

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK**

WILLIAM OUWELEEN,

Plaintiff,

vs.

HOWARD ZUCKER, in his official capacity as
Commissioner of the New York State
Department of Health.

Defendant.

Case No. 6:21-cv-6522

**VERIFIED COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

DEMAND FOR JURY TRIAL

“Liberty is the soul's right to breathe and, when it cannot take a long breath, laws are girdled too tight.” Henry Ward Beecher (1858)

Plaintiff, WILLIAM OUWELEEN, by and through his undersigned counsel, sues Defendant, Howard Zucker, in his official capacity as the Commissioner of the New York State Department of Health, and alleges as follows:

PRELIMINARY STATEMENT

1. Plaintiff challenges a new “emergency” regulation promulgated by Defendant Howard Zucker, M.D., acting in his official capacity as the Commissioner of the New York State Department of Health (“NYSDOH”).

2. The emergency regulation, published in the New York State Register on July 14, 2021, amends Part 66 of Title 10 NYCRR to add a new subpart, 10 NYCRR 66-3, entitled “COVID-19 Emergency Regulations” (emergency regulation hereinafter referred to as the “Mask Mandate”).¹

¹ The new regulation was promulgated on an “emergency” basis on June 23, 2021, published in the Register on July 14, 2021, and is in effect until September 20, 2021, unless extended or adopted as a permanent regulation.

3. The Mask Mandate provides that: “any person who is over age two and able to medically tolerate a face-covering shall be required to cover their nose and mouth with a mask or face-covering when in a public place and unable to maintain, or when not maintaining, social distance, unless such person is fully vaccinated.” 10 NYCRR § 66-3.1(a). It further requires that unvaccinated employees must always wear a mask when interfacing with the public (even when socially distanced) and unvaccinated employees working in food service must always wear a mask even when the public is not present and even when the employee is working alone. 10 NYCRR §66-3.1(b).

4. Noncompliant individuals and businesses employing them face extensive fines, and other penalties such as criminal prosecution, jail time and forced closures or suspension of privileges to conduct business. 10 NYCRR § 66-3.2; *see also* N.Y. Pub. Health Law (“PBL”) § 229 and § 12-b.

5. The NYSDOH and local health departments routinely advise employers to demand proof from employees regarding their vaccination status, and then ensure that the employees are wearing masks if they are not vaccinated.

6. The stated purpose of the Mask Mandate is “to control the spread of communicable disease in situations in which the Governor has declared a state disaster emergency.”

7. However, the “emergency” regulation was promulgated on the same day that Governor Cuomo declared the state disaster emergency was over. It was first published in the State Register three weeks after the Governor’s declared state disaster emergency was no longer in effect.

8. The Mask Mandate is unlawful under international, federal, constitutional, and state law. It is also irrational and discriminatory and violates Plaintiff’s equal protection rights as it is

imposed on unvaccinated people but similarly situated vaccinated people are exempt. There is no rational reason to discriminate between the two.

9. It is well established by evidence-based science that the vaccines available to protect against SARS-CoV-2 are not able to provide sterilizing immunity. From the beginning, public health officials acknowledged that SARS-CoV-2 vaccines would likely provide personal protection from serious symptomatic disease but the vaccines were not designed to stop infection and transmission of the virus.

10. The Centers for Disease Control (“CDC”) recently released the findings of a study that confirms the vaccinated are as infectious as the unvaccinated. The study also showed the vaccinated are as likely to contract COVID-19 and to end up in the hospital with serious cases of COVID-19 as the unvaccinated.²

11. To date, no peer reviewed study supports the assumption that the vaccinated are not able to spread SARS-CoV-2 or are less dangerous than unvaccinated people. On the contrary, transmission was not even studied in clinical trials, and it was expressly acknowledged from the outset that these vaccines cannot provide sterilizing immunity. They were not designed to stop transmission and they do not stop transmission of SARS-CoV-2.

12. Defendant did not issue the discriminatory Mask Mandate based on any science that showed it was necessary or appropriate (or even safe) to impose burdens on the unvaccinated but not the vaccinated. Rather, in his official capacity, Defendant promulgated the discriminatory regulation as part of a political strategy to coerce people into participating in the experimental

² Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings – Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep. ePub: 30 July 2021. DOI<http://dx.doi.org/10.15585/mmwr.mm7031e2> Last Viewed on August 4, 2021.

vaccine program. The widely discussed theory was that by easing restrictions only for the vaccinated, the unvaccinated would be shamed, burdened, or coerced into getting vaccinated as well.

13. This is not an acceptable purpose. The most basic and well protected international human right is the right to uncoerced informed consent, which the Supreme Court has recognized as a fundamental right subject to strict scrutiny.

14. This right is nearly absolute in the context of an experimental medical product. After World War II, physicians were found by U.S. Military Tribunals to have committed war crimes and hanged for having forced *or even coerced* subjects into participating in vaccine trials with experimental vaccines. Arguments that vaccine trials advance the greater good were unavailing. Without meaningful consent, it is a war crime to force a medical experiment on subjects. The fundamental right of informed consent is so widely adopted and accepted as to establish *jus cogens*.

15. The right of informed consent is also codified in the laws of the United States. The federal law by which the Food and Drug Administration (“FDA”) issued the Emergency Use Authorization (“EUA”) for mask use and SARS-CoV-2 vaccine policy provides that EUA products must be optional. It preempts the Mask Mandate under the Constitution’s Supremacy Clause.

16. Pursuant to Title 21 of the United States Code, products and devices authorized under an EUA must be optional to the user as the basic standards for testing, evaluation, and approval have been bypassed by the FDA due to an emergency. Title 21 United States Code, Section 360bbb-3(e)(1)(A)(ii).

17. Vaccines and masks used for a medical purpose are regulated by the FDA.

18. The FDA has not approved any vaccine or mask intended to be used for general use against SARS-CoV-2 other than through an EUA.

19. It is unlawful under the EUA to even represent that the vaccines or the masks are safe or effective, leave aside to mandate or coerce them.

20. Even if the FDA were to rush through approval of one or more COVID-19 vaccine, as the news media suggests might happen, these vaccines are still in the experimental phase and will be for many years to come and cannot be mandated.

21. There has never been a vaccine produced and brought to market as rapidly as the COVID-19 vaccines currently authorized under EUA. Typically even the most hasty vaccines take years or decades to properly develop and test.

22. In late May 2020, President Trump initiated Operation Warp Speed, a controversial federal program to rush the development of vaccines to combat SARS-CoV-2 in record time.

23. The COVID-19 vaccines were pushed through various hasty iterations of unfinished clinical trials, skipped even the more common basic steps normally employed before those trials, and were rushed to market in a matter of months not decades.

24. This is particularly significant as the COVID-19 vaccines employ a novel technology that has not previously ever been able to pass the trial phase and become licensed for use in human beings due to significant safety problems identified in animal and other trials.

25. Long term effects, effects on vulnerable subpopulations and general adverse effects for the COVID-19 vaccines are still largely unknown.

26. While many people have valid reasons to take a leap of faith and hope the benefits outweigh the risks, there are also valid reasons to exercise caution.

27. Masks, when used for the purpose of infection mitigation, are also experimental devices and are only authorized for general use outside of hospitals pursuant to their own EUAs.

