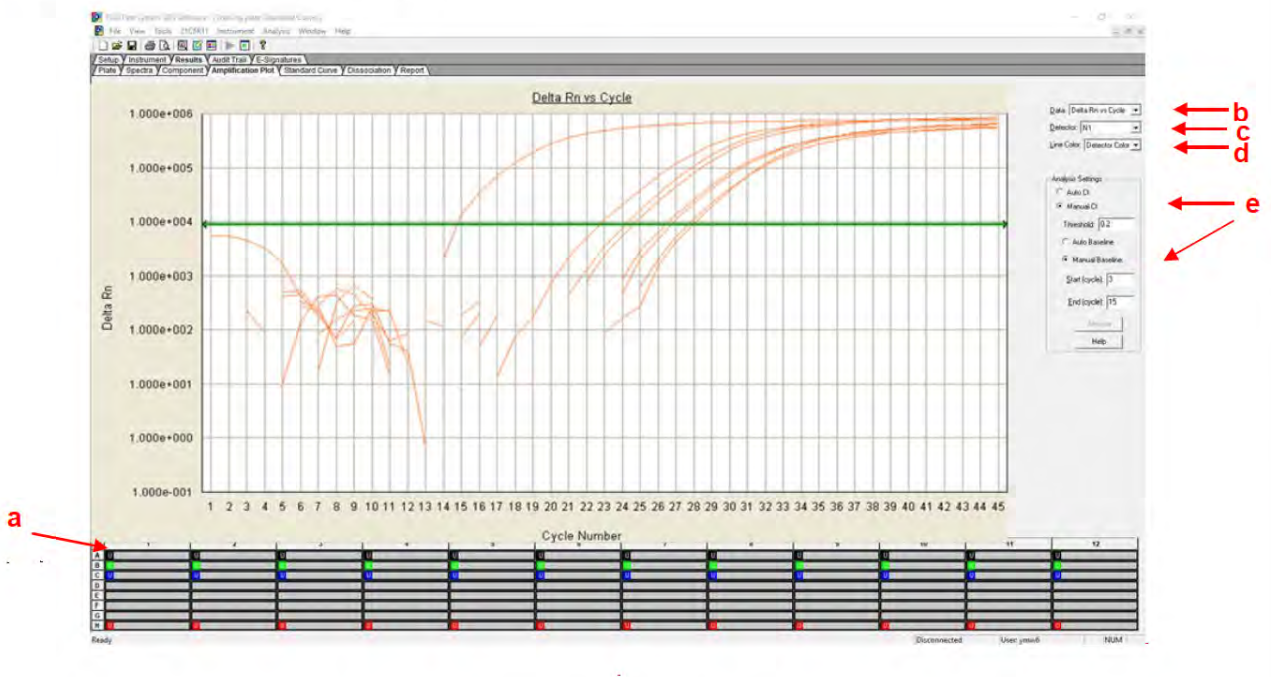
www.fda.gov/media/134922/download

**Expected Performance of Controls Included in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel**

Control Type	External Control Name	Used to Monitor	2019 nCoV_N1	2019 nCoV_N2	RP	Expected Ct Values
Positive	nCoVPC	Substantial reagent failure including primer and probe integrity	+	+	+	< 40.00 Ct
Negative	NTC	Reagent and/or environmental contamination	-	-	-	None detected
Extraction	HSC	Failure in lysis and extraction procedure, potential contamination during extraction	-	-	+	< 40.00 Ct

**If any of the above controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.**

Figure 17. Amplification Plot Window



- 3) Start by highlighting all the samples from the run; to do this, click on the upper left-hand box (a) of the sample wells (Figure 17). All the growth curves should appear on the graph.
- 4) On the right-hand side of the window (b), the **Data** drop down selection should be set to **Delta Rn vs. Cycle**.
- 5) Select **N1** from (c), the **Detector** drop down menu, using the downward arrow.
  - a. Please note that each detector is analyzed individually to reflect different performance profiles of each primer and probe set.
- 6) In the **Line Color** drop down (d), **Detector Color** should be selected.
- 7) Under **Analysis Settings** select **Manual Ct** (e).
  - b. Do not change the **Manual Baseline** default numbers.
- 8) Using the mouse, click and drag the red threshold line until it lies within the exponential phase of the fluorescence curves and above any background signal (Figure 18).

**Summary** – Cycle Threshold (Ct) Values are the key to understanding Qualitative COVID RT-PCR testing. RT-qPCR is an amplification technique whereby a sample is collected, and then the genetic material present is amplified many times to increase the genetic material available for detection of viral fragments.



It is important to note that viral fragments are not virus and therefore cannot determine whether the sample being tested is infectious without the corroboration of other testing methods.

One analogy for this process is photocopying. If you have a single document that you intend to photocopy, it will yield two copies, the original and the photocopy. If you photocopy both of those copies simultaneously, then you will have four copies. Photocopy those four copies again and you will have eight copies including the original.

Qualitative COVID RT-PCR testing is set to be amplified (photocopied) 45 times. If we applied this to the original example for photocopying documents, 45 amplification cycles would yield 17,592,186,044,416 copies (Geometric Sequences Formula  $x_{45}=1*2^{(45-1)}$ ). It is easy to understand the allure of this style of relatively inexpensive lab test. A small sample can be amplified to detect what is present genetically.

However, at what point (or Cycle threshold) is the genetic material a mess of DNA and RNA rendering the test unreliable beyond that point?

The CDC and FDA have set the Ct Value at 40.00. What this means is that if viral fragments are detected below 40.00 cycle amplifications, then the sample is deemed positive—and the patient from which the sample was collected is deemed positive for COVID-19 and treated as if they are infectious.

It is also important to note that there is an enormous difference between COVID-19 and the SARS-CoV-2 virus. COVID-19 is the diagnosis that asserts the person with the diagnosis is infectious, while SARS-CoV-2 is the virus.

Qualitative COVID RT-PCR tests are currently only calibrated to detect viral fragments, not the entire SARS-CoV-2 viral genomic sequence.

Additionally, we know from studies published by the CDC that viral fragments can be detected in amplified samples for up to 12 weeks following the end of the infectious period for people diagnosed with COVID.

Therefore, using the Qualitative COVID RT-PCR test in its current calibration can detect whether a person has been infected by the SARS-CoV-2 virus over the previous 12 weeks, but it CANNOT detect whether a person is currently infectious and should be considered an active COVID case.

**Qualitative COVID RT-PCR tests are being used to do exactly what they are not calibrated to do.**

This is a major problem.

The key to solving this problem presented by this qualitative test is the Cycle Threshold (Ct) Value.

To determine whether or not a person is infectious, live human cell cultures (Caco-2, HUH7.0, or 293T) can be used to discover if replication-competent virus is present in the sample being tested.

If replication-competent virus can be cultured, then the person is definitively infectious.

If replication-competent virus cannot be cultured, then the person is definitively not infectious.

When researchers can determine the average Ct value at which replication-competent virus is no longer able to be cultured in human cell lines that establishes with reasonable certainty what the actual Ct Value should be.

Dr. Fauci is on record as stating, “[I]f you get a cycle threshold of 35 or more...the chance of it being replication-competent are [sic] miniscule. And we have patients – and it’s very frustrating for the patients as well as for the physicians – somebody comes in and they repeat their PCR, and it’s like 37 cycle threshold, but you almost never can culture virus for a 37-cycle threshold. So, I think if someone does come in with 37-38, even 36, you got to say, ‘You know, it’s just dead nucleotides, period.’”

Dr. Darcie Johnston of the Department of Health and Human Services, in a public email record dated January 6, 2021 stated, “Anything over 34 cycles becomes unreliable.”

On January 13, 2021, the World Health Organization stated, “WHO reminds IVD users that disease prevalence alters the predictive value of test results; as disease prevalence decreases, the risk of false positive increases. This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as prevalence decreases, irrespective of the claimed specificity.”

<https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05>

This begs the question, if respected voices know the Ct Value is too high, why has this known error gone on for almost a year?

It is widely agreed that a Ct Value of 40.00 is far too high of a threshold and therefore opens the door to a large number of false positive COVID cases.

Many PCR experts say that the most accurate Ct value should be in the range of 24 to 34 instead of 40. Why? Because if a signal is detected at cycle amplifications less than 24, then it is a reasonable assumption that that patient is likely infectious.

In order to calibrate this flawed Qualitative COVID RT-PCR test to be used diagnostically, researchers are working to determine the Ct Value level that should be set by taking symptomatic patients with positive Qualitative COVID RT-PCR test results and attempting to culture the positive sample in a live cell culture.

The limitation of many of these studies is that researchers are using VERO monkey kidney cells, which are much more susceptible to infection with the SARS-CoV-2 virus than human cell lines. Still, it is a move in the direction of logic and reason.

Additional concerns regarding the Qualitative COVID RT-PCR test surround the threshold detection line and the possibility that lab technicians can manipulate the threshold detection line to an arbitrary value. The instruction manual states on page 33, “**Using the mouse, click and drag the red threshold line until it lies within the exponential phase of the fluorescence curves and above any background signal.**” The threshold detection value does not appear to be numerically defined in the document titled, ‘CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel’ (CDC-006-00019, Revision: 06, 12/01/2020) published by the FDA.

## Oxford Academic Clinical Infectious Disease Meta-Analysis

<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217>

**Key Quotes** – “[From La Scola 2020 [W15] Nasopharyngeal swabs or sputum specimens.]

*183 [specimens tested positive] (4,384 specimens from 3,466 patients [collected])*

*183 specimens testing positive by RT-PCR (9 sputum specimens and 174 nasopharyngeal swabs) from 155 patients, were inoculated in cell cultures. SARS-CoV-2. RNA rtPCR targeted the E gene.*

*Nasopharyngeal swab fluid or sputum specimen were filtered and then inoculated in Vero E6 Cells. All specimens were inoculated between 4 and 10 h after sampling and kept at + 4 °C before processing. After centrifugation they were incubated at 37 °C.*

*They were observed daily for evidence of cytopathogenic effect. Two subcultures were performed weekly and scanned by electron microscope and then confirmed by specific RT-PCR targeting E gene.*

*Of the 183 specimens inoculated in the studied period of time, 129 led to virus isolation. Of these 124 specimens had detectable cytopathic effect between 24 and 96 h. The letter by Jaafar et al adds that 1941 SARS-Cov-2 30 isolate cultures were positive out 3,790 inoculated specimens. These could be seen after the first inoculation or up to 2 blind subcultures. At a Ct of > 34 2.6% of specimens yielded a positive culture.*

*There was a significant relationship between Ct value and culture positivity rate: specimens with Ct values of 13–17 all had positive culture. Culture positivity rate decreased progressively according to Ct values to 12% at 33 Ct. No culture was obtained from specimens with Ct > 34. The 5 additional isolates obtained after blind subcultures had Ct between 27 and 34, thus consistent with low viable virus load.”*

**Summary** – This is a meta-analysis of 29 studies attempting to correlate PCR cycle thresholds with proof of infectiousness via live cell culture of available samples. Focusing on the work of the La Scola, which is among the most thorough studies provided in the Jefferson meta-analysis, we find the following:

1. One hundred eighty-three specimens from 155 Qualitative COVID RT-PCR positive patients were collected.
2. Of the 183 specimens, 129 led to the isolation of the SARS-CoV-2 virus in VERO E6 monkey cells. VERO E6 monkey cells have proven to be more susceptible to infection than human cell lines to date. (See Additional Resources at The End Of This Subtopic)
3. Additionally, in a companion study (by Jaafar) only 30 out of 3,790 samples led to VERO E6 isolates.
4. Samples with a Ct up to 17 all yielded replication-competent virus in a VERO E6 cell culture.
5. Only 12% of samples with a Ct of 33 were able to produce replication-competent virus.



6. Samples with a Ct of 34 or higher were unable to produce replication-competent virus (La Scola). Only 2.6% of samples with a Ct of 34 or higher were able to produce replication-competent virus (Jaafar).
7. All participants were symptomatic for COVID.

### **PHD Analysis of FOIA Cycle Threshold Values Rhode Island**

<https://rationalground.com/covid-19-pcr-testing-cycle-threshold-values-are-the-missing-piece-of-the-pandemic-puzzle-until-now/>

**Key Quotes** – *“We can see that nearly half of the positive tests had Ct scores of greater than 32 – meaning they were probably not infectious. Only 42% were likely infectious, and this is during a time when RI was smack in the middle of the spring pandemic, AND when they were mainly testing symptomatic people!*

*We can analyze the data further by looking at what percentage of Ct scores was above 32 (likely not infectious) by month. As the Spring progresses, we see more tests with higher Ct values = more people with lower viral loads, to the point where 2/3 of tests in June were likely not infectious.*

*As May approaches, the average Ct score of positive tests rises linearly through the “maybe infectious” zone into the “not infectious” zone, again showing clearly that viral loads were decreasing (fewer people were actually sick).*

*Finally, if we overlay fatalities, we can clearly see the potential predictive effect of Ct score trends relative to pandemic severity.*

*Perhaps one might object that this is just one data set (sadly), so maybe this is a fluke. Well, we did manage to procure a second small data set from a lab on the U.S. west coast, also from the spring. And voila, the Ct score distributions are remarkably similar to those in RI.*

*It is frankly negligent that officials and “experts” on both sides of pandemic policy are ignoring or cannot access this data. Labs simply don’t provide them, apparently because they are not required to do so.”*

**Summary** – In Rhode Island, based upon Freedom of Information Act (FOIA) requests for public records, 44% of all Qualitative COVID RT-PCR positive results had a Ct of 32 or higher which correlates to replication-competent virus via live cell culture being remarkably unlikely.

### **New England Journal of Medicine Ct, Live Cell Culture in Hospitalized Patients**

<https://www.nejm.org/doi/full/10.1056/NEJMc2027040>

**Key Quotes** – *“SARS-CoV-2 was cultured in 29 of the 89 samples (33%). The median time from symptom onset to viral clearance in culture was 7 days (95% confidence interval [CI], 5 to 10), and the median*

*time from symptom onset to viral clearance on real-time RT-PCR was 34 days (lower boundary of the 95% CI, 24 days).*

*The latest positive viral culture was 12 days after symptom onset (in Patient 6).*

*Viable virus was identified until 3 days after the resolution in fever (in Patient 14).*

*Viral culture was positive only in samples with a cycle-threshold value of 28.4 or less.*

*The incidence of culture positivity decreased with an increasing time from symptom onset and with an increasing cycle-threshold value.”*

**Summary** – Only 33% of samples from hospitalized, symptomatic patients were able to be cultured in a live cell. The type of cell used was not identified in the peer-reviewed manuscript. Cell culture was only possible in samples with a Qualitative COVID RT-PCR Ct Value of 28.4 or less.

**Position** – The La Scola/Jaafar study and similar studies provided by the New England Journal of Medicine (NEJM) and the Jefferson meta-analysis confirm that symptom presentation is an essential factor in producing replication-competent virus during cell culture. This is also confirmed by the NEJM published study. Asymptomatic persons have yet to be proven to produce replication-competent viral cell cultures.

However, the Jefferson meta-analysis also confirms that it is potentially possible to calibrate the existing Qualitative COVID RT-PCR for infectiousness by using live cell culture of positive samples. Once it is established at which cycle threshold value replication-competent virus is no longer able to be cultured, then the cycle threshold for all Qualitative COVID RT-PCR tests can compare against the delineation line at which infectiousness is no longer likely.

While replication-competent virus is possible in symptomatic patients with Ct Values above 28, there is a point of diminishing returns regarding accuracy. For example, at a Ct Value of 33, only 12% of symptomatic patients will produce replication-competent virus—meaning that 88% will not.

This affirms that cycle threshold values set above 33 open the door for false positives, meaning that **people can test positive using Qualitative COVID RT-PCR and not be infectious.**

Considering that many non-symptomatic people are volunteering to be tested for a variety of reasons, it is important to ensure that all people tested have clinical symptoms consistent with COVID. From there, it is possible to set a Ct value that reasonably correlates with the production of replication-competent virus (See the figure below).

**PROPOSAL FOR CALIBRATING COVID RT-qPCR TESTING BASED UPON VIRAL REPLICATION-COMPETENCE**

DIAGNOSTIC INTERPRETATION	CYCLE THRESHOLD	PROPOSED ACTION
<b>Infectious</b>	<b>&lt; 25.00</b>	Quarantine/Isolation Until No Longer Symptomatic + 2 Days. Administration Of Evidence-Based Nutritional Guidance. Retest Serologic Antibodies To Confirm (+ IgG, - IgM).
<b>Possibly Infectious</b>	<b>25.00 - 33.99</b>	Confirmatory Lab Testing. Serologic Antigen Or Live Human Cell Culture. Quarantine/Isolation Until Confirmed. Administration Of Evidence-Based Nutritional Guidance As Precaution.
<b>Not Infectious</b>	<b>≥ 34.00</b>	Recommendation Of Evidence-Based Nutritional Guidance As Precaution.

Oxford Academic (Jefferson) - <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1764/6018217>  
 NEMJ Hospital Study - <https://www.nejm.org/doi/full/10.1056/NEJM2027040>  
 Caco-2 Cell Human Cell Line Infectiveness - <https://pubmed.ncbi.nlm.nih.gov/32966582/>  
 VERO Monkey, HUH7.0 Human, 293T Human Cell Line Infectiveness - [https://wwwnc.cdc.gov/eid/article/26/6/20-0516\\_article](https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article)

**Note from Peer-Reviewer Dr. James Lyons-Weiler** – The protocols in use are not quantitative in a manner that would allow for a quantitative estimate of viremia (amount of virus in the sample). This is fundamental to the problem of using PCR in this way. The sampling procedure (nasopharyngeal swab) adds variation in the total amount of virus in the sample, so an internal control is needed. The internal control should have a spiked amount of a similar sequence with known concentration. This is why PCR testing for the SARS-CoV-2 virus needs to be based upon Sanger sequencing.

A public health testing strategy such as this would effectively calibrate the existing Qualitative COVID RT-PCR to be used diagnostically, establish a range for additional testing that is socially responsible, and prevent the collateral damage created by false positives (e.g., people who test positive but who are not capable of transmitting the virus).

Additional solutions include bringing a RT-PCR test to market that uses Sanger sequencing rather than viral fragments, or to serologically test for the SARS-CoV-2 antigen and accompanying antibodies. For decades, this has been the clinical methodology for the definitive diagnosis of infectious diseases.

Solutions to this major testing problem exist and affirm an age-old medical proverb, “Never guess when you can know.”

**Additional Subtopic References**

- “In another study, the Nevada Department of Public Health found an average Ct value of 23.4 in people who died from Covid-19, compared with 27.5 in those who survived their illnesses. People who were asymptomatic had an average value of 29.6, suggesting they carried much less virus than the other two groups.” (New York Times, Dec. 2020, Mandavilli)

<https://www.nytimes.com/2020/12/29/health/coronavirus-viral-load.html>

- “Two strains of SARS-CoV-2 infected human induced pluripotent stem cell-derived cardiomyocytes as demonstrated by detection of intracellular double-stranded viral RNA and viral spike glycoprotein expression. Increasing concentrations of viral RNA are detected in supernatants of infected cardiomyocytes, which induced infections in Caco-2 cell lines, documenting productive infections. SARS-CoV-2 infection and induced cytotoxic and proapoptotic effects associated with it abolished cardiomyocyte beating.” (Cardiovascular Research, Dec. 2020; Bojkova et al).

<https://pubmed.ncbi.nlm.nih.gov/32966582/>

- “We passaged virus isolate 2 more times in Vero CCL-81 cells and titrated by determining the 50% tissue culture infectious dose (TCID50). Titers were 8.65 × 10<sup>6</sup> TCID50/mL for the third passage and 7.65 × 10<sup>6</sup> TCID50/mL for the fourth passage...In contrast, HUH7.0 and 293T cells showed only modest viral replication, and A549 cells were incompatible with SARS-CoV-2 infection. These results are consistent

with previous susceptibility findings for SARS-CoV and suggest other common culture systems, including MDCK, HeLa, HEP-2, MRC-5 cells, and embryonated eggs, are unlikely to support SARS-CoV-2 replication...In brief, we infected Vero CCL-81 and HUH7.0 cells with SARS-CoV-2 at a low multiplicity of infection (0.1) and evaluated viral replication every 6 h for 72 h post-inoculation, with separate harvests in the cell-associated and supernatant compartments (Figure 4). Similar to SARS-CoV, SARS-CoV-2 replicated rapidly in Vero cells after an initial eclipse phase, achieving  $10^5$  TCID<sub>50</sub>/mL by 24 h postinfection and peaking at  $>10^6$  TCID<sub>50</sub>/mL...Replication in HUH7.0 cells also increased quickly after an initial eclipse phase but plateaued by 24 h post-inoculation in the intracellular compartment at  $2 \times 10^3$  TCID<sub>50</sub>/mL and decreased after 66 h post-inoculation.” (U.S. CDC, June 2020; Harcourt et al).

[https://wwwnc.cdc.gov/eid/article/26/6/20-0516\\_article](https://wwwnc.cdc.gov/eid/article/26/6/20-0516_article)

- “While we’re lucky to have reasonably accurate tests available so early in the course of a newly identified virus, we need better tests and easy access to them. All tests should undergo rigorous vetting by the FDA as soon as possible.”

<https://www.health.harvard.edu/blog/which-test-is-best-for-covid-19-2020081020734>

- FDA Emergency Use Authorizations for Medical Devices

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen>

- New York Times article discussing whether or not the PCR test should be considered positive for cycle thresholds above 30 in the absence of clinical symptoms.

<https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html>

## PCR Testing Position

Current Qualitative COVID RT-PCR Testing is not calibrated to be used diagnostically to determine who is infectious and who is not, but it can be calibrated by using human cell lines (Caco-2, HUH7.0, or 293T) to calibrate the cycle threshold value at which replication-competent virus is no longer able to be cultured.

The safe and effective practice of medicine depends upon accurate lab testing to help clinicians arrive at definitive rather than presumptive diagnoses.

Using Qualitative COVID RT-PCR tests, incapable of determining infectiousness, renders the most widely used test in the world completely incapable of determining who is and who is not infectious. This fact severely limits medical professionals’ ability to mitigate the spread of the infection.

Therefore, actions taken to impede the effectiveness of clinical diagnosis essential to slowing the spread of infection is possibly another example of willful misconduct.

To further complicate matters, Pfizer/BioNTech clinical trials for their experimental COVID biologic depended upon Qualitative COVID RT-PCR tests. If the test used in the clinical trial is incapable of determining infectiousness, then by extension, the data collected and analyzed for safety and efficacy is similarly compromised. This compromises the scientific integrity of the clinical trial.

Is this evidence of willful misconduct? There are severe flaws in how PCR testing is being used and nothing has been done to rectify these issues in more than 300 days and continued use of the flawed tests as a gold-standard is potentially a willful act of misconduct. Knowing that the flaws are leading to numerous misdiagnoses and severe collateral damage is certainly professional misconduct.

Doctors and nurses working on the front line deserve to have the most accurate diagnostic tools for reaching definitive diagnoses to help mitigate the spread of the virus.

All people being adversely impacted by public health policies deserve to have the most accurate data to prove the existence of an emergency beyond any reasonable doubt.

People consenting to the use of experimental COVID biologics based upon compromised clinical trials still ongoing deserve to know this information about PCR testing before consenting.

**Without a test or group of tests that can definitively determine who is and who is not infectious, it is impossible to state with certainty that an emergency exists or that any infective spread can be responsibly mitigated.**

Approving a test to be used diagnostically that is not calibrated to be used diagnostically when other testing options exist suggests possible willful misconduct.

# People Worthy of Our Remembrance



## **Ana Martinez Died Alone**

“I was dismissed, given the run-around, and my valid concerns were downplayed. Health-care workers fed me half-truths, assuring me my mother was healthy and safe when all the while she was suffering with COVID-19, gasping for air. My family was not notified until weeks after my mother’s passing that her nursing home had been admitting COVID-19 patients in accordance with a statewide mandate Cuomo had issued on March 25. Cuomo closed the doors on loved ones and opened them instead for the deadly coronavirus.”

<http://thegoodnewstoday.org/my-mother-died-alone-after-andrew-cuomo-trapped-her-in-a-nursing-home-with-covid/>

<https://www.voicesforseniors.com/>

## Topic 3 – Effective Treatments For COVID

**Topic Introduction** – The FDA and CDC could have prevented thousands of fatalities from COVID-19 if these agencies had deployed a series of dietary, nutritional, and lifestyle guidelines; bulletins; and action alerts to our nation’s medical professionals, hospitals, and senior care facilities for high-risk demographic individuals. Since March 2020, the high-risk demographic has been clearly identified as persons over 65 years of age with at least one major pre-existing (comorbid) condition. Moreover, a compendium of published literature has emerged that clearly demonstrates that inexpensive, safe, and effective pharmaceutical treatments exist for the treatment of COVID-19.

The emergence of COVID-19 occurred amidst a chronic disease crisis in the United States, where more than 73% of all people living in the United States are overweight or obese despite the CDC’s insistence that this number hovers around 20%.<sup>109</sup> According to the CDC, statistics state that more than 10% of the U.S. population is diabetic, and more than 88 million adults are pre-diabetic. Forty-five percent of adults live with hypertension, and 500 million deaths directly or indirectly involve hypertension.

Diabetes, hypertension, and obesity are significant risk factors for adverse events and mortality risk from COVID-19, and these three comorbidities comprise significant percentages of “contributing factors” listed on death certificates, as reported by the CDC.

The overwhelming evidence obtained through the analysis of federally funded and published NHANES data indicates that large percentages of the U.S. population are clinically deficient in essential micronutrients—vitamins A, C, D, E, and zinc.

An overwhelming body of evidence, extracted from several decades of published literature, demonstrates the necessity of these nutrients for basic physiology as well as for innate and adaptive immunity, particularly among high-risk demographics living with comorbidities. Additional evidence exists to support the use of basic nutritional guidelines to drastically reduce hospital overwhelm and disease severity while enhancing and expediting recovery from COVID-19.

NHANES data analysis enables a deeper understanding of the nutritional and micronutrient needs for a nation in crisis. This topic provides an extensive review of research from the COVID frontlines, ranging from small cohorts to large pooled meta-analyses.

On March 23, 2020, in Shanghai, China, a panel of medical experts convened to expand the clinical uses of vitamin C prophylactically as well as in clinical treatment for COVID-19.<sup>103</sup> The panel reviewed medical literature, as well as publications from the National Cancer Institute, which identified the use of IV vitamin C in randomized controlled trials for the treatment of sepsis in the prevention of viral diseases as well as an adjunctive treatment for numerous types of cancer. The panel of medical experts also reviewed the pharmacokinetics of vitamin C as well as many of the well understood immunological mechanisms of ascorbate. This included their understanding that vitamin C inhibits viral proliferation via enhanced macrophage phagocytosis as well as the ability for ascorbate to modulate T-cell and natural killer (NK) cell activities.<sup>101, 102</sup> The Shanghai panel of medical experts went forward with their recommendations for the use of ascorbate for COVID-19 in hospital settings:



“For therapeutic applications for COVID-19, the Shanghai protocol recommends that dosing regime should allow sustained high plasma levels to be achieved through twice daily doses of 12 to 15 g administered at 12 ml/h. The dosage recommendation will vary with the severity of the illness ranging from 50 to 200 mg/kg/day to as much as 16,000 mg/kg/day administered IV.”

The panel of Shanghai medical experts quoted a recently published study from January 2020, which consisted of infectious disease clinicians discussing the limited utility of developing new vaccines for rapidly changing viruses. These clinicians spoke to the importance of basic nutrition to optimize human immune function:

“...Supplementing above the RDA for certain immune supporting vitamins, promotes optimal immune function, helps to control the impact of infections, and could help limit the emergence of novel, more virulent strains of pathogenic viruses. We, therefore, strongly encourage public health officials to also include nutritional strategies in their arsenal to improve public health and to limit the impact of seasonal and emerging viral infections.”<sup>104</sup>

Despite these recommendations by the Shanghai panel and other peer-reviewed publications, U.S. health agencies did not employ evidence-based nutritional guidance to protect the public from COVID-19. To this date, not a single treatment for COVID-19 has been approved by the FDA. Not a single nutritive recommendation has been endorsed by the FDA. To the contrary, the FDA instead decided to police the nutritional supplement industry by issuing warning letters to any business or medical practitioner attempting to make claims as to the efficacy of nutrition to prevent or treat COVID-19.<sup>18</sup>

Such is the shortsightedness of U.S. health agencies. Despite the enormous financial budgets of the CDC and FDA, the rate of chronic disease growth in the United States is substantial, alarming, and unprecedented. **It is our position that these federal agencies have failed the public for decades, have ignored the essentiality of basic health measures, are mired in conflicts of interests with the pharmaceutical industry, and show no willingness to improve the health of the U.S. population by including nutrition as a foundational mitigation and preventative strategy.** As a direct result of their failed public health policies, incompetence, conflicts of interest, and willful ignorance, millions of Americans have unnecessarily died, and many more will die until severe nutritional deficiencies are scientifically addressed.

***“Optimum nutrition is the medicine of tomorrow.”***

- Linus Pauling, 2-time Nobel Laureate

***“An important scientific innovation rarely makes its way by gradually winning over and converting its opponents. What does happen is that its opponents gradually die out and that the growing generation is familiar with the idea from the beginning.”***

- Max Planck, Nobel Laureate

## The CDC and FDA Knew, Yet Did Nothing

As of the date of this initial publication, 16% of all COVID-19 fatalities in the United States feature “Diabetes” as a comorbidity on death certificates and 20% of total fatalities feature “Hypertension.” As early as March 9, 2020, the CDC, FDA, U.S. Federal Government, and leading research institutions were all aware of the demographics at high risk of developing COVID-19.

On March 9, 2020, the CDC alerted Americans over the age of 60 and with comorbidities such as obesity, diabetes, and hypertension that they were likely at a higher risk for fatality if they contracted the SARS COV-2 virus.<sup>6</sup> This knowledge emerged from published comorbidity data obtained from the Italian Health Ministry, South Korea, and China and was eventually confirmed by the New York State Department of Health via its COVID-19 Tracker.

At the onset of COVID-19 emergence in the United States, early reports of high-risk comorbidities associated with COVID-19 fatalities were hypertension, diabetes, cardiovascular disease, and obesity. As of January 18, 2021, the CDC attributes, 322,441 total fatalities to COVID-19.<sup>13</sup> “Contributing Conditions” as listed on death certificates are provided, which yield comorbidity data for this demographic: Influenza and Pneumonia: 141,763; Respiratory Failure: 117,102; Hypertensive Diseases: 65,600; Diabetes: 51,222; Adult Respiratory Distress Syndrome: 36,915; Sepsis: 29,517.

Nowhere since the arrival of COVID-19 has the FDA or CDC initiated public health strategies involving exercise, dietary modification, or nutrition for reducing the risk of disease severity or mortality for any population. If the CDC and FDA worked to create a series of public health strategies focused on the inclusion of evidence-based nutritional guidance, hospital and healthcare overwhelm could have been reduced, rates of survival could have been improved, and recovery could have been accelerated.

Hyperglycemia and pre-existing diabetes is positively associated with disease severity from COVID-19, increased ICU and hospital admissions, and increased mortality.<sup>41-49</sup> Hemoglobin A1C values of 6.5% and higher are associated with greater COVID-19 disease progression and higher mortality risk.<sup>59-61</sup> Elevated body mass index (BMI) is positively associated with tracheal intubation and/or death within seven days.<sup>51</sup> Obesity triples the risk of hospitalization due to SARS-CoV-2 infection, reduces immunocompetence, and increases the risk of severe illness.<sup>71</sup> For hypertensive COVID-19 patients, there is an increased risk for mortality, disease severity, disease progression, ARDS (acute respiratory distress syndrome), and need for ICU care.<sup>64,65</sup>

A compendium of meta-analyses from all over the world reveals diabetes mellitus and obesity can be adequately controlled and, in some instances, reversed, by dietary, nutritional, and lifestyle management.<sup>52-58</sup> The CDC and FDA could have initiated federally funded exercise and diet programs, with the objective of helping obese patients reduce BMI, reducing A1C scores, and improving the chances of survival from COVID-19 by reducing known risk factors.

These actionable items should have been implemented once the CDC was made aware of the high-risk demographics associated with COVID-19. Doing so would have reduced hospital and ICU overwhelm, empowered patients towards better health and immunocompetence, and shifted patients in the high-risk demographics towards an increased likelihood of accelerated recovery if infected.

## The CDC Knew Millions Had Low Nutrient Intakes and Deficiencies

National Health and Nutritional Evaluation Survey (NHANES) is a bi-yearly, federally funded, national data collection program that began in 1971, implemented and published by the CDC. Widespread nutritional deficiencies and their association to disease have been reported upon for several decades using NHANES data sets.<sup>33,34</sup>

The CDC was well aware of its own data findings of widespread nutrient deficiency when their 2003-2004 NHANES dataset revealed alarming metrics, such as an estimated 21 million Americans suffering from severe vitamin C deficiency and 66 million citizens being at a high risk of deficiency due to lifestyle and pharmacological interactions.<sup>29,30</sup>

A recent, published analysis of NHANES datasets ranging between 2005-2016 examined micronutrient intake from food and supplementation. The population size for the 11 years of NHANES data included a total of 26,282 adults between 19 and 99 years of age.<sup>16</sup> The NHANES methodologies included survey data on the population, represented as a percentage below the estimated average requirement (EAR) and above the upper limit (UL). The EAR is an estimate of the minimal amount of nutrition that is required to prevent disease based upon the RDA, RDI, ODA, and similar concepts of minimal nutrient requirements. The NHANES survey data also accounts for the effect of nutritional supplementation on the EAR/UL. The following describes the results:

### Vitamin A

- From Diet: 45% did not meet EAR
- From Diet with Supplementation: 35% still did not meet EAR
- Average Vitamin A Intake from Diet: 639ug (2,130 IU). EAR=700-900ug (2,333- 3,000 IU/day)

### Vitamin C

- From Diet Alone: 46% did not meet EAR
- From Diet with Supplementation: 37% still did not meet EAR
- Average Vitamin C Intake from Diet: 83mg/day. Optimal Daily Intake = 200mg/day

### Vitamin D

- From Diet: 95% did not meet EAR
- From Diet with Supplementation: 65% still did not meet EAR
- Average Vitamin D Intake from Diet: 188 IU/day. RDA = 600-800 IU/day
- **Note 1:** Endocrine Society recommends 1,500-2,000 IU/day
- **Note 2:** Since vitamin D levels can also be greatly influenced by sun exposure, it is necessary to review NHANES data on deficiency status, based on serum 25-OHD levels. NHANES data 2011-2014 (n=2,283) revealed that 17.4% of the population is deficient in 25-OHD, as defined by 25-OHD levels less than 20 ng/ml (50 nmol/l) by the

National Academy of Medicine. Severe deficiency of 25-OHD levels defined as less than 12 ng/ml (30 nmol/l) was found in 3.4% of the NHANES population.<sup>15</sup>

- **Note 3:** In U.S. clinical settings, serum 25-OHD levels below 50 ng/ml (125 nmol/l) is considered deficient in vitamin D status and serum 25-OHD levels below 30 ng/ml (75 nmol/l) is considered severely deficient in vitamin D status. In the context of COVID-19, strong associations exist between low values of 25-OHD and disease severity, increased hospitalizations, and mortality.

## Vitamin E

- From Diet: 84% did not meet EAR
- From Diet with Supplementation: 60% still did not meet EAR
- Average Vitamin E Intake from Diet: 9mg (13 IU/day). RDA = 15mg/daily (22 IU/day)
- **Note 4:** Recommendation for Older Adults for Immune Health: 134mg/day (200 IU/day)

## Zinc

- From Diet: 15% did not meet EAR
- From Diet with Supplementation: 11% still did not meet EAR
- Average Zinc Intake from Diet: 12mg/day. RDA = 8-11mg/day
- **Note 5:** Recommended Optimal Intake for Higher Risk Populations: 30mg/day

NHANES NUTRITIONAL ANALYSIS STUDIES - SUMMARY				
Nutrient	RDA/EAR/ODI	Adults 2005-2016	Nutritional Deficit For Minimum Requirements	% US Population Deficient*
Vitamin A	2,333-3,000 IU	2,130 IU	870 IU	35-45%
Vitamin C	75-200 mg	83 mg	117 mg	37-46%
Vitamin D	600-800 IU	188 IU	612 IU	65-95%
Vitamin E	22-200 IU	13 IU	187 IU	60-84%
Zinc	8-30 mg	12 mg	18 mg	11-15%

Data Source - NVSS Published By CDC - <https://www.cdc.gov/nchs/nhanes/index.htm>

\*Low End Of Range Adjusted For Supplemental Nutrient Intake Plus Dietary Intake - Reider, C. A., Chung, R. Y., Devarshi, P. P., Grant, R. W., & Hazels Mitmesser, S. (2020). Inadequacy of Immune Health Nutrients: Intakes in US Adults, the 2005-2016 NHANES. *Nutrients*, 12(6), 1735. doi:10.3390/nu12061735

With such alarming numbers, it would be reasonable for nationally accredited nutrition programs to receive increased federal funding for community outreach, education, and actionable distribution of nutritional supplements to support high risk COVID-19 populations. To date, this has not occurred.

Depleted levels of vitamin C have been consistently observed among patients with diabetes mellitus. While this may involve dietary inadequacy, other variables are significant contributors. This may involve competition between ascorbate and glucose transporters and rapid oxidation of ascorbate due to preexisting oxidative stress.<sup>3,8,9,32</sup> Based on this data, it has been proposed that the RDA for vitamin C in patients with diabetes should be increased by 35mg for both men and women.<sup>10</sup> From a therapeutic side, the greatest reduction in fasting blood sugar was observed in studies where subjects consumed a minimum daily dose of 1,250mg of vitamin C daily for at least three months.<sup>10,11</sup>

A meta-analysis study published in 2014 selected 38 articles (26 observational, 12 RCT), pooled from 5 RCTs for their meta-analysis, and found that single intake of ascorbic acid is significantly associated with lower fasting glucose levels compared to placebo.<sup>10</sup>

NHANES data taken from 2003-2006 examined the relationship between Hemoglobin A1C (A1C) levels and plasma levels of vitamin C (n=7,697) and noted a significant inverse association (p=0.0017), with strong association in the 18-44 age group.<sup>21</sup>

The inaction of the CDC to recognize the significance of vitamin C for high-risk COVID-19 diabetic patients may represent willful misconduct, particularly as it is related to the known inverse association between plasma ascorbate (a nutrient known to be depleted among diabetics) and hemoglobin A1C levels—and the fact that the CDC is well aware that diabetics are at a higher risk for COVID-19 disease severity.

## **What is the Point of Having NHANES Data If It is Never Used?**

Beginning in 1971, and published by the CDC, NHANES data is a bi-yearly, cross sectional evaluation of health across the U.S. population. NHANES datasets reveal vital statistics related to the following factors: (1) socioeconomic; (2) diet and nutrition; (3) dental hygiene; (4) physiologic measurements; (5) prevalence of chronic disease; and (6) laboratory tests.

To enhance the reliability of statistical analysis, NHANES over-samples data collection from elderly populations (60 and over) as well as Hispanic and African American communities. If implemented scientifically, NHANES datasets of elderly populations could have played a vital role in helping to reduce mortality risk. This is particularly relevant because 81% of all COVID-19 fatalities have occurred in the 65+ age range as of January 19, 2021.<sup>13</sup>

Important historical data obtained from NHANES II during 1976-1980 (n=27,801) was integral in establishing the associations between vitamin C status, stroke, and cardiovascular disease (CVD). From this historical dataset, it was observed that serum concentrations of vitamin C between 63-153 umol/l were associated with a 26% reduced relative risk of both stroke and cardiovascular disease.<sup>34</sup> In support of this, subsequent published research identified lower vitamin C status in association with several cardiovascular disease risk factors such as smoking, hypertension, elevated LDL, and lower HDL.<sup>3,4,5</sup>

Data obtained from NHANES 2001-2004 examined the association between 25-hydroxy vitamin D (25-OHD) levels and all cause cardiovascular disease mortality among adults with hypertension (n=2,609). Following the initial NHANES data collection, there were 191 deaths (7.3%) from all causes, and 68 deaths (2.6%) from cardiovascular disease with hypertension. Among the recorded fatalities attributed to cardiovascular disease with hypertension, mean levels of 25-OHD were 20.9 ng/ml, compared to 23.2 ng/ml for survivors.

After multivariate adjustments were applied for a variety of lifestyle factors, a significant inverse relationship between 25-OHD levels, mortality from all causes (p=0.012), and CVD (p=0.010) appeared. Significantly, this study's researchers identified that hypertensive adults with 25-OHD levels less than

17 ng/ml had a 221% increased risk of morbidity from cardiovascular disease compared to the same patient population who had 25-OHD values of 29 ng/ml or higher.<sup>19</sup>

Even though these vitamin D levels are still clinically deficient, the body only needs the smallest amount to function. The question is, “Why is vitamin D not being tested for and administered to all patients with a serologic level below 50 ng/ml upon admission to the hospital?”

The lack of utility of the CDC’s own NHANES data reveals a widespread disconnect between the fundamental responsibilities of the agency and the population it is supposed to support. NHANES data should not exist for the purpose of intellectual neglect and indifference. NHANES data should be presented front and center for scientific application during a national health crisis. The people with knowledge of such data who do not act upon it are potentially guilty of willful misconduct.

## **Key Nutrients Associated with COVID-19 Treatment Efficacy**

### **Linus Pauling Institute at Oregon State University**

The premier nutrient research center in the United States is undoubtedly the Linus Pauling Micronutrient Information Center at Oregon State University. In addition to their in-depth analyses of clinical applications for nutrition, they have authored brilliantly researched meta-analyses on the role of nutrition and natural immunity.

Their ‘Overview of the Immune System’ authored by Dr. Victoria Drake and Dr. Giana Angelo is supported by 267 peer-reviewed references relating to the role that nutrition plays in effective immune function. In this meta-analysis, they highlight several key micronutrients (Vitamins A, C, D, E, B6, B12, and folate; essential fatty acids; zinc; selenium; iron; copper; and probiotics) as essential co-factors for optimal immune response to all microbial infections.<sup>105</sup>

A meta-analysis such as this takes on added relevance when contrasted against the NHANES studies that clearly show rampant deficiencies of vitamins A, C, D, and E as well as zinc deficiency among Americans.

### **Recent findings on COVID-19 Immunopathogenesis and Immunotherapies**

A recent peer-reviewed study published in December 2020 in the journal *International Immunopharmacology* Volume 89 (Part B) further illustrates the critical importance of nutrient therapy as a primary clinical therapeutic strategy.<sup>106</sup>

“Vitamin D (1,25(OH)2VD3) exerts its immunomodulatory effects by inhibiting T cell proliferation, expression of IL-2, and IFN- $\gamma$ . 1,25(OH)2VD3 directs differentiation of Th cells toward the Th2 responses by inducing of IL-4 production and blocking differentiation to Th1 responses by suppressing the IL-12 production. Given the downregulatory effects on IL-6 and IL-23, 1,25(OH)2VD3 inhibits the differentiation of naïve T cells to Th17 cells. Vitamin D also raises the production of IL-10 along with downregulation of IL-12 synthesis, leading to deviation of Th1 response to IL-10-producing Treg cells. In addition to its modulatory effects on T cells, 1,25(OH)2VD3 also downregulates B cell proliferation and



consequently IgG production by indirectly affecting on the immunologic synapse in the antigen presenting cells (APCs)-Th cells interface. Although vitamin D exhibits inhibitory function on adaptive immunity, it has stimulatory effects on the innate immune responses.

In contrast to vitamin D, vitamin A (Retinoic acid) promotes cytotoxic capability of the immune system and also T cells expansion that may be beneficial responses in case of COVID-19. It assists signal transduction in T cells and enhances the secretions of IL-2. The definite effect of retinoic acid on B cells is not clear, however; it presumably inhibits B cells apoptosis. Similar to vitamin D, retinoic acid also aids differentiation of T cells towards Th2 response. In addition, vitamin A stimulates the production of type I interferon, thereby, exerting antiviral activities. In addition, vitamin A confers a therapeutic potential in autoimmunity by modulating the Th17/Treg balance. Taken together, vitamin A might be beneficial in COVID-19 patients by modulating immune system toward an anti-inflammatory setting during remission phase of the disease and by stimulation of anti-viral state.

Other vitamins including C, E, and B complex have also been reported to be involved in some nonspecific reactions. For instance, vitamin C exhibits antioxidant activity and vitamin E acts as a scavenger or key cellular regulator. There are scattered studies reporting that vitamin C and E perform anti-inflammatory activities. Furthermore, vitamin E has been reported to stimulate the production of type I IFN in the cells.”

### **Vitamin C Deficiency in Hospital Settings**

A Colorado-based hospital study evaluated the status of serum levels of vitamins C and D, among a critically ill COVID-19 cohort. Of 21 patients, only 11 survived (48% mortality). Mean vitamin C values for non-survivors was 15.4 umol/l (hospital range: 17-154 umol/l) compared to survivors 29.1 umol/l.

The mean Hemoglobin A1C of all patients was 7.6, indicative of the known diabetes-interactive mortality risk association with COVID-19. Mean vitamin D levels were low for the entire cohort. Age was a factor, with the median age of survivors being 52 compared to non-survivors, 69. The study's authors identified that older age and vitamin C levels were co-dependent risk factors for mortality from this critically ill, diabetic, patient group.<sup>1</sup>

Similar findings were reported in another ICU cohort study where 17 of 18 COVID-19 patients (median age 59 ± 9), who developed ARDS (acute respiratory distress syndrome) exhibited non-detectable levels of vitamin C.<sup>2</sup>

Despite being small-sized cohorts, hospital-based studies such as these provide real world data from the frontlines that could be used to bolster recovery efforts in hospital settings.

### **Vitamin C Therapeutics**

Vitamin C administration could have been used to enhance the rate of recovery from COVID-19 in hospitals, as evidenced by meta-analysis research that identified vitamin C administration reduces ICU stays by 7.8-8.6% and time on mechanical ventilation by 14-18.2% for severe respiratory infections.<sup>31, 35, 36</sup> Hospital treatment costs for vitamin C administration are estimated to be \$12-24 per day.<sup>37</sup>

A Chinese hospital treated approximately 50 cases of moderate to severe COVID-19 infection with Intravenous Ascorbic Acid (IVAA). The IVAA dosing was moderate and affordable, and the dose was determined by clinical status. The dose strategy was 100% effective at successful management of cytokine storms.

All 50 patients who received IVAA improved.

There was no mortality in the IVAA group.

There were no side effects reported from any patients in the IVAA group. COVID-19 patients had a 30-day hospital stay on average, but COVID-19 patients who received IVAA had a hospital stay that was 3 to 5 days shorter compared to the non IVAA treated patients.<sup>66</sup>

Special mention should be given to researcher Dr. Doris Loh for her exhaustive and extensive publication on the potential mechanisms of ascorbic acid in COVID-19 patients, particularly as it is related to the regulation of free heme, redox mechanisms, ascorbate recycling, minimizing hypoxia, and serving as an antioxidant for cellular and mitochondrial mechanisms.<sup>100</sup>

## **Vitamin D**

A meta-analysis and systematic review evaluated the relationship between vitamin D deficiency among patients diagnosed with COVID-19. The researchers identified 1,542 articles and selected 27 for analysis. While vitamin D deficiency was not associated with increased risk of COVID-19 infection (OR = 1.35; 95% CI = 0.80–1.88), vitamin D deficiency was associated with increased hospitalizations (OR = 1.81, 95% CI = 1.41–2.21) and increased mortality (OR = 1.82, 95% CI = 1.06–2.58).

Severe cases of COVID-19 were 64% more likely to be vitamin D deficient than mild cases of COVID-19 (OR = 1.64; 95% CI = 1.30–2.09).<sup>14</sup>

## **Vitamin D Therapeutic Studies**

A cohort observational study of 43 consecutive hospitalized COVID-19 patients aged 50 and above, in a tertiary academic hospital, evaluated those that received nutrient combination therapy (vitamin D, magnesium, and vitamin B-12 (DMB)) compared to a recent cohort who did not. DMB combination was associated with a significant reduction of clinical deterioration and fewer individuals requiring oxygen support and/or intensive care support compared to the non-intervention group.<sup>67</sup>

A randomized, placebo-controlled study involving 40 SARS-CoV-2, RNA positive individuals, aimed to study the proportion of RNA negative subjects following a 21-day trial period of either vitamin D3 (60,000 I.U.) or placebo. For the intervention group, vitamin D was given at a dosage of 60,000 I.U. daily for 7 consecutive days. 25-OHD serum values were collected at day 7. Supplementation was continued for individuals whose 25-OHD value was <50ng/ml. SARS Co-V-2 RNA was measured periodically, along with inflammatory markers: (1) fibrinogen; (2) D-dimer; (3) procalcitonin; (4) CRP; and (5) ferritin. Compared to the placebo group, the intervention group turned a greater proportion of individuals SARS-CoV-2 negative after 21 days, as well as having reduction in fibrinogen measures.<sup>68</sup>

At the time of publication, the literature reports that several clinical trials are in process involving high dose vitamin D3 or Calcifediol for COVID-19 patients. Initial clinical trials have been published suggesting that the use of high dose vitamin D3 (Calcifediol) could have prevented ICU overwhelm, increased recovery rates, and reduced mortality. This important research is not receiving the media coverage that it deserves.

A pilot study conducted in a hospital in Spain involved 76 consecutive COVID-19 patients, who exhibited acute respiratory infection confirmed by radiographic imaging, a SARS-CoV-2 PCR positive test, and recommended hospital admission (based on CURB65 >1). All patients received the best available therapy per hospital protocol, which included a combination of hydroxychloroquine, and azithromycin. Eligible patients for the clinical trial were randomized to receive either vitamin D3 (21,280 IU (0.532mg)) or no vitamin D3. On days 3 and 7, vitamin D3 patients were continued with a lower dose (10,640 IU (0.266mg)) and then a weekly dosage until hospital discharge or admission to the ICU. The outcomes of this study are listed as: (1) rate of ICU admission and (2) deaths. Of the 50 total patients who received vitamin D3, 1 was admitted to the ICU (2%). Of the 26 patients who were not administered vitamin D3, 13 were admitted to the ICU (50%).

Of the 50 patients treated with vitamin D3, zero deaths occurred, and all 50 patients were eventually discharged without complications. Of the 13 untreated Calcifediol patients admitted to the ICU, 2 died and 11 were eventually discharged. The non-vitamin D3 treated patients who were not admitted to the ICU recovered and were discharged. This randomized clinical trial demonstrates that vitamin D3 significantly reduced ICU admission rates as well as reduces the severity of COVID-19.<sup>94</sup>

The study authors concluded:

***“Our pilot study demonstrated that administration of a high dose of Calcifediol or 25-hydroxyvitamin D, a main metabolite of vitamin D endocrine system, significantly reduced the need for ICU treatment of patients requiring hospitalization due to proven COVID-19. Calcifediol seems to be able to reduce severity of the disease, but larger trials with groups properly matched will be required to show a definitive answer.”***

A study in the United States used a retrospective, observational analysis between mid-March and mid-June 2020 with respect to serologic vitamin D levels (25(OH)D) with matching results from the preceding 12 months.<sup>111</sup>

The study authors concluded:

***“A total of 191,779 patients were included (median age, 54 years [interquartile range 40.4–64.7]; 68% female. The SARS-CoV-2 positivity rate was 9.3% (95% C.I. 9.2–9.5%) and the mean seasonally adjusted 25(OH)D was 31.7 (SD 11.7). The SARS-CoV-2 positivity rate was higher in the 39,190 patients with ‘deficient’ 25(OH)D values (<20 ng/mL) (12.5%, 95% C.I. 12.2–12.8%) than in the 27,870 patients with ‘adequate’ values (30–34 ng/mL) (8.1%, 95% C.I. 7.8–8.4%) and the 12,321 patients with values ≥ 55 ng/mL (5.9%, 95% C.I. 5.5–6.4%). The association between 25(OH)D levels and SARS-CoV-2 positivity was best fitted by the weighted second-order polynomial regression, which indicated strong correlation in the total population (R2 = 0.96) and in analyses stratified by all studied demographic factors. The association between lower SARS-CoV-2 positivity rates and higher circulating 25(OH)D levels remained significant in a multivariable logistic model adjusting for all included demographic***

***factors (adjusted odds ratio 0.984 per ng/mL increment, 95% C.I. 0.983–0.986; p<0.001). SARS-CoV-2 positivity is strongly and inversely associated with circulating 25(OH)D levels, a relationship that persists across latitudes, races/ethnicities, both sexes, and age ranges. Our findings provide impetus to explore the role of vitamin D supplementation in reducing the risk for SARS-CoV-2 infection and COVID-19 disease.”***

## **Zinc**

A hospital-based study evaluated the fasting zinc status of COVID-19 patients upon admission (n=47), compared to healthy controls (n=45). COVID-19 patients displayed significantly lower zinc levels (median=74.5ug/dl) compared to the healthy control group (105.8ug/dl). 57% of COVID-19 patients were zinc deficient. Zinc-deficient COVID-19 patients had “higher rates of complications (p = 0.009), acute respiratory distress syndrome (18.5% vs 0%, p = 0.06), corticosteroid therapy (p = 0.02), prolonged hospital stay (p = 0.05), and increased mortality (18.5% vs 0%, p = 0.06). The odds ratio (OR) of developing complications was 5.54 for zinc deficient COVID-19 patients.”

## **Zinc Therapeutics**

An observational retrospective study was performed to evaluate the effect of zinc sulphate as an adjunct when used with hydroxychloroquine and azithromycin versus hydroxychloroquine and azithromycin alone. The study recruited 411 patients for the zinc sulphate / hydroxychloroquine / azithromycin group, and 521 for the group using hydroxychloroquine and azithromycin without zinc sulphate. While the addition of zinc did not impact the length of hospitalization, ICU duration, or need for ventilation, the addition of zinc sulphate reportedly reduced the need for mechanical ventilation and increased the frequency of patients being discharged. Significantly, after the researchers adjusted for the time in which zinc sulphate was added to protocols, the zinc sulphate group had a significant reduction in mortality or transfer to hospice among patients who did not require ICU care (OR 0.449, 95 % CI 0.271–0.744).<sup>69</sup>

## **Combination Nutritional and Oxidative Therapies for COVID-19: Vitamins A, C, D, Iodine, Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), and Ozone (O<sub>3</sub>)**

A study published in the journal *Science, Public Policy & The Law* (July 2020), involved a combination of nutrient and oxidative therapies for 107 COVID-19 patients (median age=56.5). Patients were given dosing instructions for oral supplementation for four days at symptom onset: vitamin A (100,000 IU/day), vitamin C (1,000mg/hour during waking), vitamin D (50,000 IU/day), and Lugol’s iodine (25mg). Most patients in the study were instructed to nebulize a solution of 0.04% hydrogen peroxide in saline solution with magnesium sulfate. If symptoms worsened, patients were treated with intravenous, or intramuscular nutrition of vitamin C (35%), hydrogen peroxide (30%), and intramuscular ozone (35%).

One hundred seven out of 107 patients fully recovered within seven days of treatment initiation.<sup>38</sup>

## Vitamin D and Potential Immunological Mechanisms of Action

### Pathophysiologic, Pleiotropic, Immunologic, and Antiviral Actions

Vitamin D in its myriad forms exerts a multitude of pleiotropic effects on neuroendocrine, immunological, and antiviral actions in humans. While the active form of vitamin D is known as Calcitriol (1,25 dihydroxy vitamin D), a myriad number of vitamin D isoforms exert their pleiotropic effects on human physiological functions. This includes 25-OH vitamin D3 (Calcifediol). This section is predominantly focused on the known research of vitamin D in its many forms on COVID-19 related mechanisms and its therapeutic potential as a powerful clinical nutritive agent.

Vitamin D sits at the center of the SARS-CoV-2 pathophysiology. The first revealing sign is the strong association between vitamin D deficiency and increased COVID-19 related hospitalizations, increased pathogenic severity, and increased mortality. Indeed, previous meta-analysis studies have reported that vitamin D deficiency is associated with higher infection rates, increased incidence of sepsis, and increased mortality risk among critically ill populations.<sup>82</sup>

In terms of the pathophysiology related to COVID-19, one of the central focuses of research literature with respect to the SARS-CoV-2 viral etiology is related to the angiotensin converting enzyme-2 (ACE-2) receptor. Notably, the SARS-CoV-2 spike protein has been shown to bind to ACE-2 in upper and lower lung epithelium as well as in neuronal tissues, with unexpectedly exceptional efficiency.

The binding of SARS-CoV-2 to the ACE-2 receptor can lead to a suppressive effect on the expression and function of ACE-2.<sup>92</sup> This effect has been proposed to lead to the induction of pulmonary edema in COVID-19 patients and severe lung failure.<sup>90,91</sup> Importantly, vitamin D has a net effect of promoting the function of ACE-2 expression via regulation of the ACE-2/Ang-(1-7)/MasR axis.

ACE-2 is an integral component of the renin angiotensin system (RAS) and the regulation of blood pressure. Notably, vitamin D is known to negatively regulate the RAS system via the induction and promotion of the ACE-2/Ang-(1-7)/MasR axis, which serves as a key feedback axis of cardiometabolic function.<sup>78</sup>

It is speculated that the association between hypertension and low vitamin D status may be causally related to vitamin D's regulatory effects on the ACE-2/Ang-(1-7)/MasR axis and the RAS.<sup>81</sup>

Research studies have identified that chronic vitamin D deficiency can: (1) induce excessive cytokine storms; (2) directly activate the RAS; (3) dysregulate the expression of ACE-2 in lungs; (4) increase renin secretion; (5) disrupt blood pressure and blood volume; (6) diminish lung function; and (7) increase the risk of fibrosis.<sup>83,84,85,93</sup> This pathologic profile constitutes a significant percentage of critically ill COVID-19 patients.

Vitamin D exerts wide-reaching influences on human immunological mechanisms. Of notable interest, the active form of vitamin D (Calcitriol) stimulates immune cell biosynthesis of the powerful anti-bacterial and anti-viral cationic host defense peptide (CHDP), cathelicidin, known as LL-37.<sup>73</sup>

As a cationic peptide, vitamin D-derived LL-37 has been shown efficacious in reducing cytokine storms that result in lung inflammation and damage, while also reducing rates of viral replication.<sup>74</sup>

LL-37 has been studied for its antiviral actions in numerous types of viruses, including HSV-1, HIV, rhinovirus, and dengue virus.<sup>75,76,77</sup>

Vitamin D is a direct and indirect regulator of T-cell functions. As a prohormone, vitamin D exerts both paracrine and autocrine actions. Vitamin D can increase memory T-cells, as well as induce signaling of immunosuppressive TREG's cells.<sup>88,89</sup>

Vitamin D can reduce the expression of inflammatory TH1 cells and thus reduce expression of type 1 inflammatory cytokines as well as the auto inflammatory TH17 pathway.<sup>79,80,98</sup>

Importantly, high dose vitamin D has been shown to reduce the neutrophil to lymphocyte ratio (NLR) and CRP pro-inflammatory levels.<sup>95</sup>

NLR has been shown in several COVID-19 studies, including a meta-analysis, to be an independent risk factor for COVID-19 disease severity and mortality.<sup>96,97</sup>

A strong association exists between vitamin D deficiency among COVID-19 patients with ARDS, with some studies reporting vitamin D deficiency in 81% of patients.<sup>99</sup>

**Position** – The evidence for therapeutic application of vitamins A, C, D, E, and the mineral zinc as primary clinical strategic responses to COVID-19 diagnosis is overwhelming. At minimum, determining the vitamin D status for every hospital admission should be standard procedure, and all admissions with a serologic vitamin D status below 50 ng/ml should be administered an oral loading dose of vitamin D3 as follows: (1) Days 1 to 4 – 20,000 to 50,000 IU/day, (2) Days 5 to 14 – 5,000 to 10,000 IU, (3) Days 15 to discharge – 5,000 IUs.

For admissions with a serologic vitamin D status above 50 ng/ml, patients can be safely administered 5,000 IU/day of vitamin D3 orally to accelerate recovery and reduce hospital stays and medical expenses.

In the position summary to conclude this topic, we will share a proposal for safe and effective nutritional guidance based upon the evidence presented for vitamins A, C, D, E, and the mineral zinc divided by age.



## Ivermectin – Evidence as an Effective Therapeutic Intervention

### Peer-Reviewed Studies:

“Addition of Ivermectin to standard care is very effective drug for treatment of COVID-19 patients with significant reduction in mortality compared to Hydroxychloroquine plus standard treatment only. Early use of Ivermectin is very useful for controlling COVID 19 infections; prophylaxis and improving cytokines storm.”

- <https://www.researchsquare.com/article/rs-100956/v2>

“One aspect that the NIH expert panel may debate is on the grade of recommendation that should be assigned to ivermectin. Based on the NIH rating scheme, the strongest recommendation possible would be an A-I in support of ivermectin, which requires ‘one or more randomized trials with clinical outcomes and/or laboratory endpoints.’ Given that data from 16 randomized controlled trials (RCTs) demonstrate consistent and large improvements in ‘clinical outcomes’ such as transmission rates, hospitalization rates, and death rates, it appears that the criteria for an A-I level recommendation has been exceeded.”

- <https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Ivermectin-in-the-prophylaxis-and-treatment-of-COVID-19.pdf>

“We report here that Ivermectin, an FDA-approved anti-parasitic previously shown to have broad-spectrum anti-viral activity in vitro, is an inhibitor of the causative virus (SARS-CoV-2), with a single addition to Vero-hSLAM cells 2 h post infection with SARS-CoV-2 able to effect ~5000-fold reduction in viral RNA at 48 h.”

- <https://www.sciencedirect.com/science/article/pii/S0166354220302011>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7129059/>

“Viral clearance was treatment dose- and duration-dependent. In six randomized trials of moderate or severe infection, there was a 75% reduction in mortality (Relative Risk=0.25 [95%CI 0.12-0.52]; p=0.0002); 14/650 (2.1%) deaths on ivermectin; 57/597 (9.5%) deaths in controls) with favorable clinical recovery and reduced hospitalization.”

- <https://europepmc.org/article/PPR/PPR268166>
- Full text: [https://assets.researchsquare.com/files/rs-148845/v1\\_stamped.pdf](https://assets.researchsquare.com/files/rs-148845/v1_stamped.pdf)

**Publication Note:** Many of the studies used in the meta-analysis were not peer-reviewed.

“Raw data for asymptomatic family close contacts of confirmed COVID patients show that 2 doses of ivermectin 72 h apart resulted in only 7.4% of 203 subjects reporting symptoms of SARS-CoV-2 infection, in contrast to 101 control untreated subjects, of whom 58.4% reported symptoms; evidence of prophylaxis by ivermectin.”

- <https://clinicaltrials.gov/ct2/show/NCT04422561>

“Recovery rate of the 28 patients that received ivermectin/AZM/cholecalciferol was 100%, with mean symptomatic recovery 3.6 days (negative PCR confirmed day 10). Imaging on day 10 showed improvement in all patients with pneumonia. Authors conclude the combination therapy might mitigate disease progression without significant adverse effects, but further studies required (preferably controlled).”

- <https://www.alliedacademies.org/articles/effects-of-ivermectinazithromycincholecalciferol-combined-therapy-on-covid19-infected-patients-a-proof-of-concept-study-14435.html>

“Raw data shows a significant reduction in the number of 183 patients with late clinical recovery (requiring >12 days to show clinical improvement) in the ivermectin/DOC group compared to placebo (23 versus 37.2%), as well as a significant reduction (8.7 versus 17.8%) in patients showing clinical deterioration (from mild/moderate to moderate or severe), and a significant reduction (7.7 versus 20%) in persistent Covid-19 positive patients at 14 days compared to 180 control patients; evidence of efficacy for ivermectin/DOC.”

- <https://clinicaltrials.gov/ct2/show/results/NCT04523831>

“Professor Borody says his research has led him to a triple therapy of Ivermectin, zinc and an antibiotic – which are all TGA and FDA approved – which could be the fastest and safest way to stop the Victorian outbreak within 6-8 weeks...The therapy comprises:

1. Ivermectin – TGA and FDA approved as an anti-parasitic therapy with an established safety profile since the 1970s. Known as the “Wonder Drug” from Japan.
2. Zinc
3. Doxycycline – TGA and FDA approved tetracycline antibiotic that fights infections, such as acne, urinary tract infections, intestinal infections, respiratory infections, eye infections, gonorrhea, chlamydia, syphilis, periodontitis (gum disease), and others.”

- <https://www.miragenews.com/wonder-drug-ivermectin-in-a-triple-therapy-should-be-used-for-covid-19-cure-and-prevention/>

“The effect of ivermectin on viral clearance was most pronounced in the randomized trials evaluating doses of up to five days of ivermectin treatment, using doses of 0.4mg/kg (Figure 1). At these doses, there were statistically significant effects on viral clearance in all four randomized trials.”

Figure 1: Effects of Ivermectin on Time to Viral Clearance

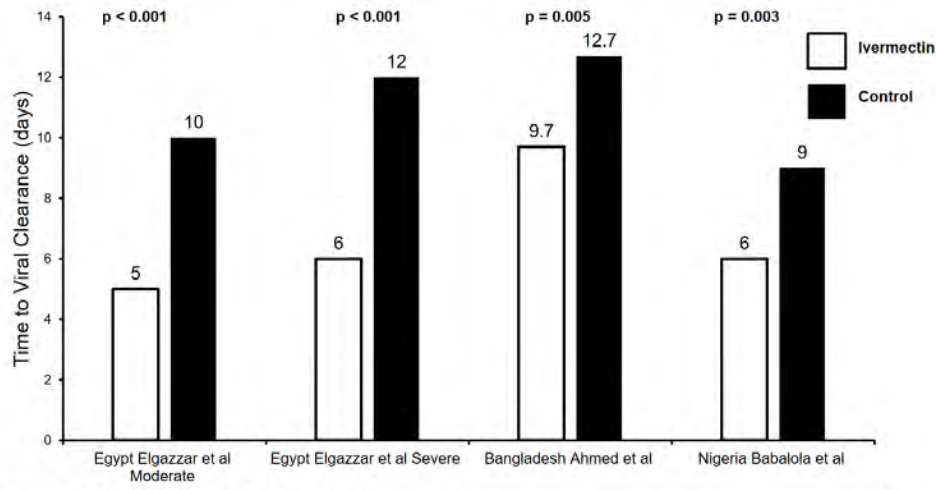


Figure 1: Effects of ivermectin on time to viral clearance

- [https://assets.researchsquare.com/files/rs-148845/v1\\_stamped.pdf](https://assets.researchsquare.com/files/rs-148845/v1_stamped.pdf)

“Several studies reported antiviral effects of ivermectin on RNA viruses such as Zika, dengue, yellow fever, West Nile, Hendra, Newcastle, Venezuelan equine encephalitis, chikungunya, Semliki Forest, Sindbis, Avian influenza A, Porcine Reproductive and Respiratory Syndrome, Human immunodeficiency virus type 1, and severe acute respiratory syndrome coronavirus 2.”

- <https://www.nature.com/articles/s41429-020-0336-z>

“...Among the many mechanisms by which it performs its function, the most consolidated one sees ivermectin as an inhibitor of nuclear transport mediated by the importin  $\alpha/\beta$ 1 heterodimer, responsible for the translocation of various viral species proteins (HIV-1, SV40), indispensable for their replication. This inhibition appears to affect a considerable number of RNA viruses...Ivermectin could prove to be a powerful antiviral, therefore also useful for a possible treatment of the new corona- virus associated syndrome, even from a new perspective. This could happen assuming its role as an ionophore agent...”

- <https://link.springer.com/content/pdf/10.1007/s00210-020-01902-5.pdf>

“A scoping review revealed that ivermectin has demonstrated inhibitory effects against RNA and DNA viruses, thereby opening the doors for further research and development particularly in treating the respiratory viral infections.”

- <https://journaljammr.com/index.php/JAMMR/article/download/30512/57209>

## **Anecdotal Evidence/Case Reports:**

“In Bangladesh, a team of medical doctors reportedly had “astounding” success in treating patients suffering from COVID-19 with two commonly used drugs, doxycycline and ivermectin. Dr. Tarek Alam from the Bangladesh Medical College Hospital, and one of the senior members of the team, reportedly stated that a combination of the two drugs were administered to 60 patients, all of whom experienced full recoveries within four days.”

- <https://zeenews.india.com/india/covid-19-cure-in-sight-bangladeshi-doctors-claim-ivermectin-with-doxycycline-can-treat-coronavirus-patients-2285317.html>

“Doctors have administered the drug ivermectin in several simultaneous trials in several countries sometimes in combination with other common medications.

Physicians who participated in the study report that patients’ viral loads began declining almost immediately after they began administering ivermectin, a widely available prescription drug approved to combat parasites, scabies, and head lice.

It has not been approved for COVID-19 patients, but doctors familiar with clinical trials described patients’ results as dramatic.”

- <https://www.newsmax.com/t/newsmax/article/968688?section=us&keywords=ivermectin-drug-virus&year=2020&month=05&date=22&id=968688&oref=m.facebook.com>

## **HCQ – Evidence as an Effective Therapeutic Intervention**

### **Lancet Retraction of Hydroxychloroquine Study**

On June 4, 2020, the Lancet, billed as “the world’s leading independent medical journal,” issued a public apology after being forced to retract a study that said the anti-malarial drug hydroxychloroquine did not help to curb COVID-19 and might cause death in patients.

The study was withdrawn because the company that provided data for the retracted study refused to provide full access to a request for data from independent investigators so they could perform a more extensive peer-review. The company that balked at fulfilling the data request said to do so would violate client agreements and confidentiality requirements.

The Lancet statement reads:

***“Based on this development, we can no longer vouch for the veracity of the primary data sources. Due to this unfortunate development, the authors request that the paper be retracted.”***

[https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(20\)31180-6.pdf](https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(20)31180-6.pdf)

<https://www.webmd.com/lung/news/20200605/lancet-retracts-hydroxychloroquine-study>

## Hydroxychloroquine Meta-Analysis (192 studies)

- HCQ is effective when used early in the course of SARS-CoV-2 infection. Early treatment is most successful, with 100% of studies reporting a positive effect and an estimated reduction of 67% in the effect measured (death, hospitalization, etc.) using a random effects meta-analysis (RR 0.33 [0.25-0.43]).
- 91% of randomized controlled trials (RCTs) for early, PrEP, or PEP treatment report positive effects. The probability of this happening for an ineffective treatment is 0.0059%.
- There is evidence of bias towards publishing negative results. 88% of prospective studies report positive effects whereas only 75% of retrospective studies do.
- Studies from North America are 3.8 times more likely to report negative results than studies from the rest of the world combined ( $p = 0.00000017$ ). “The probability that an ineffective treatment generated results as positive as the 192 studies to date is estimated to be 1 in 1 quadrillion ( $p = 0.00000000000000097$ ).”

<https://hcqmeta.com>

## Hydroxychloroquine Meta-Analysis (43 studies)

"HCQ is consistently effective against COVID-19 when provided early in the outpatient setting, it is overall effective against COVID-19, it has not produced worsening of disease and it is safe."

- <https://www.sciencedirect.com/science/article/pii/S2052297520301281>

"This study demonstrated that voluntary HCQ consumption as pre-exposure prophylaxis by HCWs is associated with a statistically significant reduction in risk of SARS- CoV-2."

- <https://www.medrxiv.org/content/10.1101/2020.06.09.20116806v1>

Four-plus doses of HCQ is associated with a significant decline in the odds of getting infected, and a dose-response relationship exists.

- <https://www.ijmr.org.in/article.asp?issn=0971-5916;year=2020;volume=151;issue=5;spage=459;epage=467;aulast=Chatterjee>

"... The risk analysis showed that HCQ is also useful as a prophylactic agent for people over 50 years of age. This study, therefore, provides evidence of the necessity for higher-order analytics (such as MCA) in the presence of large data sets that include unknown confounders."

- [https://www.researchgate.net/publication/344369617\\_Hydroxychloroquine\\_as\\_Post-Exposure\\_Prophylaxis\\_for\\_Covid-](https://www.researchgate.net/publication/344369617_Hydroxychloroquine_as_Post-Exposure_Prophylaxis_for_Covid-)

## 19 Why simple data analysis can lead to the wrong conclusions from well-designed studies

A 90% reduction in cases with HCQ pre-exposure prophylaxis. Retrospective study of 604 healthcare workers. “The use of HCQ as preexposure prophylaxis in HCWs was associated with reduced risk of COVID-19, suggesting its role as an effective chemoprophylactic agent.”

- <https://www.marinemedicalsociety.in/article.asp?issn=0975-3605;year=2020;volume=22;issue=3;spage=98;epage=104;aulast=Mathai>

Study of SARS-CoV-2-IgG antibodies in 1122 health care workers found 87% fewer positives with HCQ prophylaxis compared to those with no HCQ prophylaxis (1.3% HCQ versus 12.3%). Adequate prophylaxis is defined as 400mg 1/wk for >6 weeks.

- [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3689618](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3689618)

Retrospective study - 616 patients. “The use of hydroxychloroquine at an early stage is a potential therapeutic strategy for treating patients before irreversible severe respiratory complications occur. The early use of hydroxychloroquine decreased the improvement time and the duration of COVID-19 detection in throat and stool swabs.”

- [https://www.jstage.jst.go.jp/article/bst/advpub/0/advpub\\_2020.03340/\\_article/-char/ja/](https://www.jstage.jst.go.jp/article/bst/advpub/0/advpub_2020.03340/_article/-char/ja/)

“... Both HCQ and azithromycin can be helpful to promote the recovery of most patients and reduced their signs and symptoms significantly. It also shows some manageable side effects mostly those related to heart rhythm. In the absence of FDA-approved medications to treat COVID-19, the repurposing of HCQ and azithromycin to control the disease signs and symptoms can be useful.”

- <https://onlinelibrary.wiley.com/doi/10.1111/ijcp.13856>

“The authors’ analysis suggested that hydroxychloroquine, with or without azithromycin, was associated with a reduced hazard ratio for death when compared with receipt of neither medication.”

- <https://www.sciencedirect.com/science/article/pii/S1201971220305300>

“... Patients treated with HCQ at the time of early hospital recovered faster than those who treated later...”

- <https://onlinelibrary.wiley.com/doi/abs/10.1002/jmv.26193>



A 100% reduction in hospitalization and cases with early treatment using HCQ+AZ+zinc. “HCQ could possibly provide protection against infection with SARS-CoV-2 (prophylaxis), and could, if used early, help to control the COVID-19 infection (treatment).”

- <https://www.sciencedirect.com/science/article/pii/S2052297520301657>

“... Treatment of COVID-19 outpatients as early as possible after symptom onset using triple therapy, including the combination of zinc with low-dose hydroxychloroquine, was associated with significantly fewer hospitalisations.” 79% lower mortality and 82% lower hospitalization with early HCQ+AZ+Z treatment.

- <https://www.sciencedirect.com/science/article/pii/S0924857920304258>

Retrospective study of 2,882 patients in China, showing that HCQ treatment can reduce systemic inflammation and inhibit the cytokine storm, thus protecting multiple organs from inflammatory injuries.

**Note:** The significantly lower dose used here is potentially related to the different observations from the RECOVERY trial results.

- <https://link.springer.com/article/10.1007/s11427-020-1782-1>

“Our findings suggest that patients confirmed of COVID-19 infection should be administrated HCQ as soon as possible.”

- <https://icjournal.org/DOIx.php?id=10.3947/ic.2020.52.3.396>

“... For [time to clinical recovery] TTCR, the body temperature recovery time and the cough remission time were significantly shortened in the HCQ treatment group. Besides, a larger proportion of patients with improved pneumonia in the HCQ treatment group (80.6%, 25 of 31) compared with the control group (54.8%, 17 of 31).”

