## UNITED STATES DISTRICT COURT DISTRICT OF CONNECTICUT

JAMES N. BELLATONI, JR., GINA REICHERT, BETTE KITIK, MELISSA DORISH, MICHAEL COSTANZA, MARCIA BACKSAY, MICHAEL SELEARIS, MICHAEL PIETRUSZKA, LISA M. RICCI-BOYLE, LISA SIBLEY, DON FARNEN, STACEY WALLER, KELLEY WHITTAKER, MICHELLE BOND, KAHSEIM OUTLAW

**FEBRUARY 9, 2022** 

Plaintiffs,

v.

EDWARD M. LAMONT, Governor of the State of Connecticut, MANISHA JUTHANI, Commissioner, Connecticut Department of Public Health

Defendants,

# **COMPLAINT AND DEMAND FOR TRIAL BY JURY**

1. The Plaintiffs in this lawsuit are teachers situated throughout the state of Connecticut. The Plaintiffs bring this action to challenge Governor Lamont's COVID-19 vaccine mandate, contained in Executive Order 13D, and subsequently amended by Executive Order 13G ("Vaccine Mandate"), which is designed and implemented for one purpose: to coerce the Plaintiffs into taking an experimental gene therapy that is euphemistically branded as a "vaccine."

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2. The Plaintiffs in this action are seeking a declaratory judgment that Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D, and amended by Executive Order 13G, is unconstitutional because it violates the Plaintiffs' right to bodily autonomy, medical privacy and equal protection guaranteed under the Fourth, Fifth and Fourteenth Amendments to the United States Constitution.

3. The Plaintiffs also seek a judgment declaring that Governor Lamont's Vaccine Mandate is preempted by federal law because the only available COVID-19 vaccines are being administered under the "Emergency Use Authorization" statute—21 U.S.C. §360bbb-3—which explicitly requires informed consent and prohibits any action that has the effect of coercing an individual into taking an experimental drug. (Sec. III.B).

4. In support of their claim that the Defendant's COVID-19 Vaccine Mandate violates their constitutional rights the Plaintiffs will demonstrate the following:

(i) The COVID-19 vaccines are not safe, which is evidenced by data from Pfizer's own clinical trials as well as the official safety data collected by the U.S. federal government through the Vaccine Adverse Events Reporting System (VAERS). (Sec. III.C).

(ii) The COVID-19 vaccines are not effective in preventing infections of COVID-19. The data from Pfizer's Phase 3 clinical trials demonstrates its COVID-19 vaccine has an absolute risk reduction of only .84% (.0084) at their peak performance, and any protection completely disappears within only a few months thereafter. (Sec. III.D).

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(iii) The COVID-19 vaccines do not stop transmission of COVID-19 and therefore do not provide any benefit to the public health. Consequently, this negates any plausible argument for mandating the COVID-19 vaccines. (Sec. III.E).

(iv) Clinical studies and data published by the Connecticut Department of Health demonstrates that COVID-19 vaccines have actually made the pandemic worse because the COVID-19 vaccines have <u>negative efficacy</u> against the "Omicron" variant. In other words, the vaccines actually *increase* the likelihood of contracting COVID-19. (Sec. III.F).

(v) The Defendant's Vaccine Mandate fails to recognize naturally acquired immunity to COVID-19, which is superior to any protection afforded by the COVID-19 vaccines because it is more robust and durable than vaccine induced immunity. (Sec. III.G).

(vi) The mandatory testing provision of the Vaccine Mandate has no basis in evidentiary science because it requires the unvaccinated Plaintiffs to submit to mandatory weekly testing while exempting their vaccinated coworkers, even though the evidence demonstrates that vaccinated individuals are more likely to test positive for COVID-19. Thus, the sole purpose of mandatory testing is to punish the Plaintiffs and coerce them into taking a COVID-19 vaccine against their will. (Sec. III.I).

5. Finally, the Plaintiffs claim that the Governor Lamont intentionally, knowingly, recklessly, and wontly violated the Plaintiffs' constitutional rights and acted under color of Connecticut State Law in doing so because the Defendant grossly exceeded his statutory

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authority to issue a mandatory vaccination order under C.G.S. §19a-131e, and no scientific evidence exists which could possible justify his Vaccine Mandate.

#### I. JURISDICTION AND VENUE

This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1343(3) in that the controversy arises under the United States Constitution and under 42 U.S.C. §1983.

7. This court has supplemental jurisdiction under 28 U.S.C. §1367(a) to hear and adjudicate state law claims.

8. Venue is proper under 28 U.S.C. §1391 as the parties are residents of this judicial district and the acts or occurrences giving rise to these claims took place in Connecticut.

#### II. PARTIES

9. The plaintiff, James N. Bellantoni Jr., is an individual residing in Connecticut. At all times relevant to this lawsuit, Mr. Bellantoni has been employed as a teacher in the New Haven, Connecticut public school system. On September 4, 2021, he was given notice that his employment would be terminated if he did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before October 1, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, Mr. Bellantoni

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obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save his job.

10. The plaintiff, Gina Reichert, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Reichert has been employed as a teacher in the West Haven, Connecticut public school system. On September 24, 2021, she was given notice from the administrative assistant to superintendent that her employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job.

11. The plaintiff, Michelle Bond, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Bond has been employed as a teacher in the Madison, Connecticut public school system. On August 25, 2021, she was given notice from human resources, that her employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as

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required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job.

12. The plaintiff, Bette Kitik, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Kitik was employed as a teacher at Eli Whitney Technical High School in the Connecticut Technical Education and Career System. On September 21, 2021, she was given notice from the Central Office at CTECS, that her employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine on October 19, 2021 and was told that she would need to submit to weekly testing, pursuant to the Defendant's Vaccine Mandate. She was denied a religious exemption from mandatory weekly testing in lieu of vaccination, according to the Defendants' Vaccine Mandate. Ms. Kitik was then placed on unpaid administrative leave on November 5, 2021, and then formally terminated from her employment on December 22, 2021 for failing to comply with the Defendants' Vaccine Mandate.

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13. The plaintiff, Melissa Dorish, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Dorish has been employed as a teacher in the Wallingford, Connecticut public school system. On September 1, 2021, she was given notice from the Assistant Superintendent of Personnel, that her employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job, pursuant to the Defendant's Vaccine Mandate.

14. The plaintiff, Michael Costanza, is an individual residing in Connecticut. At all times relevant to this lawsuit, Mr. Costanza has been employed as a teacher in the North Stonington, Connecticut public school system. Beginning on August 20, 2021, Mr. Costanza was given several notices from North Stonington public schools Superintendent that his employment would be terminated if he did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant

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to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, Mr. Costanza obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save his job, pursuant to the Defendant's Vaccine Mandate.

15. The plaintiff, Marcia Backsay, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Backsay has been employed as a teacher in the Bridgeport, Connecticut public school system. On September 1, 2021, she was given notice from the Assistant Superintendent of Personnel that her employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job, pursuant to the Defendant's Vaccine Mandate.

16. The plaintiff, Michael Selearis, is an individual residing in Connecticut. At all times relevant to this lawsuit, Mr. Selearis has been employed as a teacher in the New Haven public school system. On September 24, 2021, he was given notice from New Haven public

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school district that his employment would be terminated if he did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, he obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save his job, pursuant to the Defendant's Vaccine Mandate.

17. The plaintiff, Don Farnen, is an individual residing in Connecticut. At all times relevant to this lawsuit, Mr. Farnen has been employed as a teacher in the West Haven, Connecticut public school system. On August 26, 2021, he was given notice from the city of West Haven that his employment would be terminated if he did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, he obtained a religious exemption from receiving the COVID-19 vaccine and has

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been forced to submit to weekly testing under protest in order to save his job, pursuant to the Defendant's Vaccine Mandate.

18. The plaintiff, Stacey Waller, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Waller is employed as a teacher in the Hartford, Connecticut public school system. In August 2021 she was given notice from the superintendent of the school system that her employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job, pursuant to the Defendant's Vaccine Mandate.

19. The plaintiff, Michael Pietruszka, is an individual residing in Connecticut. At all times relevant to this lawsuit, Mr. Pietruszka has been employed as a teacher in the Capitol Region Education Council. On September 17, 2021, he was given notice that his employment would be terminated if he did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and

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submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, Mr. Pietruszka was placed on unpaid administrative leave on October 15, 2021 for not complying with the Defendants' Vaccine Mandate.

20. The plaintiff, Lisa M. Ricci-Boyle, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Ricci-Boyle is employed as a teacher in the Guilford, Connecticut public School system. On September 3, 2021 she was given notice from Guilford public school system, that their employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she has been forced to submit to weekly testing under protest in order to save her job, pursuant to the Defendant's Vaccine Mandate.

21. The plaintiff, Lisa Sibley, is an individual residing in Connecticut. At all times relevant to this lawsuit, Ms. Sibley has been employed as a teacher in the West Haven, Connecticut public school system. On September 24, 2021, she was given notice from the administrative assistant to the Superintendent that her employment would be terminated if she

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did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job, pursuant to the Defendant's Vaccine Mandate.

22. The plaintiff, Kelley Whittaker, is an individual residing in Connecticut. At all times relevant to this lawsuit, Kelley is employed as a school psychologist in the Hartford Public School system. At the beginning of this school year in early September, she was given notice from the superintendent that their employment would be terminated if she did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, to be fully vaccinated or by obtaining a valid exemption and submit to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that certified staff who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, she obtained a religious exemption from receiving the COVID-19 vaccine and has been forced to submit to weekly testing under protest in order to save her job, pursuant to the Defendant's Vaccine Mandate.

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23. The plaintiff, Kahseim Outlaw, is an individual residing in Connecticut. At all times relevant to this lawsuit, Mr. Outlaw was employed as a teacher in the Wallingford, Connecticut public school system. He was given notice that his employment would be terminated if he did not comply with Governor Lamont's Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G, by receiving a first dose of a COVID-19 vaccine on or before September 27, 2021, or by obtaining a valid exemption and submitting to a weekly testing protocol as required pursuant to the Defendants' Vaccine Mandate. The notice also stated that teachers who received the COVID-19 vaccine would not be required to submit to weekly testing. In response, Mr. Outlaw was placed on unpaid administrative leave on September 27, 2021, for not complying with the Defendants' Vaccine Mandate.

24. Defendant, Edward M. Lamont, is the duly elected Governor of the State of Connecticut. Governor Lamont is made a party to this action in both his official capacity and his personal capacity.

25. Defendant, Manisha Juthani, is the Commissioner of the State of Connecticut Department of Public Health Department.

### **III. STATEMENT OF FACTS**

26. By January 2020 news about an outbreak of a novel coronavirus in Wuhan, China was being disseminated across America. The novel virus was named as "Wuhan coronavirus" or "2019 novel coronavirus (2019-nCov)" by the Chinese researchers. The

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International Committee on Taxonomy of Viruses named the virus as "SARS-CoV-2" and the disease as "COVID-19."<sup>1</sup>

27. On March 10, 2020, Governor Lamont formally declared a "public health emergency" due to COVID-19.<sup>2</sup> At that time, the Connecticut Department of Public Health ("CT DPH") did not have a single reported case of COVID-19 or COVID-19 associated death in Connecticut. <sup>3</sup>

28. On August 19, 2021, Governor Lamont issued Executive Order No. 13D which mandates that the Plaintiffs receive the COVID-19 vaccines as a condition of their ongoing employment.<sup>4</sup> Executive Order 13D was subsequently amended by Executive Order 13G, which was issued on September 30, 2021.<sup>5</sup> Executive Order 13D and Executive Order 13G are collectively referred to as the "Vaccine Mandate" hereinafter.

<sup>&</sup>lt;sup>1</sup>. Shereen, Muhammad, et al. (2020), COVID-19 Infection: Emergence, transmission, and characteristics of human coronaviruses, *Journal of Advanced Research* Vol. 24 (July 20, 2020), *available at* <u>https://www.sciencedirect.com/science/article/pii/S2090123220300540</u>

<sup>&</sup>lt;sup>2</sup>. Governor Edward Lamont, Declaration of Emergency and Civil Preparedness, March 10, 2020, <u>https://portal.ct.gov/-/media/Office-of-the-Governor/News/20200310-declaration-of-civil-preparedness-and-public-health-emergency.pdf</u>

<sup>&</sup>lt;sup>3</sup>. CT DPH, COVID-19 Tests, Cases, Hospitalization and Deaths, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Tests-Cases-Hospitalizations-and-Deaths-S/rf3k-f8fg;</u>

<sup>&</sup>lt;sup>4</sup>. Gov. Lamont, Protection of Public Health and Safety During COVID-19 Pandemic-Vaccinations Required For State Employees, School Employees and Childcare Facility Staff, Executive Order No. 13D (Aug. 19, 2021), <u>https://portal.ct.gov/-/media/Office-of-the-</u> <u>Governor/Executive-Orders/Lamont-Executive-Orders/Executive-Order-No-13D.pdf</u>

<sup>&</sup>lt;sup>5</sup>. Gov. Lamont, Protection of Public Health and Safety During COVID-19 Pandemic-Vaccinations Required For State Employees, School Employees and Childcare Facility Staff,

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29. The Defendants' Vaccine Mandate required all "covered workers" to receive a COVID-19 vaccine on or before September 27, 2021 or submit to mandatory weekly testing. A "covered worker" was defined as "all employees, both full and parttime, contract workers, providers, assistants, substitutes, and other individuals working in a public or non-public pre-K to grade 12 school system." The Plaintiffs fall within the definition of a "covered worker" and therefore were directly subject to the Defendant's Vaccine Mandate.