28. The FDA recognizes that the data on prolonged mask use is limited and it is not legal to represent that prolonged mask-use by the general public to mitigate transmission of pathogens is either safe or effective for such use pursuant to the terms of their EUA.

29. No peer reviewed study has yet found that widespread use of cloth masks or reusable surgical masks can mitigate the spread of SARS-CoV-2 or any other similar aerosolized pathogens. At best, there are hypothetical “modeling” studies which are inherently unreliable and subject to layered, flawed assumptions. Thus far, the models have not been established to be true by any hard science.

30. The only randomized controlled trial of cloth masks showed that cloth masks actually increase the risk of health complications and spread of disease rather than help stop its spread. Based on this study, guidelines were updated to recommend that it is safer for healthcare workers to have no mask than to use a cloth or reusable mask.

31. The peer-reviewed evidence available shows that serious adverse health outcomes can and do occur from prolonged mask use.

32. A recent study out of India found a significant correlation between prolonged use of cloth masks and black fungal lung infections.

33. Other known serious health effects that can be induced by prolonged mask use include but are not limited to fungal, bacterial and viral infection in the mouth and respiratory tract, fatigue, loss of concentration, headaches, loss of brain function, long-term neurodegenerative disease, lack of normal cognitive development, increased susceptibility to viral infections and illnesses, cardiovascular disease, hypertension, exacerbation of existing chronic disease,

premature aging, premature death, hypoxia, hypercapnia, shortness of breath, increased lactate concentration, acidosis, toxicity, chronic inflammation, self-contamination, increase in stress hormone levels, increased muscle tension, immunosuppression, panic, anxiety, claustrophobia, mood disturbances, and compromised cognitive performance.

34. Plaintiff cannot medically tolerate wearing a mask and is unwilling to use an experimental product that the science shows likely puts him at increased risk of serious disease. Nor is he willing to be deputized to police his employees or customers and invade their fundamental rights to medical privacy and choice.

35. Plaintiff is, however, eager to help stop the spread of SARS-CoV-2. Though he has already had COVID-19 and likely has natural immunity, he purchased and installed an air and surface purifying technology approved by NASA that studies show has a 99.9% effectiveness at killing SARS-CoV-2. It is currently in use by the Cleveland Clinic and was inducted into the Space Foundation in recognition of its lab-proven technology.

36. Notwithstanding these efforts (and the fact that Plaintiff cannot medically tolerate masks) Plaintiff received two complaints regarding mask use and was told by public health officials that if he receives a third, the NYSDOH may close the Winery that he operates or assess substantial fines and penalties.

37. The Mask Mandate and accompanying coercive effect on the right to refuse the EUA vaccines implements a mandatory human experiment under which Plaintiff and other residents of and visitors to New York are being forced to either use an unlicensed medical device or take an experimental vaccine when the medical impact of either has not been tested, evaluated, or approved by the FDA or established to be safe and effective.

38. This mandate is a clear violation of our most sacred laws under international law, federal law, and New York law. Moreover, the NYSDOH lacks the authority to issue this Mask Mandate *sua sponte*, particularly after the enhanced emergency powers previously granted to the Executive branch have expired.

39. For the reasons set forth in this complaint, Plaintiff respectfully seeks declaratory and injunctive relief to prevent the ongoing violation of his most basic rights, dignity, and safety.

JURISDICTION AND VENUE

40. This Court has jurisdiction to hear all federal claims asserted in this case under 28 U.S.C. § 1331, which confers original jurisdiction on federal district courts to hear suits arising under the laws and Constitution of the United States; the Supremacy Clause of the Constitution of the United States, which allows federal district courts to hear suits alleging preemption of state and local laws by the Constitution and federal laws made in pursuance thereof; and 42 U.S.C. § 1983 and 28 U.S.C. § 1343 in relation to Defendants' deprivation and infringement under color of law of the Individual Plaintiff's rights, privileges, and immunities secured by the United States Constitution and laws, as detailed further herein.

41. This Court has jurisdiction over the claims asserting violations of the laws and Constitution of the State of New York through its supplemental jurisdiction under 28 U.S.C. § 1367(a), as those claims are so closely related to the Plaintiff's federal question and Section 1983 claims that they form part of the same case or controversy under Article III of the United States Constitution.

42. This Court has the authority to award the requested declaratory relief under 28 U.S.C. § 2201; the requested injunctive relief under 28 U.S.C. § 1343(a); and attorneys' fees and costs under 42 U.S.C. § 1988.

43. The United States District Court for the Western District of New York is the appropriate venue for this action pursuant to 28 U.S.C. § 1391(b)(1) and (2) because it is the district in which Defendant deprived Plaintiff of his rights and liberties under the laws and Constitution of the United States and violated the laws and Constitution of the State of New York, as further alleged herein. It is also the district in which a substantial part of the events giving rise to Plaintiff's claims occurred and continue to occur.

PARTIES

44. Plaintiff William Ouweleen (hereinafter, "Mr. Ouweleen"), is the Vintner at O-Neh-Da® Vineyard (the "Winery"). The Winery was founded in 1872. It is the oldest producer of sacramental wine in the United States. Mr. Ouweleen is subject to and objects to the Mask Mandate as a worker, employer, business operator and as an individual. He has received two complaints from his local health department, which informed him that the Winery will likely be shut down if he receives a third. Mr. Ouweleen resides and operates the Winery in Conesus, New York, and has standing to bring this case, which presents a justiciable issue for the Court.

45. Defendant Howard Zucker, M.D. ("Commissioner Zucker"), is the duly appointed Commissioner of the NYSDOH. He is sued in his official capacity and in that capacity is ultimately charged with enforcing and issuing NYSDOH regulations, including those complained of herein. Acting under color of state law, Commissioner Zucker personally promulgated the Mask Mandate that deprives and infringes or threatens to deprive and infringe Plaintiff of rights, privileges, and immunities under the laws and Constitution of the United States, the laws, and Constitution of the State of New York, and under international law so widely adopted and accepted as to establish *jus cogens*.

FACTUAL BACKGROUND

The Mask Mandate

46. On June 24, 2021, Governor Cuomo announced that the COVID-19 state disaster emergency was officially declared over. Simultaneously, the NYSDOH issued an “emergency” Mask Mandate alleged to be tied to the Governor’s power to issue new laws pursuant to his emergency powers during a declared disaster.

47. The Mask Mandate is novel among New York’s various emergency mask mandates in that it only applies to unvaccinated people. Vaccinated people are exempt.

48. Pursuant to its terms, the Mask Mandate requires every unvaccinated person over the age of two who can medically tolerate it to wear a mask or face covering over her mouth and nose when “not maintaining” social distance of at least six feet from all other persons outside the immediate family. 10 NYCRR § 66-3.1(a). No exception is made for eating or swimming or any other previously applied carve-outs found in the previous mask mandates.

49. Neither is any protection or direction provided to ensure that those who cannot medically tolerate a mask will be allowed to exercise their exemption free from unconstitutional interference or burdens on their privacy rights from third parties or employers who doubt that they should be medically exempt. Medical exemptions are routinely discounted or denied by public health officials, employers, and schools. It is unclear what the criteria is for being allowed to exercise the medical exemption. Yet, individuals and employers can be fined or jailed if determined noncompliant.