- <https://www.medrxiv.org/content/10.1101/2020.03.22.20040758v3>

“By administering hydroxychloroquine combined with azithromycin, we were able to observe an improvement in all cases, except in one patient who arrived with an advanced form, who was over the age of 86, and in whom the evolution was irreversible. For all other patients in this cohort of 80 people, the combination of hydroxychloroquine and azithromycin resulted in a clinical improvement that appeared superior when compared to outcomes of other hospitalised patients, as described in the literature.”

- <https://www.sciencedirect.com/science/article/pii/S1477893920301319#bib18>

“In the present study, multivariate analysis performed using Cox regression modeling and propensity score matching to control for potential confounders affirmed that treatment with hydroxychloroquine alone and hydroxychloroquine in combination with azithromycin was associated with higher survival among patients with COVID-19. Patients that received neither medication or azithromycin alone had the highest cumulative hazard.”

- <https://www.sciencedirect.com/science/article/pii/S1201971220305348>

“A total of 3,119 patients received HCQ-AZ for at least three days. QTc prolongation (>60 ms) was observed in 25 patients (0.67%), resulting in discontinuation of treatment in 12 cases, including three cases with QTc > 500 ms. No cases of torsade de pointe or sudden death were observed, including in the 9.5% of patients over 65 years of age...

Our current observations and practices illustrate the efficacy of this risk management procedures associated with the prescription of HCQ-AZ, which presents an excellent safety profile in COVID-19 patients, including elderly patients.”

- <https://www.sciencedirect.com/science/article/pii/S0924857920304556>

“Our findings show that hydroxychloroquine is safe for COVID-19 and not associated with a risk of ventricular arrhythmia due to drug-induced QTc interval prolongation. Additionally, hydroxychloroquine was well tolerated, and there were no drug-related non-serious adverse events leading to treatment discontinuation in the majority of patients who were stable and did not require hospitalization.”

- <https://www.sciencedirect.com/science/article/pii/S0735675720311335>

“HCQ administration is safe for a short-term treatment for patients with COVID-19 infection regardless of the clinical setting of delivery, causing only modest QTc prolongation and no directly attributable arrhythmic deaths.”

- <https://academic.oup.com/europace/article/22/12/1855/5910968>

“Data from 3 outpatient COVID-19 trials demonstrated that gastrointestinal side effects were common but mild with the use of hydroxychloroquine, while serious side effects were rare. No deaths occurred related to hydroxychloroquine.”

- <https://academic.oup.com/ofid/article/7/11/ofaa500/5930834>

“This comparative analysis of coronavirus infection and death among 2.4 billion persons around the world demonstrates a wide (two orders of magnitude or one hundred-fold) disparity in coronavirus fatality rates between well-developed and less-developed countries....The current data demonstrates the surprising fact that those in more affluent countries are about one hundred times more likely to become infected with coronavirus infection and die. This effect is most apparent when these countries are compared to countries with the highest rates of endemic malaria...the mortality data presented here is highly probative for the hypothesis that prophylactic antimalarial use by its incoming visitors markedly attenuates a country’s coronavirus fatality rate.”

- [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3586954](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3586954)

## Global Survey of Physicians Working on the Front Lines

- 85% said that hydroxychloroquine is at least somewhat effective for COVID-19.
- Hydroxychloroquine was the most utilized treatment for COVID-19 patients.
- 35%-40% of the doctors using the drug called it very effective or extremely effective against COVID-19.
- 65% of doctors said they would prescribe hydroxychloroquine for COVID-19 to their family members.

<https://wattsupwiththat.com/2020/07/07/hydroxychloroquine-based-covid-19-treatment-a-systematic-review-of-clinical-evidence-and-expert-opinion-from-physicians-surveys/>

## Remdesivir

“By way of comparison, the 13% mortality observed in this remdesivir compassionate-use cohort is noteworthy, considering the severity of disease in this patient population; however, the patients enrolled in this compassionate-treatment program are not directly comparable to those studied in these other reports. For example, 64% of remdesivir-treated patients were receiving invasive ventilation at baseline, including 8% who were receiving ECMO, and mortality in this subgroup was 18% (as compared with 5.3% in patients receiving noninvasive oxygen support), and the majority (75%) of patients were male, were over 60 years of age, and had coexisting conditions...Specifically, improvement in oxygen-support status was observed in 68% of patients, and overall mortality was 13% over a median follow-up of 18 days.”

- <https://www.nejm.org/doi/10.1056/NEJMoa2007016>

“There was a strict correlation (Spearman test,  $p = 0.017$ ) between the position of doctors towards hydroxychloroquine and the average amount paid to them by the company Gilead Sciences between 2013 and 2019. In all, only 13 doctors out of 98 CMIT members did not receive any benefit, remuneration or agreement from the Gilead Sciences company between 2013 and 2019. Among these

13 doctors, seven were very favourable to the use of hydroxychloroquine, one was favourable, one was neutral and four have not taken a position. In contrast, among the 13 doctors that received the most important funding from Gilead Sciences, six were very unfavourable to the use of hydroxychloroquine, one was unfavourable, three were neutral and three had not taken a position.”

“None of the studies involving remdesivir or lopinavir/ritonavir could show any effectiveness of these drugs in the prevention of mortality or the reduction of the viral load of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), whereas four studies have now shown significant differences in clinical course, radiological course, mortality and viral load for hydroxychloroquine.”

- <https://www.sciencedirect.com/science/article/pii/S2052297520300627?via%3Dihub>

## Effective Treatments for COVID Position

Modern medical practice is at a pivotal crossroads. The inclusion of evidence-based nutritional research and biochemistry must become an integral component of modern medical practice.

Despite 73% of medical schools not meeting the National Academy of Sciences minimal recommendation of 25 contact hours for nutritional education, nutritional medicine plays an essential role in the health of a nation.<sup>110</sup>

This includes nutritional medicine’s role in disease prevention and treatment. What is currently ordained as accepted medical treatment has historically been reserved for patentable, and therefore profitable, pharmaceuticals and technologies.

The inherent bias of patent/profit-centric medicine is not synonymous with therapeutic efficacy. To the contrary, the exclusion of evidence-based nutritional science, as well as off-label inexpensive drugs, severely restricts the practice of medicine. The exclusion of evidence-based nutritional science does not allow healthcare providers to practice patient-centric, personalized medicine.

If modern conventional medicine no longer envisions itself as personalized and patient-centric, then it has abdicated its primary duty to humanity to be of ethical and moral service to the people of the world.

During a global health crisis, once the most vulnerable populations are established, it is the essential duty and responsibility of federal, state, and county health agencies to disseminate evidence-based guidance to ensure the most vulnerable are as well-protected as possible. However, this was not the case with COVID-19.

Guidance for evidence-based hygiene was initially disseminated. Guidance for masking of healthy people was disseminated without evidence. Guidance for social distancing of healthy people was disseminated without evidence.

Yet, guidance for clinical nutrition was inexplicably never shared with the American public or medical professionals despite the overwhelming abundance of evidence of its efficacy. Nutrition is proven to not only prevent the spread of the SARS-CoV-2 virus, but it is also uniquely positioned to accelerate recovery times and reduce severe adverse events. In a series of public health policy failures, history

may view the failure to inform the public and medical professionals regarding nutrition as the most egregious failure.

Evidence-based information must be disseminated to promote health within the population. Failure to inform the public of efficacious treatment/prevention options such as vitamin D, vitamin C, vitamin A, vitamin E, zinc, ivermectin, and hydroxychloroquine during a crisis goes beyond unethical and enters the territory of potentially criminal behavior.

This failure to inform is aggravated when it is buttressed by letters to medical practitioners from the FDA threatening to suspend licenses for using evidence-based therapeutics, and national media campaigns actively censoring any professional discussion of the efficacy of evidence-based treatments for COVID-19.

How many lives could have been saved? How much faster could this crisis have been concluded had nutrition been the primary strategy for nationwide mitigation and treatment?

These concerns are made even more troubling when one realizes that the CDC knew for more than 20 years that Americans were significantly nutrient deficient in key immune nutrients and did nothing to resolve it.

Under the pretext of a chronic disease epidemic, where 10% of the nation's population is diabetic, at least 73% of our citizens are overweight or obese, and healthcare costs for chronic disease exceed 2.8 trillion dollars annually (which comprises 86% of all healthcare costs in the United States), it is unconscionable that the CDC and FDA failed Americans regarding nutritional guidance.

How difficult is it to issue basic nutritional guidance for vitamins and minerals in addition to issuing guidance about hygiene, masking of the symptomatic, and social distancing for the symptomatic?

The collaborative efforts between federal agencies should have additionally resulted in the initiation of a series of basic nutrition, exercise, and supplement guidelines for the underprivileged, malnourished, and chronically ill Americans, whom these agencies knew were at a higher risk of dying.

At minimum, the issuance of nutritional guidance and recommendation of vitamin D prophylactically, especially upon admission for hospital care, would have helped flatten the curve.<sup>14</sup>

Vitamin C administration could have been used to enhance the rate of recovery in hospitals, as evidenced by meta-analysis research, which identified that vitamin C administration reduces ICU stays by 7.8-8.6% and time on mechanical ventilation by 14-18.2% for severe respiratory infections.<sup>31,35,36</sup>

Given that the projected cost of vitamin C administration in hospitals is \$12-24 per day, there is no ethical or economic reason why the evidence surrounding vitamin C is being willfully ignored by federal, state, and county health agencies.<sup>37</sup>

Well over 12 months into the COVID-19 crisis, a large body of peer-reviewed evidence has been amassed that causally links vitamin D deficiency to the risk of disease severity, mortality, and ICU overwhelm.

A considerable body of literature directly places vitamin D deficiency at the front-row-center position in terms of the pathophysiology of SARS-CoV-2 infectivity, subsequent cytokine storms, ARDS,

pulmonary edema, and severe respiratory complications, particularly among those in the high-risk demographics (60 years of age with major comorbidities).

Furthermore, ongoing clinical trials have demonstrated significant promise for vitamin D analogues, such as Calcifediol to reduce ICU overwhelm, reduce mortality, and enhance recovery from COVID-19.

The CDC had a duty and responsibility to utilize NHANES data to protect Americans. At the very least, by May/June 2020, the CDC had the duty and responsibility to ensure that every hospital admission was serologically tested for vitamin D deficiencies and provide guidance to medical professionals to ensure this easily correctable correlation to outcome was not overlooked.

Is the CDC so entrenched in the profitability of disease that they have lost their basic humanity?

Why were safe and effective treatments withheld from Americans who needed them the most? Why were so many opportunities to resolve this crisis missed? Incompetence? Willful neglect? Over reliance on a single experimental strategy?

We hope the reasons behind this epic failure of public health policy and strategy are ultimately proven to be gross, well-intentioned incompetence, and over-reliance on a single experimental strategy. We are currently unable to objectively rule out willful neglect, corruption, and greed.

Even after the former director of the CDC, Dr. Tom Frieden, announced in the media that vitamin D supplementation can likely help COVID-19 patients—and may improve resistance to infection—neither the CDC nor the FDA made any official statements to the public to correct course.<sup>17</sup>

In fact, the CDC has exhibited a pattern of willful neglect in its dealings with elected officials attempting to correct gross misstatements it has made to the American people.<sup>107</sup>

**Perhaps it is time that the public finally acknowledges that the CDC is a multinational corporation with locations in 61 countries around the world.**<sup>108</sup>

**Withholding evidence-based treatments is not only unethical, it is also tantamount to being criminal.**

**We find that withholding evidence-based treatment from people in dire need constitutes a clear dereliction of duty to the American public the CDC and FDA are sworn to serve.**

The CDC's fiscal year budget for 2018 was \$11.9 billion. In 2020, the CDC received an additional \$500 million in funding through the CARES Act. The amount allocated to states for nutritional guidance and education is minuscule by comparison compared to what has been allocated for PCR testing, the promotion of the Asymptomatic Transmission theory, and experimental COVID biologic development.

If serologic vitamin D testing had been performed for every hospital admission, it could have led to the immediate collection of a large and statistically significant body of data that in turn, could have been utilized to guide healthcare professionals on what was working rather than holding out hope for a warp speed experimental COVID biologic to swoop in and save the day.

Yet, it is nutritional guidance that is desperately needed for a nation trapped in what has now surpassed a year-long crisis.



## Proposal for Safe and Effective Nutritional Guidance

**Note:** Therapeutic range is a compilation of the following resources:

- Suggested Optimal Nutrient Allowance (SONAs)
- Linus Pauling Institute Micronutrient Research Center
- Summary of well-known Naturopathic clinical texts (Murray, Pizzorno, Marz, Mateljan, etc.)
- PubMed and Google Scholar research updates, Thorne research, Pure Encapsulations research, research of trusted nutraceutical companies
- Observations in clinical practice shared and confirmed by colleagues and student practitioners since 2007 (n>3500).
- Recommending use of supplementation from reputable companies with at least one of the following certifications for purity and potency: cGMP, NSF, USP, UL, NonGMO Project, or ConsumerLabs.

### Seniors, Adults, and Teens

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,500-2,167 IU
VITAMIN C	3000-5000 mg	65-125 mg
VITAMIN D3	10,000 IU (14-Days) 5,000 IU (After)	600-800 IU
VITAMIN E	200-600 IU	22-28 IU
ZINC	25-40 mg (min 30mg for High-Risk)	8-11 mg

- Age 13 and up.
- For all genders.
- Includes expecting mothers and breastfeeding mothers.
- Nutrients should be taken with a small amount of food to minimize nausea.
- Multivitamin and omega 3 fatty acids recommended as well.

### Children Ages 5 to 12

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	5,000 IU	1,000-2,000 IU
VITAMIN C	2,000-4,000 mg	25-45 mg
VITAMIN D3	5,000 IU (14-Days) 2,000 IU (After)	200 IU
VITAMIN E	100 IU	10-17 IU
ZINC	25 mg	8 mg

- Age 5 to 12.
- For all genders.
- Nutrients should be taken with a small amount of food to minimize nausea.
- Multivitamin and omega 3 fatty acids recommended as well.

**Children Ages 1 to 4**

KEY NUTRIENTS	THERAPEUTIC RANGE	RDA
VITAMIN A (Beta-Carotene)	2,000 IU	1,000-1,500 IU
VITAMIN C	500-1,000 mg	15-50 mg
VITAMIN D3	1,000-2,000 IU	200 IU
VITAMIN E	50 IU	6-9 IU
ZINC	10 mg	3 mg

- Age 1 to 4.
- For all genders.
- For infants no longer breastfeeding.
- Liquid multivitamin and omega 3 fatty acids are recommended as well.

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## People Worthy of Our Remembrance



### **Hayden Hunstable, 12, Died by Suicide**

"What I remember is hugging him," Brad Hunstable said. "I miss kissing him on the head and feeling his hair. I miss playing football with him. I miss joking around with him and wrestling." There's so much to miss for a dad who is missing his son.

"My son died from the coronavirus as I mentioned," Hunstable says in his online video. "But not in the way you think. The isolation...there's no doubt in my mind [it] had an affect," he said. "No doubt in my mind there was something missing."

<https://www.10tv.com/article/news/local/ohio-state-alum-shares-story-childs-suicide-tells-parents-covid-19-isolation-real-2020-may/530-c62f7060-3775-448a-bfd9-d21ad5aeeca5>

## Topic 4 – Violations of Federal Law and Data Quality

**Topic Introduction** – There is nothing more important to public health policy development than accurate and verifiable data. Decisions that will impact hundreds of millions of people have to be held to the highest standards of integrity. This responsibility to be impeccable from a data perspective takes on even greater importance during a nationwide and global crisis.

To ensure that data collected, analyzed, and published is always accurate and of the highest quality, various U.S. Congresses have displayed a visionary wisdom with the implementation of the Administrative Procedures Act (APA), Paperwork Reduction Act (PRA), and Information Quality Act (IQA) enacting federal laws that apply to all federal agencies and agents whether elected or appointed.

**The Administrative Procedures Act** (5 U.S.C. Chapter 5) was first made federal law in 1946. The APA is responsible for (1) requiring agencies, including the FDA and CDC, to keep the public informed of how the agency is organized and functions to ensure transparency, (2) ensuring the public can participate in rulemaking through public comment, (3) establishing uniform standards for the formal means of rulemaking and addressing of concerns, and (4) defining the scope of judicial review so there is appropriate oversight over all agencies.

**The Paperwork Reduction Act** (44 U.S.C. §§ 3501-3521, Public Law 96-511, 94 Stat. 2812) was first made federal law in 1980. Despite its name, the PRA is far more than a simple attempt to reduce paperwork. The PRA is responsible for establishing and empowering the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). The PRA gives the OIRA the responsibility of federal oversight over all federal agencies to ensure each agency is in full compliance. An amendment to the PRA in 1995 (44 U.S.C. §§ 3501-3521, Public Law 104-13, 109 Stat. 182) explicitly empowered the OIRA with authority over all federal agencies for the collection, analysis, and publication of data. The PRA (44 U.S.C. §§ 3506 (c)(2)(A)) specifically requires all federal agencies to report any potential changes to data collection, analysis, and/or publication to the federal register to accomplish 2 compliance objectives: (1) notification of the OIRA of intention to make modifications to data and (2) launch of a 60-day opportunity for public comment and scientific review.

**The Information Quality Act** (Section 515 of the Congressional Consolidation Appropriations Act, 2001 Public Law 106-554) was made federal law in 2002. This federal law defined four key principles for information quality including: (1) quality, (2) objectivity, (3) utility, and (4) integrity.

- **Quality** is defined as an encompassing term comprising objectivity, utility, and integrity.
- **Objectivity** is defined as a measure of whether disseminated information is accurate, reliable, and unbiased AND whether that information is presented in an accurate, clear, complete, and unbiased manner.
- **Utility** is defined as the usefulness of the information for the intended audience's anticipated purposes, which is the basis for opening public comment.

- **Integrity** is defined as the security of the information from unauthorized modification to ensure the information is not compromised through corruption or falsification.

The brilliance of these three laws is that they ensure oversight that make corruption exceedingly difficult, but admittedly not impossible. These three laws demand all agencies to uniformly follow the same laws, protect public opportunities for participation in their own governance, create transparency, and ensure that the data being provided for public consumption is accurate, reliable, unbiased, clear, complete, useful, and free from intentional and unintentional modification.

These three laws, when strictly enforced, build public trust in our government.

However, when these three laws are violated, as the following paper alleges and substantiates, the vision for our country that great men and women created becomes blurry and dark.

We have laws for a reason, and these laws are intended to protect and serve the people of our great nation. All just laws such as these must always be followed. A global crisis is the opportunity to reaffirm the wisdom of these laws—not ignore, bypass, and disregard them as has occurred repeatedly and without any accountability to date.

## **Modifying Fatality Data Without Oversight or Public Comment**

### **COVID-19 Data Collection, Comorbidity and Federal Law: A Historical Retrospective**

[https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864\\_c39029cd980642e48797cdb2ef965972.pdf](https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_c39029cd980642e48797cdb2ef965972.pdf)

**Key Quotes** – *“Supportive data comparisons suggest the existing COVID-19 fatality data, which has been so influential upon public policy, maybe substantially compromised regarding accuracy and integrity, and illegal under existing federal laws.*

*The key to initiating legal regulatory oversight of all proposed changes to data collection, publication, and an analysis is the Federal Register.*

*This decision was made despite pre-existing rules, approved by the OMB, issued by the CDC, and in use nationwide for at least 17 years without incident. These rules are published as, 2003 CDC’s Medical Examiners’ and Coroners’ Handbook on Death Registration and Fetal Death Reporting and the CDC’s Physicians’ Handbook on Medical Certification of Death.*

*Considering these handbooks have been approved by the OMB and in use without incident for 17 years, there was no justifiable reason for the CDC to implement these changes, bypass the oversight of the OMB, and fail to provide 60-days for public comment, as they are legally obligated to do.*

*By failing to act in accordance with Congress’ clear intent as to how an agency may propose changes to data collection as codified in 44 USC 3506 (c)(2)(A), there is no record of information the CDC relied upon to make its decision to change how deaths are reported.*



*Previous reports detailed the substantial changes on how causes of death were forcibly modified by the CDC through the NVSS, and how together, both federal agencies inflated the actual number of COVID-19 fatalities by approximately 90.2% through July 12th, 2020.”*

**Summary** – On March 24, 2020, the CDC, by way of the National Vital Statistics System (NVSS), issued COVID-19 Alert No. 2, which significantly changed how death certificate reporting would be submitted for all fatalities with probable or confirmed COVID-19 involvement. This change in data reporting was exclusive for COVID-19 and in direct contrast to the previous guidelines used nationwide for the previous 17 years. The previous guidelines can be found within the *2003 CDC Medical Examiners’ and Coroners’ Handbook on Death Registration and Fetal Death Reporting* and the *2003 CDC Physicians’ Handbook on Medical Certification of Death*.

The major changes were as follows:

- *“COVID-19 should be reported on the death certificate for all decedents where the disease caused or is assumed to have caused or contributed to death. Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc. **If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II.**”*

For the previous 17 years pre-existing/comorbid conditions were reported in Part I, not Part II, which can impact statistical aggregation according to certified death reporting clerks interviewed. Additionally, in the presence of pre-existing/comorbid conditions, infectious disease that directly led to the fatality could be listed on the last line item in Part I as an initiating factor.

However, that determination was always left to the discretion of the attending medical examiner, coroner, or physician who are far more familiar with the deceased patient’s medical history.

Additionally, if significant pre-existing/comorbid conditions were present making the patient more susceptible to infections, these were more commonly entered in Part II as contributing factors rather than causative factors in Part I for COVID-19 related fatalities only.

The point of contention of this change is that it was made without official notification in the federal register to initiate federal oversight and mandatory public comment.

- *“The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the **underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not.**”*

This quote tells the medical professional filling out the certificate of death what the cause of death is EXPECTED to be more often than not.

Not only is this presumptuous, but it also comes with the knowledge that the NVSS can reject any death certificate registration that they feel is in conflict with this alert or they can alter the

final record without the knowledge of the signatory medical professional without oversight. This leaves the family of the deceased with the responsibility of correcting the public record should a grieving family member desire to take on more burden.

Additionally, one must objectively consider how COVID diagnoses were unethically incentivized financially by the Department of Health and Human Services (HHS) for hospitals and congregate care centers where most of the reported fatalities have occurred.

**Position** – Laws in place, since 1946, are in place for a reason and must be followed, especially during times of crisis. Modifying certificate of death registration for only one disease greatly compromises the accuracy, clarity, and unbiased nature of the data. In doing so, it compromises the objectivity and renders the utility of the date virtually useless. Additionally, because the APA and PRA were procedurally violated, it calls into question the integrity of the data that effectively shaped the reactionary response to public health policy development.

Because fatalities associated with COVID are recorded differently than non-COVID associated fatalities, comparison between them for analysis is additionally compromised. The proverbial ability to compare apples (COVID) to apples (Flu) is impossible without correcting all certificates of death.

Nonetheless, there is hope.

Each fatality with a confirmed PCR test must have a record at the conducting lab of the date of the test and the cycle threshold value that determined the positive lab result. According to the published work of Dr. Jefferson, we know that replication-competent virus is unlikely above a Ct of 25 and certainly above 34.

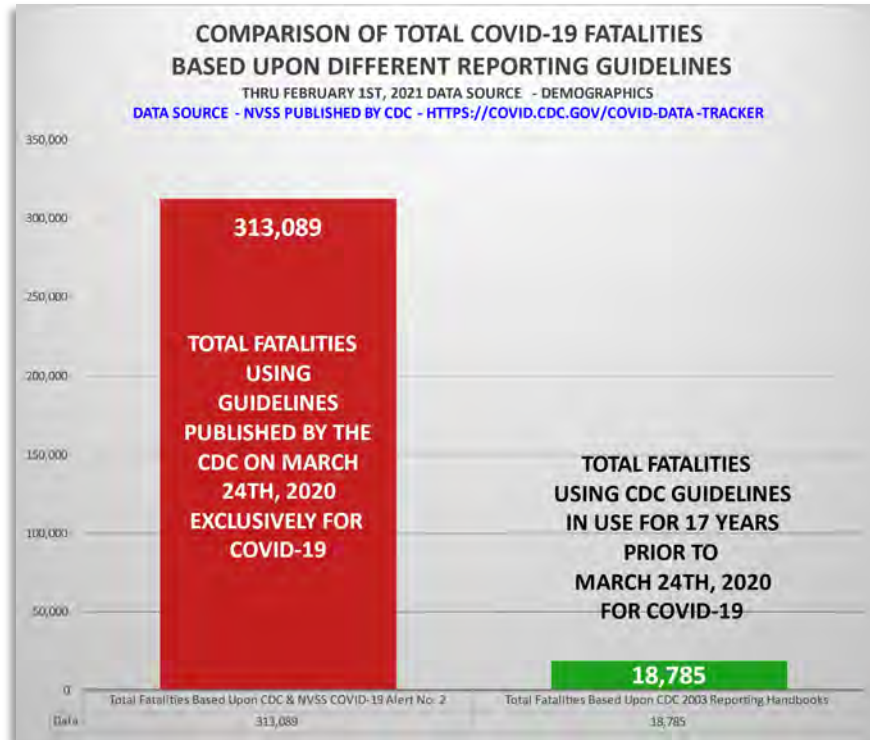
If we were able to have the date of the death certificate, the date of the positive PCR, the Ct value that a signal was detected on the individual's PCR, and a basic knowledge of pre-existing/comorbid conditions, we could accomplish the following:

- (1) For all reported fatalities associated with COVID, we could eliminate all presumptive fatalities
- (2) Eliminate all fatalities from injury that were misclassified as COVID related
- (3) Eliminate all fatalities with significant comorbid conditions as those conditions should have been listed in Part I
- (4) Eliminate all certificates of death with a cycle threshold greater than 25 (or conservatively, 34)
- (5) Eliminate all certificates of death where the last positive PCR was more than 28 days before the day of death

This would provide a way to effectively correct death certificate reporting and clarify the number of deaths that could confidently be considered caused by COVID-19 versus the deaths attributable to pre-existing comorbidities where COVID-19 was not a significant contributor.

In August 2020, the CDC admitted that 94% of COVID fatalities had on average 2.6 major pre-existing comorbidities. Our previous statistical analysis from each individual state health department publishing

comorbidity data through August ranged from an aggregate 90.8 to 95.2%, which was similar to the CDC’s confirmation. Based upon this finding, and in light of our research into the appropriate 2003 medical examiner, coroner, and physician handbooks on death certificate reporting, we were able to extrapolate the following analysis in anticipation of what death counts might look like during a full audit for COVID-19 had the 2003 guidelines been followed.



## Modifying Case Data Without Oversight or Public Comment

### COVID-19 Data Collection, Comorbidity, & Federal Law: A Historical Retrospective

[https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864\\_c39029cd980642e48797cdb2ef965972.pdf](https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_c39029cd980642e48797cdb2ef965972.pdf)

**Key Quotes –** “Supportive data comparisons suggest the existing COVID-19 fatality data, which has been so influential upon public policy, maybe substantially compromised regarding accuracy and integrity, and illegal under existing federal laws.

The key to initiating legal regulatory oversight of all proposed changes to data collection, publication, and an analysis is the Federal Register.

By employing a non-governmental organization (Council of State and Territorial Epidemiologists - CSTE), free from the oversight of the OMB and the laws detailed by Congress via the IQA and PRA, the CDC bypassed the oversight of the OMB Director’s Information Resources Management policies, plans, rules, regulations, procedures, and guidelines for public comment. We allege this is a violation of 44

U.S. Code 3517(a), which requires an agency to provide interested persons an “early and meaningful opportunity to comment.

On April 14th, the CDC adopted a position paper authored by the Council of State and Territorial Epidemiologists (CSTE), a 501c (6) non-profit organization, with the assistance of four CDC-employed subject matter experts (Dr. Susan Gerber, Dr. Aron J. Hall, Sandra Roush and Dr. Tom Shimabukuro). This document was sanctioned by Dr. Robert R. Redfield, Director of the CDC.”

**Summary** – Early into this crisis, the CDC outsourced the definitions for diagnostic criteria to a little-known non-profit organization outside of federal government regulation known as the Council of State and Territorial Epidemiologists (CSTE). On April 14, 2020, the CDC adopted this position paper for which the CDC provided subject matter experts but technically did not author. Therefore, a question arises. Why would a federal agency like the CDC, with many respected PhDs, need to outsource the development of diagnostic criteria to a non-profit organization outside of federal jurisdiction?

That does not immediately make sense unless in doing so, the CDC was attempting to bypass federal laws (APA and PRA) to avoiding oversight and public comment. Even if other reasons arise, the CDC compromised the quality of the data collected, analyzed, and published in alleged violation of the IQA.

Below are the major flaws with the CSTE position paper that could have been unearthed if federal oversight and opportunity for public comment had been legally honored:

- **Failure to Prevent the Same Person from Being Counted as a New Case Multiple Times**

*“Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance. **N/A until more virologic data are available.**”* (Section VII.B, Page 6)

**Position** – The presence or absence of data is not a prerequisite requirement for ensuring that the same person cannot be inaccurately counted multiple times as unique new cases.

- **Asserting Asymptomatic Carriers Exist Without Scientific Proof or Citation**

*“Symptoms of COVID-19 are non-specific and the **disease presentation can range from no symptoms (asymptomatic)** to severe pneumonia and death.”* (Section VI.A, Page 3)

**Position** – A statement such as this requires the application of the 5 gold-standards for medical intervention previously described in the Asymptomatic Transmission topic.

- **Defining ‘Probable’ Cases Based on Flimsy Medical Criteria**

*“At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s) **OR At least one of the following symptoms: cough, shortness of breath, or difficulty breathing** OR Severe respiratory illness with at least one of the following: Clinical or radiographic evidence of pneumonia, or Acute respiratory distress syndrome (ARDS). **AND No alternative more likely diagnosis.**”* (Section VII.A2, Page 5)

**Position** – There are many pathologies that can lead to fever and chills, myalgia, headache, fever, and/or sore throat. These are not symptoms unique to COVID-19, and thus compromises the accuracy of the data. Additionally, there are MANY pathologies where a cough or shortness of breath or difficulty breathing are common symptoms. These are not symptoms unique to COVID-19. Radiographic evidence of pneumonia is not diagnostic for the cause of pneumonia. To assert that all of these qualify a patient to be diagnosed with COVID as a ‘probable’ or ‘presumptive’ case is not the way appropriate and accurate medical diagnoses occur. The CSTE position paper adopted by the CDC throws medical investigation out the window, and then the HHS incentivizes the COVID diagnosis above all other possibilities. This clearly compromises data accuracy and therefore quality.

Applying these criteria greatly inflates case, hospitalization, and fatality data making it impossible to be reasonably confident that the data being collected, analyzed, and published is accurate for public health policy development.

- **Failure to Establish a Reasonable Cycle Threshold Value for Infectiousness**

**Position** – Missing from this CSTE position paper is any discussion of cycle threshold (Ct) values even though molecular amplification is openly discussed to confirm a case. PCR testing, as it is currently utilized globally, cannot determine infectiousness, but it can produce an inordinate number of false positives where replication-competent virus is unable to be cultured. The CSTE would have been wise to state a recommended cycle threshold of 30 Ct based upon what is accepted as a reasonable Ct for other infectious respiratory disease.

- **Empowering Contact Tracers to Practice Medicine Without a License**

*“In a person with clinically compatible symptoms with one or more of the following exposures in the 14 days before onset of symptoms: Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2; OR Close contact\*\* with a person diagnosed with COVID-19; OR Member of a risk cohort as defined by public health authorities during an outbreak.” (Section VI.A3, Page 3)*

**Position** – While the HHS, FDA, and CDC are much more responsible for authorizing the creation of the contact tracing industry, the CSTE position paper laid the groundwork for its birth. Nowhere in this document is there concern for infectiousness, which is the key component required for precision curtailing of spread. Had there been legitimate concern for infectiousness, this document would have discussed the need for replication-competent virus cell culture to calibrate PCR testing at the correct cycle threshold. Had there been legitimate concern for infectiousness, this document would have scoffed at any notion of ‘probable’ cases. Had there been legitimate concern for infectiousness, testing would have focused on antigen testing until the PCR is properly calibrated. Had there been legitimate concern for infectiousness, this paper would have never based diagnosis on such capricious criteria as what has been established for contact tracers. Contact tracers are empowered to diagnose a person that they have never examined, or even spoken to, with COVID. This is a blatant violation of existing medical licensing laws and only further compromises the accuracy, objectivity, utility, and integrity of the data being collected, analyzed, and published.

## Additional Subtopic References

- CDC/NVSS COVID-19 Alert No. 2 issued March 24, 2020  
<https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>
- CSTE Position Paper adopted by CDC on April 14, 2020  
[https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01\\_COVID-19.pdf](https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf)

## Federal Law and Data Quality Position

Oversight and protection of public participation in governance are hallmarks of the United States of America. They are a part of our DNA because they have worked for hundreds of years and what is not broken should not be discarded, only improved. Our country was born because the founding fathers were unable to participate effectively in their own governance and decisions were made unilaterally by an oligarch across an ocean without significant oversight for checks and balances.

Their experiences of ever-present tyranny gave them incredible insight on how to thwart corruption and protect public participation in their own governance. While their early model was admittedly hypocritical and far from perfect, it was the beginning of a great nation, which was passed down from generation to generation. This has been demonstrated by the historical timeline from 1946 to 2002 of the three key federal laws enacted from three different generations of legislators as illustrated throughout this topic.

Yet in 2020, our elected and appointed officials chose to abandon what has worked so well for our country for centuries in favor of a private, 'we know what's best' mentality that has produced historical levels of collateral damage and severely injured the trust that citizens must have in their government to effectively co-exist and create a promising future for younger generations to emerge into.

In data analysis, there is a common colloquial phrase, 'garbage in becomes garbage out.' What this means is that if the data that is entered is inaccurate then any calculations for analysis will also be inaccurate.

With COVID-19 Alert No. 2 and the CSTE Position Paper, it is clear why oversight and the protection of public participation is essential to solving this crisis and the forward direction as a unified country. After all, how can a country be united when significant portions of the electorate do not trust the accuracy of the data or the people promoting the data as accurate?

Perhaps the best way to solve this problem is to start over and use the methods for data collection that have been used for all other infectious disease and then turn all efforts towards correcting death certificate reporting and case counts.

It is our duty to thoroughly investigate how this happened, who was responsible, and hold those responsible accountable to the strictest letter of the law so that this level of incompetence and



malfeasance, if proven, will never happen again in a country where everyone's birthright is life, liberty, and the pursuit of happiness.

## People Worthy of Our Remembrance



### **Irene Wright Died Alone**

"I just felt helpless. Couldn't do nothing. Couldn't see her, couldn't go over there. Nothing I could do," Irene Wright's daughter Geraldine Wiggins said. "The nurse was in the room and she answered the phone," Wiggins recalled. "I asked her if she could put the phone up against my mother's ear -- she did -- I said 'Mom, I want you to get well, and I love you.' She said, 'I love you too.' But Wright never recovered. Three days later she needed CPR, but Wiggins said it was too late. Wright died alone.

<https://abc11.com/coronavirus-covid-19-death-vance-county-dies-alone/6173081/>

## Topic 5 – Projection Models Lead Us Astray

**Topic Introduction** – Computer projection models have been used for decades to provide planners and decision-makers with important estimates of key statistics and to study how changes in assumptions may affect financial, health, ecological, and even social outcomes. As early as 1967, Klaus Dietz’s paper, “Epidemic and Rumours: A Survey,” discussed the use of epidemic models for tracking ***“the propagation of ideas, rumours and consumers’ goods.”***

Because epidemic models can be used to track the spread of ideas as well as diseases, it is especially important for democratic nations to understand the nature of such models and how they can be used and abused.

Improvements in computing speed have made it possible to build more complex computer models and use them to model increasingly complex phenomena. Today, it is possible to simulate individual behavior and perform complex multivariate regression modeling of disease parameters that earlier model builders never imagined.

Improvements in computer languages and modeling tools have increased the availability of potential model builders and lowered the cost of model building.

As a result, computer projection models are ubiquitous today.

As with all computer programs, the phrase, “Garbage in, garbage out” applies to computer projection models. Model output quality depends entirely on how well the inputs and the internal algorithms fit the reality they are supposed to model. Unfortunately for modelers, reality is extremely complex.

Modelers are forced to make many assumptions that have a direct impact on the chosen modeling algorithm and the ultimate outcome. Due to the complex nature of these models, the assumptions are simplified, and in a complex environment, these simplifications ultimately result in measurement error and face external validity threats. Assumptions allow the modeler to reduce the many uncertain factors that *influence* reality to a few easily measured quantities that can be used as inputs to the model. Additionally, every computer program requires tradeoffs among speed, accuracy, ease of use, development time, development cost, program organization, and readability. Assumptions enable the modeler to make practical choices when programming the model’s internal algorithms.

These decisions are made for ease of modeling and do not necessarily match reality.

At the start of an epidemic like COVID-19, it can be difficult to determine what assumptions are reasonable and more difficult to reliably measure key inputs. Unreasonable assumptions and inaccurate inputs lead to poor projections. For this reason, projection models are not reliable guides for policy decisions. In general, computer models are better used as part of a framework to design actual clinical trials and to refine measurement instruments.

Despite the impossibility of accurate modeling at the start of an epidemic, policymakers face intense pressure to take informed action. People want to know how the epidemic will unfold before it is

possible to predict. In earlier times, kings facing an epidemic consulted specialists to interpret dreams, read tea leaves, toss bones, or roll dice to explain the future. Today, policymakers hire specialists to develop computer projection models that incorporate mathematics, statistics, and computers.

The human desire to know what the future holds has not changed, and neither has blind faith in the modern approach to predicting how the future will look. Yet, even with new technologies that make people feel increasingly secure in the predictions being made, the future remains uncertain.

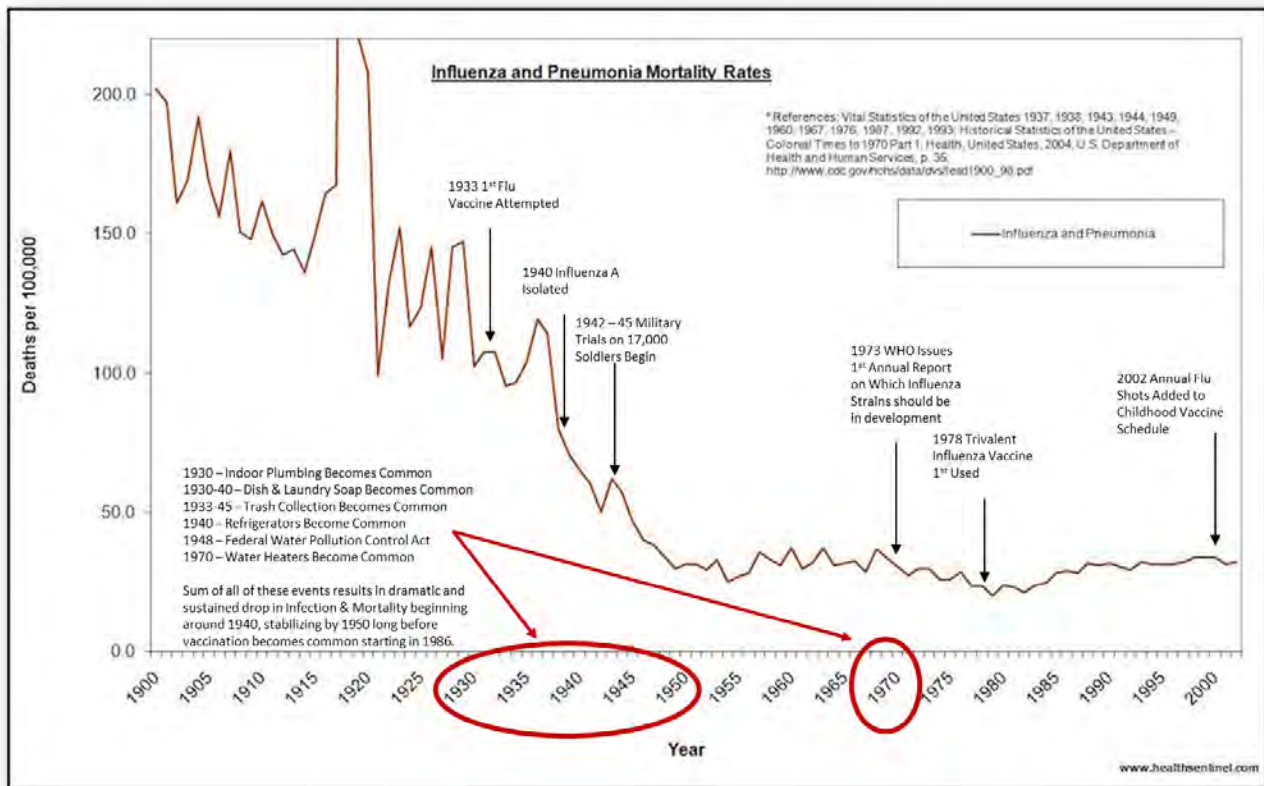
This strong desire to predict the future combined with technological advances created a huge market for computer projection models. That market strongly believes that such models will provide useful projections if they can get the assumptions and inputs correct.

One assumption, central to all current COVID-19 models, is that the spread of germs is the main factor in disease transmission, even though susceptibility to infection is the main factor. A related assumption is that people are equally susceptible to infection. In fact, susceptibility depends on variables such as available nutrient status, pre-existing conditions, age, genetic predispositions, socioeconomics, individual mental outlook, stress exposure, amount of sleep, bioaccumulation of chemical pollution, environmental exposure, place of residence, and a host of other factors unique to the individual. These aspects of reality are much more difficult to model than the germ “reproduction rate.”

As a result, all disease projection models focus entirely on modeling the spread of germs, which is far from an exact science, and ignore the state of the bodies that the germs identify as susceptible hosts for infection. For example, age clearly influences the activity of many diseases, but often plays a limited role in most epidemiological models.

Other basic assumptions built into current projection models are that interventions like lockdowns, social distancing, and masks work to reduce transmission of germs. Such interventions have not been independently proven to do so. By building the assumption of expected success of these interventions into the model, it becomes impossible to use the model to test whether such interventions work as assumed.

Other assumptions are missing. It is well known that improved sanitation during the 19th century led to a significant reduction in deaths from infectious diseases. In fact, all major diseases were already in considerable decline before vaccines were introduced. Yet none of the current models can project the impact of environmental factors such as nutritional intervention, HVAC air purification, or reductions in chemical, air, or noise pollution on disease transmission or outcomes.



Current disease projection models are self-limiting and self-referential. If their fundamental assumptions are incorrect, they're unable to uncover this truth. Instead, they discover that their projections do not fit the data.

The usual response to a mismatch between projections and reliable data is to adjust the model to fit the data as new facts emerge. Model designers confidently assert they have applied the scientific method to improve their model, and *now* the model gives better results. **They ignore the fact that their original model was simply wrong and thusly, so were its projections.**

Retrofitting a model to incorporate prior data does not mean the model has become any better at forecasting. If that were so, the world would be filled with millionaires who invested based on financial models that fit the past performance of stocks; such models are plentiful, but millionaires are not. Disease modelers, like many investors, never question their fundamental assumptions.

Due to the demand for computer models as well as the supply of potential model builders, it is inevitable that model quality will be highly variable. It is also inevitable that models will sometimes be developed for situations where they are irrelevant and inaccurate. With many people involved, there will also be considerable variations in skill and knowledge. As a result, some people will misuse their models, and some will misinterpret the outputs. New features and new approaches have made epidemiological modeling much more complex; this added complexity makes it more difficult for individuals to properly understand and assess model performance.

From the onset of the pandemic, computer projection models were widely adopted to deal with the COVID-19 health emergency. Everyone wanted to know what the health impacts of COVID-19 would be

long before it was possible to know. Those COVID-19 models led to policy decisions that have dramatically infringed upon people's lives and have distanced people, globally, from their traditional constitutional rights.

As stated earlier, mathematical modeling has great potential to support the design of strong clinical trials and measurement instruments, but projection models should not be used to make policy decisions. Projection models suffer from both internal and external validity threats and the variable rates of measurement error built into the models are extremely difficult to quantify.

It is reasonable to expect that policy decisions that have weighed so heavily on so many people's lives would rely on actual data rather than assumption-based computer models. If not, the policy makers certainly owe their citizens an explanation.

## What Kinds of Disease Projection Models Are in Use?

Disease projection models can be described along several dimensions. Models can be macroscale or microscale, deterministic or stochastic, compartmental or phenomenological. Additionally, models may eschew traditional biological approaches in favor of a purely data-driven, curve-fitting approach.

### Macroscale vs. Microscale

*Macroscale* models deal with the entire population at once and use differential or algebraic equations to determine how fractions of the population change status from susceptible, to exposed, to infected, and hopefully to recovered. Traditional epidemiological models have been macroscale models.

In contrast, *microscale* models attempt to simulate interaction among either individuals or small groups of individuals. Such models require much more computing power than macroscale models. They also require detailed assumptions about individuals that may affect disease transmission and it can be difficult to estimate values for such assumptions.

Microscale models may use differential equations like a macroscale model, but more commonly use random numbers and probability distributions to model individual decisions and their consequences. Projections are usually average values of outputs obtained after running the microscale model multiple times. Unfortunately, microscale models, intended to better fit reality, are more complex and more difficult to validate than macroscale models.

**Reference** - Saltelli, Andrea; Funtowicz, Silvio (2014). "When all models are wrong". *Issues in Science and Technology*. 30 (2): 79–85.

### Deterministic vs. Stochastic

In a *deterministic* model, the output of the model is fully determined by parameter values and initial conditions. Traditional epidemiological models solved three or more differential equations after



estimating certain parameter values and making assumptions about starting values. Once such features are set, the model will always predict the same results.

Of course, at the outset of an epidemic, correct values for parameters cannot be precisely known. Hence, to be useful, a deterministic model must adjust its parameters as additional data becomes available. The adjusted parameters will produce a fixed result, but it will be different from a previously reported result using other parameters.

In contrast, *stochastic* models include randomness. The same set of parameter values and initial conditions can lead to different results. Reality includes a great deal of variation and seemingly random events that are best modeled using probabilities. A typical stochastic model uses probabilities to decide such things as whether someone becomes infected, how long they remain sick before recovery, or when they die.

Unfortunately, building probability estimates into a model adds complexity and requires either additional assumptions or separate statistical validation based on actual data. Typically, a stochastic model is run multiple times and the outputs analyzed statistically to determine ranges of value for such numbers as expected new deaths or new cases.

### **Mechanistic vs. Phenomenological**

The term *mechanistic* is typically used to describe a model in which biological processes are assumed to occur that explain disease data such as deaths or cases. Parameters are built into the model to describe the effect of those biological processes. Because the parameters have biological meanings, they can be independently derived from other aspects of the epidemic than the data the model is trying to describe. For example, a mechanistic model would not attempt to estimate its key parameters from counts of deaths, because dead people cannot infect anyone and are no longer part of the model from a biological standpoint.

A *phenomenological* model is a *statistical* model and the terms are interchangeable. A statistical model incorporates assumptions that certain factors influence observed outcomes like deaths, but the model does not require or specify a biological reason for the connection. The model uses statistical multivariate regression to find equations that best model the observed data. It relies upon assumptions about, and estimates of, factors that influence the observed data. It assumes that past relationships among the factors of influence and the data will continue. The IHME model includes both mechanistic and statistical components and has been heavily criticized by traditional epidemiologists for its heavy reliance on statistical regression rather than the standard disease transmission concepts of biology.

### **Compartmental Models**

Many models use compartments to organize either fractions of a population or individuals and the compartmental approach has the longest history, dating back a century. Models that ground themselves in biological assumptions tend to use compartments to analyze disease transmission.

The usual compartments are S= susceptible to a disease; E= exposed but not yet contagious; I= infected and contagious; and R= formerly infectious, removed by death, recovery with immunity, or isolation. This set of compartments describes an SEIR model. Some modelers have added categories to account for temporary immunity of infants after birth or temporary immunity after recovery. Traditionally, the “(E) exposed” compartment has reflected the time lapse between infection and the appearance of symptoms because traditional SEIR models associated the appearance of symptoms with the start of contagiousness.

SEIR models typically assume everyone starts out as equally susceptible to a virus. Modelers estimate a rate at which people become infected based on the available data. Infected people are initially considered exposed but not infectious and the modeler must estimate how long it takes on average for someone to become infectious after exposure. The modeler also needs to estimate a recovery rate and a mortality rate among infected people, as well as how long it takes on average for people to recover or die. These various estimates are used as parameters in equations that allow the model to predict transitions across the population from the susceptible class to the exposed class to the infected class to the recovered class.

Any effort to model COVID-19 using an SEIR-type model runs into certain immediate difficulties because “cases” do not always indicate infectiousness, individuals are often isolated without proof of infectiousness, and if truly asymptomatic carriers exist, there is no clear way to determine a time from infection to infectiousness in such people. Each of these issues makes it difficult to determine proper parameters for an SEIR model. These issues are discussed further below.

### **Curve-Fitting Approaches**

A new curve-fitting approach to modeling has appeared with COVID-19.

## **CASE STUDY – The IHME and University of Texas Models**

The popular IHME model is a product of the Institute for Health Metrics and Evaluation at the University of Washington. It is one of many ongoing disease management projects at IHME that have been made possible by large grants from the Bill & Melinda Gates Foundation.

According to the Foundation press release announcing a 2017 grant:

*“The \$279 million grant is the largest private donation in the university's history and continues a long tradition of critical investments in the University of Washington by the Gates Foundation, which include grant awards across its academic disciplines including library science, global health, education, law and others. As of January 25, 2017, the foundation has awarded the University of Washington over 250 grants totaling nearly \$1.25 billion.”*

**Reference January 25, 2017** - <https://www.gatesfoundation.org/Media-Center/Press-Releases/2017/01/IHME-Announcement>

According to Tim Schwab writing in The Nation in December 2020:

*“Fueled by ... funding from the Bill & Melinda Gates Foundation... the IHME has outgrown and overwhelmed its peers, most notably the World Health Organization (WHO), which previously acted as the global authority for health estimates.*

*“In a relatively short period of time, the IHME has exerted a certain kind of hegemony or dominance on global health metrics production,’ says Manjari Mahajan, a professor of international studies at the New School. ‘It’s a kind of monopoly of knowledge production, of how to know global health trends in the world. And that produces a concentration of...power that should make anybody uncomfortable.’*

*“It’s quite impossible to criticize or indeed comment on their methods, since they are completely opaque,’ says Max Parkin, from the International Network for Cancer Treatment and Research.”*

**Reference** - <https://www.thenation.com/article/society/gates-covid-data-ihme/>  
“Are Bill Gates’ Billions Distorting Public Health Data?”

This “completely opaque” IHME organization produced a highly popular COVID-19 projection model. The IHME model describes itself as a hybrid modeling approach **“which incorporates elements of statistical and disease transmission models,”** and states it is **“grounded primarily in real-time data instead of assumptions about how the disease will spread.”** According to current documentation, **“The primary model for estimating future infections and deaths is a mechanistic compartmental model ... an SEIR model.”**

Instead of estimating the biological parameters used in the equations of an SEIR model, the IHME model calculates values for parameters that the modelers claim are associated with COVID-19 transmission. These “covariate” parameters include such things as social distancing mandates, population mobility, testing per capita, mask effectiveness and use, pneumonia seasonality, lower respiratory infection mortality, altitude, smoking, ambient particulate matter pollution, population density, and demography.

The model’s documentation explains why such factors may be associated with the rate of transmission and details how each is calculated. The calculation of each parameter estimate requires its own statistical mini model inside the overall IHME model.

Once these time-based parameter values are calculated, the IHME model uses multivariate regression to develop an equation connecting these parameters to the transmission rate. It then projects these parameters into the future using several scenario-based assumptions and uses the projected parameter values to forecast future transmission intensity and future infections. The IHME model then uses these forecast infections to forecast deaths.

The documentation explains that the **“final component of the modelling approach uses past, current, and future infections and deaths to estimate hospitalisations[sic], including estimates of ICU usage and invasive ventilation need.”**

**Reference** - ([https://static-content.springer.com/esm/art%3A10.1038%2Fs41591-020-1132-9/MediaObjects/41591\\_2020\\_1132\\_MOESM1\\_ESM.pdf](https://static-content.springer.com/esm/art%3A10.1038%2Fs41591-020-1132-9/MediaObjects/41591_2020_1132_MOESM1_ESM.pdf) - page 6)

IHME's current approach is significantly more complex than the approach used in early 2020. The model changed to better reflect the effect of government interventions on the curve of death rates.

In essence, the March/April 2020 version of the IHME model for COVID-19 used mortality data from Wuhan, China; Italy; and Spain to develop a standardized COVID-19 mortality pattern. That pattern can be visualized as a type of bell curve showing newly reported deaths by time period. The model then used a short time sequence of local death data to estimate where on that graph a given city, state, or country fit at a given moment. It attempted to use the nearby shape of the standardized graph of deaths to project the future deaths for that jurisdiction. The early IHME model assumed that the pattern of deaths would be fairly similar across locations and was roughly shaped like a bell curve.

The original IHME model deviated significantly from conventional practice and was heavily criticized for doing so.

One sharply critical article from April 2020, for example, focused mostly on issues connected with the mortality data that drove the model—assumptions, sources, and reliability.

The authors also criticized the wide prediction bands offered by the model, suggesting that:

*“Unaccounted sources of uncertainty arise from inaccurate temporal data on mortality and hospitalization counts; model misspecification, including parametrization[sic] choices; and inaccuracies in assumptions regarding the timing and effect of social distancing policies across regions.”*

The critics also took issue with the volatility of the IHME model projections, apparently failing to consider that a curve-fitting model would necessarily be more sensitive to changes in data than a model dependent on biological parameters.

The final criticism concerned misleading publicity surrounding the model's projections. Misleading publicity about epidemic projection models should concern everyone. The pressure to be the first to deliver a disease projection model is much like the pressure to deliver any new type of software in a competitive landscape.

The first researchers to deliver a model, even a bad one, get the most prestige, and their model becomes standard among public officials who watch each other's choices. At the beginning of an epidemic, public officials are simultaneously desperate for “science” to justify their decisions, and incompetent to judge model quality. It is a prescription for hype and poor choices.

The authors concluded that:

*“Ultimately, IHME's model may be reliable only for short-term projections... It is also unlikely that a ‘one-size’ model will fit all regions at all times. Policymakers will be best served when they consider projections from multiple models, thus increasing the understanding of factors that influence disparate projections and enhancing comprehension of unaccounted uncertainty in any one model. Major policy decisions need model input, but models are valuable only to the*

*extent that outputs are transparent, are valid, are based on accurate documented sources, are rigorously evaluated, and yield robust and reliable projections.”*

**Reference** - “Caution Warranted: Using the Institute for Health Metrics and Evaluation Model for Predicting the Course of the COVID-19”- <https://doi.org/10.7326/M20-1565>

A single example of the model’s mistaken projections should suffice to explain the widespread concern.

One of the early attractions of the IHME model was its ability to forecast hospital demand. For New York State as of April 4, the IHME model projected a need for 65,400 hospital beds; 15,905 were used and new hospitalizations continued to fall. For that same date, the IHME model projected a need for 12,000 ICU beds but only 4,100 were used.

**Reference** - <https://www.thegatewaypundit.com/2020/04/bill-gates-funded-ihme-coronavirus-model-wrong-12000-icu-beds-projected-new-york-today-4100-used/>

Researchers at the University of Texas developed a competing curve-fitting model, and in April 2020 published a paper comparing their model to the IHME model.

**Reference** - “Projections for first-wave COVID-19 deaths across the U.S. using social-distancing measures derived from mobile phones”- [https://COVID-19.tacc.utexas.edu/media/filer\\_public/d8/c1/d8c133e3-8814-4b30-9d3f-f0992ca66886/ut\\_COVID-19\\_mortality\\_forecasting\\_model.pdf](https://COVID-19.tacc.utexas.edu/media/filer_public/d8/c1/d8c133e3-8814-4b30-9d3f-f0992ca66886/ut_COVID-19_mortality_forecasting_model.pdf)

The Univ. of Texas paper states that:

*“At a high level, our model shares some key properties of the IHME model.”* Those properties are *“a statistical curve-fitting approach”* that uses *“time-evolving Gaussian curves”* whose parameters are calculated using *“regression on social-distancing covariates.”*

The Texas researchers explained that the IHME:

*“... model postulates that COVID-19 deaths will rise exponentially and then decline in a pattern that roughly resembles a bell curve (i.e., normal distribution). The model assumes that the shape of the curve will be curtailed by social distancing measures. Key inputs driving this component of the IHME model include the reported dates of state-wide shelter-in-place orders and shapes of COVID-19 epidemiological curves observed in Chinese and European cities following the implementation of similar measures.”*

They further explain that:

*“... our model is purely statistical: we are fitting a curve and a probabilistic error model to observed death rates in a state, and we are extrapolating from that curve. The advantage of this approach is that it does not require estimates of critical epidemiological parameters, some of which remain elusive. The disadvantage is that it cannot project longer-term epidemiological dynamics beyond the initial wave of mitigated transmission. For this reason, we do not use the model to make projections beyond a moderate (2-3 week) horizon.”*

The Texas model uses the same family of curves as IHME to approximate expected daily death rates over time. The Texas curve relies on three parameters that evolve over time as a function of state-level factors assumed to be associated with the death rates. The resulting curves, when plotted over time, differ markedly from traditional bell curves. The modelers claim that “[c]hanges in each state’s social-distancing covariates can ‘flatten the curve’ by changing the peak death rate, the timing of that peak, and the deceleration in death rate near the peak.”

It is crucial to remember what has happened. A computer model has flattened a hypothetical curve by adding certain parameters. This does not mean that the real world factors these parameters are assumed to model cause any “flattening” observed in actual data. This conclusion is a leap of faith, not science.

## Farr’s Law – A Lesson from History

Critics have complained about IHME’s use of curve fitting and the assumption that all death curves would be approximately the same, regardless of jurisdiction. IHME’s approach breaks with tradition and seems disconnected from biology. Nevertheless, the model fits comfortably within Farr’s Law.

Farr’s Law relates to an observation made in 1840 by the eminent English physician, William Farr. He noted that epidemic events rise and fall in a roughly symmetrical pattern—what is now referred to as a bell curve. The pattern is determined by the ratio of changes in rates of death.

In 2018, the developers of a simplified two-parameter model known as Incidence Decay with Exponential Adjustment (IDEA) stated a specific mathematical formula for Farr’s Law and showed that Farr’s model was mathematically equivalent to their own IDEA model.

**Reference** - <https://doi.org/10.1016/j.idm.2018.03.001>, “Relatedness of the incidence decay with exponential adjustment (IDEA) model, “Farr’s Law” and SIR compartmental difference equation models”, Mauricio Santillana, Ashleigh Tuite, Tahmina Nasserie, Paul Fine, David Champredon, Leonid Chindelevitch, Jonathan Dushoff, David Fisman

Other authors have considered COVID-19 modeling in terms of Farr’s Law. For example, in an April 2020 paper, the authors suggested that “Farr’s Law is a simple arithmetical model that provides useful and important insights on epidemic dynamics, concluding that **“Farr’s Law seems to be a useful model to give an overview of COVID-19 pandemic dynamics.”**

**Reference** - Pacheco-Barrios K, Cardenas-Rojas A, Giannoni-Luza S, Fregni F (2020) COVID-19 pandemic and Farr’s Law: A global comparison and prediction of outbreak acceleration and deceleration rates. <https://doi.org/10.1371/journal.pone.0239175>

Given its simplicity and the fact that many consider it relevant to this day, it seems worth mentioning how Dr. Farr described his law and what his peers thought of it.

Dr. Farr has been often quoted:

*“The death rate is a fact; anything beyond this is an inference.”*



As Dr. Farr observed, the only fact we can observe in an epidemic is death. Everything else involves assumptions. Symptoms and ‘cases’ may be observable, but symptoms may not be unique to a disease and are never as obvious as death. In the case of respiratory diseases, even deaths may not be obviously connected to the disease being investigated; pneumonia often afflicts people suffering from such diseases.

Dr. Farr did not speculate about how diseases spread. Rather, he analyzed the incidence of deaths. The first disease he considered was smallpox.

In 1840, in a short note included in an annual report to the Registrar-General in England, Dr. Farr observed that the 30,000 smallpox deaths in a recent epidemic appeared to fit a roughly bell-shaped curve that we now refer to as a Normal or Gaussian curve.

He apparently made no further study of the matter until 1866 when England was facing a cattle epidemic. A member of the House of Commons warned that **“by the middle of April”** England would face **“a calamity beyond all calculation.”** The lord predicted that deaths **“which have been thousands, [will] grow to tens of thousands”** assuming that **“the same terrible law of increase which has prevailed”** would continue.

We see in this prediction the same fear of an exponential rise in deaths that accompanied early COVID-19 warnings everywhere.

Dr. Farr wrote a letter to his daily newspaper calmly observing that **“the law of increase which has hitherto prevailed, instead of implying ‘that the averages which have been thousands will grow to tens of thousands’ implies the reverse; and leads us to expect that the subsidence will begin in the month of March.”** Dr. Farr correctly projected the turning point of the epidemic and forecast that the rate of deaths would decline about as rapidly as it had risen.

Dr. Farr made two observations in support of his general claim that deaths follow an approximate bell curve in any epidemic. They are worth considering in the context of COVID-19.

He first noted, with reference to studies of cattle disease in Russia, that **“All the epidemic poisons are reproduced in every individual that they attack; and if they lose part of the force of infection in every body through which they pass, the epidemic has a tendency to subside from this cause, which is strengthened in its operation by the fact that the individuals left are less susceptible of attack, either by constitution or by hygienic conditions, than those destroyed.”**

It has been observed many times during the COVID-19 pandemic that the disease seems to have lost its virulence as it passed through a population. The sudden rise of deaths in Italy and Spain quite probably involved the “weakest” individuals in those countries. The regions most affected have a long history of serious symptoms from respiratory illness. Once the most vulnerable have succumbed, any disease can be expected to produce fewer deaths among those who remain. This natural rising and falling of deaths from disease has been observed for over 150 years.

Second, Dr. Farr noted that traditionally in England **“precautions as regards all common zymotic [infectious] diseases are never pushed so as to interfere with nursing, medical attendance, traveling,**

***or social intercourse in England; yet all these epidemics subside within limited terms as certainly as they spring up.”***

In other words, in the absence of any significant “social distancing” interventions, past epidemics have always died out. COVID-19 should naturally subside within a reasonable timeframe. If history is any indication, the massive efforts to “flatten the curve” that have taken such a toll on economic and social life may have merely prolonged the world’s encounter with this disease.

The reaction to Dr. Farr’s prediction is also currently relevant.

According to Dr. Brownlee’s 1915 “Historical Note on Farr’s Theory,” ***“no member of Parliament—though the cattle plague was being discussed nightly—seems to have thought it [Dr. Farr’s prediction] worthy of mention. The Lancet ignored the communication entirely.”***

**Reference** - The British medical journal. Aug 14, 1915 p250, “Historical Note on Farr’s Theory of the Epidemic” by John Brownlee, M.D., D.Sc.

Dr. Brownlee quotes the British Medical Journal’s reaction to Dr. Farr:

“Dr. Farr will not find a single historical fact to back his conclusion that in nine or ten months the disease may quietly die out—may run through its natural curve. Dr. Farr says again that the returns show that the weekly relative increase in the number of cattle which now fall with the disease is less than it was at first, and he attributes this to the view that the disease is running the usual course of epidemics. He quite forgets to take into account the fact that at the present time everyone is satisfied as to the virulently contagious nature of the disease, and consequently takes measures to prevent it.”

Dr. Farr was right. The prestigious British Medical Journal, The Lancet, and the politicians were wrong. If a broad consensus of experts could be very wrong about a cattle epidemic in 1855, then perhaps similar consensus claims about COVID-19 could be wrong today.

Based on Farr’s Law, it seems possible that COVID-19 interventions will eventually be shown to have been irrelevant to the final death toll, simply spreading deaths out over a longer time period. “Flattening the curve” might have been useful to conserve medical resources during the initial two weeks of the pandemic. But lockdowns come with a cost. **Unfortunately, epidemiologists built COVID-19 projection models to meet their own needs. Their models cannot estimate the economic and social costs of “social distancing” mandates. As a result, the true cost of “flattening the curve” may never be known.**

Existing computer models do not tell us whether government interventions work as purported.

## **Models Projecting Individual Outcomes**

In addition to models designed to project mortality, cases, and hospital requirements, models have been designed to help doctors predict the course of COVID-19 in individual patients. Such models also suggest factors that may predispose people to suffer more serious outcomes.

An ongoing systematic review of such models reported that as of April 7, 2020, the authors had “retrieved 4903 titles through our systematic search (fig 1; 1916 on 13 March 2020 and 774 on 24 March 2020... and 2213 on 7 April 2020...)”

**Reference** - <https://pubmed.ncbi.nlm.nih.gov/32265220/> “Prediction models for diagnosis and prognosis of COVID-19 infection: systematic review and critical appraisal” (original to which this is an update—BMJ, 2020 Apr 7;369)

This study shows that by early April 2020, just a few months after the first cases of COVID-19 appeared in the United States, over 4,900 studies analyzing diagnostic models had already been conducted and published. Serious medical research studies are usually time-consuming to organize and implement. It also takes time to design a reasonable computer diagnostic model for any disease. It is no surprise that the authors of this review concluded that **“proposed models are poorly reported, at high risk of bias, and their reported performance is probably optimistic. Hence, we do not recommend any of these reported prediction models for use in current practice.”**

The early diagnostic modeling effort did not serve patients, doctors, or hospitals. Who then did these models serve, and why was there such a rush to design them? Why was so much energy spent designing and writing about models, when the models had no real medical value?

Many of the diagnostic models the reviewers studied focused on analyzing easily observable factors such as body chemistry details obtained from lab reports, blood pressure, reported symptoms, and age. Easily observable criteria are appealing when researchers are rushed, but the obvious factors are not necessarily the most useful. Everyone would have benefited by broadening the search for relevant diagnostic criteria *before* proposing models.

For example, research suggests that low levels of Vitamin D are associated with severe COVID-19 outcomes. Vitamin D levels are known to be low in the elderly. Checking Vitamin D and supplementing where necessary might have avoided the COVID-19 nursing home disaster.

**Reference** -

<http://orthomolecular.activehosted.com/index.php?action=social&chash=b73ce398c39f506af761d2277d853a92.164&s=a3b8ba524fa5d84e9ad7899052087eb7>

“HOW WE CAN FIX THIS PANDEMIC IN A MONTH” - Orthomolecular Medicine News Service, June 22, 2020

Doctors had limited time to fully evaluate patients before modelers began inundating them with inadequate diagnostic tools. In the case of COVID-19, rushed diagnostic modeling seems likely to have *cost* lives.

## Fundamental Challenges in Disease Modeling

Disease modeling faces major challenges, especially when attempted at the start of an epidemic involving a disease that is not well understood. It is crucial for policy makers to be familiar with such challenges and how those modeling challenges affect projections.

## **Inadequate Experimental Foundation**

Disease projection models involve a complicated form of experimentation on human subjects. An epidemic model represents a hypothesis about how both the disease and certain types of government intervention affect a population's health. As such, each version of a computer projection model can be considered an experiment.

Appropriate and adequate experimental practice includes randomization in choosing participants and the treatments they receive, a control comparison group, blinding to prevent bias, and replication of results by third parties.

Randomization is essential in balancing the presence of unknown factors that might influence the outcome of the experiment. Control groups are needed to verify what would happen if a treatment was not applied. Blinding ensures that treatments do not produce psychological effects unrelated to the factors being analyzed. Replication helps to make sure the experimental results are not a mere coincidence.

These standard practices cannot realistically be applied to a computer model during an epidemic.

Populations analyzed by a model are not random and are often studied as an entirety rather than as individuals. Traditional disease projection models assume that all members of a population are equally susceptible to a disease. By assuming the population is homogenous, models can study subgroups without obvious sample bias. The models hide sample bias within the assumption of homogeneity.

There is no way to separate a random part of the population to serve as a control group to evaluate the effectiveness of a governmental intervention. Instead, modelers are forced to compare effects of different interventions on different populations with different contact networks. In some cases, a rural state is compared to an urban state. The variables involved become significant enough to render the models invalid.

Modelers, citizens, and policy makers know that computer simulations are being performed and that governmental interventions are happening. No "blinding" is possible under such circumstances.

The lack of blinding negatively affects disease models in at least two ways. First, the model itself influences behavior through media accounts of its projections. Predicting high death rates creates fear, which causes people to alter their behavior, even if such predictions are inaccurate. If high death rates never materialize, there is no way to know whether the original prediction was simply wrong or whether it was correct and personal choices changed the outcome. If a model predicts case counts will rise, concerned people may decide to visit their doctor to report even trivial symptoms. If reported cases do indeed rise, is it because disease transmission increased, or because more people decided to visit their doctors and report symptoms.

Second, government interventions affect modelers, citizens, and policy makers themselves. Modelers build assumptions into their models to reflect the effect they imagine interventions will have. People, thinking they are safe from disease at home, may choose to skip a visit to the doctor when they have mild symptoms. When cases drop, it is important to determine if that drop was a result of a lockdown that kept people from transmitting the disease or because confidence in the government's approach

kept people from getting tested. Quarantine measures might lead to a drop in cases because they work, or because sick people avoid doctors for fear of being quarantined. If a model predicts a flattening of the curve because of social isolation policies, and such a flattening occurs, is it because the policy worked as expected, or is it possible that the flattening would have occurred naturally?

All of the questions offered above arise because control groups and blinks are not available to test disease projection models.

Finally, most models have become so complex that third parties cannot evaluate them and verify their results before the model gets changed to reflect new data. The models themselves never face the same fact situation twice in their modeling history. Typically, a modeler will use old data in a new model to make sure the new model's projections match what is already known. Such action is not experimental "replication" but rather a form of computer regression testing to make sure the new program can do the same things the old one could.

Modelers generally report their success at reproducing the past as if it ensures their model will correctly predict the future. Since the main reason for changing models is due to the fact that actual data did not coincide with the initial model predictions, the past models were wrong. In the absence of independent validation, it is a leap of faith to believe the new models are any better.

### **Assumptions and Uncertain Inputs**

All computer projection models make assumptions and require inputs. Understanding these aspects of projection models is crucial to understanding model outputs. Unfortunately, uncertainty surrounds most inputs, especially at the start of an epidemic.

A SEIR model requires an estimate of how many people are susceptible to a disease. Regarding COVID-19, some models assume everyone is susceptible. Other models assume a fraction, such as 60% of the population, is susceptible. How do we determine which models are correct? Some research suggests that prior exposure to other coronaviruses, including the common cold, provides some level of T-cell immunity to COVID-19 and is an important reason why so many show few or no symptoms. If so, the number of people susceptible may be much lower than models anticipate. Modelers should test the sensitivity of their models to assumptions about susceptibility and report that sensitivity analysis to users of the model.

When estimating numbers of exposed and infected people, an SEIR model makes the underlying assumption that it is possible to reliably count the number of infectious individuals at any given time. Variations in assumptions about how many infected people are circulating will lead to large variations in predictions.

A SEIR model must also make assumptions about how frequently infected individuals come in contact with susceptible people and how often such contacts lead to infection. These numbers are unknown. The modelers guess or estimate values.

The IHME modelers chose to use complicated statistical regression analysis to sidestep the issue of not knowing these numbers. They claim their approach has made their model independent of assumptions

about infection rates. In fact, their model incorporates an implied infection rate because past case counts and mortality data feed into the model's multivariate regression analysis.

Most models assume that the frequency of contact among the infected and the susceptible population will decrease with government interventions such as lockdowns or masks. This assumption is often built into the model. A parameter may decrease over time after a given date when a governmental intervention took place or is contemplated. The models reverse the effect when modeling re-opening plans.

It has not been independently proven that lockdowns, masks, or social distancing reduce transmission of a disease. The experience of the countries and states that did not apply stringent social distancing measures raises doubt that such measures work as claimed. Unfortunately, the structure of current models makes it impossible to use the model outputs to study the matter because all models assume that such interventions affect transmission in a predetermined way.

### **Hidden Feedback Loops and Unstable Inputs**

As epidemiological models change to reflect real world data, they take on characteristics of a machine-learning system. Google engineers have analyzed such systems extensively. Referenced are two issues with such systems that may affect the accuracy of disease projections.

**Reference** - "Machine Learning: The High-Interest Credit Card of Technical Debt"

<https://storage.googleapis.com/pub-tools-public-publication-data/pdf/43146.pdf>

*"Another worry for real-world systems lies in hidden feedback loops. Systems that learn from world behavior are clearly intended to be part of a feedback loop... In such a setting, the system will slowly change behavior... Gradual changes not visible in quick experiments make analyzing the effect of proposed changes extremely difficult..."*

When a disease model takes its outputs for inputs in any form, it establishes a feedback loop as described above. Feedback loops of any kind (e.g., the high-pitched squeal of a microphone to speaker link) can have unanticipated and hard-to-detect consequences. For example, do predictions of high transmission rates cause the exceedingly high rates predicted? Disease modelers rarely consider the impact of feedback loops on their models. How can modelers guard against such a result if the impact of feedback loops is often not considered?

Additionally, unstable inputs are known to lead to unreliable outputs. The engineers observe **"changes and improvements to the input signal may be regularly rolled out... [and] may have arbitrary, sometimes deleterious, effects that are costly to diagnose and address."** (p4)

The inputs to all disease projection models are regularly out of the control of the modelers. Governments make changes to data reporting practices on a whim during an emergency. One example is a decision to stop reporting mortality data on weekends, as happened for a month in one state in 2020. Modelers and the users of models may not discover such changes until long after the changes have distorted projections.



To see a potential feedback loop in a disease projection model, we need only examine the IHME documentation.

*“3.5.2 Deaths as a function of reported cases and hospitalizations*

*“In the first stage we model the cumulative death rate with either the cumulative case rate or the cumulative hospital admission rate as independent variable. Where data for both of these variables are available, a separate model is run for each.”*

*“3.6 Estimating infections from deaths*

*“Conditioning on the death draws produced in SI Section 2.5 and the Infection Fatality Rate (IFR) and age-specific mortality rate (MR) calculated in SI Sections 4.2 and 4.1, daily infections are inferred by stratifying all-age deaths into age-specific deaths, using the age-specific IFR to determine the number of infections that would have led to this quantity of age-deaths, and then backshifting the infections in time to account for the lag between infection and deaths.”*

**Reference** - <https://doi.org/10.1038/s41591-020-1132-9>

According to the documentation, cases are used to estimate deaths. After undergoing extensive statistical manipulation, deaths are used as an input to project infections. Are infections the same as cases? Perhaps this question is answered somewhere in the 92-page “supplement” to the main documentation. How many users of the model know or care about the answer?

### **Models Within Models Within Models**

What do modelers do when certain input data is not available or is unreliable? They search for other seemingly relevant data that *is* available or *is* reliable and instead use statistical methods to use that data.

Consider, for example, what happens when a model, such as the IHME model, needs daily death data. Some jurisdictions delay their death report, some report data on different schedules, and some occasionally skip reporting entirely. Without modifying the death data, models will treat missing data as “no deaths” for the day in question and projections will be distorted.

*“States report at different rates. Currently, 63% of all U.S. deaths are reported within 10 days of the date of death, but there is significant variation between states.*

*“It takes extra time to code COVID-19 deaths. While 80% of deaths are electronically processed and coded by NCHS within minutes, most deaths from COVID-19 must be coded by a person, which takes an average of 7 days.”*

**Reference** - <https://www.cdc.gov/nchs/nvss/covid-19.htm>

As a result of these variations, all projection models that use daily death data “smooth” the data. They usually do so by calculating rolling averages of reported death data. Such rolling averages conceal spikes that may be important and do not correctly handle unusual delays.