30. The Defendants' Vaccine Mandate further provided that any "covered worker" who did not comply with the Vaccine Mandate was subject to the penalties and enforcement provisions set forth with more particularity therein.

## A. <u>THE DEFENDANTS MANIPULATED AND MISREPRESENTED THE</u> <u>EMPERICAL DATA CONCERNING COVID-19</u>

31. As of January 13, 2022, the CT DPH reports there have been a total of Seven Thousand One Hundred Eighteen (7,723) confirmed deaths associated with COVID-19 in Connecticut.<sup>6</sup>

32. Of that total, the CT DPH reported 4,973 COVID-19 associated deaths occurred in 2020. However, 3,111, or 62.5%, of those COVID-19 associated deaths occurred during the nine weeks between March 24, 2020 and May 31, 2020, and only 1,862 deaths occurred in the

Executive Order No. 13G (Sept. 30, 2021), <u>https://portal.ct.gov/-/media/Office-of-the-Governor/Executive-Orders/Lamont-Executive-Orders/Executive-Order-No-13G.pdf</u> <sup>6</sup>. CT DPH, COVID-19 Tests, Cases, and Deaths (Statewide), <u>https://data.ct.gov/Health-and-Human-Sevices/COVID-19-Tests-Cases-and-Deaths-By-Town-/28fr-ignx</u>

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subsequent seven months between June 1, 2020 and December 31, 2020. Only 2,559 COVID-

19 associated deaths occurred in 2021.

- 33. To put these numbers in context, the CT DPH reports that in 2019 there were:
  - 15,556 deaths related to heart disease;
  - 6,441 deaths due to cancer (malignant neoplasms);
  - 3,047 deaths related to hypertension;
  - 2,808 deaths due to chronic lower respiratory disease;
  - 2,081 deaths related to diabetes
  - 1,084 drug related deaths; and
  - 1,025 accidental poisonings.<sup>7</sup>

34. As of January 13, 2022, the confirmed deaths associated with COVID-19

reported by the CT DPH break down along age demographics as follows:

Age	Total Deaths	
Group	(Confirmed)	%
80+	4,076	52%
70-79	1,772	23%
60-69	1,126	14%
50-59	491	6%
40-49	168	2%
30-39	65	<1%
20-29	20	<1%
10-19	4	<1%
0-9	1	<1%

<sup>&</sup>lt;sup>7</sup>. CT DPH, Mortality Statistics, <u>https://portal.ct.gov/DPH/Health-Information-Systems--</u> <u>Reporting/Mortality/Mortality-Tables</u>

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35. In other words, the median age of all COVID-19 associated deaths in Connecticut is over Eighty (80) years old; Seventy-Five Percent (75%) of COVID-19 associated deaths in Connecticut are among individuals seventy (70) years old and above; and nearly Ninety Percent (90%), of the confirmed COVID-19 associated deaths in Connecticut have been amongst individuals sixty (60) years old and above.

36. Because the population of Connecticut is approximately 3.57 million people,<sup>8</sup> during the nearly two years of the pandemic between March 10, 2020 and January 13, 2022, only two tenths of one percent (.2% or .002) of the Connecticut population has had a COVID-19 associated death. <sup>9</sup>

37. However, the amount of COVID-19 associated deaths reported by the CT DPH are significantly inflated because early in 2020, the CT DPH adopted several policies that guaranteed that COVID-19 deaths would be significantly overcounted, including the adoption of the CDC's recommended definition of a "COVID-19 associated death" which conflates individuals who died <u>from</u> COVID-19, with those individuals who merely died <u>with</u> COVID-19. These actions include:

(A) On March 11, 2020, the CT DPH issued a directive (BLAST FAX 2020-8) regarding "Guidance for Certifying COVID-19 Deaths" which directs that "Coronavirus

<sup>&</sup>lt;sup>8</sup>. CT DPH, Population Statistics, <u>https://portal.ct.gov/DPH/Health-Information-Systems--Reporting/Population/Population-Statistics</u>

<sup>&</sup>lt;sup>9</sup>. (Covid-19 associated deaths) / (CT Population) = (7,723) / (3,570,000) = .002

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Disease 2019 or 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....<sup>10</sup>

(B) On March 18, 2020, a directive was issued to all nursing homes in the state of Connecticut entitled, "Connecticut: Blast Fax 2020-15" which attached a notice from the Office of the Chief Medical Examiner ("OCME") directing "all suspected and confirmed COVID-19 cases should be reported to the [Office of Chief Medical Examiner]."<sup>11</sup>

(C) On March 30, 2020 the CT DPH issued a directive entitled "Connecticut: Blast Fax 2020-15A" containing further direction from the OCME regarding how to certify deaths which were "associated" with COIVD-19.<sup>12</sup>

(D) On May 7, 2020, the CT DPH issued CT BLAST FAX 2020-51 directing that any "presumptive case" of COVID-19 should be reported to CT DPH, and which defines a "presumptive case to include individuals who have tested negative for COVID-19.<sup>13</sup>

38. The CT DPH adopted the polymerase chain reaction (PCR) tests as the primary diagnostic tool for identifying a COVID-19 infection.<sup>14</sup>

<sup>&</sup>lt;sup>10</sup>. CT DPH, BLAST FAX 2020-8, <u>https://portal.ct.gov/DPH/Facility-Licensing--</u> Investigations/Facility-Licensing--Investigations-Section-FLIS/Blast-Fax-Page

<sup>&</sup>lt;sup>11</sup>. CT DPH, BLAST FAX 2020-15, <u>https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/Facility-Licensing--Investigations/Blast-Faxes/Blast-Fax-202015-Notice-from-the-Chief-Medical-Examiner.pdf</u>

<sup>&</sup>lt;sup>12</sup>. CT DPH, BLAST FAX 2020-15A, <u>https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/Facility-Licensing--Investigations/Blast-Faxes/Blast-Fax-202015A-COVID19-Information-from-the-Chief-Medical-Examiner.pdf</u>

<sup>&</sup>lt;sup>13</sup>. CT DPH, BLAST FAX 2020-51, <u>https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/Facility-Licensing--Investigations/Blast-Faxes/Blast-Fax-202051-LTCF-COVID19-Daily-Reporting-System.pdf</u>

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39. Invented by Nobel laureate Kary Mullis in 1983, PCR technology amplifies selected pieces of DNA by using primers that target a sequence of nucleotides; once the primers locate the targeted genomic sequence the polymerase enzyme creates copies of the DNA sequence targeted by the primers. "At the end of this process, the total amount of target DNA will have doubled; and the whole process can be repeated again; each cycle results in a doubling of the target region." The number of cycles utilized is called the cycle threshold (Ct) count.<sup>15</sup>

40. Therefore, the accuracy of a positive PCR test, which is used as a proxy for an active COVID-19 infection, is entirely dependent on:

- (i) The cycle threshold (Ct) count used; and
- (ii) The primers utilized by the PCR test

However, as described below, these fundamental features of the PCR tests are easily manipulatable, and have been manipulated by the Defendants for purely political purposes.

41. Because the PCR test exponentially increases the amount of target DNA with each additional cycle count, the accuracy of a positive tests decreases exponentially with each

<sup>&</sup>lt;sup>14</sup>. CT DPH, Where do I go to get tested for COVID-19? How do I know If I should be tested? (July 2, 2020), *available at <u>https://portal.ct.gov/Coronavirus/Covid-19-Knowledge-Base/COVID-19-Testing</u>;* 

<sup>&</sup>lt;sup>15</sup>. Watson, James, DNA: THE STORY OF THE GENETIC REVOLUTION (Kindle), Alfred A Knopft (2017), pp. 171-172; Flint, Jane, et al., PRINCIPLES OF VIROLOGY, VOL. 1: MOLECULAR BIOLOGY (Kindle, 5<sup>th</sup> Edition 2020), ASM Press, p. 45

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additional cycle such that a cycle threshold (Ct) count above a 28 is effectively meaningless; a fact reported by the *New York Times* in August 2020.<sup>16</sup>

42. Without knowing the cycle threshold (Ct) count associated with each positive COVID-19 test, it is impossible to evaluate the validity of the positive test results reported by the CT DPH. However, the CT DPH does not report the cycle threshold (Ct) count associated with each positive case that is reported, nor are they currently required to under Connecticut law.<sup>17</sup>

43. The CT DPH, at the direction of the CDC, has utilized the cycle threshold (Ct) mechanism to manipulate and skew the COVID-19 data to artificially inflate the number of unvaccinated people testing positive for COVID-19 compared to vaccinated people by setting the cycle threshold to 40 (Ct) for unvaccinated people, while setting the cycle threshold to 28 (Ct) for vaccinated individuals.<sup>18</sup>

<sup>17</sup>. CT DPH, Reporting SARS-CoV-2 (COVID-19) Test Results and Cases: Guidance for Laboratories, Point of Care Providers, and Others, <u>https://portal.ct.gov/-</u>/media/DPH/HAI/COVID19-Test-Reporting 092020V11.pdf;

Connecticut General Assembly (Jan. Session 2021), Proposed Bill No. 6023, An Act Concerning Cycle Threshold Values in Polymerase Chain Reaction Test Results for COVID-19, <u>https://www.cga.ct.gov/2021/TOB/H/PDF/2021HB-06023-R00-HB.PDF</u>

<sup>&</sup>lt;sup>16</sup>. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel-Instruction for Use, p. 34, <u>https://www.fda.gov/media/134922/download;</u> Mandavilli, Aprrova, Your Coronavirus Test Is Positive. Maybe It Shouldn't Be, *NY Times* (Aug. 29, 2020), <u>https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html</u>

<sup>&</sup>lt;sup>18</sup>. CT DPH, COVID-19 Guidance for Healthcare Professionals and Healthcare Facilities, <u>https://portal.ct.gov/DPH/HAI/COVID-19-Healthcare-Guidance;</u>

CDC, How to Send Sequence Data or Respiratory Specimens From Suspected Vaccine Breakthrough Cases < or equal to 28, <u>http://www.cdc.gov/vaccines/covid-19/health-</u>

44. Both the CDC and the FDA admit that the PCR tests do not just detect the presence of the SARS-CoV-2 (COVID-19) virus, but also detect the presence many types of bacteria and other viruses such as influenza and the common cold.<sup>19</sup>

45. In fact, when the FDA approved the PCR tests for emergency use in detecting the SARS-CoV-2 virus, the FDA explicitly stated that the PCR test "cannot rule out diseases caused by other bacterial or viral pathogens."<sup>20</sup>

46. This is because the United States government has never had an isolated sample of the SARS-CoV-2 virus to use in creating the primers for the PCR tests. Instead, the primers of the PCR test were created using the genomic sequences of different coronaviruses that had been previously isolated, sequenced and published in GenBank,<sup>21</sup> the NIH's public archive of genomic sequences for all known viruses:

"Since no quantified virus isolates of the 2019-nCoV were available for CDC use at the time the test was developed and this study conducted, assays designed for detection of the 2019-nCoV RNA were tested with characterized stocks of in vitro transcribed full length RNA (N gene; GenBank accession: MN908947.2) of known titer (RNA copies/ $\mu$ L) spiked into a diluent consisting of a suspension of human A549 cells and viral transport medium (VTM) to mimic clinical specimen."

<sup>&</sup>lt;u>departments/breakthrough-cases.html</u>; FDA, Revision 07 PCR Cycle Threshhold for Infection, 40.00 Ct., <u>https://fda.gov/media/134922/download</u>

<sup>&</sup>lt;sup>19</sup>. CDC, Diagnostic Tests for COVID-19, last updated Aug. 7, 2021, available at <u>https://www.cdc.gov/coronavirus/2019-ncov/lab/testing.html</u>

<sup>&</sup>lt;sup>20</sup>. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel-Instruction for Use, p. 38, <u>https://www.fda.gov/media/134922/download</u>

<sup>&</sup>lt;sup>21</sup>. NIH, GenBank Overview, <u>https://www.ncbi.nlm.nih.gov/genbank/</u>

<sup>&</sup>lt;sup>22</sup>. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel-Instruction for Use, p. 41, <u>https://www.fda.gov/media/134922/download</u>

47. In other words, the PCR test uses primers to detect the genomic sequence of the SARS-CoV-2 virus, but the primers were not created based upon the genomic sequence of the SARS-CoV-2 virus itself. Instead, the primers were designed based on speculation as to what the genomic sequence of the SARS-CoV-2 virus might be.