50. Additional rules apply in the workplace. Pursuant to the Mask Mandate, unvaccinated workers must wear a face covering whenever they are interacting with the public, even if they are able to maintain six feet distance, and unvaccinated workers working at a business that serves food must always wear a face covering, even if working alone and not interacting with

the public in any way. 10 NYCRR § 66-3.1(b).

51. Pursuant to the Mask Mandate, anyone who is “fully vaccinated” for COVID-19 is exempt from all mask requirements. *Id.*

52. The NYSDOH routinely advises businesses that employers must ensure that unvaccinated employees comply with the rules or else the business owners will face penalties. Penalties for noncompliance with the Mask Mandate include a fine of \$1,000 per day, along with any other available remedies in the Sanitary Code or local policies, including closure of a noncomplying business and criminal prosecution and jail time of up to one year for willful noncompliance.

The COVID-19 Vaccines Cannot Stop Transmission of SARS-CoV-2

53. There is no valid reason to discriminate against unvaccinated people in this manner. Not only does it burden their fundamental rights to medical privacy and self-determination in medical choices, but it is also irrational.

54. The COVID-19 vaccines were not designed to stop transmission of SARS-CoV-2. Rather, these vaccines are in the “non-sterilizing” category that may provide personal protection from severe disease symptoms, but still allow for infection, replication, and transmission of virus to others.

55. NYSDOH understood this fact at the time it issued the Mask Mandate. NYSDOH’s intention behind the disparate treatment of vaccinated and unvaccinated people must have been to coerce people into getting the vaccines.

56. New data announced last week by the CDC confirms that vaccinated people are as infectious as unvaccinated people.

57. Moreover, a large body of peer-reviewed evidence establishes that widespread use

of non-sterilizing vaccines puts pressure on viruses to mutate into more virulent and dangerous strains, thereby putting the public at risk. This fact is so well-settled that it is sometimes referred to as “evolutionary immunology 101” among scientists.

58. Because the COVID-19 vaccines allow a recipient to become infected and transmit disease, mass use of these vaccines is likely to put pressure on SARS-CoV-2 to become a far more dangerous disease.

59. The COVID-19 vaccines have not been adequately tested to ensure safety and effectiveness for the user either. They were brought to market after only a few months of clinical trials under a controversial program entitled “Operation Warp Speed.”

60. Long-term health impacts, and their impact on vulnerable sub-populations is not known yet. Neither is the range of potential complications.

61. No vaccine against SARS-CoV-2 is licensed by the FDA. Rather, they are authorized under a limited EUA that requires uncoerced informed consent before use and prohibits representations that the product is safe or effective.

Masks Have No Benefit in Reducing or Preventing Infection From SARS-CoV-2

62. Even if the unvaccinated were somehow more dangerous to society than the vaccinated, which is not an evidence-based claim, there would still be no rational reason to force them to wear masks.

63. The science does not support an assumption that masks can stop the spread of SARS-CoV-2.

64. Viruses are a thousand times smaller than the thread diameter of a mask. Multiple peer-reviewed studies show masks are ineffective at preventing viral transmission. And the only randomized, controlled trial finds that masks cannot mitigate the spread of COVID-19.

The Physical Properties of Masks Establish That They Cannot Prevent Virus Spread.

65. From a physical standpoint, the properties of masks versus the SARS-CoV-2 virus prove that masks simply cannot prevent the virus from exiting the nose and mouth of infected individuals into the air around them to be breathed in by others. According to current knowledge, the SARS-CoV-2 virus has a diameter of 60 nm to 140 nm [nanometers (a billionth of a meter)]. Medical and non-medical facemasks' thread diameter, on the other hand, ranges from 55 μm to 440 μm [micrometers (one millionth of a meter)], which is more than 1,000 times larger than the diameter of the virus. Due to the difference in sizes between SARS-CoV-2 diameter and facemasks thread diameter (the virus is 1000 times smaller), SARS-CoV-2 can easily pass through any face mask like a mosquito through a chain link fence.

66. Historians and public health scholars similarly describe the known futility of the masks employed during influenza 1918, often referencing the famous quote that "it is like trying to keep out dust with chicken wire."

67. The physical impossibility of filtering the SARS-CoV-2 virus with masks is exacerbated by the lack of any seal between the wearer's face and the mask, which allows breath to exit wholesale sans any filtering whatsoever into the air around the wearer to be breathed in by others.

68. The Occupational Safety and Health Agency sets standards for the use of masks to prevent infection by viruses. These masks seal effectively around the nose and mouth and prevent the inhalation or exhalation of viruses into the air by those wearing them but can only be used with an external source of oxygen being pumped into the mask, much like a diver wearing an oxygen tank. The face coverings commonly used by the public at large are not such masks, and are therefore not designed to, nor do they, prevent or reduce infection by the

SARS-CoV-2 virus.

69. The seal problem is more pronounced for those who have beards, like Plaintiff. Since the 1980s, several studies that examined the impact of beard hair on standardized respirator masks provided the basis for agency guidelines. Although one study examining workplace protection factors found no clear relationship, multiple studies provided evidence that beards cause an impaired seal, reduced fit factors and detrimental impacts on respirator performance. This led agencies to advise against bearded workers using masks (in a workplace setting) and in the US to prohibit their use and fit testing for bearded workers.

70. Plaintiff's religious beliefs prevent him from shaving his beard off. To the extent that masks offer any protection when they are not properly fitted and lack the proper seal, they cannot offer such protection to Plaintiff.

The FDA and Scholarly Studies Establish Masks Have No Benefit.

71. The FDA determined that the efficacy of face coverings for reducing or preventing infection from SARS-CoV-2 is not established, and that it would be misleading to state that they are effective in preventing or reducing such infection.

72. In the authorizing EUA for face masks to prevent transmission of COVID-19, the FDA stated that it "would misrepresent the product's intended use" to state that it "is for use such as infection prevention or reduction."

73. Similarly, in its Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised),³ the FDA stated in three instances that face masks are not intended to reduce or prevent infection:

³ Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised May 2020), <https://www.fda.gov/media/136449/download> Last viewed on August 3, 2021

The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses ***or uses for infection prevention or reduction or related uses*** and does not include particulate filtration claims.

Id. at 7-8.

74. The first and only randomized, controlled trial evaluating the impact of mask-wearing on the spread of SARS-CoV-2 in six thousand individuals concluded that there was no statistically significant difference among the masked and unmasked controls sufficient to show that masks are effective in reducing or preventing infection from SARS-CoV-2.⁴

75. A study by the Centers for Disease Control published in the *Emerging Infectious Disease Journal* in May 2020 found that ten randomized control trial studies of the use of face masks to control the influenza virus, a virus essentially the same size as the SARS-CoV-2 virus, showed no significant reduction in influenza transmission with the use of face masks.⁵ These studies covered a wide range of environmental settings from University dorms to households, but the results were the same in each context.