Delays happen and can be significant:

*“The South Carolina Department of Health and Environmental Control said a system upgrade to their Vital Statistics system led to the slow down of deaths being reported in a timely manner by coroners and other medical officials who confirm and record death in the state.*

*“Due to the upgrade issue, DHEC announced on Thursday [January 28, 2021] 254 confirmed and probable COVID-19 deaths for individuals who died over the last several weeks.”*

**Reference January 28, 2021** - <https://www.live5news.com/2021/01/28/dhec-database-issue-leads-delay-covid-deaths-reported/>

Unfortunately, the parameters needed by a traditional SEIR disease projection model are simply not known and can only be estimated by manipulating source data. To avoid the uncertainty surrounding the biological parameters of a traditional SEIR mode, the IHME model resorts to a great deal of statistical complexity. It uses multivariate regressions involving many factors the modelers assume affect disease transmission. Each factor requires its own data sources and often its own smoothing operations because of variations among sources.

Here is one example involving the “mobility” covariate as described in the IHME Supplemental Documentation (**Reference** - <https://doi.org/10.1038/s41591-020-1132-9>, p15-16):

*“These data come from mobile phone users. We used four primary resources to gauge the changes in relative mobility of populations within each state:*

*“Google Community Mobility Reports (<https://www.google.com/covid19/mobility/>),*

*“Facebook Data for Good (<https://dataforgood.fb.com/docs/covid19/>),*

*“Safegraph (<https://www.safegraph.com/dashboard/covid19-shelter-in-place>), and*

*“Descartes Laboratories (<https://www.descarteslabs.com/mobility/>).*

*“Each of these sources have different definitions of mobility.”*

For Google data, ***“No further processing is undertaken prior to modelling.”***

For Descartes Laboratories, ***“the top 10% of their data is removed due to possible inclusion of outlier data due to poor GPS recording. The index is reported from 01 March, 2020 through to three days prior to-date. The index is transformed by subtracting 100 from the m50\_index value.”***

For Safegraph, IHME, ***“determine[s] an index representing the percent difference between the number of devices that flagged as having not stayed within their home range as compared to the mean number of devices that stayed within their home range over a baseline reference period (08 February and 14 February, 2020). ... Using the associated FIPS codes, we can aggregate to the various analysis locations (whether counties, or states, or territories) by taking the device-weighted mean of the census block group ratios.”***

Facebook Data for Good seems to require the most manipulation, as it requires 24 lines of details to describe its use. Here are a few of the manipulations needed:

*“For each [location-specific administrative region], a baseline period for future comparison is developed by considering the prior 45 days of Facebook user activity. Subsequent to the date of initiation, all future days of reporting cross-reference their own baseline activity period...Where latitudes and longitudes were missing or did not accurately represent a location, we manually assigned a model geography by name. Using the start location from out[sic] modelled geographies, we find the mean percent change in mobility... We weight this mean by the number of users who normally take this trip (n\_baseline). Given the variable baseline periods, we must transform Facebook data so that it is comparable to other sources...”*

The mobile phone data section concludes:

*“There are several steps to smooth and standardise the data. We observe strong patterns in mobility by the day of the week. The data from Google is already corrected for these day-of-week patterns. For all other sources we calculate a 7-day rolling mean to account for weekly trends.”*

To estimate mobility data, IHME removes some data, shifts data, calculates a special index value, aggregates device data using a weighted mean of calculated ratios, fills in missing data, calculates mean percent changes in mobility and weights them by an estimated number of people, only to then smooth and standardize the results using a 7-day rolling mean.

But specifying the data is just the beginning:

*“To account for differences in time coverage between sources we calculate the median ratio between each available pair of sources for each location across the time series. In locations where we are missing the time series for a given source, we impute based on all other sources and the median ratio in that location over time... Because the sources tend to provide systematically different estimates, and when a given location is missing data from a component source, we impute values for the missing source based on the available source(s) and the global median ratio(s) with the missing source.*

*“After all missing dates and sources have been imputed, we average across sources and take a 5-day rolling mean using Gaussian process regression to smooth over time. For locations where we are missing data early in the time series, we use Holt smoothing back in time, linear damped with  $\phi = 0.9$  to create a full time series...”*

Mobility is just one of twelve covariates described in the documentation. It takes four pages of densely detailed documentation to explain how just this covariate is used in the model.

How many officials who relied on this model understand the significance of the mobility covariate? How many can judge how accurate the estimated values are, what accuracy may be needed, and how significant the covariate is to the model’s projections? Has anyone ensured IHME does all the work described?

Each time a model uses another model to estimate an input, it compounds the uncertainty in its projections and moves further from reality. Worse, models within models compound the difficulty in testing the model and in understanding whether inputs serve the purpose claimed. They also make it

almost impossible for a third-party investigator or a public official to understand and evaluate the accuracy of the model's projections.

Statistics and statistical regressions can be calculated for any data and it is always up to people to decide if such calculations make sense. Because modelers provide detailed explanations of the way they manipulate data to obtain parameters, it is easy for everyone to lose sight of the fact that most inputs are speculations. Each time we speculate, it may be wrong. As speculations increase, the chance of being wrong also increases. Like ancient peoples, our strong desire to predict the future leads us to believe our methods work without any empirical evidence that they actual do.

But as programmers often say, "Garbage in, garbage out."

## Practical Challenges in COVID-19 Modeling

In addition to the weaknesses faced by any epidemiological model, the COVID-19 models face certain practical difficulties related to how deaths and cases are counted. Also, although asymptomatic transmission of viruses has historically been extremely difficult to establish, COVID-19 modelers chose to include parameters to model this unproven theory. Modelers also have chosen to make various assumptions about how government interventions affect COVID-19 transmission and have chosen to build those factors directly into their models.

### Mortality

All COVID-19 models rely on COVID-19 mortality data in some way. SEIR models need estimated mortality and recovery rates. Curve-fitting models like IHME use actual death counts.

Unfortunately, when the CDC changed death certificate reporting for COVID-19 in March 2020, they created a situation where many reported COVID-19 deaths involve pre-existing conditions such as cancer, heart attacks, strokes, and pneumonia—conditions that would have traditionally been reported as the cause of death. COVID-19 is merely one of many opportunistic infections that might otherwise cause death in the elderly who were suffering from co-morbidities.

What this change means is that there is no real connection between reported "cases" of COVID-19 and reported deaths because the deaths are from other causes. Incorrect death projections should be no surprise because models have built in the false assumption that COVID-19 cases and deaths are correlated.

The May 2020 Vox article ***"This coronavirus model keeps being wrong. Why are we still listening to it?"*** criticized the IHME model because ***"as the weeks have passed, it has become clear that the IHME's projections have been too optimistic, and slow to adjust to reflect the fact that deaths have plateaued rather than rapidly decreasing to zero."***

The reported "plateau" may well have been a consequence of the fact that COVID-19 mortality data after March 2020 included mostly deaths from common diseases, which occur at a fairly constant rate.

It seems entirely possible that the IMHE model projections would have been quite accurate if adjusted to reflect the CDC change.

Unfortunately, no one can know exactly how many deaths would have been reported using the earlier death reporting rules.

### **Asymptomatic Transmission Rate**

All SEIR models make some assumptions about how frequently asymptomatic people infect others. The underlying assumption is that it *is* possible for asymptomatic people to infect others. This assumption is widespread but is contradicted by the extensive study of nearly 10 million people carried out in Wuhan, China.

Assuming a model could estimate an asymptomatic rate of infection, the model would also have to estimate how many asymptomatic people exist and how the disease progresses in each individual. Since asymptomatic individuals appear like everyone else, it is impossible to estimate how many asymptomatic individuals exist. Nevertheless, some studies suggest that from 20% to 40% of all COVID-19 cases are entirely asymptomatic.

A 2018 study investigated the impact of asymptomatic transmission assumptions on model projections about the impact of potential health interventions.

**Reference** - <https://royalsocietypublishing.org/doi/pdf/10.1098/rsos.172341>, “Implications of asymptomatic carriers for infectious disease transmission and control”

In their introduction, the authors observed that:

*“In practice, incorporating asymptomatic carriers into models is challenging due to the sparsity of direct evidence. This absence of data leads to uncertainty in estimates of model parameters and, more fundamentally, in the selection of an appropriate model structure.... selecting an inappropriate model structure, even when parameters are correctly estimated, may lead to over- or under-estimates of intervention effectiveness.”*

The authors’ analysis ***“reveals that interventions that alter the relative incidence of symptomatic infections compared to asymptomatic carriers are particularly vulnerable to being incorrectly assessed by models with inappropriate structure.”***

Recall that no actual data mentions how government interventions such as lockdowns, social distancing, and masks actually affect disease transmission. This study should generate questions about the reliability of model projections about such interventions as well as asymptomatic transmission of COVID-19.

### **Case Counts do not Measure Infectious Individuals**

All SEIR models must estimate the infected population and how that population will spread infection. Case counts are the go-to answer for COVID-19 models. Unfortunately, case count data based on PCR

testing, as currently used, cannot identify people who are contagious when tested. According to the CDC, people who have recovered from COVID-19 can test positive for up to 12 weeks post-recovery. Such people belong in the “Recovered” category, but if they happen to test positive within twelve weeks of their recovery, they add to the case counts and inflate the size of the “Infected” class.

If a rate of infection cannot be reliably estimated, an SEIR model fails to produce reliable outputs.

## Private Models Raise Special Concerns

When the government relies on private computer models, it gives up control over fundamental aspects of the information supply required to make policy decisions and the public no longer has legal access to essential details that affect their lives.

### Where Does the Buck Stop?

The Los Alamos National Laboratory COVID-19 projection model, LANL, includes this disclaimer with its reports:

*“Unless otherwise indicated, this information has been authored by an employee or employees of the Triad National Security, LLC., operator of the Los Alamos National Laboratory with the U.S. Department of Energy. The U.S. Government has rights to use, reproduce, and distribute this information. The public may copy and use this information without charge, provided that this Notice and any statement of authorship are reproduced on all copies. While every effort has been made to produce valid data, by using this data, User acknowledges that neither the Government nor Triad makes any warranty, express or implied, of either the accuracy or completeness of this information or assumes any liability or responsibility for the use of this information. Additionally, this information is provided solely for research purposes and is not provided for purposes of offering medical advice. Accordingly, the U.S. Government and Triad are not to be liable to any user for any loss or damage, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, even if foreseeable, arising under or in connection with use of or reliance on the content displayed on this site.”*

Surely no one wants people suing the government or the companies working with it for publishing data they hope will be of use during an emergency. But there is a dark side to this kind of disclaimer.

First, who owns the reports? It seems that Triad National Security owns the reports rather than the U.S. Government. Did Triad pay for the preparation of these reports, the development of the model, or the collection of the data? Only the government and Triad know. If Triad owns the reports, they are not subject to Freedom of Information Requests.

Computer models and the deliberations that produce them are also free from public records requests if they are in private hands. Public access to discussions among model developers might go far to reduce concerns about model assumptions and functionality.



## How Secure are Models and Data?

Private projection models share many of the risks of commercial software. Computer operating systems such as Microsoft Windows have been attacked by hackers for years. The open-source software movement arose partly as a response to security concerns with privately developed software that no one other than the developer could analyze. Recently, several private networking devices have been found to have hidden “backdoors” that allow foreign agents to take over those devices to hack into government and business networks. Phone apps are regularly found to contain hidden functions that transmit private data to third parties. Even security firms are finding their software and networks hacked.

Any disease projection model, especially ones developed and controlled by private parties, should raise questions about who created the model and how robust and secure the model is. Very few are currently asking such questions.

Accurate data is crucial to all data modeling. When models affect lives, like COVID-19 models have, the public has reason to expect that everyone involved with modeling pays close attention to data quality and security. The medical research community seems to be approaching data sharing about COVID-19 in an idealistic way that may have been appropriate before international actors with conflicting agendas joined the community.

One example is Data.World (<https://data.world/datasets/covid-19>), which explains that ***“When you create a free account, you don’t just gain access to a rich bank of open data and a powerful platform for analytics and insights: you become a member of the world’s largest collaborative open data community. Together, our community members uncover new insights, helping the world get answers and formulate response strategies.”*** The website seems to mention nothing about data quality or security.

Another example is the COVID-19 open database managed by the National Institutes of Health Office of Science Strategy (<https://datascience.nih.gov/covid-19-open-access-resources>). The entry page contains the disclaimer: ***“The Office of Data Science Strategy seeks to provide the research community with links to open-access data, computational, and supporting resources. These resources are being aggregated and posted for scientific and public health interests. Inclusion of a resource on this list does not mean it has been evaluated or endorsed by NIH.”***

One dataset listed is the COVID Digital Pathology Resource (COVID-DPR). It states that, “Although hosted at the NIH, the COVID-19 DPR seeks international and U.S. submissions, and is designed to support both clinical need and foster research for all investigators.”

The contribution form for its COVID-19 Digital Pathology Repository (<https://covid19pathology.nih.gov/request>) states ***“A rigorous QA policy will be enforced to ensure patient privacy, diagnostic accuracy and image quality.”***

The form is reassuring because it refers to a rigorous quality assurance policy. Yet, a search on “quality assurance” on the website lists nothing but general documents describing international standards for data quality.

Does the NIH check data quality as the form suggests? Or does it not, as the entry page to the database suggests? Only the NIH knows for sure.

A quick internet search reveals dozens of stories about university researchers who have been charged with espionage or with accepting secret funding and concealing contacts with the Chinese government. This fact should make policy makers ask difficult questions about the models developed by universities or other private organizations and the data sources they rely on.

The entire field of epidemiology and genetics has become so important and so potentially threatening that perhaps it is time to require a security clearance for all researchers, disease modelers, and data suppliers.

### **Are Private Models Transparent?**

Most private computer projection models publish extensive information about their assumptions, algorithms, and limitations. Some use open-source programming and allow the public to examine their source code. Some reveal to the public the data they use for inputs.

All of this creates an illusion that these models are transparent.

Ask yourself how often you read the “User Agreements” required by social media sites and internet providers. How often do you read credit card and other contract terms before enrolling?

It seems reasonable to wonder how many public health officials, at the start of the COVID-19 pandemic, read and understood the complex documentation that accompanies COVID-19 projection models. How many health departments studied a model’s code before its adoption?

In 2014, two European researchers noted a **“background of declining trust and increasing problems with the reliability of scientific knowledge in the public sphere”** and observed that **“the dangers for science become most evident when models—abstracts of more complex real-world problems, generally rendered in mathematical terms—are used as policy tools. Evidence of poor modeling practice and of negative consequences for society abounds.”**

They suggested a need **“to revisit statistician George E. P. Box’s 1987 observation that ‘all models are wrong, but some are useful,’”** and proposed that **“a key implication of Box’s aphorism for science policy [is] that stringent criteria of transparency must be adopted when models are used as a basis for policy assessments. Failure to open up the black box of modeling is likely to lead only to greater erosion of the credibility and legitimacy of science as a tool for improved policymaking.”**

**Reference** - Saltelli, Andrea; Funtowicz, Silvio (2014). "When all models are wrong". *Issues in Science and Technology*. 30 (2): p80

## Can We Trust the Programming and the Modelers?

Using models created by academics or private institutions raises other important questions. Can government leaders trust the actual computer programming in the models and have the modelers demonstrated their ability by successfully modeling in prior epidemics?

If referring to The Imperial College Model used to forecast deaths at the start of the COVID-19 pandemic, the answer is a resounding no.

## CASE STUDY: The Imperial College Model

The Imperial College Model predicted that by October 2020, more than 500,000 people in Great Britain and 2 million people in the U.S. would die from COVID-19 in 2020. The prediction incited so much global panic that nearly every government chose to resort to widespread lockdowns, irrespective of risk to various age groups.

After the source code for the model was released, two experienced software developers published an editorial in the Telegraph on May 16, 2020 criticizing the code. The critics were David Richards, founder and chief executive of WANdisco, and Dr. Konstantin Boudnik, vice-president of architecture at WANdisco, author of 17 U.S. patents and a veteran developer of a software framework that allows computers to solve problems using vast amounts of data.

**Reference** - "Neil Ferguson's Imperial model could be the most devastating software mistake of all time" <https://www.telegraph.co.uk/technology/2020/05/16/neil-fergusons-imperial-model-could-devastating-software-mistake/>

These critics observed:

*"One file alone in the Imperial model contained 15,000 lines of code... Industry best practice would have 500 separate files instead. In our commercial reality, we would fire anyone for developing code like this and any business that relied on it to produce software for sale would likely go bust."*

They noted further that:

*"...[t]he approach ignores widely accepted computer science principles known as "separation of concerns," which date back to the early 70s and are essential to the design and architecture of successful software systems... Without this separation, it is impossible to carry out rigorous testing of individual parts to ensure full working order of the whole."*

Their conclusion was:

*"Ultimately, this [epidemiological modeling] is a computer science problem and where are the computer scientists in the room? Our leaders [in the UK] did not have the grounding in computer science to challenge the ideas and so were susceptible to the academics. I suspect the Government saw what was happening in Italy with its overwhelmed hospitals and panicked."*

Earlier in May, a person using the pseudonym Sue Denim and claiming to be an experienced Google software engineer, published an even harsher critique of the Imperial Model.

**Reference** - “Code Review of Ferguson’s Model” <https://lockdownsceptics.org/code-review-of-fergusons-model/>

She noted that the source code released to the public:

*“...isn’t the code Ferguson ran to produce his famous Report 9. What’s been released on GitHub is a heavily modified derivative of it, after having been upgraded for over a month by a team from Microsoft and others. This revised codebase is split into multiple files for legibility and written in C++, whereas the original program was ‘a single 15,000 line file that had been worked on for a decade.’”*

The team had cleaned up the code before releasing it to the public and what was released was not what misled the world. It is interesting to note that the Bill & Melinda Gates Foundation has provided substantial disease research support to the Imperial College of London for at least a decade. With that connection, it should be no surprise that Microsoft helped the Imperial College improve a data model whose original programming was an embarrassment.

Ms. Denim further criticized the indeterminate nature of the algorithms the model uses. She noted, **“the code produces critically different results, even for identical starting seeds and parameters.”** The term ‘seed’ refers to an input that is placed into a random number generator to ensure the generator always produces the same string of digits. Such reproducibility is essential to testing any probabilistic computer model.

Ms. Denim goes on to cite tests demonstrating that the model produced different results when run on single-CPU and multi-CPU computers and also produced different results when code was changed to make the program run faster or more efficiently.

For example, a team at Edinburgh University tried storing data tables in a more efficient format for faster loading. The team discovered that the **“resulting predictions varied by around 80,000 deaths after 80 days.”**

Unpredictable results from a computer program should always be a cause for concern.

Since programming epidemiological models often goes wrong, who *should* create them?

According to Ms. Denim, insurance businesses would be a better choice than academic institutions.

*“Insurers employ modelers and data scientists, but also employ managers whose job is to decide whether a model is accurate enough for real world usage and professional software engineers to ensure model software is properly tested, understandable and so on. Academic efforts don’t have these people, and the results speak for themselves.”*

Apparently, the Imperial College Model that drove the entire world’s early COVID-19 decision-making was poorly programmed, generated unpredictable results, and was designed in a way that made it impossible to reliably test and adjust.

We might charitably chalk up government reliance on such a poor model to a sense of urgency and plain bad luck.

But Neil Ferguson, the driver behind the model, has been poorly forecasting for a long time. His models for swine flu and mad cow disease also produced wildly inflated mortality projections. In an interview in 2005, Ferguson likened bird flu to the deadly 1918 Spanish flu and predicted that up to 200 million people might die. Approximately 100 people died. In 2009, his models led the British government to forecast a worst-case scenario of 65,000 dead from swine flu. In fact, only 457 died.

The British Government could surely have demanded access to the source code before accepting the Imperial College model projections. But they did not. Even a cursory review of that source code by an experienced software engineer would have revealed the flaws.

### **Can Anyone Reproduce the Results?**

A fundamental problem in epidemiology is that people cannot be willingly infected to test the results of various approaches to manage an epidemic. It is difficult to provide a treatment to one group while withholding it from another if the treatment is believed to be effective. This problem is magnified when it comes to larger social measures such as quarantines.

Unfortunately, this means there are limited scientific ways to test disease interventions. Disease projection models suffer from the same problem.

Modelers uniformly imply their models are scientific. A key characteristic of scientific claims is that they should be replicable. An official might read the documentation associated with a model (IHME provides a 92 page 'Supplement' with detailed formulas), but that does not imply that the official understands either the model or its projections.

The only way to know a model works as proposed is to try to reproduce the model's outputs.

In the case of private models, there are two reasons that attempts to replicate output are not performed. First, neither the source code nor inputs are necessarily available when a model has been privately developed. Travel data, for example, is often purchased from private trade associations such as the International Air Transport Association (IATA). Anyone wishing to verify a model using IATA data must purchase their own license to use that data. Second, all COVID-19 models are being actively changed to "better reflect" new data. Which version of a rapidly changing model should be tested for accuracy?

If the older versions were accurate, they would not have to be changed. The time needed to verify a model exceeds the time before it gets changed, rendering it nearly impossible to confirm any scientific claims about COVID-19 models.

### **The Only Way to Choose**

Because it is difficult to independently confirm models, public officials commonly compare the results of different privately created models and select the one they prefer. Some officials choose a model

because it presents numbers they favor; others choose a model because a well-known institution developed it.

The inability to verify a disease projection model suggests such models are not chosen for their quality but for some other reason. Since model quality is not a factor in choosing a model, inaccurate and sometimes unnecessary policy decisions result.

Some officials avoid relying on a single model. Instead, after comparing several models, they accept the “consensus” predictions. Unfortunately, valid science is not a matter of consensus. If it were, we would still believe the sun revolves around the earth or that Newtonian physics describes the universe. Agreement among models may demonstrate that modelers share implicit assumptions and rely on similar data sources. Everyone may be making similar mistakes.

In the 1983 movie *Wargames*, an AI computer programmed to play games is about to “play” nuclear war and destroy the world. After it plays tic-tac-toe, it finally learns that some games cannot be won, and the world is saved.

There seems to be no ‘tic-tac-toe’ to teach the world’s policymakers the facts about disease modeling. Nevertheless, the only way for policy makers to win the disease modeling game is not to play.

## **Position Regarding Projection Models**

When an epidemic occurs, government officials are often charged with the need to make potentially life-changing decisions for citizens. When such decisions are based on preliminary disease projection models that exaggerate harm, policy choices reflect projected worst-case scenarios.

Although the possibility of an early exponential increase in deaths and hospitalizations exists, it often decreases as people adjust their behavior with respect to their interpretation of perceived danger.

This suggests there is more of a time cushion than some policy makers may realize. It also suggests that modelers should strive not to exaggerate and inflate data.

Disease projection models are inherently complex and unscientific because they attempt to model a rapidly changing real world phenomenon without experimental verification. Before relying on a model, it is crucial for policy makers to understand what key assumptions that model makes and how the model gets its inputs. Elaborate statistical methods used to manipulate data to obtain model inputs can be expected to increase error and raise the overall uncertainty in the model’s outputs.

Private projection models, even when sponsored by a university, are associated with risks including poor programming practices, lack of transparency in the documentation, an inability to verify that the model works as described, and possible security issues with personnel and data.

Governments have public health emergency laws on the books and these laws usually require emergency planning. As part of that planning, every government could create general rubrics to help in selecting a disease projection model. Legislators could pass laws requiring full public transparency in any disease projection model the government adopts.



Models exist and will continue to be used before they are ready. Modelers should ensure their models do not exaggerate threats and policy makers should hesitate before imposing drastic restrictions based on doubtful projections.

Rushed decisions are frequently bad decisions.

Regardless of how impressive the model is, or how well it fits the past, the future will always be unpredictable.

And “garbage in” will always lead to “garbage out” when it comes to data analysis.

## People Worthy of Our Remembrance



### **Dylan Buckner, 18 Died by Suicide**

Buckner's father, Chris Buckner, said the teen had been battling depression the last few years but "his depression worsened significantly after COVID hit."

"The family believes that had COVID not happened, or the country's response to COVID had been more effective, Dylan would still be alive today," In a statement, Chris Buckner wrote, "We are really, really going to miss him."

Buckner, who played quarterback and was captain of the school's football team, was expected to graduate with honors and hoped to play football at MIT in the fall, his family said. He had received 14 offers to play football at Division III schools, according to his father.

<https://www.nbcchicago.com/news/local/suburban-football-star-dies-in-apparent-suicide-family-says-covid-worsened-depression/2411545/>

## Topic 6 – History of Medical Ethics

**Topic Introduction** – For more than 2,000 years, the first fundamental law governing the safe and effective practice of medicine has been exceedingly clear in its simplicity, “First, do no harm.”

It is a powerful statement that establishes the primary responsibility each medical practitioner has with respect to their patients and forms the foundation for the key concepts shaping virtually all ethics for medical conduct.

Throughout history, this altruistic ethos has been repeatedly challenged by people who operate outside of this philosophy and often, for their own selfish pursuits of fortune and control.

With each violation of this philosophy, innocent people suffer, sometimes individually and sometimes en masse, wherein the perpetrators falsely claim that their intentions were in the best interests of “scientific breakthrough” or the more nebulous “greater good.” Their claims shroud the true nature of their motives; they argue disingenuously that the small number of people harmed is a necessary component of scientific advancement for society. Did the injured parties share that same perspective?

People who do not know history are doomed to repeat it and this unfortunate reality confronts us yet again regarding COVID-19.

Central to any discussion regarding medical ethics, duty, and conduct is the basic concept of helping those in need with every possible avenue of assistance. This is why the earlier topics about the issues with projection modeling, data manipulation, PCR testing, asymptomatic transmission, and especially the withholding of evidence-based treatments is so alarming.

Also critical to this discussion is how the concept of informed consent came into existence. Interestingly, while the development of the legal concept of informed consent has taken centuries to become codified, it affirms each person’s right to decide what is in their own best interest.

**Where there is medical risk, there must always be medical freedom of choice.**

The very notion of consent is the philosophical affirmation that each patient (or research subject) has basic human rights that supersede all medical opinions, experiments, and ideological concepts of serving “the greater good” at the expense of the individual’s sovereignty. Each patient and research subject should maintain full autonomy and control over their own body and this autonomy must be legally protected.

The very notion of being appropriately informed is an acknowledgement that historically, patients (and research subjects) have been purposely misled, coerced, lied to, and even forced to do as the doctor (or scientist) said without question or ability to protest and terminate the procedure or experiment.

Failing to provide known options from which to choose and to properly inform a patient about the risk of experimental therapies is the gateway for harm to be done, a direct violation of the first fundamental law in the practice of medicine ‘First, do no harm,’ and therefore evidence of willful misconduct.

Before illustrating violations of medical ethics relative to COVID-19, it is important to revisit two key historical events, the Nuremberg Military Tribunal and the Tuskegee Experiment. We will then take a tour through the widely adopted Patient Bill of Rights and 45 C.F.R. 46, the code of federal regulations that establishes specific and extensive protections for all human research subjects.

As this subject begins, it is important to establish that the horrors of war are never one-sided and that history is often biased towards the victors who get to write it.

Additionally, it is important to acknowledge the polarizing effect any discussion of race potentially conjures within the subconscious. So often, the very thing we need to discuss in order to dispel its destructive influence upon objectivity, is the thing that is avoided in an ineffectual attempt to preserve the feelings of people presumed to be sensitive to the topic. This conversation will not shy away from this topic as the stakes are simply too great.

## **The Nuremberg Code, Eugenics and Slavery**

**Overview** – In 1946, during the time for the Nuremberg Military Tribunal to deliberate over the allegations of war crimes perpetrated by members of the Nazi party, twenty-three high ranking Nazi physician-scientists were charged with conducting human experimentation on non-consenting prisoners. The “medical experimentation” they were accused of consisted of mutilation, starvation, chemical poisoning, injecting prisoners with infectious diseases, and various other forms of torture.

Artifacts recovered from the concentration camps by the Allied Forces were damning examples of human experimentation that forced people around the world to reconsider what is right and openly question how something like this could take place. With the advent of video and newsreels, images that can never be unseen were sent around the world.

In the final analysis of the 23 defendants, seven were sentenced to death, seven were acquitted, and nine were sentenced to prison terms. The nine sentenced to prison were ultimately released before serving their full terms.

The commonality among the guilty was their belief in eugenics. Eugenics is the morally corrupt philosophy that asserts that its mission is to improve the overall genomic profile of a population by eliminating people deemed “unfit” genetically to procreate and contribute to that genomic profile.

The philosophy of eugenics asserts that one group of people, always wealthy, have the right to choose the fate of those deemed to be beneath their socioeconomic status. This is the basic philosophy that forms the foundation of racism that justified the existence of slavery in the U.S. from 1619 to 1865. History has repeatedly proven that when a group of people of excessive wealth pool their resources, they create the ability to turn any lie into a believable truth backed by the force of the laws they purchase.

The methods used to accomplish the implementation of eugenic philosophies have historically varied from society to society. The methods include such practices as forced euthanasia of the elderly, poor, mentally disabled, and physically disabled; homosexuals; and people deemed unintelligent or unproductive. Historically, eugenic methods have also included forced sterilization, forced abortion,

legal limitations to family size, and even government issued passports and licenses authorizing select people to be “free” to procreate.

Eugenics in practice removes individual sovereignty and empowers the government to control the lives of people deemed “unfit.” Eugenics was a hallmark of Hitler’s vision for the world’s future, but interestingly, many of his adopted philosophies were born from U.S. slavery laws and practices as well as U.S. forced sterilization laws from 1907 to 1981.

In fact, the State of California has the dubious distinction, during what was known as the “Progressive era,” of forcefully sterilizing approximately 80% of all people who were legally forced to be sterilized in the U.S. Overall, an estimated 65,000 people were forcefully sterilized in 33 states under various sterilization laws in the U.S., most of whom were Black, Latina, or Native American women.

Forced sterilization was not a new concept to the U.S. For more than 200 years, castration of male slaves deemed uncontrollable, and therefore a threat, was routine.

How can a society that openly legalizes the philosophies of eugenics be considered free?

Historically, the U.S. has had extended periods of being a free society—in name only—for a substantial percentage of her citizens. Nazi Germany was not a free society. Freedom is the right to life, liberty, and the pursuit of happiness. Intrinsic to these rights are the right to decide what goes into and upon one’s body.

The lessons of history underscore the essential nature of preserving an individual’s right to decide what is in their best interest. When exploring how informed consent laws have come into existence, it is important to begin by examining the Nuremberg Military Tribunal and the Code that set the stage for the evolution of informed consent.

**The Nuremberg Code is as follows:**

1. The voluntary consent of the human subject is essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed, based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. **No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur;** except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

**Key Quote** – *“The defendants in this case are charged with murders, tortures, and other atrocities committed in the name of medical science... All of them have in common a callous lack of consideration and human regard for, and an unprincipled willingness to abuse their power over the poor, unfortunate, defenseless creatures who had been deprived of their rights by a ruthless and criminal government. All of them violated the Hippocratic commandments which they had solemnly sworn to uphold and abide by, including the fundamental principles never to do harm—'primum non nocere.'”*

<https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code>

**Position** – Where medical experimentation of human subjects or the use of experimental medical therapy is concerned, the individual sovereignty of the person must always be affirmed and protected.

The Nuremberg Code was established during the trial of the 23 Nazi physician-scientists after they argued on their behalf that they could not break laws that did not exist. To thwart this defense strategy, prosecutors met during breaks in the trial to develop a “legal” code based upon the principle of doing no harm in an effort to convict the 23 Nazi physician-scientists of known atrocities.

While the ethics of creating a “legal” code during an ongoing trial is highly questionable, it does stand as the first framework for ensuring that individual sovereignty is a fundamental human right—a fundamental human right that we must all agree is worthy of eternal preservation.

To be clear, laws can be unethical as clearly evidenced by the legal practice of slavery and WWII internment camps. The absence of compassion is also unethical. How can it be that it took the horrors of a 20<sup>th</sup> century World War to realize the sovereignty of the individual against medical experimentation is wrong? The presence or absence of law does not dictate or determine what is right. The tolerance of the public often dictates righteousness.

The more people tolerate injustice, the greater injustice will proliferate.



The legal codification of eugenic philosophies is akin to allowing a government to “play God” over a life it did not create and does not own. Throughout World War II, over 60 million people died before the legalized eugenic philosophy of Nazi Germany was defeated. During slavery, at least 60 million people died before legalized eugenic practices were defeated.

Born from these horrific experiences of human suffering was a wisdom that affirms the medical ethics of “doing no harm” and a wisdom that protects the individual sovereignty of each life.

Idealized objectives for recycled eugenic initiatives masquerading as goodwill cannot supersede the wisdom born of horrific experience that affirms fundamental human rights for body sovereignty.

As a historical reminder, masking and social distancing are not new. While the rationale and implementation may be different, the psychological impact is similar. It matters not that the masks of today are cloth and the enforcement of distancing was done using iron chains in years past. The psychological impact that eugenics practices foster dehumanize and injure the psyche to the point where the only choices for those deemed “unfit” are to surrender their will to their oppressor, take their own life, flee, or fight. The ultimate right to decide what is in the best interest of the individual must remain with the individual.

So, what happens when the ability to flee is no longer an option? What happens when the surrender of will is also giving up life, liberty, and the individual pursuit of happiness?

Eugenics is an ethically reprehensible philosophy that the Nuremberg Code makes the first modern attempt to preempt. The ultimate right to decide what is in the best interest of the individual must remain with the individual eternally. If we are not the owners of our body, then we will set the stage for the repetition of many of the worst chapters in human history.

Those who don’t know history are doomed to repeat it.

### **Additional Subtopic References**

- Masterful Legal History of Informed Consent beginning in 1905 by Ms. Michelle Wandler via Harvard University composed on April 12, 2001 during her 3<sup>rd</sup> year in study. Beautifully referenced and incredibly insightful.  
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- Nazi Eugenic Practices and Philosophy Overview  
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<https://www.smithsonianmag.com/history/california-targeted-latinas-forced-sterilization-180968567/>
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<https://nmaahc.si.edu/explore/exhibitions/slavery-and-freedom>
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<https://answersafrica.com/8-most-horrific-and-inhuman-black-slaves-punishment-in-the-history-of-slavery.html>

- Slavery by The Numbers

<https://www.theroot.com/slavery-by-the-numbers-1790874492>

## The Tuskegee Experiment

**Overview** – The story of the United States of America cannot be written with any level of authenticity without responsibly acknowledging centuries upon centuries of vicious human rights violations thrust upon black men, women, and children (and all peoples of non-European descent) in the name of progress, financial gain, and medical advancement. This is an indisputable fact, not open to public debate or individual rationalization.

As authors, we do not support any concept that suggests anyone should feel guilty due to the atrocities of their ancestors. Similarly, we do not support anyone attempting to rewrite the historical record in order to minimize the atrocities of their ancestors.

Tell people the truth, do it in a non-judgmental way, and let people decide for themselves what to think and feel. History is meant to be studied so that the wise may learn from the mistakes of the past and be freed from repeating them.

That slavery has existed since the first Egyptian dynasties does not in some way ameliorate the horrific realities of its existence in American history. In many ways, the end of the Civil War in 1865 was just the beginning of the long walk to freedom for Black Americans.

At the beginning of this long walk, acclaimed scholar (and former slave turned freedman) Dr. Booker T. Washington founded the Tuskegee Institute on July 4, 1881. His vision and self-determined approach to cultural upliftment for all Black people led the charge for economic empowerment following the end of slavery. Until his passing in 1915, Dr. Washington worked tirelessly writing, speaking, organizing, and advising Presidents on behalf of all Black Americans.

Seventeen years after his passing, in 1932, a medical experiment one can assume he would have rejected, was instead approved by the leadership that followed his tenure as President of the school. The “Tuskegee Study of Untreated Syphilis in the Negro Male” would become known as the Tuskegee Experiment and would ultimately form the basis for current informed consent laws due to egregious violations of medical ethics and willful misconduct.

While this experiment began prior to the establishment of the Nuremberg Code (1946-47), it extended long after despite many opportunities to terminate the experiment that exploited hundreds of Black men and their families.

In 1932 the Tuskegee Experiment began with a lie.

The medical experiment began by offering 600 Black men in Macon County, AL free medical care in exchange for samples of their blood, so that so-called ‘Bad Blood’ could be studied. In reality, what was

being studied were the long-term negative health consequences if an infectious disease was purposely left untreated throughout their lifetimes.

These 600 Black men did not receive free medical care they were promised, as their actual diagnosis of Syphilis was intentionally withheld from them. All were well educated in agricultural practices, many were semi-literate at best, but none were informed of their true disease state even following the discovery of a treatment.

Of the many willful failures that directly harmed these Americans and their families, the most reprehensible was the misconduct of withholding evidence-based treatments from them for over 29 years.

In 1943, doctors at the U.S. Marine Hospital on Staten Island discovered that penicillin could effectively treat syphilis. By 1947, the United States Public Health Service (USPHS) established 'Rapid Treatment Centers' for syphilis, but none of the 399 Tuskegee men with confirmed syphilitic infections were notified of their conditions or offered the opportunity for treatment.

It wasn't until 1968, 36 years after the inception of the medical experiment and 25 years after the discovery of penicillin for the treatment of Syphilis, that a USPHS investigator, Peter Buxton, stumbled upon the existence of the Tuskegee Experiment and raised his objections within the USPHS, to the ongoing clinical trial. His objections were based upon valid concerns of medical ethics violations following the development of the Nuremberg Code just 22 years earlier.

The collective response of officials at the USPHS was as shocking as it was deplorable.

In 1969, the CDC, a part of the USPHS, willfully ignored the violations of medical ethics and the criminal withholding of an efficacious treatment from these Americans. To further exemplify their willful disregard of the clinical trial participants, the CDC employed the support of the American Medical Association and National Medical Association to ensure the study continued as designed without notifying the enrolled participants.

By 1972 with all internal efforts exhausted, Peter Buxton was left with no alternative except to whistle-blow the medical experiment to Jean Heller of the Associated Press.

In July 1972, Jean Heller published the information and national outrage over the story resulted in the immediate termination of the medical experiment, but not before significant damage to those affected had been done.

**By the time the truth came to light, 28 of the enrolled participants had died from Syphilis, 100 more had died due to syphilitic-related complications, 40 of the men's spouses had contracted Syphilis, and at least 19 of their children had been born with Syphilis.**

In 1973, Congressional hearings were held to investigate the violations and the victims' heirs were compensated for the pain and suffering of their patriarchs. Yet none of those responsible for withholding treatment and violating medical ethics were brought to trial or held accountable for their crimes.

In 1974, the National Research Act (NRA) was created to establish criteria for responsible and safe involvement of human participants in medical experiments. The National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research (NACPSBB) was commissioned by the NRA.

In 1979, the NACPSBB published the Belmont Report that identified three clear ethical principles for the protection of human research subjects: (1) Respect for Persons which reaffirmed the basic human rights for autonomous decision making of all persons and the essential nature of informed consent, (2) Beneficence which reaffirmed the foundational philosophy of doing no harm and maximizing benefits while minimizing risks, and (3) Justice which spoke directly to the exploitation of disadvantaged people by the Nazi party in Germany and the Tuskegee Experiment here in the U.S.

The Belmont Report would begin the process of formally defining informed consent based on three principles: (1) Information which discusses the complete disclosure of clear and detailed information, (2) Comprehension which addresses the ability for a test subject to comprehend the information provided, and (3) Voluntariness which reaffirms that medical research can never be mandated and must always be voluntary and free from coercion.

The intention of the Belmont Report was to have it codified as law in its entirety but this never took place, despite public outrage surrounding the Tuskegee Experiment.

But many of these principles elucidated by the Belmont Report were included and expanded upon in what would become 45 C.F.R. 46, the code of federal regulations that establishes specific and extensive protections for all human research subjects under informed consent laws.

**Key Quotes** – *“In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the ‘Tuskegee Study of Untreated Syphilis in the Negro Male.’*

*“The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease. **The study was conducted without the benefit of patients’ informed consent.** Researchers told the men they were being treated for “bad blood,” a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. Although originally projected to last 6 months, the study actually went on for 40 years.*

*“1947 - USPHS establishes ‘Rapid Treatment Centers’ to treat syphilis; men in study are not treated, but syphilis declines.*

*“1968 - Concern raised about ethics of study by Peter Buxton and others.*

*“1969 - CDC reaffirms need for study and gains local medical societies’ support (AMA and NMA chapters officially support continuation of study).”*

<https://www.cdc.gov/tuskegee/timeline.htm>

**Position** – Enrolling participants into a clinical trial under false, coercive, deceitful pretense is deplorable. But even transgressions such as these pale in comparison to the willful act of intentionally withholding evidence-based treatments. As it pertains to COVID-19, the question before us is, ‘Has the CDC once again withheld evidence-based treatments from people in need?’

Maya Angelou is quoted as saying, “When someone shows you who they are, believe them the first time.” When we apply the wisdom of this quote to the Tuskegee Experiment, is it any wonder why Black Americans routinely distrust the CDC and public health officials?

As presented during the previous topic on Effective Treatments for COVID-19, there is overwhelming evidence for the safe and efficacious use of Intravenous Ascorbic Acid (IVAA) and additional oral nutrient therapies (e.g., ivermectin, hydroxychloroquine, and remdesivir). Yet, more than 12 months since the first confirmed case of COVID-19 in the U.S., the FDA and CDC have not approved any of the evidence-based treatments presented in this position paper as therapeutic options for Americans most in need.

To make matters even worse, the FDA has openly threatened licensed medical practitioners who attempt to provide potentially life-saving therapeutics to their patients with fines and revocation of their license.

Is it murder to willfully withhold evidence-based treatments from people in need?

Is it murder to not only withhold evidence-based treatments, but to aggressively prevent licensed medical professionals from providing potentially life-saving treatments to people in need?

How many lives could have been saved had the FDA authorized the use of IVAA, oral nutritional therapies (Vitamins D, C, A, E, and the mineral zinc), ivermectin, and hydroxychloroquine?

Sadly, we will never know, but some epidemiologists like Dr. Harvey Risch of Yale University and Dr. Dolores Cahill of the World Freedom Alliance estimate hundreds of thousands of American lives could have been saved.

When the CDC showed us who they are during the Tuskegee Experiment, perhaps we should have believed them.

### **Additional Subtopic References**

- Brief History of the Tuskegee Experiment  
<https://www.history.com/news/the-infamous-40-year-tuskegee-study>
- National Research Act  
<https://www.congress.gov/bill/93rd-congress/house-bill/7724>
- Detailed History of the Tuskegee Experiment  
<http://tuskegeestudy.weebly.com/informed-consent.html>
- The Full Belmont Report

## Current Federal Informed Consent Laws

[https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)

[https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117)

**Summary** – For the purposes of this section, the entirety of 45 C.F.R §46.116 (General requirements for informed consent) and 45 C.F.R §46.117 (Documentation of informed consent) will be quoted, which make up the backbone for informed consent laws in the U.S. Comments and positions will not be offered, and all topics and key revisions will be bolded for reference only.

#### **§46.116 General requirements for informed consent**

(a) **General.** General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements established in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) **Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.**

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative **sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.**

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) **Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.** This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) **Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates** the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) **No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.**



(b) **Basic elements of informed consent.** Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) **A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;**

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) **A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;**

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) **For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;**

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) **A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;** and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) **Additional elements of informed consent.** Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) **A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;**

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) **Any additional costs to the subject that may result from participation in the research;**

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) **A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;** and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) **Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.** Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) **An explanation of whom to contact for answers to questions about the subject's rights** and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

**(e) Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials.**

(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

- (A) Public benefit or service programs;
  - (B) Procedures for obtaining benefits or services under those programs;
  - (C) Possible changes in or alternatives to those programs or procedures; or
  - (D) Possible changes in methods or levels of payment for benefits or services under those programs; and
- (ii) The research could not practicably be carried out without the waiver or alteration.

**(f) General waiver or alteration of consent**

(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) Alteration. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) **Requirements for waiver and alteration.** In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

- (i) The research involves no more than minimal risk to the subjects;**
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and**
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**(g) Screening, recruiting, or determining eligibility.** An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

**(h) Posting of clinical trial consent form.**

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

**(i) Preemption.** The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

**(j) Emergency medical care.** Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

**(Approved by the Office of Management and Budget under Control Number 0990-0260)**

#### **§46.117 Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, **informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic**

**format) by the subject or the subject's legally authorized representative.** A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, **the informed consent form may be either of the following:**

(1) A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c) **[Untitled Section]**

(1) **An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:**

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) **That the research presents no more than minimal risk of harm to subjects** and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

## The Patient Bill of Rights

<https://www.ama-assn.org/delivering-care/ethics/patient-rights>

**Key Quotes** – *“The health and well-being of patients **depends on a collaborative effort between patient and physician in a mutually respectful alliance.** Patients contribute to this alliance when they fulfill responsibilities they have, to seek care and to be candid with their physicians, for example.*

*Physicians can best contribute to a mutually respectful alliance with patients by serving as their patients’ advocates and by respecting patients’ rights. **These include the right:***

- a) *To courtesy, respect, dignity, and timely, responsive attention to his or her needs.*
- b) *To receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician’s objective professional judgment.*
- c) *To ask questions about their health status or recommended treatment when they do not fully understand what has been described and to have their questions answered.*
- d) ***To make decisions about the care the physician recommends and to have those decisions respected. A patient who has decision-making capacity may accept or refuse any recommended medical intervention.***
- e) *To have the physician and other staff respect the patient’s privacy and confidentiality.*
- f) *To obtain copies or summaries of their medical records.*
- g) *To obtain a second opinion.*
- h) *To be advised of any conflicts of interest their physician may have in respect to their care.*
- i) *To continuity of care. Patients should be able to expect that their physician will cooperate in coordinating medically indicated care with other health care professionals, and that the physician will not discontinue treating them when further treatment is medically indicated without giving them sufficient notice and reasonable assistance in making alternative arrangements for care.*

**AMA Principles of Medical Ethics: I, IV, V, VIII, IX:”**

**Summary** – In 1973, the American Hospital Association’s House of Delegates adopted a Patient’s Bill of Rights following the revelations of the Tuskegee Experiment. While these rights have yet to be officially adopted into federal law, they have been adopted in various forms by such reputable organizations as



the American Medical Association and are widely taught around the world in most courses on medical ethics.

The key statutes acknowledge that a doctor's responsibility is to work in collaboration with their patients to offer recommendations for treatment and clearly places their patients in charge of all decisions. The key statutes assert to protect patient's rights to refuse any treatment and to protect each patient's rights to privacy, which is also required under existing HIPAA laws.

**Position** – The Patient Bill of Rights is well reasoned and has historical ties to seminal events we universally agree should never be repeated. The Patient Bill of Rights is a clear affirmation of individual sovereignty that no medical treatment should ever be mandated upon a person in need and no evidence-based option ever withheld.

While there are 27 Constitutional Amendments, the 26<sup>th</sup> Constitutional Amendment was first proposed and ratified in 1971. Since that time, the only Constitutional Amendment to be ratified is the 27<sup>th</sup> amendment which was first proposed in 1789 but not officially ratified until 1992.

A patient's Bill of Rights that reaffirms the Constitutional right to refuse medical treatments and protects both informed consent and medical privacy, while also affirming that no evidence-based treatment can ever be withheld is long overdue.

#### **Additional Subtopic References**

- Health Insurance Portability and Accountability Act of 1996 (HIPAA)

<https://www.cdc.gov/phlp/publications/topic/hipaa.html>

## **History of Medical Ethics Position**

“Those who don't know history are doomed to repeat it.”

“Fools rush in.”

“Quick to judge, quick to be wrong.”

“When someone shows you who they are, believe them the first time.”

Incredible wisdom lies in quotes such as these—a wisdom born often from horrific experiences that we must ensure never happen again.

Mistakes with unintended consequences may occur. But withholding evidence-based treatments is not a mistake. It is a demonstration of willful intent to harm—or at least ensure that nothing is done to prevent harm.

The public depends upon individuals of high moral character to protect them from attempts at misconduct.

When we are discussing human rights, ethics, and COVID, there is no such thing as acceptable casualties. This is the mentality of war.

Living is not an act of war.

Life is a sacred event, a fortunate blessing that didn't have to happen, but how amazing that it did?

Health isn't a war against disease, it's is the promotion of life.

Medical professionals aren't promoting life when they're withholding evidence-based treatments.

If withholding evidence-based treatment from 399 American men during the Tuskegee Experiment was wrong, then the withholding of evidence-based treatments from 332 MILLION Americans during COVID-19 is as well.

# People Worthy of Our Remembrance



## **Rosanna Un Died Alone**

“In the early hours of Dec. 13, as her mother’s breathing became shallow and laboured, Natalia Munnion was told to leave her mother’s long-term care facility. Her one-hour compassionate visit with her mother, Roseanna Un, was over. The nurse said her mother would be better by morning, and that she would call Munnion with any news then.

“Two hours later, the nurse called Munnion to say the serious chest infection had slowed her mother’s breathing more and that she should get there as soon as she could. Munnion rushed back to Hawthorne Seniors Care Community in Port Coquitlam with her sister, but their mother had already died. Un was 88. ‘My mom didn’t have to go that way. My mom did not have to die alone,’ said Munnion, who lives in nearby Coquitlam.”

<https://ca.news.yahoo.com/mom-did-not-die-alone-165144824.html>

## Topic 7 – Violations of Medical Ethics During COVID

**Topic Introduction** – Considering the medical ethics presented, a deeper dive can reveal a thorough examination of the multitude of violations of medical ethics throughout the global reaction to the SARS-CoV-2 virus led by the World Health Organization and the Centers for Disease Control and Prevention.

### Incentivizing Disease and Death

**Summary** – In April 2020, highly respected senator and physician Dr. Scott Jensen was wrongfully vilified for a statement he made regarding incentivizing medical insurance reimbursements for COVID-19.

Dr. Jensen was quoted as saying, *“Hospital administrators might well want to see COVID-19 attached to a discharge summary or a death certificate. Why? Because if it's a straightforward, garden-variety pneumonia that a person is admitted to the hospital for – if they're Medicare – typically, the diagnosis-related group lump sum payment would be \$5,000. But if it's COVID-19 pneumonia, then it's \$13,000, and if that COVID-19 pneumonia patient ends up on a ventilator, it goes up to \$39,000.”*

Ultimately, Dr. Jensen’s brave statement of fact was substantiated by at least seven independent fact-checking services, including USA Today, but that did not stop the attacks that ensued.

As this crisis unfolded, Dr. Jensen’s statement regarding the potential for corruption and egregious violations of medical ethics became reality. An investigative report by the New York Times followed the sad story of RC Kendrick, an 88-year-old senior with dementia.

*“On a chilly afternoon in April, Los Angeles police found an old, disoriented man crumpled on a Koreatown sidewalk.*

*“Several days earlier, RC Kendrick, an 88-year-old with dementia, was living at Lakeview Terrace, a nursing home with a history of regulatory problems. His family had placed him there to make sure he got round-the-clock care after his condition deteriorated and he began disappearing for days at a time.*

*“But on April 6, the nursing home deposited Mr. Kendrick at an unregulated boardinghouse—without bothering to inform his family. Less than 24 hours later, Mr. Kendrick was wandering the city alone.*

*“According to three Lakeview employees, Mr. Kendrick’s ouster came as the nursing home was telling staff members to try to clear out less-profitable residents to make room for a new class of customers who would generate more revenue: patients with Covid-19.”*

The New York Times investigation confirmed that according to 22 watchdogs and dozens of elder-care attorneys, this deplorable situation was occurring across the nation.

**Key Quote** – *“CMS this week will begin sending a 20% increase in Inpatient Prospective Payment System (IPPS) payments for patients previously treated for COVID-19 — far in advance of the latest quarterly update. The payments, as required by the CARES Act, will be automatically sent to previously paid providers that used the COVID-19 code (diagnosis code B97.29).*

*“CMS on April 21 will start to increase inpatient hospital payments by 20% for Medicare claims related to the care of COVID-19 patients on April 1 or later (diagnosis code U07.1).”*

<https://www.hfma.org/topics/news/2020/04/increased-medicare-payments-for-covid-19-care-to-stretch-back-to.html>

**Position** – The example of RC Kendrick is exactly why financially incentivizing any infectious disease during a crisis is unethical. It sets the stage for corruption because criminal activity cannot keep pace with opportunistic human parasites willing to do wrong.

It’s assumed that all persons associated with care of those in need are working from the highest ideals of professional integrity. While many in the healthcare industry are, many are not. Hospitals have become profit-focused organizations and if a hospital administrator is concerned about profitability at a time when they are forced to reduce services, but incentives offer an opportunity to mitigate financial losses, they may be forced into problematic ethical decisions. Should they refuse the economic gains and risk the long-term viability of their facility or accept the economic opportunity even though they know it is morally bankrupt?

Incentivizing death and disease introduces chaos into a situation already rife with chaos, creating ethical dilemmas that compromise the integrity of medical practice. In turn, this invites the corruption and harm that Dr. Jensen brought to the public’s attention, which he was subsequently vilified for.

### **Additional Subtopic References**

- Center for Medicare and Medicaid Services Coverage and Payment Bulletin for COVID  
<https://www.cms.gov/files/document/03052020-medicare-covid-19-fact-sheet.pdf>
- USA Today Exonerates Dr. Jensen  
<https://www.usatoday.com/story/news/factcheck/2020/04/24/fact-check-medicare-hospitals-paid-more-covid-19-patients-coronavirus/3000638001/>
- New York Times Investigative Article  
<https://www.nytimes.com/2020/06/21/business/nursing-homes-evictions-discharges-coronavirus.html?referringSource=articleShare>
- LA Times Investigative Article  
<https://www.latimes.com/california/story/2020-05-03/coronavirus-nursing-homes-financial-profits>

## Problems with Clinical Trials for Experimental Biologics

**Summary of Pfizer Experimental COVID Biologic Clinical Trial Design** – An experimental COVID biologic has no previously known or FDA-authorized use in human subjects and therefore must be categorized as experimental until significant long term data is collected and analyzed for safety and efficacy over a significant sample size. Given that this mRNA biologic therapy is experimental, its only legal administration should be in an ongoing clinical trial with volunteer participants and signed informed consent authorizations.

**Key Quotes** – *“Estimated Study Completion Date – January 31, 2023. Recruitment - Active, not recruiting.*

*“In Phase 1 participants, SARS-CoV-2 serum neutralizing antibody levels, expressed as GMTs [Time Frame: Through 2 years after the final dose] As measured at the central laboratory*

***“In the first 360 participants randomized into Phase 2/3, percentage of participants reporting serious adverse events [Time Frame: From dose 1 through 6 months after the last dose] As elicited by investigational site staff***

*“Confirmed COVID-19 in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years] Per 1000 person-years of follow-up*

*“Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19*

***“Phase 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.***

*“Phase 1 only: Any screening hematology and/or blood chemistry laboratory value that meets the definition of a  $\geq$  Grade 1 abnormality.*

*“Phase 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit.*

***“Phase 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.***

*“Responsible Party: BioNTech SE*

*“Study Sponsor: BioNTech SE*

*“Collaborators: Pfizer*

*“Investigators: Pfizer CT.gov Call Center”*

<https://clinicaltrials.gov/ct2/show/record/NCT04368728>

## **Clinical Trial Design Phase 1**

Enrolled Participants: **45**

Measurement Length: **2 Years**

Placebo: **Saline**

Prescreening for Serologic IgM and IgG Antibodies: **Yes**

Prescreening Nasal PCR for Viral Fragments: **Yes**

Other Prescreening Laboratories: **No**

Post Inoculation Evaluation of Antibody Production: **Yes**

Measurement of adverse events: **1 month, all participants**

Measurement of serious adverse events extends: **6 months, all participants**

Sample size reduction may occur due to placebo participant's right to decline the offer of experimental COVID biologics at a later date, participants exercising legal right to withdraw from study at any time for any reason, or death.

Second 100 microgram inoculation was withheld from administration *"because of the increased reactogenicity and a lack of meaningfully increased immunogenicity after a single dose compared with the 30- $\mu$ g dose."*

It appears a second 30 microgram dose was administered in place of the previously intended 100 microgram dose.

### **Additional Subtopic References**

- <https://pubmed.ncbi.nlm.nih.gov/32785213/>

## **Clinical Trial Analysis Phase 2/3**

Enrolled Participants: **43,998**

Measurement Length: **2 Years**

Placebo: **Saline**

Prescreening for Serologic IgM and IgG Antibodies: **No**

Prescreening Nasal PCR for Viral Fragments: **No**

Other Prescreening Laboratories: **No**

Post Inoculation Evaluation of Antibody Production: **No**

Measurement of adverse events: **1 month, first 360 participants**

Measurement of serious adverse events extends: **6 months, first 360 participants**



No measurement of adverse events or serious adverse events in the remaining participant population is mentioned.

Sample size reduction may occur due to placebo participant's right to decline the offer of experimental COVID biologics at a later date, participants exercising legal right to withdraw from study at any time for any reason, or death.

**Position** – Without long-term data and with Phase 3 clinical trials still underway, anyone electing to, or being coerced into, receiving either of the two current COVID experimental COVID biologics is agreeing to the use of an experimental biologic still under investigation within an ongoing clinical trial. Therefore, each person should be protected by the same informed consent laws that enrolled participants are.

If a clinical trial is active and the medical treatment being tested is not FDA approved, which the COVID experimental COVID biologics are not (they are only EUA approved), then each person consenting to receiving the dual inoculation, or being coerced into receiving the dual inoculation, is effectively entering a clinical trial.

As such, the authors of the clinical trial and the entities that authorized the clinical study should become immediately liable for any injuries incurred by those being coerced by public health officials (as well as news and media outlets) to consent to an experimental COVID biologic. The coercion tactics make no mention of risks and reports of adverse events, including a growing number of **fatalities** resulting from the administration of the experimental COVID biologics.

Again, evidence-based treatments for COVID-19 exist and have existed since February 2020. Each existing treatment is exceedingly inexpensive and saves lives via prevention, accelerated recovery, and reduced hospital stay.

Despite warnings during the Phase 1 clinical trial of increasing reactogenicity in a significant percentage of enrolled participants, the clinical trial was approved to move into Phase 2/3 by the IRB. This is why government oversight is established—to ensure poor choices such as this never make it to the public as well as to protect human participants enrolled in clinical trials.

Federal health agencies and corporate researchers have no idea about the long-term effects of the COVID biologic. Will persons subjecting their body to the experimental COVID biologic develop autoimmune conditions? Will they become infertile? Will pregnant women experience spontaneous abortion and fetal loss up to full gestation, as has been documented in numerous VAERS reports?

Federal health agencies and corporate researchers know that experimental COVID biologics will, in fact, inflict harm.

In Phase 1 of the clinical trial, modifications were made to the design of the clinical trial in progress, which is one of many red flags. During Phase 1, in a sample size of only 45 participants further subdivided into two experimental groups of 11 to 12 participants, the BNT162b1 experimental biologic was shown to generate greater adverse events and was thus discontinued, while the BNT162b2 scheduled second dose of 100 micrograms was discontinued after concerns were raised. The result for

the BNT162b2 Phase 1 clinical trials was that only half of the enrolled participants in that experimental group received the single 30 microgram dose.

Additionally, Phase 2/3 did not prescreen participants for the presence of IgM or IgG antibodies and did not prescreen for previous infection using PCR nasal swab or serologic viral antigen, compromising the purity of the entire participant population and rendering the results of the study null and void due to the likelihood of sample population contamination with pre-existing exposure to the SARS-CoV-2 virus.

Further, Phase 2/3 did not include measurement of antibody production post-inoculation or binding capacity of the antibodies produced to isolated SARS-CoV-2 virus in live human cell culture, which is the point of the study. Efficacy for these experimental COVID biologics is based upon the verification that they could indeed co-opt cellular ribosomal complexes to produce viral antigen fragments and ultimately inspire an immunological response that cultivated long-term antibody immunity.

What was performed in the Pfizer clinical trial is not science, *it's the appearance of science*. The Pfizer study is severely flawed and compromises the integrity of all test results.

Humans should not be treated as guinea pigs and are protected by law. Yet we're treated like guinea pigs and are being coerced through a variety of deeply troubling tactics to consent to the use of experimental COVID biologics that are being investigated in an ongoing clinical trial.

Is the public being informed that these biologics are neither as safe or as effective as people with vested financial interests would lead them to believe?

How a clinical trial of this importance reaches approval for the enrollment of human subject without data from preceding animal experiments is a scientific travesty that sets the stage for this experimental COVID biologic to not only be ineffective, but also injure people.

Again, this clinical trial isn't science...*it's the appearance of science*.

It is reasonable to expect independent and transparent oversight of the experimental COVID biologic clinical trials. Why was the public not given the opportunity to comment on the design of these clinical trials before they began enrolling participants?

Why were the corporations, with clear financial conflicts of interest, essentially allowed to police themselves?

Why were the experimental COVID biologics able to reach the market in eight months when it typically takes eight years?

Evidence of safe and effective treatments has been in existence from the beginning of this crisis, which creates time for experimental COVID biologics to undergo rigorous safety and efficacy testing. There was never a need to rush development of a new technology.

Rushing a "warp speed" technology to the public without long-term proof of safety and immediate proof of efficacy is ethically capricious and scientifically irresponsible.

This should not happen in a free society.

This cannot happen with so much at stake.

## Problems with Clinical Trials for Experimental Biologics – Analysis

**Summary Pfizer Experimental COVID Biologic Clinical Trial Analysis** – Experimental COVID biologic has no known nor FDA authorized use in human subjects and therefore must be categorized as experimental until significant long term data is collected and analyzed for safety and efficacy over a significant sample size of participants. As this mRNA biologic therapy is experimental, its only legal administration can be in a clinical trial with willing participants and signed informed consent authorizations.

<https://www.nejm.org/doi/10.1056/NEJMoa2034577>

**Key Quotes** – *“In an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial, we randomly assigned persons 16 years of age or older in a 1:1 ratio to receive two doses, 21 days apart, of either placebo or the BNT162b2 vaccine candidate (30 µg per dose).*

*“A total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo.*

*“There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo;*

*“BNT162b2 was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6).*

*“The first primary end point was the efficacy of BNT162b2 against confirmed Covid-19 with onset at least 7 days after the second dose in participants who had been without serologic or virologic evidence of SARS-CoV-2 infection up to 7 days after the second dose; the second primary end point was efficacy in participants with and participants without evidence of prior infection. Confirmed Covid-19 was defined according to the Food and Drug Administration (FDA) criteria as the presence of at least one of the following symptoms: 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, or vomiting, combined with a respiratory specimen obtained during the symptomatic period or within 4 days before or after it that was positive for SARS-CoV-2 by nucleic acid amplification–based testing, either at the central laboratory or at a local testing facility (using a protocol-defined acceptable test).*

*“An explanation of the various denominator values for use in assessing the results of the trial is provided in Table S1 in the Supplementary Appendix, available at NEJM.org. In brief, the safety population includes persons 16 years of age or older; a total of 43,448 participants constituted the population of enrolled persons injected with the vaccine or placebo. The main safety subset as defined by the FDA, with a median of 2 months of follow-up as of October 9, 2020, consisted of 37,706 persons, and the reactogenicity subset consisted of 8183 persons. The modified intention-to-treat (mITT) efficacy population includes all age groups 12 years of age or older (43,355 persons; 100 participants who were 12 to 15 years of age contributed to person-time years but included no cases). The number of persons*

who could be evaluated for efficacy 7 days after the second dose and who had no evidence of prior infection was 36,523, and the number of persons who could be evaluated 7 days after the second dose with or without evidence of prior infection was 40,137.

*“The 95.0% credible interval for vaccine efficacy and the probability of vaccine efficacy greater than 30% were calculated with the use of a Bayesian beta-binomial model. The final analysis uses a success boundary of 98.6% for probability of vaccine efficacy greater than 30% to compensate for the interim analysis and to control the overall type 1 error rate at 2.5%. Moreover, primary and secondary efficacy end points are evaluated sequentially to control the familywise type 1 error rate at 2.5%. Descriptive analyses (estimates of vaccine efficacy and 95% confidence intervals) are provided for key subgroups.*

*“These data do not address whether vaccination prevents asymptomatic infection; a serologic end point that can detect a history of infection regardless of whether symptoms were present (SARS-CoV-2 N-binding antibody) will be reported later. Furthermore, given the high vaccine efficacy and the low number of vaccine breakthrough cases, potential establishment of a correlate of protection has not been feasible at the time of this report.*

*“This report does not address the prevention of Covid-19 in other populations, such as younger adolescents, children, and pregnant women.*

*“The development of BNT162b2 was initiated on January 10, 2020, when the SARS-CoV-2 genetic sequence was released by the Chinese Center for Disease Control and Prevention and disseminated globally by the GISAID (Global Initiative on Sharing All Influenza Data) initiative.*

*“Pfizer was responsible for the design and conduct of the trial, data collection, data analysis, data interpretation, and the writing of the manuscript. BioNTech was the sponsor of the trial, manufactured the BNT162b2 clinical trial material, and contributed to the interpretation of the data and the writing of the manuscript.*

*“(Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)”*

**Investigative Note** – Links to all PDF supplementary materials are broken or not responding at the time of investigation (February 22, 2021). Multiple attempts to access hyperlinks provided by the NEJM on a variety of computers were unsuccessful.

### **Clinical Trial Analysis Phase 2/3**

Enrolled Participants: **43,998**

Number of Participants Receiving Inoculations: **43,448**

Number of Participants Receiving BNT162b2 Experimental Biologic: **21,720**

Number of Participants Receiving Saline Placebo: **21,728**

Main Safety Subset Participants: **37,706**

Participants Exhibiting Reactogenicity: **8,183**

Final Number of Participants: **40,137**

Number of Enrolled Participants Who Withdrew or Were Removed from Trial: **3,861**

Trial Status: **Ongoing For 2 Year from Date of 2<sup>nd</sup> Inoculation**

Post Inoculation Laboratory Methods for Assessment of Safety and Efficacy: **Unknown**

Exact methods for verifying presence or absence of post-inoculation infection are not clearly identified via the NIH Clinical Trial Study Detail or New England Journal of Medicine Published Manuscript.

If PCR tests were used, there is no mention of the company or NIH-approved entity processing the results or the cycle threshold value used to determine a positive versus negative result.

Safety percentages were calculated based upon the first 360 participant reports rather than the full subset of participants according to the published NIH clinical trial study details.

Serologic and PCR Prescreening for participants before entry into the clinical trial was not performed during Phase 2/3.

### **Reprint of Clinical Trial Analysis Phase 2/3 from Previous Subtopic Section**

<https://clinicaltrials.gov/ct2/show/record/NCT04368728?view=record>

Prescreening for Serologic IgM and IgG Antibodies: **No**

Prescreening Nasal PCR for Viral Fragments: **No**

Other Prescreening Laboratories: **No**

Post Inoculation Evaluation of Antibody Production: **No**

Measurement of adverse events: **1 month, first 360 participants**

Measurement of serious adverse events extends: **6 months, first 360 participants**

No measurement of adverse events or serious adverse events in the remaining participant population is mentioned.

**Position** – Concerns include that Pfizer and BioNTech had a demonstrative role in the analysis of the safety and efficacy of the clinical trials. It is unethical and a definitive conflict of interest for the corporations that have vested financial interests in the approval of their experimental biologics to have authorship regarding the analysis of their products during a crisis.

This confirms that no independent analysis was conducted to verify the accuracy, objectivity, and integrity of their analysis. No legal penalties for data manipulation were acknowledged by Pfizer/BioNTech. What is the deterrent for data manipulation or exclusion of enrolled participants that might adversely impact the final analysis?

Another flaw in the study design and analysis is the reckless absence of thorough prescreening. To validate that the participant population is definitively free from prior exposure to the SARS-CoV-2 virus, serologic IgM and IgG antibody tests and molecular tests with stated cycle threshold values must be provided prior to entry into the study.

Due to this failure, it is impossible to state with scientific integrity or confidence that the participants in the study demonstrated a pure sample population to accurately assess both efficacy and especially safety.

An additional flaw in the analysis is the omission of data of at least 3,861 enrolled participants who either voluntarily withdrew or were withdrawn from the study. What happened in each of these cases? Where is the data for independent evaluation?

The declarative statement of safety and efficacy of an experimental biologic that is still in an ongoing clinical trial is also a flaw in the analysis. With roughly two years of data still to be collected, how can an objective scientist make such a presumptive statement regarding safety and efficacy?

These are scientifically irresponsible conclusions to come to while data is still being collected and the clinical trial is still in progress.

The final major flaw in analysis is the headline suggesting 95% clinical efficacy of the vaccine in prevention of infective spread following dual dose administration.

First, this information is not based on equal environmental controls for the experimental and control groups as there is no means to establish a definitive equivocal number of actual confirmed exposures to infectious persons following administration without placing all participants in highly controlled environments that would violate ethical standards of clinical trial design.

Second, the methods used for testing are not clearly stated. Are these subjective determinations or laboratory objective determinations?

If the methods included laboratory testing, which testing was used? If PCR was used, which PCR tests were used and what was the cycle threshold used as the cut off for positive signal detection?

If PCR testing was used, is the cycle threshold calibrated for infectiousness or merely prior existence of possible infection?

If the goal of the experimental COVID biologic clinical trial is to prove efficacy, then the question is, *efficacy of what, inducing viable immunological IgM and IgG antibody responses?*

Although answering such questions makes sense, unfortunately the clinical trial is not designed to answer them in Phase 2/3 (or even completely in Phase 1).

If efficacy was truly priority, then antibodies for all participants administered the experimental biologic would have been confirmed. This happened for a small sample size of participants in Phase 1 only.

If efficacy was truly priority, then the ability of any antibodies produced to bind to the isolated SARS-CoV-2 virus in a live human cell culture would have been confirmed. This did not occur during any phase of the clinical trial.

As a result, both Pfizer and BioNTech are relying exclusively on Phase 1 studies, with exceedingly small sample sizes, to gain any cursory understanding of antibody production resulting from their experimental COVID biologic.

The Phase 1 clinical trial involved only 45 participants, some of whom received the saline placebo and some of whom received the BNT162b1 experimental biologic that was discontinued for Phase 2/3 evaluation, and some of whom received the BNT162b2 experimental biologic.

What this means is that the data being collected for actual efficacy of this experimental COVID biologic is based upon an exceedingly small sample size of participants.

The design of this clinical trial compromises the investigatory objectives rendering all data and subsequent analysis of the data for safety and efficacy incomplete until the conclusion of the clinical trial. At worst, the severely flawed design of the clinical trial renders the data and subsequent analysis null and void.



# Phase 3 Clinical Trial – Administration and Surveillance

## Vaccine Adverse Events Reporting System (VAERS) Database

<https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=D1E28EE61A7BAC75C32778FDBCF3>

**Reported Fatalities - December 13, 2020, to March 12, 2021**

**1,739 Reported Fatalities Related to Experimental COVID Biologics**

**Reported Adverse Events – December 13, 2020, to March 12, 2021**

**38,444 Reported Adverse Events Related to Experimental COVID Biologics**

The screenshot shows the CDC WONDER interface for the Vaccine Adverse Event Reporting System (VAERS) Results. The page title is "The Vaccine Adverse Event Reporting System (VAERS) Results". The interface includes navigation tabs for "Request Form", "Results", "Map", "Chart", "Report", and "About". Below the tabs are links for "Dataset Documentation", "Other Data Access", "Help for Results", "Printing Tips", and "Help with Exports". There are buttons for "Save", "Export", and "Reset". A search bar is visible in the top right corner. The main content area displays a table with columns for "Age", "Events Reported", and "Percent (of 1,739)". The table data is as follows:

Age	Events Reported	Percent (of 1,739)
1-2 years	2	0.12%
18-29 years	11	0.63%
30-39 years	12	0.69%
40-49 years	33	1.90%
50-59 years	88	5.06%
60-64 years	92	5.29%
65+ years	1,282	73.72%
Unknown	219	12.59%
<b>Total</b>	<b>1,739</b>	<b>100.00%</b>

# Reported Fatalities Search Criteria

wonder.cdc.gov/controller/datarequest/D8;jsessionid=0AD10E7888ED49F2F980323EA9D4

For more information on how many persons have been vaccinated in the US for COVID19 to date, see <https://covid.cdc.gov/covid-data-tracker/#vaccinations/>

**Help:** See [The Vaccine Adverse Event Reporting System \(VAERS\) Documentation](#) for more information.

**Query Date:** Mar 22, 2021 7:24:59 PM

[Top](#) [Options](#) [Notes](#) [Citation](#) [Query Criteria](#)

**Suggested Citation:**  
 United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/12/2021, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Mar 22, 2021 7:24:59 PM

[Top](#) [Options](#) [Notes](#) [Citation](#) [Query Criteria](#)

**Query Criteria:**

**Date Report Received:** Dec., 2020 to Mar., 2021  
**Event Category:** Death  
**Vaccine Products:** COVID19 VACCINE (COVID19)  
**Group By:** Age  
**Show Totals:** True  
**Show Zero Values:** False

Content source: CDC WONDER

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**The Vaccine Adverse Event Reporting System (VAERS) Results**

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**Messages:**

- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 38,444 total events.
- Rows with zero Events Reported are hidden. Use Quick Options above to show zero rows.

Age	Events Reported	Percent (of 38,444)
< 6 months	3	0.01%
6-11 months	6	0.02%
1-2 years	31	0.08%
6-17 years	154	0.40%
18-29 years	4,205	10.94%
30-39 years	7,467	19.42%
40-49 years	7,202	18.73%
50-59 years	6,339	16.49%
60-64 years	2,462	6.40%
65+ years	7,294	18.97%
Unknown	3,281	8.53%
<b>Total</b>	<b>38,444</b>	<b>100.00%</b>

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

## Reported Adverse Events Search Criteria

Data contains VAERS reports processed as of 3/12/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. [More information.](#)

For more information on how many persons have been vaccinated in the US for COVID19 to date, see <https://covid.cdc.gov/covid-data-tracker/#vaccinations/>

**Help:** See [The Vaccine Adverse Event Reporting System \(VAERS\) Documentation](#) for more information.

**Query Date:** Mar 22, 2021 7:33:26 PM

[Top](#) [Options](#) [Notes](#) [Citation](#) [Query Criteria](#)

**Suggested Citation:**

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/12/2021, CDC WONDER On-line Database. Accessed at <http://wonder.cdc.gov/vaers.html> on Mar 22, 2021 7:33:26 PM

[Top](#) [Options](#) [Notes](#) [Citation](#) [Query Criteria](#)

**Query Criteria:**

**Date Report Received:** Dec., 2020 to Mar., 2021  
**Vaccine Products:** COVID19 VACCINE (COVID19)  
**Group By:** Age  
**Show Totals:** True  
**Show Zero Values:** False

Content source: CDC WONDER

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**Summary** – When examining data from the federal Vaccine Adverse Events Reporting System (VAERS), it is important to note several key facts to maintain objectivity.

- (1) VAERS is a federal database with criminal penalties for submitting fraudulent records.  
**“Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.”**
- (2) Providers are legally required to report the following adverse events to VAERS for all experimental COVID biologics per Emergency Use Authorization:
  - a. Death
  - b. Life-threatening Adverse Event
  - c. Inpatient or Prolonged Hospitalization
  - d. Persistent or Significant Incapacity or Substantial Disruption of the Ability to Conduct Normal Life Functions
  - e. Congenital Anomaly/Birth Defects
  - f. All Important Medical Events That Based on Appropriate Medical Judgment May Jeopardize the Individual and May Require Medical or Surgical Intervention to Prevent One of the Outcomes Listed Above
  - g. Cases of COVID-19 That Result in Hospitalization or Death

- h. Cases of Multisystem Inflammatory Syndrome
- i. Vaccine Administration Errors, Whether or Not Associated with an Adverse Event

<https://vaers.hhs.gov/faq.html>

**Position** – Humans are not guinea pigs. Use of experimental COVID biologics should not be mandated based upon the reported injuries alone.