48. The FDA also readily acknowledges that the accuracy of the PCR tests becomes even less reliable as time passes and the virus mutates:

"If the virus mutates in the rRT-PCR [primer] target region, 2019-nCoV may not be detected or may be detected less predictably. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARSCoV-2 and their prevalence, which change over time."<sup>23</sup>

49. On July 21, 2021, the CDC issued notice that it was withdrawing its EUA for use

of the PCR test to detect COVID-19, effective December 31, 2021, citing the inability of the

PCR test to differentiate between the SARS-CoV-2 and the influenza virus. <sup>24</sup>

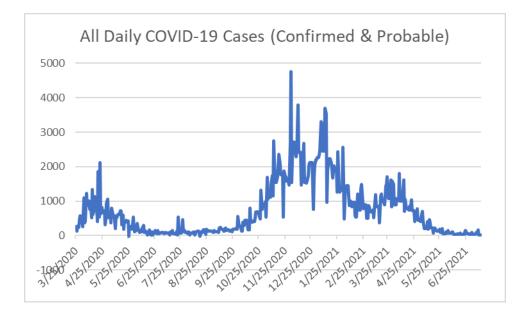
50. On July 20, 2020 it was discovered that 90 out of 144 people – or sixty-three percent (63%) - tested for COVID-19 between June 15 and July 17, 2020 received a false positive COVID test.<sup>25</sup>

<sup>&</sup>lt;sup>23</sup>. *Id.* at p. 37

<sup>&</sup>lt;sup>24</sup>. CDC, 07/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing, https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes\_CDC\_RT-PCR\_SARS-CoV-2\_Testing\_1.html

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51. Because the PCR tests cannot differentiate the presence of SARS-CoV-2 virus from any other respiratory virus, the epidemiological curve of COVID-19, for the first 16 months following the public health emergency, follows the pattern of every other respiratory virus:<sup>26</sup>



52. The graph above illustrates that COVID-19 cases spike between the months of November and February—commonly known as cold and flu season. Because respiratory viruses of all kinds are most prevalent in Connecticut during cold and flu season between

positive-covid-19-test-results/#/questions

<sup>&</sup>lt;sup>25</sup>. Ceneviva, Alex, State Public Health Lab discovers false-positive COVID-19 test results (July 20, 2020), *CT News8*, https://www.wtnh.com/news/health/coronavirus/state-public-health-lab-discovered-false-

<sup>&</sup>lt;sup>26</sup>. Connecticut Department of Health, COVID-19 Tests, Cases Hospitalizations, and Deaths, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Tests-Cases-Hospitalizations-and-Deaths-S/rf3k-f8fg</u>

November and February, and the PCR test cannot differentiate between SARS-CoV-2, influenza, or other coronavirus, a seasonal spike in COVID-19 cases would be excepted during the time of year that respiratory viruses are ubiquitous.

53. The graph above also evidences that COVID-19 is effectively non-existent during the during the spring and summer: This is consistent with findings of numerous studies demonstrating that heat, humidity and ultraviolet (UV) light, are very effective at killing COVID-19.<sup>27</sup>

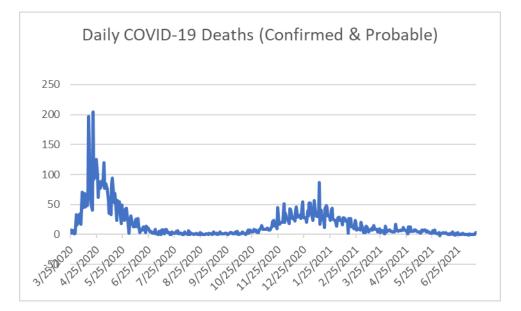
54. The seasonality of COVID-19 is also a result of decreased Vitamin D levels during the winter months. Vitamin D is critical to preventing COVID-19 infections and is naturally produced with skin exposure to sunlight. Vitamin D levels are lowest during the winter when days are shortest, and people spend the most time indoors.<sup>28</sup> Consequently, Connecticut residents are more likely to test positive for COVID-19 during the winter months when Vitamin D levels among the population are at their lowest.

<sup>&</sup>lt;sup>27</sup>. Ma, Yiqun (2021), Role of Meteorological Factors in the Transmission of SARS-CoV-2 in the United States, *Nature Communications* (June 14, 2021), https://www.nature.com/articles/s41467-021-23866-7

<sup>&</sup>lt;sup>28</sup>. *See e.g.*, Ghelani, Drishti, et al. (2021), Vitamin D and COVID-19: An Overview of Recent Evidence, *Int. J. of Mol. Science* (Oct. 22, 2021), *available at* <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8509048/</u>

55. Moreover, the vast majority of COVID-19 transmission occurs in the household as opposed to public settings.<sup>29</sup> This further establishes that the Defendants' claim that the workplace poses a high risk for transmission of COVID-19 is entirely false.

56. The data published by the CT DPH demonstrates that COVID-19 associated deaths have followed the same seasonal pattern:<sup>30</sup>



<sup>&</sup>lt;sup>29</sup>. Madewell, Zachary, et al. (2020), Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis, *Journal American Medical Association* (Dec. 14, 2020, available at <u>https://pubmed.ncbi.nlm.nih.gov/33315116/;</u> Lewis, Nathaniel, et al. (2020), Household Transmission of Severe Acute Respiratory Syndrome Coronavirus-2 in the United States, *Clinical Infectious Disease* Vol. 73 (7), (Oct. 1, 2021), available at <u>https://pubmed.ncbi.nlm.nih.gov/33185244/</u>

<sup>&</sup>lt;sup>30</sup>. Connecticut Department of Health, COVID-19 Tests, Cases Hospitalizations, and Deaths, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Tests-Cases-Hospitalizations-and-Deaths-S/rf3k-f8fg</u>

57. Because the COVID-19 PCR tests will detect any number of different viral pathogens such as flu, pneumonia and any other known coronavirus, including the common cold, a positive test result indicates the presence of <u>a</u> virus, it does not indicate which type of virus is present. In other words, a positive test result may indicate that the PCR test detected the presence of flu or pneumonia, not COVID-19. Consequently, positive PCR-test results are not admissible for the purposes of establishing the existence of SARS-CoV-2 because they fail to meet the threshold for admissibility of scientific evidence set forth in *Daubert v. Merrell Dow Pharmaceutical, Inc.*, 509 U.S. 579 (1993).

## B. <u>THE COVID-19 VACCINES ARE BEING ADMINISTERED EXCLUSIVELY</u> <u>UNDER EMERGENCY USE AUTHORIZATION</u>

58. The Food, Drug and Cosmetic Act ("FDCA") generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until the U.S. Food and Drug Administration ("FDA") has approved the drug or biological product as "safe and effective for its intended use." FDCA §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 US.C. § 262(a).

59. A vaccine is both a drug and a biological product under the FDCA. FDCA \$201(g), 21 U.S.C. \$321(g); 42 U.S.C. \$262(i)(1).

60. Section 564 of the FDCA (21 U.S.C. §360bbb-3), authorizes the FDA to issue an "emergency use authorization" (EUA) for a medical drug, device or biologic, such as a vaccine, under certain emergency circumstances. Pursuant to subsection (c)(3), this

26

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authorization is expressly conditioned on the non-existence of any "adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition."

61. On December 11, 2020, the FDA issued EUA 27034 to Pfizer, Inc. for use of the Pfizer-BioNTech COVID-19 Vaccine ("BNT162b2") to prevent COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act.<sup>31</sup> One week later the FDA issued EUA 27073 for the Moderna COVID-19 vaccine ("mRNA-1273 Vaccine")<sup>32</sup> and subsequently issued an EUA for the Johnson & Johnson COVID-19 vaccine ("Janssen Vaccine") on February 27, 2021.<sup>33</sup>

62. The FDA subsequently issued a Decision Memorandum extending EUA 27034 for Pfizer's BNT162b2 vaccine on May 10, 2021.<sup>34</sup> In its decision to extend EUA 27034, the FDA admitted that they did not have fundamental and critical information concerning the Pfizer BNT162b2 COVID-19 vaccine including the following:

- Duration of protection
- Effectiveness in certain populations at high risk of severe COVID-19
- Effectiveness in individuals previously infected with SARS-CoV-2

 <sup>&</sup>lt;sup>31</sup>. FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer) (Dec. 11, 2020), <u>https://www.fda.gov/media/144416/download</u>
 <sup>32</sup>. FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna) (Dec. 18, 2020), <u>https://www.fda.gov/media/144673/download</u>
 <sup>33</sup>. FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen) (Feb. 27, 2021), <u>https://www.fda.gov/media/146338/download</u>
 <sup>34</sup>. FDA, Comirnaty and Pfizer-Biontech Vaccines, Memorandum Decision (May 10, 2021), p. 38, <u>https://www.fda.gov/media/148542/download</u>

- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Vaccine effectiveness against asymptomatic infection
- Vaccine effectiveness against long-term effects of COVID-19 disease
- Vaccine effectiveness against mortality
- Vaccine effectiveness against transmission of SARS-CoV-2

63. The FDA subsequently extended EUA 27034 again on August 12, 2021.<sup>35</sup>

64. On August 23, 2021, pursuant to Section 564 of the FDCA, 21 U.S.C. §360bbb-

3, the FDA issued a letter to BioNTech, care of Pfizer, approving a Biologics License for

"COMIRNATY" a COVID-19 vaccine for individuals 16 years of age and older pursuant to

Section 564 of the Act.<sup>36</sup>

65. However, also on August 23, 2021, the FDA issued a "Letter of Authorization"

to Pfizer extending EUA 27034 for the BNT162b2 COVID-19 vaccine. <sup>37</sup>

66. In the August 23, 2021 Letter of Authorization, extending EUA 27034 for the

BNT162b2 vaccine, the FDA admitted that the Comirnaty and BNT162b2 vaccines are

"legally distinct with certain differences."38

67. Pursuant to 21 U.S.C. §360bbb-3(c)(3), once the FDA issued the Biologics

- <sup>37</sup>. FDA, Comirnaty and Pfizer-Biontech Vaccines, Letter of Authorization [Pfizer-Bionetch] (Aug. 23, 2021), last reissued (Jan. 3, 2022),
- https://www.fda.gov/media/150386/download

<sup>38</sup>. *Id.* at FN. 8, <u>https://www.fda.gov/media/150386/download</u>

 <sup>&</sup>lt;sup>35</sup>. FDA, Comirnaty and Pfizer-Biontech Vaccines, Memorandum Decision (Aug. 12, 2021), <u>https://www.fda.gov/media/151613/download</u>

<sup>&</sup>lt;sup>36</sup>. FDA, Comirnaty and Pfizer-Biontech Vaccines, Comirnaty, Approval Letter (Aug. 23, 2021), available at <u>https://www.fda.gov/media/151710/download;</u>

FDA, FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), <u>https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine</u>

License for Comirnaty, the FDA was legally required to retract and/or rescind its EUA for the BNT162b2 vaccine as well as the mRNA-1273 and Janssen vaccines. However, the FDA did not retract and/or rescind the EUA for the BNT162b2, mRNA-1273 and Janssen vaccines because the Comirnaty vaccine is currently **not available** for distribution and consumption at the time the FDA issued its BLA:

"Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age or older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA." <sup>39</sup>

In other words, on August 23, 2021, the FDA granted a Biologics License for the

"Comirnaty" vaccine even though it is currently not available in the United States.

68. This is confirmed by the CDC which states the following concerning the

availability of the Comirnaty vaccine:

"COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels: Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename. At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish

<sup>&</sup>lt;sup>39</sup>. *Id.* at FN. 9, <u>https://www.fda.gov/media/150386/download</u>

these new codes until Pfizer has determined when the product will be produced with the BLA labels."  $^{40}$ 

69. The FDA executed the same bait-and-switch again with Moderna's COVID-19 vaccine. On January 31, 2022, the FDA issued a press release stating that it granted BLA to Moderna for their COVID-19 vaccine labeled "SPIKEVAX."<sup>41</sup> However, unlike the BLA issued for Pfizer's "Comirnaty," as of the date of this lawsuit, there is no BLA letter issued to Moderna under the "Regulatory Action" section of the FDA website.<sup>42</sup>

70. On January 31, 2022, the FDA issued a Letter of Authorization to Moderna extending EUA 27073 for its mRNA-1273 vaccine just as the FDA did with Pfizer's products in August of 2021. <sup>43</sup> In this Letter of Authorization the FDA sates that Spikevax is "legally distinct" from the mRNA-1273 vaccine,<sup>44</sup> and that "there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA."<sup>45</sup>

71. Moreover, as of the date of this lawsuit, the CDC does not list Spikevax as a

https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html

<sup>41</sup>. FDA, Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine, <u>https://www.fda.gov/news-events/press-</u> <u>announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-</u> 19-vaccine

<sup>&</sup>lt;sup>40</sup>. CDC, COVID-19 Vaccine Codes,

<sup>&</sup>lt;sup>42</sup>. FDA, Spikevax and Moderna Vaccine, <u>https://www.fda.gov/emergency-preparedness-</u> and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine

<sup>&</sup>lt;sup>43</sup>. FDA, Letter of Authorization, <u>https://www.fda.gov/media/144636/download</u>

<sup>&</sup>lt;sup>44</sup>. *Id.* at FN. 9

<sup>&</sup>lt;sup>45</sup>. *Id.* at FN. 11

licensed or available product.46

72. The legal distinction between Pfizer's Comirnaty and the BNT162b2 vaccine, as well as Moderna's Spikevax and mRNA-1273 vaccine, is critical. The EUA statute incorporates the long-recognized principle of informed consent, stating that anyone to whom the product (i.e., the vaccine) is administered must be informed of the option to accept or refuse it, as well as the alternatives to the product and the risks and benefits of receiving it.