76. Similarly, a study of nearly two thousand United States Marine Corp recruits published in the *New England Journal of Medicine* on November 11, 2020, indicated that masks did not reduce or prevent the spread of SARS-CoV-2.⁶

⁴ Henning Bundgaard et al., Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial: *Annals of Internal Medicine*: Vol 174, No 3, <https://www.acpjournals.org/doi/pdf/10.7326/M20-6817> Last viewed on August 3, 2021

⁵ Xiao J, Shiu E, Gao H, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. *Emerging Infectious Diseases*. 2020;26(5):967-975. doi:10.3201/eid2605.190994, https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article, Last viewed on August 3, 2021

⁶ Andrew G. Letizia, M.D. et al., SARS-CoV-2 Transmission among Marine Recruits during Quarantine, <https://www.nejm.org/doi/full/10.1056/NEJMoa2029717>, last viewed on August 3, 2021

77. The WHO announced in 2020 that “at present, there is no direct evidence (from studies on COVID-19) on the effectiveness face masking of healthy people in the community to prevent infection of respiratory viruses, including COVID-19.”⁷

Prolonged or Improper Mask Use Can Cause Harm

78. More importantly, prolonged, or improper use of masks can cause harm to the wearer and increased risk of serious respiratory disease.

79. A randomized, controlled trial conducted on 1,607 health care workers in 2015 found that “the rate of influenza-like illness is significantly higher” in the cloth mask controls than in those who wore no mask. The study concluded that “moisture retention, reuse of cloth masks and poor filtration made cloth masks more likely to lead to increased risk of infection for the wearer” and finished by stating that “cloth masks should not be recommended” and “guidelines need to be updated.”⁸

80. During a pandemic for a virus that is usually mild but can quickly develop into a deadly respiratory illness for unknown reasons, any intervention which could increase the likelihood of severe respiratory symptoms would understandably be unacceptable to some people.

81. Another study shows that the temperature of the perioral skin rises after use of

⁷ World Health Organization. (2020). Advice on the use of masks in the context of COVID-19: interim guidance, 5 June 2020. World Health Organization. . <https://apps.who.int/iris/handle/10665/332293>. License: CC BY-NC-SA 3.0 IGO. Last viewed on August 3, 2021

⁸ C Raina MacIntyre et al., A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, <https://pubmed.ncbi.nlm.nih.gov/25903751/>, Last viewed on August 3, 2021

face masks for even one hour.⁹ Coupled with prolonged casual use, moisture retention, reuse, and touching, the Mask Mandate creates the perfect breeding ground for dangerous viral, bacterial, and fungal infections. These again can lead to increased respiratory illness and death.

82. A study by Anthony Fauci, M.D. and others in 2008 established that most of the deaths in the pandemic of 1918 were not from influenza, but rather from secondary bacterial infections that developed into pneumonia.¹⁰ Certainly, any intervention that creates increased risk of localized bacterial and fungal infections should be avoided during a pandemic.

83. A recent study from India found that cloth mask use significantly increases the risk of developing Coronavirus disease-associated mucormycosis (“CAM”)(a deadly fungal infection of the lungs seen in primarily in COVID-19 patients in India).¹¹ “Use of surgical or cloth masks for prolonged periods was found to be associated with an increased risk of CAM.”

⁹ Scarano A, Inchingolo F, Lorusso F. Facial Skin Temperature and Discomfort When Wearing Protective Face Masks: Thermal Infrared Imaging Evaluation and Hands Moving the Mask. *Int J Environ Res Public Health*. 2020;17(13):4624. Published 2020 Jun 27. doi:10.3390/ijerph17134624 Last Viewed on August 3, 2021.

¹⁰ Morens DM, Taubenberger JK, Fauci AS. Predominant role of bacterial pneumonia as a cause of death in pandemic influenza: implications for pandemic influenza preparedness. *J Infect Dis*. 2008;198(7):962-970. doi:10.1086/591708 Last Reviewed August 5, 2021.

¹¹ Novel risk factors for Coronavirus disease-associated mucormycosis (CAM): a case control study during the outbreak in India
Umang Arora, Megha Priyadarshi, Varidh Katiyar, Manish Soneja, Prerna Garg, Ishan Gupta, Vishwesh Bharadiya, Parul Berry, Tamoghna Ghosh, Lajjaben Patel, Radhika Sarada, Shreya Garg, Shubham Agarwal, Veronica Arora, Aishwarya Ramprasad, Amit Kumar, Rohit Kumar Garg, Parul Kodan, Neeraj Nischal, Gagandeep Singh, Pankaj Jorwal, Arvind Kumar, Upendra Baitha, Ved Prakash Meena, Animesh Ray, Prayas Sethi, Immaculata Xess, Naval Vikram, Sanjeev Sinha, Ashutosh Biswas, Alok Thakar, Sushma Bhatnagar, Anjan Trikha, Naveet Wig
medRxiv 2021.07.24.21261040; doi: <https://doi.org/10.1101/2021.07.24.21261040> Last Viewed on August 3, 2021

84. In short, science does not support the proposition that the Mask Mandate can or will reduce or prevent the spread of SARS-CoV-2; rather, it shows it may cause increased risk of viral, bacterial, and fungal infection.

85. Masks have become a political, not a scientific issue. Virtue signaling, shaming and rejection of any discussion of the actual evidence have become common in the public discourse and to a large extent the messaging from public health officials, who universally cautioned at the start of the pandemic that prolonged use of masks in healthy and asymptomatic people could lead to worse public health outcomes.

86. The public narrative is that the WHO, CDC, and Anthony Fauci each initially intentionally lied to the public when they advised against prolonged mask use because the public health authorities were trying to conserve protective gear for medical personnel on the front lines.

87. But the evidence, when examined, does not support this narrative. In fact, as will be shown at trial, the evidence at the start of the pandemic showed that mask use by healthy or asymptomatic people is more harmful than helpful on an individual and general level. The hard evidence that has emerged since it became a political issue to embrace masks (which some studies have discussed as a “security blanket” for a frightened public) has not largely changed.

88. Breathing is one of the most important and necessary physiological functions to sustain life and health. The human body requires a continuous and adequate oxygen supply to all organs and cells for normal function and survival. Breathing is also an essential process for removing metabolic byproducts, like carbon dioxide, occurring during cell respiration.

89. Masks are detrimental to human breathing function because they force users to rebreathe their own expelled air over extended periods of time, increasing levels of carbon dioxide and other detrimental elements in the body. They also impede the airflow and make it

difficult to breathe, particularly for people with anxiety or respiratory issues. These concepts, though sometimes vilified by the public discourse as overblown, are not hard to prove.

90. As will be further developed at trial, serious health effects that can be induced by prolonged mask use include but are not limited to fungal, bacterial and viral infection in the mouth and respiratory tract, fatigue, loss of concentration, headaches, loss of brain function, long-term neurodegenerative disease, lack of normal cognitive development, increased susceptibility to viral infections and illnesses, cardiovascular disease, hypertension, exacerbation of existing chronic disease, premature aging, premature death, hypoxia, hypercapnia, shortness of breath, increased lactate concentration, acidosis, toxicity, chronic inflammation, self-contamination, increase in stress hormone levels, increased muscle tension, immunosuppression, panic attacks, anxiety, claustrophobia, mood disturbances, and compromised cognitive performance.

91. Plaintiff has experienced many of these adverse impacts and cannot medically tolerate wearing a face covering for extended periods.

92. Moreover, prolonged mask use imposes psychological trauma on many people, including Plaintiff.

93. Historically, masks have been used as a form of torture in prisons and to isolate prisoners from one another and to dehumanize them.

94. Masks are particularly dehumanizing when mandated in a discriminatory manner to publicly identify and shame an already stigmatized and vilified group (those who are not vaccinated) which can and has led to significant social, economic, and emotional consequences and pressures for Plaintiff and others who are required to submit to the mandate.