To maintain informed consent, all persons considering the use of the experimental COVID biologics must: (1) be informed of the reports in VAERS, (2) be informed that the experimental COVID biologics are still being evaluated for long-term adverse events in ongoing clinical trials, (3) be informed of whether or not there is any data for their demographic, (4) be informed of the existence of evidence-based treatment options, (5) be informed of how the theoretical mechanism of action works, (6) be informed of the ingredients, (7) be confirmed to have had no prior adverse reactions to vaccine administration, (8) be informed of the potential for autoimmunity and infertility, and (9) be made aware that there is no requirement to provide their consent.

As more tech companies begin to endeavor into medicine, it is critical that they don't view the human body as they view a computer, where viral codes and antivirus measures can be uploaded and updated with little consequence.

Ethically, if we consider the fact that clinical trials are ongoing, then the global distribution of these experimental COVID biologics is an ongoing experiment due to the absence of long-term data. The ever-growing number of fatalities and adverse events demonstrates that harm is ongoing. Further, will we be able to compare the use of the biologic to the use of known evidence-based treatments for efficacy and safety and provide people a choice? This is a disappointing outcome of poorly designed clinical trials for completely new medical technologies that were rushed through evaluation at "warp speed."

This isn't a science fiction movie, although science fiction methodologies have been implemented to market it. We won't have the choice to walk out of the theater if we don't like what we're watching.

This is a global science experiment with no long-term data available.

## Phase 3 Clinical Trial – Liability

<https://www.lawinsider.com/dictionary/vaccine>

**Key Quotes for Legal Definition of Vaccine** – *“(1) a specially prepared antigen which, upon administration to a person, will result in immunity and, specifically for the purposes of this rule, shall mean influenza and pneumococcal vaccines, (2) a specially prepared antigen administered to a person for the purpose of providing immunity, or (3) a specially prepared antigen, which upon administration to a person may result in immunity.”*

**Summary** – This legal definition is based on over 90 references. There is no mention of experimental COVID biologic technology in these definitions.



**Position** – By legal standards, these new experimental COVID biologics do not meet the criteria for vaccine categorization. As such, we have elected to use the phrase “experimental COVID biologics” until the exact classification of the biologics are universally agreed upon following global scientific comment and subsequent legal codification.

**Key Quotes Granting Vaccine Manufacturers Immunity from Civil Litigation** – *“42 USC 300aa-11(2)(A) No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death...*

*“42 USC 300aa-11(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.*

*“42 USC 300aa-22(b)(1) Unavoidable adverse side effects; warnings: No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.”*

<https://www.law.cornell.edu/uscode/text/42/300aa-11>

<https://www.law.cornell.edu/uscode/text/42/300aa-22>

PREP Declaration and Amendments <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

**Summary** – Vaccine manufacturers are currently exempt from civil litigation involving vaccine injuries from FDA approved vaccines only. But the apparent law governing liability is the PREP Act, which can only be bypassed in the pursuit of compensation for injury if willful misconduct can be proven.

**Position** – With the evidence already amassed regarding violations of Federal Laws for data collection and with the FDA willfully withholding evidence-based treatments for COVID from the public, we believe willful misconduct can be successfully argued.

As experimental COVID biologics do not meet the legal criteria as a vaccine, and whereas the current experimental COVID biologics are not FDA approved due to the respective ongoing clinical trials, Pfizer, BioNTech, Moderna, and any pharmaceutical manufacturer should be liable for all death and injuries related to administration of their experimental COVID biologics.

Pfizer, BioNTech, and Moderna do not qualify for protection from civil litigation normally provided by 42 USC 300aa-11(2)(A), 42 USC 300aa-11(3), and 42 USC 300aa-22(b)(1). This is clear.

But the PREP Act is the obstacle that must be surmounted to protect the Constitutional rights of anyone injured by the experimental COVID biologics.

If willful misconduct can be proven, then this may make way for an eventual repeal of sections 42 USC 300aa to finally place the burden of liability upon the very industry reporting record annual profits and incessantly pushing legislation for mandating the use of their products.

If a company/industry stands to profit in the billions annually from their product, they should assume all liability when their product injures or leads to death.

No other product in the world has protection from civil litigation because civil litigation is how the public can enact oversight over the industry to ensure product safety and efficacy.

We demand that federal legislators protect all people consenting to the use of experimental COVID biologics and to go one step further and repeal 42 USC 300aa-11(2)(A), 42 USC 300aa-11(3), and 42 USC 300aa-22(b)(1) immediately.

Allow Americans to hold vaccine manufacturers financially responsible for products they profit from.

**Key Quote Affirming the Legal Liability of Clinical Trial Sponsors –** *“45 CFR 46-116(a)(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.”*

[https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pid=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pid=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)

**Summary –** Informed consent law affirms that sponsors of clinical trials are liable for negligence.

**Position –** Is it negligent to accept billions of U.S. taxpayer dollars to develop a new technology and enroll human participants in a clinical trial without first performing routine animal clinical trials to verify safety?

Is it negligent to progress the clinical trial from Phase 1 to Phase 2/3 when injuries were discovered in Phase 1?

Is it negligent to expedite Emergency Use Authorization and rush a poorly tested product to market when evidence-based treatments exist?

Is it negligent to approve for public use a fast-tracked, poorly tested experimental COVID biologics that are still in ongoing clinical trials?

Is it negligent to produce an experimental COVID biologic for public administration without fulfilling informed consent, including daily updates of reports of experimental COVID biologic induced injury and death?

These are questions that will have to be argued and determined in a court of law.

Anyone injured, while subsequently not being properly informed about the risks and progress of the existing clinical trial should have a right to seek appropriate compensation for their injuries through personal rights of action in civil court.

Release of an experimental medical therapy proven to injure people is unethical when evidence-based treatments exist.

In the case of these experimental COVID biologics, all recipients have rights that are being trampled upon and thus, must be protected.

## **Position Regarding Violations of Medical Ethics During COVID**

Are the experimental COVID biologics FDA-approved? **No, they are EUA-approved as of this publication date.**

Did the experimental COVID biologics undergo animal clinical trials before being approved under Emergency Use Authorization? **Yes and no. Animal clinical trials were completed on September 9, 2020, well after human participants were enrolled in the human clinical trials.**

Are there significant flaws in the design of the clinical trials? **Yes.**

Are there significant flaws in the analysis of the clinical trials? **Yes.**

Were Pfizer/BioNTech and Moderna/NIH allowed to police themselves without opportunity of public comment, independent scientific peer-review, and oversight? **Yes.**

Is the Phase 2/3 human clinical trial still active? **Yes: Oct. 27, 2022 (Moderna) and Jan. 31, 2023 (Pfizer).**

Is the medical experiment ongoing? **Yes. Trials are ongoing (see above).**

Are the experimental COVID biologics new technologies with no long-term data? **Yes.**

Are people being coerced into participation by company mandates that threaten their employment if they don't comply? **Yes.**

Are people being coerced into participation by government officials eager to simultaneously ignore safety concerns for the experimental COVID biologics and pretend that evidence-based, low-cost treatments for COVID-19 don't exist? **Yes.**

Is this a violation of medical ethics and informed consent? **Yes.**

Have people died following the administration of the experimental COVID biologics? **Yes.**

Has every person receiving experimental COVID biologics been properly informed that the Phase 2/3 clinical trials are ongoing, that they are not FDA approved and are therefore experimental, that they have been shown to induce serious adverse events, that people have died, and that there are risks because of the lack of longitudinal data? **Unknown.**

Has every person been made aware of their rights, protected under 45 CFR 46-116 and 45 CFR 46-117, to decline participation regardless of repeated attempts to coerce entry into the clinical trial? **Unknown.**



Has every person agreeing to receive the experimental COVID biologics signed an authorization certifying the legal obligations for informed consent have been achieved? **Unknown.**

Is every person being given a copy of the paperwork they are signing before receiving the experimental COVID biologic? **Unknown.**

Has every person been notified that effective treatments both natural and pharmaceutical exist prior to consenting to use the experimental COVID biologics? **No.**

Who is ultimately liable for injuries induced by these experimental COVID biologics? **This remains to be seen, but the law suggests these biologics do not meet the legal definitions for a vaccine, which removes the protections of 42 USC 300aa-11 and 42 USC 300aa-22 for these manufactures from civil litigation. Additionally, as clinical trials are still ongoing, 45 CFR 46-116 and 45 CFR 46-117 potentially place liability on the sponsors of these clinical trials.**

**If willful misconduct can be successfully argued based upon the summary of findings throughout this position paper, then the protections of the PREP Act can be challenged. At the very least, the call for discovery can be made to further investigate.**

**As in the Tuskegee Experiment, where the withholding of treatment was an example of willful misconduct, with respect to COVID-19, evidence-based treatments exist and have also been withheld.**

Has any vaccine ever reached the public in less than four years? **No.**

Is a person's body their autonomous sovereign territory? **Yes.**

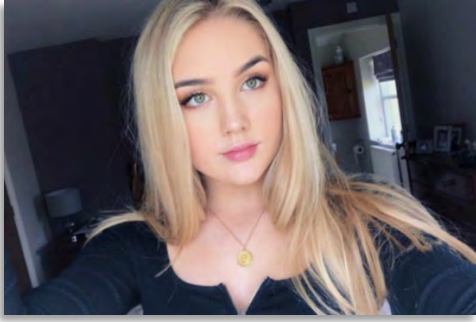
The existential right to choose what goes into and upon one's sovereign territory must always remain with the person. Human beings are not guinea pigs.

Human beings, as property, ended in 1865. We are not property of the state or of corporations.

In the face of repeated violations regarding COVID-19 and with people being adversely impacted by public health policies, investigation into the potential of willful misconduct is reasonable and appropriate. If willful misconduct is proven, then all individuals and entities responsible should be held accountable for any damages.

The time has come for us to come together and say in one voice...**ENOUGH!**

## People Worthy of Our Remembrance



### **Emily Owen, 19 Died by Suicide**

“Our darling, beautiful, crazy daughter and sister tragically decided that she could no longer cope and tried to take her own life on Wednesday. She has been in critical care since then. ‘The decision has been made today to turn off her life-support tomorrow afternoon, giving time for the hospital to prepare for organ donation, something she signed up for in 2012 when she was only 12-years-old. That sums her up – always caring for other people.’”

<https://metro.co.uk/2020/03/25/teenager-19-kills-fears-will-stuck-inside-coronavirus-12453434/>

## Topic 8 – Formal Grand Jury Petition

**Conclusions** – It is undeniable that public trust in our governance and public health departments has been significantly eroded. As this position paper has presented, there have been significant and consistent problems with nearly every aspect of how this crisis has been handled as death tolls and collateral damage from public health policies continue to mount.

Perhaps the best method for restoring faith in our governance and public health officials is for them to take ownership of their failures and open in-person dialogue with citizens whose voices have been muted throughout this crisis.

**The first step to fixing a problem is admitting that one exists.**

The second step to fixing a problem is to discontinue using strategies and tactics that have proven ineffective.

The third step to fixing a problem is to start listening to new ideas.

The fourth step to fixing a problem is acting on objective, independent, science that is free from financial conflicts of interest as opposed to fear-based narratives masquerading as “the science.”

If the first step never becomes reality, citizens have other peaceful means of legal discovery, so we can understand who was responsible for what went wrong.

This legal tool is known in the United States as a Special Grand Jury Investigation.

On the following pages is a copy of the formal grand jury petition filed on October 16, 2020 to the U.S. Department of Justice, All U.S. Attorney Generals, and their administrative staff via printed and electronic filing.

Disappointingly, this formal petition was never responded to despite proof of receipt and more than 200 copies of the petition being distributed.

We are not deterred because we have a constitutional right to know what elected officials and corporate influencers are doing behind closed doors.

We are confident that a Formal Grand Jury Petition will ultimately be heard, and the truth will be brought to light. If willful misconduct did take place, then it will undoubtedly be uncovered.

If willful misconduct did not occur, then citizens can rest at night knowing gross incompetence was rampant.

Something is broken and we have to determine what it is so we can work together to fix it.

When we lift up our voices and sing so loudly that we can no longer be ignored, the truth will find us.

For our ancestors, for our children, for the children yet to come, it is our duty to place the mantle of freedom upon our shoulders and carry it until the next generation is prepared to do so.

# ON BEHALF OF ALL CONCERNED CITIZENS

## Formal Citizen Petition Overview<sup>1-8</sup>

This petition is presented by a group of American citizens with professional expertise in medicine, law, statistics, and death certificate reporting who have come together to investigate irregularities in COVID-19 data:

- Irregularities that played a significant role in justifying executive orders.
- Irregularities that were used to establish excessive and ineffective health policies.
- Irregularities that have led to major collateral damage, including: (1) historic economic collapse, (2) dramatic rises in mental illness, and (3) unnecessary loss of life.

Several exhibits are provided within this **formal citizen petition for a grand jury investigation into the legalities of COVID-19 data collection** for your review. This exhibit is a synopsis of the agencies involved and potential violations of law that led to irregularities in COVID-19 data collection and recording. Additionally, a peer-reviewed research paper is included that provides an in-depth, historical summary of key findings relative to COVID-19 data collection. Several documents and links are also provided to aid the research process and assist your confirmation of key findings. On behalf of all concerned citizens, we ask you to review each exhibit within this citizen petition and exercise your power as a U.S. Attorney to formally initiate a grand jury investigation based upon the evidence provided within these exhibits. Our volunteer investigative research is in honor of every American who has sacrificed so much so that we all may live again freely and justly.

Your Honor, this is our formal petition.<sup>1-8</sup>

**Note: Expert witness list available upon request via [AllConcernedCitizens@protonmail.com](mailto:AllConcernedCitizens@protonmail.com).**

1. The right to petition a grand jury is codified in the first amendment to the United States Constitution and in **18 USC §3332 Powers and Duties**; "It shall be the duty of each such grand jury impaneled within any judicial district to inquire into offenses against the criminal laws of the United States alleged to have been committed within that district. Such alleged offenses may be brought to the attention of the grand jury by the court or by any attorney appearing on behalf of the United States for the presentation of evidence. Any such attorney receiving information concerning such an alleged offense from any other person shall, if requested by such other person, inform the grand jury of such alleged offense, the identity of such other person, and such attorney's action or recommendation."
2. This right is also affirmed again by **In Re Grand Jury Application** (No. 85 Civ. 2235 (VLB), 617 F. Supp 199 | 1985); "Since the United States Attorney has been requested to present certain information to the grand jury he must do so. I will not relieve him of a duty which Congress has seen fit to impose. 18 U.S.C. § 3332(a) imposes a "plainly defined and peremptory duty" on the part of the United States Attorney to present the plaintiffs' information concerning the alleged wrongdoing of the other defendants to the grand jury."
3. The right to petition a grand jury pre-exists codification, and we stand on this right. See **McDonald v Smith**, (472 U. S. 479, 482–484 | 1985) and **District of Columbia v. Heller**, (554 U.S. 570, 579, 592 | 2008).
4. Yet, when we examine English common law, we see this right pre-exists both the Constitution and the United States Code when, in 1689, the Bill of Rights enacted of William and Mary stated: "[I]t is the Right of the Subjects to petition the King."
5. The **US Attorney Manual** confirms the independence of the grand jury; "The prosecutor must recognize that the grand jury is an independent body." (USAM Chapter 9-11.010 – Introduction).
6. The Fifth Amendment "presupposes an investigative body acting independently of either prosecuting attorney or judge." **United States v. Dionisio**, (410 U.S. 1, 16 | 1973)
7. In **Frisbie v. United States** (157 U. S. 160), it is said by Justice Brewer, "But, in this country, it...is for the grand jury to investigate any alleged crime, no matter how or by whom suggested to them, and, after determining that the evidence is sufficient to justify putting the party suspected on trial, to direct the preparation of the formal charge or indictment."
8. "They [grand juries] are not appointed for the prosecutor or for the court; they are appointed for the government and for the people..." **Hale v. Henkel, 201 US 62**.

# Summary of Primary Concerns

All federal agencies are required to comply with all federal laws. For your convenience, relevant federal agencies and excerpts of relevant laws are included later in this exhibit.

The CDC and National Vital Statistics System (NVSS), a federal agency within the CDC, are required to comply with the Administrative Procedures Act (APA), the Paperwork Reduction Act (PRA), and the Information Quality Act (IQA). As you are aware, these three laws ensure essential oversight of our federal agencies to ensure accuracy in data collection, analysis, and publication.

Upon investigation, the following has been revealed:

- (1) There is solid evidence that the CDC and NVSS violated the APA, PRA, and IQA by issuing COVID-19 Alert No. 2 on March 24, 2020. This alert significantly modified how death certificates were recorded and did so exclusively for COVID-19. This alert ensured COVID-19 was emphasized as the cause of death. This modification was made exclusively for COVID-19 fatalities, thereby making COVID-19 exclusively a cause of death and rarely a **contributing factor to death**. The 2003 CDC *Medical Examiner's and Coroner's Handbook on Death Registration and Fetal Death Reporting* states that in the presence of pre-existing conditions, **infectious disease is recorded as the contributing factor to death, not the cause**. This modification was medically unnecessary, as existing rules for data collection and recording had been in use nationwide without incident for the previous 17 years. Most egregiously, this material modification does not apply to any other infectious disease, creating a double-standard exclusively for COVID-19 data collection. **As a result, COVID-19 fatality data used to shape public health policy is significantly inflated.**
- (2) The CDC violated the APA, PRA, and IQA by adopting the Council of State and Territorial Epidemiologists' (CSTE) Interim-20-ID-01 COVID-19 Standard Surveillance position paper on April 14, 2020. This position paper significantly increased COVID-19 case counts. As seen in Section VII.B on page 6, the CSTE paper acknowledged the need to define a methodology for ensuring multiple tests on the same person were not counted multiple times as new cases, and then declined to define one.

Additionally, Section 5 of the CSTE paper creates the option of “probable” COVID-19 cases with an extraordinarily low standard of proof for diagnosis. For example, the standard of medical diagnosis in this section allows a simple cough to be sufficient to diagnose a patient as COVID-19 positive. Even without confirmatory symptoms or lab testing, this patient can now be included in data collection such as total cases, hospitalizations, and cause of death. The adoption of the CSTE position paper creates material modifications exclusively for COVID-19 data collection that does not apply to any other infectious disease. **As a result, COVID-19 case and fatality data used to shape public health policy is significantly inflated.**

- (3) The Office of Management and Budget (OMB) is appointed to oversee data collection for all federal agencies. Should a federal agency, even in an emergency situation, desire to modify any aspect of their data collection, analysis, or publication, they must first notify the Federal Register. Notification of intent to modify any aspect of data collection, analysis, or

publication in the Federal Register alerts the Office of Information and Regulatory Affairs (OIRA) within the OMB. Notification in the Federal Register also opens the mandatory 60-day period for public comment on proposed modifications to data collection, analysis, or publication. The CDC and NVSS failed to notify the Federal Register and therefore failed to comply with federal law. **The CDC has made unilateral changes, with far-reaching consequences, to data collection and recording exclusively for COVID-19, without federal oversight, independent of peer-review, and without public comment.**

- (4) Due to the historical levels of collateral damage created, the actions of the CDC and NVSS may have violated additional laws such as 18 USC §1035 (False Statements Related to Healthcare Matters), 18 USC §1001 (False Statements), 18 USC §1040 (Fraud in Connection with Major Disaster or Emergency Benefits), 18 USC §1038 (False Information & Hoaxes), 18 USC §371 (Conspiracy to Defraud the United States), 18 USC §242 (Deprivation of Rights Under Color of Law), 18 USC §241 (Conspiracy Against Rights), 18 USC §2331 - Chapter 113B (Domestic Terrorism), 18 USC §1031 (Major Fraud Against the United States), 18 USC §3333 (Malfeasance), 18 USC §1622 (Subornation of Perjury), 18 USC §4 (Misprison of Felony). **Considering these potential violations and referring to 18 USC §3332 (Powers and Duties), we are formally calling for a grand jury investigation into the legality of events related to COVID-19 data collection by the CDC and NVSS.**

## Relevant Federal Agencies

Research conducted points to, but is not limited to, the following federal agencies being immediately worthy of grand jury investigation regarding the potential illegal composition and collection of COVID-19 data:

### Office of Management and Budget (OMB)

The Office of Management and Budget (OMB) is a federal agency within the Executive Branch that serves the President of the United States by assisting the President with management and regulatory objectives, among other things, and to fulfill the agency's statutory responsibilities.

### Office of Information and Regulatory Affairs (OIRA)

Within the OMB, the Office of Information and Regulatory Affairs (OIRA) is tasked with ensuring that all federal agencies are in legal compliance with the APA, PRA, and IQA.

### Department of Health and Human Services (HHS)

The Department of Health and Human Services (HHS) is a cabinet-level department. HHS is a federal agency within the Executive Branch.

### Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention (CDC) is a federal agency within HHS. The CDC is responsible for developing evidence-based public health strategies, monitoring disease statistics, and providing effective guidance for citizens and public officials in times of public health crises.

## National Center for Health Statistics (NCHS)

The National Center for Health Statistics (NCHS) is a federal agency within the CDC. NCHS is the nation's principal health statistics agency, compiling statistical information to guide actions and policies to ensure the health of the population.

## National Vital Statistics Service (NVSS)

The National Vital Statistics System (NVSS) is a federal agency within the NCHS. NVSS is responsible for the accurate collection of data for all births, deaths, and disease processes attributed to citizens of the United States of America.

## Relevant Law

All federal agencies are required to comply with the Administrative Procedures Act, the Paperwork Reduction Act, and the Information Quality Act. Below is a brief summary of relevant law.

### Administrative Procedures Act (APA)

One of the primary objectives of the Administrative Procedures Act (APA) 5 USC §551 et seq. (1946) is to govern the process by which federal agencies develop and issue regulations. This includes requirements for publishing in the Federal Register notices of both proposed and final rulemaking and it provides opportunities for public comment on proposed rules. Most rules have a 30-day delayed effective date. The APA also addresses other agency actions including the issuance of policy statements. (See Additional Considerations Regarding the APA on Page below.)

### Paperwork Reduction Act (PRA) and Creation of the Office of Information of Regulatory Affairs (OIRA)

The Paperwork Reduction Act (PRA) (44 U.S.C. §§ 3501–3521, Public Law 96-511, 94 Stat. 2812), passed on December 11, 1980 and later amended on May 22, 1995 (44 U.S.C. §§ 3501–3521, Public Law 104-13, 109 Stat. 182), gives authority over collection of certain information by Federal agencies to the Office of Management and Budget (OMB).

To facilitate this, the PRA created within the OMB a new Office of Information and Regulatory Affairs (OIRA). The OIRA is the “central authority for the review of Executive Branch regulations, approval of Government information collections, establishment of Government statistical practices, and coordination of Federal privacy policy.”

<https://www.whitehouse.gov/omb/information-regulatory-affairs/>

### Information Quality Act (IQA)

Congress passed the Information Quality Act (IQA) in 2000, which amended the PRA and added two additional requirements. (Section 515 of the Congressional Consolidated Appropriations Act, 2001 Public Law 106-554.)



The first provision directs the OMB to issue information quality guidelines for Federal agencies to follow to ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by federal agencies.

The second provision sets out the requirements for those guidelines, including the requirement that affected federal agencies must establish a process for people to submit correction requests when they believe that the information quality guidelines have not been followed.

#### 18 USC §1035 – False Statements Related to Healthcare Matters

“Whoever, in any matter involving a healthcare benefit program, knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services shall be fined under this title or imprisoned not more than 5 years, or both.”

<https://www.law.cornell.edu/uscode/text/18/1035>

#### 18 USC §1001 (a) – False Statements

“Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; (2) makes any materially false, fictitious, or fraudulent statement or representation; or (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both. If the matter relates to an offense under chapter 109A, 109B, 110, or 117, or section 1591, then the term of imprisonment imposed under this section shall be not more than 8 years.”

<https://www.law.cornell.edu/uscode/text/18/1001>

#### 18 USC §1040 – Fraud in Connection with Major Disaster or Emergency Benefits

“Whoever, in a circumstance described in subsection (b) of this section, knowingly (1) falsifies, conceals, or covers up by any trick, scheme, or device any material fact; or (2) makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or representation, in any matter involving any benefit authorized, transported, transmitted, transferred, disbursed, or paid in connection with a major disaster declaration under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5170) or an emergency declaration under section 501 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5191), or in connection with any procurement of property or services related to any emergency or major disaster declaration as a prime contractor with the United States or as a subcontractor or supplier on a

contract in which there is a prime contract with the United States, shall be fined under this title, imprisoned not more than 30 years, or both.”

<https://www.law.cornell.edu/uscode/text/18/1040>

#### 18 USC §1038 – False Information and Hoaxes

“Whoever engages in any conduct with intent to convey false or misleading information under circumstances where such information may reasonably be believed and where such information indicates that an activity has taken, is taking, or will take place that would constitute a violation of chapter 2, 10, 11B, 39, 40, 44, 111, or 113B of this title, section 236 of the Atomic Energy Act of 1954 (42 U.S.C. 2284), or section 46502, the second sentence of section 46504, section 46505(b)(3) or (c), section 46506 if homicide or attempted homicide is involved, or section 60123(b) of title 49, shall (A) be fined under this title or imprisoned not more than 5 years, or both; (B) if serious bodily injury results, be fined under this title or imprisoned not more than 20 years, or both; and (C) if death results, be fined under this title or imprisoned for any number of years up to life, or both.”

<https://www.law.cornell.edu/uscode/text/18/1038>

#### 18 USC §371 – Conspiracy to Defraud the United States

“If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.”

<https://www.law.cornell.edu/uscode/text/18/371>

#### 18 USC §242 – Deprivation of Rights Under Color of Law

“Whoever, under color of any law, statute, ordinance, regulation, or custom, willfully subjects any person in any State, Territory, Commonwealth, Possession, or District to the deprivation of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States, or to different punishments, pains, or penalties, on account of such person being an alien, or by reason of his color, or race, than are prescribed for the punishment of citizens, shall be fined under this title or imprisoned not more than one year, or both; and if bodily injury results from the acts committed in violation of this section or if such acts include the use, attempted use, or threatened use of a dangerous weapon, explosives, or fire, shall be fined under this title or imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse, or an attempt to commit aggravated sexual abuse, or an attempt to kill, shall be fined under this title, or imprisoned for any term of years or for life, or both, or may be sentenced to death.”

<https://www.law.cornell.edu/uscode/text/18/242>

### 18 USC §241 – Conspiracy Against Rights

“If two or more persons conspire to injure, oppress, threaten, or intimidate any person in any State, Territory, Commonwealth, Possession, or District in the free exercise or enjoyment of any right or privilege secured to him by the Constitution or laws of the United States, or because of his having so exercised the same; or If two or more persons go in disguise on the highway, or on the premises of another, with intent to prevent or hinder his free exercise or enjoyment of any right or privilege so secured. They shall be fined under this title or imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse or an attempt to commit aggravated sexual abuse, or an attempt to kill, they shall be fined under this title or imprisoned for any term of years or for life, or both, or may be sentenced to death.”

<https://www.law.cornell.edu/uscode/text/18/241>

### 18 USC §2331 (Chapter 113B) – Domestic Terrorism

“Definitions: As used in this chapter (5) the term “domestic terrorism” means activities that (A) involve acts dangerous to human life that are a violation of the criminal laws of the United States or of any State; (B) appear to be intended (i) to intimidate or coerce a civilian population; (ii) to influence the policy of a government by intimidation or coercion; or (iii) to affect the conduct of a government by mass destruction, assassination, or kidnapping...”

<https://www.law.cornell.edu/uscode/text/18/2331>

### 18 USC §1031 – Major Fraud Against the United States

“Whoever knowingly executes, or attempts to execute, any scheme or artifice with the intent (1) to defraud the United States; or (2) to obtain money or property by means of false or fraudulent pretenses, representations, or promises, in any grant, contract, subcontract, subsidy, loan, guarantee, insurance, or other form of Federal assistance, including through the Troubled Asset Relief Program, an economic stimulus, recovery or rescue plan provided by the Government, or the Government’s purchase of any troubled asset as defined in the Emergency Economic Stabilization Act of 2008, or in any procurement of property or services as a prime contractor with the United States or as a subcontractor or supplier on a contract in which there is a prime contract with the United States, if the value of such grant, contract, subcontract, subsidy, loan, guarantee, insurance, or other form of Federal assistance, or any constituent part thereof, is \$1,000,000 or more shall, subject to the applicability of subsection (c) of this section, be fined not more than \$1,000,000, or imprisoned not more than 10 years, or both.”

<https://www.law.cornell.edu/uscode/text/18/1031>

### 18 USC §3333 – Malfeasance

“A special grand jury impaneled by any district court, with the concurrence of a majority of its members, may, upon completion of its original term, or each extension thereof, submit to the court a report: (1) concerning noncriminal misconduct, malfeasance, or misfeasance in office involving organized criminal activity by an appointed public officer or employee as the basis for a recommendation of removal or disciplinary action; or (2) regarding organized crime conditions in the district (etc.).”

<https://www.law.cornell.edu/uscode/text/18/3333>

#### 18 USC §1622 – Subornation of Perjury

“Whoever procures another to commit any perjury is guilty of subornation of perjury and shall be fined under this title or imprisoned not more than five years, or both.”

<https://www.law.cornell.edu/uscode/text/18/1622>

#### 18 USC §4 – Misprision of Felony

“Whoever, having knowledge of the actual commission of a felony cognizable by a court of the United States, conceals and does not as soon as possible make known the same to some judge or other person in civil or military authority under the United States, shall be fined under this title or imprisoned not more than three years, or both.”

<https://www.law.cornell.edu/uscode/text/18/4>

#### 18 USC §3332 – Powers and Duties

“It shall be the duty of each such grand jury impaneled within any judicial district to inquire into offenses against the criminal laws of the United States alleged to have been committed within that district. Such alleged offenses may be brought to the attention of the grand jury by the court or by any attorney appearing on behalf of the United States for the presentation of evidence. Any such attorney receiving information concerning such an alleged offense from any other person shall, if requested by such other person, inform the grand jury of such alleged offense, the identity of such other person, and such attorney’s action or recommendation.”

<https://www.law.cornell.edu/uscode/text/18/3332>

## Additional Exhibits

The following exhibits provide evidence corroborating what appears to be violations of relevant law.

#### COVID-19 Data Collection, Comorbidity & Federal Law: A Historical Retrospective

This is a detailed look into the historical timeline describing how the CDC appears to have violated federal law and how these violations have adversely impacted COVID-19 data leading to public health policies that compromised the Constitutionally protected rights of all Americans. (Printed, attached, and link provided.)

<https://www.publichealthpolicyjournal.com/ethics-in-science-and-technology>

#### March 24, 2020 NVSS COVID-19 Alert No. 2 Published By the CDC

This document significantly modified how certificates of death were recorded exclusively for COVID-19. (See Executive Summary at the beginning of this document for visual examples.)

<https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf>

#### April 5, 2020 CSTE Interim-20-ID-01 Position Paper Adopted by the CDC on April 14, 2020

This document significantly lowered the medical standards for what constitutes a COVID-19 case and has had far-reaching consequences by inaccurately increasing case counts, hospitalizations, and fatalities. This document also neglected to define a methodology for ensuring that the same individual was not counted multiple times in data collection. The CSTE is not a federal agency. It is a non-profit organization. This paper includes authors from state health departments, and subject matter experts from the CDC. (Printed, attached, and link provided.)

[https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01\\_COVID-19.pdf](https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf)

#### Medical Examiner's and Coroner's Handbook on Death Registration and Fetal Death Reporting

This handbook, published by the CDC, has been in use nationwide, in every state, since 2003, without incident. This is the proven handbook that the CDC and NVSS elected to abandon in favor of new and untested guidelines for certificate of death recording that did not have proper legal oversight, opportunity for independent peer-review, or public comment. (Attached and link provided. Not Printed.)

[https://www.cdc.gov/nchs/data/misc/hb\\_me.pdf](https://www.cdc.gov/nchs/data/misc/hb_me.pdf)

#### Physician's Handbook on Medical Certification of Death

This handbook was published by the CDC and has been in use nationwide in every state since 2003 without incident. Another proven handbook that the CDC and NVSS elected to abandon in favor of new and untested guidelines for certificate of death recording that did not have proper legal oversight, opportunity for independent peer-review, or public comment. (Attached and link provided. Not Printed.)

[https://www.cdc.gov/nchs/data/misc/hb\\_me.pdf](https://www.cdc.gov/nchs/data/misc/hb_me.pdf)

#### If COVID Fatalities Were 90.2% Lower, How Would You Feel About Schools Reopening?

Data analysis compiled from every state health department concerning comorbidity, global research supporting the safety of children attending in-person school, as well as participating in athletics, performance arts, and extracurricular activities. (Attached and link provided. Not Printed.)

<https://childrenshealthdefense.org/news/if-covid-fatalities-were-90-2-lower-how-would-you-feel-about-schools-reopening/>

#### COVID-19...Have You Heard? There Is Good News!

Data analysis compiled from every state health department supporting many new cases and hospitalizations were the result of the CDC's test-based diagnosis strategy from June 13, 2020 to July 17, 2020. (Attached and link provided. Not Printed.)

<https://childrenshealthdefense.org/news/covid-19have-you-heard-there-is-good-news/>

## Are Children Really Recovering 99.9584% of the Time From COVID-19?

Data analysis compiled from every state health department supports extremely high recovery rates without the use of FDA approved vaccines or treatments regardless of infection rates. (Attached and link provided. Not Printed.)

<https://childrenshealthdefense.org/news/are-children-really-recovering-99-9584-of-the-time-from-covid-19/>

## U.S. District Judge William Stickman IV Ruling in Pennsylvania

"The congregate gathering limits imposed by defendants' mitigation orders violate the right of assembly enshrined in the First Amendment; (2) that the stay-at-home and business closure components of defendants' orders violate the due process clause of the Fourteenth Amendment; and (3) that the business closure components of defendants' orders violate the Equal Protection Clause of the Fourteenth Amendment..." (Attached and link provided. Not Printed.)

<https://www.courthousenews.com/wp-content/uploads/2020/09/butler-v-wolf.pdf>

# Additional Considerations Regarding the Administrative Procedures Act (APA)

Did COVID-19 Alert No. 2 and the Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19) create a new rule that required APA informal rulemaking procedure?

APA §551(4) defines a rule as "...any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy..."

*COVID-19 Alert No. 2* adopted a new ICD-10 code for COVID-19 as well as the *Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19)* that changed the death certificate recording such that, **"COVID-19 should be reported on the death certificate for all decedents where the disease caused or is assumed to have caused or contributed to death... If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II."**

This is a fundamental change in policy in the way deaths are recorded on certificates. Under the guidance of the 2003 death registration handbooks, the chronic conditions mentioned in the example in the paragraph above would be reported in Part I of the death certificate and not Part II.

This change in policy should have required the APA §553 rulemaking steps to be followed.

Was APA §553 properly followed?

Under APA §553, three steps must be adhered to. The first step involves publishing notice of the proposed rulemaking in the Federal Register except if "the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that

notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”

APA §553 does not specifically mention emergency rules, instead mentioning “good cause.” A pandemic does not necessarily qualify as “good cause” for immediate policy change relating to data collection for infectious disease when data collection rules for other infectious diseases already exist and are used nationwide. By declaring “good cause,” the CDC would be exempt from providing notice for public opportunity to comment but not from federal oversight for data accuracy. The CDC would be able to unilaterally make changes they determined to be necessary, even if they understood proposed changes may compromise the integrity and accuracy of COVID-19 data.

The CDC is required to provide a brief statement of notice, prior to enacting the changes that elucidate the medical and statistical rationale for “good cause.” This notice should state the rationale for the enactment of changes and why notifying the Federal Register to initiate federal oversight, independent peer-review, and public comment is impracticable, unnecessary, or contrary to the public interest. The CDC is also required to publish their rule changes in final form within the Federal Register. The CDC appears to have failed to provide this brief statement of notice or report their changes in final form to the Federal Register.

###



## People Worthy of Our Remembrance



### **Tom Keveney Died Alone**

“My younger brother, Tom Keveney, died last month. My family’s deep sadness was understandable and unavoidable, but the coronavirus pandemic ravaged our ability to mourn his death.

“We’re all feeling loss resulting from the pandemic. It could be a graduation ceremony or a job; it’s likely to be freedom of movement and a basic sense of security. The fallout from COVID-19 makes the death of a family member inestimably worse.

“My family’s experience isn’t unique; if anything, it’s too common in these unprecedented times. Many families’ losses have been crueler; each death cuts to the bone. They all need to be remembered.”

<https://www.usatoday.com/story/life/2020/05/07/covid-19-made-my-brothers-death-harder-grieve/5170437002/>

# Disclaimer

All information provided within this manuscript is for consideration in educational and legal matters only. Any use of material presented for any other purpose is done so at the sole discretion of the person or persons using the information with the clear understanding that they assume all responsibility and liability for the use of the material.

All authors disclose no financial conflicts of interest and state no desire to profit from this work individually. This work is intended to be public domain and therefore accessible at no cost for access to the information presented herein. This work is a volunteer effort and a labor of love on behalf of all people who have suffered during this crisis so that we may collaborate with public health policy makers to arrive at solutions that serve all concerned citizens.

# Authors and Reviewers

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This paper was reviewed for accuracy by a team of medical professionals, Ph.D. scientists, and attorneys.

# Appendix

**Dr. Lee's Petition to FDA For Stay of Phase 2/3  
Pfizer Clinical Trial**

**VIA ELECTRONIC FILING**

November 25, 2020

Division of Dockets Management  
Department of Health and Human Services  
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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 : Docket No. FDA-2020-P-2225  
CLINICAL TRIALS OF COVID-19 :  
VACCINES :**

**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)<sup>1</sup>

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<sup>1</sup> 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.<sup>2</sup>

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.<sup>3</sup>

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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<sup>2</sup> 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>.

<sup>3</sup> 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...”<sup>4</sup> 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.

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<sup>4</sup> <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.<sup>5</sup>

- 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.”<sup>6</sup>
- 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.”<sup>7</sup>
- 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.<sup>8</sup>
- 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.<sup>9</sup>

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<sup>5</sup> 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.

<sup>6</sup> 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>.

<sup>7</sup> 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>.

<sup>8</sup> 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>.

<sup>9</sup> 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](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.<sup>10</sup> 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.<sup>11</sup> 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.<sup>12</sup>
- 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).<sup>13</sup>

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<sup>10</sup> 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> .

<sup>11</sup> 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>.

<sup>12</sup> 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>.

<sup>13</sup> 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.<sup>14</sup>

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5400 Cepheid Xpert Xpress SARS-CoV-2 test

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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.<sup>15</sup>

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<sup>14</sup> 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>.

<sup>15</sup> 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, Agüero-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.”<sup>16</sup>
- 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).”<sup>17</sup>

<sup>16</sup> 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>.

<sup>17</sup> Rakotosamimanana N, Randrianirina F, Randremarana R, Raheison 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  $\geq 39.0^{\circ}\text{C}$  ( $\geq 102.1^{\circ}\text{F}$ ).
- 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.<sup>18</sup> If the Sponsor (BioNTech/Pfizer) is unable to perform confirmatory Sanger sequencing tests on these 180 RNA extract residual samples, the Petitioner hereby offers

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<sup>18</sup> 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<sup>19</sup> 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.**”<sup>20</sup> 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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<sup>19</sup> 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>.

<sup>20</sup> <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,

A handwritten signature in blue ink, appearing to read "Sin Hang Lee", written in a cursive style.

Dr. Sin Hang Lee

# **FDA Response to Dr. Lee's Petition**



December 11, 2020

Aaron Siri  
Siri & Glimstad LLP  
200 Park Avenue  
17<sup>th</sup> Floor  
New York, NY 10166

Re: Citizen Petition and Petition for Administrative Stay of Action (Docket Number: FDA-2020-P-2225)

Dear Mr. Siri,

This letter responds to the following citizen petition and petition for administrative stay of action that you submitted to the Food and Drug Administration (FDA, the Agency, we) on behalf of Dr. Sin Hang Lee (Petitioner) relating to the Phase 3 trial of the BNT162b vaccine to prevent the novel coronavirus SARS-CoV-2 (COVID-19):

- The citizen petition dated November 23, 2020 (the CP); and
- The petition for administrative stay of action dated November 25, 2020 (the PSA)

(collectively, the Petitions).

In the CP, Petitioner requests FDA to amend “the study design for the Phase III trial[] of BNT162b (NCT04368728)” 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.

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).

CP at 1-2 (internal citation omitted).

**U.S. Food and Drug Administration**  
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Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

In the PSA, Petitioner requests FDA to “[s]tay the Phase III trial of BNT162 (NCT04368728) until its study design is amended” to conform with Petitioner’s request. PSA at 2. The Petitioner’s request in the PSA is the same as that of the CP indicated above. PSA at 2.

This letter responds to the CP and the PSA in full. FDA has carefully reviewed the Petitions, comments submitted to the docket, and other information available to the Agency. Based on our review of these materials and for the reasons described below, we conclude that the Petitions do not contain facts demonstrating any reasonable grounds for the requested action. In accordance with 21 CFR §§ 10.30(e)(3) and 10.35(e), and for the reasons stated below, FDA is denying the Petitions.

## **I. Background**

There is currently a pandemic of respiratory disease, Coronavirus Disease 2019 (COVID-19), caused by a novel coronavirus, SARS-CoV-2. The COVID-19 pandemic presents an extraordinary challenge to global health. On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19.<sup>1</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>2</sup> There are currently no FDA-licensed vaccines to prevent COVID-19. Commercial vaccine manufacturers and other entities are developing COVID-19 vaccine candidates, and clinical studies of these vaccines are underway. On November 20, 2020, Pfizer, Inc. (Pfizer) submitted an Emergency Use Authorization (EUA) request to FDA for an investigational COVID-19 vaccine, BNT162b2, intended to prevent COVID-19.<sup>3</sup> As announced by FDA on December 11, 2020, the Agency is granting an EUA for the Pfizer-BioNTech COVID-19 Vaccine.<sup>4</sup>

## **II. Vaccines that Are FDA-Licensed or Receive an Emergency Use Authorization Meet Relevant Statutory Requirements**

### **A. Licensed Vaccines**

FDA has a stringent regulatory process for licensing vaccines.<sup>5,6</sup> The Public Health Service Act (PHS Act) authorizes FDA to license biological products, including vaccines, if they have been demonstrated to be “safe, pure, and potent.”<sup>7</sup> Based on the PHS Act and FDA’s regulations, the licensure process for a vaccine requires the sponsor to establish, through carefully controlled

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<sup>1</sup> Secretary of HHS Alex M. Azar, Determination that a Public Health Emergency Exists, originally issued January 31, 2020, and subsequently renewed, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>2</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, issued March 13, 2020, <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

<sup>3</sup> FDA Briefing Document, Pfizer-BioNTech COVID-19 Vaccine, Vaccines and Related Biological Products Advisory Committee Meeting, December 10, 2020 at 6, <https://www.fda.gov/media/144245/download>.

<sup>4</sup> EUA letter for Pfizer-BioNTech COVID-19 Vaccine dated December 11, 2020, <https://www.fda.gov/media/144412/download>.

<sup>5</sup> CDC, Ensuring the Safety of Vaccines in the United States, February 2013, <https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf>.

<sup>6</sup> Vaccine Safety Questions and Answers, last updated March 2018, <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/vaccine-safety-questions-and-answers>.

<sup>7</sup> 42 U.S.C. § 262(a)(2)(C)(i)(I).

laboratory and clinical studies, as well as through other data, that the product is safe and effective for its approved indication(s) and use. FDA’s multidisciplinary review teams then rigorously evaluate the sponsor’s laboratory and clinical data, as well as other information, to help assess whether the safety, purity, and potency of a vaccine has been demonstrated.<sup>8</sup> FDA regulations explicitly state that “[a]pproval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products.”<sup>9</sup> Only when FDA’s standards are met is a vaccine licensed.

For more information on FDA’s thorough process for evaluating vaccines, see Appendix I of this letter, *Aspects of Vaccine Development and Process for Licensure*.

## **B. Emergency Use Authorization**

Congress established the EUA pathway to ensure that, during public health emergencies, potentially lifesaving medical products could be made available before being approved. The EUA process allows the Secretary of HHS, in appropriate circumstances, to declare that EUAs are justified for products to respond to certain types of threats. When such a declaration is made, FDA may issue an EUA, which is different from the regulatory process for vaccine licensure.

Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 360bbb-3) authorizes FDA to, under certain circumstances, issue an EUA to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear threat agents when there are no adequate, approved, and available alternatives.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.<sup>10</sup> On the basis of such determination, on March 27, 2020, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564(b)(1) of the FD&C Act (21 U.S.C. § 360bbb-3(b)(1)).<sup>11</sup>

Based on this declaration and determination, under section 564(c) of the FD&C Act (21 U.S.C. § 360bbb-3(c)), FDA may issue an EUA during the COVID-19 pandemic after FDA concludes that the following statutory requirements are met:

- The agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.

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<sup>8</sup> Vaccines, last updated June 2020, <https://www.fda.gov/vaccines-blood-biologics/vaccines>.

<sup>9</sup> 21 CFR § 601.2(d).

<sup>10</sup> 85 FR 7316, February 7, 2020, <https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>.

<sup>11</sup> 85 FR 18250, April 1, 2020, <https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>.

- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

Although EUAs are governed under a different statutory framework than a Biologics License Application (BLA), FDA has made clear that issuance of an EUA for a COVID-19 vaccine would require that the vaccine demonstrated clear and compelling safety and efficacy in a large, well-designed phase 3 clinical trial. In the guidance document *Emergency Use Authorization for Vaccines to Prevent COVID-19* (October 2020 Guidance), FDA has provided recommendations that describe key information that would support issuance of an EUA for a vaccine to prevent COVID-19.<sup>12</sup> In the October 2020 Guidance, FDA explained that, in the case of such investigational vaccines, any assessment regarding an EUA will be made on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.<sup>13</sup> FDA has also stated, in the October 2020 Guidance, that for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.<sup>14</sup>

A Phase 3 trial of a vaccine is generally a large clinical trial in which a large number of people are assigned to receive the investigational vaccine or a control. In general, in Phase 3 trials that are designed to show whether a vaccine is effective, neither people receiving the vaccine nor those assessing the outcome know who received the vaccine or the comparator.

In a Phase 3 study of a COVID-19 vaccine, the efficacy of the investigational vaccine to prevent disease will be assessed by comparing the number of cases of disease in each study group. For Phase 3 trials, FDA has recommended to manufacturers in guidance that the vaccine should be at least 50% more effective than the comparator, and that the outcome be reliable enough so that it is not likely to have happened by chance.<sup>15</sup> During the entire study, subjects will be monitored for safety events. If the evidence from the clinical trial meets the pre-specified criteria for success for

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<sup>12</sup> Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry, October 2020, <https://www.fda.gov/media/142749/download>.

<sup>13</sup> Id. at 3.

<sup>14</sup> Id. at 4.

<sup>15</sup> Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry, June 2020 (June 2020 Guidance), <https://www.fda.gov/media/139638/download>.



efficacy and the safety profile is acceptable, the results from the trial can potentially be submitted to FDA in support of an EUA request.

Several investigational COVID-19 vaccines are now being studied in Phase 2 or Phase 3 trials. Following clinical trials, manufacturers analyze data prior to submitting to FDA a BLA to request approval from FDA to market the vaccine. A BLA for a new vaccine includes information and data regarding the safety, effectiveness, chemistry, manufacturing and controls, and other details regarding the product. The goal timelines for FDA’s comprehensive BLA review and evaluation are detailed in the PDUFA goals letter and range from 6 – 10 months after the application has been filed.<sup>16</sup> During the current public health emergency, manufacturers may, with the requisite data and taking into consideration input from FDA, choose to submit a request for an EUA.

It is FDA’s expectation that, following submission of an EUA request and issuance of an EUA, a sponsor would continue to evaluate the vaccine and would also work towards submission of a BLA as soon as possible.

### **III. Discussion**

The Petitions pertain to “the study design for the Phase III trial[] of BNT162b (NCT04368728).” FDA’s investigational new drug process applies to the development of new drugs and biological products, including vaccines.<sup>17</sup>

#### **A. Investigational New Drugs**

Before a vaccine is licensed (approved) by FDA for use by the public, FDA requires that it undergo a rigorous and extensive development program to determine the vaccine’s safety and effectiveness. This development program encompasses preclinical research (laboratory research, animal studies<sup>18</sup>) and clinical studies. At the preclinical stage, the sponsor focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. Clinical studies, in humans, are conducted under well-defined conditions and with careful safety monitoring through all the phases of the investigational new drug application (IND) process. FDA’s regulations governing the conduct of clinical investigations are set out at 21 CFR Part 312.

Before conducting a clinical investigation in the United States in which a new drug or biological product is administered to humans, a sponsor must submit an IND to FDA.<sup>19</sup> The IND describes the proposed clinical study in detail and, among other things, helps protect the safety and rights

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<sup>16</sup> PDUFA Reauthorization Performance Goals And Procedures Fiscal Years 2018 Through 2022; <https://www.fda.gov/media/99140/download>.

<sup>17</sup> See 21 CFR § 312.2 (explaining that the IND regulations apply to clinical investigations of both drugs and biologics).

<sup>18</sup> We support the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

<sup>19</sup> See 21 CFR § 312.20(a).

of human subjects.<sup>20</sup> In addition to other information, an IND must contain information on clinical protocols and clinical investigators. Detailed protocols for proposed clinical studies permit FDA to assess whether the initial-phase trials will expose subjects to unnecessary risks. Information on the qualifications of clinical investigators (professionals, generally physicians, who oversee the administration of the experimental drug) permits FDA to assess whether they are qualified to fulfill their clinical trial duties. The IND includes commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB),<sup>21</sup> and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials, unless FDA informs the sponsor that the trial may begin earlier. During this time, FDA reviews the IND. FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and Phase 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety. 21 CFR § 312.22(a).

FDA's regulations provide that, once an IND is in effect, the sponsor may conduct a clinical investigation of the product, with the investigation generally being divided into three phases. With respect to vaccines, the initial human studies, referred to as Phase 1 studies, are generally safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies may include up to several hundred individuals and are designed to provide information regarding the incidence of common short-term side effects such as redness and swelling at the injection site or fever and to further describe the immune response to the investigational vaccine. If an investigational new vaccine progresses past Phase 1 and Phase 2 studies, it may progress to Phase 3 studies. For Phase 3 studies, the sample size is often determined by the number of subjects required to establish the effectiveness of the new vaccine, which may be in the thousands or tens of thousands of subjects. Phase 3 studies provide the critical documentation of effectiveness and important additional safety data required for licensing.

At any stage of development, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies; FDA may also halt ongoing clinical studies. The FD&C Act provides a specific mechanism, called a "clinical hold," for prohibiting sponsors of clinical investigations from conducting the investigation (section 505(i)(3) of the FD&C Act; 21 U.S.C. § 355(i)(3)), and FDA's IND regulations in 21 CFR § 312.42 identify the circumstances that may justify a clinical hold. Generally, a clinical hold is an

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<sup>20</sup> For additional information regarding the IND review process and general responsibilities of sponsor-investigators related to clinical investigations see Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators; Draft Guidance for Industry, May 2015, <https://www.fda.gov/media/92604/download>.

<sup>21</sup> The IRB is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research. IRBs approve clinical study protocols, which describe the type of people who may participate in the clinical study; the schedule of tests and procedures; the medications and dosages to be studied; the length of the study; the study's objectives; and other details. IRBs make sure that the study is acceptable, that participants have given consent and are fully informed of the risks, and that researchers take appropriate steps to protect patients from harm. See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, last updated November 2017, <https://www.fda.gov/drugs/drug-information-consumers/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective>.

order issued by FDA to the sponsor of an IND to delay a proposed clinical investigation or to suspend an ongoing investigation.<sup>22</sup>

## **B. The Citizen Petition**

The Petitioner requests that FDA “amend” the clinical trial “study design” for the Phase 3 trial of “BNT162 (NCT04368728),” a product being developed by Pfizer, to include certain design characteristics. Because FDA does not itself create or amend drug or vaccine investigations,<sup>23</sup> we interpret the CP as asking that FDA require the sponsor to make the requested changes.<sup>24</sup> As explained above, with certain exceptions, clinical investigations in which a drug is administered to human subjects must be conducted under an IND submitted to FDA by the sponsor. FDA’s review of an IND includes a review of the study protocol which describes, among other things, the design of the clinical study, including the identified endpoints and methods for assessing the effectiveness of the investigational product.

Turning to the specific requests, Petitioner asks that “[b]efore an EUA or unrestricted license is issued for the Pfizer vaccine, or for other vaccines” that use the polymerase chain reaction (PCR) testing as evidence of infection in clinical trials, the late-stage trials “should have their infection status confirmed by Sanger sequencing.” CP at 1. The CP states that this is necessary “given the high cycle thresholds used in some trials” that “have been widely acknowledged to lead to false positives.” CP at 1-2. The CP maintains that the Sanger sequencing should be used “to confirm that the tested samples in fact contain a unique SARS-CoV-2 genomic RNA.” CP at 2.

### **1. Background Regarding Testing Technology and SARS-CoV-2 Testing**

FDA agrees that accurate testing is an important part of ensuring the reliability of vaccine trial outcomes. An accurate test helps identify whether the investigational vaccine prevents COVID-19 (or not) by confirming whether study participants are infected with SARS-CoV-2. Indeed, FDA’s June 2020 Guidance states that “[d]iagnostic assays used to support the pivotal efficacy analysis (e.g., RT-PCR) should be sensitive<sup>[25]</sup> and accurate for the purpose of confirming infection and should be validated before use.”<sup>26</sup>

Nucleic acid-based amplification tests (NAAT), also referred to as PCR tests, are used to show if individuals have active SARS-CoV-2 infection by detecting the virus’s genetic material. In PCR testing, a machine located in a laboratory or at a point of care, depending on the test, runs a series of reactions. These reactions first convert the virus’s ribonucleic acid (RNA), if present, into deoxyribonucleic acid (DNA) and then amplify it (make millions of copies of the DNA); the test then detects this DNA. By running multiple amplification cycles, a PCR test can sense even low

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<sup>22</sup> 21 CFR § 312.42(a).

<sup>23</sup> Rather, sponsors are responsible for creating study designs. FDA reviews INDs and may place INDs on clinical holds pursuant to 21 CFR § 312.42 if the Agency identifies certain deficiencies.

<sup>24</sup> To the extent the Petitioner asks for FDA to itself amend a sponsor’s investigational study design, we deny the Petition because that is not FDA’s role with respect to clinical trials.

<sup>25</sup> Sensitivity and specificity are basic measures of performance for a diagnostic test. Together, they describe how well a test can determine whether a specific condition is present or absent. “Sensitivity” refers to how often the test is positive when the condition of interest is present; “specificity” refers to how often the test is negative when the condition of interest is absent. See Guidance for Industry and FDA Staff, Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests, March 2007, at 21 (Statistical Guidance for Diagnostic Tests), <https://www.fda.gov/media/71147/download>.

<sup>26</sup> June 2020 Guidance at 17.

levels of viral genetic material in a patient's sample, so these tests tend to be highly sensitive (especially laboratory PCR tests).

In a Sanger sequencing-based method, dideoxy-nucleotide (ddNTP) chain terminators are used to determine the specific nucleotide sequence of the target nucleic acid. Current Sanger sequencing-based methods are most commonly carried out via a multistep process, which includes not only appropriate sampling and nucleic acid extraction, but also: 1) conventional PCR amplification of the target region; 2) PCR cleanup for removal of unincorporated primers and nucleotides; 3) a sequencing reaction in which the PCR product is used as template for the incorporation of fluorescently labeled dideoxy chain terminators; 4) sequencing reaction cleanup for removal of unincorporated fluorescent dideoxy chain terminators; and 5) simultaneous size-dependent separation and nucleic acid sequence determination.

PCR, when used in conjunction with Sanger-based or other sequencing, can detect and identify viral genetic material in a clinical sample. Historically, PCR has been used with reverse transcription to amplify viral RNA to indicate whether there was a positive signal of any suitable genetic material present, and sequencing has been used to confirm the nucleic acid sequence of the amplified genetic material. As PCR technology has evolved, however, PCR testing does not need to be followed by Sanger or other sequencing for purposes of clinical diagnosis. Currently, reverse real-time PCR (RT-PCR) tests can both amplify and confirm the identity of viral genetic material in a single reaction, without a separate sequencing step.<sup>27</sup> Many of the NAATs for detection of SARS-CoV-2 that FDA has authorized are based on the technology that both amplifies and confirms viral genetic material without the need for an additional sequencing step.

We have determined there is not scientific merit in requiring the Phase 3 trial for BNT162 or other COVID-19 vaccine candidates to qualify a PCR diagnosis of COVID-19 with Sanger sequencing. Testing used to support the detection of SARS-CoV-2 infection should be sensitive and accurate, and PCR assays can be sufficiently sensitive and accurate without the need for Sanger sequencing.<sup>28</sup>

FDA's current recommendations for SARS-CoV-2 molecular diagnostic tests include that developers confirm the performance of their assay by testing a minimum of 30 positive specimens and 30 negative natural clinical specimens as determined by an authorized assay.<sup>29</sup> Additionally, the clinical performance data should demonstrate a minimum of 95% positive percent agreement (i.e., sensitivity) and negative percent agreement (i.e., specificity).<sup>30</sup> But FDA

<sup>27</sup> For more background on this topic, see A Closer Look at Coronavirus Disease 2019 (COVID-19) Diagnostic Testing, November 2020, <https://www.fda.gov/media/143737/download>.

<sup>28</sup> FDA has provided information and recommendations regarding validation testing for SARS-CoV-2 tests which reflect FDA's current thinking on the data and information that developers should submit to facilitate FDA's review of an EUA request for a SARS-CoV-2 test pursuant to Section 564 of the FD&C Act. See Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff, May 2020, at 17-20 (COVID-19 Testing Guidance), <https://www.fda.gov/media/135659/download>. These recommendations are based on the totality of scientific evidence currently available to FDA regarding the clinical performance estimates for molecular diagnostic tests (i.e., tests that detect SARS-CoV-2 nucleic acids from human specimens) that, under the current circumstances of the COVID-19 public health emergency, are generally necessary to satisfy the effectiveness and risk/benefit standards for issuance of an EUA.

<sup>29</sup> Id. at 18.

<sup>30</sup> Molecular Diagnostic Template for Commercial Manufacturers, July 2020, at 16 (Molecular Test Template), <https://www.fda.gov/media/135900/download>.

has not identified any need to require PCR testing for clinical cases to be followed by Sanger-based or other sequencing. We believe that clinical diagnoses can be supported following PCR analyses with a positive percent agreement and negative percent agreement greater than or equal to 95%.<sup>31</sup>

## 2. Petitioner's Argument Regarding HPV Testing

Petitioner asserts that Sanger sequencing confirmation would be “[c]ongruent with FDA requirements for a confirmed diagnosis of human papillomavirus (HPV) using PCR.” CP at 2. As support, Petitioner refers to an FDA guidance document that recommends that, in some situations, PCR testing be followed by Sanger sequencing for the evaluation of a device’s ability to detect HPV.<sup>32</sup> But the recommendations in that guidance have no applicability to the clinical trials for COVID-19 vaccines. The recommendations in the HPV Testing Guidance are for developers of new tests and relate to evaluation of new testing products. Specifically, the guidance recommends that developers of a new HPV test evaluate the ability of the new test to detect the targeted HPV genotypes by comparing the results obtained using the new test to results obtained using either an FDA-approved HPV test that detects the same genotypes, or PCR followed by Sanger sequencing.<sup>33</sup> That is, when developing a new HPV testing technology, one option for manufacturers to evaluate the accuracy of the technology is to confirm whether clinical specimens in fact contain the targeted HPV genotype by comparing the results from the manufacturer’s test to the results from Sanger sequencing. The HPV Testing Guidance that Petitioner identifies does not recommend that PCR tests used to diagnose HPV infections in individuals be followed by Sanger sequencing when the tests are used for aiding the diagnosis of an individual’s infection.

Therefore, we do not agree that Petitioner’s example supports Petitioner’s requested action.

## 3. Petitioner's Arguments Regarding Vaccine Trial Protocols

Petitioner asserts that a portion of the Pfizer public protocol<sup>34</sup> states that when study participants experience certain symptoms, they are to be tested with nasal swabs which will be tested for SARS-CoV-2. CP at 3-4. Petitioner points to three specific tests that are identified in the public protocol that have been issued EUAs by FDA: Cepheid Xpert Xpress SARS-CoV-2,<sup>35</sup> Roche

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<sup>31</sup> When a new test is evaluated by comparison to a non-reference standard because no consensus reference standard exists, information on the accuracy of the new test cannot be estimated directly. As a result, performance is demonstrated by the ability of the new test to agree sufficiently with a comparative method. The comparative results are called “positive percent agreement” (which corresponds to sensitivity) and “negative percent agreement” (which corresponds to specificity). The use of this language reflects that the estimates are not of accuracy but of agreement of the new test with the non-reference standard. See Statistical Guidance for Diagnostic Tests, at 11.

<sup>32</sup> Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses, Guidance for Industry and Food and Drug Administration Staff, September 2017, (HPV Testing Guidance) <https://www.fda.gov/media/92930/download>.

<sup>33</sup> Id. at 17.

<sup>34</sup> Petitioner does not appear to identify the source of information about the Pfizer public protocol, but we note that Pfizer publicly released a protocol for the COVID-19 vaccine clinical trial. For purposes of this response, we presume that is the protocol that Petitioner refers to. See [https://pfe-pfizercom-d8-prod.s3.amazonaws.com/2020-11/C4591001\\_Clinical\\_Protocol\\_Nov2020.pdf](https://pfe-pfizercom-d8-prod.s3.amazonaws.com/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf).

<sup>35</sup> See EUA letter for Xpert Xpress SARS-CoV-2 test dated March 20, 2020 (Xpert Xpress EUA Letter), <https://www.fda.gov/media/136316/download>.



cobas SARS-CoV-2 real-time RT-PCR test,<sup>36</sup> and Abbott Molecular/RealTime SARS-CoV-2 assay.<sup>37</sup> CP at 4. Petitioner states that these test kits “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.”<sup>38</sup> CP at 4. Petitioner states that this is because the results from these tests “cannot be analyzed by automated Sanger sequencing as the products of conventional PCR can” and that Sanger sequencing “is needed” for accuracy. CP at 4. As support for this assertion, Petitioner includes 11 points, listed in paragraphs (a)-(k). CP at 4-8. We respond to each of the Petitioner’s listed points, using the same (a)-(k) paragraph designations. For clarity, we quote Petitioner’s assertions and respond to each assertion:

- a. Petitioner’s assertion: “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[.]” CP at 4.

FDA response: We generally agree that “DNA sequencing” after PCR testing is “accepted technology,” but we do not agree that this means PCR testing for SARS-CoV-2 must be followed by Sanger-based sequencing for confirmation of infectious agents. That is, for the reasons explained above, we do not agree that PCR testing for SARS-CoV-2 must be followed by Sanger-based sequencing in order to diagnose a clinical case of COVID-19,<sup>39</sup> in a clinical trial or otherwise.

- b. Petitioner’s assertion: “The World Health Organization (WHO) guidance . . . advised [real time PCR testing] with confirmation by nucleic acid sequencing when necessary.” CP at 4. The guidance identified in this paragraph is “WHO Laboratory testing for coronavirus disease (COVID-19) in suspected human cases-Interim guidance dated 19 March 2020.”<sup>40</sup> CP at 4.

FDA response: This WHO guidance does not state that nucleic acid sequencing is critical in all circumstances in order to test accuracy. Rather, it states that the sequencing should be performed “when necessary.” Among other things, the guidance contains testing recommendations for when the virus is known to be circulating in a geographic area, and for when the virus is not known to be circulating. When the virus is *not* known to be circulating in an area, the WHO guidance recommends sequencing as an option. But for areas with established COVID-19 virus circulation, the WHO guidance does not list

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<sup>36</sup> See EUA letter for cobas SARS-CoV-2 dated October 15, 2020 (cobas EUA Letter),

<https://www.fda.gov/media/136046/download>.

<sup>37</sup> See EUA letter for Abbott RealTime SARS-CoV-2 assay dated March 18, 2020 (Abbott EUA Letter),

<https://www.fda.gov/media/136255/download>.

<sup>38</sup> We disagree with Petitioner’s characterization. FDA has issued EUAs for the tests based on FDA’s finding that the tests meet our regulatory standards for an EUA.

<sup>39</sup> This is the view of the U.S. Centers for Disease Control and Prevention (CDC) as well. The CDC case definition for COVID-19 notes that confirmatory laboratory evidence is “[d]etection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical specimen using a molecular amplification detection test.” The CDC does not include a specific recommendation for the use of sequencing as confirmatory evidence of SARS-CoV-2 infection. See CDC, Coronavirus Disease 2019 (COVID-19) 2020 Interim Case Definition, Approved April 5, 2020, <https://www.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/>.

<sup>40</sup> WHO, Laboratory testing for coronavirus disease (COVID-19) in suspected human cases, Interim guidance, March 2020, <https://www.who.int/publications/i/item/10665-331501>.

sequencing as a recommended testing option. We note that this WHO guidance was drafted towards the beginning of the current pandemic, before the development of many of the NAATs that are currently in use. We also note that it does not make any recommendations related to confirming COVID-19 cases in vaccine clinical trials.

- c. Petitioner’s assertion: “The FDA also recognizes the inherent inaccuracy of the RT-qPCR<sup>[41]</sup> tests.” CP at 5. As support for this statement, Petitioner identifies a letter of EUA that FDA issued the CDC for a specific test kit developed by the CDC.<sup>42</sup>

FDA response: We disagree. The letter of authorization did not make any statements regarding the general soundness of any particular type of testing technologies. Nothing in the letter suggests that samples that are positive for SARS-CoV-2 based on PCR testing should be confirmed by Sanger-based sequencing.

- d. Petitioner’s assertion: “In addition to false-negative results, these RT-qPCR test kits under EUA also generate false-positive test results.” CP at 5.

FDA response: While we agree that no test is 100 percent accurate, this does not support Petitioner’s request that FDA require PCR positive cases to be confirmed with Sanger-based sequencing in clinical trials for COVID-19 vaccines.

- e. Petitioner’s assertion: “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.” CP at 5.

FDA response: While FDA has identified some flaws with some tests, there are many FDA-authorized tests for which FDA has not issued any such alerts (including many tests that use PCR technology, such as Cepheid Xpert Xpress SARS-CoV-2, Roche cobas SARS-CoV-2 real-time RT-PCR test, and Abbott Molecular/RealTime SARS-CoV-2 assay). Moreover, FDA has not stated that samples identified as positive in PCR testing need to be confirmed by Sanger-based sequencing.

- f. Petitioner’s assertion: “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.” CP at 5. As support for this statement, Petitioner cites the Molecular Test Template.<sup>43</sup>

FDA response: FDA’s COVID-19 Testing Guidance states that all clinical tests should be validated prior to use, and provides recommendations for developers regarding testing

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<sup>41</sup> Throughout the Petition, Petitioner asserts that the three assays identified in the Pfizer public protocol – Cepheid Xpert Xpress SARS-CoV-2, Roche cobas SARS-CoV-2 real-time RT-PCR test, and Abbott Molecular/RealTime SARS-CoV-2 assay – are “RT-qPCR” tests (i.e., NAATs that employ reverse transcription quantitative PCR). CP at 3-4. That assertion is incorrect. As stated in the EUAs for each of those tests, the three assays identified in the Pfizer public protocol are not quantitative tests; rather, each is only indicated for use in the *qualitative* detection of nucleic acid from SARS-CoV-2. See cobas EUA Letter, at 1; Xpert Xpress EUA Letter at 1; Abbott EUA Letter at 1.

<sup>42</sup> EUA letter for CDC 2019-Novel Coronavirus (2019-nCoV, renamed as SARS-CoV-2) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel dated March 15, 2020.

<sup>43</sup> See Molecular Test Template at 16.



that should be performed to demonstrate, in support of an EUA submission, that a SARS-CoV-2 test is validated based upon the underlying technological principles of the test.<sup>44</sup> However, FDA does *not* recommend that clinical results generated from PCR testing should be corroborated with Sanger-based sequencing in order to confirm the clinical performance of a test. Rather, the Molecular Test Template merely states that false results observed during the evaluation of an assay “*can* be investigated using an additional EUA RT-PCR assay, and/or Sanger sequencing” in order to provide the results of the discordant analysis to FDA.<sup>45</sup>

- g. Petitioner’s assertion: “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” is recommended. CP at 6.

FDA response: See above discussion regarding the HPV Testing Guidance. FDA’s recommendations regarding validation are for the testing technology, not clinical results. Petitioner’s requested action would *not* be consistent with FDA’s recommendations for clinical testing for HPV when performed by sensitive and accurate PCR tests.

- h. Petitioner’s assertion: “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 the publicly available protocol states that the samples may be sent to a central laboratory using a Cepheid test that uses a “mean Ct value . . . as high as 42.9. . . . At Ct values between 36.0 and 44.9, many RT-qPCR positive test results are false positives.” CP at 6.

FDA response: While a test sample that is analyzed with a Ct value of 42.9 may find a very small concentration of viral fragments that may be of uncertain clinical significance, Petitioner does not provide any evidence that the Cepheid test being used in Pfizer’s (or any other) clinical trial is being used to analyze samples that actually have a Ct value of 42.9. It appears that Petitioner found the 42.9 number in the Instructions for Use document for the Cepheid test, available on FDA’s website.<sup>46</sup> However, the levels cited by Petitioner refer only to the range of concentrations analyzed to establish the test’s limit of detection—not to the number of amplification cycles to be used for clinical diagnosis. Therefore, the levels cited by Petitioner do not demonstrate any accuracy problems with the test. The levels cited by Petitioner also do not demonstrate the need for follow-up Sanger-based sequencing.

- i. Petitioner’s assertion: “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.” CP at 6.<sup>47</sup>

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<sup>44</sup> See COVID-19 Testing Guidance at 15, 18.

<sup>45</sup> Molecular Test Template at 16 (emphasis added).

<sup>46</sup> Xpert Xpress SARS-CoV-2, Instructions for Use, Table 4, <https://www.fda.gov/media/136314/download>.

<sup>47</sup> In this paragraph, Petitioner also includes a table from a study showing that the Cepheid Xpert kits have classified many Abbott kit negative cases as positives. See Basu, et al., Performance of Abbott ID NOW COVID-19 rapid nucleic acid amplification test in nasopharyngeal swabs transported in viral media and dry nasal swabs, in a New York City academic institution, *Journal of Clinical Microbiology*, May 2020,

FDA response: We agree that no test is 100 percent accurate, and there may be small differences in the analytical performance between different test kits – even kits that are well-validated and reliable. But we do not agree that this justifies Petitioner’s requested action – requiring follow-up with Sanger-based sequencing. Tests that are well-validated and reliable may appropriately be used to confirm COVID-19 diagnoses in patients, including study participants.

- j. Petitioner’s assertion: “One of the Cepheid Xpert kit users has put out an alert” relating to false positives.<sup>48</sup> CP at 8.

FDA response: The alert Petitioner identifies was issued by Diagnostic Laboratory Services Inc., a clinical testing laboratory in Hawaii, and appears to concern the Cepheid GeneXpert testing platform,<sup>49</sup> not the Cepheid Xpert Xpress SARS-CoV-2 assay that is identified in the Pfizer public protocol and with which Petitioner takes issue. In any case, the fact that tests run by one laboratory in Hawaii on Cepheid GeneXpert instruments may have yielded suspect results does not justify the action requested by Petitioner. If sponsors for vaccine clinical trials are using SARS-CoV-2 tests that are well-validated and reliable, there is no scientific reason to require follow-up Sanger-based sequencing.

- k. Petitioner’s assertion: “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.” CP at 8. The Petitioner cites to a study published in *The Lancet Global Health* for its proposition.<sup>50</sup>

FDA response: While the study cited by Petitioner found that some samples that were reported as positives using the Cepheid Xpert Xpress SARS-CoV-2 test did not report as positives using the comparison test, the study authors state that “[i]t is difficult to address the question on whether these specimens are true negative samples or low-positive samples with residual viral particles.”<sup>51</sup> That is, for the samples that were positive using

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<https://jcm.asm.org/content/58/8/e01136-20>. But the Abbott test used in the study, which is compared to the Cepheid Xpert Xpress SARS-CoV-2 test, is the Abbott ID NOW COVID-19, not the Abbott RealTime SARS-CoV-2 assay that is listed in the public protocol identified by Petitioner. We note that, on May 14, 2020, FDA issued a release alerting the public to early data that suggest potential inaccurate results from using the Abbott ID NOW point-of-care test to diagnose COVID-19 because the test may return false negative results. See Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test, May 14, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-informs-public-about-possible-accuracy-concerns-abbott-id-now-point>. Therefore, the fact that the Abbott ID NOW COVID-19 and the Cepheid Xpert Xpress SARS-CoV-2 test produced different results is not surprising. The existence of different results from the Abbott ID NOW COVID-19 and the Cepheid Xpert Xpress SARS-CoV-2 test do not support a need for follow-up Sanger-based sequencing from PCR tests that have demonstrated a positive percent agreement and negative percent agreement greater than or equal to 95%, which include the tests identified in the Pfizer public protocol.

<sup>48</sup> See Diagnostic Laboratory Services Inc., Technical Alert, Possible False Positive SARS-CoV-2 (COVID-19) PCR, June 2020 (Technical Alert), <https://dlslab.com/documents/bulletins/2020/tech-memo-sars-cov-2-pcr-possible-false-positive-6-19-2020.pdf>.

<sup>49</sup> See Technical Alert subject header which refers to “Cepheid GeneXpert and BD Max Instruments may be Reporting False Positives.”

<sup>50</sup> See Rakotosamimanana et al., GeneXpert for the diagnosis of COVID-19 in LMICs, *The Lancet Global Health*, October 2020, [https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(20\)30428-9/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(20)30428-9/fulltext).

<sup>51</sup> Id. at 1.

Cepheid Xpert Xpress SARS-CoV-2 but not the other test, the study authors do not state that the samples were actually negative. Moreover, the study does not make any recommendations regarding the purported need to use follow-up Sanger-based sequencing on results that report to be positive using PCR testing.

In addition, Petitioner seems to also claim that follow-up Sanger sequencing is needed to address an asserted bias in the study design. Petitioner asserts that “it is commonly known” that injection of saline (i.e., the placebo) “will not cause fever, local redness and swelling, and severe pain, or systemic reactions.” CP at 8. Study participants who receive a placebo therefore “intuitively and reasonably know that they were not injected with a vaccine[.]” CP at 9. Petitioner states that this is relevant to his requested action because, according to Petitioner, this makes placebo participants more likely to report symptoms than vaccine recipients, thereby leading to the use of test kits that will cause “[a] higher number of false-positive test results” among participants in the placebo arm. CP at 9. However, Petitioner has not pointed to any evidence that use of saline injections biases the reporting of symptoms – much less that this asserted compromise leads to a greater number of false positives. Therefore, we do not agree that Petitioner has demonstrated that purported unblinding justifies the action requested.<sup>52,53,54</sup>

### C. The Petition for Stay of Action

In the PSA, Petitioner requests FDA to “[s]tay the Phase III trial of BNT162 (NCT04368728) until its study design is amended” to conform with Petitioner’s request. PSA at 2. Specifically, Petitioner requests the study designs be amended to provide that:

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<sup>52</sup> Petitioner also states that he is willing to personally perform follow-up Sanger sequencing and that therefore “there is no excuse for the Sponsor” to not use such sequencing to confirm positive cases. CP at 9. We note that FDA has not stood in the way of Petitioner offering his services to Pfizer or any other sponsor.