73. The FDCA explicitly states that a drug or biologic under EUA cannot be administered to an individual unless the individual is informed: (1) that the product is being administered under an Emergency Use Authorization; (2) of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown; and (3) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. 21 U.S.C. §360bbb-3(e)(1)(A)(ii).

74. Under the EUA statute, the FDA must ensure that "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed" of certain things, including "the option to accept or refuse administration of the product." FDCA §564 $\in$ (1)(A)(ii)(III); 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)

75. In furtherance of its obligation to implement and imposes and the "option to

<sup>&</sup>lt;sup>46</sup>. CDC, COVID-19 Vaccine Codes, https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html

accept or refuse" condition under §360bbb-3(e)(1)(A)(ii)(III), the FDA by requiring that every potential recipients of a vaccine under EUA receive a copy of the Fact Sheet which states: "It is your choice to receive or not receive [the vaccine]."

76. Moreover, the FDA has made clear that, "[i]In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A—those that the FDA has determined to be necessary or protect the public health—be strictly followed and that <u>no additional conditions be imposed</u>.<sup>47</sup>

77. It impossible for the Plaintiffs to give informed consent to receive the COVID-19 vaccines because the FDA has gone to extraordinary lengths to conceal critical data concerning the safety and efficacy of the COVID-19 vaccines from the public. For example, in response to a Freedom of Information Act ("FOIA") request for a copy of all documents and information the FDA relied upon in granting licensure to the Comirnaty vaccine, the FDA asked the federal court to delay complete disclosure over the course of seventy-five (75) years. Ultimately, the FDA was ordered to disclose 55,000 pages of information every month beginning on January 31, 2022 so that full disclosure would be completed by the end of the year.<sup>48</sup> Similarly, the CDC is making an extraordinary effort to avoid disclosing vaccine safety

<sup>&</sup>lt;sup>47</sup>. FDA, *Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders,* January 2017, available at <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities</u>

<sup>&</sup>lt;sup>48</sup>. Public Health and Medical Professionals for Transparency v. Food and Drug Administration, Case No.: 4:21-cv-1058-P, ECF Nos. 20, 29, 35 (Jan. 6, 2020)

data collected by the "v-safe" surveillance platform.<sup>49</sup>

## C. THE COVID-19 VACCINES ARE NOT SAFE

78. In issuing the Vaccine Mandate, the Defendants claimed that the COVID-19 vaccines are safe and effective, but this representation is demonstrably false.

79. The COVID-19 vaccines employ a novel mRNA technology—most accurately classified as a gene therapy—that has never been used in any previous vaccine distributed to the public. Prior to COVID-19, a vaccine has always been understood by the public as an injection of an attenuated (i.e. weakened) strain of a virus which allows the body's immune system to learn how to fight the virus to prevent future infection and transmission of the targeted disease.<sup>50</sup>

80. The COVID-19 vaccines, on the other hand, utilize mRNA technology that sends genetic coding information to a person's cells which instructs the ribosome to create the "spike protein" of the original Alpha (i.e. Wuhan or wild type) strain of the SARS-CoV-2 virus.<sup>51</sup> Simultaneously, adjuvants in the vaccine stimulate the body's immune system so that

<sup>&</sup>lt;sup>49</sup>. Informed Consent Action Network v. Centers for Disease Control and Prevention, Case No. 1:21-cv-01179, ECF No. 1

<sup>&</sup>lt;sup>50</sup>. Flint, Jane, et al., PRINCIPLES OF VIROLOGY, VOL. 1: MOLECULAR BIOLOGY (Kindle, 5<sup>th</sup> Edition 2020), ASM Press, pp. 9, 562

<sup>&</sup>lt;sup>51</sup>. CDC, Understanding How COVID-19 Vaccines Work, *available at* <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html</u>; see also, Seneff (2021), Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19, *International Journal of Vaccine Theory, Practice and Research* 2(1), May 10, 2021, pp. 42- 43, *available at* <u>https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF</u>

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the immune system attacks the "spike proteins" which were created by the ribosomes. This process programs the individual's immune system to recognize and attack the "spike protein" of the Alpha (i.e. Wuhan or wild type) strain of the SARS-CoV-2 virus when is encountered in the future. <sup>52</sup>

81. While the pharmaceutical companies and vaccine manufacturers claim that the "spike protein" produced by the ribosomes are inert, researchers from the Salk Institute published a paper on March 31, 2021 which found that the "spike protein" produced by the COVID-19 vaccines are not harmless, but are cytotoxic and linked to inflammation and related disease.<sup>53</sup>

82. In addition to licensing the "Comirnaty" vaccine despite it not being available in the United States, the August 23, 2021 BLA letter contained several other anomalies and red flags that are strong indicia of deceitful, fraudulent and corrupt conduct on part of the FDA. For example:

<sup>~1.</sup>PDF (mRNA is encoding information, naturally created by the human body in the process of cell replication and production, which instructs the ribosome to produce certain proteins); Flint, Jane, et al., PRINCIPLES OF VIROLOGY, VOL. 1: MOLECULAR BIOLOGY (Kindle, 5<sup>th</sup> Edition 2020), ASM Press, pp. 3,19,21.

<sup>&</sup>lt;sup>52</sup>. Seneff, Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19, *International Journal of Vaccine Theory, Practice and Research* 2(1), May 10, 2021, at pp. 42-43, 47-48, *available at* <u>https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF</u> ~1.PDF

<sup>&</sup>lt;sup>53</sup>. Lei, Yuyang, et al. (2021), SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2, Circulation Research (March 31, 2021), https://pubmed.ncbi.nlm.nih.gov/33784827/

- (i) The FDA explicitly represented that it was issuing the BLA for COMIRNATY in reliance of National Clinical Trial Numbers: NCT04368728 and NCT04380701.
   However, these trials are not even completed. NCT04368728 will not be completed until May 2, 2023,<sup>54</sup> and NCT04380701 will not be completed until April 2023.<sup>55</sup>
- (ii) The FDA failed to convene its outside independent expert panel to deliberate on the

Pfizer Comirnaty licensure, stating:

"We did not refer your application to the Vaccines and Related Biological Products Advisory Committee (VRBPAC) because our review of information submitted in your BLA, including the clinical study design trial results, *did not raise concerns or controversial issues* that would have benefited from an advisory committee discussion." (emphasis added)

83. Less than two weeks after approving licensure for Comirnaty, the Director

Officer of Vaccines Research and Review, Marion Gruber, along with Deputy Director, Phil

Krause, abruptly resigned from the FDA on September 1, 2021, citing political pressure to

approve the Biden Administration's plan to recommend "booster" shots of the COVID-19

vaccines.56

84. During the VRBPAC meeting on September 17, 2021, there was a discussion of

- <sup>55</sup>. A Trial Investigating the Safety and Effects of Four BNT162 Vaccines Against COVID-19 in Health and Immunocompromised Adults, https://clinicaltrials.gov/ct2/show/NCT04380701
- <sup>56</sup>. Brufke, Juliegrace, Two Senior FDA Officials Resign Over Biden Administration Booster Shot Plan, *NY Post* (Sept.. 1, 2021), available at <u>https://nypost.com/2021/09/01/two-</u> senior-fda-officials-resign-over-biden-administration-booster-shot-plan/

<sup>&</sup>lt;sup>54</sup>. Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals, https://clinicaltrials.gov/ct2/show/NCT04368728

data from Pfizer's six month update on its still ongoing Phase 3 trial (NCT04368728), published in *The New England Journal of Medicine*, which revealed significant red flags concerning the safety of its BNT162b2 vaccines. <sup>57</sup> For example, the data reported in Table S3 from Pfizer's Phase 3 trial (NCT04368728), reproduced below, evidenced that there were 5,241 related adverse events reported in the vaccine arm of the trial compared to 1,311 such events reported in the placebo group (+300%); 262 severe adverse events in the vaccine cohort compared to 150 such events in the placebo group (+75%); and 127 serious adverse events (defined as ER or hospitalizations) in the vaccine arm compared to 116 events in the placebo arm (+10%).<sup>58</sup>

Adverse Event	BNT162b2 (N <sup>a</sup> =21,926) n <sup>b</sup> (%)	Placebo (N <sup>a</sup> =21,921) n <sup>b</sup> (%)
any event	6617 (30.2)	3048 (13.9)
Related <sup>c</sup>	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)

<sup>&</sup>lt;sup>57</sup>. FDA, Vaccines and Related Biological Products Advisory Committee September 17, 2021, <u>https://www.fda.gov/advisory-committee/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement</u> (discussing Thomas, Stephen, et al. (2021), Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine Through 6 Months, *The New England Journal of Medicine* (Sept. 15, 2021), <u>https://pubmed.ncbi.nlm.nih.gov/34525277/</u>)

<sup>&</sup>lt;sup>58</sup>. Thomas, Stephen, et al. (2021), Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine Through 6 Months, *The New England Journal of Medicine* (Sept. 15, 2021), <u>https://pubmed.ncbi.nlm.nih.gov/34525277/</u>, Supp. Appendix, Table S3, <u>https://www.nejm.org/doi/suppl/10.1056/NEJMoa2110345/suppl\_file/nejmoa2110345\_appen\_dix.pdf</u>

Any serious adverse event	127 (0.6)	116 (0.5)
Related <sup>c,d</sup>	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related <sup>c</sup>	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all  $\geq$ 16-year-old participants who received  $\geq$ 1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting  $\geq$ 1 occurrence of the specified event category. For 'any event', n=number of participants reporting  $\geq$ 1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmalventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants werereported previously.<sup>11</sup>

85. In an extraordinary departure from standard procedure, Pfizer unblinded its Phase 3 trial (NCT04368728) after two months by offering the BNT162b2 vaccine to everyone in the placebo group and thereby eliminating the control group of the trial. Perhaps most shocking, however, at the time of the unblinding there were more total deaths (15) in the vaccine group than in the placebo group (14).<sup>59</sup>

Reported Cause of Death <sup>a</sup>	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1

<sup>59</sup>. *Id.*, at Supp. Appendix, Table S4,

Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population,  $\geq$ 16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

Furthermore, Pfizer reported an additional five (5) deaths amongst those individuals who took

the BNT162b2 vaccine following the unblinding of the trial. Therefore, there were a total of

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<u>Twenty (20) total deaths amongst people who took Pfizer's BNT162b2 vaccine, compared to</u> only Fourteen (14) people who died in the placebo group.<sup>60</sup>

86. When the FDA published its Clinical Review Memorandum in connection with Pfizer's Biologics License Application, the FDA documented that Pfizer's Phase 3 trial (NCT04368728) evidenced a total of six (6) additional deaths amongst those individuals who took the vaccine following the unblinding period. The FDA's official records reflect a total of Twenty One (21) total deaths amongst the individual who received Pfizer's vaccine, compared to Seventeen (17) deaths amongst those who did not.<sup>61</sup>

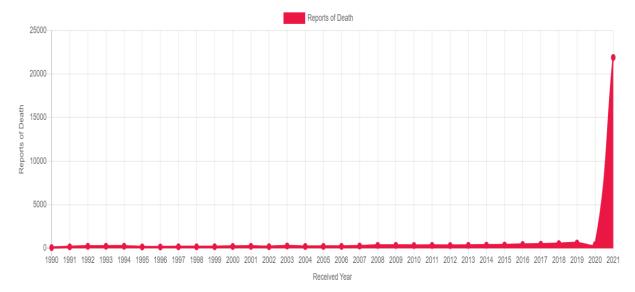
87. The Vaccine Adverse Event Reporting System (VAERS) data reveals unprecedented levels of deaths and other adverse events since the FDA issued Emergency Use Authorizations (EUAs) for three COVID-19 vaccines. By December 31, 2021, there were a total of 21,382 deaths associated with the COVID-19 vaccines. In the entire thirty-year history of VAERS prior to the rollout of the COVID-19 vaccines, there were a total of 9,254 deaths reported to VAERS for all other vaccines combine. This disparity is illustrated in the graph below.<sup>62</sup>

<sup>&</sup>lt;sup>60</sup>. Thomas, Stephen, et al. (2021), Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine Through 6 Months, *The New England Journal of Medicine* (Sept. 15, 2021), <u>https://pubmed.ncbi.nlm.nih.gov/34525277/</u>,

<sup>&</sup>lt;sup>61</sup>. FDA, BLA Clinical Review Memorandum (May 18, 2021), p. 23 https://www.fda.gov/media/152256/download

<sup>&</sup>lt;sup>62</sup>. VAERS Vaccine Adverse Event Reporting System data, available at <u>https://vaers.hhs.gov; https://openvaers.com</u>





88. In addition to the deaths reported with the COVID-19 vaccines described above, as of December 31, 2021, there have been over ONE MILLION (1,016,999) adverse events reported to the VAERS system associated with the COVID-19, including 113,303 hospitalizations, 12,765 reports of bell's palsy, 10,863 heart attacks, 23,713 cases of myocarditis/pericarditis, and 36,758 permanent disabilities.<sup>63</sup>

89. The carnage caused by the COVID-19 vaccines is unprecedented by any historical measure. The 1976 vaccination program in response to the "swine flu" provides a sobering example. In response to a reported case of "swine flu" at a military base in January 1976, Congress implemented a mass inoculation program in April 1976 by purchasing over 200 million batches of flu vaccination. The immunization program was quickly ended only

<sup>&</sup>lt;sup>63</sup>. *Id*.

several months later after 45 million people were vaccinated resulting in the deaths of thirty four (34) people and four hundred and fifty (450) cases of Guillain-Barré Syndrome caused by the flu vaccines.<sup>64</sup> By 1985 CBS News, through their *60 Minutes* program, had uncovered many disturbing issues about the actions of the federal government and a possible cover-up of policy decisions that needlessly destroyed the lives of thousands of Americans resulting in a total of \$3.5 billion dollars in claims. These injuries were needless because 60 Minutes uncovered that the outbreak of "swine flu" claimed by the public health officials advising the federal government never materialized as *no cases of swine flu* were ever confirmed outside of the alleged first case identified in January 1976. As it turned out, 45 million people needlessly took the "swine flu" vaccination based on an unfounded fear generated by propaganda pushed by the same corporate media outlets that are pushing the fear of COVID-19.<sup>65</sup>

## D. THE COVID-19 VACCINES DO NOT PREVENT INFECTION

90. When the mRNA vaccines were originally rolled out between December 2020 and January 2021, Pfizer reported that its BNT162b2 COVID-19 vaccine was "95% effective."<sup>66</sup> These claims were based upon its two month report of its Phase 3 trial published

<sup>&</sup>lt;sup>64</sup>. Rohde, Wayne (2014), THE VACCINE COURT: THE DARK TRUTH OF AMERICA'S VACCINE INJURY COMPENSATION PROGRAM, Skyhorse Publishing (Kindle Ed., 2014), at p. 14

<sup>&</sup>lt;sup>65</sup>. *Id.* at 16, 18-19 (the 60 Minutes story is available at

http://www.youtube.com/watch?v=8elE7Ct1jWw)

<sup>&</sup>lt;sup>66</sup>. See e.g., Fox, Maggie, et al., Pfizer and BioNTech say final analysis shows coronavirus vaccine is 95% effective with no safety concerns, *CNN* (Nov. 18, 2020), <u>https://www.cnn.com/2020/11/18/health/pfizer-coronavirus-vaccine-safety/index.html</u>; Lovelace Jr., Berkley, Pfizer says final data analysis shows Covid vaccine is 95% effective,

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in the *New England Journal of Medicine*.<sup>67</sup> However, as shown below, Pfizer's claim as to the efficacy of the BNT162b2 vaccine was knowingly misleading because it was a statement of comparative risk reduction, rather than absolute risk reduction. The FDA's official position is that comparative risk reduction is misleading and recommends that claims about vaccine efficacy be stated in terms of absolute risk reduction, rather than comparative risk reduction.<sup>68</sup>

91. The data from Pfizer's clinical trials showed that 162 out of 18,325 (.88%) of the individuals in the placebo group contracted COVID-19, versus 8 out of 18,198 (.04%) of the individuals in the vaccine group contracted COVID-19.

plans to submit to FDA in days, *CNBC* (Nov. 18, 2020), https://www.cnbc.com/2020/11/18/coronavirus-pfizer-vaccine-is-95percent-effective-plansto-submit-to-fda-in-days.html

<sup>&</sup>lt;sup>67</sup>. Thomas, Stephen, et al. (2020), Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine, *The New England Journal of Medicine* (Dec. 31, 2020), <u>https://pubmed.ncbi.nlm.nih.gov/33301246/</u>

<sup>&</sup>lt;sup>68</sup>. FDA, Fischhoff, *Communicating Risks and Benefits: An Evidence Based User's Guide* (2011), at pp. 59-60, <u>https://www.fda.gov/media/81597/download</u>

Efficacy End-Point Subgroup		T162b2 =18,198)		ขลcebo =18,325)	Vaccine Efficacy, % (95% CI)†
No. of Cases	Surveillance Time (No. at Risk)*	No. of Cases	Surveillance Time (No. at Risk)*		
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0-97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4-98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6-98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7–99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (-13.1-100.0
Sex					
Male	3	1.124 (8,875)	81	1.108 (8,762)	96.4 (88.9-99.3)
Female	5	1.090 (8,536)	81	1.114 (8,749)	93.7 (84.7-98.0)
Race or ethnic group‡					
White	7	1.889 (14,504)	146	1.903 (14,670)	95.2 (89.8-98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2-100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6–99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7–98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9-98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3–99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1–99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6-98.2)

\* Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.
 † The confidence interval (CI) for vaccine efficacy is derived according to the Clopper-Pearson method, adjusted for surveillance time.
 ‡ Race or ethnic group was reported by the participants. "All others" included the following categories: American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported.

Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported.

Thus, Pfizer's own data demonstrates that its claim that its vaccine is "95% effective" refers to the relative risk of contracting COVID-19 in the vaccinated cohort compared to the unvaccinated cohort.<sup>69</sup> The absolute risk reduction provided by Pfizer's BNT162b2 vaccine is actually only a meager .84% (.0084).<sup>70</sup>

92. The FDA relied upon this same data from Pfizer's Phase 3 clinical trials when it issued EUA 27034 for the BNT126b2 vaccine on December 11, 2020. Thus, the FDA knew that it was issuing EUA 27034 based upon comparative risk reduction, not absolute risk

<sup>&</sup>lt;sup>69</sup>. VE=100\*(1-(.04% /.88%)) = 95%

 $<sup>^{70}</sup>$ . .88% - .04% = .84%

reduction.<sup>71</sup>

# E. <u>THE COVID-19 VACCINES DO NOT PREVENT TRANSMISSION OF</u> <u>COVID-19</u>

93. Clinical studies have also demonstrated that COVID-19 vaccines do not stop transmission of COVID-19. The reason is because the vaccines cause only the original "spike protein" to be presented to the immune system. This results in the body's immune system producing a very narrow spectrum of immunity limited to only variants of the virus that present the "spike protein" associated with the original (Alpha a/k/a Wuhan) strain. Most notably, findings from Pfizer's own clinical studies demonstrated that protection from the BNT162b2 vaccine substantially wanned by six months following receipt of the second dose correlating with the rise of the Delta variant, which became the predominate strain by July 2021.<sup>72</sup>

94. Independent studies have also consistently found that the antibodies produced by the COVID-19 vaccines will substantially wane over time.

95. For example, a study published on October 6, 2021 in the *New England Journal of Medicine* concluded that "six months after receipt of the second dose of the BNT162b2 [Pfizer-BioNTech] vaccine, the humoral response was substantially decreased, especially

<sup>&</sup>lt;sup>71</sup>. FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer) (Dec. 11, 2020), pp. 23-24, https://www.fda.gov/media/144416/download

<sup>&</sup>lt;sup>72</sup>. Tartof, Sara (2021), Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study, *The Lancet* (Oct. 4, 2021), *available at* <u>https://doi.org/10/1016/S0140-6736(21)02183-8</u>

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among men, among persons 65 years of age or older, and among persons with immunosuppression."<sup>73</sup>

96. A similar study performed by scientists at Oxford University (England) found that the vaccine's ability to reduce transmission of the SARS-COV-2 virus "declined over time since second vaccination, for Delta reaching similar levels to unvaccinated individuals by 12 weeks" and that "protection from vaccination in contacts also declined in the 3 months after second vaccination." In other words, the vaccine's ability to prevent viral transmission disappeared complete in three months, and after this time, vaccinated individuals were just as likely to spread the virus as the unvaccinated. This correlated directly with an analogous reduction in the vaccine's ability to provide protection from infection.<sup>74</sup>

97. Another study performed by researchers from Emory, Stanford and Wisconsin University found that the "data demonstrates a substantial waning of antibody responses and T-cell immunity to SARS-CoV-2 and its variants, at 6 months following the second immunization with the BNT162b2 vaccine." The researchers found that vaccines ability to provide protection against infection of SARS-CoV-2 virus began to decrease a mere two

<sup>&</sup>lt;sup>73</sup>. Levin, et al., Waning Immune Humoral Response to BNT162b2 COVID-19 Vaccine Over 6 Months, *New England Journal of Medicine*, Oct. 6, 2021, https://www.nejm.org/doi/full/10.1056/NEJMoa2114583

<sup>&</sup>lt;sup>74</sup>. Eyre, David, et al. (2021), The Impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission, *medRxiv* preprint, *available at* https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1

months after the second dose of the BNT162b2 and mRNA-1273 [Moderna] vaccines.<sup>75</sup>

98. In fact, the very reason the FDA issued an EUA for a third "booster" dose of Pfizer's BNT162b2 vaccine six months after the second dose was because the antibodies created by the vaccine quickly disappear and could not provide protection against the Delta variant:<sup>76</sup>

"Concerns have been raised that declining neutralizing antibody titers or reduced effectiveness against symptomatic disease may herald significant declines in effectiveness against severe disease. The recent emergence of the highly transmissible Delta variant of SARS-CoV-2 resulted in a new wave of COVID-19 cases in many parts of the world and has led to considerations for administration of booster doses to individuals who received primary series of vaccines in an effort to enhance immunity, and thus sustain protection from COVID-19..."

99. The FDA approved a third or "booster" dose of the Moderna mRNA-1273

vaccine despite a dearth of evidence that the third "booster" dose provides any additional

benefit:77

"Based on the data in the Hall et. al manuscript, the administration of a third dose of the Moderna COVID-19 vaccine appears to be only moderately effective in increasing antibody titers in the individuals studied. It is also unclear whether the antibodies generated from the third dose are protective and durable."

100. The CT DPH knew that the COVID-19 vaccines could not stop infection and

https://www.medrxiv.org/content/10.1101/2021.09.30.462488

<sup>&</sup>lt;sup>75</sup>. Suthar, Mehul, et al. (2021), Durability of Immune Response to the BNT162b2 mRNA vaccine, *medRxiv* preprint, *available at* 

<sup>&</sup>lt;sup>76</sup>. FDA, Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum, (Sept. 22, 2021), <u>https://www.fda.gov/media/152432/download</u>

<sup>&</sup>lt;sup>77</sup>. FDA, Decision Memorandum, Emergency Use Authorization (EUA) for Moderna COVID-19 Vaccine (Aug. 12, 2021), <u>https://www.fda.gov/media/151611/download</u>

transmission of COVID-19 as early as February 2021. In preparation for the COVID-19 vaccines to fail to prevent COVID-19 infections, the CT DPH adopted the term "breakthrough infection," to classify a person who tests positive for COVID-19 after being "fully vaccinated."<sup>78</sup>

101. By July 2021, six months after the vaccination rollout began and concurrent with the emergence of the "delta" variant, "breakthrough infections" had become so prevalent that the CDC had no choice but to publicly admit that the COVID-19 vaccines do not stop transmission of the SARS-CoV-2 virus.<sup>79</sup> In July 2021, CDC director Rochelle Wilensky admitted that "Delta infection resulted in similarly high SARS-CoV-2 viral loads in vaccinated and unvaccinated people. High viral loads suggest an increased risk of transmission and raised concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus."<sup>80</sup>

102. On December 15, 2021, Dr. Anthony Fauci admitted that the COVID-19 vaccines did not stop infection and transmission of COVID-19 in an article published in the New England Journal of Medicine, writing, that the vaccines "protective efficacy wanes over

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<sup>&</sup>lt;sup>78</sup>. CT DPH, COVID-19 Breakthrough Recommendations (Feb. 23, 2021), <u>https://portal.ct.gov/-/media/DPH/HAI/COVID19-Vaccine-Breakthrough-</u> Recommendations.pdf

<sup>&</sup>lt;sup>79</sup>. CDC, Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021, <u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm</u>

<sup>&</sup>lt;sup>80</sup>. Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR (July 30, 2021), <u>https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html</u>

time, necessitating booster doses. Vaccination has also been unable to prevent 'breakthrough' infection, allowing subsequent transmission to other people..."<sup>81</sup>

103. Once it became impossible to deny that the COVID-19 mRNA vaccines could not prevent infection and transmission of the SARS-CoV-2 virus, the CDC changed the definition of "vaccine" so that it no longer required providing immunity to the infectious disease targeted by the drug.<sup>82</sup> On August 26, 2021, the CDC defined a "vaccine" as follows:

**Vaccine**: A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease.<sup>83</sup>

However, by September 2, 2021, the CDC changed the definition of "vaccine" to be:

**Vaccine**: A preparation that is used to stimulate the body's immune response against diseases.<sup>84</sup>

104. Therefore, the Defendant's Vaccine Mandate, including the mandatory testing imposed on "unvaccinated" individuals, is entirely arbitrary and capricious because the COVID-19 vaccines do not prevent infection or transmission of COVID-19.

<sup>&</sup>lt;sup>81</sup>. Fauci, Anthony, et al. (2021), Universal Coronavirus Vaccines—An Urgent Need, *The New England Journal of Medicine* (Dec. 15, 2021), https://www.nejm.org/doi/full/10.1056/NEJMp2118468

 <sup>&</sup>lt;sup>82</sup>. The CDC defines "Immunity" as, "Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."
 <sup>83</sup> FDA, Vaccine Basics (Aug. 26, 2021),

https://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm

<sup>&</sup>lt;sup>84</sup>. FDA, Vaccine Basics (September 2, 2021),

https://web.archive.org/web/20210902194040/https://www.cdc.gov/vaccines/vac-gen/imzbasics.htm

## F. <u>THE COVID-19 VACCINES HAVE CAUSED THE PANDEMIC TO BECOME</u> <u>WORSE</u>

105. At the time Governor Lamont issued the COVID-19 vaccine mandate in Executive Order 13D on August 19, 2021, Connecticut was one of the most highly vaccinated states in the country. As of August 18, 2021, the vaccination rate broken down by age demographic was by follows:<sup>85</sup>

Age	Percentage Vaccinated
Group	(2 doses)
75+	84.6%
65-74	89.3%
55-64	82.9%
45-54	72.7%
35-44	68.7%
25-34	59.8%
16-24	57.3%

106. At the time Governor Lamont issued the COVID-19 Vaccine Mandate in Executive Order 13D on August 19, 2021, scientists around the world had been warning that mass vaccination using the COVID-19 mRNA vaccines would cause the pandemic to get worse due to an evolutionary phenomenon known as "mutagenic escape" (a/k/a "immune escape"), where the virus mutates in order to avoid the narrow and limited protection provided by the COVID-19 vaccines. This phenomenon was explained in detail by world renowned

<sup>&</sup>lt;sup>85</sup>. CT DPH, COVID-19 Vaccinations by Age Group, <u>https://data.ct.gov/Health-and-</u> <u>Human-Services/COVID-19-Vaccinations-by-Age-Group/vjim-iz5e</u>

vaccinologist, Geert Vanden Bossche, in a letter to the World Health Organization, entitled "Public Health Emergency of International Concern: Why Mass Vaccination Amidst a Pandemic Creates an Irrepressible Monster," wherein he warned against mass vaccination against SARS-CoV-2 using the COVID-19 vaccines:

"[s]imilar to the rules applying to classical antimicrobial antibiotics, it is paramount that our self-made 'antiviral antibiotics' are made available in sufficient concentration and are tailored at the specific features of our enemy. This is why in case of bacterial disease it is critical to not only chose the right type of antibiotic (based on the results from an antibiogram) but to also take the antibiotic for long enough (according to the prescription). Failure to comply with these requirements is at risk of granting microbes a chance to survive and hence, may cause the disease to flare up. A very similar mechanism may also apply to viruses, especially to viruses that can easily and rapidly mutate (which is, for example, the case with Coronaviruses); when the pressure exerted by the army's (read: population's) immune defense starts to threaten viral replication and transmission, the virus will take on another coat so that it can no longer be easily recognized and, therefore, attacked by the host immune system. The virus is now able to escape immunity (so-called: 'immune escape')."<sup>86</sup>

107. The Defendants have known that mass vaccination programs using the COVID-

19 vaccines were likely to cause mutagenic escape long before issuing the Vaccine Mandate on August 19, 2021. Research funded by the National Institute of Health (NIH) and published in November of 2020, before the rollout of the mass vaccination program even began, warned that the COVID-19 vaccines would cause the SARS-CoV-2 virus to quickly mutate so that the virus evaded the protection provided by the vaccines:

<sup>&</sup>lt;sup>86</sup>. Geer Vanden Bosche, Public Health Emergency of International Concern: Why Mass Vaccination Amidst a Pandemic Creates an Irrepressible Monster, Letter to the WHO (Aug. 2, 2021), *available at* http://geertvandenbossche.org

"Much like antimicrobial drug resistance, vaccine resistance can and does evolve. When it does evolve, vaccine resistance is achieved through mechanisms such as serotype replacement, antigen change, or increases in disease severity.... To our knowledge, all documented cases of vaccine resistance can be attributed to the absence of at least one of three key features that most vaccines possess: 1) the vaccine induces an immune response that protects hosts by targeting multiple virus epitopes simultaneously thereby generating redundant and evolutionarily-robust protection, 2) the vaccine suppresses pathogen growth [viral replication] within hosts and stops transmission from vaccine-protected hosts, and 3) the vaccine-induced immune response protects against all circulating serotypes of the target pathogen."<sup>87</sup>

The researchers concluded that the virus would evolve to develop resistance to COVID-19 vaccines because the COVID-19 fell into all three categories outlined above: (1) the COVID-19 vaccines only provide protection against a limited number of epitopes—specifically only those presented by the "spike protein" on the original Alpha (Wuhan) strain; (2) the COVID-19 vaccines do not stop viral replication or transmission of SARS-CoV-2; and (3) the vaccines do not protect against variants, namely the Delta and Omicron variants.

108. Another study funded by the National Institutes of Allergy and Infectious Diseases (NIAID) and published on April 8, 2021, found that the antibodies produced by the COVID-19 vaccines would lose their ability to provide protection against future variants of the virus because, as the virus evolves, the spike protein mutates to escape neutralization by

<sup>87</sup>. Kennedy, David, Read, Andrew, Monitor for COVID-19Vaccine Resistance Evolution During Clinical Trials, *PLOS Biology*, Nov. 9, 2020, available at <u>https://doi.org/10.1371/journal.pbio.3001000</u>

antibodies generated by the COVID-19 vaccines.88

109. Therefore, at the time the Defendants issued the Vaccine Mandate through Executive Order 13D on August 19, 2021, the Defendants knew that the Delta variant evolved to evade the limited protection offered by the COVID-19 vaccines which were specifically formulated to provide protection against the Alpha (i.e. Wuhan or wild-type) strain of the virus.<sup>89</sup>

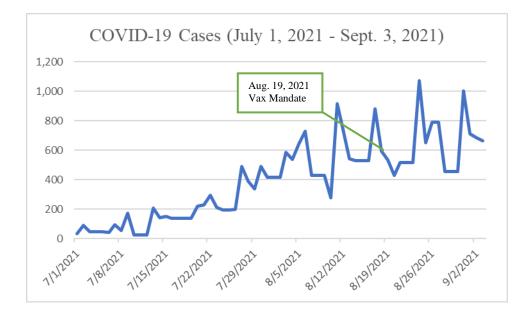
110. The data published by the CT DPH, and illustrated in the graph below, evidences that "immune escape" was occurring in Connecticut simultaneously with the emergence of the Delta variant as the predominate circulating strain beginning in July 2021. <sup>90</sup>

<sup>&</sup>lt;sup>88</sup>. Eguia, Rachel, et al. (2021), A Human Coronavirus Evolves Antigenically to Escape Antibody Immunity, *PLOS Pathogens* (April 8, 2021), <u>https://pubmed.ncbi.nlm.nih.gov/33831132/</u>

<sup>&</sup>lt;sup>89</sup>. Sevellita, Venice, et al. (2021), Predominance of antibody-resistant SARS-CoV-2 variants in Vaccine Breakthrough Cases from the San Franscico Bay Area, California, *medRxiv* preprint, *available at*, <u>http://www.doi.org/10.1101/2021.08.1921262139</u>

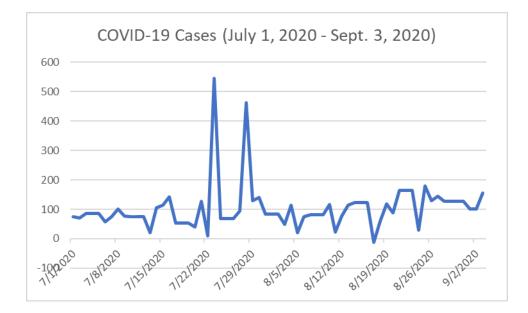
Liu, Yafei, et al. (2021), The SARS-CoV-2 Delta Variant is Poised to Acquire Complete Resistance to Wild Type Spike Vaccines, *BioRxiv* preprint, available at <u>https://www.biorxiv.org/content/10.1101/2021.0822.457114v1</u>

<sup>&</sup>lt;sup>90</sup>. Connecticut Department of Public Health, COVID-19 Tests, Cases Hospitalizations, and Deaths, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Tests-Cases-Hospitalizations-and-Deaths-S/rf3k-f8fg</u>



111. Comparing the number of COVID-19 cases during the same time period in 2020, when mRNA COVID-19 vaccines were not available, demonstrates that this increase in cases beginning in July 2021 is the result of the mass vaccination policies rather than the normal epidemiology of the SARS-CoV-2 virus:<sup>91</sup>

<sup>&</sup>lt;sup>91</sup>. Connecticut Department of Health, COVID-19 Tests, Cases Hospitalizations, and Deaths, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Tests-Cases-Hospitalizations-and-Deaths-S/rf3k-f8fg</u>



112. It is clear that the Defendants were not making an innocent mistake in issuing the unscientific Vaccine Mandate, however, because it was not rescinded after more evidence was published confirming that the COVID-19 vaccines were making the pandemic worse. For example, in September 2021, scientists from Harvard University published a meta-analysis study investigating the relationship between the percentage of a population fully vaccinated and new COVID-19 cases across 68 countries and across 2947 counties in the U.S. found that there is "no discernable relationship between population fully vaccinated and new COVID-19 cases...." In fact, the only correlation found in the study was that "countries with a higher percentage of population fully vaccinated have higher COVID-19 cases per [capita]." <u>In other words, by September 30, 2021, data from around the world demonstrated that countries which have the highest percentage of their population vaccinated will have the most COVID-19</u>

cases.92

113. The trend of the COVID-19 vaccine failing to stop transmission of the SARS-CoV-2 virus and making the pandemic worse, has become more pronounced since the emergence of the "Omicron" variant in last week of November 2021.<sup>93</sup>

114. A study published in December 2021 demonstrated that any protection from the Omicron variant provided by either the BNT162b2 or mRNA-1273 vaccine disappears completely within sixty days following vaccination. But even more shocking is that the study found that after ninety (90) days the vaccines have a **negative efficacy** against the "Omicron" variant. The study found the BNT162b2 (Pfizer) vaccines has an efficacy of -76.5%; and the mRNA-1273 (Moderna) had an efficacy of -39.3%.<sup>94</sup> In other words, this study found that people who were vaccinated were **more likely** to contract COVID-19 than those who were unvaccinated.

115. A meta-analysis study analyzing data from around the world (145 Countries) found that the COVID-19 mRNA vaccines "cause more COVID-19 associated cases and deaths than otherwise would have existed with zero vaccines. Consequently, these

<sup>&</sup>lt;sup>92</sup>. Subramanian & Kumar (2021), Increases in COVID-19 are unrelated to levels of vaccination across 68 Countries and 2947 Counties in the United States, *European Journal of Epidemiology* (Sept. 30, 2021), available at <u>https://doi.org/10.1007/s10654-021-00808-7</u>
<sup>93</sup>. CDC, Omicron Variant: What you Need to Know,

https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html <sup>94</sup>. Hansen, et al. (2021), Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort Study (Dec. 20, 2021), *medRxiv* preprint, available at https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v2

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experimental gene therapy injections known as COVID-19 vaccines cannot be mandated by any public policy that intends to continue following the regulations of the Nuremberg Code, the Helsinki Accord, and the Human Rights Declaration on Bioethics."<sup>95</sup>

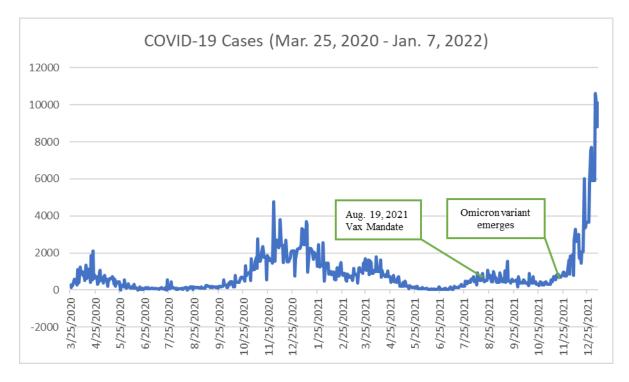
116. Although it may seem impossible that vaccines could actually increase the risk of contracting the disease they were developed to prevent, these COVID-19 vaccines are not the first time that negative vaccine efficacy has been observed. For example, in February 2020, the NIAID had to suddenly halt Phase 3 clinical trials of its most promising HIV vaccine when the NIAID realized that the vaccines were *raising* the risk of AIDS in the vaccinated individuals.<sup>96</sup>

117. These studies finding that efficacy of the COVID-19 vaccines become negative when confronted with the "Omicron" variant perfectly explains why COVID-19 cases have exploded in Connecticut since the emergence of the "Omicron" variant, as illustrated by the graph below of all COVID-19 cases in Connecticut since the beginning of the pandemic in

<sup>&</sup>lt;sup>95</sup>. Beattie, Kyle (2021), Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with COVID-19:A BigData Analysis of 145 Countries (Nov. 15, 2021), *Research Gate* (DOI:10.13140/RG.2.2.34214.65605), available at https://www.researchgate.net/publication/356248984\_Worldwide\_Bayesian\_Causal\_Impact\_Analysis\_of\_Vaccine\_Administration\_on\_Deaths\_and\_Cases\_Associated\_with\_COVID-19\_A\_BigData\_Analysis\_of\_145\_Countries

<sup>&</sup>lt;sup>96</sup>. Kennedy Jr., Robert F. (2021), THE REAL ANTHONY FAUCI: BILL GATES, BIG PHARMA, AND THE GLOBAL WAR ON DEMOCRACY AND PUBLIC HEALTH (Kindle Ed.), Skyhorse Publishing, p.623 (citing Julie Steenhuyesen, "Trial of Promising HIV Vaccine Halted after Failing to Show Benefit," Reuters (Feb. 3, 2020), <u>https://www.reuters.com/article/us-healthhiv-vaccine-idUSKBN1ZX2QO</u>)





118. As of January 5, 2022 the vaccination rate broken down by age demographic was by follows:<sup>98</sup>

Age	Percentage Vaccinated
Group	(2 doses)
75+	86.9%
65-74	92.6%

<sup>&</sup>lt;sup>97</sup>. CT DPH, COVID-19 Tests, Cases Hospitalizations, and Deaths, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Tests-Cases-Hospitalizations-and-Deaths-S/rf3k-f8fg</u>

<sup>&</sup>lt;sup>98</sup>. CT DPH, COVID-19 Vaccinations by Age Group, <u>https://data.ct.gov/Health-and-Human-Services/COVID-19-Vaccinations-by-Age-Group/vjim-iz5e</u>

55-64	88.1%
45-54	79.8%
35-44	79.3%
25-34	72.1%
16-24	67.6%

119. Yet despite the overwhelming evidence that the COVID-19 vaccines have made the pandemic worse, the Defendants have continued their policy of trying to increase vaccination rates through reprehensible forms of coercion: Threat of job loss, segregation, and desperate punitive treatment—including mandating that the unvaccinated Plaintiffs submit to weekly testing while exempting their vaccinated co-workers, even though those vaccinated co-workers are more likely to test positive for COVID-19 than the Plaintiffs.

### G. <u>THE DEFENDANTS' VACCINE MANDATE IGNORES NATURAL</u> <u>IMMUNITY DESPITE BEING SUPERIOR TO VACCINE IMMUNITY</u>

120. The Defendant's COVID-19 Vaccine Mandate, including the testing for "unvaccinated" individuals, has no scientific basis whatsoever because it completely ignores acquired natural immunity which has been shown to be far superior to vaccine induced immunity, if any, provided by the mRNA COVID-19 vaccines.

121. "Natural immunity" is a term which describe a person who is infected by a disease causing pathogen and then subsequently recovers thereby acquiring immunity from future infection due to the person's immune system learning how to fight off the pathogen.

122. Over the course of the pandemic there have been well over one hundred comprehensive studies demonstrating that natural immunity provides a significantly more

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robust and durable (i.e. long lasting) immunity to COVID-19 compared to protection acquired from any of the COVID-19 vaccines.<sup>99</sup>

123. For example, a recent study found that individuals who had been vaccinated, as opposed to acquiring natural immunity, were at a 13.1 times greater risk of testing positive, 27 times greater risk of symptomatic disease, and 8.1 times greater risk of hospitalization than unvaccinated individuals with naturally acquired immunity.<sup>100</sup>

124. In fact, the CDC has admitted that there is no evidence that a person with naturally acquired immunity could transmit COVID-19 to another person. On September 2, 2021, the Informed Consent Action Network ("ICAN") sent a Freedom of Information Act ("FOIA") request to the CDC seeking any evidence that individuals who had naturally acquired immunity, but had never received a COVID-19 vaccine, could transmit the disease. Specifically, the FOIA request directed the CDC to provide all:

"Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."<sup>101</sup>

 <sup>&</sup>lt;sup>99</sup>. Alexander, Paul, 146 Research Studies Affirm Naturally Acquired Immunity to COVID-19, Brownstone Institute (Oct. 17, 2021), <u>https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/</u>
 <sup>100</sup>. Gazit, Sivan, et al. (2021), Comparing SARS-CoV-2 natural immunity to vaccineinduced immunity: reinfections versus breakthrough infections, *medRxiv* preprint, *available at*

https://doi.org/10.1101/2021.08.24.21262415

<sup>&</sup>lt;sup>101</sup>. ICAN FOIA Request to CDC, *available at* <u>https://www.sirillp.com/wp-</u> content/uploads/2021/11/IR0552-CDC-Reinfection-and-Transmission FINAL-5.pdf

On November 5, 2021, the CDC responded that they had no documents that were responsive to the FOIA request, thereby admitting that they had no evidence that a person with naturally acquired immunity could infect someone with COVID-19.<sup>102</sup>

125. On January 19, 2022, the CDC finally admitted that the protection provided by natural immunity is superior to that acquired through vaccination stating that, "[b]y early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone."<sup>103</sup>

126. This is particularly significant because all of the Plaintiffs have, or believe they have, naturally acquired immunity to COVID-19.

127. Therefore, the Defendant's Vaccine Mandate contained in Executive Order 13D, including the mandatory testing imposed on "unvaccinated" employees, is entirely arbitrary and capricious because the COVID-19 vaccines do not prevent infection or transmission of COVID-19 and the mandate entirely ignores natural immunity.

# H. <u>MANDATING THE COVID-19 VACCINES CAN CAUSE VACCINE</u> <u>ENHANCED DISEASE</u>

128. Because the Defendants' Vaccine Mandate requires the Plaintiffs to take a COVID-19 vaccine without regard to whether the Plaintiffs have acquired natural immunity

<sup>&</sup>lt;sup>102</sup>. CDC, FOIA response to ICAN, *available at* <u>https://www.sirillp.com/wp-content/uploads/2021/11/21-02152-Final-Response-Letter-Brehm-1.pdf</u>

<sup>&</sup>lt;sup>103</sup>. CDC, COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May-November 2021 (Jan. 19, 2022), <u>https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm</u>

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from prior infection, the Defendants' Vaccine Mandate is very likely to cause Vaccine Enhanced Disease ("VED").

129. First discovered in 1964, VED has been shown to occur after widespread administration of a leaky vaccine.<sup>104</sup> "Vaccines that let the hosts survive but do not prevent the spread of the pathogen creates the evolutionary conditions for a virus to become more virulent are called 'leaky vaccines.' When vaccines prevent transmission, as is the case for nearly all vaccines used in humans, this type of evolution toward virulence is blocked."<sup>105</sup> The COVID-19 vaccines are therefore leaky vaccines because they do not prevent infection or transmission of the SARS-CoV-2 virus.

130. The CDC, and consequently the Defendants, have always been aware that the COVID-19 vaccines presented the risk of creating VED (Vaccine Enhanced Disease) because studies of mRNA vaccines developed in response to the outbreak of the original SARS virus in 2003 were shown to cause VED.<sup>106</sup>

131. A specific form of VED is called Antibody Dependent Enhancement ("ADE"):

<sup>&</sup>lt;sup>104</sup>. Hawkes, R.A. (1964), Enhancement of the Infectivity of Arboviruses by Specific Antisera Produced in Domestic Fowls, *Australian Journal of Experimental Biology and Medical Science* 42(4), 465-482, *available at* https://onlinelibrary.wiley.com/doi/abs/10.1038/icb.1964.44

<sup>&</sup>lt;sup>105</sup>. Read, Andrew, et al., Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens, *PLOS Biology* (July 27, 2015), https://pubmed.ncbi.nlm.nih.gov/26214839/

<sup>&</sup>lt;sup>106</sup>. CDC, COVID-19 Vaccine Safety Considerations. <u>https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-07/COVID-03-Edwards-508.pdf</u>

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"ADE is a special case of what can happen when low, non-neutralizing levels either specific or cross-reactive antibodies against a virus are present at the time of infection. *These antibodies might be present due to prior exposure to the virus, exposure to a related virus, or due to prior vaccination against the virus*. Upon reinfection antibodies insufficient to neutralize the virus nevertheless bind to the virus. These antibodies then facilitate viral entry into the cell subsequently enhancing the infectivity of the virus." Consequently, "there is sufficient reason to suspect that antibodies to the spike protein will contribute to ADE provoked by prior SARS-CoV-2 infection or vaccination, which may manifest as either acute or chronic autoimmune and inflammatory conditions."<sup>107</sup>

132. In other words, ADE has been shown to occur when: (i) individuals are exposed to a virus after being vaccinated with a non-sterilizing, leaky vaccine, such as the COVID-19 vaccines; or (2) an individual is vaccinated against a disease while already having sufficiently high titers (levels) of antibodies against the disease.

133. Because the Defendants' Vaccine Mandate requires the Plaintiffs to take a COVID-19 vaccine without regard to whether the Plaintiffs have acquired natural immunity from prior infection or their present antibody levels, the Defendants' Vaccine Mandate is very likely to cause VED, and ADE more specifically.

<sup>&</sup>lt;sup>107</sup>. Seneff, Stephanie (2021), Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19, *International Journal of Vaccine Theory, Practice and Research* 2(1), May 10, 2021, at p. 50, *available at* <u>https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF</u> ~1.PDF

## I. <u>THE MANDATORY TESTING PORTION OF DEFENDANTS' VACCINE</u> MADATE IS ARBITRARY AND CAPRIRIOUS

134. The mandatory testing portion of Defendant's Vaccine Mandate is entirely arbitrary and capricious because the COVID-19 vaccines do not prevent infection or transmission of COVID-19.

135. In fact, the evidence demonstrates that a person who is vaccinated and then is infected with COVID-19 will often have a viral load that is even higher than a person who is unvaccinated and contracts COVID-19.<sup>108</sup>

136. Because the COVID-19 vaccines have negative efficacy against the Omicron variant, and therefore make vaccinated teachers more likely to be infected with COVID-19 than the Plaintiffs, mandating that only the Plaintiffs submit to mandatory weekly testing is the opposite of an evidenced based public health policy. It is an arbitrary, capricious and discriminatory policy intended to coerce the Plaintiffs into taking the experimental gene therapy drugs, euphemistically called COVID-19 vaccines.

137. In order to comply with the mandatory testing provision of the Defendant's Vaccine Mandate, the Plaintiffs have been compelled to take significant personal time outside of normal work hours, and in addition to the work hours required for all teachers, to get a

<sup>&</sup>lt;sup>108</sup>. Nguyen, et al. (2021), Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam, *The Lancet* (preprint), (Oct. 11, 2021), *available at* <u>https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3897733</u>; Statement from CDC Director Rochelle P. Walensky, MD, MPH on Today's MMWR (July

<sup>30, 2021), &</sup>lt;u>https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html</u>

COVID-19 test every week in order to comply with the Defendants' Vaccine Mandate.

138. In order to comply with the Defendant's Vaccine Mandate, the Plaintiffs have had to electronically submit their COVID-19 test results on a weekly basis without any guarantee that their private medical information would be safe guarded from third parties.

139. The Plaintiffs' private medical information is, in fact, not being kept confidential. It is being shared and disseminated amongst individuals within the public school districts without the consent of the Plaintiffs and amongst individuals who do not have a need to know the Plaintiffs' medical information.

140. The Plaintiffs' vaccination status has been made public knowledge within their respective work places which has resulted in the Plaintiffs being singled out and ostracized by their superiors and co-workers because they did not receive a COVID-19 vaccine.

141. The mandatory testing provision of the Defendant's Vaccine Mandate has no basis in evidence, science, medicine or public health, and serves no other purpose than to punish the Plaintiffs for not taking an experimental COVID-19 vaccine and coercing the Plaintiffs to do so.

# J. <u>THE DEFENDANTS' VACCINE MADATE VIOLATES THE PLAINTIFFS'</u> <u>CIVIL LIBERTIES GUARANTEED UNDER THE U.S. CONSTITUTION</u>

142. The Defendants' Vaccine Mandate, contained in Executive Order 13D, and amended by Executive Order 13G, is illegal because it violates, *inter alia*, the Plaintiffs' right

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to bodily autonomy, informed consent, and equal protection guaranteed under Fourth, Fifth, and Fourteenth Amendments to the U.S. Constitutional Provisions.

143. The Supreme Court of the United States has long recognized that "no right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law. This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." See e.g., *Cruzan by Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990) (citing *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891)).

144. The Fifth Amendment, made applicable to the States through the Fourteenth Amendment provides that private property shall not be taken for public use, without just compensation. *Phillips v. Washington Legal Foundation*, 524, U.S. 156, 163-164 (1998). A competent person has a liberty interest under the Due Process Clause which includes the right to informed consent and in refusing unwanted medical treatment. *Cruzan by Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990).

145. Under the Fourth Amendment, incorporated through the Fourteenth Amendment, competent individuals have a right to privacy which includes the fundamental liberty interest in bodily autonomy and to be free from restraint and intrusion on that bodily autonomy by the

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State. See e.g., Schmerber v. California, 384 U.S. 757, 772 (1966); Washington v. Harper, 494 U.S. 210, 221 (1990); Parham v. J.R., 442 U.S. 584, 600 (1979).

146. Limitations on the right of privacy and bodily autonomy are permissible only if they survive "strict" constitutional scrutiny, that is, only if the governmental entity imposing the restriction can demonstrate that the limitation is both necessary and narrowly tailored to serve a compelling governmental interest. *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965).

147. Defendants' Vaccine Mandate set forth in Executive Order 13D, as amended by Executive Order 13G, including the mandatory testing provision, violates the Plaintiffs' rights to privacy and bodily autonomy because it is designed coerce the Plaintiffs to receive an experimental gene therapy, euphemistically termed a vaccine, under threat of loss of employment and livelihood.

148. Defendants' Vaccine Mandate is unconstitutional because there is no scientific, evidentiary, or medical justification for requiring the Plaintiff's to receive a COVID-19 vaccine, or submit to weekly testing if an exemption is obtained, because:

- The vaccines do not prevent infection from COVID-19
- The vaccines do not prevent transmission of COVID-19
- The COVID-19 vaccines have negative efficacy against the Omicron variant and therefore increase your chance getting sick
- The COVID-19 vaccines are not safe
- Any personal benefit received from the COVID-19 vaccine is temporary and will disappear entirely within less than six months.

- Naturally acquired immunity is far superior to vaccine induced immunity, but is entirely ignored by the Defendants' Vaccine Mandate
- Vaccinated employees are more likely be infected with COVID-19 but are not required to submit to weekly testing

149. Moreover, the mandatory testing provision of the Vaccine Mandate, requiring the Plaintiffs to submit to weekly testing because they are unvaccinated, while exempting vaccinated teaches without any basis in evidenced based science to do so, violates the equal protection clause of the Fourteenth Amendment.

150. 42 U.S.C. §1983 creates a private cause of action for individuals to remedy constitutional violations of civil rights. The statute is derived from §1 of the Civil Rights Act of 1871, 17 Stat. 13 and it was intended to create "a species of tort liability" in favor of persons deprived of federally secured rights. *Carey v. Piphus*, 435 U.S. 247, 253 (1978).

## K. <u>THE VACCINE MADATE IS PREEMPTED BY FEDERAL LAW</u>

151. The Defendant's COVID-19 Vaccine Mandate is entirely inconsistent, incompatible, and in direct conflict with the FDCA which requires that recipients of any vaccine being administered under an EUA be informed of the significant known and unknown benefits and risks of such use and the choice to accept or refuse them, as well as the prohibition against any and all coercive action against the administration of experimental drugs or biologics.

152. Because all of the COVID-19 vaccines are being administered under an EUA pursuant to the FDCA, which requires informed consent and the ability of the individual to refuse the vaccine in the absence of any coercive measure such as loss of employment, or mandated weekly testing, the Defendants' Executive Order 13D, as amended by Executive Order 13G, is preempted by federal law. U.S. Const. art. VI, cl. 2; *see also Hughes v. Talen Energy Marketing, LLC,* 136 S. Ct. 1288, 1297 (2016) ("federal law preempts contrary state law," so "where, under the circumstances of a particular case, the challenged state law stands as an obstacle to the accomplishment and execution of the pull purposes and objectives of Congress" the state law cannot survive).

153. For the same reasons, Defendants' Vaccine Mandate, set forth in Executive Order 13D (as amended), violates the 1947 Nuremberg Code, a multilateral agreement governing human experimentation which was created as a direct response to the horrors perpetrated by the Nazis during the Holocaust. The Nuremberg Code expressly states that "[the voluntary consent of human subject is *absolutely essential*" and prohibits experimental medical treatments on anyone using "force, fraud, deceit, duress, overreaching, or other ulterior forms of constraint or coercion."<sup>109</sup>

154. For the same reasons the Defendant's Vaccine Mandate, set forth in Executive Order 13D (as amended), violates the Helsinki Declaration and the International Covenant on

<sup>&</sup>lt;sup>109</sup>. United States Holocaust Museum, *Nuremberg Code*,

https://ww.ushmm.org/information/exhibitions/ online-exhibitions/special-focus/doctors-trial/Nuremberg-code.

Civil and Political Rights adopted by the United Nations, to which the United States is a party.<sup>110</sup>

## L. <u>THE DEFENDANT KNOWINGLY AND INTENTIONALLY VIOLATED</u> PLAINITFFS' RIGHTS ACTING UNDER COLOR OF CONNECTICUT LAW

155. Defendant's Vaccine Mandate, Executive Order 13D, as amended by Executive Order 13G, is unlawful in that it clearly exceeds the Defendants' statutory authority under C.G.S. §19a-131a, *et seq.* because the Defendants cannot prove that an ongoing "public health emergency" due to COVID-19 existed on August 19, 2021 when the Vaccine Mandate was issued, or in February 2021, when the declaration of a "public health emergency" was last extended prior to the Vaccine Mandate being issued.

156. The Vaccine Mandate clearly exceeds the Defendants' statutory authority under C.G.S. §19a-131e in that the statute expressly limits the authority to order mandatory vaccination to the commissioner of public health, rather than the Governor.

157. The Vaccine Mandate grossly exceeds the Defendants' statutory authority under C.G.S. §19a-131e because the statute does not authorize the issuance of a mandatory vaccination order based upon vocation or occupation. Rather, the statute expressly limits the authority to issue mandatory vaccination orders to "such individuals or individuals present

<sup>&</sup>lt;sup>110</sup>. *See*, International Covenant on Civil and Political Rights, pt III, art. 7, *available at* <u>http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx</u>; World Medical Association, WMA Declaration of Helsinki \_- Ethical Principles for Medical Research Involving Human Subjects, *available at* <u>http://www.wma.net/policies-post/wma-declaation-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/</u>

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within a geographic area." Therefore, the Defendant's Vaccine Mandate is unlawful because it is fundamentally incompatible with Connecticut statutes.

158. The Vaccine Mandate grossly exceeds the Defendants' statutory authority under C.G.S. §19a-131e because the statute explicitly limits any mandatory vaccination order to only those individuals the "commissioner deems reasonable and necessary in order to prevent the introduction or arrest the progress of the communicable disease or contamination that caused the declaration of such public health emergency," Because the COVID-19 vaccines do not prevent infection or transmission of COVID-19, the COVID-19 vaccines cannot "prevent the introduction" or "arrest the progress" of COVID-19. Moreover, because the COVID-19 vaccines have negative efficacy against the Omicron variant, the effect of the Vaccine Mandate contradicts its stated purpose.

159. The Defendants' Executive Order 13D, as amended by Executive Order 13G, is *per se* unlawful because all of the COVID-19 vaccines are being administered under an EUA pursuant to the FDCA which requires informed consent and the ability of the individual to refuse the vaccine in the absence of any coercive measure such as loss of employment or submitting to weekly testing.

#### IV. CAUSES OF ACTION

#### **COUNT ONE:** Declaratory Judgement

1-159. Paragraphs 1 through 159 are hereby re-alleged herein by reference as Paragraphs 1 through 159 of Count One.

160. The Plaintiffs bring this action pursuant to 42 U.S.C. §1983 obtain a declaratory judgment that the Defendants' vaccine mandate set forth in Executive Order 13D, and amended by Executive Order 13G, is unconstitutional because it violates the Plaintiff's right of bodily autonomy, medical privacy, and equal protection guaranteed under the Fourth, Fifth and Fourteenth Amendments to the U.S. Constitution.

#### **COUNT TWO:** Declaratory Judgement

1-159. Paragraphs 1 through 159 are hereby re-alleged herein by reference as Paragraphs 1 through 159 of Count Two.

160. The Plaintiffs bring this action pursuant to 42 U.S.C. §1983 to obtain a declaratory judgment that the Defendants' Vaccine Mandate set forth in Executive Order 13D, and amended by Executive Order 13G, is preempted by federal law, 21 U.S.C. §360bbb-3, and/or the Nuremberg Code, because the only COVID-19 vaccines available in the United States are experimental drugs being administered exclusively under Emergency Use Authorization

#### **COUNT THREE:** Declaratory Judgement

1-159. Paragraphs 1 through 159 are hereby re-alleged herein by reference as Paragraphs 1 through 159 of Count Three.

160. The Plaintiffs bring this action pursuant to 42 U.S.C. §1983 to obtain a declaratory judgment that:

(i) the Defendants' intentionally, recklessly, willfully, wantonly and knowingly violated the Plaintiffs constitutional right to bodily autonomy and medical privacy guaranteed under the Fourth, Fifth, and Fourteenth Amendment by issuing their Vaccine Mandate, set forth in Executive Order 13D, as amended by Executive Order 13G; and

(ii) in doing so, the Defendants acted under color of Connecticut State law.

## **COUNT FOUR:** *Injunction*

1-159. Paragraphs 1 through 159 are hereby re-alleged herein as Paragraphs 1 through159 of Count Four by reference.

160. The Plaintiffs bring this action pursuant to 42 U.S.C.§1983 to obtain a declaratory judgment that the Defendants' intentionally, recklessly, willfully, wantonly and knowingly issued their Vaccine Mandate, set forth in Executive Order 13D, and amended by Executive Order 13G, under color of Connecticut state law.

## COUNT FIVE: (Gov. Lamont) - 42 U.S.C. §1983

1-160. Paragraphs 1 through 160 of Count Three are hereby re-alleged herein as Paragraphs 1 through 160 of Count Five by reference.

160. Under 42 U.S.C. §1983 the Defendant is liable to the Plaintiffs for intentionally, recklessly, willfully, and wantonly violated the Plaintiffs' right to bodily autonomy, medical privacy, and equal protection guaranteed under the U.S. Constitution in issuing their Vaccine Mandate, set forth in Executive Order 13 D, as amended by Executive Order 13G, and acting under color of law in doing so.

# VI. DEMAND FOR RELIEF

WHEREFORE, the Plaintiffs hereby request the court grant the following relief:

- 1. A judgment declaring the Vaccine Mandate, set forth in Executive Order 13D and amended by 13G, to be unconstitutional, and is therefore void *ab initio*, because it violates the Plaintiffs' right to bodily autonomy, medical privacy, and equal protection guaranteed under the Fourth, Fifth and Fourteenth Amendment to the U.S. Constitution;
- 2. A judgment declaring that the Vaccine Mandate, set forth in Executive Order 13D and amended by 13G, is preempted by federal law and therefore is void *ab initio*;
- 3. A judgment declaring that the Defendants intentionally, recklessly, willfully, wantonly and knowingly violated the Plaintiffs' constitutional right to bodily autonomy, medical privacy, and equal protection guaranteed under the Fourth, Fifth, and Fourteenth Amendment of the U.S. Constitution in issuing the Vaccine Mandate, set forth in Executive Order 13D and amended by Executive Order 13G; and in doing so the Defendants were acting under color of state law;
- 4. An injunction against the Defendants preventing enforcement of the Defendants' Vaccine Mandate;
- 5. Monetary damages;
- 6. Attorney's fees pursuant to 42 U.S.C. §1983;
- 7. Court costs;
- 8. Any other relief as this Court deems proper under the circumstances.

Dated at Wethersfield, Connecticut this 9th day of February, 2022.

Respectfully Submitted,

/s/\_\_\_\_

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### **CERTIFICATE OF SERVICE**

I hereby certify that on February 9, 2022, a copy of the foregoing Complaint was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the Court's CM/ECF System.

<u>/s/</u> Matthew S. Carlone, their attorney Fed. Bar No. CT29094, Juris No. 432761 81 Wolcott Hill Road Wethersfield, CT 06109 (860) 563-9494 – Phone (860) 563-6088 - Fax MCarlone@Terkcarlone.com