95. Moreover, masks break down the social structure that human beings naturally require and can lead to depression, feelings of disconnect and other serious psychological

consequences.

The Mask Mandate Coerces Participation in the Experimental Vaccine Trials

96. Receipt of a COVID-19 vaccine is and for many years to come will be, participation in experimental medicine. It requires the absolutely free and uncoerced consent of the subject.

97. There is no FDA approved vaccine to prevent COVID-19. Each of the COVID-19 vaccines is available only on an experimental basis and only under an EUA authorization.

98. Even if “full approval” were to be rushed through, as some sources announce may occur this fall due to political and corporate pressures, the vaccines have not been tested for any sufficient length of time to be categorized as anything other than experimental for purposes of fundamental rights analysis.

99. Clinical trials have shown some reduction in serious symptomatic disease for many vaccinated individuals, but the trials are ongoing and there is limited data about the effectiveness of the vaccines in protecting vaccinated individuals from various subpopulations or in response to emerging mutations and variants or the length of such protection. More importantly, there is extremely limited data about long term and population specific safety issues.

100. While it is possible individuals may benefit greatly on a personal level from taking one of these vaccines, it is also possible that they could die, sustain a vaccine injury, or suffer other ill-effects. It is also entirely possible, as the recent CDC study illustrates, that they could suffer adverse effects and *also* remain unprotected from both asymptomatic infection and hospitalization due to a so-called “breakthrough infection” of COVID-19.

101. One serious complication that is known is the potential for vaccine-elicited, antibody-dependent enhancement (ADE), which studies show is likely to occur to some degree

with COVID-19 vaccines. ADE is very serious and can cause death and severe injury to a person whose immune system is improperly primed, and thus overreacts to subsequent encounters with a virus that they are vaccinated for, or even another similar virus. It is not uncommon for ADE reactions to result in death.

102. A recent study found that the risk of ADE and other known potential serious adverse outcomes from the new vaccines was not being sufficiently communicated to recipients of the COVID-19 vaccines to meet the requirements of the right of informed consent.¹²

103. Though information is a very important component to informed consent, the most important component is that the participant indeed is able to freely consent (or not). Where, as here, there is serious risk, the risk/benefit analysis must remain with the individual.

104. This is especially true in the context of non-sterilizing vaccines, which can only provide personal protection and are entirely outside the purview of the state's police powers to protect the public from disease transmission. The state's police powers do not authorize usurpation of our right to make medical decisions about what is best for our own bodies.

105. On July 27, 2021, the Centers for Disease Control confirmed that new studies establish that vaccinated individuals are as contagious as unvaccinated individuals for the most commonly circulating variants of SARS-CoV-2. Because COVID-19 vaccines can only provide personal protection, this is a personal decision.

106. Nor is there an overall benefit to society from an evolutionary perspective. The consensus of basic evolutionary immunology is that widespread use of non-sterilizing vaccines

¹² Cardozo T, Veazey R. Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease. *Int J Clin Pract.* 2021 Mar;75(3): e13795. doi: 10.1111/ijcp.13795. Epub 2020 Dec 4. PMID: 33113270; PMCID: PMC7645850. Last Reviewed August 5, 2021.

that suppress symptoms but allow transmission puts significant pressure on viruses to mutate into more dangerous variants. By contrast, the peer-reviewed evidence also shows that circulation of disease among *unvaccinated* populations tends to put pressure on viruses to stay less virulent.¹³¹⁴¹⁵ To the extent that the mainstream media quotes health authorities as urging vaccination to stop the emergence of variants, this could only be true if the COVID-19 vaccines were able to provide sterilizing immunity. If they can still allow transmission, which we now know they do, then widespread use will in fact put pressure on the virus to mutate into more dangerous strains. The claim that the unvaccinated will lead to the development of more virulent strains of COVID-19 than those vaccinated with a non-sterilizing vaccine is not evidence-based.

107. In sum, there is no rational reason to impose different burdens on unvaccinated people from a public health perspective. Unvaccinated workers are not any more dangerous to society than vaccinated workers. Widespread use of a non-sterilizing vaccine will likely make the virus more dangerous to everyone.

108. Forcing unvaccinated workers to share their private medical information with their employers and to have to then essentially announce private medical decisions to the world through mandatory unvaccinated-only face coverings already has resulted in stigma, harassment,

¹³ See, e.g., Andrew F. Reed, et al., *Imperfect Vaccination Can Enhance the Transmission of Highly Virulent Pathogens*, PLOS Biology (Jul. 27, 2015), <https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002198#abstract0>. Last viewed on August 5, 2021.

¹⁴ Melinda Wenner Moyer, *Vaccines Are Pushing Pathogens to Evolve*, QUANTAMAGAZINE, (Aug. 4, 2021, 8:15 AM), <https://www.quantamagazine.org/how-vaccines-can-drive-pathogens-to-evolve-20180510/>

¹⁵ Kate Kelland, *Russia vaccine roll-out plan prompts virus mutation worries*, REUTERS, (Aug. 4, 2021, 8:15 AM), <https://www.reuters.com/article/us-health-coronavirus-vaccine-russia-mut/russia-vaccine-roll-out-plan-prompts-virus-mutation-worries-idUSKBN25H1FC>.

embarrassment, and bullying. It is an invasion of basic bodily autonomy and privacy rights. It also burdens the fundamental right to voluntary consent or refusal of a medical intervention and violates the terms of the EUA license for masks and vaccines.

109. There is no rational reason to violate the constitutionally protected rights of unvaccinated workers in this discriminatory manner.

The Use of Face Coverings by the General Population is Experimental, and the Mask Mandate is a Forced Human Experiment.

110. Like vaccines, masks are regulated by the FDA when used for a medical purpose such as preventing the spread of communicable disease.

111. None of the currently available face coverings for COVID-19, other than NIOSH-approved N95 particulate filtering facepiece respirators (when used in specific settings), is approved or licensed by the federal government; they are authorized under Emergency Use Authorization only and may not be mandated. They have not received final approval from the FDA as having been adequately tested to establish safety or effectiveness. Rather, like the vaccines, they are *unapproved products* that have been authorized only for emergency use.

112. Plaintiff alleges, and will show at trial, that the Mask Mandate is in fact a medical experiment being forced on unwilling participants.

113. In fact, the FDA defines them as such and has labeled masks experimental devices requiring, *inter alia*, that the person using the unapproved experimental device be advised of his or her right to refuse administration of the product. *See* 21 U.S.C. § 360bbb-3(e)(1)(A) (“Section 360bbb-3”).

114. The FDA has taken the position that the terms and conditions of both the Mask EUA and the Vaccine EUA preempts state and local laws. *See* 21 U.S.C. § 360(k)(a), “GENERAL RULE Except as provided in subsection (b), no State or political subdivision of a State may establish or

continue in effect with respect to a device intended for human use any requirement that would impose obligations that are inconsistent with those terms and conditions.” *See* Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders at 39-40 available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>.¹⁶

115. The Mask EUA specifies that “emergency use of face masks must be consistent with, and may not exceed, the terms of this letter...”. Further, the Mask EUA states that the product must not be labeled in such a manner that would misrepresent the product’s intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction.

116. The NYSDOH Mask Mandate not only misleads the public by implying that masks can be used for antiviral protection and to stop the spread of COVID-19, but conflicts with the EUA’s terms and is preempted under the Supremacy Clause.