<sup>53</sup> We note that one of the reasons Petitioner identifies for the requested action is that “both governments and employers may make this product mandatory (in general, or for airline or international travel) or may recommend it for widespread use.” Id. at 2. Petitioner states that “proper efficacy trials” are needed because otherwise “the Petitioner and the public may not have the opportunity to object to receiving the vaccine.” Id. Concerns about vaccination requirements or recommendations are better addressed to any government or private entity (e.g., airline) that may issue requirements or recommendations related to vaccination. FDA does not mandate use of vaccines. But to the extent that Petitioner’s concern about vaccination requirements is based on questions about the magnitude of data supporting the vaccine’s authorization, we note that our science-based review process for COVID-19 vaccines is designed to ensure that all statutory standards are satisfied prior to authorization or licensure.

<sup>54</sup> Petitioner also states that good efficacy data is needed because otherwise “any potential acceptance or mandate of these vaccines is likely to be based on inaccurate evidence regarding the vaccine.” Id. Petitioner specifies that, by “inaccurate evidence,” Petitioner means “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.” Id. Petitioner states that “[t]he Pfizer trial protocol is currently not designed to determine whether either of those objectives can be met.” Id. at 2-3. To the extent that Petitioner is asserting that lack of Sanger follow-up testing means that any FDA authorization or license will be “based on inaccurate evidence,” we disagree. As we explain in this response, lack of Sanger-based follow-up testing does not itself call into question the accuracy of the testing used in vaccine clinical trials. FDA has provided guidance emphasizing the need for accurate and reliable testing, and FDA has reviewed trial protocols with this need in mind. But Petitioner seems to also assert that there is something “inaccurate” in the fact that the Pfizer public protocol that Petitioner identifies does not include endpoints of preventing severe COVID-19 or stopping transmission. As FDA explains in its response to the citizen petition submitted under Docket Number FDA-2020-P-2180, FDA does not agree that those are necessary endpoints to support authorization. See Appendix A. Moreover, we do not agree that there is anything “inaccurate” about these endpoints not being used in any particular clinical trial.

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.

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).

PSA at 2 (internal citation omitted).

### **1. Criteria for Granting an Administrative Stay of Action**

FDA’s regulation at 21 CFR § 10.35(e) sets out the standard for review of a petition for stay of action as follows, in part:

The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition...The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:

- (1) The petitioner will otherwise suffer irreparable injury.
- (2) The petitioner’s case is not frivolous and is being pursued in good faith.
- (3) The petitioner has demonstrated sound public policy grounds supporting the stay.
- (4) The delay resulting from the stay is not outweighed by public health or other public interests.<sup>55</sup>

Section 10.35(e) also contains a provision for the discretionary implementation of a stay in any proceeding if it is in the public interest and in the interest of justice (§ 10.35(e)).

As stated in the regulation, the Commissioner shall grant a stay if all four of the criteria in 21 CFR § 10.35(e) apply. As explained below, we find that Petitioner has failed to demonstrate three of the four criteria in section 10.35(e). Consequently, we need not address Petitioner’s assertion that the PSA is not frivolous and is being pursued in good faith. FDA also has the discretion to grant a stay if it is in the public interest and in the interest of justice to do so. We

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<sup>55</sup> 21 CFR § 10.35(e).

also decline to grant the PSA on the basis that Petitioner has not established that a stay would be in the public interest or the interest of justice.

**a. Petitioner Has Not Demonstrated Irreparable Injury**

Petitioner contends that a stay must be granted because Petitioner will suffer irreparable injury. Petitioner’s argument is that “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*.” PSA at 10 (emphasis in original). Petitioner also asserts that once FDA licenses the vaccine, “both governments and employers may make this product mandatory (in general, or for airline or international travel)” and that if the conditions are not satisfied “the vaccine will not have been properly tested.” PSA at 2. Petitioner continues that “[i]f the vaccine is not properly tested, important public policy decisions regarding its use will be based on misleading evidence.” PSA at 2-3.

Petitioner’s claim of injury is too remote. Petitioner asserts that Petitioner will be forced to receive an inadequately vetted vaccine due to mandatory vaccination requirements that purportedly may be issued by entities such as airlines and States. However, the PSA does not seek a stay of any FDA decision that will force any individuals to receive vaccines. FDA does not mandate vaccination. Rather, Petitioner seeks to stay a Phase 3 clinical trial due to asserted problems with the testing protocol but has not demonstrated that the continuation of the trial will cause States, airlines, or any other entity to issue requirements that will in turn cause Petitioner to be vaccinated against Petitioner’s will. There are numerous regulatory steps between the conduct of clinical trials and the existence and distribution of a vaccine that is available to the public – much less before any State or other entity makes any potential decisions regarding mandatory vaccination.<sup>56</sup> The continuation of clinical trials, alone, will not cause the asserted harm.<sup>57</sup>

Thus, Petitioner has not demonstrated that the continuation of clinical trials under FDA IND will cause irreparable injury.

**b. Petitioner Has Not Demonstrated Sound Public Policy Grounds Supporting the Stay**

Petitioner does not make any argument about sound public policy, but Petitioner does assert that the public interest weighs in favor of the requested relief “because improving the inaccurate 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.” PSA at 3.

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<sup>56</sup> Concerns about potential State vaccine requirements are better directed to the States. FDA does not mandate use of vaccines. However, to the extent that Petitioner has concerns about inadequately vetted vaccines, we note that FDA’s science-based decision-making process is designed to assure that any vaccine that is authorized or approved meets all relevant statutory requirements.

<sup>57</sup> Furthermore, for the reasons described above, we do not agree with Petitioner that it is problematic for clinical trials to use PCR testing of study participants. We also do not agree with Petitioner that the proposed solution—following PCR diagnoses with Sanger-based sequencing—is necessary. Therefore, we do not agree with Petitioner’s assertion that there is harm to begin with.



We do not agree that Petitioner has demonstrated sound public policy grounds supporting a stay. Petitioner seeks a stay of a Phase 3 clinical trial. Although the mechanism by which FDA may “stay” a clinical trial is to issue a clinical hold, Petitioner has not identified any basis under 21 CFR § 312.42 or section 505(i)(3) of the FD&C Act for any clinical trial that would justify a clinical hold.

We conclude that a stay of a clinical trial is warranted only when a basis has been demonstrated for a clinical hold in accordance with 21 CFR 312.42 and section 505(i)(3) of the FD&C Act. Because Petitioner has not identified any such basis, we disagree that Petitioner has demonstrated sound public policy grounds supporting the requested stay. We note that if FDA becomes aware of circumstances justifying clinical holds, FDA will order clinical holds in accordance with 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act.

We also note that we disagree with the Petitioner’s justification for the request that PCR clinical diagnoses of COVID-19 be followed with Sanger-based sequencing (see discussion above). It would not be sound public policy to require testing protocols that lack scientific merit. Requiring scientifically-unjustified protocols would add unnecessary costs to the clinical trial process, which could disincentivize important medical research.

### **c. Delay Would Be Outweighed by Public Health or Other Public Interests**

Petitioner does not make any specific arguments that delay resulting from the stay would not be outweighed by public health or other public interests. However, Petitioner does assert that without granting the requested relief, acceptance of the vaccine “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.” PSA at 3. Petitioner further states that the “Pfizer trial protocol is currently not designed to determine whether either of those objectives can be met.” PSA at 3.

We assume that Petitioner believes that delay resulting from the stay would not be outweighed by public health or other public interests because Petitioner believes that the requested stay would lead to more “accurate” evidence about the vaccine’s effectiveness.

First and foremost, any vaccine to prevent COVID-19 will only be authorized or licensed based on FDA’s science-based decision-making process to assure that the relevant regulatory requirements are met.

In addition, the extraordinary current public health situation further argues against any unnecessary delay in the timely development of a COVID-19 vaccine that meets all relevant regulatory requirements. This is especially true when Petitioner has not identified a single basis for FDA to stay (or place on hold) any clinical trials under FDA IND.<sup>58</sup> Furthermore, Petitioner has not demonstrated that the requested relief will lead to more “accurate” effectiveness results, because Petitioner has not demonstrated that there is scientific merit in requiring that COVID-19 cases be confirmed using follow-up Sanger-based sequencing (see discussion above).

In short, the public health and public interest in adequate and well-controlled clinical trials for COVID-19 vaccines is strong. We conclude that staying clinical trials without justification

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<sup>58</sup> See discussion above regarding Petitioner’s failure to identify any basis for clinical holds under 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act.

would not be in the public health or public interest, and Petitioner has not set forth any justification under our regulations for staying trials that are under FDA IND. The interests of public health would not be served if a stay interfered with the conduct of clinical trials without justification.

## **2. Neither the Public Interest nor the Interest of Justice Support Granting a Discretionary Stay of Action**

Section 10.35 also provides that FDA may grant a stay of administrative action if the Agency believes it is in the public interest and in the interest of justice. As discussed above, we do not agree that a stay is in the public interest or the interest of justice at this time. It is in the public interest and the interest of justice to ensure that clinical trials for COVID-19 vaccines continue to determine whether there are vaccines that meet all relevant regulatory requirements. Stays (or clinical holds) may only be justified when there is a basis to do so under 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act. It is not in the public interest or the interest of justice to stay clinical trials in response to a Petition that fails to demonstrate any justification under 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act for a hold.

Furthermore, if we required unnecessary steps in the testing to confirm COVID-19 diagnoses, the public interest would not be served because clinical trials should not be required to include protocols that lack scientific merit. Requiring scientifically-unjustified protocols would add unnecessary costs to the clinical trial process, which could disincentivize important medical research.

## **IV. Conclusion**

FDA has considered Petitioner's requests as they relate to the "study design for the Phase III trial[] of BNT162b (NCT04368728)" and COVID-19 vaccine clinical trials. For the reasons given in this letter, FDA denies the requests in the CP and also denies the requests in the PSA. Therefore, we deny the Petitions in their entirety.

Sincerely,

A handwritten signature in black ink that reads "Peter Marks". The signature is written in a cursive, slightly slanted style.

Peter Marks, MD, PhD  
Director  
Center for Biologics Evaluation and Research

cc: Dockets Management Staff



## **Appendix I: Aspects of Vaccine Development and Process for Licensure**

### **A. Vaccines are Biologics and Drugs**

Vaccines are both biological products under the Public Health Service Act (PHS Act) (42 U.S.C. § 262) and drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321). The PHS Act defines a “biological product” as including a “vaccine...or analogous product...applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i)(1). The FD&C Act defines drug to include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.” 21 U.S.C. § 321(g)(1)(B).

Under the PHS Act, a biological product may not be introduced or delivered for introduction into interstate commerce unless a biologics license is in effect for the product. 42 U.S.C. § 262(a)(1)(A).

### **B. Clinical Investigations of Vaccines**

Before a vaccine is licensed (approved) by FDA and can be used by the public, FDA requires that it undergo a rigorous and extensive development program that includes laboratory research, animal studies, and human clinical studies to determine the vaccine’s safety and effectiveness. The PHS Act and the FD&C Act provide FDA with the authority to promulgate regulations that provide a pathway for the study of unapproved new drugs and biologics. 42 U.S.C. § 262(a)(2)(A) and 21 U.S.C. § 355(i). The regulations on clinical investigations require the submission of an Investigational New Drug application (IND), which describes the protocol, and, among other things, assures the safety and rights of human subjects. These regulations are set out at 21 CFR Part 312. See 21 CFR § 312.2 (explaining that the IND regulations apply to clinical investigations of both drugs and biologics).

The regulations provide that, once an IND is in effect, the sponsor may conduct a clinical investigation of the product, with the investigation generally being divided into three phases. With respect to vaccines, Phase 1 studies typically enroll fewer than 100 participants and are designed to look for very common side effects and preliminary evidence of an immune response to the candidate vaccine. Phase 2 studies may include up to several hundred individuals and are designed to provide information regarding the incidence of common short-term side effects, such as redness and swelling at the injection site or fever, and to further describe the immune response to the investigational vaccine. If an investigational new vaccine progresses past Phase 1 and Phase 2 studies, it may progress to Phase 3 studies. For Phase 3 studies, the sample size is often determined by the number of subjects required to establish the effectiveness of the new vaccine, which may be in the thousands or tens of thousands of subjects. Phase 3 studies are usually of sufficient size to detect less common adverse events.

If product development is successful and the clinical data are supportive of the proposed indication, the completion of all three phases of clinical development can be followed by submission of a Biologics License Application (BLA) pursuant to the PHS Act (42 U.S.C. § 262(a)), as specified in 21 CFR § 601.2.

### **C. Biologics License Applications**

A BLA must include data demonstrating that the product is safe, pure, and potent and that the facility in which the product is manufactured “meets standards designed to assure that the

biological product continues to be safe, pure, and potent.” 42 U.S.C. § 262(a)(2)(C)(i). FDA does not consider an application to be filed until FDA determines that all pertinent information and data have been received. 21 CFR § 601.2. FDA’s filing of an application indicates that the application is complete and ready for review but is not an approval of the application.

Under § 601.2(a), FDA may approve a manufacturer’s application for a biologics license only after the manufacturer submits an application accompanied by, among other things, “data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency.” The BLA must provide the multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.) with the Chemistry, Manufacturing, and Controls (CMC)<sup>59</sup> and clinical information necessary to make a benefit-risk assessment, and to determine whether “the establishment(s) and the product meet the applicable requirements established in [FDA’s regulations].” 21 CFR § 601.4(a).

FDA generally conducts a pre-license inspection of the proposed manufacturing facility, during which production of the vaccine is examined in detail. 42 U.S.C. § 262(c). In addition, FDA carefully reviews information on the manufacturing process of new vaccines, including the results of testing performed on individual vaccine lots.

FDA scientists and physicians evaluate all the information contained in a BLA, including the safety and effectiveness data and the manufacturing information, to determine whether the application meets the statutory and regulatory requirements. FDA may also convene a meeting of its advisory committee to seek input from outside, independent, technical experts from various scientific and public health disciplines that provide input on scientific data and its public health significance.

As part of FDA’s evaluation of a vaccine as a whole, FDA takes all the ingredients of a vaccine into account (including preservatives and adjuvants). FDA licenses a vaccine only after the Agency has determined that the vaccine is safe and effective for its intended use, in that its benefits outweigh its potential risks.

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<sup>59</sup> Also referred to as Pharmaceutical Quality/CMC.

## **Dr. Lee's Reply to FDA's Response**

# Siri | Glimstad

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## VIA ELECTRONIC FILING

February 10, 2021

Division of Dockets Management  
Department of Health and Human Services  
Food and Drug Administration  
Commissioner Stephen M. Hahn, M.D.  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

*Re: Citizen Petition and Petition for Administrative Stay of Action (Docket Number:  
FDA-2020-P-2225)*

Dear Commissioner Hahn,

Attached is an amended reply to the FDA's December 11, 2020 response to Dr. Sin Lee's Citizen Petition and petition for administrative stay of action regarding efficacy endpoints of the Phase III trial of BNT162 and COVID-19 cases being confirmed by Sanger sequencing.

This demands your careful attention and Dr. Lee looks forward to receiving a timely response. Dr. Lee is available to answer questions and provide any relevant additional information.

Very truly yours,

/s/ Aaron Siri

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# **Rebuttal to the December 11, 2020 Food and Drug Administration’s Response to Citizen Petition and Petition for Administrative Stay of Action (Docket Number: FDA-2020-P-2225)**

**February 10, 2021**

## **Executive Summary**

The Center for Biologics Evaluation and Research of the Food and Drug Administration (FDA), has made an arbitrary and capricious decision to deny the requests of the Citizen’s Petition and of the Petition for Stay of Action in the matter of efficacy evaluation of the Pfizer’s mRNA vaccine for COVID-19 prevention. The FDA knew or should have known:

- 1) In the Pfizer’s vaccine Phase 3 clinical trial, the definition of the 162 confirmed COVID-19 cases in the placebo-receiving participants, which were used as the endpoints to support a 95% vaccine efficacy claim, was the presence of a mild non-specific clinical symptom plus a SARS-CoV-2 NAAT (nucleic acid amplification test)-positive result. Since the mild clinical symptom is non-specific, the pivotal criterion to qualify as a case of COVID-19 in the clinical trial was the NAAT result.
- 2) The NAAT test (or tests) used for detection of SARS-CoV-2 in the clinical trial was not cleared or approved by the FDA. It was allowed to be used for preliminary detection of SARS-CoV-2 in clinical specimens under Emergency Use Authorization only. These PCR-based tests are known to generate false-positive and false-negative test results.
- 3) Sanger sequencing-based NAAT is an established irrefutable molecular biology technology for verification of target nucleic acid and SARS-CoV-2 RNA in clinical specimens.
- 4) Sanger sequencing can confirm the 162 samples as true-positive for SARS-CoV-2, which were used to support the 95% efficacy claim for the Pfizer vaccine, or can re-classify some of these 162 cases as false-positive to revise the percentage of vaccine efficacy.

The FDA rejected the Petitioner’s request to re-test the residues of the 162 positive samples by Sanger sequencing, a procedure that could have been accomplished in 2-5 days, for result confirmation to raise public confidence in a newly introduced messenger RNA vaccine, which has no safety track record. The FDA denying consumers the opportunity of having a validated effective and safe vaccine for prevention of COVID-19 is unacceptable.

## **The Rebuttal**

The December 11, 2020 letter signed by Dr. Peter Marks, Director, Center for Biologics Evaluation and Research on behalf of the Food and Drug Administration (FDA) and addressed to Attorney Aaron Siri in response to Dr. Sin Hang Lee’s citizen petition dated November 23, 2020 (the CP) and citizen petition for administrative stay of action dated November 25, 2020 relating to the Phase 3 trial of the BNT162b vaccine [the Pfizer vaccine] to prevent the infection by novel coronavirus SARS-CoV-2 (COVID-19) (hereafter referred to as The Letter) [1] must be challenged with a rebuttal for the following reasons.

1. Dr. Peter Marks announced *“I’m the FDA point person on COVID-19 vaccines. We’ll make sure they’re safe and effective.”* This announcement was published in the newspaper USA TODAY on October 27, 2020. [2] In this announcement, Dr. Marks pledged *“to do our duty to the best of our ability, independently and without conflicts of interest, and we will be transparent about FDA decisions.”* Dr. Marks recognized *“Trust means everything. Trust in vaccines facilitated the incredible positive impact that vaccination had on public health in reducing illness and death*

*over the past century. In the middle of a global pandemic, it is precisely a safe and effective COVID-19 vaccine that will help bring life back to normal if people are willing to receive the vaccine because they have confidence in it. Therefore, it is critical to be open and transparent about the process that the U.S. Food and Drug Administration will follow to help make safe and effective COVID-19 vaccines available.” Dr. Marks made a promise to the public that there would be “Careful evaluation and no rushing” and stated further “this process will not be rushed. There will be no shortcuts in developing the relevant phase 3 efficacy results.” [2]*

However, the Letter denying the petition and stay shows that the FDA has not conducted an adequate evaluation of the Pfizer vaccine’s efficacy, especially concerning issues about the accuracy of RT-qPCR testing of SARS-CoV-2 in clinical specimens. The FDA has misled the public. The key misleading statements are analyzed below point-by-point according to the sequence of their presentation in the Letter but under the following four categories for the convenience of the readers.

- A. Cherry-picking to eviscerate the guidance for issuance of an EUA for a COVID-19 vaccine
- B. Knowingly promoting inaccurate PCR tests for SARS-CoV-2
- C. Finding excuses for using PCR tests with high false-positive rates for this vaccine trial
- D. Glossing over potential risks of an mRNA vaccine while concealing its true efficacy

## **A. CHERRY-PICKING TO EVISCERATE THE GUIDANCE FOR ISSUANCE OF AN EUA FOR A COVID-19 VACCINE**

2. Under **II. B. Emergency Use Authorization of the Letter** the FDA omitted some essential elements from the “Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry-October 2020” (October 2020 Guidance) [3] in quoting this Guidance as the basis for rejection of Dr. Lee’s Citizen Petitions as follows.

*“Although EUAs are governed under a different statutory framework than a Biologics License Application (BLA), FDA has made clear that issuance of an EUA for a COVID-19 vaccine would require that the vaccine demonstrated clear and compelling safety and efficacy in a large, well-designed phase 3 clinical trial. In the guidance document Emergency Use Authorization for Vaccines to Prevent COVID-19 (October 2020 Guidance), FDA has provided recommendations that describe key information that would support issuance of an EUA for a vaccine to prevent COVID-19.<sup>12</sup> In the October 2020 Guidance, FDA explained that, in the case of such investigational vaccines, any assessment regarding an EUA will be made on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.<sup>13</sup> FDA has also stated, in the October 2020 Guidance, that for a COVID-19 vaccine for which there is adequate manufacturing information to ensure its quality and consistency, issuance of an EUA would require a determination by FDA that the vaccine’s benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine’s safety and efficacy in a clear and compelling manner.<sup>14</sup> A Phase 3 trial of a vaccine is generally a large clinical trial in which a large number of people are assigned to receive the investigational vaccine or a control. In general, in Phase 3 trials that are designed to show whether a vaccine is effective, neither people receiving the vaccine nor those assessing the outcome know who received the vaccine or the comparator.”*

However, in this quotation of the October 2020 Guidance as the legal basis for granting EUA to the Pfizer vaccine, the FDA has omitted the pivotal parts of the Guidance. The omitted part

is: under **III. CRITERIA AND CONSIDERATIONS FOR THE ISSUANCE OF AN EUA FOR A COVID-19 VACCINE**, the October 2020 Guidance states the following:

*“On February 4, 2020, pursuant to section 564(b)(1)(C) of the FD&C Act (21 U.S.C. 360bbb3(b)(1)(C)), the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of such determination, on March 27, 2020, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564(b)(1) of the FD&C Act (21 U.S.C. 360bbb-3(b)(1)).<sup>3</sup>Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3))(Ref. 3):*

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.*
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.*
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.*
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.*

*In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA will be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.*

### **C. Safety and Effectiveness Information**

*The EUA request should include the following safety and effectiveness information, which will inform FDA’s determination regarding the product’s benefit-risk profile:*

#### **1. Bioassays for assessment of clinical endpoints**

*The diagnostic bioassays that were used to assess study endpoints of clinical studies supportive of the EUA request should be identified. FDA expects that the standard operating procedures (SOPs) and validation reports for the final assay methods, and a list of all laboratories where the clinical samples have been tested, will be submitted to support the EUA request.”*

3. The Letter shows that the FDA has ignored the statutory requirements in issuing an EUA to the Pfizer vaccine without considering the “*totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.*” because the analysis of the primary outcomes was



based on 170 confirmed cases of COVID-19, including 162 cases in the placebo arm and 8 cases in the BNT162b2 vaccine arm. These 170 cases were trial participants developing any one of the mild symptoms, including 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; or vomiting. Since none of these mild symptoms is specific of COVID-19 or serious or life-threatening disease or condition, evaluation of these clinical endpoints alone does NOT make it “reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.” Therefore, the statutory requirements for EUA of the Pfizer vaccine have not been met by selecting participants with mild symptoms for vaccine efficacy evaluation.

4. The Letter shows that the FDA has allowed the vaccine manufacturer and the FDA to completely depend on confirmation of COVID-19 cases without serious or life-threatening disease or condition as endpoints, but by relying on a positive RT-qPCR testing result alone. In addition, both the vaccine manufacturer and the FDA failed to evaluate the “totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat” any condition that can be caused by SARS-CoV-2. Failure to evaluate the totality of scientific evidence available, including data from adequate and well-controlled trials, is the major flaw of the FDA in granting EUA to the Pfizer vaccine in violation of its own October 2020 Guidance. The totality of scientific evidence available includes evidence of faulty RT-qPCR tests being used to qualify COVID-19 cases as endpoints for Pfizer vaccine efficacy evaluation, as claimed in the Citizen’s Petitions, which was not reviewed by the FDA. This issue will be discussed further below.
5. The Letter totally omitted the section of “**Bioassays for assessment of clinical endpoints**” as required for EUA of COVID-19 vaccines by the October 2020 Guidance. This requirement states “The diagnostic bioassays that were used to assess study endpoints of clinical studies supportive of the EUA request should be identified. FDA expects that the standard operating procedures (SOPs) and validation reports for the final assay methods, and a list of all laboratories where the clinical samples have been tested, will be submitted to support the EUA request.” This was perhaps an intentional omission because no data of the diagnostic bioassays that were used to assess study endpoints of clinical studies supportive of the EUA request were presented at the open meeting or published for transparency.
6. The Letter states “A Phase 3 trial of a vaccine is generally a large clinical trial in which a large number of people are assigned to receive the investigational vaccine or a control. In general, in Phase 3 trials that are designed to show whether a vaccine is effective, neither people receiving the vaccine nor those assessing the outcome know who received the vaccine or the comparator.” Therefore, it is reasonable to expect that unblinding between participants receiving vaccine and participants receiving saline placebo did not occur in the Pfizer vaccine Phase 3 trial. This is especially important in view of the Pfizer’s report as follows. [4]

*“Pfizer reported safety data for 5,664 people ages 18 to 64 and 1,816 people ages 65 to 85 who received one dose. In the younger group, 38% reported fatigue afterward, while 35% reported headache and 16% had chills. Eleven percent or fewer suffered joint pain, diarrhea or chills. The side effects percentages were lower among the older age group.*

*After the second dose, 36% of trial participants aged 18 to 64 reported fatigue, while 28% reported a headache and 18% reported muscle pain. Again, the data were blinded between placebo and the vaccine candidate.*

*Most side effects after the second dose were mild to moderate, but some participants did experience severe or grade 4 side effects that could be life-threatening or disabling, according to the presentation. There were more severe side effects after the second dose as compared with the first dose, even though a smaller number of participants—1,682—were in that group.”*

So, based on this report after the first dose of the Pfizer vaccine, 38% of the participants had fatigue, 35% a headache, 16% chills, and up-to 11% joint pain, diarrhea or chills. In other words, about all participants receiving vaccine injection experienced some form of vaccine reactions, which would not have occurred among participants receiving sterile normal saline placebo injection.

Since all trial participants were instructed that “*During the 7 days following each vaccination, potential COVID-19 symptoms that overlap with specific systemic events (ie, fever, chills, new or increased muscle pain, diarrhea, vomiting) should not trigger a potential COVID-19 illness visit...*” (8.13 of trial protocol),[5] participants receiving vaccine injection would reasonably assume that they had been protected from COVID-19 and might not trigger a potential COVID-19 illness visit even when they developed a 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; or vomiting because these symptoms overlap with vaccination reactions and may be caused by numerous pathogens other than SARS-CoV-2.

In contrast, the participants receiving saline injection knew that they were not injected a vaccine product due to the lack of vaccination reactions and felt “unprotected”. As a result, the participants in the placebo group tended to contact the trial manager whenever they felt sick with any of those listed mild symptoms, triggering a potential COVID-19 illness visit, which was to be followed by an RT-qPCR test. Such an unblinding process was built-in in the Pfizer vaccine trial design.

Instead of questioning the vaccine sponsor about such a potential unblinding event that might affect the outcomes of vaccine efficacy evaluation, the FDA wanted the Petitioner to produce evidence to prove that “*use of saline injections biases the reporting of symptoms – much less that this asserted compromise leads to a greater number of false positives.*” No evidence is needed to prove that 0.5 mL of sterile normal saline is an innocuous material when injected intramuscularly into a healthy person. For the past century, students interested in health care science worldwide have been injecting 0.5 mL of sterile normal saline to each other’s buttock in their practical educational classes under supervision of a nurse or physician instructor, with no adverse outcomes other than the minor “prick” from the needle. [6] Furthermore, potential unblinding by lack of symptoms following placebo injections was discussed by VRBPAC members at the December 10 meeting regarding the vaccine. It has been discussed in literature published subsequently. It is disingenuous to assert otherwise.

## **B. KNOWINGLY PROMOTING INACCURATE PCR TESTS FOR SARS-COV-2**

7. Under **III. B. 1. Background Regarding Testing Technology and SARS-CoV-2 Testing** of the Letter, the FDA states the following:

*“FDA agrees that accurate testing is an important part of ensuring the reliability of vaccine trial outcomes. An accurate test helps identify whether the investigational vaccine prevents COVID-19 (or not) by confirming whether study participants are infected with SARS-CoV-2. Indeed, FDA’s June 2020 Guidance states that “[d]iagnostic assays used to support the pivotal efficacy*

*analysis (e.g., RT-PCR) should be sensitive<sup>[25]</sup> and accurate for the purpose of confirming infection and should be validated before use.”<sup>26</sup>*

*Nucleic acid-based amplification tests (NAAT), also referred to as PCR tests, are used to show if individuals have active SARS-CoV-2 infection by detecting the virus’s genetic material. In PCR testing, a machine located in a laboratory or at a point of care, depending on the test, runs a series of reactions. These reactions first convert the virus’s ribonucleic acid (RNA), if present, into deoxyribonucleic acid (DNA) and then amplify it (make millions of copies of the DNA); the test then detects this DNA. By running multiple amplification cycles, a PCR test can sense even low levels of viral genetic material in a patient’s sample, so these tests tend to be highly sensitive (especially laboratory PCR tests).*

*In a Sanger sequencing-based method, dideoxy-nucleotide (ddNTP) chain terminators are used to determine the specific nucleotide sequence of the target nucleic acid. Current Sanger sequencing-based methods are most commonly carried out via a multistep process, which includes not only appropriate sampling and nucleic acid extraction, but also: 1) conventional PCR amplification of the target region; 2) PCR cleanup for removal of unincorporated primers and nucleotides; 3) a sequencing reaction in which the PCR product is used as template for the incorporation of fluorescently labeled dideoxy chain terminators; 4) sequencing reaction cleanup for removal of unincorporated fluorescent dideoxy chain terminators; and 5) simultaneous size dependent separation and nucleic acid sequence determination.*

*PCR, when used in conjunction with Sanger-based or other sequencing, can detect and identify viral genetic material in a clinical sample. Historically, PCR has been used with reverse transcription to amplify viral RNA to indicate whether there was a positive signal of any suitable genetic material present, and sequencing has been used to confirm the nucleic acid sequence of the amplified genetic material. As PCR technology has evolved, however, PCR testing does not need to be followed by Sanger or other sequencing for purposes of clinical diagnosis. Currently, reverse real-time PCR (RT-PCR) tests can both amplify and confirm the identity of viral genetic material in a single reaction, without a separate sequencing step.<sup>27</sup> Many of the NAATs for detection of SARS-CoV-2 that FDA has authorized are based on the technology that both amplifies and confirms viral genetic material without the need for an additional sequencing step.*

*We have determined there is not scientific merit in requiring the Phase 3 trial for BNT162 or other COVID-19 vaccine candidates to qualify a PCR diagnosis of COVID-19 with Sanger sequencing. Testing used to support the detection of SARS-CoV-2 infection should be sensitive and accurate, and PCR assays can be sufficiently sensitive and accurate without the need for Sanger sequencing.<sup>28</sup>*

*FDA’s current recommendations for SARS-CoV-2 molecular diagnostic tests include that developers confirm the performance of their assay by testing a minimum of 30 positive specimens and 30 negative natural clinical specimens as determined by an authorized assay.<sup>29</sup> Additionally, the clinical performance data should demonstrate a minimum of 95% positive percent agreement (i.e., sensitivity) and negative percent agreement (i.e., specificity).<sup>30</sup> But FDA has not identified any need to require PCR testing for clinical cases to be followed by Sanger based or other sequencing. We believe that clinical diagnoses can be supported following PCR analyses with a positive percent agreement and negative percent agreement greater than or equal to 95%.<sup>31</sup>*

The untrue and half-true statements in this “Background Regarding Testing Technology and SARS-CoV-2 Testing” section must be pointed out for the record as follows.

- a) The FDA’s statement “*Nucleic acid-based amplification tests (NAAT), also referred to as PCR tests, are used to show if individuals have active SARS-CoV-2 infection by detecting the virus’s genetic material*” is misleading and deviates from established FDA guidelines. For example, “FDA defines SARS-CoV-2 molecular diagnostic tests as tests that detect SARS-CoV-2 nucleic acids from human specimens.” [7] In a document titled “Molecular Diagnostic Template for Commercial Manufacturers” of SARS-CoV-2 test kits, which the FDA also cited as a reference in its Letter, the FDA specifically defines that the measurand of the diagnostic test is the specific nucleic acid sequences from the genome of the SARS-CoV-2. [8]. In another FDA Memorandum titled “*Guidelines for the Validation of Analytical Methods for Nucleic Acid Sequence-Based Analysis of Food, Feed, Cosmetics and Veterinary Products*”, the FDA states that Sanger sequencing is used to determine the specific nucleotide sequence of the target nucleic acid. [9]

The Letter has not cited any existing FDA guidance that recommends relying on using PCR, especially qPCR or RT-qPCR, to determine the specific nucleotide sequence of the target nucleic acid. With no justification, the FDA has created a set of less stringent standards for evaluation of the accuracy of critical diagnostics and the efficacy of vaccines for humans, relative to FDA’s standards for Analysis of Food, Feed, Cosmetics and Veterinary Products.

All nucleic acid tests, including nucleic acid-based amplification test (NAAT), are designed to determine the sequence of nucleotides. NAAT for SARS-CoV-2 means demonstration of a unique unambiguous SARS-CoV-2 genomic nucleotide sequence in a sample derived from a clinical specimen, to be compared with the known reference sequences annotated in the GenBank database for validation. PCR, including RT-qPCR, cannot determine nucleic acid sequences. To equate PCR with NAAT is misleading.

- b) FDA’s statement in the Letter “*Indeed, FDA’s June 2020 Guidance [10] states that “[d]iagnostic assays used to support the pivotal efficacy analysis (e.g., RT-PCR) should be sensitive<sup>[25]</sup> and accurate for the purpose of confirming infection and should be validated before use.*”<sup>26</sup> is a reasonable statement, but unsupported by the reference cited. The statement cited reference<sup>25</sup>, titled “Guidance for Industry and FDA Staff-Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests Document issued on March 13, 2007” [11] to support the declaration “*[d]iagnostic assays used to support the pivotal efficacy analysis (e.g., RT-PCR) should be sensitive<sup>[25]</sup>*. However, the entire reference<sup>25</sup> [11] does not contain the words of “pivotal efficacy”, “RT-PCR”, or “PCR” at all. The document is about statistical guidance. PCR, a nucleic acid amplification tool, does not need statistics. The sensitivity of PCR does not depend on statistical analysis. This document does not deal with vaccine pivotal efficacy analysis or PCR. The second cited document<sup>26</sup>, which is identified as “June 2020 Guidance at 17” in the Letter, apparently refers to a document titled “Development and Licensure of Vaccines to Prevent COVID-19, Guidance for Industry U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research June 2020”. [10] However, this June 2020 Guidance does not cite the March 13, 2007 [11] statistical guidance<sup>25</sup> at all. Instead, it emphasizes “*• Diagnostic assays used to support the pivotal efficacy analysis (e.g., RT-PCR) should be sensitive and accurate for the purpose of confirming infection and should be validated before use.*” The key question is how to validate an RT-PCR test result. It is obvious that a positive or negative RT-PCR test whose purpose is to determine if a SARS-CoV-2 gene nucleotide sequence is present in a clinical specimen cannot be validated by statistical manipulations.

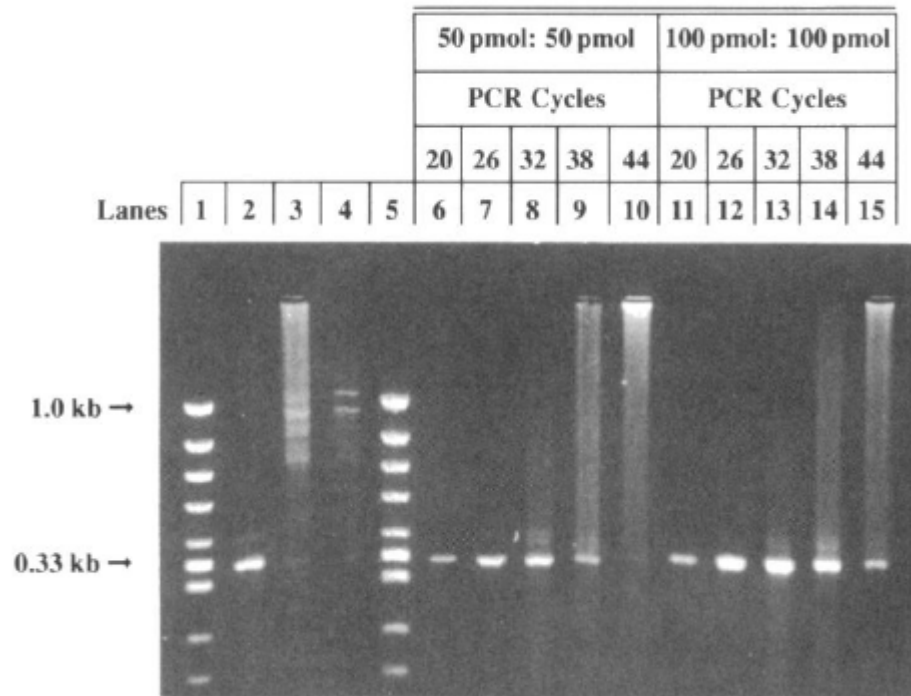
FDA has never validated any EUA SARS-CoV-2 PCR tests. It has never established a reference standard.

- c) In the Letter, the FDA appears to exhibit confusion regarding the terms RT-PCR, RT-qPCR, RT-quantitative PCR (RT-qPCR) or real-time RT-PCR. The FDA June 2020 Guidance [10] specifically mentions under VII. DIAGNOSTIC AND SEROLOGICAL ASSAYS – KEY CONSIDERATIONS that the “*pivotal efficacy analysis (e.g., RT-PCR) should be sensitive and accurate for the purpose of confirming infection and should be validated before use.*” According to the National Cancer Institute (NCI) Dictionary of Genetics Terms, “*RT-PCR is a laboratory method used to make many copies of a specific genetic sequence for analysis. It uses an enzyme called reverse transcriptase to change a specific piece of RNA into a matching piece of DNA. This piece of DNA is then amplified (made in large numbers) by another enzyme called DNA polymerase. The amplified DNA copies help tell whether a specific mRNA molecule is being made by a gene. RT-PCR may be used to look for activation of certain genes, which may help diagnose a disease, such as cancer. It may also be used to study the RNA of certain viruses, such as the human immunodeficiency virus (HIV) and the hepatitis C virus, to help diagnose and monitor an infection. Also called reverse transcription-polymerase chain reaction.*” [12] The key sentences in this definition are “*RT-PCR is a laboratory method used to make many copies of a specific genetic sequence for analysis. It uses an enzyme called reverse transcriptase to change a specific piece of RNA into a matching piece of DNA. This piece of DNA is then amplified (made in large numbers) by another enzyme called DNA polymerase.*” Therefore, RT-PCR is a method to turn a segment of RNA into a segment of matching DNA, which is to be used to generate large numbers of DNA. However, the process of making large numbers of matching DNA pieces in itself does not determine nucleotide sequence. The RT-PCR products need to be validated, especially for vaccine “pivotal efficacy analysis”, according to the FDA June 2020 Guidance.[10] As stated above, in a Memorandum titled “Guidelines for the Validation of Analytical Methods for Nucleic Acid Sequence-Based Analysis of Food, Feed, Cosmetics and Veterinary Products”, the FDA stated that Sanger sequencing is used to determine the specific nucleotide sequence of the target nucleic acid. [9]
- d) In the Letter, FDA’s statement “*Historically, PCR has been used with reverse transcription to amplify viral RNA to indicate whether there was a positive signal of any suitable genetic material present, and sequencing has been used to confirm the nucleic acid sequence of the amplified genetic material. As PCR technology has evolved, however, PCR testing does not need to be followed by Sanger or other sequencing for purposes of clinical diagnosis. Currently, reverse real-time PCR (RT-PCR) tests can both amplify and confirm the identity of viral genetic material in a single reaction, without a separate sequencing step.*”<sup>27</sup> is a half-truth. The sentence “*sequencing has been used to confirm the nucleic acid sequence of the amplified genetic material*” is true. But the sentence “*reverse real-time PCR (RT-PCR) tests can both amplify and confirm the identity of viral genetic material in a single reaction, without a separate sequencing step*” while citing an FDA news media pamphlet titled “*A Closer Look at Coronavirus Disease 2019 (COVID-19) Diagnostic Testing*” [13] as supportive reference is totally untrue. The latter news media pamphlet merely summarizes the various types of laboratory tests available for diagnosis of COVID-19. It does not discuss the sensitivity and accuracy of each testing type, let alone presenting any scientific data to support FDA’s assertion “*As PCR technology has evolved, however, PCR testing does not need to be followed by Sanger or other sequencing for purposes of clinical diagnosis. Currently, reverse real-time PCR (RT-PCR) tests can both amplify and confirm the identity of viral genetic material in a single reaction, without a separate sequencing step.*”
- e) In the Letter, the FDA stated “*We have determined there is not scientific merit in requiring the Phase 3 trial for BNT162 or other COVID-19 vaccine candidates to qualify a PCR diagnosis*

*of COVID-19 with Sanger sequencing. Testing used to support the detection of SARS-CoV-2 infection should be sensitive and accurate, and PCR assays can be sufficiently sensitive and accurate without the need for Sanger sequencing.*<sup>28</sup> This statement is an untruth because the entire cited #28 document titled “Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff” [14] has not indicated that “*PCR assays can be sufficiently sensitive and accurate without the need for Sanger sequencing*”. In contrast, this FDA document emphasizes the need to assure “*publicly available SARS-CoV-2 sequences that can be detected by the proposed molecular assay*”. The FDA does not dispute that Sanger sequencing is the method customarily used to determine nucleotide sequences.

- f) The FDA’s statement “*By running multiple amplification cycles, a PCR test can sense even low levels of viral genetic material in a patient’s sample, so these tests tend to be highly sensitive (especially laboratory PCR tests)*” is misleading because that is a half-truth. In fact, by running too many amplification cycles, a PCR test may generate cumulative irrelevant fluorescent signals leading to false-positive results even when there is no target viral genetic material in a patient’s sample. It has been known for the past 30 years that excessive cycling may convert PCR products to random-length higher molecular weight fragments even under ideal controlled experimental conditions when no other DNAs are present in the reaction mixture to interfere with the enzymatic process. After 30 cycles of amplification, most of the PCR primers whose base sequences fully match those of their template have been converted into PCR product, and there are no more DNA molecules with fully complementarily matching sequences like the primers and their intended template in the reaction mixture. Under this condition, if amplification cycling continues, the DNA polymerase will be adding nucleotides to the 3’-end of any ssDNA attached to another ssDNA. In other words, by running too many amplification cycles, reaction conditions favor the annealing of the 3’-OH ends of the PCR product to genomic template or to itself after the fully matching primers have been exhausted. As a result, the 3’-OH ends of the PCR product are then extended to higher molecular weight DNA and are randomly terminated during the additional cycles. These random-length products are the likely components of the smear observed with agarose gel electrophoresis. For example, a 1991 study reported that when PCR was used to amplify a target DNA of 0.33kb long, the PCR products were observed as a band after 20-26 cycles of amplification (see Lanes 6, 7, 11, and 12 in the image of agarose gel electrophoresis stained with ethidium bromide below when the gel plate was exposed to ultraviolet light). However, when the cycle numbers increased to 32-44 (Lanes 8, 9, 10, 13, 14 and 15), the PCR products visualized as fluorescent dsDNA/ethidium bromide complexes were no longer tightly identified as one PCR amplicon, but as totally unexpected multiple diffuse high molecular weight products. [15]

## A. Agarose Gel



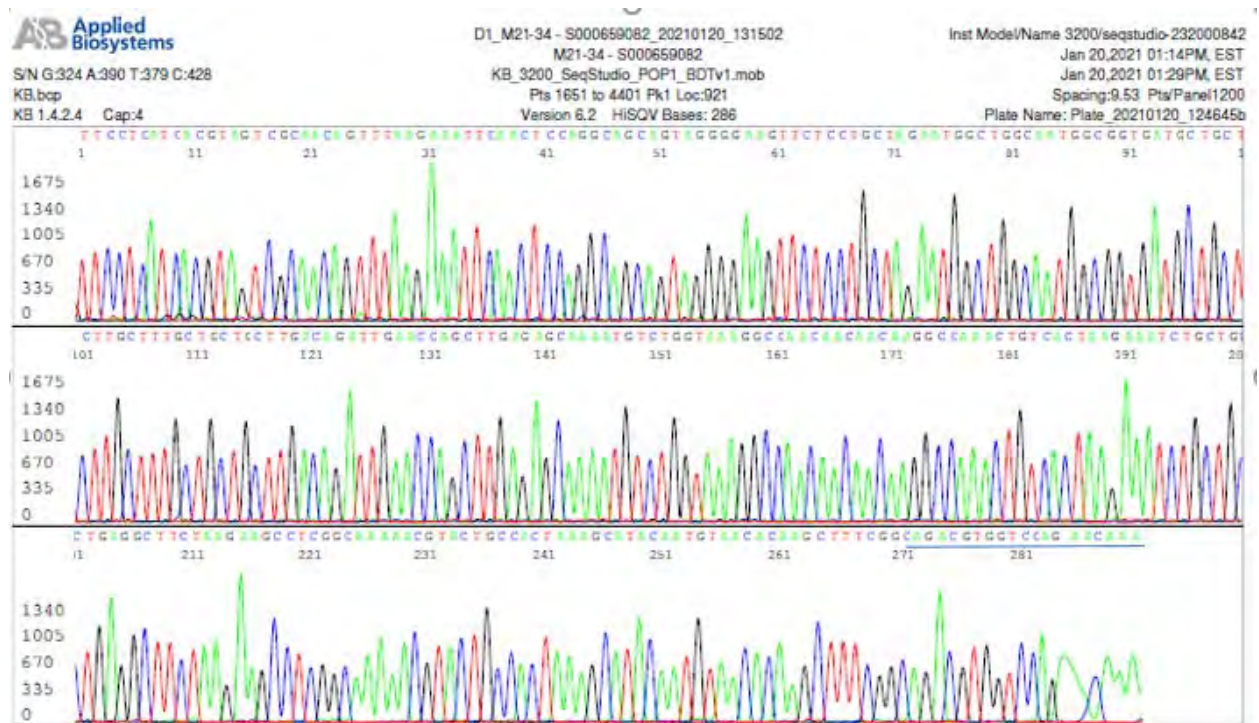
If a fluorometer is used to measure the total signals of fluorescence contained in a test tube without gel electrophoresis, as in the case of qPCR, the fluorometer cannot determine if the total fluorescence is emitted from DNA molecules that would form smears on gel electrophoresis, or is emitted from DNA molecules that would form a specific narrow band on gel electrophoresis. And only the fluorescent molecules that can form a specific band on electrophoresis are likely to be the products of desirable PCR amplification resulting from primer-initiated, template-directed DNA synthesis.

The experiment presented above shows that in the absence of fully matching sequences, any single-stranded DNA (ssDNA) molecules, including PCR primers without fully matching template, will anneal to any ssDNA molecules with partially matching nucleotide sequences at annealing temperature during a PCR cycle. A minimum of only 6 nucleotides matching the sequence of any DNA at the 3' end of an annealing primer is required to initiate enzymatic primer extension.[16] Random PCR amplification may take place if there is any nontarget DNA with two segments of sequences partially matching those of the primer pair in the reaction mixture to initiate the first PCR cycle. Exponential primer-defined PCR amplification of non-target DNA will proceed after the first PCR cycle is completed. PCR amplification of undesirable DNA in clinical diagnostic work is a well-known phenomenon. For examples, PCR amplification of unintended DNA from *Pusillimonas*, an environmental bacterial species often contaminating patient blood samples, by a pair of specific primers designed for *Borrelia burgdorferi* DNA amplification,[17] PCR amplification of human genomic DNA by PCR primers designed for human papillomavirus L1 gene DNA amplification, [18 ] and unexpected PCR amplification of Homo sapiens BAC clone RP11-154F14 by the CDC's primers designed for the human RNase P gene [19 ] have been confirmed by DNA sequencing and reported in peer-reviewed journals. These Sanger sequencing-proven nonspecific PCR products, in the absence of intended target DNA, which were observed during testing of clinical samples, were all due to partial base-matching

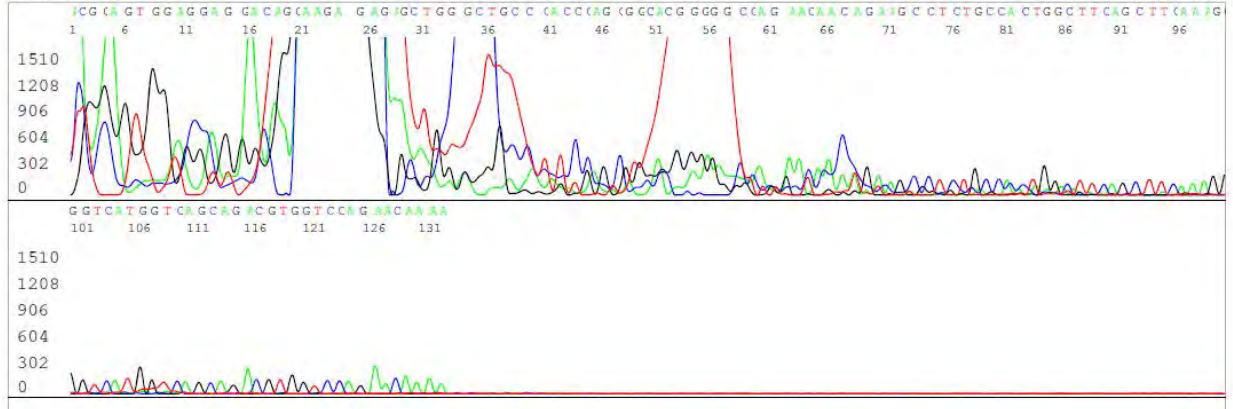


between primer and unintended DNA, and provided a mechanism for false positives in PCR-based SARS-CoV-2 testing.

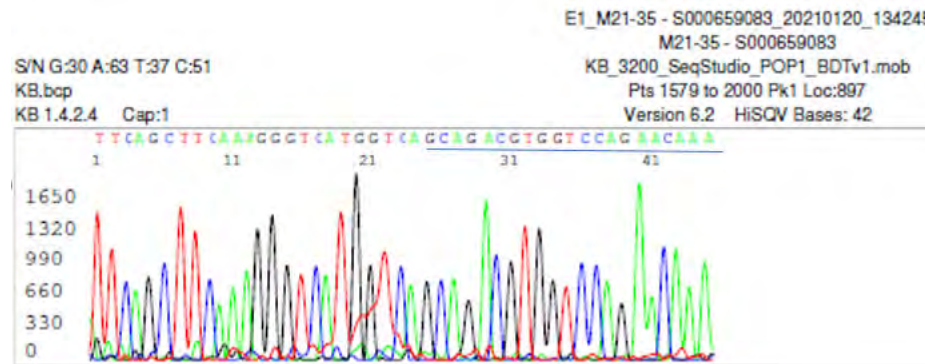
In order to demonstrate the mechanism of how the current EUA RT-qPCR test kits are generating false positives, the Petitioner sequenced 30 human nasopharyngeal swab samples, which had been re-tested at least twice with different EUA test kits and certified as positive for SARS-CoV-2 N gene RNA by a company recommended by the FDA as one of the suppliers of SARS-COV-2 validation panels for new RT-qPCR test developers. [20] The Petitioner designed a pair of 21-base nested PCR primers to amplify a 398-base highly conserved segment of the N gene of SARS-CoV-2 to be used as the template for Sanger sequencing.[19] The sequence of the reverse primer is 5'-TTTGGTTCTGGACCACGTCTGC-3'. The results showed that only 16 of the 30 (53%) samples certified to be positive for SARS-CoV-2 N gene based on RT-qPCR were in fact true positives. The complementary sequence of the reverse primer-binding site 3'-GCAGACGTGGTCCAGAACAAA-5' (underlined at the end) is illustrated in the following sequencing electropherogram, showing a unique segment of the SARS-CoV-2 N gene sequence in a true-positive sample (ID# M21-34).



However, parallel sequencing of an adjacent sample ID# M21-35, which was also PCR-positive, showed no SARS-CoV-2 genomic nucleic acid sequence. Instead, the PCR products were composed of various amplified DNA molecules, which were randomly terminated with fluorescent ddNTPs during the Sanger reaction, including one segment of human chromosome 1 DNA that shares part of the sequence of the primer identified above. The raw sequencing electropherogram is pasted below.



Magnification of the readable ending sequence with the 21-base primer DNA (underlined) joining an unintended DNA in sample M21-35 is illustrated below.



Submission of the readable sequence excised from the false-positive sequencing data illustrated in sample M21-35 electropherogram to the GenBank for BLAST analysis elicited return of a report as follows,

**Homo sapiens heparan sulfate proteoglycan 2 (HSPG2), RefSeqGene on chromosome 1**  
Sequence ID: [NG\\_016740.1](#) Length: 122014 Number of Matches: 1

Score	Expect	Identities	Gaps
84.2 bits(45)	2e-13	45/45(100%)	0/45(0%)

Query\_1 GCCTCTGCCCCCTGGCTTCAGCTTCAAAGGGTCATGGTCCGACGAGC 45  
|||||  
sbict\_32609 GCCTCTGCCCCCTGGCTTCAGCTTCAAAGGGTCATGGTCCGACGAGC 32653

GCAGACGTGGTCCAGAACAAA (CoV primer)  
GCCTCTGCCCCCTGGCTTCAGCTTCAAAGGGTCATGGTCCGCAGACGTGGTCCAGAACAAA (chimeric)  
GCCTCTGCCCCCTGGCTTCAGCTTCAAAGGGTCATGGTCCGCAGACTCTGAGGGATGCCA (human)

This experiment confirms that a minimum of only 6 nucleotides (GCAGAC) matching the sequence of any DNA at the 3' end of an annealing primer is required and sufficient to initiate enzymatic primer extension.[16] In the absence SARS-CoV-2, PCR primers designed for SARS-CoV-2 nucleic acid may amplify any undesirable DNAs with partially matching sequences

from various sources (in this case partially matching nucleotides are typed in red for comparison), leading to false positives if DNA sequencing is not performed to verify the PCR products.

- g) In the Letter, the FDA claimed that RT-PCR or RT-qPCR are reliable diagnostic assays for SARS-CoV-2 infection. However, they are not. PCR was invented and perfected as a tool in chemistry for replication of a selected segment of DNA in the test tube to prepare templates for sequence analysis without the need of cloning in the 1980s, as stated in an article by Appenzeller in 1991, before Kary Mullis was awarded a Nobel Prize in 1993 for his discovery.[21] Real-time or quantitative PCR (qPCR) was first described in 1993 to monitor the accumulation of double-stranded DNA (dsDNA) being generated in each PCR using the increase in the fluorescence of ethidium bromide (EtBr) that results from its binding to dsDNA as the PCR products. The kinetics of fluorescence accumulation during thermocycling are directly related to the starting number of DNA copies in the PCR mixture. The basic principle dictates that the fewer cycles necessary to produce a detectable fluorescence, the greater the number of target sequences in the original sample being tested. Results obtained with this approach indicate that a kinetic approach to PCR analysis can quantitate the numbers of a known dsDNA in the mixture, [22] when there are no other interfering DNAs in the PCR mixture. This process is referred to as dye-based qPCR for quantitation of small amounts of target DNA known to exist in a sample. It is widely acknowledged as the most sensitive method to quantify minute amounts of nucleic acids and its applications split into two main types referred to as: relative and absolute quantification. In relative quantification the analyte, often reverse-transcribed mRNA or microRNA, is quantified relative to an endogenous reference. In absolute quantification the targeted nucleic acid (the analyte) is measured relative to a set of standards used to construct a standard curve. [23] qPCR was not designed to determine if a target DNA is present or absent in the sample being tested.

When qPCR is adapted into a “plus/minus” or a “yes/no” assay for the purpose of making the diagnosis of an infectious disease, the dye-based qPCR is converted to a probe-based qPCR. Instead of a free dye like EtBr, a target-specific probe that is an oligonucleotide (ssDNA) of about 25 bases long, complementary to a segment of the target DNA sequence, is introduced into the probe-based qPCR in addition to the PCR primers. The most common probe type is a hydrolysis probe, which incorporates a fluorophore attached to the 5’ end and a quencher attached to the 3’ end of the probe, as the TaqMan® probes commonly used in the SARS-CoV-2 RT-qPCR test kits. [24]

Fluorescence resonance energy transfer (FRET) prevents fluorescence emission of the fluorophore due to proximity of the quencher while the probe is intact. If a target DNA template, among other undesirable DNAs, is present in the PCR mixture, the probe is hydrolyzed during enzymatic primer extension and amplification of the specific sequence to which the primer is bound. The cleavage and degradation of the probe by the 5’-3’ exonuclease activity of the *Taq* polymerase separate the fluorophore from the quencher, allowing fluorescence of the fluorophore and resulting in an amplification-dependent increase in fluorescence. In other words, diagnostic qPCR actually uses the PCR process to test if a DNA/DNA binding (hybridization) has taken place between a set of known oligonucleotides (primers and probe) and a target DNA molecule, which may be present in the sample being tested. It assumes the primers and the probe were all bound to their respective segments of a target ssDNA with fully matching bases before a fluorescence signal was emitted as the result of PCR amplification-dependent degradation of the probe.

In reality, however, this assumption is not always valid. In the nasopharyngeal swab samples taken from patients, there are numerous human cells, bacteria, viruses, plasmids and fungi all of which can contribute nucleic acids, namely DNAs and RNAs, to the sample extract being tested even when there is no SARS-CoV-2 RNA in the specimen. In the absence of fully matching SARS-CoV-2 genomic RNA or cDNA as the preferred target template, the PCR primers and the probe can bind to any partially matched DNA and initiate enzymatic primer extensions and probe degradation. As pointed out above, a minimum of only 6 nucleotides matching the sequence of any DNA at the 3' end of a primer is required to initiate enzymatic primer extension.[16] PCR amplification may take place if there is a nontarget DNA with two segments of sequences partially matching those of the primer pair in the reaction mixture to initiate the first PCR cycle. Exponential primer-defined PCR amplification of non-target DNA will proceed after the first PCR cycle is completed.

If such an unintended PCR amplification should take place and if the interprimer region of the PCR product also had a sequence matching part of the probe, the probe would attach to the PCR product and undergo hydrolysis by the action of the DNA polymerase during PCR amplification, leading to separation of the fluorophore from its quencher, cycle after cycle, and eventually to a false-positive result. In one DNA/DNA hybridization research study, the authors designed a set of binding partners to a 50-mer oligonucleotide containing complementary stretches from 6 nucleotides (nt) to 21 nt in length. The authors found that stable partial duplexes can form when only 12 bp (12/50) of complementary sequence are present, resulting in the appearance of significant signals from an unintended binding partner, in the absence of the intended fully matched DNA target. [25]

- h) In the Letter, the FDA claims “*FDA’s current recommendations for SARS-CoV-2 molecular diagnostic tests include that developers confirm the performance of their assay by testing a minimum of 30 positive specimens and 30 negative natural clinical specimens as determined by an authorized assay.*”<sup>29</sup> Additionally, the clinical performance data should demonstrate a minimum of 95% positive percent agreement (i.e., sensitivity) and negative percent agreement (i.e., specificity).<sup>30</sup> But FDA has not identified any need to require PCR testing for clinical cases to be followed by Sanger-based or other sequencing. We believe that clinical diagnoses can be supported following PCR analyses with a positive percent agreement and negative percent agreement greater than or equal to 95%.<sup>31</sup> In the Footnotes, reference <sup>29</sup> is listed as “<sup>29</sup> Id. at 18.”, which in turn directs to a statement “<sup>18</sup> We support the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if it they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.” There is no definition of authorized assay in this statement. So, the FDA has failed to name an assay that he or the FDA considers authorized. In the Footnotes it refers to a document “<sup>30</sup> *Molecular Diagnostic Template for Commercial Manufacturers, July 2020, at 16, <https://www.fda.gov/media/135900/download>.*” However, The FDA Molecular Diagnostic Template for Laboratories [8] states:

“**B. MEASURAND:** *Specific nucleic acid sequences from the genome of the SARS-CoV-2.*”

So, according to the FDA the measurand, also known as an object being measured, is specific nucleic acid sequences from the genome of the SARS-CoV-2. PCR cannot determine specific nucleic acid sequences.

In order to cover up the failure to follow FDA’s Guidance stated in The Molecular Test Template, the agency simply glossed over it by writing a Footnote “<sup>31</sup> *When a new test is*

*evaluated by comparison to a non-reference standard because no consensus reference standard exists, information on the accuracy of the new test cannot be estimated directly. As a result, performance is demonstrated by the ability of the new test to agree sufficiently with a comparative method. The comparative results are called “positive percent agreement” (which corresponds to sensitivity) and “negative percent agreement” (which corresponds to specificity). The use of this language reflects that the estimates are not of accuracy but of agreement of the new test with the non-reference standard. See Statistical Guidance for Diagnostic Tests, at 11.”“*

It was astonishing to read a statement from the FDA as late as December 11, 2020 claiming “no consensus reference standard exists” on evaluation of the accuracy of the new test for detection of SARS-CoV-2 RNA while hundreds of thousands of full-length genomic sequences have been deposited and published in the GenBank and other global databases. These nucleotide sequences do show that a consensus reference standard, in terms of viral genomic sequences, does exist. The FDA Molecular Diagnostic Template for Laboratories [8] clearly states that the currently used SARS-CoV-2 assay is a real-time RT-PCR test intended for the [**presumptive**] qualitative detection of nucleic acid from the SARS-CoV-2. The FDA Molecular Diagnostic Template for Laboratories [8] further states “*False results can be investigated using an additional EUA RT-PCR assay, and/or Sanger sequencing.*” Since no EUA RT-PCR assays have been validated for their ability to detect specific SARS-CoV-2 nucleic acid sequences, Sanger sequencing is the only reliable technology to detect and verify the consensus reference SARS-CoV-2 RNA.

8. Under **III. B. 2. Petitioner’s Argument Regarding HPV Testing** in the Letter the FDA states the following:

*“But the recommendations in that guidance have no applicability to the clinical trials for COVID-19 vaccines. The recommendations in the HPV Testing Guidance are for developers of new tests and relate to evaluation of new testing products. Specifically, the guidance recommends that developers of a new HPV test evaluate the ability of the new test to detect the targeted HPV genotypes by comparing the results obtained using the new test to results obtained using either an FDA-approved HPV test that detects the same genotypes, or PCR followed by Sanger sequencing.<sup>33</sup> That is, when developing a new HPV testing technology, one option for manufacturers to evaluate the accuracy of the technology is to confirm whether clinical specimens in fact contain the targeted HPV genotype by comparing the results from the manufacturer’s test to the results from Sanger sequencing. The HPV Testing Guidance that Petitioner identifies does not recommend that PCR tests used to diagnose HPV infections in individuals be followed by Sanger sequencing when the tests are used for aiding the diagnosis of an individual’s infection.*

*Therefore, we do not agree that Petitioner’s example supports Petitioner’s requested action.”*

In this statement, the FDA tries to justify its double standard used in asymmetrical implementation of drug laws in diagnostics, i.e., one for developers of new tests and one for regulating tests for diagnosis of an individual’s infection, or another one for the clinical trials in vaccine development. However, the FDA must use a uniform standard for all because double standards come at the expense of public interest, and are in opposition to FDA regulations. The FDA has not advanced any theoretical or scientific justification for the existence of such double standards. The basis for the Petitioner using the HPV testing guidance of the FDA in supporting the demand for Sanger sequencing confirmation of all SARS-CoV-2 RT-qPCR positive test results is that the HPV guidance has already created the precedent. Specifically, the FDA Guidance on HPV testing advises “*One way to do this is to perform an FDA-approved HPV test*



that detects the same genotypes as your test, or you may perform PCR followed by sequencing of the amplicon (PCR/Sequencing) on your clinical specimens and compare these results to the results of your device.”[26] This standard can be applied to any nucleic acid tests for SARS-CoV-2. Since none of the RT-qPCR tests marketed under EUA are FDA-approved, the only acceptable option is to perform a bi-directional Sanger sequencing on the cDNA PCR amplicon.

The FDA should be familiar with its own Guidance documents on NAAT assays for the detection of pathogen genomes, using nucleic acid sequencing for confirmation of test results. Additional examples are illustrated as follows.

a) In a document entitled “Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA - Class II Special Controls Guidance for Industry and FDA Staff, the FDA advises “*Detection of an EV genome in CSF by two different well-characterized and validated nucleic acid amplification tests (NAAT). The NAAT primers pairs should generate amplicons from different genomic regions. One of the NAAT assays should provide sequence information. **Bi-directional sequencing should be performed** on both strands of the amplicon and the generated sequence should be of an acceptable quality (quality score of 40 or higher as measured by PHRED or similar software packages) and should match the reference or consensus sequence.*”[27]

b) In a document entitled “Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens - Class II Special Controls Guideline for Industry and Food and Drug Administration Staff, the FDA advises:

**“(1) Reference Method**

*Your clinical studies must compare the performance of your device to a composite reference method derived from the results of culture and identification, and direct specimen nucleic acid amplification. More specifically, the composite reference method is defined as testing for MTB-complex by:*

*i. Mycobacterial culture and isolate identification **AND***

*ii. Direct specimen testing using a FDA cleared or approved nucleic acid amplification based diagnostic device or a non-FDA cleared or approved validated direct nucleic acid PCR **amplification test followed by bi-directional sequencing.***

*If you use a non-FDA cleared or approved validated direct nucleic acid PCR amplification test followed by **bi-directional sequencing**, then you must provide additional information regarding the safety and effectiveness of the test to support a determination by the Agency that the test is appropriate for use.*

*A positive result is defined as a sample which tests positive by **either i or ii** above.*

*A negative result is defined as a sample which tests negative by **both i and ii** above.”[28]*

Based on FDA established guidance for molecular diagnostic tests for HPV infection, enterovirus infection and *Mycobacterium tuberculosis* infection, a validated direct nucleic acid PCR amplification test followed by bi-directional sequencing is an acceptable molecular diagnostic method even though these sequencing-based tests are non-FDA cleared or approved. There is no good reason for the FDA to reject validated direct nucleic acid PCR amplification test followed by bi-directional sequencing to perform accurate assays for detection of SARS-CoV-2 RNA in clinical specimens for patient management as well as for vaccine efficacy evaluation since there are no FDA-cleared or FDA-approved tests available. There is no acceptable excuse for the FDA to allow vaccine manufacturers to use presumptive tests only without subsequent confirmatory tests in clinical trials for vaccine efficacy evaluation.

## C. FINDING EXCUSES FOR USING PCR TESTS WITH HIGH FALSE-POSITIVE RATES FOR THIS VACCINE TRIAL

9. Under **III. B. 3. Petitioner’s Arguments Regarding Vaccine Trial Protocols** in the Letter, the FDA states the following:

- a) *“We (FDA) generally agree that “DNA sequencing” after PCR testing is “accepted technology,” but we do not agree that this means PCR testing for SARS-CoV-2 must be followed by Sanger-based sequencing for confirmation of infectious agents. That is, for the reasons explained above, we do not agree that PCR testing for SARSCoV-2 must be followed by Sanger-based sequencing in order to diagnose a clinical case of COVID-19,<sup>39</sup> in a clinical trial or otherwise.”*

To support its position of relying RT-qPCR testing for diagnosing SARS-CoV-2, the FDA further quoted reference <sup>39</sup> *““The CDC case definition for COVID-19 notes that confirmatory laboratory evidence is “[d]etection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical specimen using a molecular amplification detection test.”“*

As elucidated above, in molecular science RT-qPCR assays measure cumulative fluorescent signals as a result of DNA probe hydrolysis, and do not detect severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA). For detection of viral RNA, the FDA guidance as expressed in “Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA” clearly stated *“**Bi-directional sequencing** should be performed on both strands of the amplicon and the generated sequence should be of an acceptable quality (quality score of 40 or higher as measured by PHRED or similar software packages) and should match the reference or consensus sequence.”*[27] The FDA is trying to create an inferior standard for NAAT detection of viral RNA in order to inflate the number of SARS-CoV-2 infections, by deviation from the established FDA standard for the detection of viral RNA in clinical samples.

- b) In response to the Petitions about the WHO guidance on using nucleic acid sequencing for SARS-CoV-2 RNA detection, the FDA claimed *“This WHO guidance does not state that nucleic acid sequencing is critical in all circumstances in order to test accuracy. Rather, it states that the sequencing should be performed “when necessary.” Among other things, the guidance contains testing recommendations for when the virus is known to be circulating in a geographic area, and for when the virus is not known to be circulating. When the virus is not known to be circulating in an area, the WHO guidance recommends sequencing as an option. But for areas with established COVID-19 virus circulation, the WHO guidance does not list sequencing as a recommended testing option. We note that this WHO guidance was drafted towards the beginning of the current pandemic, before the development of many of the NAATs that are currently in use. We also note that it does not make any recommendations related to confirming COVID-19 cases in vaccine clinical trials.”* In this statement, the FDA agrees that for a geographic area where the SARS-CoV-2 is not known to be circulating, DNA sequencing confirmation is *“an option”*, and for areas with established COVID-19 virus circulation, DNA sequencing is not needed, according to the WHO Guidance.

However, in the WHO document cited by the FDA, the phrase *“areas with established COVID-19 virus circulation”* also refers to *“areas where COVID-19 virus is widely spread”*. [29] In the Letter, The FDA has not proposed how to define *“established COVID-19 virus circulation”* or *“areas where COVID-19 virus is widely spread”*. However, according to the CDC COVID DATA TRACKER where average daily cases per 100,000 in the last 7 days in different states and the U.S. territories are tabulated and published, [30] as of January 4, 2021, there were no COVID-19



cases in American Samoa, Federated States of Micronesia, Northern Mariana Islands, Palau and the Republic of Marshall Islands. The states with the highest numbers of daily cases of >80/100K are Arizona 121.8, California 97.1, Tennessee 92.5, South Carolina 90.9, Kansas 88.5, Arkansas 88, Oklahoma 83.6, Utah 82.9, West Virginia 82.5, and New York 80.6. The states and the territories with the lowest daily case numbers are Minnesota 29.1, Oregon 27.2, Puerto Rico 23, Vermont 17.5, Hawaii 9.2. Virgin Islands, 7.4, Guam 5.4.

Data Table for Average Daily Cases per 100k in Last 7 Days

COVID | Updated: Jan 4 2021 12:16PM

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State/Territory †	Average Daily Cases per 100k in Last 7 Days ‡
Arizona	121.8
California	97.1
Tennessee	92.5
South Carolina	90.9
Kansas	88.5
Arkansas	88
Oklahoma	83.6
Utah	82.9
West Virginia	82.5
New York*	80.6
Rhode Island	79.3
Georgia	78.9
Alabama	76.6
Mississippi	74.8
Connecticut	69.6
Indiana	68.4
Massachusetts	67.1
Louisiana	66.6
North Carolina	66.5
Nevada	66.4
Delaware	66
Kentucky	63.2
Ohio	62.3
Texas	61.5
Florida	60.5
New Hampshire	59.3
Pennsylvania	57.9
New York City*	57.6
New Mexico	57.4
Virginia	52.5
Nebraska	51.9
South Dakota	50.7
Idaho	50.3
New Jersey	49.6
Illinois	47.3
Missouri	46
Alaska	44.4
Maryland	44
Wisconsin	43.3
Iowa	42.5
Wyoming	41.3
Colorado	40.3
Maine	38.8
Montana	34.8
Washington	33.7
District of Columbia	31.6
North Dakota	31.5
Michigan	31.2
Minnesota	29.1
Oregon	27.2
Puerto Rico	23
Vermont	17.5
Hawaii	9.2
Virgin Islands	7.4
Guam	5.4
American Samoa	0
Federated States of Micronesia	0
Northern Mariana Islands	0
Palau	0
Republic of Marshall Islands	0

According to a public document titled “Pfizer and Biontech announce vaccine candidate against covid-19 achieved success in first interim analysis from phase 3 study”, the Phase 3 clinical trial of BNT162b2 began on July 27, 2020 and enrolled 43,538 participants. The first interim efficacy analysis was conducted on November 8, 2020 by an external, independent Data Monitoring Committee (DMC) from the Phase 3 clinical study. So, the entire Phase 3 study was observed in a period of 105 days from July 27 to November 8, 2020 [31], and eventually data collection extended to November 14, 2020, according to information presented at the VRBPAC meeting.

During these 111 days of observation, there were 170 mild cases of COVID-19, as specified in the study protocol and 10 severe cases of COVID-19, which were observed in the trial. [32]

As a result, the Pfizer vaccine Phase 3 clinical trial was conducted in a population whose average daily COVID-19 cases per 100K was  $[(170+10) \times 100,000/43,538]/111=3.7$

The number 3.7 is even lower than the lowest number of the average daily COVID-19 cases per 100K observed in any American states and territories (Guam 5.4) except those far-away islands with zero cases. Therefore, it can be readily concluded that the Pfizer vaccine Phase 3 clinical trials were conducted in areas where COVID-19 virus is NOT widely spread, or the virus is NOT known to be circulating in the population, or the trial missed many cases. As the FDA agrees with the WHO Guidance that nucleic acid testing for SARS-Cov-2 in area where the virus is NOT known to be circulating, nucleic acid sequencing should be an option for COVID-19 case confirmation. Refusal to confirm the preliminary positive RT-qPCR test results by nucleic acid sequencing for evaluation of the Pfizer vaccine efficacy is against the standard set by the WHO, which is also promulgated by the FDA itself.

It is well known that when the case prevalence is extremely low in a population, the positive predictive value of an imperfect test may drop down to an unacceptable level. Due to the lack of specificity of symptoms that have been used to trigger RT-qPCR testing for SARS-CoV-2, it is likely that many positive test results are false positives in the Phase 3 trial unless the positive samples are re-tested by Sanger sequencing for confirmation.

The FDA's statement "*We also note that it does not make any recommendations related to confirming COVID-19 cases in vaccine clinical trials*" is of interest because it implies that in its opinion laboratory tests for confirming COVID-19 cases in vaccine clinical trials can be totally deviated from acceptable international standards without transparency.

In the Letter, FDA's statement "*We note that this WHO guidance was drafted towards the beginning of the current pandemic, before the development of many of the NAATs that are currently in use.*" implies that the WHO Guidance emphasizing the need for confirmation of SARS-CoV-2 RT-qPCR test results is old and out of date. This is absolutely untrue. As late as December 14, 2020 the WHO issued a new notice titled "*WHO Information Notice for IVD Users Nucleic acid testing (NAT) technologies that use real-time polymerase chain reaction (RT-PCR) for detection of SARS-CoV-2*". In this Notice the WHO states "*WHO has received user feedback on an elevated risk for false SARS-CoV-2 results when testing specimens using RT-PCR reagents on open systems.*" The WHO advises "*Users of RT-PCR reagents should read the IFU carefully to determine if manual adjustment of the PCR positivity threshold is necessary to account for any background noise which may lead to a specimen with a high cycle threshold (Ct) value result being interpreted as a positive result. The design principle of RT-PCR means that for patients with high levels of circulating virus (viral load), relatively few cycles will be needed to detect virus and so the Ct value will be low. Conversely, when specimens return a high Ct value, it means that many cycles were required to detect virus. In some circumstances, the distinction between background noise and actual presence of the target virus is difficult to ascertain. Thus, the IFU will state how to interpret specimens at or near the limit for PCR positivity. In some cases, the IFU will state that the cut-off should be manually adjusted to ensure that specimens with high Ct values are not incorrectly assigned SARS-CoV-2 detected (sic) due to background noise.*" [33]

A more recent document titled "Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health. Geneva: World Health Organization", published on January 8th, 2021, further confirms the position of the WHO on the role of gene sequencing by

declaring that “SARS-CoV-2 gene sequencing can be used in many different areas, including improved diagnostics, development of countermeasures, and investigation of disease epidemiology.” [34] Vaccine is definitely one of the countermeasures.

It is irresponsible for the FDA to allow Pfizer to use unverified RT-qPCR test results with a very high Ct value to qualify COVID-19 cases with mild non-specific clinical symptoms in a population with a very low COVID-19 prevalence rate as endpoints in vaccine efficacy evaluation while intentionally misquoting the WHO Guidance to cover up its actions.

c) In the Letter, the FDA disagrees that when FDA issued a letter authorizing emergency use of the CDC 2019-Novel Coronavirus (2019-nCoV) Real Time Reverse Transcriptase (RT)-PCR Diagnostic Panel for the presumptive qualitative detection of nucleic acid from the 2019-nCoV on February 4, 2020, the very word “**presumptive**” carries the meaning of uncertainty in diagnosis. The FDA has allowed laboratories to use “presumptive” molecular tests to diagnose COVID-19 cases based on which public health policies are made for population lockdowns and shutting down schools and businesses, and for artificially inflating the vaccine efficacy in the Pfizer vaccine clinical trials while they know that a simple routine Sanger sequencing of a short segment of SARS-CoV-2 gene RNA can eliminate all false-positive test results. This very action with its resulting negative impacts on the economies of the country should be brought to public attention, and the responsible agencies should be held accountable.

d) In the Letter, the FDA wrote:

*Petitioner’s assertion: “In addition to false-negative results, these RT-qPCR test kits under EUA also generate false-positive test results.” CP at 5.*

*FDA response: While we agree that no test is 100 percent accurate, this does not support Petitioner’s request that FDA require PCR positive cases to be confirmed with Sanger-based sequencing in clinical trials for COVID-19 vaccines.*

This statement does not make sense. First, the FDA is wrong in claiming “no test is 100% accurate”, an attempt to gloss over the false-positive test results often generated by the RT-qPCR test kits permitted to be marketed under EUA by the FDA. The fact is that a correctly performed bi-directional Sanger sequencing of a unique 398-base segment of the SARS-CoV-2 N gene is 100% specific with no possibility of false positivity.[19] Submission of a 398-base sequence to the GenBank for BLAST analysis will induce a report of 100% ID sequence match with that of SARS-CoV-2 with an e-value of 0.0, as shown in the copy of a BLAST report, pasted below. An e-value of 0.0 in a BLAST report is indicative of 100% specificity in molecular identification. Even the FDA cannot refute its validity.

Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/  
human/USA/Wuhan-Hu-1/2020, complete genome.

Sequence ID: MW425855.1 Length: 29840 Number of Matches: 1

Score	Expect	Identifies	Gaps	Strand				
736 bits (398)	0.0	398/398 (100%)	0/398 (0%)	Plus/Plus				
Query 1	CAATCC	TGCTAA	CAATGCTGCA	ATCGTCA	CAACTTCTCA	AGGAAACA	CAATTGCCAAA	60
Subjct 28698	CAATCC	TGCTAA	CAATGCTGCA	ATCGTCA	CAACTTCTCA	AGGAAACA	CAATTGCCAAA	28757
Query 61	AGGCTT	TCTACG	AGAGGAGC	AGAGCGGC	AGTCAAGC	CTTCTCGT	TTCATCACG	120
Subjct 28758	AGGCTT	TCTACG	AGAGGAGC	AGAGCGGC	AGTCAAGC	CTTCTCGT	TTCATCACG	28817
Query 121	TAGTCG	CAACAG	TTCAAGAA	TTCAACTC	CAGGAGC	AGTAGGG	GAACCTTCTC	180
Subjct 28818	TAGTCG	CAACAG	TTCAAGAA	TTCAACTC	CAGGAGC	AGTAGGG	GAACCTTCTC	28877
Query 181	AATGGC	TGGCAAT	TGGCGGTG	ATGCTT	TGCTT	TGCTGCT	TGACAGATTGA	240
Subjct 28878	AATGGC	TGGCAAT	TGGCGGTG	ATGCTT	TGCTT	TGCTGCT	TGACAGATTGA	28937
Query 241	GCTTGAG	AGCAAAA	TGCTTGG	TAAAGGC	CAACAACA	CAAGGC	CAAACTGCTCA	300
Subjct 28938	GCTTGAG	AGCAAAA	TGCTTGG	TAAAGGC	CAACAACA	CAAGGC	CAAACTGCTCA	28997
Query 301	ATCTGC	TGCTGAG	GCTTCTA	AGAAGC	CTTGGCA	AAAAAC	GTAAGC	360
Subjct 28998	ATCTGC	TGCTGAG	GCTTCTA	AGAAGC	CTTGGCA	AAAAAC	GTAAGC	29057
Query 361	TGTAA	CAAGCTT	TCGGAG	ACGCTGGT	CCAGAACAAA	398		
Subjct 29058	TGTAA	CAAGCTT	TCGGAG	ACGCTGGT	CCAGAACAAA	29095		

In essence, the FDA first created an untruth, which is “no test is 100 percent accurate”, by making a declaration without any scientific basis. Then he in turn claimed that this untruth “does not support Petitioner’s request that FDA require PCR positive cases to be confirmed with Sanger-based sequencing in clinical trials for COVID-19 vaccines.”-because “no test is 100 percent accurate”. The purpose may have been to allow using inaccurate RT-qPCR tests to manipulate endpoint statistics for inflating the efficacy of the Pfizer vaccine in prevention of COVID-19.

e) In the Letter, the FDA wrote:

*While FDA has identified some flaws with some tests, there are many FDA-authorized tests for which FDA has not issued any such alerts (including many tests that use PCR technology, such as Cepheid Xpert Xpress SARS-CoV-2, Roche cobas SARS-CoV-2 real-time RT-PCR test, and Abbott Molecular/RealTime SARS-CoV-2 assay). Moreover, FDA has not stated that samples identified as positive in PCR testing need to be confirmed by Sanger-based sequencing.*

The FDA admitted that some of the FDA-authorized tests have been found to be flawed. However, the FDA has followed a uniform protocol to authorize RT-PCR tests for SARS-CoV-2 RNA detection under EUA. Specifically, the FDA Guidance [8] recommends using a Comparator Method for percent agreement performance calculations for evaluation of new RT-PCR test kits. The FDA requires re-testing with the newly introduced test kit a minimum 30 natural positive clinical specimens and a minimum 30 natural negative clinical specimens for comparisons. Positive percent agreement should be calculated in comparison to an EUA RT-PCR test. Negative result agreement may be calculated in comparison to an EUA RT-PCR test. FDA uses 95% positive and negative agreement as acceptable clinical performance for EUA. Therefore, all EUA RT-PCR test kits on the market should have the same degree of performance accuracy, including bad or good results. If the FDA has found that these EUA RT-PCR test kits, which were supposed to be comparable in performance, are in fact generating test results that are no longer comparable, a reasonable expectation is for the FDA to demand using Sanger sequencing to find out: Which EUA RT-PCR test kits are really at fault? It is irresponsible for the authorized civil servants in the FDA to gloss over such an important issue, which is affecting the health of the citizens and the national economy.

f) In the Letter, the FDA wrote:

*FDA’s COVID-19 Testing Guidance states that all clinical tests should be validated prior to use, and provides recommendations for developers regarding testing that should be performed to demonstrate, in support of an EUA submission, that a SARS-CoV-2 test is validated based*

*upon the underlying technological principles of the test.<sup>44</sup> However, FDA does not recommend that clinical results generated from PCR testing should be corroborated with Sanger-based sequencing in order to confirm the clinical performance of a test. Rather, the Molecular Test Template merely states that false results observed during the evaluation of an assay “can be investigated using an additional EUA RT-PCR assay, and/or Sanger sequencing” in order to provide the results of the discordant analysis to FDA.*

This is an ambiguous statement designed so that the manufacturers of the test kits do not have to use generally accepted scientific approach to validate the analyte for accurate molecular COVID-19 diagnosis. The FDA continued issuing warnings of faulty EUA RT-PCR tests on the market, as late as January 4, 2021.[35] Manufacturers of newly introduced faulty RT-PCR kits are able to shop around to find the most suitable equally faulty EUA RT-PCR assay for generating a set of comparable test results to meet the FDA acceptable requirement when Sanger sequencing is not used as a standard for result comparisons. FDA regulations require validation of tests according to a gold standard, not to a standard chosen by the test developer.

- g) In response to Petitioner’s assertion: “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 is recommended”, the FDA wrote:

*“FDA’s recommendations regarding validation are for the testing technology, not clinical results. Petitioner’s requested action would not be consistent with FDA’s recommendations for clinical testing for HPV when performed by sensitive and accurate PCR tests.”*

This is a convoluted and confusing statement made by the FDA. The FDA appears to be claiming that validation for testing technology has no relationship with clinical testing or is different from technology used to identify HPV infection. Every medical doctor in practice and every medical student knows that there are no “*clinical results*” of HPV infection of the uterine cervix because HPV infection is asymptomatic. HPV infection is totally dependent on detection of HPV genomic DNA in the cervicovaginal cell specimens. The FDA guidance clearly stated that if the manufacturer of a new test cannot use an FDA-approved test as the comparator for accurate evaluation, they can use a conventional PCR amplicon as the template for a bi-directional Sanger sequencing for test validation. There are no “*FDA’s recommendations for clinical testing for HPV when performed by sensitive and accurate PCR tests.*” The latter statement is a fabrication. Since there are no FDA-approved RT-qPCR test kits available for SARS-CoV-2 detection, it is entirely reasonable for the FDA to require Sanger sequencing of a PCR amplicon to verify all RT-qPCR test results, especially for the test results used in vaccine efficacy evaluation, as stated in the October 2020 Guidance as follows- It is all about Clinical Endpoints, Clinical Studies and Clinical Samples to be validated by laboratory testing:

***“ C. Safety and Effectiveness Information.***

*The EUA request should include the following safety and effectiveness information, which will inform FDA’s determination regarding the product’s benefit-risk profile:*

*1. Bioassays for assessment of clinical endpoints*

*The diagnostic bioassays that were used to assess study endpoints of clinical studies supportive of the EUA request should be identified. FDA expects that the standard operating procedures (SOPs) and validation reports for the final assay methods, and a list of all laboratories where the clinical samples have been tested, will be submitted to support the EUA request.” [3]*

For another example, the FDA standard guidance on Clinical Studies for the Detection of viral RNA can be found in a document titled “**Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA - Class II Special Controls Guidance for Industry and FDA Staff**”. [27]

In this document, the FDA clearly stated “***Bi-directional sequencing should be performed on both strands of the amplicon and the generated sequence should be of an acceptable quality (quality score of 40 or higher as measured by PHRED or similar software packages) and should match the reference or consensus sequence***”. The relevant section is copied and pasted below as evidence.

#### **“8. Clinical studies**

*You should conduct prospective clinical studies to determine the performance of your device for all the specimen types you claim in your labeling. You should prospectively collect the specimens from individuals with signs and symptoms consistent with clinical suspicion of meningitis or meningoencephalitis. You should describe the protocol of each clinical study (including the inclusion and exclusion criteria, study endpoints, acceptance criteria), and a description of how the studies support the proposed intended use. You should include a sufficient number of samples so that results will be statistically and clinically meaningful. Archived samples may be useful to provide specimens from patients who have symptoms of meningitis, and from whom fresh specimens may not be readily available (e.g., CSF from very young patients). When using the archived specimens, selection protocols should be used to minimize bias, and appropriate archives should be selected. Furthermore, samples should be masked to avoid testing bias. If both fresh and archived frozen samples are tested, we recommend that you analyze the data separately. For archived samples, results should be represented as percent agreement.*

*We recommend that you assess and compare the performance of your device to a predetermined algorithm that uses composite reference methods. Additionally, your device should also be compared to EV viral culture. The composite reference methods should include laboratory results such as:*

- 1. Methods that provide clinical evidence consistent with meningitis, for example, laboratory results such as CSF Gram stain, CSF bacterial culture, CSF glucose, CSF-blood glucose ratio, CSF total protein concentration, CSF leukocyte count. Results from additional specimen types, e.g., stool specimen may also be part of the composite reference method.*
- 2. Detection of an EV genome in CSF by two different well-characterized and validated nucleic acid amplification tests (NAAT). The NAAT primers pairs should generate amplicons from different genomic regions. One of the NAAT assays should provide sequence information. ***Bi-directional sequencing should be performed on both strands of the amplicon and the generated sequence should be of an acceptable quality (quality score of 40 or higher as measured by PHRED or similar software packages) and should match the reference or consensus sequence [Ref. 10, 17].****

h) In the Letter, the FDA wrote:

*“While a test sample that is analyzed with a Ct value of 42.9 may find a very small concentration of viral fragments that may be of uncertain clinical significance, Petitioner does not provide any evidence that the Cepheid test being used in Pfizer’s (or any other) clinical trial is being used to analyze samples that actually have a Ct value of 42.9. It appears that Petitioner*



*found the 42.9 number in the Instructions for Use document for the Cepheid test, available on FDA's website.<sup>46</sup> However, the levels cited by Petitioner refer only to the range of concentrations analyzed to establish the test's limit of detection—not to the number of amplification cycles to be used for clinical diagnosis. Therefore, the levels cited by Petitioner do not demonstrate any accuracy problems with the test. The levels cited by Petitioner also do not demonstrate the need for follow-up Sanger-based sequencing.”*

The FDA's assertion that, “a test sample that is analyzed with a Ct value of 42.9 may find a very small concentration of viral fragments that may be of uncertain clinical significance” is untrue because it is not supported by scientific evidence. RT-qPCR tests using Ct 42.9 as cut-off will mostly detect back-ground non-target DNAs. For example, in an extensive research article titled “SARS-CoV-2 Transmission among Marine Recruits during Quarantine”, the authors reported that among marine recruits under strict observations and controlled studies SARS-CoV-2 genomes were finally obtained from only 32 of 51 participants (62.7%) who had positive RT-qPCR results for SARS-CoV-2 even when the Ct values used as the positive cut-off was set below 30. [36]

In an article titled “Correlation Between 3790 Quantitative Polymerase Chain Reaction–Positives Samples and Positive Cell Cultures, including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates”, the authors reported that patient samples tested “positive” for SARS-CoV-2 by RT-qPCR at Ct 25 yielded up to 70% virus culture-positive results. At Ct 30, the virus culture-positive rate dropped to 20%. At Ct 35, the value the authors used to report a positive result for RT-qPCR, <3% of cultures were positive. [37] That means a 97% false-positive rate in routine RT-qPCR if virus culture is used as the gold standard for comparison.

Another group of scientists in Australia tested a commercial RT-qPCR test kit and found its positive predictive value for SARS-CoV-2 infection to be only 55.56%. The authors suggested that any positive results derived from one commercial test kit should be confirmed using another nucleic acid test or nucleotide sequencing. [38]

The WHO advised on December 14, 2020 “Users of RT-PCR reagents should read the IFU (Instructions for User) carefully to determine if manual adjustment of the PCR positivity threshold is necessary to account for any background noise which may lead to a specimen with a high cycle threshold (Ct) value result being interpreted as a positive result. The design principle of RT-PCR means that for patients with high levels of circulating virus (viral load), relatively few cycles will be needed to detect virus and so the Ct value will be low. Conversely, when specimens return a high Ct value, it means that many cycles were required to detect virus. In some circumstances, the distinction between background noise and actual presence of the target virus is difficult to ascertain.” [33]

The FDA defended Cepheid for setting a Ct 42.9 to detect a very small concentration of SARS-CoV-2 in clinical samples without supportive data. The FDA has not performed any experiments to back up this statement on behalf of Cepheid. The FDA wanted the Petitioner to prove that this high “number of amplification cycles to be used for clinical diagnosis” was being employed by Pfizer in its Phase 3 trials. This is grossly unreasonable. It was FDA's duty to request or to force the vaccine manufacturers to disclose the details of their laboratory specifications and data for transparency. The FDA is authorized to perform this official function. Citizen petitioners do not have this kind of power.

i) In the Letter, the FDA wrote:

*“We agree that no test is 100 percent accurate, and there may be small differences in the analytical performance between different test kits – even kits that are well-validated and reliable. But we do not agree that this justifies Petitioner's requested action – requiring follow-up with Sanger-based sequencing. Tests that are well-validated and reliable may appropriately be used to confirm COVID-19 diagnoses in patients, including study participants.”*

Where is the evidence that the PCR tests being used are “well validated and reliable”? There is none. According to an official correspondence titled “College of American Pathologists (CAP) Microbiology Committee Perspective: Caution must be used in interpreting the Cycle Threshold (Ct) value”, which was published in Clin Infect Dis. 2020 Aug 12:ciaa1199 and pasted below, the current NAATs granted EUA are not reproducible, even using split samples. Reproducibility using the same kit between labs is much worse. The Petitioner is concerned about a yes-or-no answer to a question: Is there in fact a genomic RNA of SARS-CoV-2, a life-threatening virus, in a person’s respiratory tract specimen when the sample tested is labeled RT-qPCR-positive? The consequences between a positive test result and a negative test result for SARS-CoV-2 detection are not “small differences” as the FDA is trying to lead the public to believe. The truth is that a yes or a positive answer may have serious consequences, including quarantine of the person being tested, putting this person into the same isolation room with COVID-19 patients for dangerous exposure, locking down the schools and businesses in the community with all negative impacts on local economies, and qualifying COVID-19 cases as endpoints for vaccine efficacy evaluation. The differences between yes and no answers are not small both to the individual citizens and to society. The FDA has been placed into a position of responsibility by the taxpayers to make very important decisions. Knowingly choosing not to use the best available technology to perform NAAT for the diagnosis of COVID-19 is inexcusable. In the entire Letter, the FDA has not denied that Sanger sequencing can be 100% accurate with 100% specificity in confirming SARS-Cov-2 detection. The agency refused to use it.

**College of American Pathologists (CAP) Microbiology Committee Perspective: Caution Must Be Used in Interpreting the Cycle Threshold (Ct) Value**

TO THE EDITOR—We read with great interest the article by Magleby and colleagues entitled “Impact of SARS-CoV-2 Viral Load on Risk of Intubation and Mortality Among Hospitalized Patients with Coronavirus Disease 2019” [1]. This article adds to the growing body of work on using the polymerase chain reaction (PCR) cycle threshold (Ct)-value associated with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA detection in clinical specimens as a prognostic indicator and to establish criteria for active infection and transmissibility. Although we recognize the importance of studying laboratory results and their relevance to care of patients with coronavirus disease 2019 (COVID-19), we wish to inform your readers of potential caveats that must be considered when applying published findings regarding Ct-values to their own patients’ results.

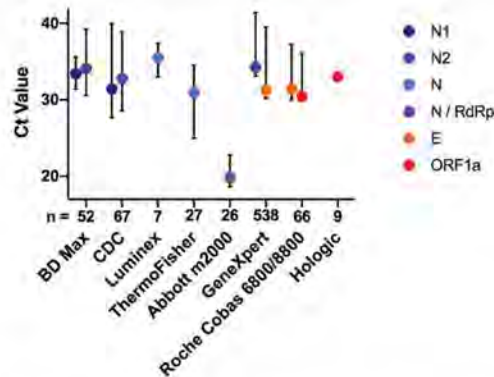
- 1) Specimen collection method, specimen source, transport media type and volume, duration from specimen collection to analysis, and days from infection to specimen collection can all impact the amount of viral RNA that could be detectable by an assay, and these variables are reflected in the Ct values.
- 2) No quantitative SARS-CoV-2 assays have received Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA). Additionally, no international, commutable standardized reference material is currently available, which would be needed for validation of quantitative assays that generate comparable results across manufacturers and

laboratories. Although specimens with lower Ct-values generally have more viral RNA than specimens with higher Ct-values, the quantitation and precision associated with those differences in Ct-values have not been determined.

- 3) Only traditional real-time PCR assays produce a Ct-value. Some diagnostic assays used to detect SARS-CoV-2 RNA use isothermal amplification methods, which do not produce a Ct-value. Other PCR platforms use nested PCR, which is not designed for quantitative interpretation.
- 4) Ct-values can vary significantly between and within methods. The College of American Pathologists (CAP) recently surveyed more than 700 laboratories using proficiency testing material produced from the same batch (Figure 1). The median Ct-values reported by the instruments for different FDA EUA methods varied by as much as 14 cycles. Within a single

test performed on the same instrument, the difference in the median Ct-values for different targets was as high as 3.0 cycles. Finally, within a single gene target for a single method, up to 12.0 cycle differences were seen across all laboratories. The assay and gene target used by Magleby et al, ORF1a detected by the Roche cobas system, differed by approximately 6.0 cycles across all laboratories responding to the survey. Many clinical laboratories are using multiple tests that assess different gene targets for SARS-CoV-2 and are performing testing on different platforms. This adds to the potential variability of Ct-values produced by a single laboratory.

The ongoing shortage of commercial testing reagents presents a major obstacle to conducting large research studies comparing testing platforms. We thus believe that data from the CAP proficiency testing survey



**Figure 1.** Ct values for gene targets and manufacturers for the same batch of testing material. Median Ct values (filled circles) and the range of Ct values from low to high (whiskers) are shown. The number of survey respondents using each method is indicated below the x-axis. Of note, the material used for the PT Survey did not contain all gene targets in use by commercial assays, and Ct values entered by laboratories under “Miscellaneous” were not incorporated into the data. Data from the users of the Cepheid GeneXpert and GeneXpert Xpress System were combined into a single category for the purposes of this visualization, as both systems employ the same test cartridge and there was likely misreporting between these 2 categories by survey participants. The Hologic category only includes values from the Panther Fusion SARS-CoV-2 assay, as the Hologic Aptima assay does not produce Ct values. Abbreviations: Ct, cycle threshold; PT, proficiency testing; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

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j) In the Letter the FDA wrote about the Cepheid test kits as follows:

*“The alert Petitioner identifies was issued by Diagnostic Laboratory Services Inc., a clinical testing laboratory in Hawaii, and appears to concern the Cepheid GeneXpert testing platform,<sup>49</sup> not the Cepheid Xpert Xpress SARS-CoV-2 assay that is identified in the Pfizer public protocol and with which Petitioner takes issue. In any case, the fact that tests run by one laboratory in Hawaii on Cepheid GeneXpert instruments may have yielded suspect results does not justify the action requested by Petitioner. If sponsors for vaccine clinical trials are using SARS-CoV-2 tests that are well-validated and reliable, there is no scientific reason to require follow-up Sanger-based sequencing.”*

This statement indicates that the FDA knows that various versions of EUA RT-qPCR test kits, even those made by the same manufacturer for the detection of SARS-CoV-2, such as the Cepheid GeneXpert testing platform and the Cepheid Xpert Xpress SARS-CoV-2 assay, may generate different test results, which may lead to false positives or false negatives. After being informed that a clinical testing laboratory in Hawaii was concerned about Cepheid GeneXpert testing platform generating false-positive result for SARS-CoV-2 in clinical specimens, the FDA engaged in covering up the potential defects of the Cepheid products and the faulty Phase 3 trial protocol for the Pfizer vaccine development instead of requesting the raw data from the vaccine manufacturer for a stringent review, as promised.

- k) In the Letter, the FDA further explained away the potential false positives generated by the Cepheid test kits as follows:

*“While the study cited by Petitioner found that some samples that were reported as positives using the Cepheid Xpert Xpress SARS-CoV-2 test did not report as positives using the comparison test, the study authors state that “[i]t is difficult to address the question on whether these specimens are true negative samples or low-positive samples with residual viral particles.”<sup>51</sup> That is, for the samples that were positive using Cepheid Xpert Xpress SARS-CoV-2 but not the other test, the study authors do not state that the samples were actually negative. Moreover, the study does not make any recommendations regarding the purported need to use follow-up Sanger-based sequencing on results that report to be positive using PCR testing.”*

Then the FDA further justified the “no need for Sanger sequencing evaluation” for the EUA RT-qPCR tests by stating the following:

*“<https://jcm.asm.org/content/58/8/e01136-20>. But the Abbott test used in the study, which is compared to the Cepheid Xpert Xpress SARS-CoV-2 test, is the Abbott ID NOW COVID-19, not the Abbott RealTime SARS-CoV-2 assay that is listed in the public protocol identified by Petitioner. We note that, on May 14, 2020, FDA issued a release alerting the public to early data that suggest potential inaccurate results from using the Abbott ID NOW point-of-care test to diagnose COVID-19 because the test may return false negative results. See Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test, May 14, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fdainforms-public-about-possible-accuracy-concerns-abbott-id-now-point>. Therefore, the fact that the Abbott ID NOW COVID-19 and the Cepheid Xpert Xpress SARS-CoV-2 test produced different results is not surprising. The existence of different results from the Abbott ID NOW COVID-19 and the Cepheid Xpert Xpress SARS-CoV-2 test do not support a need for follow-up Sanger-based sequencing from PCR tests that have demonstrated a positive percent agreement and negative percent agreement greater than or equal to 95%, which include the tests identified in the Pfizer public protocol.”*

These statements confirm that the FDA contradicts itself. First, the agency claimed the Cepheid Xpert Xpress SARS-CoV-2 test reported was compared with the Abbott ID NOW COVID-19, not

the Abbott RealTime SARS-CoV-2, implying that the latter Abbott test kit might generate better comparative results than the other Abbott kit without citing any evidence to support its claim. However, at the same time, the agency affirmed that all RT-PCR test kits granted EUA by the FDA have demonstrated a positive percent agreement and negative percent agreement greater than or equal to 95%. If the second statement is true, the first claim cannot be valid because the Abbott ID NOW COVID-19 test kit and the Abbott RealTime SARS-CoV-2 would have yielded similar results for comparison with the Cepheid Xpert Xpress SARS-CoV-2 test kit. Since all the test kits cannot generate consistent comparable results, Sanger sequencing is urgently needed as the *de facto* gold standard to find out the true positives among the “presumptive” positive specimens labeled by all EAU RT-qPCR tests. This would reveal the truth. The FDA chose to close its eyes at the expense of public interest. The Abbott RealTime SARS-CoV-2 assay apparently has different sensitivities of detection because the NAAT Detectable Units/mL by this assay can range from 5400 to 2700, according to the data published on the FDA website [39], which are copied and pasted below.

5400	Cepheid	Xpert Xpress SARS-CoV-2 test
5400	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay
2700	Abbott Molecular	Abbott RealTime SARS-CoV-2 assay

Why hasn't the FDA inquired which Abbott assay was in fact used for the Pfizer vaccine Phase 3 clinical trial and how the Abbott assay results were compared with the Cepheid test results?

- l) In the Letter, the FDA claimed that the Petitioner did not point out evidence that intramuscular injection of a very small amount of sterile saline in the placebo participants will not cause fever, local redness and swelling, and severe pain, or systemic reactions, which may cause unblinding and bias the reporting system in the Pfizer vaccine Phase 3 trials. The statement of the FDA is copied and pasted as follows.

*“In addition, Petitioner seems to also claim that follow-up Sanger sequencing is needed to address an asserted bias in the study design. Petitioner asserts that “it is commonly known” that injection of saline (i.e., the placebo) “will not cause fever, local redness and swelling, and severe pain, or systemic reactions.” CP at 8. Study participants who receive a placebo therefore “intuitively and reasonably know that they were not injected with a vaccine[.]” CP at 9. Petitioner states that this is relevant to his requested action because, according to Petitioner, this makes placebo participants more likely to report symptoms than vaccine recipients, thereby leading to the use of test kits that will cause “[a] higher number of false-positive test results” among participants in the placebo arm. CP at 9. However, Petitioner has not pointed to any evidence that use of saline injections biases the reporting of symptoms – much less that this asserted compromise leads to a greater number of false positives. Therefore, we do not agree that Petitioner has demonstrated that purported unblinding justifies the action requested.<sup>52,53,54</sup>*

As pointed out above, it is common knowledge that 0.5 mL of sterile normal saline is an innocuous material when injected intramuscularly into a healthy person. For the past century, students interested in health care science worldwide have been injecting 0.5 mL of sterile normal saline to each other's buttock in their practical educational classes under supervision of a nurse or physician instructor, with no adverse outcomes other than the minor “prick” from the needle. [6] Concerns about a breach in blindness or unblinding in the Phase 3 trials due to lack of vaccine-induced symptoms in the participants receiving saline placebo injection, which may lead to more PCR tests among the placebo-receiving participants, have been openly expressed by other scientists. [40]

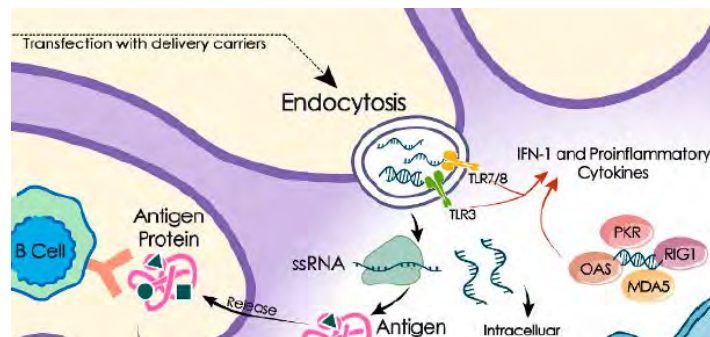


## D. GLOSSING OVER POTENTIAL RISKS OF AN mRNA VACCINE WHILE CONCEALING ITS TRUE EFFICACY

10. Under III. C. 1. a. **Petitioner Has Not Demonstrated Irreparable Injury** in the Letter, the FDA states the following:

*“Petitioner’s claim of injury is too remote. Petitioner asserts that Petitioner will be forced to receive an inadequately vetted vaccine due to mandatory vaccination requirements that purportedly may be issued by entities such as airlines and States. However, the PSA does not seek a stay of any FDA decision that will force any individuals to receive vaccines. FDA does not mandate vaccination. Rather, Petitioner seeks to stay a Phase 3 clinical trial due to asserted problems with the testing protocol but has not demonstrated that the continuation of the trial will cause States, airlines, or any other entity to issue requirements that will in turn cause Petitioner to be vaccinated against Petitioner’s will. There are numerous regulatory steps between the conduct of clinical trials and the existence and distribution of a vaccine that is available to the public – much less before any State or other entity makes any potential decisions regarding mandatory vaccination.<sup>56</sup> The continuation of clinical trials, alone, will not cause the asserted harm.<sup>57</sup> Thus, Petitioner has not demonstrated that the continuation of clinical trials under FDA IND will cause irreparable injury.”*

The FDA should know that all vaccines, including the Pfizer mRNA vaccine, have associated potential adverse reactions after injection into healthy humans. The nanoparticles composed of mRNA coated with phospholipids may act as potent toll-like receptor (TLR) agonists after endocytosis, causing local and systemic surges of IFN-1 and proinflammatory cytokines. The molecular focal point of this reaction is illustrated in the diagram cropped from a review article titled “mRNA Vaccine Era-Mechanisms, Drug Platform and Clinical Prospection.” [41]



TLR activation may lead to a variety of autoimmune disorders. Some of them are fatal. For example, TLR 7 activation may lead to severe thrombocytopenia in experimental animals, [42] and might have been the cause of death of a 56-year-old physician who developed fatal thrombocytopenia after receiving Pfizer vaccines. [43] Therefore, before introducing such a new vaccine whose active ingredient is synthetic mRNA coated with phospholipids in the form of nanoparticles without safety track record, a high benefit-to-risk ratio must be demonstrated without a reasonable doubt. The FDA is the gatekeeper to maintain this high benefit-to-risk ratio for approval of the Pfizer vaccine. The Petitioner simply requested that the FDA use due diligence to ensure that the preliminary laboratory test results, which the vaccine manufacturer used as the pivotal criteria in qualifying COVID-19 cases as endpoints for vaccine efficacy evaluation, are properly verified. If the vaccine’s efficacy is not as high as claimed due to false-positive test results in the Phase 3 clinical trials, the Petitioner and his fellow citizens may be forced by various business operators to take a vaccine with high risk and uncertain benefits in the name of COVID-19 prevention even if there is no government mandate to do so.

In an arbitrary dismissal of the Petitions, the FDA claimed that the Petitioner “has not demonstrated that the continuation of the trial will cause States, airlines, or any other entity to issue requirements that will in turn cause Petitioner to be vaccinated against Petitioner’s will” even though the Petitioner specifically pointed out such a probability. However, as soon as the FDA approved the Pfizer vaccine, the New York Times published a report titled “Employers Can Require Workers to Get Covid-19 Vaccine - The federal Equal Employment Opportunity Commission said employees could be barred from the workplace if they refused the vaccine.” [44] The Health News reported that the International Air Transport Association is in the final stages of developing a digital COVID-19 vaccine passport for travelers. [45] The Los Angeles Unified School District Superintendent already stated on record that students in the Los Angeles school district will have to be vaccinated before returning to the classroom. [46] Therefore, the FDA is cognizant that vaccine requirements are being rolled out by schools, industries, and International Air Transport operators to force large segments of the citizens, some against their will, to be injected with a potentially harmful vaccine, whose efficacy was evaluated using a preliminary test method whose false positive and negative rates are unknown, and which lacks FDA approval. It has been reported that a survey of the staff in a Chicago’s west side community hospital right before the vaccine came out showed that 40 percent of health care workers actually said they would not get the vaccine when it was their turn to take the vaccine [47] provided they had a choice.

**11. Under III. C. 1. b. Petitioner Has Not Demonstrated Sound Public Policy Grounds Supporting the Stay** of the Letter, the FDA states the following:

*Petitioner does not make any argument about sound public policy, but Petitioner does assert that the public interest weighs in favor of the requested relief “because improving the inaccurate 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.” PSA at 3.*

*We do not agree that Petitioner has demonstrated sound public policy grounds supporting a stay. Petitioner seeks a stay of a Phase 3 clinical trial. Although the mechanism by which FDA may “stay” a clinical trial is to issue a clinical hold, Petitioner has not identified any basis under 21 CFR § 312.42 or section 505(i)(3) of the FD&C Act for any clinical trial that would justify a clinical hold.*

*We conclude that a stay of a clinical trial is warranted only when a basis has been demonstrated for a clinical hold in accordance with 21 CFR 312.42 and section 505(i)(3) of the FD&C Act. Because Petitioner has not identified any such basis, we disagree that Petitioner has demonstrated sound public policy grounds supporting the requested stay. We note that if FDA becomes aware of circumstances justifying clinical holds, FDA will order clinical holds in accordance with 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act.*

*We also note that we disagree with the Petitioner’s justification for the request that PCR clinical diagnoses of COVID-19 be followed with Sanger-based sequencing (see discussion above). It would not be sound public policy to require testing protocols that lack scientific merit. Requiring scientifically-unjustified protocols would add unnecessary costs to the clinical trial process, which could disincentivize important medical research.”*

To support these assertions, the FDA repeatedly declared: “<sup>57</sup>... we do not agree with Petitioner that it is problematic for clinical trials to use PCR testing of study participants. We also do not agree with Petitioner that the proposed solution—following PCR diagnoses with Sanger-based sequencing—is necessary. Therefore, we do not agree with Petitioner’s assertion that there is harm to begin with.”



The FDA refused to accept the fact that the PCR testing system used for study of the vaccine trial participants in a population where the average daily rate of very mild COVID-19 cases, if confirmed, per 100,000 was as low as 3.7, is problematic. Numerous publications, including many from the WHO and the FDA as cited in this rebuttal, had already pointed out by December 2020 the potential false-positives and false-negatives generated by the EUA RT-qPCR tests permitted for preliminary detection of SARS-CoV-2 in clinical specimens. The Petitioner objects to the use of preliminary test results as the pivotal criteria to qualify COVID-19 cases as the endpoints for vaccine efficacy evaluation. The fact that the FDA rejected Sanger-based sequencing for confirmation of PCR test results as “testing protocols that lack scientific merit” shows that the agency does not understand that all NAATs are designed to determine the nucleotide sequence of the target DNA and that PCR is just a tool used to prepare the template for nucleotide sequence analysis. Alternatively, the FDA might have deliberately made such declaration to achieve a non-science-based agenda. In either case, the agency’s recommendation for approval of the Pfizer vaccine without diligent review of the raw data should be rescinded to protect the interests of the public.

12. Under **III. C. 1. c. Delay Would Be Outweighed by Public Health or Other Public Interests** of the Letter, the FDA states the following:

*“We conclude that staying clinical trials without justification would not be in the public health or public interest, and Petitioner has not set forth any justification under our regulations for staying trials that are under FDA IND. The interests of public health would not be served if a stay interfered with the conduct of clinical trials without justification.”*

The FDA claimed that the stay would have delayed the conduct of clinical trials. This is untrue. In the Petition to Stay, the Petitioner stated ***“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. If the Sponsor (BioNTech/Pfizer) is unable to perform confirmatory Sanger sequencing tests on these 180 RNA extract residual samples, the Petitioner hereby offers to re-test them immediately with Sanger sequencing 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.”***

The FDA knew or should have known that it would take 2 days to five days at the most for Pfizer to re-test the residues of the maximum 180 PCR-positive samples by Sanger sequencing to obtain irrefutable evidence to support its claimed 95% vaccination efficacy in prevention of COVID-19. It is disingenuous for the agency to claim that a delay of the vaccine approval for 2-5 days required for re-testing 180 sample residues to gain public confidence in the vaccine’s efficacy would have outweighed Public Health or Other Public Interests. The re-testing is especially crucial to support the claimed 95% vaccine efficacy in view of an alternative calculation showing that the vaccine efficacy is actually between 19% and 29%, [48] a figure much lower than the 95% as claimed.

13. Under **III. C. 2. Neither the Public Interest nor the Interest of Justice Support Granting a Discretionary Stay of Action** of the Letter, the FDA states the following:

*It is in the public interest and the interest of justice to ensure that clinical trials for COVID-19 vaccines continue to determine whether there are vaccines that meet all relevant regulatory requirements. Stays (or clinical holds) may only be justified when there is a basis to do so under 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act. It is not in the public interest or the interest of justice to stay clinical trials in response to a Petition that fails to demonstrate any justification under 21 CFR § 312.42 and section 505(i)(3) of the FD&C Act for a hold. Furthermore, if we required unnecessary steps in the testing to confirm COVID-19 diagnoses, the public interest would not be served because clinical trials should not be required to include*

*protocols that lack scientific merit. Requiring scientifically-unjustified protocols would add unnecessary costs to the clinical trial process, which could disincentivize important medical research.*

The FDA's claim that an extra 2-5 days re-testing to confirm the 180 preliminary positive test results would be against public interest or the interest of justice, and could disincentivize important medical research, is disingenuous. It is the FDA's agreement to accept data generated using an obviously flawed procedure that lacks scientific merit. Using added unnecessary costs to the clinical trial process as an excuse for the FDA's inaction is absurd because the Petitioner has offered the Sanger retesting for all 180 positive samples free of charge, and will submit the data to the FDA for evaluation.

14. Under **IV. Conclusion** of the Letter, the FDA states the following:

*“FDA has considered Petitioner’s requests as they relate to the “study design for the Phase III trial[] of BNT162b (NCT04368728)” and COVID-19 vaccine clinical trials. For the reasons given in this letter, FDA denies the requests in the CP and also denies the requests in the PSA. Therefore, we deny the Petitions in their entirety.”*

This is an arbitrary and capricious conclusion.

According to the Fact Sheet published by the FDA, each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19. [49]

According to the Pfizer Phase 3 trial protocol, “8.1. Efficacy and/or Immunogenicity Assessments,” 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.*

Since the mild clinical symptoms listed above are non-specific for COVID-19, the pivotal criterion for qualifying COVID-19 in the clinical trials is “SARS-CoV-2 NAAT-positive”. How to define “SARS-CoV-2 NAAT-positive” is the fundamental question in Pfizer vaccine efficacy evaluation. The vaccine must be proven truly effective in protecting against COVID-19 before it is used in the general population because the long-term safety of such a new vaccine in various segments of the population is unknown.

The Pfizer vaccine is the first of any prophylactic mRNA vaccines scheduled to be injected into healthy humans without a safety-and-efficacy track record. In principle, the synthetic mRNA encoding the spike protein (S protein) of SARS-CoV-2 is packaged as stable nanoparticles consisting of ionizable cationic lipids, natural phospholipids, cholesterol and polyethylene glycol (PEG). The purpose is to direct the human cells to produce a virus protein as an antigen. If successful, the virus protein produced by the host cells will serve as a subunit virus antigen to stimulate immune responses in the host. However, subunit and synthetic peptide/protein antigens by themselves are relatively weak immunogens and require the assistance of specially designed adjuvants to generate a robust and persistent immune response. The stable nanoparticles composed of ssRNA coated with phospholipids have self-adjuvanting properties after being transfected into the cytoplasm by endocytosis. After entering the endosomal/lysosomal compartments of the cell, these adjuvants can activate certain toll-like receptors to initiate a series of innate immune responses, which are required to boost antibody production. And PEG can extend the half-life of these nanoparticles in the host after injection. Since ssRNAs are potent TLR 7/8 agonists and phospholipids are potent TLR 4 agonists, they will activate a series of toll-like receptors, which will lead to strong and long-lasting adaptive immune responses through tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interferon- $\gamma$  (IFN- $\gamma$ ) and other proinflammatory cytokines that are secreted by activated immune cells.[41] However, TNF- $\alpha$  and IFN- $\gamma$  may cause serious adverse effects in certain genetically and physically predisposed individuals.

Since the 1980s, TNF- $\alpha$ , especially in combination with IL-1 $\beta$ , has been known to cause myocardial depression in animals and humans with potentially fatal outcomes. [50-52] Some of the sudden unexpected deaths after injection of the Pfizer vaccine have been reported in the news media. For example, a formerly healthy 41-year-old female healthcare worker died unexpectedly 48 hours after injection of the Pfizer coronavirus vaccine. [53] On January 27, 2021, a local news radio reported that a 60-years old X-ray technician at South Coast Global Medical Center in Santa Ana, California died after receiving 2nd Pfizer vaccine. The deceased apparently died of uncontrollable hypotension and renal failure. [54] These and other similar unexpected deaths after injection of the Pfizer vaccine cannot always be explained away by declaring “lack of evidence linking vaccination to death”. In fact, these unexpected heart failures may be caused by a sudden discharge of TNF- $\alpha$  by macrophages with activated toll-like receptors while these activated cells were clustering in the myocardium. Another vaccine, Gardasil, which is also known to contain viral nucleic acids according to an FDA announcement [55], has been reported to be associated with unexpected deaths among healthy vaccinees after receiving Gardasil injections. At autopsy, these unexpected death cases may show no cause of death. The anatomical findings in the myocardium may range from totally normal to extensive inflammatory cell infiltration. [56, 57]

IFN- $\gamma$  is known to play important roles in the pathogenesis of autoimmune neuroinflammation, which under certain conditions may lead to multiple sclerosis. [58]

Overproduction of TNF- $\alpha$  in women may lead to obstetric complications, such as recurrent pregnancy loss, early and severe pre-eclampsia, and recurrent implantation failure syndrome. [59]

Therefore, there is scientific evidence in the public domain to suggest that potential health risks may be associated with injection of mRNA vaccines into the human body. The FDA is responsible to ensure that the benefits of the newly introduced mRNA vaccine indeed outweigh its potential risks. The primary benefit for the American citizens who consent to be injected with this potentially harmful vaccine is to reduce the risk of getting SARS-CoV-2 infection, or the risk of becoming a case of COVID-19. Since the Phase 3 clinical trial for the efficacy of the Pfizer mRNA vaccine was primarily based on surveys of the participants developing a mild nonspecific symptom associated with a presumptive positive RT-qPCR result for SARS-CoV-2 RNA in a nasopharyngeal swab

specimen, the presumptive positive RT-qPCR test results were the pivotal criteria to qualify COVID-19 cases as the endpoints for vaccine efficacy evaluation. As none of the RT-qPCR tests used to obtain the presumptive positive results for endpoint determination in the Pfizer vaccine clinical trials have been compared and verified with an FDA-approved test, it is reasonable to request that the FDA demand the vaccine manufacturer to re-test the residues of the presumptive positive samples with a Sanger sequencing method to prove that every one of the 170 to 180 presumptive positive samples in fact contains a segment of SARS-CoV-2 genome. This would be the minimum requirement to gain trust of the American citizens who may be forced to take this vaccine in order to return to normal life. The FDA has not presented a science-based reason to support its arbitrary and capricious denial of the requests in the Citizen's Petition and in the Petition for Stay of Action.

By denying the requests in the Citizen's Petition and in the Petition for Stay of Action, the FDA has deprived the American citizens of their basic rights to informed consent, which must be made based on reliable truthful clinical trial data presented to the FDA for evaluation.



Sin Hang Lee, MD, F.R.C.P.(C)

Petitioner

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# **Allegheny County v. The Cracked Egg**

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IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PA

COUNTY OF ALLEGHENY,  
a political subdivision  
of the Commonwealth of  
Pennsylvania,

Plaintiff,

v.

THE CRACKED EGG,  
LLC,

Defendant.

CIVIL DIVISION

GD No. 20-9809

TYPE OF PROCEEDINGS:  
Preliminary Injunction

DATE:  
January 27-29, 2021  
January 29, 2021 - Vol. III

BEFORE:  
Hon. John T. McVay, Jr.

REPORTED BY:  
Melissa J. Gasper  
Official Court Reporter

COUNSEL OF RECORD:  
For the County:  
Vijyalakshini Patel, Esq.  
Michael A. Parker, Esq.

For the Defendant:  
James R. Cooney, Esq.  
Sy O. Lampl, Esq.  
Robert Lampl Law Office

Dennis M. Blackwell, Esq.  
The Blackwell Law Firm

VOLUME III

PROCEEDINGS HELD VIA TEAMS

1  
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## I N D E X

David Magill	
Examination by Mr. Cooney	371
Examination by Ms. Patel	380, 390
Kelly Miller	
Examination by Mr. Cooney	395, 419
Examination by Ms. Patel	405, 441
James Lyons-Weiler, Ph.D.	
Examination by Mr. Lampl	453, 467
Examination by Ms. Patel	458, 505

## 1 P R O C E E D I N G S

2 THE COURT: Good morning everyone. This  
3 is Judge McVay. I believe that we have everybody.  
4 My law clerk checked.

5 I want to briefly reiterate the remote  
6 access rules. I think that I have said them just  
7 about every morning and everyday at some point.

8 You just can't record or take pictures or  
9 audio or any kind of reproduction of today's hearing.  
10 That is what the court reporter basically does by  
11 taking down the transcript and that becomes the  
12 official record, but that's the rule, and if you were  
13 to violate it arguably it sets up a situation where  
14 you could be prosecuted and/or found in contempt.

15 I think that I have gone over that with  
16 everybody and I believe that everybody has agreed.  
17 With that we're going to proceed.

18 I believe that we need to hear from about  
19 three more witnesses I think from defense, clean up  
20 exhibits and hear closing arguments today. That's  
21 basically the game plan for today as far as I think.

22 Mr. Cooney, it looks like you are calling  
23 the next witness. Is that correct?

24 MR. COONEY: I am calling the next  
25 witness, Your Honor. We're calling David Magill.

1 THE COURT: Mr. Magill, where are you?

2 THE WITNESS: I am right here, Your  
3 Honor.

4 THE COURT: Would you raise your right  
5 hand for me.

6 -----

7 DAVID MAGILL

8 a witness herein, having been first duly sworn, was  
9 examined and testified as follows:

10 -----

11 DIRECT EXAMINATION

12 BY MR. COONEY:

13 Q. Good morning, Mr. Magill. Would you spell  
14 your name, please.

15 A. Yes. My name is David Magill, M-a-g-i-l-l.

16 Q. Mr. Magill, are you a restaurant owner in  
17 the Commonwealth of Pennsylvania?

18 A. Yes. I am at my current location for 23  
19 years now.

20 Q. And what is the name of your restaurant?

21 A. Magill's Grill and Mogi's Irish Pub.

22 Q. What kind of restaurant is it? Can you tell  
23 us.

24 A. It is a full service family oriented --

25 MS. PATEL: Objection. What is the

1 relevance of this witness' testimony?

2 THE COURT: You are asking for a proffer?

3 MS. PATEL: Yes.

4 MR. COONEY: I am happy to make an offer  
5 of proof. Mr. Magill is going to testify about his  
6 23 years in business, how many employees that he has,  
7 how many tables that he has, how the COVID mitigation  
8 orders have impacted his business both financially  
9 and with his employee situation and his customers,  
10 and he is going to talk about his knowledge of the  
11 restaurant business in general, statistics related to  
12 percentage or number of restaurants that have closed  
13 in Pennsylvania because of the shutdown and he is  
14 going to talk about the fact that he is aware of  
15 statistics and studies that show that restaurants are  
16 very small contributors to the spread of the COVID-19  
17 virus.

18 MS. PATEL: Your Honor, Mr. Magill is not  
19 being offered as an expert witness, so his knowledge  
20 of the restaurant industry or any statistic is  
21 irrelevant. On top of that, he is not subject to  
22 health department orders because his restaurant is  
23 located in Westmoreland County.

24 I see no relevance to this witness'  
25 testimony to whether The Crack'd Egg is subject to



1 the orders that were issued by the health department  
2 on August 11th.

3 THE COURT: Well, go ahead. You wanted  
4 to respond briefly, Mr. Cooney?

5 MR. COONEY: Yes, I do, Your Honor. The  
6 restaurants in Westmoreland County are subject to the  
7 same restrictions. They are subject to the  
8 governor's targeted mitigation order --

9 THE COURT: Yes. Let me interrupt you.  
10 I am not too worried about Westmoreland County. It  
11 is more to me where does this fit into the injunction  
12 analysis? That would be what I would like you to  
13 respond to.

14 It is a relevancy objection. I am not  
15 worried about -- well, let me ask it this way.

16 Are you offering him as some kind of expert  
17 at the moment?

18 MR. COONEY: No, Your Honor.

19 THE COURT: So he is a fact witness and  
20 he is a lay witness and he is allowed to have an  
21 opinion even as a lay witness, but it is largely  
22 related to restaurants, the impact the orders have on  
23 the restaurant business --

24 MR. COONEY: That's correct.

25 THE COURT: And where does that fit into

1 the injunction analysis?

2 MR. COONEY: I think that it fits into  
3 the defense, irreparable harm --

4 MS. PATEL: Your Honor, irreparable harm  
5 is about The Crack'd Egg and the constituents -- or  
6 Allegheny County itself. It is not about Mr. Magill  
7 or his restaurant and they are not subject to the  
8 health department.

9 THE COURT: I am going to allow the  
10 testimony to the extent that I have to weigh the  
11 harm. I have to look at the public health and to me  
12 the harms, and we're going to hear argument at the  
13 end of the case, but I will tell you right now that I  
14 have to weigh the potential harm to the public health  
15 and then what the other interest is here in The  
16 Crack'd Egg, and to the extent that there is a  
17 business interest certainly and an impact on the  
18 business, that seems to be the main argument that I  
19 have heard, that the orders are a nullity, but  
20 clearly yesterday I heard a lot of significant  
21 testimony from The Crack'd Egg and primarily from  
22 Mrs. Waigand saying the impact on her business. That  
23 was what she told me mostly.

24 She told me that she never required masks  
25 either, but she said that this had a -- I think that

1 she told me roughly \$50,000 to let's say \$10,000 or  
2 \$12,000 based on the orders, loss of gross revenues.  
3 So she has testified to an impact.

4 I am going to allow this testimony, too,  
5 along those lines, and we will consider it in the  
6 overall analysis of the injunction when I am weighing  
7 the interests that need to be analyzed under the six  
8 prongs.

9 I understand that you are saying irreparable  
10 harm here is to the general public and that I think  
11 is the analysis that I have to undertake, but you  
12 still have to analyze the other interest of the other  
13 party too in the context of the six prongs, and to  
14 the extent that this evidence may be helpful, I am  
15 going to hear it and overrule your objection.

16 MR. COONEY: Thank you, Your Honor.

17 THE COURT: You may proceed.

18 Q. Mr. Magill, and you may have said this, how  
19 long have you been in business?

20 A. At this location going on 23 years.

21 Q. Did you have prior restaurants?

22 A. Absolutely. I have opened restaurants  
23 involved with other partners and as I opened mine  
24 myself.

25 Q. And your current restaurant, Mogie's Irish

1 Pub, how many employees do you have?

2 A. Currently I bounce between 12 and 14 due to  
3 the COVID restrictions.

4 Q. Before the COVID did you have more  
5 employees?

6 A. I have had as many as 29 and 30 in the past,  
7 yes.

8 Q. And how did the COVID impact the number of  
9 employees?

10 A. The lack of business to support them. When  
11 you are -- nobody opens a restaurant or pub saddled  
12 with a restriction of 25 or 50 percent of occupancy  
13 of prospective business.

14 So with the drop to 50 percent and then 25  
15 percent something had to give and it was mostly wait  
16 staff, some kitchen personnel and expediting  
17 personnel, so we had to short staff in order to cut  
18 payroll.

19 Q. And you said that the drop to 50 percent and  
20 then to 25 percent that would be the governor's  
21 occupancy limits imposed by the targeted mitigation  
22 order?

23 A. Correct.

24 Q. And have you complied with those limits?

25 A. I have.

1 Q. How has that impacted your bottom line?

2 A. My profits have dropped exponentially.

3 During the initial closing I lost \$92,000 in gross  
4 sales when we were relegated to take out only.

5 Over the holiday restrictions and closings I  
6 had lost \$76,000 in gross sales, they were Christmas  
7 parties that were canceled, and that didn't include  
8 the alcohol or liquor sales that would have stemmed  
9 from that also with that. So I was probably looking  
10 at over \$100,000 loss over the holiday season.

11 Q. And what is your profit margin at your  
12 restaurant?

13 A. Well, it varies. It depends on which --  
14 where your sales are, where your profit margin is  
15 higher on alcohol and it is lower, much lower on food  
16 generated sales, which we are relegated to.

17 So with the restrictions on bar and alcohol  
18 sales internally profit margins were skewed and  
19 dropped drastically and that is where we make up our  
20 difference usually to cover our overhead and our  
21 wages.

22 Q. Are you aware of general trends in the  
23 restaurant industry in Pennsylvania?

24 A. Absolutely.

25 Q. How do you keep aware of those things?

1           A.     I keep a history, a history log on weekly,  
2           monthly and annual statistics on weather, I keep  
3           weather because I have outdoors also, and I go by  
4           where the economy stands a lot of times.

5           Q.     Are you aware of how the COVID-19 mitigation  
6           efforts have affected the restaurant industry in  
7           general?

8           A.     Nationwide it is -- we're looking at around  
9           50 percent loss in our aspect of the service industry  
10          itself with another 20 percent perpetual free fall.  
11          Fifty percent of restaurants, mostly independents,  
12          will go out of business for good.

13          Q.     Is that trend similar in Pennsylvania?

14          A.     Absolutely probably more so than the  
15          nationwide statistics because there are a lot of  
16          states that aren't as heavily restricted as  
17          Pennsylvania is.

18          Q.     Are you aware of any studies on impact of  
19          restaurants on the spread of COVID-19?

20          A.     Yes. There are a few impact studies. None  
21          were done in the Commonwealth of Pennsylvania  
22          whatsoever. Studies that I read came out of -- one  
23          came out of Stanford and I don't remember if it was  
24          Harvard or another university where they did impact  
25          studies. However, the Commonwealth itself has done

1 nothing to prove its stance on mitigating by closures  
2 and restrictions.

3 Q. Do you have an opinion of whether or not  
4 restaurants contribute to the spread of COVID than  
5 any other business?

6 A. Do I have an opinion on that? Yes, I think  
7 that we're being scapegoated, I think that it was  
8 someone had to be picked in order to push this  
9 narrative.

10 I mean, whenever you see box stores and  
11 shopping malls and places as such, grocery stores,  
12 where there are way more people on top of each other  
13 and they are allowed to operate freely while we are  
14 the ones that are being restricted and closed. I  
15 said that it is a very arbitrary decision made by the  
16 Commonwealth and by other people as well.

17 Q. Do you have anything that you would like to  
18 add to this proceeding?

19 A. Absolutely. I am watching -- I consult  
20 restaurant -- Your Honor, I consult many restaurant  
21 and tavern owners. I have been doing so for probably  
22 the past eight months through all of this.

23 I am certainly well read in my business, I  
24 have been very successful in every business that I  
25 have ever opened. I have never lost one. I do very



1 well at what I do.

2 I listen to grown men and women crying,  
3 literally sobbing because they are losing it. There  
4 is nothing being offered by the Commonwealth of  
5 Pennsylvania or the County of Allegheny in order to  
6 supplement the losses that these businesses are  
7 incurring. They expect them to just close their  
8 doors, take their loss and try and recoup later with  
9 no help whatsoever.

10 I find it astounding that someone could go  
11 along with actions like this and feel like it is a  
12 fair practice. It is destroying a free market,  
13 destroying independent business owners.

14 MR. COONEY: Your Honor, I would like to  
15 just pause for a moment if I can.

16 THE COURT: Sure.

17 MR. COONEY: No further questions, Your  
18 Honor.

19 THE COURT: Cross-examination, Ms. Patel.

20 MS. PATEL: Yes.

21 CROSS-EXAMINATION

22 BY MS. PATEL:

23 Q. Mr. Magill, where is your facility located?

24 A. In Lower Burrell, Pennsylvania.

25 Q. What county is that in?

1           A.     Westmoreland.

2           Q.     Has the Allegheny County Health Department  
3 ever conducted an inspection of the facility?

4           A.     No, it has not.

5           Q.     Has the facility ever been issued a permit  
6 to operate from the Allegheny County Health  
7 Department?

8           A.     No, it has not.

9           Q.     Has the facility ever received any orders  
10 from the Allegheny County Health Department?

11          A.     No, it has not.

12          Q.     Are you aware of any restaurants who have  
13 had financial success during the pandemic caused by  
14 COVID-19?

15          A.     Financial success as in growth or as in just  
16 being able to stay afloat and stay open?

17          Q.     Where their profits have been decreased  
18 significantly or in some cases have actually  
19 increased?

20          A.     I am certain that there are probably some  
21 that have, absolutely. Pizza shops and take-out  
22 restaurants have exponentially grown because that is  
23 what they do for a living right off the bat. They  
24 don't have any indoor dining whatsoever. So once  
25 indoor establishments are shut down, those take-out

1 places grew.

2 Q. So are you suggesting that indoor dining  
3 establishments are not able to provide take out?

4 A. They can provide take out, but that is not  
5 what they are set up for. That is not how they are  
6 established. That is now how they do the majority of  
7 their sales.

8 Q. Has your facility ever been inspected by the  
9 Commonwealth, any agency of the Commonwealth?

10 A. Inspected? In what manner?

11 Q. Any manner. Food safety or just general  
12 health inspections.

13 A. We have a health department in Westmoreland  
14 County and yes, they always inspect our businesses.  
15 You have to have a health license.

16 Q. What about the Commonwealth of Pennsylvania;  
17 have they inspected your facility?

18 A. Once again, is it a health related question?

19 Q. Any COVID related inspections?

20 A. Is it an alcohol related question like --

21 Q. Yes, alcohol.

22 A. Certainly. They always have to come in  
23 also.

24 Q. You said that you did research across the  
25 Commonwealth, you looked at restaurants?

1           A.     No.

2           Q.     Maybe I am misunderstanding what you had  
3           said earlier.

4                     Did you say that you had done many research  
5           of food facilities across the Commonwealth and you  
6           created some kind of documents regarding your  
7           findings?

8           A.     I do research? No. I said that I have read  
9           research and I said that there is no research  
10          produced by the Commonwealth and proof that the  
11          service industry or restaurant industry is related to  
12          the spikes in COVID. The Commonwealth has done no  
13          research on that or produced any proof of that.

14          Q.     And you are saying that you haven't done any  
15          research either?

16          A.     I have read the articles on both sides, but  
17          none from inside the Commonwealth.

18          Q.     What do you mean by both sides and not from  
19          the Commonwealth?

20          A.     There are claims from a couple universities  
21          where they state that vaguely where the spike comes  
22          from and there are some articles that deny that the  
23          restaurant industry is responsible for spikes in  
24          COVID.

25          Q.     Have you researched the accuracy of any of

1           these articles, the method of the employee to conduct  
2           those studies?

3           A.       Most of them are usually sample surveys.

4           Q.       So you can't --

5           A.       I am not a fact checker. I couldn't give  
6           you a fact checking on their articles. I just read  
7           articles and make my own assessment.

8           Q.       Are you saying that you can't testify as to  
9           the accuracy of any of the articles that you just  
10          testified to today?

11          A.       The Stanford article, no, I can't say if it  
12          is true or false and I can't say that any of the  
13          articles are true or false on either side. They  
14          contradict each other.

15          Q.       Since you have admitted that some facilities  
16          could have done well during this COVID-19 pandemic  
17          would it be correct to say that maybe it was a poor  
18          business model for some facilities who did not do  
19          well financially in the last ten months?

20          A.       Yes, that would be a really, really absurd  
21          statement especially with the fact that places that  
22          are set up as indoor facilities are not set up to  
23          compete with places -- smaller overhead  
24          establishments that are set up for take out only and  
25          delivery only. It is a pretty broad stroke to paint.

1           Q.     You discussed sales and profit margins  
2           regarding not only your facility but other facilities  
3           in general that you said that you have looked at.

4                     Have you brought any of that paperwork with  
5           you today?

6           A.     No.  It wasn't requested.

7           Q.     The articles that you said that you read  
8           from Stanford and other sources that were not named  
9           by you, other than Stanford, did you bring any of  
10          those articles with you here today?

11          A.     No, I did not.

12          Q.     Do you have any medical epidemiological or  
13          immunological expertise?

14          A.     No, I do not.

15                     MS. PATEL:  Those are all the questions  
16          that I have for Mr. Magill.

17                     THE COURT:  I have a couple.  I think  
18          that I understand your testimony and I can tell you  
19          that I pretty much already believe -- well, I  
20          believed Mrs. Waigand yesterday on her numbers, and I  
21          think that it is almost common sense and I can take  
22          judicial notice of a reduction in capacity having a  
23          negative impact on a business.

24                     I just don't know anything about restaurants  
25          and I admire entrepreneurs that undertake that and

1 common sense tells me that there is an impact on the  
2 business by the governor's orders and a negative one  
3 and a loss of income just by numbers.

4 I also know that people fail when they try  
5 to a lot of people fail when they try to start a  
6 restaurant and when you said that the impact of 50  
7 percent, I just wanted to understand what you told me  
8 on that, that 50 percent will go out of business.

9 Is that your understanding from somewhere  
10 and maybe the Stanford article that as a result of  
11 executive orders or --

12 THE WITNESS: The 50 percent came from a  
13 national -- I believe that it was a national  
14 restaurant association.

15 THE COURT: Okay.

16 THE WITNESS: They had made the claim  
17 that 50 percent -- these are independents. They are  
18 the ones who take the --

19 MS. PATEL: Your Honor, can I object?

20 THE COURT: No. I asked the question, so  
21 he is answering my question, so I am sorry and I am  
22 going to overrule.

23 MS. PATEL: It is hearsay. He has been  
24 allowed a lot of hearsay statements.

25 THE COURT: Perhaps, but I wanted to hear



1 his opinion and the impact. Again, I ruled up front  
2 that I am allowing this in because I have to -- the  
3 irreparable harm that you are claiming is to the  
4 public, I agree, potentially, but I have to weigh the  
5 greater injury under the second prong and that is a  
6 balancing and that is related to the business. So I  
7 want to hear some evidence here and some testimony.  
8 That is where I am going.

9 Do I understand he going off some hearsay  
10 and things that he read? Yes, I understand that, but  
11 he is also a business owner, and again, I think that  
12 I can take judicial notice that there would be a  
13 significant negative impact on a business based on  
14 the orders.

15 It doesn't mean that I automatically think  
16 that the governor can't do what he did or whether the  
17 County -- I haven't ruled yet. I have to weigh and  
18 that is what I am doing.

19 Mr. Magill, if you can complete your answer  
20 or did I go on too long that you forgot what you were  
21 saying?

22 THE WITNESS: I believe that where we  
23 were looking at was --

24 THE COURT: The 50 percent.

25 THE WITNESS: Right.

1 THE COURT: Because restaurants go out of  
2 business.

3 THE WITNESS: Your Honor, the claim was  
4 at 50 percent and this was a few months back before  
5 this last closing of three weeks before the holidays.  
6 The claim was that 50 percent of restaurants or  
7 related service, industry-related businesses, will  
8 close their doors for good with another 20 percent in  
9 free fall.

10 Yes, I did read this. These were numbers  
11 that were impacted by the National Restaurant  
12 Association and passed forward.

13 As far as irreparable damage to the public,  
14 there is also irreparable damage to the business and  
15 those employees who work there, and people who can't  
16 pay their bills, people who couldn't buy their  
17 children things for Christmas, and people who can no  
18 longer find jobs in the industry.

19 THE COURT: I get that beyond the owners  
20 there are employees and so forth, yes, but that is  
21 part of the information, something that I have to  
22 analyze.

23 THE WITNESS: It is an additional  
24 fallout.

25 THE COURT: Again, but I don't know if

1           you answered my question. The 50 percent that is  
2           COVID related, that has nothing to do with the normal  
3           people that failed?

4                         THE WITNESS: In the top ten businesses  
5           for success in the United States, the restaurant  
6           business was number one. In the top ten businesses  
7           for failure in the United States, the restaurant  
8           business was also rated number one to help you  
9           understand.

10                        Now, did COVID push -- did COVID closures  
11           and restrictions push businesses to close that were  
12           already teetering? Absolutely, I am very certain  
13           that it did. There are very small margins for profit  
14           on the restaurant business and that absolutely put  
15           them over the edge further.

16                        THE COURT: I think that you have pretty  
17           much explained it for me. Any questions as a result  
18           of mine?

19                        I note your objection and I will put on the  
20           record, yes, I did give a lot of leeway on this  
21           witness, but I wanted to hear as it related to the  
22           injury conceptually to a restaurant business and  
23           employees. I would recognize that too.

24                        Anything else question-wise of this witness?  
25           I will go back to Mr. Cooney just in case.

1                   MR. COONEY: Your Honor, I think that the  
2 subject has been covered. I don't have anything  
3 else.

4                   THE COURT: And please, Ms. Patel, don't  
5 feel like if there is something that I asked that you  
6 want to ask about now, please ask.

7                   EXAMINATION

8                   BY MS. PATEL:

9                   Q.       Mr. Magill, have you conducted any  
10 independent research of your own on the effect of  
11 COVID-19 on the restaurant industry?

12                  A.       Have I had researched? Yes, I have  
13 discussed with many, many restauranteurs what they  
14 have gone through with via COVID-19 restrictions and  
15 closures. That is research.

16                   Have I talked to many, many people? Yes. I  
17 have talked to many, many restauranteurs on a weekly  
18 basis. They call me for assistance and advice.

19                  Q.       What do you talk to them about?

20                  A.       I give them advice about how to keep their  
21 business alive and keep it afloat and deal with the  
22 restrictions.

23                  Q.       So are you telling me that these anecdotal  
24 statements from people that you have spoken to is  
25 your research?

1           A.       Anecdotal? That would be --

2                   THE COURT: All right. I know. Yes. It  
3 is what it is and he answered your research question.

4                   Is it peer review double blind studies? No.  
5 He talked to other restaurant owners. I get it.

6                   THE WITNESS: The difference between  
7 success and failure, Your Honor. I am very  
8 successful in what I do.

9                   THE COURT: I get it. Any other  
10 questions, Ms. Patel?

11                   MS. PATEL: No, Your Honor.

12                   THE COURT: Thank you. Next witness,  
13 Mr. Cooney.

14                   MR. COONEY: Your Honor, I have a witness  
15 that is maybe not available for a couple minutes.

16                   THE COURT: We can take a quick recess.  
17 Is that what you want to do?

18                   MR. COONEY: Can we start at 10:00?

19                   THE COURT: Yes, we can start back at  
20 10:00.

21                   MR. LAMPL: Your Honor, just for  
22 housekeeping before we break, our final two witnesses  
23 will be Kelly Miller, who will be going first, and  
24 then James Weiler will be going second. Dr. Weiler  
25 will be available after 11:00.

1                   THE COURT: Okay. We will figure it out.  
2                   We're going to get all the testimony done today. I  
3                   am happy about that and then we will clean up the  
4                   exhibits, closing arguments and there we go.

5                   MR. COONEY: Thank you, Your Honor.

6                   (A short recess was taken.)

7                   THE COURT: This is Judge McVay. I'm  
8                   back in the conference. Let's go back on the record.

9                   I believe that, Mr. Cooney, this is your  
10                  next witness; correct?

11                  MR. COONEY: That's correct, Your Honor.  
12                  Our next witness will be Kelly Miller, but before I  
13                  start with Ms. Miller, I want to make a proffer.

14                  We talked about it the last two days that I  
15                  have a number of other restaurant owners that are  
16                  willing to testify. Their testimony would not be the  
17                  same as Mr. Magill's, but in large part it would be.

18                  My proffer is that Steven Salvi from  
19                  Cenacolo Restaurant, Colleen Melari-Baldwin from  
20                  Tootsie's Diner, Tracy Wilson from Devil's Eye  
21                  Brewing Company, Katie Yeschenko from Ham N Eggars  
22                  Diner --

23                  THE COURT: I am going to interrupt you  
24                  for just a minute just because I don't know if the  
25                  court reporter will need spellings and so forth, but

1 I am going to accept this proffer.

2 MR. COONEY: Your Honor, in addition we  
3 would have Jen Weight from Night Court, Mark  
4 McCandless from Wildlife Lanes and Lisa and David  
5 Spear from David's Diner.

6 THE COURT: Anything for the record,  
7 Ms. Patel? I had asked that we do it that way rather  
8 than hear from all nine witnesses. Anything that you  
9 want to add to that?

10 MS. PATEL: I would just say that --

11 THE COURT: You are largely objecting to  
12 that whole line of testimony?

13 MS. PATEL: Yes, yes.

14 THE COURT: I got it.

15 MS. PATEL: Irrelevant.

16 THE COURT: Yes, you are saying  
17 irrelevant, and my ruling was that it fits into the  
18 injury analysis. I have to decide whether the public  
19 health and the possible irreparable harm there and  
20 then the injury on the other side.

21 I am paraphrasing the six prongs, but I find  
22 it to be relevant in analyzing the interest that I  
23 have to balance under the preliminary injunction case  
24 law analysis.

25 MS. PATEL: I would like to add under the



1           injunction analysis it is the harm on the public  
2           versus the harm on The Crack'd Egg and that is why I  
3           find irrelevant any testimony that would be provided  
4           from any other food facility wherever it is located  
5           because it is not The Crack'd Egg.

6                        THE COURT: I note your objection.  
7           Mr. Cooney, next witness.

8                        MR. COONEY: Your Honor, the Defendant  
9           calls Kelly Miller occupational health and safety  
10          consultant.

11                      THE WITNESS: I am here, Jim.

12                      THE COURT: Where are you? I don't see  
13          you. I have my video on and my sound on.

14                      THE CLERK: The reason that she doesn't  
15          appear is that she is using her cell phone or  
16          landline for the audio. I can see the video, but  
17          because the Teams picks up the audio it is probably  
18          pulling her 717 number to the top. So if you scroll  
19          through the bottom, you should be able to find the  
20          video somewhere and then pin it if you would like to  
21          see her testify, her face.

22                      THE COURT: Another technological  
23          challenge for me here. I see her on the video and I  
24          would ask you to unmute and raise your right hand.

25                      Raise your right hand, Ms. Miller.

1 (Witnesses were severally sworn.)

2 THE COURT: Thank you.

3 MS. PATEL: And I ask that Ms. Miller  
4 speak up a bit.

5 THE WITNESS: Absolutely. Can you hear  
6 me better now?

7 MS. PATEL: A little bit.

8 THE WITNESS: I apologize. My computer,  
9 my laptop does not want to interphase the microphone,  
10 so calling in was my only other option.

11 THE COURT: Let's proceed.

12 -----

13 KELLY MILLER

14 a witness herein, having been first duly sworn, was  
15 examined and testified as follows:

16 -----

17 DIRECT EXAMINATION

18 BY MR. COONEY:

19 Q. Ms. Miller, do you prefer that I call you  
20 Ms. Miller or Kelly?

21 A. Either one, Kelly is fine, Judge, or Jim. I  
22 am not sure who asked the question.

23 Q. I asked the question.

24 Can you tell the Court about your  
25 educational background and how it relates to PPP.

1           A.       Yes.   Jim.   So I attended the Harrisburg  
2           Area Community College of Emergency Medical Services  
3           Academy in 2012, which I graduated with my EMT B  
4           certification and that is the basic level of  
5           certification for an emergency technician in  
6           Pennsylvania.

7                       From there I started to work as an EMT out  
8           in the field for several years, and during that  
9           course I also obtained my certification in  
10          ophthalmology and I eventually served as an EMT with  
11          Amazon.com.

12                      During that tenure with Amazon I was  
13          introduced to occupational health and safety in a  
14          much more specific way. As an EMT you are introduced  
15          to occupational health and safety as it relates to  
16          medicine because there are dangers that go along with  
17          any type of medical job and occupational safety.

18                      So when I started working at Amazon my role  
19          was to treat associates for both work related and  
20          non-work-related injuries, and in that role you work  
21          very closely, you are a member of the safety team and  
22          you work very closely with the workers' compensation  
23          department.

24                      So that's where I kind of got more of an  
25          introduction into -- actually I would say the

1 microintroduction into OSHA guidelines, OSHA  
2 regulations, occupational health and safety.

3 I also during that time went back to  
4 Harrisburg Area Community College and got my  
5 certification as a state instructor. So I became  
6 certified to teach EMS for the state of Pennsylvania  
7 and worked those jobs simultaneously.

8 I also went back to school at HACC to obtain  
9 my EMT A certification, advanced EMT. So that is a  
10 new level of certification basically between a basic  
11 and a paramedic, so that allows intravenous care,  
12 some other things that an EMT does not include. So  
13 education-wise technical or formal education I think  
14 that that covers the spectrum.

15 Q. Now, you touched on it that you were  
16 employed by Amazon.

17 Do you have prior employment that relates to  
18 PPE issues here today?

19 A. Yeah. So before Amazon again, I became an  
20 instructor with Harrisburg Area Community College,  
21 and when you teach emergency medicine there are  
22 several segments within the curriculum that is  
23 mandated by the National Registry that specifically  
24 pertain to PPEs in the workplace.

25 So prior to Amazon I started instructing in

1           2000 -- I believe '15, '14, '15 and you really start  
2           to not only make yourself aware of personal  
3           protection of equipment and how it pertains to the  
4           workplace, but you specifically get into its medical  
5           application.

6           Q.     I think that you said that you were involved  
7           in that at Amazon?

8           A.     That's correct.  So at Amazon as a member --  
9           as an on site medical representative and as a member  
10          of the safety team, the safety team is responsible  
11          for orienting and training new hires on the PPE  
12          expectations within the facilities.

13          Per OSHA regulations any time an employer  
14          requires PPE on a job they have to have a written  
15          program that they tried the PPE, what is the purpose  
16          of it, when should it be used, what is its  
17          application, how to properly care for it, et cetera.