117. This is indeed a grand experiment.

118. Masks are traditionally worn by healthcare workers, who are typically trained in their use, and who only wear them for single use in limited circumstances and for short periods of time, replacing them frequently.

119. Before the COVID-19 pandemic, the only time masks were required for use by

¹⁶ “FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564... To the extent state or local law may impose requirements different from or in addition to those imposed by the EUA for a particular medical product within the scope of the declared emergency or threat of emergency (e.g., requirements on prescribing, dispensing, administering, or labeling of the medical product), such law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,’ and ‘conflicts with the exercise of Federal authority under [§ 564].”

lay people in public spaces in the United States was during the 1918 flu pandemic. Even then, they were only mandated in certain cities for a matter of a few weeks – certainly not for months or years.

120. Scientific consensus on the short-term and long-term medical and psychological impact on the public from large scale forced prolonged use of face coverings does not exist.

121. It is by now well-settled that medical experiments, better known in modern parlance as clinical research, may not be performed on human subjects without the prior, free, and informed consent of the individual.

122. In short, forced human experiments are so universally recognized as unethical, illegal, and abhorrent that the right of informed consent constitutes a *jus cogens* norm under international law. The globally recognized international standards established under international law are binding upon the United States and, when violated, create a cause of action enforceable by citizens of the United States damaged thereby.

The Universal Prohibition on Human Experimentation Without Consent.

123. One of the chilling horrors that emerged from the rubble of World War II was the discovery that Nazi doctors had been conducting medical experiments, including experiments with various vaccines, on unwilling victims in concentration camps.

124. On August 8, 1945, the prevailing Allies, acting “in the interest of All the United Nations” established an International Military Tribunal (the “IMT”).

125. Under the aegis of this law, U.S. military tribunals tried “lower-level” war criminals, such as doctors accused of conducting medical experiments without their subjects’ consent.¹⁷

¹⁷ Sources for the historical facts set forth herein can be found in *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009), which explains in detail the history and reasons why the prohibition

126. In August 1947, Military Tribunal 1, staffed by American Judges and prosecutors and conducted under American procedural rules, issued final judgment against fifteen doctors who were found guilty of war crimes and crimes against humanity for conducting nonconsensual experiments, which included the testing of drugs for immunization against malaria, epidemic jaundice, smallpox, and cholera. Seven of the convicted doctors were sentenced to death and the remaining eight were sentenced to terms of imprisonment. The argument that the experimentation was for the greater good was unavailing.

127. The tribunal emphasized that “in every instance appearing in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers.”

128. The Judgment concluded that “manifestly human experiments under such conditions are contrary to the principles of the law of nations as they result from usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience.”

129. As part of its final judgment, the tribunal promulgated the Nuremberg Code on Permissible Medical Experiments. Point One of the Nuremberg Code states: “**The voluntary consent of the human subject is absolutely essential.**”

130. This universal acceptance of informed consent as the most basic and fundamental human right has since been repeatedly ratified and adopted around the globe, in laws, treaties, regulations, and ethical guidelines for medical research. For example, in 1964, the World Medical Association adopted the Declaration of Helsinki, which provides that human subjects “must be volunteers and informed participants in the research project.” Declaration of Helsinki at Art. 20.

against nonconsensual human experimentation should be regarded as a *jus cogens* norm.

131. Although themselves non-binding, the principles underlying the Declaration of Helsinki and the Nuremberg Code have been incorporated into international conventions, as well as the laws and regulations of countries around the world, including the United States of America, which are binding in United States courts.

132. The International Covenant on Civil and Political Rights of the United Nations, which went into effect in 1976, provides in Article I that “all peoples have the right of self-determination” and in Article 7 that “no one shall be subjected without his free consent to medical or scientific experimentation.”

133. The informed consent principles of the Declaration of Helsinki were also incorporated by a 2001 Directive of the European Parliament and the Council of the European Union.

134. In addition, 35 members of the Council of Europe have signed the Convention on Human Rights and Biomedicine, which provides that informed consent is required for a subject’s involvement in medical research.

135. In 2005, the General Conference of UNESCO adopted the Universal Declaration on Bioethics and Human Rights, requiring prior, free, and informed consent for participation in medical treatments and research.

136. The United States clearly regards itself as bound by the provisions of the Nuremberg Code and the Declaration of Helsinki.

137. The highest courts in the United States recognize that the right to informed consent codified in the Nuremberg Code is a fundamental right guaranteed by the U.S. Constitution.

138. These principles have been adopted by statutes and regulations in the United States as well as case law.

139. In 1979, the Department of Health, Education and Welfare issued the Belmont Report, which addressed the issue of informed consent in the human experimentation setting. The Report identified respect for self-determination by “autonomous persons” as the first of three “basic ethical principles” which “demands that subjects enter into the research voluntarily and with adequate information.”

140. Ultimately, the principles of the Belmont Report, which itself was guided by the Nuremberg Code and the Declaration of Helsinki, were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. *See* 21 C.F.R. § 50.20.¹⁸

141. The Department of Health and Human Services has similarly adopted this standard in its regulations governing grants for medical research. *See* 45 C.F.R. § 46.116.

142. The State of New York has also adopted the principle of informed consent for all medical treatment. *See* § 2805-d NY Pub Health L § 2440 (2012) of the New York Public Health Law (requiring informed consent for medical treatment). Additionally, New York recognizes a common law right to informed consent, under which, forced medical interventions are batteries.

143. For these and other reasons, the prohibition against nonconsensual human experimentation must be regarded not only as established by U.S. law and regulations, but also as so broadly recognized by all nations as to constitute a *jus cogens* norm under international law.

Plaintiff’s Injury and Standing to Seek Declaratory and Injunctive Relief

Plaintiff Has Been and Continues to Be Injured by the Mask Mandate, and His Rights Have Been Violated.

¹⁸ The exceptions to this standard are extremely narrow, and require certification by a researcher and an independent physician that, for example, “[t]he human subject is confronted with a life-threatening situation necessitating the use of the test article”; informed consent cannot be obtained from the subject; time does not permit obtaining informed consent from the subject’s legal representative; and “there is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.” 21 C.F.R. § 50.23. *See also* 21 C.F.R. § 50.24 (providing a similarly narrow exception to informed consent requirements for emergency research).

144. Plaintiff is subject to the Mask Mandate, to which he objects.

145. Plaintiff operates and is paying on an installment contract to buy the O-Neh-Da® Vineyard (the “Winery”) where he is the Vintner and manages the day-to-day operations.

146. Plaintiff does not consent to prolonged mask use each day and does not consent to take an experimental vaccine.

147. Various mask guidelines were imposed through Executive Order since April 2020. Initially, Plaintiff wore a face shield as a reasonable accommodation since he could not tolerate prolonged use of masks.

148. On February 2, 2021, the Livingston County Health Department alerted Plaintiff that face shields were no longer acceptable “face coverings” under emergency regulations issued by the Governor and the NYSDOH.

149. Plaintiff has taken extensive measures to ensure the safety of his friends, co-workers, and customers during this pandemic. He wants to help stop the spread of SARS-CoV-2. He is simply unwilling to be part of a mask experiment that no real data to support it and which has documented adverse health impacts. He cannot medically tolerate a mask nor is he willing to take an experimental vaccine.

150. It is likely that Plaintiff has natural immunity to COVID-19, as he had it in early 2020 and the limited data tends to show that natural immunity is long-lasting. However, to protect the public since he was unable to tolerate prolonged mask use and it is unknown how long natural immunity lasts, Plaintiff purchased and installed ActivePure®, which has been inducted into the Space Foundation and certified and implemented by NASA. ActivePure® has been shown in laboratory studies to be 99.9% effective in reducing the SARS-CoV-2 virus.

151. When he learned about the change in the rules regarding face shields, Plaintiff

alerted the local health department that he'd recently installed the ActivePure® system and forwarded extensive information showing the data establishing its effectiveness in preventing the transmission of pathogens, including SARS-CoV-2.

152. On February 10, 2021, a representative of the Livingston County Health Department wrote to thank Plaintiff for the information about the air filtration technology, writing "it does seem to have merit." But in the same email, he let Plaintiff know that the Department had received a complaint against Plaintiff and the Winery. The sum and substance of the complaint was that Plaintiff was not wearing a mask and that he had expressed skepticism that masks are effective at preventing the spread of SARS-CoV-2.

153. On February 17, 2021, the same representative shared that they received a second complaint from a patron who had visited the Winery on February 13, 2021.

154. On that date, Plaintiff's partner was working in the Tasting Room and had a mask on. Plaintiff was not waiting on guests. He was working in the Winery more than six feet away from any guest or co-worker. He had one of the personal protective air purifiers on the whole time, which provides three feet of sterilizing protection around him, and the room was purified as well.

155. In response to the customer's concern that he was not wearing a mask, Plaintiff informed the customer from a safe distance that he was not able to medically tolerate masks and explained the air-purifying technology that they had installed in the Winery.

156. The sum and substance of the second complaint also centered around concern about Plaintiff's expression of viewpoints about mask effectiveness and safety (or lack thereof).

157. The local health department representative asked Plaintiff to call him. During the phone call, he alerted Plaintiff that the NYSDOH had imposed a three strikes rule and that if a third complaint were to be filed against Plaintiff by any random person, Plaintiff would likely be

fined and potentially would lose his liquor license or have his business shut down. The representative said that he sympathized with Plaintiff, but that his hands were tied, and that he had to follow the orders of the NYSDOH, including the three strikes rule.

158. Though Plaintiff alerted the local representative that he could not medically tolerate a mask, no serious consideration was given to the fact that the mask mandates only require those who can medically tolerate a mask to wear one.

159. To the extent he is unsuccessful in obtaining full relief sought, Plaintiff seeks declaratory relief on that point so that individuals who assert that they cannot medically tolerate a mask are protected from invasive review or further issue from employers, the complaining public or public health officials. Such a determination should be made by the individual in consultation with trusted medical professionals.

160. After the second complaint was filed against Plaintiff in February, statewide questions arose about the legality of a mask mandate in general, and the authority of the Governor to keep it in effect. Successful lawsuits established that the Governor's enhanced emergency powers expired in early March and any new directive issued by the executive would be void.

161. Plaintiff was therefore shocked to discover the July 14, 2021, publication of the new emergency regulation that imposes the Mask Mandate on him and others and puts Plaintiff once more in imminent danger of losing his business or suffering fines or other serious consequences.

162. As both complaints against him primarily centered around Plaintiff's speech related to masks (one complaining that Plaintiff indicated that masks don't work, and another complaining that masks can have health consequences), the Livingston County Health Department advised plaintiff that he should limit what he says and "lay low" to avoid business closure or other penalties

that will likely ensue if a third complaint is issued.

163. Plaintiff is not willing to waive his fundamental rights or “lay low.” He will not submit to waiving his rights to informed consent, he will not violate his employee’s or customer’s rights to medical privacy, and he will not keep silent about the problems in the science underlying the experimental mask and vaccine mandates to avoid meritless complaints that have the power to end his career and livelihood.

164. Plaintiff seeks declaratory and injunctive relief so that he can continue to exercise his rights without further threat of harassment from Commission Zucker or his agents.

165. All conditions precedent to bringing this lawsuit have been performed, excused, or waived.

COUNT I

DECLARATORY JUDGMENT ACTION BASED UPON FEDERAL PREEMPTION / VIOLATION OF THE SUPREMACY CLAUSE

166. Plaintiff hereby incorporates all other paragraphs of this Complaint as if fully set forth herein and further alleges:

167. Federal laws and regulations governing the approval and administration of medical products such as vaccines or masks completely preempt any and all contrary or inconsistent laws of the States and/or local governments.

168. The Mask Mandate is patently contrary to United States law, and thus preempted and invalid.

169. Title 21 United States Code, Section 360bbb-3(e)(1)(A)(ii), and regulations and internal protocols of the United States Food and Drug Administration promulgated thereunder, provide in relevant part that all individuals to whom an investigational product is to be

administered under an Emergency Use Authorization be informed “of the option to accept or refuse administration of the product. . . .”

170. Because the masks and vaccines at issue in this mandate are each investigational products, only permitted for use under an Emergency Use Authorization, the laws and regulations of the United States prohibit state and local governments from requiring them for any person who does not consent to their administration, including Plaintiff.

171. Plaintiff does not consent to being required to wear masks or to being vaccinated with an experimental vaccine. Under the Mask Mandate, he is forced to do one or the other. Neither can be forced.

172. As well, Title 21, Part 50 of the Code of Federal Regulations governs the protection of human subjects in the conduct of all clinical investigations regulated by the U.S. Food and Drug Administration.

173. 21 C.F.R. § 50.20 provides that, “[e]xcept as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.”

174. Under the EUA, the masks and the vaccines remain in the clinical investigation stage.

175. None of the exemptions provided in sections 50.23 and 50.24 apply to Plaintiff. He is competent to make a decision concerning medical treatment and experimentation.

176. Accordingly, the Mask Mandate also violates federal law and regulations governing the administration of experimental medicine and is thus preempted.

177. Plaintiff has no adequate remedy at law available against Defendant for the injuries and the irreparable harm he will imminently suffer as a direct result of the Mandate.

WHEREFORE, Plaintiff respectfully requests that the Court enter a declaratory judgment that Defendant's Mask Mandate violates and is preempted by the laws and regulations of the United States governing the administration of investigational medical products, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

COUNT II

VIOLATION OF SUBSTANTIVE DUE PROCESS

42 U.S.C. § 1983

178. Plaintiff hereby incorporates all other paragraphs of this Complaint as if fully set forth herein and further alleges:

179. Plaintiff has a protected liberty interest, secured by the Due Process Clause of the United States Constitution, international protocols and treaties adopted by and entered into by the United States, and by the laws and regulations of the United States, to be free from burdens on his constitutionally protected liberty rights.

180. The Mask Mandate violates several fundamental rights, including but not limited to the right to be free from forced medical experimentation.

181. This right is both a fundamental right pursuant to United States Supreme Court jurisprudence but is also recognized as a *jus cogens* norm under the laws of nations.

182. As set forth more fully above, the forced administration of either experimental vaccines or masks is, under the circumstances, experimental medicine.

183. As well, or in the alternative, Plaintiff has a protected liberty interest, secured by the Due Process Clause of the United States Constitution, to refuse non-consensual administration of any objectionable medical product, and/or to be free from the forced administration of medical procedures and devices that Plaintiff reasonably believes may cause him harm.