18          So at Amazon where I first became involved  
19          with orienting and training staff specific PPEs that  
20          pertains to their specific roles within the building.  
21          I also instructed the CPR classes for the first aid  
22          responders that worked in the Amazon warehouse, so I  
23          was responsible for teaching them the PPE that is  
24          required in that role as a medical first responder as  
25          well.

1           Q.     And then tell us about your employment with  
2           Stericycle.

3           A.     Yes.    So when I started working at Amazon,  
4           again, I really got introduced and went into depth in  
5           OSHA regulations and occupational health and safety  
6           in a more formal setting and I loved it.  I loved the  
7           balance of an employer's responsibility to keep  
8           employees safe and the employee's responsibility to  
9           function within those restrictions.

10                    I started studying more on OSHA regulations  
11           and occupational safety and health and reached out to  
12           Stericycle.  So Stericycle is a compliance company  
13           that specializes in regulating waste disposal.  That  
14           includes medical waste, sharp containers, hazardous  
15           medical waste, et cetera, and they have a position  
16           that is titled health care compliance educator.

17                    So I reached out probably about six months  
18           before I gained employment with them and interest in  
19           that role and started working for them in January of  
20           2018.

21           Q.     While you were at Stericycle what did you  
22           do?

23           A.     So as a health care compliance educator for  
24           Stericycle I was responsible for going out on site at  
25           different medical facilities -- and I hesitate to say

1           medical facilities. They were facilities that  
2           weren't medical in nature, but had paid for the  
3           service.

4                        So we go to the client site and we basically  
5           perform OSHA required training on blood borne  
6           pathogens, hazardous chemical or hazardous  
7           communications, workplace safety and training  
8           including PPE and veterinarian workplace safety  
9           training, funeral home work place safety and  
10          training.

11                      So we would go on site to meet different  
12          customers who pay for the service, perform the  
13          trainings that we were contacted to perform, and then  
14          at the same visit we would walk through the facility  
15          and check on about -- I think that it is about 162  
16          items on our checklist that pertain to OSHA  
17          regulations and workplace safety.

18                      Essentially, Jim, it was a mock audit. I  
19          didn't work for OSHA, but we walked through and said,  
20          hey, if OSHA were to walk through your facility, are  
21          these items in compliance?

22                      We would then assist our customers in  
23          logging onto Stericycle's website that would help  
24          them complete their safety plan and have training  
25          records that they would access, blank records that



1           they could use, various documents that would help  
2           them be OSHA compliant.

3                       I did that, Jim, in two different  
4           territories. My first assignment was in the northern  
5           portion of New Jersey and some parts of New York and  
6           then I also moved to Pennsylvania where my territory  
7           was to be Pennsylvania, including Pittsburgh, and  
8           Delaware, the entire state, and the northern portion  
9           of Maryland.

10           Q.       Kelly, how did you learn about these OSHA  
11           standards that you were training other people about?

12           A.       So OSHA has lots of different educational  
13           courses that you can take. The minimum for  
14           Stericycle was the 30 hour OSHA course which I took  
15           in January of 2018.

16                       It is a assistant learning, a website based  
17           learning platform where you learn about OSHA  
18           regulations in general labor, general industry, and  
19           it goes -- it takes you through OSHA regulations and  
20           how to research and find out more about specific  
21           safety user.

22           Q.       Does OSHA have any standards relating to  
23           face masks?

24           A.       So OSHA -- the occupational health and  
25           safety -- OSHA stands for Occupational Safety and

1 Health Administration and they have what they call 29  
2 CFR.

3 CFR stands for Code of Federal Regulations.  
4 1910 is the general standard that was part of the  
5 Williams-Steiger Occupational Act instituted in 1970  
6 and that code or CFR 1910 is the regulation that  
7 covers general workplace safety, and specifically to  
8 your point OSHA does have within 1910 lots of  
9 regulations about PPE.

10 If you want me to just specifically get into  
11 what they say about personal protection or --

12 Q. Yes, that would be fine.

13 A. Okay. So per OSHA.gov PPE is defined as  
14 personal protective equipment, commonly referred to  
15 as PPE, is equipment worn to minimize exposure to  
16 hazards that cause serious workplace injuries and  
17 illness.

18 The injuries and illness may result from  
19 contact with chemicals, radiological, physical,  
20 electrical, mechanical or other workplace hazards.

21 Personal protective equipment may include  
22 such items as gloves, safety glasses, shoes, earplugs  
23 or earmuffs, hard hats, respirators, coveralls, vests  
24 and full body suits.

25 If PPE is to be used, and again this is per

1 OSHA.gov, a PPE program should be implemented. This  
2 program should address the hazards present, the  
3 selection, maintenance and use of the PPE, the  
4 training of employees, and this is very important,  
5 Jim, it goes onto say the monitoring of the program  
6 to ensure its ongoing effectiveness.

7 Q. And are you familiar with any manufacturers  
8 of mask guidelines?

9 A. Yes. So OSHA and the CDC work together.  
10 OSHA has regulations that are very specific and in  
11 OSHA interpretation letters, which are published on  
12 their website usually if somebody has a question or  
13 an employer has a gray area that is not specifically  
14 spelled out by an OSHA directive, they defer to CDC  
15 guidelines.

16 So CDC has a section of their department  
17 called NIOSH. NIOSH stands for National Institute of  
18 Occupational Safety and Health. So it essentially is  
19 a federal agency responsible for conducting research  
20 and making recommendations in the prevention of  
21 workplace injury and illness.

22 So specifically when you go to NIOSH's  
23 website and you research the efficacy of masks in the  
24 workplace they point blank tell you on the website to  
25 find out specifics about the PPE check the

1 manufacturer's website. So NIOSH's website refers  
2 you to the mask manufacturer.

3 As you well know, Jim, if an employee is  
4 injured on the job and becomes injured or ill  
5 involving a PPE the manufacturer is also culpable if  
6 the PPE was used in the manner it was intended. So  
7 you always refer to the manufacturer's  
8 recommendations in trying to decide what PPE is  
9 ineffective or inappropriate.

10 THE COURT: I am sorry, Ms. Miller. I am  
11 going to interrupt just because I think that you are  
12 getting into some opinion testimony now when the  
13 focus, I think, still should be on your  
14 qualifications.

15 The way that it works is that once we go  
16 through your qualifications and Mr. Cooney makes a  
17 proffer as to your specific expertise the County gets  
18 to challenge that or agree with it and I don't want  
19 you to get into opinions yet. Okay?

20 THE WITNESS: Okay. Fair enough.

21 MR. COONEY: Your Honor, that being said,  
22 then I would proffer her as an expert in PPE based  
23 upon OSHA standards. I think that I have covered  
24 enough ground on that issue that she should be  
25 subject to cross-examination.

1                   THE COURT: I think that you did, too,  
2                   and I think that we started to go a little beyond it.  
3                   I just wanted to make sure that the County, if they  
4                   have any objections under Rule 702, which is what  
5                   we're operating under, 702 rules of evidence, so  
6                   Ms. Patel, are you handling this or is it Mr. Parker?

7                   MS. PATEL: I will be handling it, Your  
8                   Honor.

9                   THE COURT: Ms. Patel, questions on  
10                  Ms. Miller's qualifications?

11                  MS. PATEL: Yes. Hold on, please.

12                                   VOIR DIRE EXAMINATION

13                  BY MS. PATEL:

14                  Q.       Ms. Miller, we have been told that you are  
15                  an expert in PPE based on OSHA standards; is that  
16                  correct?

17                  A.       That's correct.

18                  Q.       Where in your educational background should  
19                  we look at to -- where in your educational background  
20                  are you basing your expertise in PPE and OSHA  
21                  standards on?

22                  A.       So OSHA qualifications just from the 30 hour  
23                  course alone qualify anybody who takes that course as  
24                  a person qualified to speak about general workplace  
25                  safety standards, the CFR 1910, which PPE is covered

1 in 1910.

2 So the 30 hour course alone qualifies  
3 somebody to be able to speak to the subject matter  
4 and train others. Again, demonstrated if you are  
5 looking at strictly educational -- well, if you look  
6 at education, again, my education goes back to 2012  
7 as far as starting to learn about workplace safety  
8 and then also when the state EMS board qualified me  
9 as an instructor then that gave me the ability to  
10 under Pennsylvania -- Commonwealth of Pennsylvania  
11 laws to teach others and that PPE and OSHA standards  
12 are included in that curriculum as well.

13 Q. Regarding certification from OSHA are there  
14 any other certifications that that agency provides?  
15 Is the certification that you undertook the only  
16 certification that OSHA provides or are there many  
17 more that you could have engaged in or studied in?

18 A. There are more that you can engage and study  
19 in, yeah.

20 Q. I want to go through your educational  
21 background.

22 So you said from September 2012 to December  
23 2012 you completed a course and obtained your EMT  
24 basic certificate; is that correct?

25 A. That's correct.

1           Q.     How many hours was spent in order to obtain  
2           that certificate?

3           A.     I believe that it was approximately a  
4           thousand.

5           Q.     Regarding your EMS certification in May of  
6           2015, the instructor training, how many hours did you  
7           spend in order to complete that program, that  
8           training?

9           A.     The educational in class portion 20 hours  
10          and then you have to have a proctor instructional  
11          period. I believe that that was another 60 hours, so  
12          roughly around 80.

13          Q.     Your American Heart Association Instructor  
14          Program in May 2016, how many hours did you have to  
15          spend for that to complete that program?

16          A.     That was a two-day class, so 16 hours, and  
17          then again three proctor sessions as an instructor  
18          and your sessions are about four hours, so 12, 16,  
19          right around 30.

20          Q.     Your national registration advanced EMT  
21          course in December 2016, how many hours did it take  
22          for you to complete that course?

23          A.     That course was also, I believe, right  
24          around the thousand hour mark.

25          Q.     Now, just to confirm, when you look at your

1 entire educational background that you were only  
2 pointing to the OSHA 30 hour occupational safety and  
3 health training as the basis for your expertise in  
4 PPE based on OSHA standards; is that correct?

5 A. No, I was actually involved. Again, I feel  
6 like I stated that before.

7 The national registry curriculum, to be able  
8 to teach emergency medicine, does have a segment  
9 regarding OSHA regulations and PPE safety, so on some  
10 levels I was introduced to it back then and I am well  
11 aware of it. We tested on the information and I  
12 would say that I deep dove into the information at  
13 Amazon.com in 2016. So there is kind of layers  
14 there.

15 Q. So regarding your advanced EMT course, what  
16 did you study in relation to face masks?

17 A. The national curriculum that is mandated in  
18 order to gain your A EMT has several chapters in the  
19 curriculum about PPE and OSHA guidelines.

20 Essentially in that curriculum, and I think  
21 that that is kind of where you thought that I was  
22 kind of veering a little bit, the curriculum talks  
23 about PPE and different types of protection, but the  
24 PPE is very specific when you are employed out in the  
25 work force you have to check with your employer as to



1           what PPE that they provide and what it is supposed to  
2           do.

3                       So we teach a very macro view of what PPE  
4           is, what its intention is. It is different types of  
5           PPE and gloves, masks, gowns, things of that nature,  
6           and in emergency medicine what you should look for in  
7           terms of when to use those items.

8                       Gowns are predominantly used in a trauma  
9           situation right where there is a potential for a lot  
10          of blood loss and loss of bodily fluid --

11                      THE COURT: I am going to shut you off  
12          again only because you are starting to get into that  
13          opinion area again and maybe the question might have  
14          invited a little bit of that, but stick to the  
15          qualifications, and let's wrap it up here too,  
16          Ms. Patel. I have a pretty good understanding of the  
17          educational background and I think the experience of  
18          this witness too.

19                      Any other questions?

20                      MS. PATEL: I do have quite a few, Your  
21          Honor.

22                      THE COURT: Here is what I am saying. It  
23          really needs to be about qualifications and I think  
24          that the resume, which actually I haven't reviewed  
25          because I withheld on all experts, but it is about

1           qualifications at the moment, not about the opinions  
2           that she wants to proffer.

3                       MS. PATEL: I agree. I will rephrase my  
4           question.

5           Q.       I wanted to know what courses that you took  
6           in your certification. If you could name the courses  
7           that you took.

8                       For example, did you take epidemiology, did  
9           you take immunology? That is what I am looking for  
10          in your education regarding your EMT course and your  
11          OSHA 30 hour occupational safety training.

12                      What course did you take?

13          A.       So to answer that specifically, when you  
14          talk about emergency medicine you are talking about  
15          basic pathos in pathology especially at the basic  
16          level. The advanced EMT takes that pathology a step  
17          further, but no, I did not take a course in  
18          epidemiology or the other specialties that you asked  
19          me about and I am not claiming to be an expert in  
20          those items.

21          Q.       Do you have a biomedical engineering degree?

22          A.       No, ma'am.

23          Q.       Have you ever developed a COVID-19  
24          protection plan?

25          A.       No, ma'am.

1           Q.     Do you have any self-experience or education  
2 regarding COVID-19 mitigation?

3           A.     I have the experience of what my job  
4 required when COVID was first discovered and that's  
5 the resources at OSHA that I was taught to follow,  
6 which is OSHA, and OSHA defers again, as I said  
7 earlier, and there is not a specific rule in OSHA  
8 about an item states refer to CDC. So I have the  
9 ability to research those items per CDC, but have I  
10 specifically been trained in COVID-19? No.

11          Q.     Have you ever developed or implemented a  
12 respiratory protection program in your workplace?

13          A.     Yes, I have.

14          Q.     Can you elaborate a little bit.

15          A.     At Stericycle, again as I stated, one of the  
16 functions was to go into different facilities and  
17 assist them in writing and implementing respiratory  
18 protection programs if it was required.

19                 Funeral homes have formaldehyde exposures,  
20 and based on permissible exposure limits at the  
21 funeral home, limits of formaldehyde at funeral  
22 homes, if it is above a certain level they have to  
23 write a respiratory protection program, and in the  
24 Stericycle software there is a template that helps  
25 facilities like that write their respiratory

1 programs. So I did help several funeral homes write  
2 and implement a respiratory protection program.

3 Q. This respiratory protection program that you  
4 were involved in writing and implementing, did it  
5 concern viral diseases that are primarily transmitted  
6 by droplets?

7 A. A respiratory protection program is not --  
8 in OSHA's 1910.134, it is not specific to viruses.  
9 It is -- you are asking if the respiratory program  
10 was implemented to address a certain thing.

11 Respiratory protection programs are, if they  
12 are required to be implemented, are implemented to be  
13 addressed by all respiratory facilities in their  
14 program, not just one.

15 Q. So just to confirm, just to make sure that I  
16 heard you correctly, did you say that 29 CFR 1910  
17 does not address viral diseases?

18 A. 29 1910 does not address specific  
19 pathological diseases, no. They are all clumped into  
20 a workplace hazard. Otherwise, every disease would  
21 have its own CFR regulations. If there is a  
22 potential for a workplace hazard, it is all included  
23 in 1910.

24 Q. You mentioned that you teach medicine. Can  
25 you elaborate on that.

1           A.     So, yes, I have taught several EMT and first  
2 responder courses at Harrisburg Area Community  
3 College. I taught, I would estimate, anywhere  
4 between 20 and 30 specific EMT classes probably to  
5 include roughly 300 students and I couldn't even  
6 estimate at how many CPR classes that I taught.

7                     Again, I taught for the college, I taught  
8 for a private company in several states sometimes as  
9 many as three classes a week and that would last four  
10 to five years.

11           Q.     Would it be fair to say that you do not  
12 teach medicine in a medical school?

13           A.     I do not teach medicine at a medical school.

14           Q.     Also, would it be fair to say that OSHA does  
15 not make any specific requirements regarding COVID-19  
16 mitigation in the workplace?

17           A.     That's correct.

18           Q.     The respiratory protection program -- I just  
19 want to make sure that I cover my bases -- the  
20 respiratory protection program, did it deal with any  
21 infectious disease?

22           A.     The respiratory protection program covers  
23 once again any workplace hazard that poses a  
24 respiratory threat.

25           Q.     How many years did you serve as an EMT, not

1 as an educator, but as a practitioner?

2 A. As a practitioner as an EMT, three years.

3 Q. You said Amazon. I am sorry. Can you  
4 restate what you did at Amazon.

5 A. Yes. At Amazon my title was on site medical  
6 representative. I worked in a section of Amazon  
7 called AMCARE.

8 Every Amazon distribution warehouse has an  
9 office called AMCARE and it is dedicated to treating  
10 associates who work there for any work-related injury  
11 or illness and non-work-related injury and illness.

12 That role is a member of the safety team and  
13 the safety team at Amazon is a separate entity. They  
14 separate production and safety so that that safety  
15 can operate without question, that we're operating  
16 for the employees' safety. In other words, an  
17 operations manager can't come in and tell us to make  
18 a judgment about something.

19 We operate on an autonomous separate entity.  
20 Still an entity of Amazon.

21 I also above and beyond treating emergencies  
22 or workplace illnesses I've also taught CPR, I was  
23 also responsible for orienting new hires on safety  
24 practices, I would walk the floor of the warehouse  
25 several times a day looking for safety concerns and

1 safety hazards.

2 We would coach and counsel associates as  
3 well as management on the daily practices,  
4 participated in a safety committee, and I have also  
5 worked as a liaison between production and, I am  
6 sorry, workers' comp for cases that were deemed  
7 work related.

8 Q. You said that as a part of your role at  
9 Amazon that you treat people for injuries.

10 What kind of injuries do you treat people  
11 for?

12 A. Everything from minor trauma, meaning bumps  
13 and bruises to lacerations, cuts, scrapes, and I have  
14 treated an associate for anaphylactic response,  
15 allergic reaction. I've treated associates for  
16 syncope episodes or loss of consciousness, I've  
17 treated associates with anxiety, we have several  
18 associates who were diabetic, again, both work and  
19 non-work-related injuries.

20 We treated associates for burns, mostly  
21 contusions, abrasions, trauma from bumping into  
22 things, I've treated an associate for a laceration of  
23 the cornea, a paper cut from a box. This is a gamut  
24 that goes on and on.

25 THE COURT: I want to wrap this up on

1           qualifications and get the argument under Rule 702  
2           for the record now.

3                       I think that I have allowed enough  
4           cross-examination. I have a good feel for the  
5           qualifications and the experience of this witness  
6           now.

7                       What I do want to clarify and I want to hear  
8           the motion from Mr. Cooney as to the specific  
9           expertise being proffered and then I will hear  
10          argument in response and then I will make my ruling,  
11          but I have heard enough. I get it. I have a good  
12          feel on what the experience and education of this  
13          witness is.

14                      MR. COONEY: Your Honor, my proffer would  
15          be that Ms. Miller is competent to testify on PPE  
16          selections under OSHA guidelines, under 29 CFR  
17          Section 1910. This witness is qualified to testify  
18          regarding CDC specifications for face masks  
19          regarding, and we haven't gone into this yet, but she  
20          is familiar with the specifications put out by  
21          3M Company, who is the largest manufacturer of facial  
22          protection and masks, as well as Medline.

23                      She will testify based upon those  
24          specifications put up by the manufacturer in  
25          conjunction with the OSHA guidelines with regard to



1 the effectiveness of face masks.

2 THE COURT: Response, Ms. Patel.

3 MS. PATEL: Your Honor, first I want to  
4 have on record the department did not finish its  
5 questioning regarding the qualification of  
6 Ms. Miller.

7 THE COURT: That's fair, I cut you off,  
8 but I have a good feel for the qualifications and  
9 experience. Go ahead. What else?

10 MS. PATEL: We believe that there is  
11 nothing in Ms. Miller's education or experience that  
12 qualifies her for determining whether face masks are  
13 an effective PPE measure against COVID-19.

14 She hasn't dealt with COVID-19 in her work  
15 experience, she is not in the trade of creating or  
16 evaluating mask usage in different settings, she is  
17 not a researcher, she is not a biomedical engineer.  
18 She is largely an instructor and a counselor.

19 She is not medically qualified and she has  
20 no pertinent training in relation to COVID-19  
21 regarding the epidemiology of it, the immunology of  
22 it, really anything.

23 THE COURT: While I might agree with a  
24 lot of what you just said, I will say this: I think  
25 that Rule 702, which is basically the rule that I

1 have to make my ruling under regarding expert  
2 testimony as explained in the case of Miller v. Brass  
3 Rail, that was one of our Supreme Court cases back in  
4 1995, it basically to me articulates the test for  
5 this issue to be one of reasonable pretension to  
6 assisting the trier of fact, and if so, if there is a  
7 reasonable pretension that this witness might help me  
8 as the trier of fact to determine this case, then I  
9 should allow the testimony even if the qualifications  
10 might not be the same as some of the other witnesses,  
11 which I don't think that they are, but what I do  
12 think that the witness has is qualifications as  
13 stated related to OSHA and not community spread or  
14 epidemiology either.

15 I think that there is an expertise and a  
16 knowledge about OSHA what the regs say in that regard  
17 and how they relate to the safety in the workplace.  
18 I am not sure that we even get to the question of its  
19 role in preventing community spread and some of the  
20 arguments that you are making and so forth that came  
21 out through the testimony of your experts, Ms. Patel,  
22 but again, with the test being a reasonable  
23 pretension that something might help me as the trier  
24 of fact, I am supposed to allow the witness to  
25 testify and then give it weight or not. That's to me

1           what that case says.

2                       So I get your critique, I get your concerns.  
3           I think that they have given me enough of an  
4           expertise in OSHA at least that I should hear the  
5           testimony and then maybe later on find out that it is  
6           not really something that I need to consider or give  
7           much weight or maybe I do, but application of the 702  
8           in its interpretation under Miller versus Brass Rail  
9           Tavern I will qualify limited testimony on OSHA and  
10          its relationship to the workplace. I might hear some  
11          testimony regarding masks, too, and treat it as a  
12          matter of weight and you can argue about that.

13                       You may proceed with your witness,  
14          Mr. Cooney.

15                       MR. COONEY: Thank you, Your Honor.

16                               DIRECT EXAMINATION (Continued)

17          BY MR. COONEY:

18               Q.       Kelly, you heard the arguments back and  
19               forth. I would like to start with OSHA's definition  
20               of PPE if you could provide that.

21               A.       Sure, Jim. I believe that I kind of stated  
22               that a little earlier, but just to reiterate, the  
23               OSHA definition of PPE is personal protective  
24               equipment, commonly referred to as PPE, is equipment  
25               worn to minimize exposure to hazards that cause

1 serious workplace injuries and illness.

2 These injuries and illnesses may result from  
3 contact with chemicals, radiological, physical,  
4 electrical, mechanical or other workplace hazard.  
5 Personal protective equipment may include such items  
6 as gloves, safety glasses and shoes, earmuffs or  
7 earplugs, hard hats, respirators, coveralls, vests  
8 and full body suits.

9 Q. Kelly, relating to masks, is that covered by  
10 any of the OSHA guidelines under Section 29 CFR 1910?

11 A. So in the section OSHA.gov it does specify  
12 that its PPE is to be used if a PPE program should be  
13 implemented. The program should address the hazard  
14 that is present, the collection --

15 MS. PATEL: Objection, Your Honor. The  
16 witness should not be reading off of whatever  
17 regulations or guidance documents or whatever it is  
18 that she is reading off of. We don't even know what  
19 she is reading off of.

20 THE COURT: It gets back to really even  
21 the issue, it is almost the same issue as raised with  
22 the expert, your expert report, Counselor. An  
23 expert's testimony can and is allowed and permitted  
24 to rely upon hearsay.

25 That is the rule. They are allowed. That

1 doesn't mean that it is admissible.

2 So your objection is her reading of that  
3 document I should not accept it because it is  
4 hearsay? Is that what you are articulating?

5 MS. PATEL: Yes.

6 THE COURT: Now, to the extent that she  
7 is relying upon that document, I am going to allow  
8 it. However, I will not accept it as admissible  
9 evidence as I do believe it is hearsay and I can  
10 distinguish. I know what she is reading at the  
11 moment is hearsay I agree unless there is some  
12 exception that I am unaware of that has not been  
13 argued yet by Mr. Cooney, but to read from the court  
14 from an out of state document, yes, that is hearsay.

15 Experts are alluded to rely on hearsay.  
16 That's the rule. Can I take that as substantive  
17 evidence? No, I can't. You're right. So to the  
18 extent that she is reading I will not take that as  
19 substantive evidence. All right.

20 Q. Ms. Miller, Kelly, does the OSHA regulations  
21 advise the user of PPE to consult manufacturers  
22 specifications?

23 A. Yes. The program says that the selection  
24 and maintenance of the PPE should address the hazards  
25 that are present. That is actually what the

1 regulation specifies.

2 Q. Are you familiar with any manufacturers of  
3 masks or other facial protection?

4 A. I am familiar with several, but specifically  
5 I did my research on 3M, which is one of the largest  
6 mask manufacturers in the United States.

7 Q. And does 3M have publications relating to  
8 its facial protection equipment?

9 A. Yes, they do. They have it readily  
10 available on their website which NIOSH directs you to  
11 when researching the CDC recommendations for face  
12 coverings. So 3M is actually the first one listed on  
13 NIOSH.

14 Q. Can you explain what NIOSH is again.

15 A. It is the National Institute of Occupational  
16 Safety. It is a federal agency that is responsible  
17 for research and recommendation of products in the  
18 workplace for prevention of illness and injury. It  
19 is actually a portion of the CDC.

20 Q. And NIOSH lists manufacturers of face masks?

21 A. Yes. When you go onto the NIOSH website to  
22 look at the efficacy of masks NIOSH refers you to the  
23 manufacturer to basically select and figure out which  
24 mask works for what purpose that you want it to.

25 Q. I think that you said that 3M was maybe

1 first on the list or high up on the list?

2 A. That's right. Yes, 3M specifications.

3 Q. And have you consulted the 3M specifications  
4 relating to facial masks?

5 A. Yes, I have, Jim.

6 MS. PATEL: Objection, Your Honor. Is  
7 3M, anything that 3M said being used to bolster the  
8 witness' credibility because in my opinion it looks  
9 like it is. It seems like she read something that 3M  
10 said and therefore she is an expert.

11 THE COURT: I understand the objection.  
12 Mr. Cooney.

13 MR. COONEY: Your Honor, she is going to  
14 testify regarding 3M specifications because it is  
15 directly relevant to the question of whether or not  
16 face masks are effective protection from the COVID-19  
17 virus.

18 These exhibits are on our exhibit list, they  
19 have been provided to counsel for the County and they  
20 are Exhibit 18, which is the 3M health care  
21 particulate discussing respirators and surgical  
22 masks, the 3M technical bulletin regarding  
23 respirators and surgical masks and making a  
24 comparison, an FDA publication on N95 respirators,  
25 surgical masks and face masks and the CDC publication

1 on masks and respirators, a second CDC publication  
2 understanding the difference between surgical masks  
3 and N95 respirators and Medline Industries,  
4 Incorporated publication explains ASTM F 2100 Section  
5 189.

6 Ms. Miller intends to testify that these are  
7 publications that would be used by anyone in the  
8 workplace relating to OSHA, relating to CDC, and her  
9 expertise is in this area, so I think that she is  
10 entitled to rely upon them much like the expert in  
11 Miller versus Brass Rail.

12 THE COURT: Your response?

13 MS. PATEL: Can I respond? Ms. Miller's  
14 opinion needs to be -- the opinion that she provides  
15 has to be her own opinion and not based on what 3M  
16 says. She should have her own experience and  
17 knowledge to answer Mr. Cooney's question.

18 She should not be relying on 3M and adopting  
19 3M's opinion as her own opinion and that is something  
20 that we objected to in the motion in limine. It  
21 appears that she is not really qualified to offer any  
22 opinion on this matter if she is just going to  
23 continue relying on 3M or other publications to  
24 bolster her credibility.

25 THE COURT: Mr. Cooney, frankly, the



1 beauty of being a judge and not having to worry about  
2 a jury is I am going to let the testimony go. We  
3 have to move this case along. I want to get to  
4 review everything and I want to move it along.

5 I am taking the matter under advisement as  
6 to how far that -- I am going to let her testify and  
7 I am going to hear it, but that doesn't mean that I  
8 am going to let it weigh into my ultimate decision.

9 I actually can, believe it or not,  
10 distinguish when I look at this case whether or not I  
11 should consider that testimony and whether it should  
12 be given the weight.

13 I get to rule on the evidence and I get to  
14 be the trier of facts. So I am going to put on that  
15 hat and that allows me to do that and I am going to  
16 just move things along at the moment.

17 I am going to let her testify. I understand  
18 the objection by the County and it is noted, but  
19 we're going to proceed and allow the testimony. Go  
20 ahead.

21 MR. COONEY: Thank you, Your Honor.

22 Q. Ms. Miller, again, are you familiar with the  
23 3M mask manufacturer guidelines?

24 A. Yes, I am, and to speak to the concerns, and  
25 I understand the Judge ruled, but to speak to the

1 concerns, the reason that I am referring to the  
2 manufacturer information is because that is what  
3 OSHA, which is what I am an expert in, OSHA says that  
4 an employer must do when selecting PPE.

5 Literally OSHA says, and I am not reading  
6 off anything, OSHA says as an employer if you are  
7 going to require PPE in the workplace, you must  
8 assess what the PPE function is. The way that you do  
9 that is to go to the manufacturer.

10 The manufacturer of any item is responsible  
11 for telling you what the item will do, what it won't  
12 do, how it should be maintained, stored, cared for,  
13 et cetera.

14 So the fact that I am referring to the  
15 manufacturer's recommendation is actually what OSHA's  
16 guidance is. You can't arbitrarily select an item  
17 and require it in the workplace if it will not  
18 perform in the function and manner of which you want  
19 it to perform.

20 THE COURT: I am going to jump in here.  
21 I am going to ask the witness to stick to the  
22 question and I appreciate that. I know that you want  
23 to explain and that's natural for a witness to do,  
24 but I also want to focus the testimony right now.

25 THE WITNESS: Yes, sir.

1 THE COURT: I am talking to Mr. Cooney  
2 more than anyone else and Ms. Patel. Ms. Patel says  
3 that I probably shouldn't even hear this testimony.  
4 I get that.

5 I am going to allow it. I want to give a  
6 full evidentiary hearing here and make sure that I  
7 consider everything. That is what I am doing.

8 I do want the testimony to focus because I  
9 will put out there right now that I am not sure how  
10 much weight that I would give this anyway. I am  
11 thinking about the doctor's testimony and so forth,  
12 but I do believe that this witness might have  
13 something relative to OSHA in the workplace that I  
14 should hear. That's all. So I want to focus our  
15 direct and cross-examination on that issue.

16 I certainly understand the County's  
17 objection to me allowing this witness to testify at  
18 all, and again, I think that there might be some  
19 knowledge on OSHA that I want to hear. That's all.  
20 And masks.

21 THE WITNESS: Thank you, Your Honor.

22 MR. COONEY: Thank you, Your Honor.

23 Q. Kelly, I would like to refer you to  
24 Defendant's Exhibit 18. I am going to put it up on  
25 the screen.

1           A.     Great.

2           Q.     Can you tell us what Exhibit 18 is.

3           A.     Exhibit 18 is a brochure that is available  
4           on 3M's website and that talks about their surgical  
5           masks and respirators.

6           Q.     Does it have discussion about the efficacy  
7           of surgical masks for the prevention of airborne  
8           diseases?

9           A.     Yes, it does.

10          Q.     Do you have an independent opinion on the  
11          efficacy of face masks for airborne diseases?

12                   MS. PATEL:  Objection, Your Honor.  I  
13          would like to at this time ask for a continuing  
14          objection in order to avoid any interruptions.

15                   THE COURT:  Yes, that's fine, Ms. Patel.  
16          I appreciate that.

17                   MS. PATEL:  I pretty much have an  
18          objection to everything.

19                   THE COURT:  Yes.  I know that and I  
20          understand that and maybe I didn't put that on the  
21          record, so yes, you have a continuing objection to  
22          all of the testimony of this witness ongoing and you  
23          reserve anymore specific objections.  So just to move  
24          things along, the Court will note that.

25                   MS. PATEL:  On that note I would also

1           like to object to her qualifications regarding the  
2           efficacy of masks.

3                         THE COURT: All right. I will note that  
4           too. I am going to again just hear what she has to  
5           say, that's all.

6                         Again, I think that whatever concerns that  
7           you have I still can let her testify and then maybe  
8           treat it as a matter of weight as to how much weight  
9           that I give her testimony. So that's how I am  
10          essentially in a nutshell looking at this testimony.

11                        Go ahead, Mr. Cooney.

12                        MR. COONEY: Thank you, Your Honor.

13                        THE COURT: That's a continuing  
14          objection.

15                        MR. COONEY: Understood.

16                        Q.       What does 3M say about the efficacy of  
17          surgical masks for the prevention of airborne  
18          diseases?

19                        A.       So basically 3M specifies what surgical  
20          masks can be, the application of it. They tell what  
21          the intention of the PPE is and the intention of the  
22          PPE is to protect the sterile surgical field from  
23          contamination.

24                        Basically because of the invasive nature of  
25          surgical procedures they may open non-intact skin,

1 the surgical mask is intended to protect that  
2 surgical field. It does not say anything about  
3 respiratory airborne illnesses.

4 It does state that surgical masks reduce,  
5 not prevent, but reduce large particles. Large  
6 particles at this juncture is an arguable  
7 measurement, but it does say that they sit loosely  
8 and they do not prevent spray from a cough or sneeze  
9 whereas in this literature it documents that a  
10 respirator helps reduce, again not prevent, reduce  
11 the wearer's exposure to airborne particles.

12 Q. Ms. Miller, can you tell me what particulate  
13 filtration efficiency is.

14 A. So the particulate filtration efficiency is  
15 a measuring stick for what a mask will filter and  
16 won't filter, and every mask manufacturer which I  
17 researched, which I did very diligently back in May  
18 when the CDC changed its recommendation to mask  
19 wearing, masks do not filter anything smaller than  
20 three microns and that is the measuring stick for  
21 airborne filtration particles.

22 Q. Again, this particular Exhibit, Exhibit 18,  
23 if you could, we're going to flip you over to page  
24 four.

25 A. Okay.

1           Q.     Down at the bottom of page four where it  
2           talks about particulate filtration efficiency.

3           A.     Yes.  So the PFE test, obviously you guys  
4           can read the document, tells the person considering  
5           this PPE how much filtration the mask will offer.

6                     This particular document states that the N95  
7           has a 95 percent efficacy in filtration of airborne  
8           sneezes, if you will, in this case and that is  
9           actually where the N95 gets its name, the 95 is the  
10          95 percent filtration, but this specifically relates  
11          to N95 respirators, not surgical masks.  So it is  
12          directly speaks to how efficient that piece of PPE  
13          will be to do that job.

14          Q.     I would like to refer you to Exhibit 19.  
15          Kelly, can you --

16          A.     I can't see that.  Sorry, Jim.

17          Q.     Can you see that now?

18          A.     Yes, I can.

19          Q.     Can you tell us what Exhibit 19 is.

20          A.     Exhibit 19 is a technical bulletin also  
21          published by 3M and it very clearly states at the top  
22          it is a bulletin comparing respirators and surgical  
23          masks and gives you a comparison of the two.

24          Q.     What does 3M have to say about the efficacy  
25          of surgical masks as compared to respirators?

1           A.       So surgical masks and respirators again are  
2 very, very different in what their intention is and  
3 3M clearly states that they are different for several  
4 reasons, the intended use, the fit, what they will  
5 and won't filtrate. They are very different pieces  
6 of PPE. Respirators again, N95s have the 95 percent  
7 efficacy in filtering out airborne particles whereas  
8 surgical masks do not.

9           Q.       I would like to direct your attention to  
10 page 2 of Exhibit 19 which states the conclusion of  
11 this particular technical bulletin.

12          A.       Yes, sir.

13          Q.       Do you see that?

14          A.       Yes, I do. So the conclusion section very  
15 clearly tells you that procedure masks are intended  
16 as a barrier between the wearer and environment or  
17 the sterile field.

18                   They can help keep large particles such as  
19 spit and mucous from reaching the patient, but you  
20 notice that it says may help. It definitely doesn't  
21 say that it does or guarantees to. It is meant to be  
22 a fluid barrier for the person who wears it. The  
23 personal protection equipment is intended to protect  
24 the wearer from blood spatter or fluid from the  
25 surgical site affecting the wearer.



1                   The second paragraph clearly states a  
2                   surgical procedure mask cannot provide certified  
3                   respiratory protection unless they are designed,  
4                   tested and fitted to the government standards as a  
5                   respirator.

6                   So it very clearly makes the delineation  
7                   between a mask that acts as a fluid barrier versus a  
8                   mask that acts as a respiratory barrier.

9                   Q.       That being said, I would like to jump over  
10                  to Exhibit 20.

11                  Would you take a moment to review Exhibit 20  
12                  which is on the screen.

13                  A.       Yes, sir.

14                  Q.       First of all, what is Exhibit 20?

15                  A.       I believe that that is the FDA.gov article  
16                  from the FDA.gov website.

17                  Q.       What is the significance of this piece of  
18                  literature?

19                  A.       This piece of literature once again states  
20                  that there is a large difference between surgical  
21                  masks, face masks and respirators. Specifically  
22                  lower down in the article it states that a surgical  
23                  mask may be effective in blocking splashes, blood  
24                  particle droplets. It does not filter or block very  
25                  small particles that can be transmitted by coughing

1 or sneezing or actually certain medical procedures.

2 So it is very clear that it does not filter  
3 small particulates including those expelled by a  
4 cough or a sneeze. So I think when we're talking  
5 about respiratory droplets and airborne illnesses are  
6 respiratory illnesses, a surgical mask won't even  
7 hold up against a cough or a sneeze. That is very  
8 important to note.

9 Q. Again, this is a publication by the FDA?

10 A. That's correct.

11 Q. I am going to ask you to look at Exhibit 21  
12 now. If you can, can you explain to the Court what  
13 Exhibit 21 is.

14 A. Exhibit 21 is a document that deciphers  
15 which item of PPE should be chosen, what is right for  
16 the right application, masks or respirators.

17 Q. Is there anything in Exhibit 21 that is  
18 significant to the question that we're dealing with?

19 A. I think quite a few things in the top  
20 section. Its first intended use, it very clearly  
21 states that a mask will help with reducing large  
22 particles expelled by the wearer such as thick  
23 mucous, but the intended use of the respirator is to  
24 reduce exposure to certain airborne particles.

25 When you look at the fit, which is super

1 important when we're talking about PPE, what is very  
2 important is how it fits.

3 A loosely fitting mask, such as a surgical  
4 mask, does not require a seal test, does not require  
5 a medical fit test, does not require any type of  
6 testing to make sure that it is working in the manner  
7 of protecting from airborne particles whereas you  
8 notice that the N95 has a design to fit tightly, it  
9 creates a seal between the face and -- I am sorry, it  
10 makes a seal with the face and it requires fit  
11 testing and seal checks.

12 So OSHA, back to 1910.134, OSHA's  
13 respiratory program requires that any time that you  
14 institute respiratory protection in the workplace  
15 that if you are going to require masks that they need  
16 to be N95 and approved by NIOSH and heavy fit test.

17 The third section which addresses  
18 application tells you that a surgical mask is to  
19 strictly protect the sterile surgical field. It does  
20 not say that it protects the wearer or the patient  
21 from inhaled particles.

22 It is talking about particles getting into  
23 the surgical field, okay, whereas the N95 or the  
24 respirator is designed to help reduce the exposure to  
25 certain airborne particles. It is really just going

1 on and on to say essentially the same thing.

2 One piece of PPE is designed for an certain  
3 level of protection which does not include  
4 respiratory airborne articles whereas the other  
5 piece, the respirators, do.

6 Q. I would like to now direct your attention to  
7 Exhibit 22.

8 THE COURT: What exhibit?

9 MR. COONEY: 22, Your Honor.

10 Q. Ms. Miller, can you identify Exhibit 22.

11 A. So Exhibit 22 is again another document, I  
12 believe by 3M, recognizing the difference between --  
13 I am sorry, that is straight from the CDC website  
14 which gives direction on the difference between the  
15 two masks, surgical masks and N95.

16 Q. And under filtration, which is six items  
17 down, filtration, what does it say about surgical  
18 masks?

19 A. Surgical masks do not provide the wearer  
20 with a reliable level of protection from inhaling  
21 smaller airborne particles. It is not considered  
22 respiratory protection.

23 Q. That's straight from the CDC?

24 A. Yes, sir, that is.

25 Q. Let's take a look at Exhibit 23.

1 MS. PATEL: Your Honor, I would like to  
2 object to these exhibits. None of these deal with  
3 COVID-19. She is just reading off what these  
4 companies say about the masks. How are they relevant  
5 to the issue?

6 THE COURT: Again, that's your continuing  
7 objection, the Court gets it, and we will take it as  
8 a matter of weight. I think that the testimony that  
9 I have heard so far says that respirators are better  
10 than N95s which are better than cloth masks and  
11 frankly, I believe that.

12 MS. PATEL: I would like to add that she  
13 also hasn't related this to COVID-19 in any way.

14 THE COURT: Well, maybe she is going to  
15 get there.

16 MR. LAMPL: That's coming.

17 THE COURT: Right. I haven't heard  
18 anything that frankly, with all due respect, I didn't  
19 already sort of know or common sense already know,  
20 but also I don't think that she has finished her  
21 testimony either.

22 Also she pointed out that there is some --  
23 what might be a little bit of an inconsistency  
24 certainly by the CDC, but again they changed their  
25 opinion on this at the beginning, so I know that.

1                   I also know that this is COVID. We are  
2                   learning and studying as we are going along, so all  
3                   of this I am aware of, and when I hear testimony I am  
4                   mindful of that, too.

5                   Your ongoing objection is noted. Next  
6                   question.

7                   Q.       Kelly, Exhibit 23, which now you have on the  
8                   screen, can you tell us what Exhibit 23 is.

9                   A.       So Exhibit 23 is another piece of  
10                  manufacturer literature from Medline, which is also a  
11                  very large manufacturer of medical PPE in the US.  
12                  This document explains the different filtration  
13                  levels of their masks and what will and won't be  
14                  filtrated.

15                  Q.       Moving on from the exhibits themselves, how  
16                  does this information relate to the COVID-19,  
17                  particularly the efficacy of masks?

18                  A.       So in the last exhibit, Jim, it actually  
19                  states at the bottom that the bacterial filtration  
20                  efficacy in this particular mask is an aerosol  
21                  containing bacteria three microns in size and that is  
22                  right where you are correct.

23                  How this relates to COVID-19, and you don't  
24                  need to be an expert, per Johns Hopkins University  
25                  COVID-19 particle size is .12 microns. The different

1 literature that I have read and studied on for  
2 COVID-19, although I haven't attended a formal class  
3 on it, I am well aware of how to research medical  
4 resources, COVID-19, the largest particle size that I  
5 have seen cited is .14 microns.

6 This document clearly puts the numbers to  
7 the masks that their mask will filter and it says  
8 again aerosol containing bacteria. So it clearly  
9 states that the filtration is up to three microns in  
10 size where COVID-19 is much, much smaller than that  
11 per Johns Hopkins University .12 and five.

12 Q. Do you have an opinion whether or not  
13 surgical masks are effective to prevent spread of  
14 COVID-19?

15 A. Yes, Jim. According to my OSHA training and  
16 OSHA deferrals to CDC, CDC's deferral to NIOSH and  
17 NIOSH's deferral to manufacturer recommendation,  
18 surgical masks, the ones that I have studies, which  
19 are quite a few, are not sufficient to filtrate the  
20 COVID-19 particles in a respiratory setting.

21 MR. COONEY: Can I ask the Court's  
22 indulgence to have a five-minute break so that I can  
23 use the rest room.

24 THE COURT: Yes, but before we do that,  
25 just a quick game plan. Do you have much more,

1 Mr. Cooney?

2 MR. COONEY: I am very nearly done.

3 THE COURT: Okay, because we have a lot  
4 of cross already on qualifications, so we should be  
5 able to break by about noon or 12:15 and be done with  
6 this witness is the goal.

7 We will break for five or ten. Everybody  
8 take a bathroom break and come back as soon as you  
9 can.

10 MR. LAMPL: Just to make the Court aware  
11 and everyone aware, our final witness has logged onto  
12 Teams.

13 THE COURT: Yes. Thank you, Mr. Lampl.

14 (A short recess was taken.)

15 Q. Ms. Miller, are you being paid for your  
16 testimony here today?

17 A. No, I am not.

18 MR. COONEY: Your Honor, I have no  
19 further questions of this witness, and subject to  
20 Your Honor's ruling on the motion in limine I would  
21 move for the admission of Exhibits 18, 19, 20, 21, 22  
22 and 23.

23 I understand that Your Honor has already  
24 ruled on that. I am just making that for the record.

25 THE COURT: That's fine and I am going to



1 admit noting the comprehensive objection of the  
2 County related to relevance and just an all  
3 encompassing objection to that testimony and  
4 documents, but I am going to admit and move forward  
5 to cross-examination. Ms. Patel or Mr. Parker?

6 CROSS-EXAMINATION

7 BY MS. PATEL:

8 Q. Ms. Miller, would it be correct to say that  
9 the exhibits shown to you by Mr. Cooney did not  
10 discuss COVID-19?

11 A. I am sorry. Did not what COVID-19?

12 Q. Did not discuss COVID-19?

13 A. Well, they discussed respiratory ongoing  
14 illnesses below a certain size, so they addressed the  
15 general topic.

16 Q. In your opinion, how is COVID-19  
17 transmitted?

18 A. COVID-19 is transmitted through airborne  
19 respiratory particles.

20 Q. Does the CDC recommend that the general  
21 public wear N95 masks to protect themselves from  
22 COVID-19?

23 A. The CDC initially when COVID-19 came out  
24 made the general recommendation that the general  
25 public should not wear masks and then in May they

1 changed the recommendations to simple face coverings,  
2 which is when I started to do my research as a  
3 result, because that recommendation didn't make sense  
4 with my expertise in PPE.

5 Q. So what is the CDC's current recommendation?

6 A. The CDC's current recommendation is that the  
7 general public should wear some type of face  
8 covering.

9 Q. You mentioned that surgical masks are  
10 effective for source control; is that correct?

11 A. I am sorry. For what control?

12 Q. For source control?

13 A. No, I didn't use the word source control.

14 Q. In your own words, what are surgical masks  
15 effective for?

16 A. Surgical masks are effective in a sterile  
17 environment for protecting the integrity of the  
18 sterile field which would include an incision site or  
19 non-intact skin and can also act as a splash barrier  
20 for fluids from the patient to the surgeon.

21 Q. So in your opinion if everyone wears a mask  
22 does it help everyone if it is acting as a barrier to  
23 each other?

24 A. Surgical masks do not help as a barrier for  
25 respiratory airborne illness, no.

1           Q.     You said that surgical masks do provide a  
2 barrier for fluids; is that correct?

3           A.     For fluids in the sterile environment. A  
4 sterile environment, an operatory theater is a  
5 completely different environment than the general  
6 public.

7                     Surgical suites are controlled very heavily  
8 with the temperature, humidity, oxygenation levels,  
9 ventilation levels. Those rooms are surgical. In  
10 order to gain surgical certification, the ventilation  
11 percentages have to be evaluated.

12                    So when a manufacturer says that my mask is  
13 effective in a sterile surgical environment, that is  
14 not the general public walking around.

15           Q.     When you say fluids, do you mean droplets?  
16 In your opinion are droplets fluid?

17           A.     Yes. Fluids can come in the form of  
18 droplets, sure.

19           Q.     To your knowledge, do masks provide some  
20 protection?

21           A.     They may, yes. They may provide some level  
22 of protection against fluids. Absolutely.

23           Q.     Based on your testimony previously --  
24 correct me if I am wrong -- but are you saying that  
25 the public should only wear N95 masks or nothing?

1           A.     I am not saying what the public should or  
2 shouldn't do. I was very clear that my expertise is  
3 in the subject matter of PPE in the workplace and  
4 when an employer requires a PPE, if it doesn't do  
5 what it is intended to do, that is where the  
6 disconnect comes in.

7                     I am not talking about the general public.  
8 I am not qualified to speak on that. I am qualified  
9 to speak on workplaces and employers requiring PPE to  
10 work in the manner that it does not.

11           Q.     In your opinion in the workplace do you  
12 think that it is a good idea to wear a mask that is  
13 60 percent effective rather than not wearing a mask  
14 at all?

15           A.     The difference is the word requires versus  
16 optional. When an employer requires a piece of PPE  
17 that restricts air flow then it may prevent  
18 something, but doesn't definitely, you get into  
19 people's personal medical backgrounds.

20                     Pre-existing medical conditions can be  
21 reduced by reduced air flow. Every person's body is  
22 different, so I don't think that an employer should  
23 say that no one wear a mask, it should be an optional  
24 choice.

25           Q.     But that is not my question. My question is

1 about the efficacy of mask wearing.

2 You say that your expertise is about PPE in  
3 the workplace?

4 A. Yes.

5 Q. So if your purpose is to protect your  
6 employees and those who are maybe around your  
7 employees, in your opinion is it better to wear a  
8 mask that provides even 60 percent protection rather  
9 than no mask at all?

10 A. My answer to you is that that depends on the  
11 person. Every person's body is different.

12 If you are going to implement a respiratory  
13 protection program per OSHA's guidelines they are  
14 very specific about what you have to do and a medical  
15 evaluation is one of those items so --

16 Q. But COVID-19 is going to affect everyone.

17 A. Ma'am, if a mask does not do what you want  
18 it to do it may help prevent, but it does not --

19 THE COURT: Hold on. I am going to ask  
20 for at least both of you to let each other finish.

21 Q. All that I am asking is for a simple yes or  
22 no.

23 Is it better to wear a mask that provides 60  
24 percent protection rather than no mask at all?

25 A. Not for every person.

1           Q.     In your opinion, who should be wearing N95  
2 masks in this pandemic?

3           A.     N95 masks in my opinion should definitely be  
4 worn by health care professionals in the medical  
5 setting. As far as who should outside of that, it is  
6 not for me to decide.

7           Q.     So are you saying that you cannot offer an  
8 opinion about customers who enter a food facility  
9 regarding whether they should -- whether a mask  
10 should -- regarding one, whether they should wear a  
11 mask, and two whether a mask is protective?

12          A.     So I already stated my opinion on efficacy  
13 on an N95 versus a surgical mask and I cannot speak  
14 to what a business should require of their customers.

15                   My expertise is in workplace safety and  
16 employers and employment and how that really relates.  
17 So I can't speak to customers. I can only speak to  
18 employers and employees.

19          Q.     So if you cannot make a decision as to  
20 whether people outside of a workplace should be  
21 wearing masks in your opinion, who can make that  
22 determination?

23          A.     Oh, I think that I said that I am capable of  
24 making a decision in the workplace and in the  
25 workplace if you want to decide who should be wearing

1 masks, you have to look at what the masks that you  
2 are requiring them to wear does.

3 Q. I am talking -- I am sorry.

4 A. No. Go ahead.

5 Q. I am sorry for interrupting you. I didn't  
6 mean to.

7 My question was for regarding patrons and  
8 customers, not the employees.

9 THE COURT: I do think, Ms. Patel, that  
10 she said beyond her expertise. She is saying that  
11 what an employer should require or not of her  
12 employees of the workplace and she is limiting  
13 whatever testimony that she proffered and  
14 opinion-wise today is under that, what do I want to  
15 call it, context or guideline.

16 That is the starting and ending point. If  
17 you are going beyond an employer-employee  
18 relationship, she is not saying anything today.  
19 Okay? That is my understanding of the testimony.

20 THE WITNESS: That's correct.

21 Q. To your knowledge, has there been any supply  
22 concerns regarding N95 masks during the pandemic?

23 A. Yes, there have been.

24 Q. Do you agree that it is a general consensus  
25 among medical doctors that masks are recommended?

1           A.     I actually have spoken to personally various  
2           doctors who don't agree with that. I agree that some  
3           doctors do.

4                     I would like to say that that was actually  
5           my job at Stericycle to go into medical facilities  
6           and consult with physicians, the doctors that owned  
7           the practice on selection of PPE. While infection  
8           control is certainly within the doctor's program,  
9           specific PPE and OSHA guidelines are not, which is  
10          why my job existed, so I can help doctors select the  
11          right PPE.

12          Q.     My question is: Is there a general  
13          consensus among medical doctors that wearing a mask  
14          is recommended? Not about any one or two individuals  
15          that you have met, but whether there is a consensus?

16          A.     It is more than one or two and the consensus  
17          is that they may and the key word there is "may" help  
18          prevent and it doesn't say that they do.

19                     THE COURT: That's her understanding of  
20          the consensus. I will accept it.

21          Q.     Your opinion that masks are not effective to  
22          protect against COVID is contrary to the opinion of  
23          Surgeon General Jerome Adams under President Trump's  
24          administration.

25                     He said, please, please, please wear face



1 covering when you go out in public. It is not an  
2 inconvenience, it is not a suppression of your  
3 freedom, it actually is a vehicle to achieve our  
4 goals.

5 Do you agree with that statement?

6 A. I don't agree with that statement. Not  
7 everybody can tolerate a face mask. Otherwise there  
8 would not be a medical exemption.

9 Again, I am not speaking to anything other  
10 than OSHA guidelines which clearly state if you are  
11 going to require PPE in the workplace that you must  
12 consider what it will and won't do before you can  
13 require your staff to wear it. That is what I am  
14 here to speak to.

15 Q. So based on the answer that you just gave,  
16 it appears that you don't disagree with the efficacy  
17 of masks.

18 A. No.

19 Q. Is that correct?

20 A. No, that is not correct. Surgical masks are  
21 ineffective to 100 percent provide prevention of  
22 respiratory airborne illness.

23 My expertise again is in the workplace and  
24 the OSHA guidelines are clear if you are going to  
25 institute PPE in the workplace that it needs to do

1           what you want it to do.

2                       So if somebody follows the OSHA guidelines  
3           -- if an employer follows OSHA guidelines and  
4           requires PPE and says, here is a product that I am  
5           requiring that you wear, it may not do what I want it  
6           to do, but you have to wear it that goes against OSHA  
7           guidelines.

8                       PPE recommendations have wavered back and  
9           forth, but if you follow the Pennsylvania mandates,  
10          which I am understanding that that is what we are  
11          talking about, Pennsylvania mandates said that  
12          employers have to require their staff to wear face  
13          coverings, it goes against OSHA regulations which  
14          says if you are going to require PPE it must serve  
15          the purpose that you want it to.

16                      THE COURT: I think that that pretty much  
17          sums up her testimony in a nutshell that last  
18          statement.

19                      MS. PATEL: Can I ask one more question?

20                      THE COURT: Yes, you can, and I only say  
21          that because she said the government's order to the  
22          extent that OSHA applies is inconsistent and that's  
23          all and her understanding of it, and maybe that is an  
24          argument for the lawyers, but I don't think that  
25          there is much more -- yes, you can ask other

1 questions, Ms. Patel. I just don't know that there  
2 is much more ground to go over here.

3 Q. Based on your testimony today, it appears  
4 that your opinions are just an adoption of what you  
5 have read -- would it be correct that your opinions  
6 are just an adoption of what you have read and not  
7 any studies or research that you have actually done  
8 on the efficacy of masks against different viral  
9 diseases such as COVID-19?

10 A. No, ma'am, that's inaccurate. If I was just  
11 somebody that read things on the Internet, you don't  
12 think that my testimony would be relevant here today?

13 I have worked in the occupational health and  
14 safety field for over four years including visiting  
15 over 500 medical facilities and advising doctors that  
16 own practices on how to select the proper PPE for  
17 their tasks. That includes doing research which I  
18 have done over the years continually.

19 A doctor can call me at 2:00 in the  
20 afternoon and say that I have a question about this,  
21 I would do my research, my training in how to do that  
22 research correctly. I have done research this whole  
23 time. I am not somebody that does research on the  
24 Internet.

25 I understand how OSHA regulations affect the

1 work place and how PPE regulations affect the  
2 workplace, so no, I don't agree with your statements.

3 MS. PATEL: Those are all the questions  
4 that I have.

5 THE COURT: Any redirect?

6 MR. COONEY: None, Your Honor.

7 THE COURT: And with that, we're going to  
8 break for lunch. Let's resume at 1:00. You have one  
9 more witness, Mr. Cooney?

10 MR. COONEY: That's correct, Your Honor,  
11 and Mr. Lampl will be conducting that examination.

12 THE COURT: Maybe we can wrap up what I  
13 believe has been a full evidentiary hearing on this  
14 today and go right to some closing statements and I  
15 do want to work this weekend on this. I will. I  
16 will go through this and keep moving on this. So  
17 let's break for lunch.

18 (Lunch break).

19 THE COURT: Good afternoon, everyone.  
20 Welcome. We are going to go back on the record. I  
21 see the court reporter, I see counsel, and I think  
22 that I see the next witness, who I believe will be  
23 the last witness in the case.

24 Am I right in my understanding on that as a  
25 housekeeping matter?

1                   MR. LAMPL: Correct, Your Honor. This is  
2 defense's last witness.

3                   THE COURT: Ms. Patel, you don't foresee  
4 calling any rebuttal or anything like that?

5                   MS. PATEL: At this time, no.

6                   THE COURT: That's fine, and then we have  
7 our exhibits and I can start delving into the  
8 evidence here after we finish with this witness. I  
9 am going to allow for closing arguments, too.

10                  Doctor, would you raise your right hand for  
11 me.

12                                 (Witnesses were severally sworn.)

13                   THE COURT: You may proceed, Mr. Lampl.

14                   MR. LAMPL: Thank you, Your Honor.

15                                 -----

16                                 JAMES LYONS-WEILER, Ph.D.

17 a witness herein, having been first duly sworn, was  
18 examined and testified as follows:

19                                 -----

20                                 DIRECT EXAMINATION

21 BY MR. LAMPL:

22                   Q.     Dr. Weiler, I would like to first ask you  
23 some questions about your educational background.

24                                 Could you tell me if you have any degrees,  
25 educational degrees.

1           A.     Yes, I have a BA in biology, I have a  
2           bachelor's in zoology, I have a Ph.D. in  
3           environmental -- ecology, evolution and conservation  
4           biology that is the order that they have it, I did a  
5           Ph.D. post-doc -- after my Ph.D., I did a post-doc  
6           training at Penn State University and I had a  
7           post-doc degree and fellowship in computational  
8           molecular biology.

9           Q.     And regarding those areas that you have  
10          these degrees in, could you kind of explain a little  
11          bit what exactly that means, ecology, evolution and  
12          conservation biology?

13          A.     Absolutely. So my professional research  
14          entrance to graduate school attracted me to the field  
15          of evolution in particular.

16                 I wanted to understand how evolution had  
17          occurred, the DNA sequencing, the polymerase chain  
18          reaction, all of that technology was new, and I  
19          wanted to study the effects of mutation on the  
20          emergence of new species, in particular where does  
21          all life come from? It is a fundamental question and  
22          to try to understand the processes of evolution.

23                 However, when I was a post-doc at Penn State  
24          University I shifted my career significantly to  
25          biomedical research because I could see that the

1 technologies that were being used to develop new ways  
2 of diagnosing disease in particular would require  
3 some of the expertise that I had acquired and helped  
4 develop, so I set upon a path of bioinformatics. In  
5 the post-doc itself, that was a post-doc in  
6 computational molecular biology which is pretty close  
7 to bioinformatics.

8 So my interests tracked over to biomedical  
9 research and in particular in the area of helping  
10 people understand the causes of disease.

11 New technology was coming out where we could  
12 ask of a tumor, for instance, of the 20,000 genes  
13 that are expressed in a tumor which ones are  
14 different from normal. So it was a complex data  
15 analysis situation and I set upon a path to enter  
16 bioinformatics back then. That was 1990 -- I am  
17 sorry. 1999.

18 Q. And after you finished your education or  
19 during your education what type of work experience or  
20 professional experience did you acquire related to  
21 these fields?

22 A. Right. So in addition to becoming an expert  
23 in research study design, how to design research  
24 studies, I became proficient in the tools of the  
25 trade of molecular biology including molecular

1 laboratory techniques like PCR, polymerase chain  
2 reaction, a technique that is used widely now, DNA  
3 sequencing and certainly complex data analysis.

4 I took special pains to take extra courses  
5 in graduate school in advanced statistics because I  
6 could see what was coming and how I had to master  
7 that, and of course the tools of the trade of  
8 research, you know, conducting research, proper  
9 research, ethical research and publishing.

10 Q. Dr. Weiler, have you ever been called as an  
11 expert witness in a legal case?

12 A. I have.

13 Q. Have you ever been called as an expert  
14 witness in a legal case regarding COVID-19?

15 A. Yes, I have.

16 Q. And where were you an expert in?

17 A. That was in LA County. The specifics of the  
18 case are that the California Restaurant Association  
19 had sued LA County to allow outdoor dining and to try  
20 to keep their businesses alive.

21 MR. LAMPL: If I could have one moment,  
22 Your Honor.

23 THE COURT: You can.

24 MR. LAMPL: Your Honor, at this stage I  
25 would like to move for Dr. Weiler to be accepted as



1 an expert in research study design, molecular biology  
2 including lab techniques and PCR and DNA sequencing  
3 as well as understanding data analysis related to  
4 these subjects.

5 THE COURT: I am not sure that I heard  
6 everything again. I am going to ask you to repeat  
7 it.

8 MR. LAMPL: Okay. We're moving to admit  
9 Dr. Weiler as an expert regarding research study  
10 design, molecular biology, the study of lab  
11 techniques and PCRs and data analysis and the  
12 subjects as they relate to COVID-19.

13 THE COURT: PCR and what? You are a  
14 little muffled to me.

15 MR. LAMPL: I am sorry, Your Honor. Is  
16 that better?

17 THE COURT: Yes. Much better.

18 MR. LAMPL: I will just start from the  
19 beginning again.

20 THE COURT: Okay.

21 MR. LAMPL: We're moving to admit  
22 Dr. Weiler to be an expert in research study design,  
23 molecular biology, lab techniques and PCR testing,  
24 DNA sequencing and data analysis as well as  
25 conducting and understanding research and

1 specifically as to it relating to COVID-19.

2 THE COURT: Let me allow for either a  
3 stipulation and/or cross-examination by Ms. Patel on  
4 the qualifications.

5 MS. PATEL: We will begin  
6 cross-examination, Your Honor.

7 THE COURT: You may proceed.

8 MS. PATEL: Just give me a second.

9 THE COURT: Okay.

10 VOIR DIRE EXAMINATION

11 BY MS. PATEL:

12 Q. Mr. Weiler, has your credibility as an  
13 expert ever been questioned by a presiding officer of  
14 the court or any court?

15 A. I have been a compensated witness in the  
16 National Vaccine Injury Compensation Program. The  
17 National Vaccine Compensation Program is an adverse  
18 rial system by which people that think that they were  
19 injured by vaccines have to sue the Department of  
20 Health and Human Services.

21 Vaccines are liability free, the vaccine  
22 manufacturers are not liable due to the 1986 National  
23 Vaccine Child Injury Act.

24 Q. It is a yes or no answer. Has your  
25 credibility as an expert ever been questioned by a

1           presiding officer of the court or any court?

2           A.       Officer of the court? To be able to answer  
3           that question I would have to know whether a special  
4           master constitutes an officer of the National Vaccine  
5           Injury Compensation Program.

6                       THE COURT: Yes, the Court will find that  
7           it does.

8                       THE WITNESS: So yes.

9           Q.       Do you remember which case that that was in?

10          A.       I don't remember the specific case, but I  
11          remember the context.

12          Q.       I can share both cases with you.

13          A.       Sure.

14          Q.       Give me a second. Do you remember the case  
15          Duncan versus Secretary of Health and Human Services?

16          A.       Yes.

17          Q.       A decision was issued on October 19, 2020?

18          A.       Yes.

19          Q.       Do you remember what they determined  
20          regarding your testimony?

21          A.       Not specifically, no.

22          Q.       I can direct you to that page. Do you agree  
23          that the special master determined that, and I will  
24          highlight it for you, that you did not possess  
25          adequate background to express the opinions that you

1 offered?

2 A. I remember that that was his opinion, yes.

3 Q. Do you remember this statement, "Mr.  
4 Weiler's willingness to opine on a topic on which he  
5 seems to possess no qualifications rendered suspect  
6 his credibility"?

7 A. I do remember that statement.

8 Q. Do you remember this statement? "Another  
9 problem with Mr. Lyons-Weiler's method as an expert  
10 witness is his selective reliance on questionable  
11 source material"?

12 A. I do remember that opinion.

13 Q. I would like to direct your attention up  
14 here. Do you remember this statement?

15 "Special masters have not endorsed opinions  
16 from Mr. Lyons-Weiler in deciding a case in which  
17 petitioners allege that vaccines caused their child's  
18 autism. A special master found fundamentally that  
19 Dr. Lyons-Weiler appears to be wholly unqualified to  
20 opine on the question of vaccine causation, his  
21 academic training centered on zoology and ecology,  
22 not medicine or immunology, and he does not appear to  
23 have performed a --

24 MR. LAMPL: Your Honor, I have to object.  
25 We're not here on vaccine efficacy. This is

1           irrelevant to what we're even questioning Mr. Lyons  
2           about.

3                   THE COURT: No, I am going to let her  
4           cross on this a little bit. Let me say this. I  
5           agree. He was found apparently to not be qualified  
6           to opine in vaccine cases.

7                   That seems apparent to me, but I am going to  
8           overrule the objection to the extent generally that  
9           he has been found incompetent to testify in other  
10          proceedings and I think that that is still a fair  
11          point for Ms. Patel to make to me and to that extent  
12          I will -- but I also think that I don't need to hear  
13          the whole opinion either.

14                   The simple point of it was that he was found  
15          not to be credible to testify in that case based on  
16          vaccine liability and I don't need much more on that  
17          one is I guess what I am saying.

18                   MS. PATEL: I would just like to have one  
19          more statement on a particular case.

20                   THE COURT: Go ahead.

21                   Q.       Do you recognize the statement "however, Mr.  
22          Lyons-Weiler should have known that he had incomplete  
23          information"?

24                   A.       I can read that. No, I don't specifically  
25          remember that, but okay.

1 Q. Has your credibility as an expert ever been  
2 questioned by a presiding officer in any other case?

3 A. You mentioned that there is two, yes. I  
4 would imagine that Special Master Moran doesn't like  
5 me, yes.

6 Q. Hold on, please. Is this the case that you  
7 remember, Michael Bailey, Jr. versus the Secretary of  
8 Health and Human Services issued on November 10,  
9 2020?

10 A. I didn't say that I remembered it, but I  
11 will admit that the special master probably put  
12 something of his opinion of me in there, yes.

13 Q. I just want to point out a few statements.  
14 Do you remember this statement? "Dr. DiMio and  
15 Dr. Lyons-Weiler were not qualified to opine on the  
16 issue of diagnosis and were not persuasive in  
17 contending that Mr. Bailey suffered from GBS?"

18 A. Yes.

19 MS. PATEL: Your Honor, just a few more  
20 statements and that's it.

21 Q. Do you remember this statement, "Dr.  
22 Lyons-Weiler is not a medical doctor and his  
23 background in biology and genetic sequences does not  
24 qualify him to opine as an expert or otherwise on the  
25 topic of medical diagnosis"?

1           A.     Yes.

2           Q.     And one last statement.  Do you recognize  
3 this one?  "Dr. Lyons-Weiler, a non-medical doctor,  
4 is inherently less qualified to opine upon Mr.  
5 Bailey's correct neurological diagnosis than a  
6 neurologist"?

7           A.     Yes.

8           Q.     I have a few more questions not related to  
9 that.

10                   Mr. Bailey (sic), what is the extent of your  
11 education in epidemiology and immunology?

12           A.     I think that you meant Dr. Lyons-Weiler, not  
13 Mr. Bailey.

14           Q.     Yes.  I am sorry.

15           A.     Education I have -- epidemiologists use  
16 research study design.  Research study design is a  
17 set of uniform principles that are used across many  
18 disciplines.

19                   Like ecology, epidemiology is an  
20 observational science.  It is not an experimental  
21 science.

22                   In my education I had graduate studies,  
23 statistic classes such as modern classical and modern  
24 regression techniques and multi-variant statistics  
25 and so on that are equally applied in any number of

1 disciplines such as psychology or that are  
2 observational ecology or epidemiology.

3 In my professional experience of conducting  
4 data analysis, I have conducted data analysis that is  
5 used by epidemiologists to the satisfaction of peer  
6 reviewers and published journals.

7 Q. Based on what you just said right now, would  
8 it be correct to say that although you have taken  
9 course work in statistics, you have not taken course  
10 work in epidemiology?

11 A. You can say that.

12 Q. Would it be correct to say that although you  
13 have taken course work in statistics, you have not  
14 taken course work in immunology?

15 A. You could say that, yes.

16 Q. Are you a medical doctor?

17 A. I am not a medical doctor, no.

18 Q. Would someone with a Ph.D. in epidemiology  
19 have more knowledge regarding epidemiology than  
20 someone with a Ph.D. in ecology, evolution and  
21 conservation biology?

22 A. If those are the only qualifications of the  
23 two people that I am comparing, yes.

24 Q. Would it be correct to say that medical  
25 science and epidemiology is not your area of



1 expertise then?

2 A. I don't think so. You have to consider life  
3 experience. We didn't talk about my employment at  
4 the University of Pittsburgh, nor the 100 research  
5 studies that I helped design while I was there.

6 THE COURT: Yes, and in fairness on this  
7 point I don't think that Mr. Lampl offered him as an  
8 expert in epidemiology. I think that he is going  
9 towards primarily testing and his opinion on some of  
10 the testing is where this witness is largely going to  
11 go and the data that is generated and either flawed  
12 or connecting the testing with the data I think is  
13 largely what I think that this witness will be  
14 proffered for.

15 Is that accurate, Mr. Lampl?

16 MR. LAMPL: That is a fair summary, Your  
17 Honor.

18 THE COURT: Yes, because he wants to talk  
19 about PCR, so that is the test. So that is what I  
20 think that primarily he is being proffered, and I  
21 agree he is not an epidemiologist or a biologist and  
22 he has admitted that and we're not going there with  
23 this witness. I think that he wants to analyze the  
24 data and talk about the testing I think.

25 MS. PATEL: I would say that based on

1 issues with Mr. Lyons-Weiler's credibility I do  
2 object to him being offered as an expert.

3 THE COURT: I am not even saying that you  
4 can't question anymore. I was sort of shutting down  
5 the epidemiology cross-examination, but if you want  
6 more questioning on his -- he was proffered to me it  
7 was largely -- it was also molecular biology and DNA  
8 sequencing that was proposed as an expertise.

9 So if you want to question on those areas  
10 some more I will allow it, but if not, that is okay,  
11 too. I get it, he is not an epidemiologist or  
12 biologist.

13 MS. PATEL: Yes. We don't have anymore  
14 questions for him. We would just like to have on  
15 record that we object.

16 THE COURT: Okay. I will note that in  
17 other cases that he was found maybe to testify beyond  
18 his expertise in those two cases and I think that you  
19 brought that out on cross.

20 They were different subject matters, so I  
21 don't know if the lawyers in that case maybe put him  
22 on when they shouldn't. I don't know what happened,  
23 but you pointed out two cases where of what I believe  
24 to be a court of jurisdiction to have found him to go  
25 beyond his expertise.

1                   Anything else on cross? Are you done on  
2                   that?

3                   MS. PATEL: That's it.

4                   THE COURT: Actually I will find  
5                   Dr. Lyons-Weiler to have an expertise as described by  
6                   Mr. Lampl in those areas.

7                   Again, I am thinking mostly he is going to  
8                   talk about testing, and again, I would cite my  
9                   previous ruling on the previous witness, largely I  
10                  think that our rule of evidence is sort of liberal  
11                  and it is reasonable pretension as interpreted and I  
12                  shouldn't be barring a lot of testimony.

13                  Now, whether I give it a lot of weight or  
14                  not is another matter, so that is what I am doing  
15                  here. I am going to qualify him as described by  
16                  Mr. Lampl and allow further testimony.

17                  MR. LAMPL: Thank you, Your Honor.

18   DIRECT EXAMINATION (Continued)

19                  BY MR. LAMPL:

20                  Q.     Dr. Weiler, are you familiar with the  
21                  COVID-19 coronavirus?

22                  A.     I am.

23                  Q.     And are you familiar generally with what a  
24                  coronavirus is?

25                  A.     Yes, I am.

1 Q. And would a fair statement be that  
2 coronavirus is a virus that can be transmitted  
3 between animals and humans; is that correct?

4 A. Yes.

5 Q. Are you familiar with the trends of the  
6 COVID-19 virus generally?

7 A. Yes, absolutely.

8 Q. And are you also familiar with the trend in  
9 the testing standards for the COVID-19?

10 A. Yes, I am.

11 Q. So do you know of the main scientific bodies  
12 of authority, what their current testing standards  
13 are? And by that, I mean do you know what -- what is  
14 the CDC's current testing standard? You weren't here  
15 on Wednesday, but earlier we had heard from  
16 Dr. Brink, an epidemiologist at the ACHD, that there  
17 is a gold standard used by the CDC.

18 Have you heard of this?

19 A. Not only have I heard of it, but yes, I know  
20 it in detail, yes.

21 Q. Dr. Brink had described it as a PCR, a  
22 polymerase chain reaction test.

23 Are you familiar with the PCR test?

24 A. Yes.

25 Q. What is your understanding of the PCR test?

1           A.       As a general laboratory technique PCR  
2 involves the combination of nucleic acid sequences  
3 from a target organism such as a human, a virus, a  
4 plant, bacterium, isolated DNA from that organism or  
5 RNA from that organism.

6                    It involves the inclusion of a series of  
7 nucleotides called primers. The primers are usually  
8 18 nucleotide to 21 nucleotide basis in length. They  
9 come in pairs.

10                   Primer pairs are added to the mix  
11 specifically that binds to regions that are upstream  
12 and downstream of the target sequence.

13                   DNA being a double stranded molecule the  
14 first primer has to match one of the strands and the  
15 other primer has to match the opposite strand.

16                   The polymerase chain reaction also includes  
17 events called polymerase, usually taq polymerase or  
18 related, it has been optimized synthetically, to  
19 allow the replication of DNA through a series of  
20 cycles of temperature that allow the DNA to anneal to  
21 the primers and vice versa. Then there is an  
22 extension of the -- there is a temperature at which  
23 the DNA is copied.

24                   So in the mix you also have to have free  
25 nucleotides. The mix includes primers, it includes

1 taq polymerase, it includes DNPTs, adenine, guanine,  
2 cytosine, and thymine. These are the four bases that  
3 comprise the nucleotides for which all of our DNA is  
4 made.

5 It also has to have the target sequence from  
6 the organism and there is a few other components.  
7 There is buffer and water.

8 The polymerase chain reaction involves a  
9 series of temperature cycles that allow the primers  
10 to anneal and allow the DNA to be replicated. The  
11 DNA is replicated through cycling through the  
12 temperatures that allow the primer annealing,  
13 extension and then the disassociation or the opening  
14 up again of the DNA for another cycle.

15 And through this, the reason why it is  
16 called a polymerase chain reaction is when you have a  
17 certain amount of the target nucleotide sequence from  
18 your organism the chain reaction occurs because each  
19 new copy would then yield two new copies. So every  
20 time that the temperature cycle goes through cycling,  
21 you are doubling the amount of DNA in your sample of  
22 the target sequence itself.

23 The purpose of the polymerase chain reaction  
24 was to produce enough DNA sequence so that you could  
25 use sequencing technologies to actually determine the

1 nucleotide sequences, a series of letters such as for  
2 the human genome, the original project.

3 Q. So I didn't study molecular biology, so I  
4 think that I got the gist of that, but I am going to  
5 play dumb for just a second.

6 My understanding with viruses was that it is  
7 an RNA strain that has a protein coating and then a  
8 lipid coating, and is it that RNA strain that is what  
9 the PCR is replicating to be able to tell if a person  
10 has that virus or not?

11 A. Correct. So the CDC's diagnostic criteria  
12 for diagnosing someone with COVID-19 is the presence  
13 of the virus, whether they are symptomatic or not  
14 symptomatic.

15 The virus itself is made of an RNA molecule,  
16 it is an RNA virus, which is a fast evolving virus  
17 compared to DNA viruses. The RNA itself is not as  
18 stable as DNA, it is a single strand and, therefore,  
19 a faster evolving molecule.

20 The RNA is coated in a lipid membrane that  
21 when the virus infects the cell, it binds through a  
22 series of reactions to proteins on the cell code and  
23 then merges with the cell membrane. Our cell  
24 membranes are also made with a layer, so the virus  
25 merges with and creates what is called an endosome.

1           The endosome within the human cell once the  
2 virus infects it, when it reaches a certain pH it  
3 disassociates and it releases the RNA into the human  
4 cell. That then forces the human cell to start  
5 making the viral proteins from which a new virus is  
6 constructed and the new viruses bud out of the cell  
7 and go onto infect other cells.

8           Q.     So we have heard that this PCR test is  
9 called the gold standard and previously, you weren't  
10 here on Wednesday, but Dr. Brink had testified that  
11 false positives in her opinion can only occur in the  
12 situation of a mishandling of the samples at a lab.

13                   Do you agree that false positives can only  
14 occur through human error or mishandling of the  
15 samples when doing the testing?

16           A.     Can I address the premise of the question?  
17 You said that the gold standard is the PCR?

18           Q.     That was the term used by Dr. Brink based  
19 on -- I guess that the CDC calls it the gold  
20 standard.

21           A.     You are confusing two things with that  
22 statement. The first thing is that the CDC required  
23 -- considers the presence of a virus the gold  
24 standard. If you can prove the virus is present in  
25 any way, the CDC would accept the presence of the



1 virus.

2 There are other techniques that can be used  
3 other than PCR. So CDC actually says that the  
4 presence of the virus -- and it accepts PCR as one of  
5 the levels of evidence.

6 The actual gold standard for clinical  
7 diagnostic testing using nucleic acid technology such  
8 as PCR, sorry if I am speaking fast, the actual gold  
9 standard acknowledged by the FDA is Sanger  
10 sequencing, sequencing of the nucleotide itself.

11 So PCR only shows that you have sufficient  
12 amplification in the machine. What happens during  
13 the PCR experiment or the PCR measurement is that  
14 some of the nucleotides are labeled with fluorescent  
15 molecules.

16 Those fluorescent molecules, every time that  
17 another copy is made, give off a piece of light. So  
18 the machine is telling you, yes, we have a  
19 fluorescence.

20 If you take a glass of water and run PCR on  
21 a glass of water, if you run that experiment long  
22 enough, you will eventually have the machine record a  
23 positive even though there is no virus in the sample.

24 So I don't think that the CDC's gold  
25 standard, as I understand it, is PCR alone. It is

1 the presence of the virus used for diagnosis, and if  
2 there were other technologies that could also show  
3 the presence of the sequence, then the FDA would have  
4 to -- the FDA, not the CDC determines these  
5 diagnostics.

6 First of all, the FDA would have to issue an  
7 emergency use authorization. So the CDC defines the  
8 clinical use of the PCR, but FDA defines the gold  
9 standard of the technology.

10 Q. And you had mentioned or you had given just  
11 an example of if you PCR'd water eventually you would  
12 have a fluorescent light, a green light or everyone  
13 would qualify it.

14 Why exactly is that that you can have that  
15 type of a reaction?

16 A. Well, the machine itself undertakes a  
17 fluorescent signal that will increase over time, so  
18 if you have an amount of viral material or target  
19 material in the sample, then you are more likely to  
20 reach the fluorescence sooner than if you don't have  
21 the fluorescence. Right?

22 When I used to teach PCR and when I  
23 conducted it in the laboratory, we always used a  
24 negative control sample. So we have the sample of  
25 our target and then we have the negative control.

1           It is not the presence of a fluorescence  
2           that gave us a diagnosis. It was the difference  
3           between the control sample, which did not contain  
4           any, in this case, a virus at all.

5           It is the difference in the number of cycles  
6           of the temperature that are cycling and it takes a  
7           longer time if there is less material and it takes a  
8           longer time if there is no material, but for a  
9           negative sample that is controlled there is a  
10          threshold that you reach where you say, oh, I have  
11          reached a certain amount of fluorescence.

12          It is actually the difference between the  
13          threshold that you reach for the sample that you  
14          think has the -- is positive for the virus, that you  
15          are testing for the virus and a negative control, and  
16          every kit should have a negative control in it.

17          Q.       So when you get this cycling that you are  
18          describing of how frequent the fluorescence comes out  
19          is that a measurement of the amount of the  
20          nucleotides of that virus or whatever thing that you  
21          were testing in your sample?

22          A.       For some PCR it is and for some PCR it  
23          isn't. Some PCR is not quantitative.

24          For quantitative PCR, you have to have a  
25          spiked in reference that you know the quantitative

1 amount of the starting material and then you make a  
2 comparison to the spiked and known quantitative  
3 reference material and then you can get an accurate  
4 estimate of the amount of nucleotide material, but  
5 generally speaking, yes, the lower the amount of  
6 nucleotide material that is starting the target  
7 sample, say the lower the viral copy number or the  
8 smaller the number of cells that produce the DNA,  
9 then, yes, it will take longer to reach a certain  
10 amount of fluorescence, a larger number of cycles to  
11 reach the fluorescence needed to detect.

12 Q. And that level of fluorescence would  
13 generally kind of give you a rough estimate of the  
14 amount of nucleotides of that specific thing that you  
15 were testing within that sample; correct?

16 A. Roughly speaking if you are just doing PCR  
17 and yes, quantitative PCR, and in the case of the  
18 virus, like you mentioned it is RNA, you actually  
19 have to use reverse transcription --

20 MS. PATEL: Objection.

21 THE COURT: Hold on. Objection is what?

22 MS. PATEL: How is this testimony  
23 relevant to the underlying issue of whether there  
24 needs to be masks or limited occupancy?

25 THE COURT: Yes. This is a testing

1 witness. That is what I said.

2 I agree that I don't think that it has much  
3 to do with masks or the restriction on occupancy, but  
4 I think that he is largely being offered to rebut  
5 some of the testimony of your expert, Dr. Brink, on  
6 the gold standard and just the testing and the data  
7 and the results and then the conclusions drawn there  
8 from that the health department definitely, that they  
9 are making decisions based on testing.

10 So he is challenging testing. That's all.  
11 I think. I don't think that he is going anywhere  
12 beyond testing.

13 MR. LAMPL: No, Your Honor. We're good.  
14 I am just trying to get on the record the testing  
15 standards and how they are related to COVID-19.

16 THE COURT: I get that and there are  
17 other ways to get false positives besides lab error  
18 or cross-contamination or something like that, that  
19 basically if you don't calibrate the machine right  
20 you are going to have a problem and use the right  
21 samples to compare it and so forth, I have heard that  
22 so far, but there are other means of obtaining false  
23 positives is what I have heard so far.

24 Is that fair?

25 MR. LAMPL: Yes, Your Honor. May I

1 continue?

2 THE COURT: You may continue. That's  
3 all.

4 MR. LAMPL: I just wanted to make sure  
5 that no one else had anything.

6 THE COURT: I appreciate that. Go ahead.

7 MR. LAMPL: Thank you, Your Honor. Give  
8 me one moment to look back in my notes to see where I  
9 was at.

10 Q. I believe that we were talking about the  
11 threshold, that we were discussing that you could get  
12 a rough estimation of the threshold or rather the  
13 count of nucleotides based on the cycles of the  
14 fluorescent markings during the test; correct?

15 A. Okay, yes.

16 Q. Based on your research of the testing and  
17 the literature around the testing and publications  
18 around the testing is there a uniformly accepted  
19 threshold for the count of nucleotides that should be  
20 in a PCR test?

21 A. Prior to COVID-19, no.

22 Q. Do you know currently what the CDC uses as  
23 the -- I believe that you said the CT threshold of  
24 nucleotides for a PCR test is?

25 A. We will call it cycle threshold to help you

1           so that is not as abstract. It is a cycle threshold,  
2           it is the number of cycles that we have to reach.  
3           That is what CT stand for.

4                        I would frankly be hesitant to report any  
5           number because the CDC changes things so frequently,  
6           but specifically I doubt that they have published  
7           themselves a particular CT threshold.

8                        I have to say that I am speculating, I have  
9           looked and I haven't seen a specific threshold  
10          recommended by the CDC. The World Health  
11          Organization just announced last week that they are  
12          dropping their recommended CDC to reduce the false  
13          positives.

14          Q.        And were there any other changes with the  
15          WHO related to PCR testing or requirements for what  
16          they believe would be a positive infection?

17          A.        Yes. Because they realize that setting a  
18          very large CT cycle to give a positive result when no  
19          virus is present would lead to an overestimation of  
20          the number of cases and society was shutting down  
21          businesses and society was shutting down --  
22          performing lock downs, et cetera, on the basis of  
23          potentially more false positives than true positives  
24          they decided not only to reduce the cycle number to a  
25          lower number, but they also decided that you should

1 probably take into epidemiological considerations as  
2 well as exposure history to see if, you know, that  
3 you would likely have COVID-19.

4 THE COURT: Doctor, I am going to  
5 interrupt you. When you say "they", you are  
6 referring to the World Health Organization?

7 THE WITNESS: Correct.

8 THE COURT: Okay.

9 Q. Were there any other major governmental  
10 bodies or medical authorities that adopted this new  
11 standard?

12 A. Well, I think that dependently the  
13 Department of Health in Kansas decided to reduce the  
14 cycle number by which they would count a reported PCR  
15 result as test positive for the virus, yes.

16 Q. And regarding testing, is there a way for  
17 the PCR test, if that is the sole test being used for  
18 diagnosis, to determine or to differentiate if there  
19 was a person who also had an influenza infection?

20 A. In theory or in practice?

21 Q. In theory and in practice I guess.

22 A. In theory, yes. If you ran a PCR test for  
23 influenza alongside a PCR test for coronavirus you  
24 could determine potentially if the person had both.  
25 Relying on the accuracy of both tests, however, is



1           uncertain.

2                     If you did sequencing, yes, we could  
3           definitely determine which pathogen was present that  
4           might be related to the respiratory viral symptoms.  
5           In practice, no.

6                     I am going to explain the history of  
7           respiratory illness diagnostics using molecular  
8           diagnostics such as PCR and the history of it to  
9           answer your question. It is the best way that I can  
10          answer that.

11                    Prior to 2014 the CDC separated out  
12          influenza cases that involved the influenza virus  
13          from other respiratory illnesses of unknown origin,  
14          unknown etiology.

15                    So in 2014 they changed it so that if a  
16          person didn't have a specific molecular test for  
17          respiratory -- other respiratory illnesses such a  
18          syncytial virus or the RSV virus or bacterial  
19          pneumonia or coronavirus because there were  
20          coronaviruses circulating prior to COVID-19, they  
21          created a new classification category and they called  
22          it influenza disease. Influenza disease was also  
23          known as pneumonia and influenza, P and I.

24                    So from 2014 to 2019 it was variably  
25          referred to as pneumonia and influenza, influenza

1 disease or influenza by the FDA and the CDC in the  
2 public health reports.

3 The numbers of deaths per year reported for  
4 influenza are not simply due to influenza disease  
5 from 2014 to 2019. They are a composite -- I call it  
6 a bucket diagnostic category where we really don't  
7 know in any given year what percentage, but I have  
8 estimated it to about eleven percent of the cases  
9 from 2014 to 2019 are likely due to influenza virus  
10 itself.

11 So in 2019 when coronavirus emerged and then  
12 to 2020 when it came to the United States, I think it  
13 was around April, the CDC decided to change the  
14 category of respiratory illnesses and they created a  
15 new category that we all are calling COVID-19, but in  
16 reality it is PIC, pneumonia, influenza and COVID.  
17 Right?

18 So they are not testing for influenza. So  
19 if someone has respiratory illness and they present  
20 as respiratory illness and they don't have a positive  
21 PCR test for COVID-19, they are called presumed  
22 positive for COVID, and if you look at the data over  
23 time you will see that there is no influenza being  
24 reported, practically zero influenza being reported  
25 anymore.

1           Q.     Based on your history of research and  
2           studying statistics especially related to testing  
3           results on these types of influenza does that seem  
4           unusual or out of the norm?

5           A.     From a variety perspective, from  
6           understanding the pathophysiology of disease, which I  
7           have spent a great deal of time in my professional  
8           life as a research scientist doing, I think that it  
9           is very important to understand which pathogen is  
10          present in a person.

11                     It can change the way that a person can  
12           certainly be diagnosed, but it can also change the  
13           way that that person, say, is treated.

14                     If a person has bacterial pneumonia, if they  
15           are given an errant diagnosis of influenza or an  
16           errant diagnosis of COVID they should be given  
17           protection against the bacteria in the form of  
18           antibiotics.

19                     So it is really critically important at that  
20           level for a patient by patient level and it is also  
21           critically important in reporting the causes of  
22           death.

23                     There are consequences to families if their  
24           loved one dies from coronavirus that are different  
25           than the consequences to families if their loved ones

1 die from, say, influenza.

2 Both psychologically, for instance, if they  
3 put their elderly into a nursing home situation and  
4 if there is no test that shows that there is  
5 coronavirus but they had a respiratory illness and  
6 they are given a diagnosis of COVID-19 then the  
7 family might feel, wow, what did I do, I put my loved  
8 one in harm's way and I shouldn't have put them in  
9 there, but there also should be --

10 MS. PATEL: Objection, Your Honor. He is  
11 speculating.

12 THE COURT: Yes, to a degree, but --

13 MS. PATEL: He is not a medical doctor  
14 which he admitted to.

15 THE COURT: I know and I agree, but let  
16 me say this. All that I heard was that we need to  
17 diagnose correctly and we need to categorize  
18 correctly and he thinks that there has been some  
19 incorrect bucketing, I think that bucket is used  
20 lately, and you see these influenza numbers go way  
21 down which Dr. Brink testified -- I think that it was  
22 Dr. Brink testified or Dr. Bogen, one of your experts  
23 said the same thing, basically consistent, that  
24 influenza is way down, and he is basically giving me  
25 a reason why that reporting seems to be.



1 ahead.

2 MR. LAMPL: Thank you, Your Honor.

3 Q. So you had mentioned deaths and COVID  
4 deaths.

5 Do you know the current testing or  
6 diagnostic standards for what a person doing a death  
7 certificate or determining as the cause of death,  
8 what would be necessary to qualify a person as a  
9 COVID death?

10 A. I am familiar with it through my  
11 conversations with colleagues like Scott Genten, M.D.  
12 but I could not reproducibly replicate a specific  
13 report of death -- given information in front of me,  
14 so I am going to say that I am answering this from  
15 that perspective.

16 However, I can tell you that the CDC -- as  
17 my role in editor-in-chief of a journal I reviewed a  
18 paper that was published, I sent it up for peer  
19 review, independent peer review, and the CDC changed  
20 the criterion in April and Dr. Deborah Birx made an  
21 announcement in the press, she made a press  
22 conference back in April as well, that the CDC was  
23 going to change died with to died from.

24 So whether the person died from any cause  
25 whatsoever if they detected a positive PCR test

1 result, which we just discussed and that is different  
2 than an actual true positive, a positive PCR test  
3 result, they were given a diagnosis as a cause of  
4 death of COVID-19 regardless of the symptoms.

5 MS. PATEL: Objection, Your Honor. He  
6 admitted that he doesn't have expertise in what  
7 constitutes a COVID cause of death.

8 THE COURT: Yes, I know, and I heard that  
9 and I think that he is really again -- as a matter of  
10 fact, I am already going to say that I understand  
11 that died with and died from are two different  
12 things.

13 I get that and I understand generally from  
14 just my experience that causation, and we know this  
15 as lawyers, can be disputed and then to the extent  
16 that those words are different, they do mean  
17 different things, and how they are reported is  
18 significant. That's all. I understand that.

19 So I guess what I am saying is that I am  
20 overruling your objection, but I know that he is not  
21 capable of and he even admitted that he wouldn't be  
22 able to determine a cause of death and put it on a  
23 death certificate.

24 MR. LAMPL: May I resume, Your Honor?

25 THE COURT: I am sorry. I tend to go on,

1 don't I?

2 MR. LAMPL: No.

3 THE COURT: But I want people to  
4 understand what my understanding of the testimony is  
5 and why I am ruling the way that I but because  
6 sometimes there is a point in the objection but --

7 MR. LAMPL: You are correct, Your Honor.  
8 I am not asking for him to have a medical opinion of  
9 what is a COVID death but rather his understanding as  
10 a person who does research and statistical analyses  
11 and studies of that nature.

12 THE COURT: That is how it is reported as  
13 a COVID with or COVID from is significant.

14 MR. LAMPL: Thank you, Your Honor.

15 Q. Dr. Weiler, I want to circle back before I  
16 forget on the discussion on false positive rates at  
17 the PCR testing.

18 Based on your research of the statistics  
19 being reported on COVID-19 and your knowledge of the  
20 diagnostic testing standards with PCR testing, do you  
21 have an idea of what you think could be a fair  
22 estimate of the false positive rates that are present  
23 amongst the positive diagnoses?

24 A. I do. I have a peer review publication on  
25 this, in fact. It should be in the material that I



1 think that I have provided, but there was a study in  
2 Australia that actually bothered to sequence the PCRs  
3 that we're discussing later.

4 When you do PCR you get a product. That  
5 product is called an amplicom. To know what is  
6 really present in the sample and you are not getting  
7 a false positive you have to sequence that.

8 So in the studies that have actually  
9 bothered to sequence the product of the PCR reaction,  
10 the study in Australia estimated eleven percent false  
11 positive which translates into every time that you  
12 have one case of COVID and you isolate, quarantine,  
13 et cetera, that one case of COVID, you have eleven  
14 that you are isolating that did not have it. That is  
15 what eleven percent false positive rate means.

16 Dr. Sin Hang Lee -- I was a peer reviewer on  
17 a paper, on a study, a peer review study contacted by  
18 the journal to review this based on my expertise. He  
19 produced data that showed a 20 percent false positive  
20 rate of just using PCR for diagnosis, using Sanger  
21 sequencing, which the FDA lists on their website as  
22 the gold standard for molecular diagnostics using  
23 nucleic acid technologies.

24 So that is the two data points that I am  
25 familiar with on false positive rate estimations for

1 PCR tests. It is going to vary from PCR kit to PCR  
2 kit. It is going to vary with laboratory.

3 So I agree with the testimony that you  
4 referenced earlier that there may be some variation  
5 lab to lab. Absolutely.

6 There is one other data point that I would  
7 like to bring to your attention. It is a Duke study  
8 that was recently published I think about three  
9 months ago in the New England Journal of Medicine of  
10 Marines that were recruited and put on a college  
11 campus.

12 The Marines came on campus and some of them  
13 had COVID because it was not possible to screen them  
14 because you have presymptomatic transmission. So  
15 this was a form of a natural experiment that took  
16 place and the researchers seized upon this, which was  
17 brilliant, I think. The recruits were told to mask,  
18 they were told to socially distance, they were told  
19 to bunk two by two.

20 They did most of their training exercises  
21 outside and during the six-week training period the  
22 virus continued to circulate, Marine recruits were  
23 being tested on a regular basis for the presence of  
24 the virus and anyone who tested positive, both the  
25 true positives and the false positives, were taken

1 away from campus. The virus continued to transmit to  
2 new recruits in spite of the testing, in spite of the  
3 masking and so on.

4 The important point of the study was that  
5 they could only sequence -- that they failed to  
6 sequence DNA, that they failed to actually sequence  
7 the amplicon that I was talking about in 37.5 percent  
8 of the Marine recruits.

9 So I would estimate that given my years of  
10 experience in molecular diagnostics in developing  
11 biomarkers and understanding the understanding of  
12 clinical diagnostic tests that that is a false  
13 positive rate of 37.5 percent.

14 So it is somewhere between 11 percent and  
15 37.5 percent based on empirical data, and if we're  
16 shutting down society for one test on the basis of a  
17 20 to 30 or somewhere around there, there is a lot of  
18 variation, there are just small numbers, you have to  
19 quarantine 20 people, 30 people, because to securely  
20 isolate the one person that is actually true  
21 positive, but the peer review paper I have mentioned  
22 actually asked the question what is the cost of the  
23 false positive relative to the cost of false  
24 negative, the false negative being you let somebody  
25 go, they have the virus and you don't know it, so

1           that is an optimization problem that society hasn't  
2           asked.

3                       The PCR testing biases towards false --  
4           minimizing false negatives. In fact, they have  
5           something called presumed positive where a person  
6           produces symptoms.

7                       I looked at the expert testimony from the  
8           epidemiologist and the testimony is in black and  
9           white, but if you go to the state website it is in  
10          color and you can see the presumed cases are separate  
11          from what they call confirmed cases.

12                      The presumed cases are another category of  
13          false positives where you haven't even run PCRs. The  
14          confirmed cases -- the smaller number -- the largest  
15          proportion are confirmed cases for sure, but I just  
16          want to be sure that -- there are two kinds of false  
17          positives. The ones that are confirmed that are not  
18          positive at all, they didn't even test positive, and  
19          the ones that tested positive but are not clinical  
20          COVID because it is a false positive on the technical  
21          aspect.

22                      So the false positive rate is real and we  
23          have the assumption that was made early on was that  
24          more testing is always better and that this is  
25          actually incorrect because the prevalence of COVID-19

1 is low, you are going to get far more false positives  
2 in your test results than false negatives.

3 So I think that we made a big mistake in how  
4 we have addressed this problem overall and I hope  
5 that we can improve it going forward. It seems like  
6 there are signs that people are addressing this  
7 problem by reducing the threshold number.

8 Q. Understood. And on that note, talking about  
9 false positives, on the contact tracing, we had  
10 discussed contact tracing on Wednesday with  
11 Dr. Brink.

12 She had mentioned that the health department  
13 had kept up with contact tracing up until sometime in  
14 the fall when there was what she classified as I  
15 guess the second explosion of cases that is when they  
16 had to prioritize contact tracing and have fallen  
17 behind to some extent.

18 Based on your research, statistics reported  
19 related to contact tracing, would you agree that  
20 contact tracing has been kept up or was kept up at  
21 any point?

22 A. I find it difficult to accept that any  
23 meaningful contact tracing could have been done. The  
24 history of the use of PCR testing for COVID-19 in the  
25 world is as follows.

1           The Chinese developed their PCR test, South  
2           Korea had an antigen test, the Chinese published the  
3           very first genome of the SARS-CoV-2 virus and that  
4           was downloaded by a team in Germany in January 2020.  
5           They produced a PCR test and 141 countries stopped at  
6           that PCR test.

7           All you have to do is download the prior  
8           sequences. It is literally letters that you then  
9           feed into a computer that produces the primers  
10          attached to a nucleic acid synthesizer.

11          The US declined to accept that test. It was  
12          available January 16th.

13          The CDC decided to create their own test.  
14          The CDC shipped out their test and a month later,  
15          within a month, medical doctors around the country  
16          were reporting that the test was flawed. The people  
17          around the Princess cruise ship were let go on the  
18          basis of that CDC test.

19          So right away we have hundreds and thousands  
20          of new cases early in February of the coronavirus and  
21          then it was announced that the commercial sector was  
22          going to be invited to produce their tests.

23          The commercial sector was asked to produce  
24          their test very quickly and I have downloaded and  
25          read the emergency use authorizations for the

1 hundreds of PCR tests looking for one specific data  
2 point.

3 Did the FDA require, I wanted to know did  
4 the FDA require the estimate of a false positive  
5 rate? Now, they required an estimate of -- the  
6 commercial tests had to determine whether or not they  
7 could detect the virus if it was, in fact, present.

8 That is called sensitivity. Right? The  
9 percentage of times that you see it when it is truly  
10 there, but the FDA did not require at that time any  
11 empirical, that is data driven, estimate whatsoever  
12 of the performance of the test when the virus was not  
13 present and that was puzzling to me.

14 So I wrote to Dr. Peter Marks at the FDA and  
15 I wanted to know more. He pointed me to the EUAs  
16 which I read.

17 The EUAs company after company after company  
18 all that they did to make sure that there were no  
19 false positives they took the PCR sequence of the  
20 primer sequences and they used an algorithm called  
21 blast that was invented by my post-doctoral advisor  
22 at the NCBR National Center for Biotechnology website  
23 posted by our government and they did a computational  
24 matching program, if the primer's sequence matched or  
25 did not mask the human genome because what you don't

1 want to have is if you have a virus in your lung and  
2 you take the sample out, if you are coughing and you  
3 take it out of the nasopharyngeal tract and if you do  
4 a PCR on that, you don't want -- there is going to be  
5 human genome in there as well.

6 You don't want any part of the human genome  
7 to cause a false positive amplification. So the  
8 primers can't match human genome sequences.

9 The FDA determined that this was sufficient  
10 to use any match of the primers and basically the  
11 computational reassurance that there should not be  
12 any possible positives but they did not produce any  
13 data on false positives, okay.

14 So what had to happen then is that when the  
15 false positives started to climb up and everyone saw  
16 it then the testing procedure was changed again where  
17 then you have to get a test three days later to  
18 confirm.

19 So the assumption then is that if you have a  
20 person with a given set of characteristics that you  
21 run the PCR test the one time that the person again  
22 if they test positive, they will test positive again.

23 That doesn't make any sense to me given the  
24 life history of the virus and what I understand as a  
25 biologist of the virus because there are many times





1 but again, I think that it is really just a tack on  
2 data, a tack on characterization of the data and the  
3 PCR test itself is not an inexact diagnostic tool.

4 MS. PATEL: But when he talks about  
5 impact on society or psychology --

6 THE COURT: It is pretty broad, but to  
7 the extent that we want to get if right I think that  
8 I would agree with him, but what that impact is, is  
9 that speculation by any of us to a degree, yes, but  
10 go ahead. You can finish your answer. Go ahead.

11 THE WITNESS: Thank you. So to address  
12 that question, actually, it is a fair question and I  
13 appreciate where you are coming from, I didn't do a  
14 single analysis in that peer reviewed study on the  
15 basis of a set of assumptions that gave a  
16 predetermined answer.

17 Instead what I did was that I modeled what  
18 if the cause of the false positives is much greater  
19 than the cause of the false negatives and then I  
20 varied that down to what if the cause of the false  
21 negatives is much greater than the false positives.

22 So I realized that I could address all  
23 hypothetical observations. The point there is that I  
24 did not develop an opinion in any way whatsoever that  
25 we should use PCR in some way in testing. The

1 results suggest that knowing the difference between  
2 the cause of false positives and the cause of false  
3 negatives is much more important than more or less  
4 testing.

5 As I said earlier, it was assumed that more  
6 testing is always better, but if you are  
7 indiscriminately testing or if you are randomly  
8 testing or, heaven forbid, that you test everybody at  
9 the same time in the United States of America you  
10 would think that that would be great you better  
11 follow up with locking down every person that is  
12 testing positive completely because otherwise it is  
13 just --

14 THE COURT: I am going to interrupt you  
15 because I want to understand that. Yes, it is  
16 logical to think that the more testing that we have,  
17 the better.

18 You are saying with false positives and not  
19 enough emphasis on false negatives that the more  
20 testing that we do, the more we get away from the  
21 value of the testing because the numbers, I am going  
22 to say exponentially, I am not sure if that is  
23 accurate, but the numbers get more off. They are off  
24 more by the more testing.

25 That is essentially what I think that you

1 are saying and we need to look at false negatives  
2 more than we are. The emphasis right now is on false  
3 positives, but we should really be looking at these  
4 false negatives a lot more too.

5 Is that in sum what you just told me?

6 THE WITNESS: Yes, I would agree with  
7 that. There are two ways that the number of cases  
8 will increase overtime as you increase testing.

9 Obviously on the very first day that you run  
10 a test on the very first person you have an  
11 ascertainment bias that you really haven't tested  
12 enough so you don't have a good estimate of the  
13 prevalence, you really don't know what is going on,  
14 you are just starting with one person.

15 So the more that you test, the more that you  
16 go into the population and you have to test and of  
17 course you will have more positive results.  
18 Hopefully most of those will be true positives,  
19 right?

20 So if there are false positives you are also  
21 accruing the number of false positive results.

22 THE COURT: I understand.

23 THE WITNESS: So that then brings to the  
24 question of why I am talking about the cost to  
25 society is that we asked the wrong question, the

1 whole testing paradigm was based on the assumption  
2 that more testing is always better and it is clearly  
3 not.

4 The question that the paper asks is when is  
5 it ethical to switch from symptom based testing only,  
6 you have a symptom or contact based testing to  
7 indiscriminate testing, and the answer is somewhere  
8 around 30 percent infection at any given time.

9 You have to have a 30 percent infection rate  
10 for the virus at the same time and we don't. We have  
11 one to two percent at any given time. So we're  
12 definitely overtesting, we're shutting down parts of  
13 society on the basis of false positives.

14 THE COURT: All right. I think that I  
15 understand the testimony and I certainly understand  
16 your objection, Ms. Patel.

17 MR. LAMPL: One moment, Your Honor. I  
18 think that I have a few more questions.

19 Q. On that note, based on your experience as a  
20 statistical researcher, your understanding of the  
21 statistical analysis of diseases and missed diagnoses  
22 of diseases and these other societal effects and your  
23 reading of the other societal effects, do you think  
24 that on balance there could be a net harm if the  
25 increased harms to society related to lock downs or

1 those mitigation orders outweigh the false positives?

2 MS. PATEL: I object to that question.

3 THE COURT: Yes, I am going to sustain  
4 that.

5 MR. LAMPL: I agree. I will strike that,  
6 Your Honor.

7 THE COURT: I am going to sustain. I  
8 think that is sort of what I have to figure out.

9 MR. LAMPL: I have just one or two more  
10 questions.

11 Q. Dr. Weiler, I am going to show you what is  
12 marked as Defendant's Exhibit 54.

13 Have you seen this document before?

14 A. I am a co-signer on the Great Barrington  
15 Declaration, yes.

16 MS. PATEL: Objection, hearsay.

17 THE COURT: Let me hear some more  
18 testimony on it.

19 Q. And what is your understanding of this  
20 document? Have you read this before?

21 A. Yes. As a co-signer I consider it my own  
22 declaration.

23 Q. And what are the general contents of this  
24 Great Barrington Declaration?

25 A. This Great Barrington Declaration is a

1 statement put together by a compendium of medical  
2 doctors and research scientists such as myself and  
3 other professionals, including epidemiologists, who  
4 have come to the same conclusion that I came to which  
5 is that the society's reaction to coronavirus leading  
6 to lock downs, leading to closures of businesses, has  
7 had devastating effects in so many ways.

8 The teen suicide rate is higher than it has  
9 ever been in the United States, for instance. This  
10 is due to the social isolation --

11 MS. PATEL: Objection.

12 THE COURT: Yes.

13 MS. PATEL: What is this based on? This  
14 is outside of the scope. We are talking about COVID.  
15 He is showing no reason why he could correlate lock  
16 down with suicide --

17 THE COURT: I am going to kind of limit  
18 this. I am going to take a look at the Great  
19 Barrington Declaration.

20 Again, I think that I can take a lot of  
21 judicial notice in this case both ways. As I said at  
22 the outset, we are studying COVID. We didn't know  
23 COVID until January, right?

24 So I am aware that there are disputes on all  
25 this stuff and opinions and I am already aware of and

1 a lot of it is what I am saying is a matter of just  
2 reading the newspaper, but to the extent that this  
3 Great Barrington Declaration is of the opinion that  
4 we are overregulating, I will let it in, but it is a  
5 matter of weight for me.

6 I already know a lot of this and in the end  
7 I am going to have to assess whether an injunction be  
8 granted, whether I am going to shut a business down  
9 and whether the governor acted with the proper  
10 authority along with the health department under our  
11 Constitution. That's the big picture and I haven't  
12 lost sight of it, what everybody's expertise is and  
13 what their opinions are and how far that they can go,  
14 I am very mindful of it, and I am going to allow the  
15 Great Barrington Declaration into evidence.

16 I don't need a lot of questioning on it. I  
17 can see from the preamble here what it says already  
18 and it is on the screen. So focused protection and  
19 we need to think about the ramifications of some of  
20 our policies. That's all. For that I will admit it  
21 into evidence.

22 Do I need to hear a lot about it? Not  
23 really.

24 MR. LAMPL: Your Honor, I just have one  
25 final question for the witness.



1 THE COURT: Okay.

2 Q. Dr. Weiler, were the opinions that you  
3 expressed today within a reasonable degree of  
4 scientific certainty?

5 A. Yes.

6 MR. LAMPL: That's all, Your Honor.

7 (A recess was taken.)

8 THE COURT: Ms. Patel, cross-examination  
9 of Dr. Lyons-Weiler.

10 MS. PATEL: Yes.

11 CROSS-EXAMINATION

12 BY MS. PATEL:

13 Q. Mr. Lyons-Weiler, have you ever worked in a  
14 public health setting?

15 A. My last research study is on the effects of  
16 a vaccine schedule on a pediatric publication and it  
17 is published in a public health journal, so yes.

18 Q. Who was your employer?

19 A. The Institute for Pure and Applied Knowledge  
20 where I work now.

21 Q. And you are the CEO of that?

22 A. I am the CEO/president and I am a research  
23 scientist there, yes.

24 Q. Do you have a public health practice?

25 A. No.

1 Q. Have you ever responded to a public health  
2 emergency?

3 A. No.

4 Q. Do you know the Council For State and  
5 Territorial Epidemiologists definition for COVID?

6 A. No, I don't know that particular definition.

7 Q. Do you know that council's definition for  
8 COVID deaths?

9 A. No, I don't know that particular council's  
10 definition for COVID deaths.

11 Q. Do you know what the false positive rate in  
12 Allegheny County is?

13 A. I have not seen any published estimate of  
14 the false positive rates. I have looked for them and  
15 I can't find them.

16 Q. Do you know what the false positive rate in  
17 the Commonwealth of Pennsylvania is?

18 A. I have looked for the false positive rate of  
19 -- I think that -- hang on just a minute. Do you  
20 mean the PCR tests or all kinds of testing?

21 Q. I am just talking about the false positive  
22 rate for COVID in the Commonwealth of Pennsylvania.

23 A. I could answer, but I need some  
24 clarifications. There is antigen tests and there is  
25 PCR tests.

1 Q. PCR tests.

2 A. Thank you. No, I have not seen any  
3 published statistics on the false positive rate in  
4 the Commonwealth of Pennsylvania.

5 Q. Would you agree that there are other studies  
6 that demonstrate a false positive rate lower than  
7 that which you testified to earlier today regarding  
8 COVID?

9 A. I would not rule out that there would be  
10 some, but I don't know of any because I have looked  
11 for them.

12 Q. Would you agree that the CDC and the  
13 Pennsylvania Department of Health have many  
14 epidemiologists, scientists, biologists and other  
15 laboratory personnel working there?

16 A. Absolutely.

17 Q. Are you saying that the CDC and the  
18 Commonwealth of Pennsylvania have --

19 MR. LAMPL: Your Honor, she is asking a  
20 compound question. I would ask that she break the  
21 question up.

22 MS. PATEL: I can do that.

23 Q. Are you saying that the CDC has  
24 overestimated the case count and death toll of  
25 COVID-19?

1           A.     Absolutely.

2           Q.     Are you saying that the Commonwealth of  
3           Pennsylvania has overestimated the case count and  
4           death toll of COVID-19?

5           A.     Absolutely.

6           Q.     Are you saying that the CDC and the  
7           Commonwealth of Pennsylvania's methodologies and  
8           analyses are --

9                   MR. LAMPL:  Again, Your Honor, I ask that  
10           she break up that compound question.

11                   MS. PATEL:  I can do that.

12           Q.     Are you saying that the CDC's methodologies  
13           and analogies are wrong regarding COVID-19?

14           A.     That is a general question.  There is so  
15           much going on with COVID-19 I can't answer that  
16           question.

17           Q.     Would you say that the CDC's testing and  
18           testing guidelines are wrong?

19           A.     I am sorry.  I have to be very technical  
20           about this.

21                   Do you mean the testing guidelines with  
22           respect to the use of PCR positive only as a  
23           diagnosis for COVID-19 allowing that?  Is that what  
24           you are asking?

25           Q.     Are you saying -- when you said that the CDC

1 has overestimated the case count and death toll of  
2 COVID-19 are you basing your answer on the PCR false  
3 positives?

4 A. Not only, no. Not exclusively, no.

5 Q. What else are you basing that on?

6 A. So the CDC's criteria and recommendations  
7 for the diagnosis of COVID-19, it allows a person who  
8 has tested positive for COVID-19 with two successive  
9 tests to be determined to have COVID-19. COVID-19  
10 stands for coronavirus virus infection disease and it  
11 is a medical condition.

12 A positive SARS-CoV-2 PCR test does not  
13 translate into COVID-19 and there are many experts  
14 around the country and around the world that have  
15 published in major medical journals making that  
16 distinction.

17 However, the CDC decided that the positive  
18 PCR test was going to be sufficient for counting  
19 cases as PCR. The diagnosis of PCR is done including  
20 cases that do not test positive, they are presumed  
21 positive. So, yes, they are over counted. I think  
22 that they are very much so over counted.

23 MS. PATEL: I just need a moment, Your  
24 Honor. We have no more questions.

25 THE COURT: Mr. Lampl, any further

1 questions?

2 MR. LAMPL: No further questions.

3 THE COURT: I don't think that I have any  
4 questions of the witness either. I appreciate that.

5 You are welcome to remain, Doctor, or you  
6 are excused.

7 Any other witnesses, Mr. Lampl?

8 MR. LAMPL: No. That is all for the  
9 defense, Your Honor.

10 THE COURT: Any rebuttal, Ms. Patel?

11 MS. PATEL: No.

12 THE COURT: So I think that we pretty  
13 much dealt with all the Plaintiff's exhibits and I  
14 know that they are in the 80s, as far as defense  
15 exhibits I have not reviewed them all, but I can tell  
16 you that I am basically conditionally admitting the  
17 documents and will allow for the County to provide an  
18 e-mail essentially to me obviously CC'g defense  
19 counsel with their objections to the documents.

20 Some of them you certainly have raised in  
21 court as we have dealt with them, but again, when I  
22 started out here I said that we're operating under  
23 remote operating procedures and I have a lot of  
24 documents to get through, I wanted to move the case  
25 as best that I could, so I am basically saying that I

1 am going to look at the documents. I am not saying  
2 that I am going to give them a lot of weight or maybe  
3 I won't admit them at all.

4 I am willing to rule that I am not going to  
5 admit any expert reports per se and rely on the  
6 testimony of the expert and that goes both ways of  
7 course. The objection came up with respect to  
8 Dr. Brink, but it applies to all experts.

9 I am not going to read the reports. I heard  
10 the testimony and I made my rulings as to what I  
11 thought they had as far as an expertise and I  
12 basically let everybody in and I stated my reasons.

13 In Pennsylvania I don't think that it is  
14 that hard to be qualified as an expert generally, but  
15 that doesn't mean that you give all the full weight  
16 to the testimony. That's all. That's my paraphrase  
17 of the rule. So all the expert testimony is in,  
18 their reports are not.

19 I know that you have a lot of exhibits.

20 Mr. Blackwell, are you going to deal with  
21 the evidentiary issue? Mr. Blackwell, you are muted  
22 by the way.

23 MR. BLACKWELL: I was trying to find the  
24 mouse to unmute me. I will deal with any issue that  
25 you need dealt with.

1                   THE COURT: Like I said, I kept saying  
2                   that I wanted you guys to do written objections and  
3                   stipulations and all that, but I moved you along and  
4                   you had to prepare your witnesses and be able to try  
5                   this case, so I understand that and that hasn't  
6                   necessarily been done.

7                   My plan is now to hear closing arguments.  
8                   Basically I have the exhibits that I think that I  
9                   need to have in an e-mail form and I am going to wade  
10                  through them beginning maybe tonight and if not maybe  
11                  tomorrow morning, so that's my plan.

12                 Any housekeeping or evidentiary matters that  
13                 you want to address before I move to closing?

14                 MS. PATEL: Your Honor, can we have a  
15                 recess before closing? I know that we just had one.

16                 THE COURT: No. That's fine. You want  
17                 to get your thoughts together. That's fine. We're  
18                 doing pretty good here. How long do you guys want?

19                 MS. PATEL: 15, 20 minutes.

20                 THE COURT: We can do that. I am going  
21                 to say 15.

22                 (A short recess was taken.)

23                 THE COURT: I am ready for closing. Mr.  
24                 Blackwell.

25                 MR. BLACKWELL: Sure. Thank you, Your



1 Honor. Again, Dennis Blackwell on behalf of The  
2 Crack'd Egg.

3 I was struck by something that Your Honor  
4 said right before we took what was the last break or  
5 the break before, but when you were talking about  
6 letting the evidence in, you said that I have a tough  
7 decision to make whether to shut down a business, did  
8 the County do what they were supposed to do as well  
9 as the Constitutional issues involved.

10 There is a big burden, and as the Court  
11 knows, in a preliminary injunction there is a high  
12 bar for the County to meet because of in this case  
13 the very three things that you had mentioned.

14 Also, as I was sitting here getting ready to  
15 start this speech, I remembered two things that I  
16 tell at least two of my children, one is a lawyer,  
17 one is in his second semester in law school, in any  
18 case, source documents are very important. Words are  
19 all that we have as attorneys. That is how we make  
20 our living.

21 People spend a lot of time and effort with  
22 the words that they put on paper, with the words that  
23 they put in a statute. So I went to the source  
24 documents.

25 The first thing that I started with was the

1 Allegheny County Home Rule Charter. I would like to  
2 just read the first couple sentences.

3 We, the people of Allegheny County,  
4 Pennsylvania believe that a home rule government will  
5 transfer substantial authority over our county  
6 government from the Commonwealth of Pennsylvania to  
7 the people of Allegheny County.

8 A home rule government that separates the  
9 legislative and executive functions previously vested  
10 solely in the board of county commissioners will  
11 provide checks and balances on the powers of  
12 government and protect the rights, privileges and  
13 powers reserved or guaranteed to the people by the  
14 Constitution of the United States of America and the  
15 Commonwealth of Pennsylvania.

16 Very important. The words are what we live  
17 by. That is the statute, that is the source  
18 document. That is the backdrop to everything that  
19 you've heard from the last three days.

20 Now, those principles, they are not new to  
21 Allegheny County, they are not just for Allegheny  
22 County. They are for the Commonwealth of  
23 Pennsylvania and for every other state in the union.  
24 They are also the overriding principles of the  
25 Constitution of the United States of America as set

1           forth by our forefathers.

2                         Why did they think that that was so  
3           important? They thought that checks and balances in  
4           the three legislative branches of the government were  
5           so important because they were tired of King George  
6           telling them what they had to do.

7                         You heard three days of testimony. I submit  
8           that all three of those you can decide this case the  
9           testimony that occurred in day two from Dr. Bogen  
10          when she was asked, did you seek permission or  
11          authority from any of the county commissioners or the  
12          county executive or the county board issued these  
13          orders? Her answer is very telling. No. I did not  
14          need their authority. I did it on my own.

15                        In essence, she is King George. Again,  
16          let's go to the statute.

17                        What is important is let's read the words,  
18          let's go to the source document. And their powers  
19          and duties are found in 16 PS Section 12011. Powers  
20          and duties of the county board of health.

21                        The county board of health shall exercise  
22          the rulemaking power conferred upon the county  
23          department of health by the formulation of rules and  
24          regulations for the prevention of disease. And it  
25          goes on and it explains that you have to have rules

1 and regulations and they have to be approved and you  
2 have to advertise them and there has to be debate on  
3 it and then you have to let the public know and ten  
4 days after this or that they become the rule for the  
5 county health department and/or Dr. Bogen to make her  
6 proclamation, her rule.

7           However, the most important part of that  
8 section comes at the end. No rule or regulation  
9 shall become effective sooner than the tenth day  
10 after it is approved.

11           Here we have had no approval, no testimony  
12 that anything was ever given to anybody else to  
13 approve or to debate on. The most important part,  
14 except that regulations which are declared by the  
15 board of health to be emergency measures, that is  
16 what they are talking about here, that is what this  
17 whole thing is about, the emergency measures,  
18 declared by the board of health to be emergency  
19 measures shall become effective immediately upon  
20 approval of the county commissioners or the joint  
21 county health commission.

22           Not immediately upon the edict issued by  
23 Dr. Bogen. Not immediately upon the edict issued by  
24 Governor Wolf and not immediately upon the edict  
25 issued by the secretary of health for the

1 Commonwealth.

2 Again, rules and regulations. Words. They  
3 all have meaning, they all have the import. In this  
4 particular case I would submit to Your Honor that  
5 that exchange between Mr. Cooney and Dr. Bogen is  
6 really all that you need to decide this case.

7 Yes, there are six factors, yes, this is an  
8 equity matter, but constitutionally the County did  
9 not do what they were required to do, and I think  
10 that that's really all that you need to decide this  
11 case. I don't think that it goes any further, but I  
12 will continue to address the rest of it because I  
13 know that you are going to need it.

14 So the very thing that we the people of  
15 Allegheny determined was to separate the legislative  
16 and the executive functions.

17 So we issued a trial brief, a brief for Your  
18 Honor, where we talk about what is required. Not  
19 only by the Commonwealth of Pennsylvania but by the  
20 County of Allegheny.

21 The first one of them is that the county as  
22 well as the state failed to comply with the mandatory  
23 rulemaking procedure under the Commonwealth Documents  
24 Law. Once they fail to do that, that renders all the  
25 orders invalid and unenforceable.

1                   What is the Commonwealth Documents Law?

2                   Well, that is what governs it, that is what the board  
3                   of health is governed by, that is also what the  
4                   county's board of health is governed by, and they can  
5                   enact rules and regulations only if they comply with  
6                   the mandatory rulemaking procedures.

7                   The law is clear that the Commonwealth  
8                   Documents Law, the Regulatory Review Act and the  
9                   Commonwealth Attorney's Act establishes a mandatory  
10                  formal rulemaking procedure, that is, with rare  
11                  exceptions, required for the promulgation of all  
12                  regulations.

13                  Now, I would assume the county as well as  
14                  the state they like to fall back on the emergency  
15                  powers. The governor's emergency power doctrine  
16                  lasted 90 days. After that 90 days he needs to  
17                  comply with the rest of the rulemaking authority that  
18                  is set forth in the rules and regulations on how you  
19                  go about that.

20                  It is not a continuing doctrine where he  
21                  says that yep, still an emergency, still an  
22                  emergency, still an emergency. We're a year into  
23                  this. How long does an emergency last?

24                  You didn't hear any testimony on that. The  
25                  county health department has the burden here. They

1 have the burden to come forth and explain to Your  
2 Honor why they are permitted to do what they are  
3 seeking to ask you to do.

4 The Commonwealth doctrine continues to go  
5 onto say that an agency must give notice to the  
6 public of its proposed rulemaking and an opportunity  
7 for the public to comment. None of that happened  
8 here.

9 Under the Regulatory Review Act the agency  
10 must also submit its proposed regulation to the IRRC  
11 for public comment, recommendation and ultimately the  
12 IRRC's approval or denial of a final form of the  
13 regulation. Again, none of that happened here.

14 The Commonwealth Attorneys Act requires the  
15 agency to submit all proposed regulations to the  
16 attorney general and the governor's office of the  
17 general counsel for review in form of legality.

18 They didn't do that. Had they done that,  
19 they would have been told that you can't do that. It  
20 is not legal, it is not constitutional. You are  
21 violating the rights of the citizens of the  
22 Commonwealth of Pennsylvania and in this case you are  
23 violating the rights of The Crack'd Egg.

24 Additionally, the Allegheny County Health  
25 Department failed to comply with the mandatory

1 rulemaking procedure set forth in the Local Health  
2 Administration Law.

3 The Allegheny County Health Department  
4 erroneously asserts that it can enforce its own  
5 COVID-19 mitigation measures under Article 3 of the  
6 county code. To the extent that the Allegheny County  
7 Health Department claims authority under any of its  
8 other powers it is required to follow the mandatory  
9 rulemaking procedures that we just went over.

10 In this particular case, they have not done  
11 any of that. They issued a rule by Dr. Bogen and  
12 they think that they are allowed to try to attempt to  
13 enforce that rule.

14 However, they filed for an injunction, a  
15 preliminary injunction, which is why we have been  
16 here for the last three days. The problem with that  
17 is that you used it as a court of equity. The  
18 problem with the county that is.

19 You sit as the court of equity in a  
20 preliminary injunction hearing and I want to back up  
21 as to why they didn't bring any of this up. Why  
22 didn't they bring up, and it is their burden, why  
23 didn't they bring up that they had the rules and  
24 regulations and they did it properly?

25 There can be only answer. They didn't do it



1 properly and because they didn't do it properly they  
2 know that Dr. Bogen's rule, they know that their  
3 mitigation measures, all of them, not just masks, not  
4 just social distancing, all of their mitigation  
5 measure fail as a matter of law.

6 So that is the backdrop that I think that I  
7 would like Your Honor to look into while he is  
8 looking at the injunction and while he is looking at  
9 the six-prong test.

10 So as I said, the preliminary injunction  
11 relief is an equitable remedy. Let's look at prong  
12 one. Prevent the immediate and irreparable harm that  
13 cannot be adequately compensated by damages.

14 Under that, as I said, the County is saying  
15 that they have the powers under Article 3. Article 3  
16 says imminent danger to public health.

17 Did anybody testify, Your Honor, did anybody  
18 give you guidance on what imminent danger to the  
19 public health is? I didn't hear it. So I am going  
20 to submit to you that the County has not met that  
21 burden. So, again, words have meaning.

22 What does imminent danger to public health  
23 mean? Well, I think that I know what imminent means,  
24 but I looked it up in the dictionary just in case,  
25 and what the dictionary said is it is immediate -- I

1 want to quote it exactly what it says. Imminent  
2 stands for threatening to occur immediately according  
3 to Webster's dictionary.

4 Now, what does threatening to occur  
5 immediately mean? So I looked up the word  
6 immediately. Webster's defines that as without  
7 interval of time.

8 So their imminent danger is that this is  
9 threatening to occur without interval of time. Now,  
10 in this particular case, if I go to The Crack'd Egg  
11 and they don't have a mask on, I apparently am going  
12 to get it the minute I sit down or the minute that I  
13 enter that establishment. That's their own rules,  
14 that's their words, that's their statute.

15 So let's look at the first prong. What is  
16 the immediate and irreparable harm that they are  
17 attempting to stop?

18 The August 11th order was to shut down.  
19 What testimony did we hear that there was irreparable  
20 harm that needed to be shut down immediately without  
21 the interval of time?

22 This case has been going on for six months,  
23 the virus has been here for a year. Where is the  
24 immediate harm?

25 Dr. Brink testified and had to add that

1 masks are helpful. When I talk about the six prongs  
2 most of them will deal with masks because from the  
3 evidence that I saw the only written report that they  
4 weren't social distancing and having the tables  
5 spread apart belied that allegation. That only  
6 written report said that their distancing was  
7 satisfactory and the only thing that they were cited  
8 for in writing was the masks as I remember the  
9 evidence.

10 So let's talk about the masks. Dr. Brink  
11 did not testify and as a matter of fact she admitted  
12 that masks do not stop the spread. They are helpful,  
13 but they do not stop.

14 So where is the irreparable harm? Where is  
15 the immediacy of this?

16 They talked about droplets, the size of the  
17 droplets. The masks will stop droplets. They won't  
18 stop big droplets, they won't stop little droplets.  
19 They still get through.

20 You heard testimony from one of our  
21 witnesses today, Kelly, and you also heard from  
22 Dr. Weiler today regarding masks and whether they  
23 work and whether they don't work.

24 Well, it is interesting. Let's talk about  
25 the masks and talk about the history of the masks.

1           It started out masks don't mean anything,  
2           then you had to have a mask, then you had to have a  
3           certain type of mask, then you had to have an N95 and  
4           then you had to get a shield, don't use a gator, they  
5           are not good, don't use a cloth mask, they are not  
6           good.

7           What mask is the one that works that stops  
8           it? What mask do they have out there that actually  
9           stops the spread of this virus? The answer is none.  
10          There is no mask that stops the spread of this virus,  
11          but the County wants you to believe that there is.

12          So what they do is that they bring in  
13          Dr. Brink to talk about it and they bring in  
14          Dr. Bogen to talk about it. And no one has  
15          attributed one single outbreak or one single case to  
16          The Crack'd Egg.

17          What they provided to you, Your Honor, was a  
18          chart. I think that it talked about Restaurant A  
19          through Restaurant I and they talked about the months  
20          and I think that there were eleven of them, eight of  
21          which they gave you the date of June, and here is my  
22          favorite part of all. In June they issued a press  
23          release, "they" being the Allegheny County Health  
24          Department. I would like to read from the press  
25          release.

1           "The department has not identified any  
2           apparent clusters in the travel destinations or  
3           activities. What neither health department  
4           investigators nor COVID positive residents know is  
5           exactly where or when people contracted the virus.  
6           They don't know if they were exposed before vacation,  
7           while on vacation, after returning home. They don't  
8           know if they were exposed at a bar or restaurant or  
9           if they were exposed before or after going out."

10           So we have got all these mitigation measures  
11           aimed at restaurants and bars and the County's own  
12           literature, the County's own words, they can't trace  
13           them to a bar or restaurant. That is important  
14           because when you are trying to shut down somebody's  
15           business, when you are trying to shut down their  
16           livelihood, when you are trying to shut down the  
17           livelihood of the workers at The Crack'd Egg.

18           Think about that. Their own document that  
19           they put out for public release, they can't track it.

20           Nobody has testified before you, Your Honor,  
21           that in all their tracing and their epidemiology and  
22           this and that, whatever the science that they wanted  
23           to come up with at that time, no matter what side  
24           that it is, not one person has told you that we can  
25           positively say that if you wear a mask in a

1 restaurant there will be no COVID. It is impossible  
2 to tell you that.

3 Therefore, where is the irreparable harm?  
4 Where is the harm that they can't get later on?  
5 Remember, this is just a temporary injunctive relief  
6 until you can get to a formal hearing where you get  
7 more scientists coming in, more telling you that  
8 masks are great, more telling you that masks are  
9 good, more people that are -- there isn't one person  
10 in here that will tell you that masks absolutely stop  
11 the spread of COVID. They can't do it.

12 Let's go to prong two. The prong is greater  
13 injury would result from refusing an injunction than  
14 from granting it.

15 Your Honor, I would submit that  
16 concomitantly with that the issue of an injunction is  
17 not to substantially harm other interested parties in  
18 the proceeding, and in this particular case, the harm  
19 in granting the injunction comes to the public. It  
20 comes to The Crack'd Egg. Greater injury will result  
21 from granting an injunction in this case.

22 What injury currently exists? What  
23 identifiable injury can the county health department  
24 point to that currently exists? None. They are all  
25 potential remedies, potential this, potential that,

1 but remember the department's own press release, they  
2 cannot even trace anything to a restaurant. Hence  
3 there can be no greater injury that will result and  
4 that is the standard. What is the greater injury  
5 that will result?

6 To satisfy the second prong, the parties  
7 seeking the injunction, i.e., the county health  
8 department, must show that greater injury would  
9 result from refusing an injunction than from granting  
10 it.

11 That is how it is happening here. Granting  
12 this injunction closes this restaurant because they  
13 don't wear masks, but the County has not established  
14 that they have linked any specific positive COVID  
15 case to this specific restaurant. In fact, the  
16 County has not even established that they have linked  
17 a positive COVID case to any restaurant that is not  
18 enforcing the wearing of masks.

19 Remember Dr. Brink's testimony. While she  
20 claimed that they could link clusters to restaurants  
21 despite the fact that contradictory statements by the  
22 County's own employees and press release state  
23 otherwise, she admitted that if people were wearing  
24 masks in the restaurant or not was not a  
25 consideration.

1           So in her own chart, in her own data, in her  
2           own testimony she couldn't give you a distinction  
3           between wearing masks and not wearing masks. That is  
4           important, you have a heavy burden here, and their  
5           expert, their main person, the County's own  
6           epidemiologist could not give you that information.

7           So what injury is being prevented by  
8           granting this injunction? Restaurants in general  
9           will still be open.

10           If my client decided to wear a mask, they  
11           would stay open, but it doesn't matter because the  
12           County cannot tell you that wearing masks will  
13           prevent the outbreak in a restaurant. That is their  
14           testimony.

15           Don't take my word for it, don't take any of  
16           our experts' words for it. Just listen to them.  
17           Their words tell you that they can't satisfy this  
18           problem.

19           The injury that results from granting the  
20           injunction is the irreparable damage to the business  
21           and the livelihood of its owners and its employees.  
22           The injury that results from granting the injunction  
23           is essentially approving the County, casting aside  
24           the proper procedures and fundamentals of our  
25           governmental system. Issuing the injunction causes a



1 substantial harm to the public in general because  
2 they are not following the Constitution.

3 Without the Constitution, without the rules  
4 and regulations what is it that we have, Your Honor?  
5 What is it that we tried to enforce?

6 No matter what side of the argument you fall  
7 on, if you are red or blue, R or D, it doesn't  
8 matter. In the election 74 million people think that  
9 this matters, that the Constitution matters. 74  
10 million people think that having rules and  
11 regulations matter.

12 Let's look at prong three. The injunction  
13 will properly restore the parties to their status  
14 that is as it existed immediately prior to the  
15 alleged wrongful conduct.

16 So on August 11, what was the parties'  
17 status? It is an important question. It is prong  
18 three.

19 Well, The Crack'd Egg's status is that they  
20 didn't have masks, they didn't wear masks, and on  
21 August 11th, I am not sure what the government's  
22 position was with regard to masks, that might have  
23 been in a period where they said that you didn't need  
24 a mask or you needed an N95 mask or gators were okay,  
25 but now they are not okay. There is a lot of

1 discrepancy out there.

2 The preliminary injunctive relief is an  
3 equitable remedy available in equity actions. The  
4 preliminary injunction is designed to preserve the  
5 subject of the controversy in the condition in which  
6 it is when the order is made. It is not to subvert  
7 but to maintain the existing status quo until the  
8 legality of the challenged conduct can be determined  
9 on the merits.

10 I know that this prong three seems kind of  
11 odd, but the way that you have found them, you are a  
12 court of equity, do no harm, leave them as you found  
13 them if you can.

14 So at this point in time you found them not  
15 wearing a mask. Leave them that way because there  
16 has been no evidence whatsoever to suggest that  
17 wearing the mask is going to prevent the spread of  
18 this virus.

19 Their own expert says that it might slow it,  
20 it will stop some of it, but not all of it. Again, I  
21 hate to keep repeating myself, but they cannot relate  
22 it back to this restaurant or any other restaurant  
23 masks or no masks.

24 Again, I remember back to my first day of  
25 law school one of the professors, and it was

1 Professor Gray, said that he who seeks equity must do  
2 equity. What does that mean? That means that no one  
3 is entitled to the aid of the Court when the aid has  
4 become necessary through their own fault.

5 So right now they are coming to you and they  
6 are asking you to aid them in this equity action.  
7 Aid us in making The Crack'd Egg wear masks.

8 Why are they coming to you? Because they  
9 did not follow their own rules and regulations. They  
10 did not follow the Constitution. They have dirty  
11 hands here.

12 Have they done what they were supposed to do  
13 in the last year? Forget the first 90 days of the  
14 Emergency Powers Act.

15 What have they done in the last year? Where  
16 have they gone to try to get these rules and  
17 regulations passed? What have they done for the  
18 public that had comment on it? What have they done  
19 in the debate between the legislature?

20 The answer is nothing. They have done  
21 nothing. So, therefore, they are coming to you with  
22 unclean hands with a equity action.

23 As a matter of fact, the Pennsylvania  
24 legislature wanted to go through and say that the  
25 governor didn't have the powers to do this. However,

1 the governor I think vetoed it or something like  
2 that.

3 So our own legislature is out there crying  
4 that we need to go through these rules and  
5 regulations, you can't do what you are doing. So the  
6 aid that the County once again is asking you to give  
7 is caused solely by their actions in failing to  
8 follow their own rules and regulations and what they  
9 needed to do.

10 They have violated the Constitution of we  
11 the people of Allegheny County. They have violated  
12 the Constitution of we the people of the Commonwealth  
13 of Pennsylvania.

14 So I think that that prong fails,  
15 absolutely. First I think that they all fail, but  
16 three and four definitely are failures. Prong four  
17 is the parties seeking the injunction is likely to  
18 prevail on the merits.

19 Again, Your Honor, rules and regulations. I  
20 am going to keep pounding on it and I am going to  
21 keep hounding it because it is the single most  
22 important thing here. They have not followed what  
23 they needed to do. No one can say that the county  
24 health department is likely to prevail on the merits.

25 I have been practicing law for 30 years. I

1 have never seen a case that is 100 percent full  
2 proof.

3 Most of the cases that you think that you  
4 are going to win, you lose, the cases you think you  
5 are going to lose, you win them. It happens.

6 In this particular case they need to prove  
7 that they are likely to prevail on the merits and I  
8 submit to you that they will never prevail on the  
9 merits as long as they are in violation of their own  
10 rules and regulations and in violation of the  
11 Constitution.

12 I think that great guidance here comes from  
13 our criminal courts and again this is the analogy  
14 that I came up with.

15 In a criminal case in order to convict  
16 someone it has to be beyond a reasonable doubt.  
17 Nobody knows what that means. What does beyond a  
18 reasonable doubt mean?

19 Well, when you are giving that instruction  
20 to the jury, the Court gives guidance and what they  
21 say in the charge to the jury is reasonable doubt is  
22 something that causes you to stop, pause and  
23 hesitate. I think that that is what prong four is  
24 about.

25 Are they likely to prevail on the merits?

1 If you have to stop, pause and hesitate to think  
2 about that, I would submit that then that prong  
3 fails. If you don't think that, then that prong  
4 sails through and the County has met their burden.

5 But to prevail on the merits you would have  
6 to believe that masks stop the spread 100 percent and  
7 you would have to believe that the County followed  
8 the rules and regulations provision of the two acts  
9 that I referenced earlier as well as the Constitution  
10 of this great Commonwealth. I would submit to you  
11 that that has not happened, either one of those.

12 Prong five. The injunction is reasonably  
13 suited to abate the offending activity. Even more  
14 essential, however here is the determination that the  
15 activities sought to be restrained is actionable and  
16 that the injunction issued is reasonably suited to  
17 abate such activity and unless the Plaintiff's right  
18 is clear and the wrong is manifest a preliminary  
19 injunction will not be awarded in these cases.

20 This is important because you recall once  
21 again the department's chart and Dr. Brink's  
22 testimony that even when they can link a cluster to a  
23 restaurant it isn't considered if the restaurant was  
24 wearing a mask or not.

25 That wasn't one of the questions in this

1           stuff that she sent out to people. That wasn't one  
2           of the areas that the investigators looked into.

3                     Again, don't take my word for it. That's  
4           her words. That's the doctor, that's Dr. Brink's  
5           words. Their expert, their employee, their chief  
6           epidemiologist.

7                     The department requested this injunction in  
8           an effort to slow the spread of COVID, but there is  
9           no evidence to show that the spread is higher in a  
10          restaurant not wearing a mask than in a restaurant  
11          wearing a mask. Again, that is their testimony, not  
12          ours.

13                    Shutting down The Crack'd Egg for not  
14          requiring masks is not reasonably suited to abate the  
15          spread of COVID in restaurants in general.

16                    Again, go back to their press release. They  
17          can't trace anything to know if they were exposed at  
18          a bar or a restaurant. So again, prong five fails.

19                    The sixth and final prong, the injunction  
20          will not adversely affect the public's interest.

21                    Issuing this injunction will adversely  
22          affect the public's interest. There is public  
23          interest in protecting the livelihood of the county  
24          citizens.

25                    More importantly, there is a public interest

1 in protecting the fundamentals of American democracy,  
2 the systems of checks and balances, separation of  
3 powers and the procedures of our law making rules and  
4 regulations.

5 The county cast aside those fundamentals  
6 when one person decided that they were King George  
7 and issued an injunction essentially approving the  
8 action of failing to follow the rules and  
9 regulations.

10 An established system of checks and balances  
11 does not allow that to happen. Issuing the  
12 injunction adversely affects the public's interest  
13 here, Your Honor.

14 The County would like to say that there is  
15 also a public interest in slowing the spread of  
16 COVID-19. That may be true, but the County cannot  
17 prove that in this injunction.

18 Now, these six rules are conjunctive, it is  
19 one and two and three and four and five and six. It  
20 is not "or". It is not one or two. You don't get to  
21 pick which ones that you want.

22 You have to satisfy all six prongs to get  
23 preliminary relief, and clearly, I don't believe that  
24 the County has done that. The County needs to show a  
25 clear right to relief here and under the facts



1 presented resolution of this prong is based entirely  
2 upon the satisfactory interpretation of our statute.

3 Again, go back to the statute I said in the  
4 beginning. That is what this entire case rests on,  
5 interpreting the statute.

6 Go back to the source document. Words have  
7 meaning. The County has failed in all of that.

8 One of the things that struck me when  
9 Dr. Weiler was testifying, he talked about the flu.  
10 There are no cases of the flu anymore. It is all  
11 COVID.

12 Jokingly around our office we joke that we  
13 have cured the flu, we have cured cancer, we have  
14 cured heart disease. Nobody dies from that.  
15 Everybody is attributed to dying from COVID.  
16 Everyone is attributed to dying because they got  
17 this.

18 There is co-morbidity out there. These  
19 people may have been sick or may have been going to  
20 die anyhow. The numbers are inflated, but you don't  
21 even need to get into that. That probably doesn't  
22 even come into your consideration of anything that  
23 you might have to do here.

24 I submit that, as I said in the beginning,  
25 you only need to look at Dr. Bogen's testimony and

1 the acts that we have cited. Based on that, they are  
2 not entitled to an injunction and they will never be  
3 entitled to a permanent injunction in this case.

4 That is what the civil rights lawsuit is  
5 about, all the other lawsuits pending in this case.  
6 That is what they are about.

7 How do they cure it? They can cure it.  
8 They have the ability to cure it. They can follow  
9 their statute, they can have the public debate. They  
10 can propose these rules and they can be passed one  
11 way or the other, but you don't get to say that I am  
12 Dr. Bogen, I do not need their authority. I do not  
13 need to ask them. I can do what I want.

14 I think that you have to deny this, Your  
15 Honor. Thank you.

16 THE COURT: Thank you, Mr. Blackwell.  
17 Ms. Patel.

18 MS. PATEL: Your Honor, this case is  
19 about public health. It is about whether a  
20 restaurant be allowed to ignore orders that most  
21 other facilities in the county adhered to and thereby  
22 continue to risk a great harm on the public, the  
23 public which are the very people of the county that  
24 Mr. Blackwell mentioned.

25 We have learned that COVID-19 spreads

1 through asymptomatic carriers, that these individuals  
2 that test positively unknowingly spread the virus,  
3 that the health agency, the health department has a  
4 duty to prevent current and future harm to the  
5 public. We are not here to wait until people are  
6 sick to take action.

7 The Local Health Administration Law Section  
8 12012 (c) gives the director of the health department  
9 the authority to issue orders to abate nuisances  
10 detrimental to public health.

11 We have demonstrated the health department  
12 has the authority to suspend a health permit and  
13 require corrective action for the protection of the  
14 people in the county under Article 3.

15 Article 3 is a validly executed regulation  
16 pursuant to the Local Health Administration Law. The  
17 constitutionality of the health department's actions  
18 are legal issues that will be addressed in our  
19 briefs.

20 We have heard anecdotal testimony about the  
21 harm to the restaurant industry based on significant  
22 hearsay. However, The Crack'd Egg has not  
23 demonstrated harm, financial or otherwise if it were  
24 to implement masks for patrons and employees.

25 I would like to remind this Court that the

1 department is not asking for The Crack'd Egg to shut  
2 down. The department is asking the Court to require  
3 that they comply with the COVID-19 mitigation  
4 requirements of wearing masks and limiting occupancy  
5 and if they comply they do not need to close.

6 According to the logic of their own expert,  
7 which the department disagrees with, she said that  
8 employers should require their employees to wear N95  
9 masks and implement a respiratory protection program.  
10 Thus, according to their own expert, The Crack'd Egg  
11 is in violation of OSHA.

12 When weighing relative harm the Court must  
13 weigh the harm of the exposure to the public versus  
14 the harm to The Crack'd Egg.

15 Despite Defendant's counsel and the  
16 questionable experts there is no dispute in the  
17 reputable scientific community that masks, social  
18 distancing and occupancy reduce exposure to COVID.  
19 Further, there is no credible dispute that the  
20 numbers of positive COVID patients and deaths are  
21 accurate.

22 This Court has even acknowledged that this  
23 disease exists and social distancing and masking are  
24 necessary. The Court of Common Pleas.

25 If this were not the case, I would be

1 speaking before you today in the courtroom with  
2 counsel on both side in close proximity with their  
3 clients in the presence of everyone on this call and  
4 no one would be wearing a mask or social distancing.

5 Requiring The Crack'd Egg to follow the  
6 department's corrective actions will prevent  
7 immediate and irreparable harm to the general public,  
8 the people of this county. The department will  
9 provide further argument as for a basis of the  
10 injunction in its brief to this Court.

11 THE COURT: You are welcome to submit  
12 briefs. When do you plan on getting that in,  
13 Ms. Patel?

14 MS. PATEL: When will the transcript be  
15 ready?

16 THE COURT REPORTER: My standard delivery  
17 is about two to three weeks.

18 THE COURT: The defense has given me a  
19 brief. You can give me one too.

20 I am going to start delving into this and I  
21 want to really rule soon and my goal was really to  
22 rule sometime next week and I was really hoping  
23 Monday or Tuesday.

24 I don't have the transcript either, I know,  
25 but I think that we can basically assess the six

1 prongs, I think that we know what the big testimony  
2 was, and I want to read through the documents, but I  
3 think that there is going to be further evidence  
4 challenging the efficacy of the masks and --

5 MR. BLACKWELL: Do you even need a brief,  
6 Your Honor?

7 THE COURT: I am giving you the option,  
8 but I am saying that I am moving ahead.

9 Now, you thoroughly went through the six  
10 prongs, Mr. Blackwell. I appreciate it, but I am  
11 basically leaving it up to you guys and I am moving  
12 ahead, but I will even throw out if you think  
13 particular cases that you want me to read while I am  
14 doing this that might help.

15 You don't have to write a brief, but if you  
16 think that I should read a case, e-mail me the case,  
17 but e-mail the other side of course that you want me  
18 to read that. That will help expedite. You can feel  
19 free to do that over the weekend too because I am  
20 going to be working on it.

21 File a brief if you want, don't if you don't  
22 want to and send me case law if you want, don't if  
23 you don't want to. Okay? That's basically how it  
24 works, but I am moving ahead.

25 MS. PATEL: Your Honor, just to let you

1 know, we did provide a motion for the basis of the  
2 injunction, and we can provide a brief response to  
3 their new argument that the state and the ACHD order  
4 is not viable. I would defer to my colleague,  
5 Michael Parker, but he is able to do that on the  
6 call.

7 THE COURT: I am just saying if you want  
8 to file it, file it. They filed a brief.

9 MS. PATEL: I am saying that that is  
10 something that we can address right now on the call.

11 THE COURT: Okay.

12 MS. PATEL: If you just give me a moment.

13 MR. BLACKWELL: Your Honor, just so I  
14 understand, is there new evidence coming in after  
15 closing?

16 THE COURT: No, I don't think. I think  
17 that the question was whether you are going to file a  
18 response brief or not. Right?

19 MR. BLACKWELL: That's what I understood  
20 it to be, but I thought that I just heard Ms. Patel  
21 say that someone was going to address something right  
22 now. If they are going to do it, I would rather see  
23 it in writing so we have the opportunity to decide  
24 whether we want to --

25 THE COURT: Yes, I would understand that,

1 but the question is, are you going to file a brief or  
2 not, and I am saying file what you want and I will  
3 read it, but I am moving ahead. If you want to send  
4 something to me over the weekend, just make sure that  
5 you copy the other side. I will consider it.

6 MR. PARKER: Can we file a brief, Monday,  
7 Your Honor, to address the articles concerning the  
8 validity of the orders?

9 THE COURT: Yes.

10 MR. PARKER: Thank you.

11 THE COURT: You basically want to respond  
12 to the brief that they filed; right?

13 MR. PARKER: Yes.

14 THE COURT: I will allow you to do that.  
15 Again, I am allowing both sides to file whatever they  
16 want to file.

17 So I am going to read the evidence, read the  
18 law and read what I have and try to get a ruling as  
19 soon as possible. So, yes, if you are saying that  
20 you will get me a brief on Monday and you don't want  
21 me to rule until I have that brief? Is that what you  
22 are saying?

23 MR. PARKER: Hold on just a second, Your  
24 Honor.

25 THE COURT: I would like to keep moving,



1           that's all. That is what I am saying.

2                       MR. PARKER: I am saying if we can have  
3 until Monday, yes, I would appreciate that.

4                       THE COURT: I won't make any decision  
5 before Monday at five and that's optimistic even on  
6 my end I will admit, but I want to do some reading  
7 and some evaluation of the whole thing, but I do  
8 believe that both parties need this resolved. Then  
9 however I resolve it, the other side is going to want  
10 to deal with my decision in some fashion.

11                      So both parties deserve me making some kind  
12 of decision promptly. That's all that I am saying.

13                      MR. BLACKWELL: With regard to whatever  
14 brief that they are going to file can we have it by  
15 10:00 a.m. Monday so that Mr. Cooney can get to work  
16 on a response if we need it?

17                      THE COURT: Mr. Parker, I don't think  
18 that that is necessarily unreasonable.

19                      MR. PARKER: No, Your Honor, and we are  
20 responding to their brief concerning the --

21                      THE COURT: I know, yes, and that isn't  
22 of record yet formally, your response to that. They  
23 have already argued their points on basically I am  
24 going to call it the three statutes by which they  
25 think that we're violating. Well, they also have the

1 County argument too, but to the extent that they have  
2 already argued that, you can respond.

3 They are allowed to file something in  
4 response. I can't imagine that it would be too much,  
5 but you might put something in your brief that they  
6 want to respond to. That is only fair.

7 MR. PARKER: Yes, Your Honor.

8 THE COURT: I am not going to get crazy  
9 about this. You guys can file what you want, but I  
10 am going to try to decide by Monday, hopefully, and  
11 if not --

12 MR. PARKER: Actually, our argument  
13 regarding our authority for our orders is laid out in  
14 our complaint. If you want to avoid the delay --

15 THE COURT: No. File your brief. You  
16 believe that your county argument is largely Article  
17 3. You have already addressed that; is that correct?

18 MR. PARKER: Yes, more or less, Your  
19 Honor. The Article 3 is delivered from health  
20 administration.

21 THE COURT: Right. You have raised those  
22 in your motion and so forth, but he is saying that  
23 you didn't follow the home rule charter and basically  
24 the home rule charter and the rules, the board of  
25 health authorization and you used the county



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C E R T I F I C A T E

I hereby certify that the proceedings are contained fully and accurately in the notes taken by me on the hearing of the herein cause and that this is a true and correct transcript of the same.

\_\_\_\_\_  
Melissa J. Gasper  
Official Court Reporter

The foregoing record of the proceedings upon the hearing of the herein cause is hereby approved and directed to be filed.

\_\_\_\_\_