184. As well, or in the alternative, Plaintiff has a fundamental right, secured by the Due Process Clause of the Fourteenth Amendment of the United States Constitution:

- a. to breathe fresh air;
- b. to self-determination in matters of medical care and the administration of medical products and devices;
- c. to medical privacy; and
- d. Pursuant to the First and Fourteenth Amendment, to freely express his viewpoints on masks without being threatened with fines, business closure or adverse state action.

185. The Mask Mandate promulgated by Defendant, both on its face and as applied, is not sufficiently narrowly tailored, or lacks a rational basis, as the science establishes that vaccinated people are just as infectious as unvaccinated people. There is no rational reason to impose different burdens on them.

186. Defendant's Mandate is also not sufficiently narrowly tailored, or lacks a rational basis, as the FDA itself has stated that Defendants may not represent masks as being effective against viral spread, numerous studies have confirmed that masks are not effective against viral spread, and Plaintiff will show at trial that masks are damaging in a variety of way to those who are forced to wear them consistent with the requirements of the Mask Mandate.

187. Plaintiff has no adequate remedy at law available against Defendants for the injuries and the irreparable harm they will imminently suffer as a direct result of the Mandate.

WHEREFORE, Plaintiff respectfully requests that the Court enter a declaratory judgment that Defendants' Mask Mandate violates Plaintiff's substantive Due Process rights, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

COUNT III

**VIOLATION OF THE EQUAL PROTECTION CLAUSE OF THE FOURTEENTH
AMENDMENT TO THE U.S. CONSTITUTION**

42 U.S.C. § 1983

188. Plaintiff hereby incorporates all other paragraphs of this Complaint as if fully set forth herein and further alleges:

189. By his actions, as described herein, Defendant, acting under color of statute, ordinance, regulation, custom, or usage, subjected Plaintiff to the deprivation of the rights, privileges, or immunities secured by the Constitution and law.

190. The Mask Mandate violates the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution (and corresponding provision of the New York State Constitution) because it forces unvaccinated people to use an experimental product and face burdens to their medical privacy and ability to breathe, but it allows similarly situated people in the same businesses and locations to be exempt from the mandates because they have submitted to an experimental vaccine which is unable to provide them with sterilizing immunity.

191. There is no rational basis for such a distinction. Plaintiff poses no more danger to others than a person who is participating in the trials for the experimental vaccines. The CDC acknowledges that vaccinated individuals are just as infectious as unvaccinated for SARS-CoV-2. The policy of discriminating based on an individual's willingness or ability to subject themselves to medical experimentation shocks the conscience and cannot be justified as relating to any rational

permissible goal. It is not grounded in science, but rather in the effort to coerce people into waiving their right to freely opt out of medical experimentation.

192. Not only are the vaccines unable to stop transmission, but there is also no evidence to establish that the experimental use of cloth masks can stop transmission either.

193. Petitioner now faces the prospect of a loss of his business and the violation of his civil rights and liberties as a result of the discriminatory regulation.

194. The acts or omissions of Defendant were conducted within the scope of his official duties and employment under color of law.

195. While performing those duties, Defendant intentionally deprived Plaintiff of securities, rights, privileges, liberties, and immunities secured by the Constitution of the United States of America.

WHEREFORE, Plaintiff respectfully requests that the Court enter a declaratory judgment that Defendant's Mask Mandate violates Plaintiff's Equal Protection rights, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

COUNT IV

DECLARING THE MASK MANDATE UNCONSTITUTIONAL UNDER THE UNITED STATES CONSTITUTION AND CORRESPONDING SEPARATION OF POWERS CLAUSE OF THE NEW YORK CONSTITUTION

196. Plaintiff hereby incorporates all other paragraphs of this Complaint as if fully set forth herein and further alleges:

197. NYSDOH regulations have the force of law commensurate with a statute.

198. The United States Constitution establishes three separate but equal branches of government: the legislative branch makes the laws, the executive branch enforces the laws, and

the judicial branch interprets the laws. The Framers structured the government in this way to prevent one branch of government from becoming too powerful and to create a system of checks and balances.

199. The Constitution of the State of New York similarly requires that statutes be passed by each separate house of the New York legislature before they can have the force of law.

200. Specifically, Article III, Section 13 of the Constitution of the State of New York provides that “The enacting clause of all bills shall be ‘The People of the State of New York, represented in Senate and Assembly, do enact as follows,’ and no law shall be enacted except by bill.”

201. The Mask Mandate, issued by emergency regulation through executive branch department action and published after the state disaster emergency was declared over, unbalances this constitutional framework by allowing the executive branch to issue directives with the force of law without proper delegation from the legislature.

202. Plaintiff has a clear legal right to operate the Winery under the preexisting laws of the state in the absence of a constitutionally valid directive curtailing, limiting, or prohibiting the operation of the Winery.

203. Plaintiff also has a clear legal right to breathe freely and opt out of participating in medical experimentation, to medical privacy, to refuse medical interventions that he reasonably believes may cause him harm, and to bodily autonomy.

204. Plaintiff is suffering per se irreparable injury and is threatened with irreparable injury in the future by reason of being told that if he gets any more complaints about not wearing an experimentally licensed mask or criticizing the effectiveness of the experimental masks or

vaccines that he will likely be forced to cease lawful operations at the Winery and face other personal and professional state-imposed penalties.

205. Plaintiff has no plain, adequate nor complete remedy to protect the constitutional and/or legal rights and redress the wrongs and illegal acts complained of herein, other than to seek immediate and continuing injunctive relief.

206. Absent an injunction, the harm to Plaintiff and his legal and constitutional rights exceeds any harm that the Defendant would suffer if prohibited from continuing to implement and enforce a directive that violates the separation of powers set forth in the New York and United States Constitution.

207. The NYSDOH has not been delegated specific authority to issue laws *sua sponte* mandating the use of experimental face coverings or experimental vaccines and violate the Supremacy Clause of the United States Constitution as well as the New York State Constitution.

WHEREFORE, Plaintiff respectfully requests that the Court enter a declaratory judgment that Defendant's Mask Mandate is unconstitutional and beyond the scope of permissibly delegated powers of the NYSDOH, for an injunction prohibiting enforcement of the Mask Mandate, for attorneys' fees, costs pursuant to 42 U.S.C. § 1988, and such further relief as the Court deems just.

JURY TRIAL DEMAND

Plaintiff hereby demands a trial by jury for all matters so triable.

DATED this 5th day of August 2021.

Gibson Law Firm, PLLC

/s/ Sujata S. Gibson

Sujata S. Gibson,
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JS 44 (Rev. 08/18)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

William Ouweleen

(b) County of Residence of First Listed Plaintiff Livingston
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
The Gibson Law Firm, PLLC
407 N Cayuga St, Suite 201
Ithaca, NY 14850

DEFENDANTS

Howard Zucker, in his official capacity

County of Residence of First Listed Defendant Albany
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
- 3 Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|---------------------------------------|---------------------------------------|---|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input checked="" type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Tort Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	LABOR	FEDERAL TAX SUITS
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input checked="" type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
			IMMIGRATION	
			<input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from Another District (specify)
- 6 Multidistrict Litigation - Transfer
- 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
42 U.S.C. § 1983

Brief description of cause:
Declaratory and injunctive judgment for violation of civil rights

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ _____ CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE: 08/05/2021 SIGNATURE OF ATTORNEY OF RECORD: 

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____ .

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: