Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

DR. STEPHEN T. SKOLY, Jr.,	
Plaintiff,	**Civil Case No. _____**
v.	
	DECLARATION OF
DANIEL J. MCKEE, in his official Capacity as the Governor of the State Of Rhode Island; and DR. NICOLE ALEXANDER-SCOTT, in her official capacity as the Director of the Rhode Island Department of Health,	**ROSEMARIE XIFARAS**
Defendants.	

I, Rosemarie Xifaras, hereby declare under penalties of perjury under the laws of the United States of America that the following is true and correct:

1. I was the Practice Manager for "Associates in Oral and Maxillofacial Surgery", the now closed dental and surgical practice of Dr. Stephen T. Skoly, Jr. Prior to closure, I managed a staff of eleven, including five surgical assistants. We held morning meetings to go over our schedule for the day, typically consisting of 40 patients, not including emergencies. I oversaw our computer system and all equipment, and accounts receivables and payables. I have held my current or similar positions for 24 years, during which period I have administered multiple locations with multiple doctors for Associates in Oral and Maxillofacial Surgery.

2. By a Compliance Order issued on October 1, 2021, the Rhode Island Department of Health directed Dr. Skoly to cease his dental and surgical practice. I submit this declaration in support of Dr. Skoly's motion for a Court order to restrain Rhode Island from enforcing the

Compliance Order. The forced closing of Dr. Skoly's practice has caused financial and physical harm to hundreds of Rhode Island residents, specifically his now untreated patients and the Practice's unemployed workers.

3. Prior to the March 2020 advent of Covid, Dr. Skoly and his staff serviced hundreds of Rhode Island residents at his practice's Cranston, Rhode Island office. The office contained five surgical suites, allowing Dr. Skoly and the staff to provide care for 40 patients per day excluding emergencies. The staff consisted of 11 employees - five surgical assistants, three receptionists, a bookkeeper, Dr. Skoly and me.

4. Our 800 monthly patients were representative of Rhode Island's vibrant and diverse community. We serviced the young and the old, those with private insurance and those without. The procedures Dr. Skoly provided ranged from simple dental extractions to highly skilled and complex surgical procedures.

5. Dr. Skoly never charged elderly patients in need. He was (and is) known in the community as a doctor who provided *pro bono* care.

6. In addition to Dr. Skoly's private practice, Rhode Island retained Dr. Skoly to provide surgical services to those institutionalized by the State.

7. Beginning around 1990, and continuing until October 1, 2021, Dr. Skoly was the dental surgeon – and, for the past decade, the only dental surgeon - for the Eleanor Slater Hospital, the State's psychiatric rehabilitative hospital operated by BHDDH (the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities & Hospitals).

8. Eleanor Slater is an institutional facility for patients with acute and long-term medical illnesses, as well as patients with mental health conditions. It has two campuses: In Cranston (Regan Unit) and Burriville (Zambarano Unit).

9. Eleanor Slater also has a unit whose residents are psychiatric inmates confined under the authority of the Rhode Island Department of Corrections. Dr. Skoly provided surgical dental care to the residents of that unit as well.

10. In addition to Eleanor Slater, the Adult Correctional Institute ("ACI"), the State's penitentiary complex in Cranston, retained Dr. Skoly. He was their only dental surgeon. Dr. Skoly visited ACI once a week, performing ten to 20 procedures.

11. Dr. Skoly visited Eleanor Slater (Regan) and ACI to treat patients for simple procedures. Complex surgeries, and all procedures regarding Eleanor Slater and Zambarano residents, required inmates of the psychiatric hospital or ACI to be transported to the more sophisticated operating theatre at Dr. Skoly's Cranston medical facility. He saw an ACI patient in his Cranston office just about every day.

12. The institutionalized patients could not travel to the Cranston office by themselves. Rather, they needed to be accompanied, and, in the case of prisoners, by armed guards.

13. Dr. Skoly designed his Cranston medical facility to include a large elevator so that it could accommodate the type of gurney transported in an ambulance.

14. In treating the residents of Eleanor Slater and ACI, Dr. Skoly worked with, and came into prolonged and close physical contact with, the institutions' health care workers and other employees.

15. Whether at the institutions, or at Dr. Skoly's Cranston facility, the employees would accompany the patients to and from Dr. Skoly's presence, and stay with the patients as guards.

16. When Covid hit in March 2020, we – Dr. Skoly and the staff – soldiered on.

17. As health care workers in a surgical facility, Dr. Skoly and his staff had been adhering to strict masking and other safety precautions since 1988, when Dr. Skoly began his surgical practice).

18. Post-Covid, we continued to adhere to our strict safety precautions, and added further measures advised by the profession. We held daily morning meetings to discuss and educate ourselves on current guidelines and recommendations. We have followed scrupulously the RIDOH Provider Advisory and the CDC Health Advisory. and the guidelines promulgated by our national associations, including the American Dental Association and the American Association of Oral and Maxillofacial Surgeons.

19. While much of society was sheltering in place, Dr. Skoly and we, his staff, continued to serve the public, in person – the only way that our necessary medical services can be provided.

20. Our service was not without cost. Dr. Skoly – who had never ceased his medical visits to the prison and asylums – contracted Covid in December 2020. After the required quarantine period, he returned to work.

21. I am proud to say that the practice's safety guidelines and precautions have been a success. After Dr. Skoly return to work in December 2020, we continued to serve our 800 plus patients a month. None of our staff or, to my knowledge, or any of our patients, tested positive for Covid-19 as a consequence of their work or treatment at Dr. Skoly's medical facility.

22. From December 2020 onward, we continued to provide necessary medical services to our 800 plus patients a month, including those confined in prison and the asylums.

23. That service ended abruptly when Rhode Island shut down Dr. Skoly's practice on October 1, 2021.That shutdown has caused considerable harm to our staff and the public.

24. Dr. Skoly was forced to lay off his 10 employees. Dr. Skoly had tried to keep them on payroll but could not. The employees were earning, in aggregate, $7,500 a week. That sum represents lost business to people in Rhode Island, and a personal hardship to each of the ten unemployed and their families. Some employees have families with children. Several have loans to pay and mortgages. Others are taking care of elderly family members.

25. And the closure has hurt the public. This quarter (October, November, December 2021), we have "rescheduled" over 2,100 patients. I put "rescheduled" in quotes since I do not know when, if ever these patients will see Dr. Skoly, or any doctor. There is a shortage of Oral and Maxillofacial Surgeons in Rhode Island. Patients tell me that they have been unable to schedule necessary medical treatment with any doctor, or in any time less than weeks or months in the future.

26. In addition, Eleanor Slater and the ACI have lacked a dental surgeon for over three months. Dr. Skoly was the institutions' only dental surgeon. Rhode Island has been unable to replace him.

27. At Eleanor Slater and ACI, there is a current backlog of 20 patients desperately needing surgeries that Dr. Skoly, but for the Compliance Order, is ready and eager to perform.

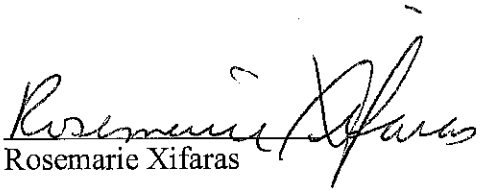
28. Dr. Skoly has four former employees available to return to resume work should the Compliance Order be stayed.

29. I believe we could be up and practicing – seeing private patients (and making Eleanor Slater and prison visits) - within 48 hours of the Court staying the Compliance Order.

30. We would prioritize the surgeries and treat the most critical first.

Dated: Cranston, Rhode Island
January 20, 2022

Respectfully submitted,



Rosemarie Xifaras

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

DR. STEPHEN T. SKOLY, Jr.,	)	
	)	
Plaintiff,	)	**Civil Case No. _____**
	)	
v.	)	
	)	**DECLARATION OF**
DANIEL J. MCKEE, in his official Capacity as the Governor of the State Of Rhode Island; and DR. NICOLE ALEXANDER-SCOTT, in her official capacity as the Director of the Rhode Island Department of Health,	)	**MATT MCLAREN**
	)	
Defendants.	)	

I, Matt McLaren, hereby declare under penalties of perjury under the laws of the United States of America that the following is true and correct:

1. I am the DDS (Donated Dental Services) Coordinator for the Dental Lifeline Network of Rhode Island ("DLN").

2. The DDS is a program of DLN, a organization that provides free, comprehensive dental treatment to vulnerable people with disabilities or who are elderly or medically fragile. These are people who cannot afford necessary treatment and cannot get public aid.

3. I am associated with Dr. Skoly through his role as a DDS volunteer. Dr. Skoly is an experienced dental surgeon who has donated surgical services to the DLN since 1991.

4. Between 1991 and 2021, Dr. Skoly has volunteered treatment to 31 impoverished and vulnerable Rhode Island patients introduced to him by the DLN.

5. In November 2021, I wrote Dr. Skoly to ask if he would treat an impoverished, seriously ill woman who needed four extractions.

6. Dr. Skoly replied that he would be willing to treat the woman but was prevented from doing so by the Compliance Order directing him to cease his medical practice.

7. The woman who needed services in November 2021 has yet to receive treatment.

8. Were Dr. Skoly's practice permitted to resume, I have been told that Dr. Skoly would be willing to resume volunteer services, for the woman referred in November if services were still needed, or for some other indigent in need.

Dated: Cranston, Rhode Island
January 7, 2022

Respectfully submitted,

Matt McLaren

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

DR. STEPHEN T. SKOLY, Jr.,	
Plaintiff,	**Civil Case No. _____**
v.	**DECLARATION OF**
DANIEL J. MCKEE, in his official Capacity as the Governor of the State Of Rhode Island; and DR. NICOLE ALEXANDER-SCOTT, in her official capacity as the Director of the Rhode Island Department of Health,	**DR. IBRAHIM SHIHADEH**
Defendants.	

I, Ibrahim Shihadeh, DMD, hereby declare under penalties of perjury under the laws of the United States of America that the following is true and correct:

1. I am a dentist licensed to practice dentistry in the State of Rhode Island. I submit this Declaration in support of Dr. Skoly's motion to vacate the Compliance Order barring him from practicing medicine.

2. In addition to a private practice, I serve as the dentist at the Eleanor Slater Hospital, the State's psychiatric hospital operated by BHDDH (the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities & Hospitals). Eleanor Slater has two campuses, one in Cranston (the Regan Unit), and a second in Burriville (the Zambarano Unit). The hospital treats patients with acute and long-term medical illnesses, as well as patients with mental health conditions. The patients include inmates of the Rhode Island Department of Corrections. I have been the dentist at Eleanor Slater since 2013.

3. Since I have been at Eleanor Slater, Dr. Skoly has provided surgical dental care – surgeries and extractions – to Eleanor Slater patients at both campuses (Regan and Zambarano). From 2013 to the present, Dr. Skoly has been the only oral surgeon retained by Rhode Island to service Eleanor Slater's patients.

4. Dr. Skoly performed his surgeries at medical facilities on the Eleanor Slater campuses, or in his Cranston medical facility. One of my jobs as dentist was to identify which patient needed care, and to arrange that the patient be transported to the appropriate location for surgery.

5. Eleanor Slater patients, of course, could not transport themselves to Dr. Skoly, whether on one of the campuses or at Dr. Skoly's Cranston medical facility. Eleanor Slater patients being treated by Dr. Skoly were accompanied to the treatment location by two workers - health care workers in the case of civilians, and, for inmates, guards.

6. Dr. Skoly's suspension has resulted in many Eleanor Slater patients being unable to receive necessary dental surgeries since October 1, 2021.

7. When Dr. Skoly was suspended in October 2021, I had scheduled Dr. Skoly for fourteen surgeries from Eleanor Slater. Those appointments were cancelled. There is a shortage of dental surgeons in Rhode Island. I was, and continue to be, unable to find a dental surgeon to replace Dr. Skoly.

8. Every week since October 1, 2021, an additional one or two Eleanor Slater patients from Cranston has needed dental surgery. To address the issue, I have been performing the less complex extractions that, prior to October 1st, I would have asked Dr. Skoly to perform.

9. Nonetheless, there is a continuing, and increasing, backlog of necessary surgeries that only a doctor of Dr. Skoly's skill could perform.

10. I understand that, were Dr. Skoly permitted to resume practice, he could re-open his medical facility and begin seeing patients in 48 hours.

11. The Eleanor Slater Hospital has a backlog of approximately twenty patients in need of immediate surgeries.

Dated: Cranston, Rhode Island
January 18, 2022

Respectfully submitted,

Ibrahim Shihadeh, DMD

Exhibit D

216-RICR-20-15-8

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 20 – INFORMATION FOR HEALTH CARE PROFESSIONALS

SUBCHAPTER 15 - INFORMATION FOR HEALTH CARE PROFESSIONALS

PART 8 – REQUIREMENT FOR IMMUNIZATION AGAINST COVID-19 FOR ALL WORKERS IN LICENSED HEALTH CARE FACILITIES AND OTHER PRACTICING HEALTH CARE PROVIDERS

8.1 Authority

A. These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws §§ 23-1-1 and 23-1-17 and are established for the purpose of requiring health care workers and health care providers to be vaccinated against COVID-19.

8.2 Definitions

A. Wherever used in this Part, the terms listed below shall be construed in the following manner:

1. "COVID-19" means the new disease caused by novel coronavirus SARS-CoV-2.

2. "COVID-19 vaccine" means any vaccine against COVID-19 that is authorized by the U.S. Food and Drug Administration or World Health Organization.

3. "Department" or "RIDOH" means the Rhode Island Department of Health.

4. "Health care facility" means a facility as defined in R.I. Gen. Laws § 23-17-2(8), as well as assisted living residences, as defined in R.I. Gen. Laws § 23-17.4.-2(4), and adult daycare programs, as defined in R.I. Gen. Laws § 23-1-52, and clinical laboratories, as defined in R.I. Gen. Laws § 23-16.2-2(2) notwithstanding the provisions of R.I. Gen. Laws § 23-17-2(8).

5. "Health care worker" means any person who is temporarily or permanently employed by or at, or who serves as a volunteer in, or has an employment contract with, a health care facility, and has or may have direct contact with a patient in that health care facility. This may include, but not be limited to, a physician, physician assistant, nurse, nursing assistant, therapist, technician, clinician, behavioral analyst, social worker,

3. By October 1, 2021, all health care workers and health care providers must be vaccinated, subject to a medical exemption set forth in Section 8.3(D) of this Part.

B. Proof of vaccination must be entered into the Rhode Island Child and Adult Immunization Registry. Health care workers and health care providers who are vaccinated in Rhode Island will have this done automatically by the vaccination administrator. Health care workers and health care providers who are vaccinated outside of Rhode Island must complete the form available at https://health.ri.gov/forms/records/COVID-Immunization-Record-Correction-Request.pdf as proof of vaccination and email the completed form to RIDOH.RICAIR@health.ri.gov.

C. As of October 1, 2021, health care facilities shall deny entrance to any health care workers who are not vaccinated, subject to a medical exemption set forth in § 8.3(D) of this Part.

D. No health care worker or health care provider shall be required to receive the COVID-19 vaccine if a medical exemption applies, but such individuals must continue to comply with the provisions of §§ 8.3(A)(1) and (2) of this Part.

1. A health care worker or health care provider shall be medically exempt from being required to be vaccinated provided that a licensed physician, physician assistant or advanced practice registered nurse signs a medical exemption stating that the health care worker or health care provider is exempt from the COVID-19 vaccine because of medical reasons, in accordance with Advisory Committee on Immunization Practices (ACIP) guidelines and determined as acceptable by the facility.

8.4 Violations

A. Health care facilities and health care providers that violate any provisions of this Part are subject to administrative action by the Department, and any other action provided for under applicable law and regulations, including R.I. Gen. Laws § 23-1-25, in addition to any action against the professional and/or facility license, as applicable. Health care facilities shall have seven (7) days from the promulgation of this Part to implement measures necessary to ensure compliance with health care worker testing requirements.

B. Each health care facility shall provide at no financial charge an adequate supply of procedure masks or higher-grade mask (e.g., KN95 or N95) to any health care worker and shall ensure the facility's compliance with § 8.3(A) of this Part, subject to a medical exemption set forth in § 8.3(D) of this Part.

216-RICR-20-15-8

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 20 - COMMUNITY HEALTH

SUBCHAPTER 15 - INFORMATION FOR HEALTH CARE PROFESSIONALS

PART 8 - REQUIREMENT FOR IMMUNIZATION AGAINST COVID-19 FOR ALL WORKERS IN LICENSED HEALTH CARE FACILITIES AND OTHER PRACTICING HEALTH CARE PROVIDERS

Type of Filing: Adoption

Agency Signature

E-SIGNED by Jacqueline Kelley on 2021-08-17 15:38:40 EDT — August 17, 2021

Agency Head Signature — Agency Signing Date

Governor's Signature

Claire Richards

Signed By

E-SIGNED by Office of the Governor on 2021-08-17 16:00:21 EDT — August 17, 2021

Governor or Designee — Governor Signing Date

Department of State

08/17/2021

Regulation Effective Date

Z.G. — August 17, 2021

Department of State Initials — Department of State Date

Exhibit E

Medical Immunization Exemption Certificate

For Use in Health Care Facilities

Section 1: Health Care Facility and Worker Information				
NAME OF HEALTH CARE FACILITY:	STREET ADDRESS:	CITY:	ZIP CODE:	PHONE:
HEALTH CARE WORKER NAME:		DATE OF BIRTH:		
STREET ADDRESS:	CITY:	ZIP CODE:	PHONE:	

Section 2: For Health Care Provider Use Only: Please provide name, address, vaccine contraindication(s), signature and date.				
NAME OF HEALTH CARE PROVIDER	STREET ADDRESS:	CITY:	ZIP CODE:	PHONE:

I certify that due to the contraindication(s) checked below the above-named individual is exempt from receiving the required vaccine(s):

☐ COVID-19 Vaccine

Vaccine	Contraindication(s) to vaccination
COVID-19 vaccine (any vaccine against COVID-19 that is authorized by the U.S. Food and Drug Administration or World Health Organization, and Novavax)	☐ Severe allergic reaction (e.g., anaphylaxis) after previous dose or to a component of the vaccine ☐ Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine ☐ History of myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine** ☐ History of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination*** ☐ Monoclonal Antibody Treatment (MABS) within the 90 days prior to October 1, 2021 (healthcare worker should get vaccinated no later than 91 to 120 days after MABS) *Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration. ** See "Considerations for vaccination of people with certain underlying medical conditions" in *CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States* for more information https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#underlying-conditions ***People with a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive COVID-19 vaccination after the episode of myocarditis or pericarditis has resolved. See "Considerations for vaccination of people with certain underlying medical conditions" in *CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States* for more information https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#underlying-conditions

Health Care Provider Signature _____ Date _____

Do not send a copy of this form to the Rhode Island Department of Health ("RIDOH").

Exhibit F

Vaccination Requirement FAQ

1. **How is the State of Rhode Island implementing a vaccination requirement for health care workers and RIDOH-licensed health care facilities?**
   The authority for RIDOH to issue this emergency regulation is in Rhode Island General Laws § 23-1-1 and 23-1-17. Under this regulation, individuals who work in RIDOH licensed health care facilities and licensed health care providers must be vaccinated. Unlicensed individuals at private, non-facility employers are strongly encouraged but not required to be vaccinated.

2. **Who is included in the regulation?**
   All individuals who work in RIDOH-licensed health care facilities *and* all licensed health care providers, whether they work in a licensed facility or not, are covered by the regulation. "Health care worker" means any person who is temporarily or permanently employed by or at, or who serves as a volunteer in, or has an employment contract with, a RIDOH-licensed health care facility, and has or may have direct contact with a patient in that health care facility. “Health care provider” means any person licensed by RIDOH to provide or otherwise lawfully providing health care services. For a more comprehensive list of persons who may fall into these categories, please refer to the regulation here.

3. **What are the facilities covered by this regulation?**
   “Health care facility” means a facility as defined in R.I. Gen. Laws § 23-17-2(8), as well as assisted living residences, as defined in R.I. Gen. Laws § 23-17.4.-2(4), adult daycare programs, as defined in R.I. Gen. Laws § 23-1-52, and clinical laboratories, as defined in R.I. Gen. Laws § 23-16.2-2(2) notwithstanding the provisions of R.I. Gen. Laws § 23-17-2(8).

4. **Are there any exemptions?**
   The sole exemption in the regulation is a medical exemption. The person must be evaluated for an applicable medical exemption by a licensed physician, physician assistant, or advanced practice registered nurse who will complete the form available at: Resources for Healthcare Professionals | RI COVID-19 Information Portal.

5. **Can medical providers list an alternative medical exemption on the designated form, where the option for “other underlying medical conditions” does not exist?**
   A medical exemption form with reasons other than those listed is not considered valid under the regulation.

6. **Are positive COVID-19 antibody tests considered evidence of immunity which would not require vaccination?**
   No.

7. **Is there a specific test that employees must use to meet twice weekly testing requirements pursuant to the regulations?**
   Any COVID-19 tests authorized by the Food and Drug Administration (FDA), e.g., PCR and BinaxNOW rapid test, may be used to meet the requirements.

8. **To be in compliance do unvaccinated staff need to have two results per week or two tests per week to continue working the following week?**
   Unvaccinated health care workers are required to get two tests per week, not two results, as we understand that the timing of results may vary.

9. **Are health care facilities required under this emergency regulation to terminate the employment of health care workers who refuse to be vaccinated against COVID-19?**
   Health care facilities are not required to terminate employment if an employee refuses to be vaccinated.

10. **Are we required to discharge employees who refuse to be vaccinated?**
    No, but unvaccinated health care workers at RIDOH-licensed facilities are not allowed in the facilities beginning October 1.

11. **Will exemptions be made for health care workers who have a documented appointment for either or both vaccination rounds (shot #1 or shot #2, when applicable) after October 1?**
    The regulation provides that all health care workers and health care providers must be vaccinated by October 1. There should be plenty of time to achieve this goal. "Vaccinated" means a person has received all recommended dose(s) of a COVID-19 vaccine authorized by the U.S. Food and Drug Administration (FDA) or the World Health Organization, or all recommended dose(s) of another COVID-19 vaccine approved by RIDOH (e.g., Novavax).

12. **I have a few employees that have not been vaccinated but are unable to due to recent COVID-19 infection. How does this affect their status?**
    Anyone who tests positive for COVID-19 must wait until completion of the applicable isolation period and no longer have symptoms before receiving a COVID-19 vaccine. Any unvaccinated non-medically exempt health care workers must be denied entry to health care facilities unless deemed critical pursuant to a corrective action plan, in which case the health care worker is permitted to enter the facility until October 31. After October 31, the health care worker cannot enter the facility until vaccinated.

13. **Are office workers within the health care sector, such as those who do not provide direct care services but work as scheduling coordinators or billing clerks for a home care provider, included within the mandates under the emergency regulation?**
    Any individual who works at a RIDOH-licensed health care facility, including those not directly involved in patient care but potentially exposed, in the course of employment, to infectious agents that can be transmitted from person to person, and any individual who is a licensed health care provider, must follow this regulation.

14. **Are homemakers, personal care attendants (PCAs) and individual providers (IPs) within the Medicaid Program included in this vaccination requirement**?
    If they are licensed health care providers in the state of Rhode Island or enter a licensed health care facility for the purposes of work, they must be vaccinated by October 1. The regulation does not apply to a patient's family member or friend who visits or otherwise assists in the care of that patient in a health care facility.

15. **I am a health care provider licensed by RIDOH, but I work out-of-state. Am I covered under the mandate and, if so, what do I need to do to maintain my license?**

You are subject to the regulation if you are a licensed health care provider providing direct patient care or you are exposed to infectious agents in your work in Rhode Island.

16. **Are essential caregivers required to be vaccinated?**
    Unless an essential caregiver fits within the definition of a health care worker or health care provider, no, an essential caregiver is not required to be vaccinated. The definition of health care worker expressly excludes a member of the patient's family or friend who visits or otherwise assists in the care of that patient in a health care facility.

17. **How does regulation apply to those practicing under a temporary/emergency license?**
    These individuals are licensed. If they are providing healthcare services under a license, they are covered.

18. **Where can I get tested?**
    The employee can be tested anywhere testing is available. All Rhode Islanders can schedule a free COVID-19 test for themselves or their dependent child online at portal.ri.gov or by calling 401-222-8022. This list has more information about each State-run test site. General testing information is available at: https://covid.ri.gov/testing.

19. **Is it the responsibility for the employer to test the employee?**
    No. Employers in RIDOH-licensed healthcare facilities are responsible for tracking testing compliance of their employees.

20. **What requirements will the employer have for tracking testing of its unvaccinated employees?**
    It will be up to the employer in a RIDOH-licensed healthcare facility to track testing of all unvaccinated staff and have data available for survey or if asked.

21. **What options are available if a healthcare employer is interested in building their own testing infrastructure**?
    The State can support with laboratory connections and training of specimen collection for employers that do not have the skill set or pre-existing laboratory relationship. If they do, our recommendation would be to utilize existing lab relationships that employers already have and add PCR testing to their current agreements. Companies have various over the counter, point-of-care test options if they choose to conduct asymptomatic screening with antigen-based tests.

22. **If someone is beginning employment in a position that would fall under this regulation, is COVID-19 vaccination required to start work?**
    Yes.

23. **Can facilities obtain COVID-19 vaccine to administer to their own healthcare workers?**
    Yes. You can either fill out our Vaccine Community Partner Interest Form (available at https://covid.ri.gov/public), which will help us work with you to set up a vaccination event, or you can enroll as a COVID-19 vaccine provider. To enroll as a vaccine provider, please follow the steps outlined at https://covid.ri.gov/vaxproviders.

24. **Do employers that do not meet the definition of health care facility have any liability if unvaccinated health care providers continue to work? Do they face any repercussions for having an unvaccinated health care provider provide services in Rhode Island?**
    Any employer that is not licensed by RIDOH does not have any obligation under this regulation to take action with regard to an unvaccinated health care provider. However, a RIDOH-licensed health care provider who is not vaccinated could face action against their license.

25. **Can RIDOH report on the vaccination status of employees?**
    No.

26. **I would like to report a healthcare worker that has a fake COVID-19 vaccination card. What do I do?**
    If the person is licensed by RIDOH, please submit your complaint through our complaint process: https://health.ri.gov/complaints/

Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

DR. STEPHEN T. SKOLY, Jr.,	)	
	)	
Plaintiff,	)	**Civil Case No. _____**
	)	
v.	)	
	)	**DECLARATION OF**
DANIEL J. MCKEE, in his official Capacity as the Governor of the State Of Rhode Island; and DR. NICOLE ALEXANDER-SCOTT, in her official capacity as the Director of the Rhode Island Department of Health,	)	**DR. SAM PAPPAS**
	)	
Defendants.	)	

I, Sam Pappas, MD, hereby declare under penalties of perjury under the laws of the United States of America that the following is true and correct:

1. I am a doctor licensed to practice medicine in the State of Virginia. My specialty is Internal Medicine. I have practiced medicine for 27 years, having graduated from the Pennsylvania State University College of Medicine medical school in 1995. I am affiliated with Virginia Hospital Center.

2. I submit this Declaration in support of Dr. Skoly's motion to vacate the Rhode Island Compliance Order barring him from practicing medicine.

3. I have reviewed Dr. Skoly's medical records.

4. Dr. Skoly has a medical history of Bell's Palsy.

5. In 2006, Dr. Skoly had an occurrence of Bell's Palsy which appeared to be related to his having had Lyme disease. The Bell's Palsy consisted of a facial paralysis around Dr. Skoly's left eye. The Bell's Palsy resolved in one week.

6. Bell's Palsy is a potentially very debilitating and challenging problem.

7. Bell's palsy is also known as a facial palsy and is a form of facial paralysis or weakness on one side of the face. This results from dysfunction of the facial nerve which directs the muscles on one side of the face, including those that control eye blinking and closing and facial expressions such as smiling. Moreover, the facial nerve also carries nerve impulses to other vital areas such as the tear glands, saliva glands, and transmits taste sensations from the tongue.

8. Bell's palsy is the most common cause of facial paralysis. Symptoms generally appear suddenly over a 48 to 72 hour period and may start to improve after a few weeks.

9. However, according to the NIH recovery of some facial or facial function may take up to six months and in some cases residual muscle weakness lasts longer or may be permanent.

https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Bells-Palsy-Fact-Sheet

10. Most scientists believe that reactivation of an existing (dormant) viral infection may cause the disorder.

11. Bell's palsy is often linked to upper respiratory infections, viral infections such as those caused by infectious mononucleosis, herpes, mumps, and HIV viruses to name a few.

12. It is thus not surprising that researchers are starting to see Bell's Palsy in the setting of COVID-19 infection https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7531061/ As these authors state, "In conclusion, peripheral facial palsy should be added to the spectrum of neurological manifestations associated with COVID-19."

13. Scientists have reported Bell's Palsy associated with influenza vaccination. https://pubmed.ncbi.nlm.nih.gov/17084492/ Post-licensure experience with a intranasal inactivated influenza vaccine in Switzerland identified an increased risk for Bell's palsy and prompted a detailed review of the Vaccine Adverse Event Reporting System (VAERS) in the U.S. from 1991 to 2001 of parenteral influenza vaccines to see if there was an increase risk for Bell's Palsy https://pubmed.ncbi.nlm.nih.gov/15317028/ . These researchers found 197 cases of such a link and recommended further studies to better quantify the increased risk they observed.

14. In December 2020, the FDA reported assessing cases of Bell's Palsy and COVID-19 vaccines and researchers concluded, "Considering the temporal association and biological plausibility, FDA recommends surveillance for cases of Bell's Palsy with deployment of the Moderna COVID-19 Vaccine into larger populations."

15. The association between vaccine administration and onset of Bell's Palsy symptoms have been previously documented with the inactivated Influenza Vaccine (Zhou et al., 2004; Mutsch et al., 2004). " https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7874945/

16. I have also personally seen some cases of Bell's Palsy in my practice from COVID-19 vaccines.

17. Since the above reports further assessments have been done by scientists reviewing EU and WHO pharmacoviglance databases of adverse events of Facial or Bell's Palsy and COVID-19 vaccines. The links are below and have observed the following:

- 7892 reports of facial paralysis from the WHO database.
- Therefore, the observed incidence of Bell's palsy in the vaccine arms is between 3·5-times and 7-times higher than would be expected in the general population.
- The risk of developing facial paralysis could be two to three times higher in individuals receiving mRNA vaccines than in those receiving traditional vaccines.
- The available data remain consistent with a more than three-fold increase in risk for Bell's palsy within 1 month of a second vaccine dose.
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8550921/
- https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00076-1/fulltext
- https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00273-5/fulltext

12. Dr. Skoly's fear is that, in light of his history of Bell's Palsy, and his age, the COVID-19 vaccination creates the risk of a re-occurrence of his facial paralysis and the danger of a delayed resolution, in effect, a possible paralysis of unknown duration.

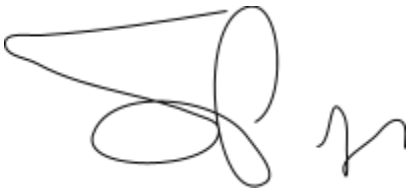
13. Dr. Skoly's fear is well-grounded in the existing science.

14. In view of Dr. Skoly's known history of Bell's Palsy, his confirmed natural immunity from prior COVID-19 infection and known protection it provides, the potential debilitating effect a recurrent Bell's Palsy incidence can produce, and the recently observed increased incidences of Bell's Palsy related to COVID-19 vaccines, it is my medical opinion that

Dr. Skoly should not get a COVID-19 vaccine. The potential significant harm to him outweighs any benefit the vaccination would incur to him or any patient he treats, particularly if he adheres to the strict masking protocols of dental surgery.

Dated: Vienna, Virginia
January 20th , 2022

Respectfully submitted,



Sam Pappas, MD

Exhibit H

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

DR. STEPHEN T. SKOLY, Jr.,	)	
	)	
Plaintiff,	)	**Civil Case No. _____**
	)	
v.	)	
	)	**DECLARATION OF**
DANIEL J. MCKEE, in his official Capacity as the Governor of the State Of Rhode Island; and DR. NICOLE ALEXANDER-SCOTT, in her official capacity as the Director of the Rhode Island Department of Health,	)	**DR. STEPHEN T. SKOLY. JR.**
	)	
Defendants.	)	

I, Stephen T. Skoly, Jr., DMD, hereby declare under penalties of perjury under the laws of the United States of America that the following is true and correct:

1. I am an oral and maxillofacial surgeon licensed by the State of Rhode Island. Prior to October 1, 2021, I conducted a dental and surgical practice, "Associates in Oral and Maxillofacial Surgery," in Cranston, Rhode Island. The history of my private practice and work for the State of Rhode Island is described in the Declaration of my office manager Rosemarie Xifaras, Exhibit A to the Complaint.

2. I submit this Declaration in support of my motion to vacate the Rhode Island Compliance Order barring me from practicing medicine.

3. In December 2020, I contracted COVID-19.

4. On September 10, 2021, I was tested for IgG COVID-19 antibodies. The test result (attached hereto) shows a positive level of IgG COVID-19 antibodies.

5. In 2006, I had an occurrence of Bell's Palsy that was believed to be a consequence of my having had Lyme disease. The Bell's Palsy consisted of a facial paralysis around my left eye. The paralysis resolved in one week.

6. Subsequently, I suffered a facial paralysis around my right eye. It resolved but the muscles around my left eye show a mild residual droopiness.

7. I am aware of medical literature showing an association between receiving a COVID-19 vaccine and the onset of Bell's Palsy. The literature does not indicate whether the onset of paralysis is more likely to occur were one a prior Bell's Palsy victim. Nor does the literature address whether, where there has been prior paralysis, a vaccine-induced re-occurrence is of similar or greater duration than the prior paralysis.

8. I am not an anti-vaxxer or opposed to vaccines. However, due to the uncertainties regarding the risk of onset, or duration, of a palsy re-occurrence in a prior paralysis sufferer such as myself, I chose to not be vaccinated.

9. If the Compliance Order is stayed, I believe I can re-assemble a token staff and resume critical patient treatments – both for private patients and those confined at Eleanor Slater and the ACI - within 48 hours.

10. My staff and I will fully comply with our standard safety precautions (including N95 masking) and any testing regimen RIDOH deems appropriate.

Dated: Cranston, Rhode Island
January 20, 2022

Respectfully submitted,

Stephen T. Skoly, Jr., DMD

Patient Name	Sex	Age	D.O.B.	Patient #	Admit Date	Print Date
SKOLY,STEPHEN	**M**	**65**	**(07/12/1956)**	**P12533105**	09/10/21	09/13/21
Phone: (401)944-0397						

Time Since Patient's Last Meal: NON-FASTING
Date/Time Specimen Collected: 09/10/2021 1:23PM

Chemistry

	Test	Results	Abnormal Results	Normals
HI	SARS-COV-2-S ABS INTERPRETATION	POSITIVE		NEGATIVE
HI	SARS-COV-2-S ABS,SEMI-QUANT	13.21		<0.80 U/ML

THE ROCHE ELECSYS ANTI-SARS-COV-2-S IMMUNOASSAY IS INTENDED FOR QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF ANTIBODIES TO SARS-COV-2 SPIKE (S) PROTEIN RECEPTOR BINDING DOMAIN (RBD) IN HUMAN SERUM AND PLASMA. THE ELECSYS ANTI-SARS-COV-2-S ASSAY IS INTENDED AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY. THE ELECSYS ANTI-SARS-COV-2-S ASSAY SHOULD NOT BE USED TO DIAGNOSE ACUTE SARS-COV-2 INFECTION.

A POSITIVE RESULT MAY NOT INDICATE PREVIOUS SARS-COV-2 INFECTION. CONSIDER OTHER INFORMATION INCLUDING CLINICAL HISTORY AND LOCAL DISEASE PREVALENCE, IN ASSESSING THE NEED FOR A SECOND BUT DIFFERENT SEROLOGY TEST TO CONFIRM IMMUNE RESPONSE.

A NEGATIVE RESULT INDICATES THE ABSENCE OF DETECTABLE ANTI-SARS-COV-2-S ANTIBODIES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. A NEGATIVE RESULT CAN OCCUR IF THE QUANTITY OF THE ANTI-SARS-COV-2 ANTIBODIES THAT ARE DETECTED AND ARE NOT PRESENT IN THE SPECIMEN IS BELOW THE DETECTION LIMITS OF THE ASSAY, OR THE ANTIBODIES THAT ARE DETECTED ARE NOT PRESENT DURING THE STATE OF DISEASE IN WHICH A SAMPLE IS COLLECTED. IT IS NOT KNOWN AT THIS TIME IF THE PRESENCE OF ANTIBODIES TO SARS-COV-2 CONFERS IMMUNITY TO RE-INFECTION.

THE ELECSYS ANTI-SARS-COV-2 ASSAY IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION (EUA) UNDER SECTION 564(D)(1) OF THE ACT, 21 U.S.C SECTION 360BBB-3(B)(1), UNLESS AUTHORIZATION IS TERMINATED OR REVOKED SOONER. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C 263A, TO PERFORM MODERATE AND HIGH COMPLEXITY TESTS.

BRIAN PICKETT, MD
905 PONTIAC AVENUE
CRANSTON, RI 02920

East Side Clinical Laboratory
Dedicated service since 1949
Walther M. Pfeifer, MD, FCAP, Laboratory Director
10 Risho Avenue, East Providence, RI 02914
(401) 455-8400
CLIA Number 41D0083868

Patient Name	Sex	Age	D.O.B.	Patient #	Admit Date	Print Date
SKOLY,STEPHEN	**M**	**65**	**(07/12/1956)**	**P12533105**	09/10/21	09/13/21

Phone: (401)944-0397

Test	Results	Abnormal Results	Normals

FACT SHEET FOR HEALTHCARE PROVIDERS:
HTTPS://WWW.FDA.GOV/MEDIA/144035/DOWNLOAD
FACT SHEET FOR PATIENTS:
HTTPS://WWW.FDA.GOV/MEDIA/144036/DOWNLOAD

*** Released By: CMAB ***

09/13/2021 02:55PM Final Report

BRIAN PICKETT, MD
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CLIA Number 41D0083868

Exhibit I

STATE OF RHODE ISLAND
DEPARTMENT OF HEALTH

IN THE MATTER OF:
Stephen T. Skoly, Jr., DMD DEN02320; DAGD02320
30 Chapel Hill Blvd #2402
Cranston, RI 02920

NOTICE OF VIOLATION AND COMPLIANCE ORDER

This Notice of Violation and Compliance Order is issued pursuant to R.I. Gen. Laws § 23-1-20, R.I. Gen. Laws § 23-21-1 *et seq*, 216-RICR-20-15-8, and 216-RICR-40-05-2.15.1 (A)(24).

FINDINGS OF FACT

1. Stephen P. Skoly, DMD (hereafter, "Respondent") is licensed by the Rhode Island Department of Health ("RIDOH") to practice dentistry, in an office located at 30 Chapel Hill Blvd #2402 in Cranston, RI 02920, under licenses DEN02320 and DAGD02320 .

2. On or about August 17, 2021, RIDOH enacted Regulation 216-RICR-20-15-8 titled "REQUIREMENT FOR IMMUNIZATION AGAINST COVID-19 FOR ALL WORKERS IN LICENSED HEALTH CARE FACILITIES AND OTHER PRACTICING HEALTH CARE PROVIDERS" (hereafter, "Covid-19 Regulation").

3. Respondent is a "health care provider" as defined by the Covid-19 Regulation, 216-RICR-20-15-8.2(A)(6).

4. Section 8.3 (A)(3) of the Covid-19 Regulation requires that all healthcare providers be vaccinated October 1, 2021, Respondent is required to be vaccinated against Covid-19 as a condition of licensure if he is either directly involved in patient care or potentially exposed to infectious agents that can be transmitted from person to person.

5. On October 1, 2021, the Providence Journal reported that Respondent stated that (a) he was not vaccinated, (b) did not meet the medical exemption incorporated in the regulation, and that he intended to directly engage in patient care or activity in which he or others would potentially be exposed to infectious agents that can be transmitted from person to person.

6. On October 1, 2021, Respondent made various public statements, including statements published in video recordings, indicating that he had engaged in the activity set forth in the previous paragraph.

7. The facts set forth above constitute reasonable grounds to believe that Respondent is in violation of 216-RICR-20-15-8 and subject to disciplinary action pursuant to 216-RICR-40-05-2.15.1 (A) (24).

ORDER

Respondent is ordered to cease professional conduct as a health care provider, as described above, unless and until he has complied with the terms and conditions of 216-RICR-20-15-8.

In accordance with R.I. Gen. Laws §§ 23-1-20 and 23-1-22, a written request for a hearing may be filed with the Director at the address below within 10 days after service of this notice. If a written request for a hearing is not made to the Director within 10 days after service of this notice, this notice shall become a compliance order by operation of law.

Failure to comply with the provisions of a compliance order may result in additional sanctions and penalties authorized by law.

A copy of this notice has been sent to the Respondent electronically via the contact provided in connection with his license.

Ordered this 1st day of October, 2021.

Nicole Alexander-Scott, M.D., M.P.H.
Director
Rhode Island Department of Health
Three Capitol Hill, Room 401
Providence RI 02908

Exhibit J

MEMORANDUM OR TENTATIVE AGREEMENT

This Memorandum of Tentative Agreement (hereinafter, "Agreement") is entered into this 12th day of NOV, 2021, by and between the State of Rhode Island (hereinafter, "State") and Rhode Island Council 94, AFSCME, AFL-CIO (hereinafter, "Union").

WHEREAS, the State and the Union have engaged in collective bargaining negotiations for a collective bargaining agreements commencing July 1, 2020 – June 30, 2021 and July 1,2021 – June 30, 2024; and

WHEREAS, the State and the Union have reached a tentative agreement which shall be subject to ratification by the Union; and

WHEREAS, as a result of the tentative agreement reached between the State and the Union, the Master Agreement between the State and the Union shall be amended to provide the benefits and provisions as hereinafter set forth. All numbering is based on the proposed new numbering of the Master Agreement.

NOW, THEREFORE, for good and valuable consideration, the exchange of which is hereby acknowledged by the State and the Union, it is hereby agreed as follows:

1. The Purpose section will read as follows:

It is the purpose of this Agreement to carry out the policy of the State ~~of Rhode Island~~ providing procedures which will facilitate free and frequent communication and ~~by~~ encourag~~eing~~ a more harmonious and cooperative relationship between the State and its employees ~~by providing for procedures which will facilitate free and frequent communication between the State and its employees~~. Therefore, b~~B~~y means of this Agreement, ~~therefore,~~ the signatories hereto bind themselves to maintain and improve the present high standards of service to the people of the State ~~of Rhode Island,~~ and agree

~~further~~ that high morale and good personnel relations through a stabilized Union relationship are essential to carry out this task ~~end~~. No negotiated Settlement Agreements or Memorandums of Agreements entered into after the ratification of this agreement will have precedential effect, amend this agreement, or provide for wage rate adjustments unless they are signed by the Director of Administration or his/her designee and the State Vice President of the Union or his/her designee.

2. Article 1, Recognition, will read as follows (certifications to be verified with the RI State Labor Relations Board:

1.1 The State hereby recognizes the Union for the purposes of this Master Agreement as the sole and exclusive bargaining agent for all State employees with regard to wages, hours, and working conditions for whom Rhode Island Council 94, AFSCME, AFL-CIO are currently certified to represent by the decision or upon certification of the State Labor Relations Board. and those State employees who are in bargaining units that are recognized by mutual agreement of the parties~~or upon certification by the State Labor Relations Board~~.

Upon such recognition, such new units shall automatically be covered by the terms of this Master Agreement and negotiations for mini-contracts shall begin immediately upon such recognition in accordance with Article 48 of this Agreement. Upon termination of the ~~Council 94~~ Union certification for any bargaining unit, the provisions of this Master Agreement ~~Contract~~ shall be automatically terminated. The terms of this Master Agreement ~~Contract~~ are non-transferable and non-assignable. The following is a list of the certificate numbers currently represented by the Union~~Council 94~~:

~~EE-1690~~	EE-1714	EE-1715	EE-1766	EE-1767	EE-1789
EE-1794	EE-1804	EE-1805	EE-1825	EE-1847	EE-1848
EE-1896	EE-1899	EE-1926	EE-1993	EE-2057	EE-2069
EE-2089	EE-2098	EE-3095	EE-3113	EE-3114	EE-3133
EE-3144	EE-3146	EE-3149	EE-3152	EE-3157	EE-3163
EE-3221	EE-3260	EE-3324	EE-3328	EE-3332	EE-3333
EE-3337	EE-3338	EE-3342	EE-3373	EE-3402	EE-3403
EE-3406	EE-3417	EE-3418A	EE-3446	EE-3504	EE-3454

3. Articles 3.2, 3.4, 3.6, 3.10 will not have any changes, however, Articles 3.1, 3.3, 3.5, 3.7, 3.8 and 3.9 will read as follows:

3.1 Upon written authorization of any state employee who is a member of the Union, the State Controller shall deduct from the employee's salary his or her Union dues on a bi-weekly basis and shall remit to the treasurer of the Union the amount deducted. The State shall submit said dues together with a list by department of the members who have had payments deducted. The State Controller shall make dues deductions, on an on-going basis, from each such employee.

3.3 Any non-member employee who is in a position within the bargaining unit may choose to voluntarily pay fees to the Union. The fee for voluntary non-members within a bargaining unit shall be established in an amount determined by the Union. The State Controller shall deduct from the voluntary non-member employee's salary such fees on a bi-weekly basis and shall remit to the treasurer of the Union the amount deducted.

The State shall submit said fees together with a list by department of the non-members who have had payments deducted.

3.5 The State Controller shall deduct back dues and/or fees arising from any arbitration award in the case of a suspension or discharge, which has been overturned by an arbitrator, and shall remit the amount to the Union.

3.7 The State shall give written notice ~~to the designated representative of the Union~~ of all new employees within the respective bargaining units who become eligible for membership in the Union to the Executive Director of the Union and the President of the Local. Said notice shall be given promptly after the hiring decision is made, but in no event later than the fifth business day following the employee's start date. Said notice ~~and~~ shall include the employee's name, address, employee I.D. number, date of hire, classification, and department. Local presidents or their designee shall be afforded the right to meet with all new members.

3.8. Effective upon ratification of this Agreement, the State shall provide the Union's designated representative, on a quarterly basis, the following information on every employee within the respective bargaining units: name, address, employee I.D. number, date of hire, classification and department.

3.9 Any member or any voluntary fee-paying non-member of the Union who wishes to change his or her membership status shall contact the designated representative of the Union. If a member or a voluntary non-member contacts the State to end his or her membership or non-member fee paying agreement, the State shall inform the employee to contact the designated representative of the Union. The State shall also promptly notify

the Union of the employee's request and the Union shall also promptly notify the State of any change in the employee's status.

4. Article 4.1 will read as follows:

4.1 The Union recognizes that except as specifically limited, abridged or relinquished by the terms and provisions of this agreement, all rights to manage, direct or supervise the operations of the State and the employees are vested solely in the State.

For example, but not limited thereto, the State ~~employer~~ shall have the exclusive rights subject to the provisions of this agreement and consistent with the applicable laws and regulations:

A. To direct employees in the performance of the duties of their positions;

B. To hire, promote, transfer, assign, and retain employees in positions within the bargaining units and to suspend, demote, discharge, or take other disciplinary action against such employees;

C. To maintain the efficiency of the operations entrusted to it;

D. To determine the methods, means and personnel by which such operations are to be conducted;

E. To relieve employees from duties because of lack of work or for other legitimate reasons;

F. To take whatever actions may be necessary to carry out its mission in emergency situations, i.e. an unforeseen circumstance or a combination of circumstances which calls for immediate action in a situation which is not expected to be of a recurring nature.

5. Article 5.2 will read as follows: (numbering of articles may change depending on the final agreement):

5.2 It is recognized that there are now other work schedules peculiar to certain classes of positions, which are recognized by the State and the Union, and such exceptions shall remain in full force and effect. In the event it becomes necessary to change the scheduled work hours in any area, the State shall notify the Union's Executive Director, and the parties hereto shall make every effort to agree mutually on the hours for such schedules and fix the hours, subject to the grievance procedure and arbitration provisions of this Agreement. In the event that a new schedule for hours of work is agreed upon, that schedule shall be posted and bid upon in accordance with the seniority provisions of this Agreement. If the hours are not agreed to, then the issue shall be submitted to expedited arbitration as set forth in Article 28.7 and 28.8 of this Agreement.

6. Article 13.11: The language will remain the same as in the current Master Agreement.

7. Article 44.10: The language will remain the same as in the current Master Agreement. The State plans to have the rollout of the performance development to union supervisors beginning January 2022 and non-supervisors in January 2023.

8. Article 3.6: The Union withdraws its proposal and the language will remain the same as in the current Master Agreement.

9. Article 8.7: The parties agree to remove the following language: (*Letter of Understanding Sick Leave Bill). The remainder of the Article's language will remain the same as in the current Master Agreement.

10. Article 9.3 will read as follows:

~~9.3~~ Whenever an employee in a standard work week (35 hours, 37 ½ hours or 40 hours weekly) or non-standard employee is required to work on a holiday which falls on their regularly scheduled work day, they shall be credited with the number of hours in their official work schedule for that day, plus the number of hours actually worked. The h~~H~~ours actually worked shall be compensated at the rate of one and one-half times. This provision as it applies to non- standard employees shall be effective upon ratification of the contract.

The parties agree that for the purpose of overtime pay under Section 9.3 of this Article, Christmas Day, New Year's Day, Fourth of July, and Veteran's Day holidays shall be observed on Saturday or Sunday in those years when such holidays fall on Saturday or Sunday rather than on Monday as provided for by R.I.G.L. 25-1-1 et seq. The parties further agree, that when such holidays fall on Saturday or Sunday employees who would have otherwise received overtime holiday pay for working on Monday, if the holiday were being celebrated on that day, shall not receive such pay but shall receive their regular rate of pay for that day.

This provision shall not apply to employees whose regularly scheduled work week is Monday through Friday.

11. Article 11.5(g): The first 2 sentences will read as follows and the remainder will stay the same as of this date:

All non-competitive positions to which the parties agree, shall be filled by the top state seniority bidder from within the bargaining unit. A list of current non-competitive positions are attached. Exhibit ___. If no bids are made from within the bargaining unit,

then it shall be filled by the top state seniority employee, who is a member of a bargaining unit represented by Council 94, who has submitted a bid.

12. Article 11.5(h) will read as follows:

If no bids are submitted from any member of a bargaining unit represented by Council 94 covered by this Master Agreement, then the State has the right to fill from outside the bargaining units covered by this Master Agreement.

13. The parties agree that the Personal Business Leave section will move from Article 40 to Article 13. All language will remain the same in the Master Agreement.

14. The parties agree that the Sick Leave section will be moved to Article 14.

Article 14.1 shall be amended to state: Article 14.1: Sick leave with pay shall be granted to employees covered by this agreement. Sick leave with pay is hereby defined to mean a necessary absence from duty due to illness, injury or exposure to contagious disease. ~~and shall include absence due to illness or death in the immediate family of the employee (per death) or necessary attendance upon a member of the immediate family who is ill, subject to the provisions of Section 5.0623 of the Personnel Rules in effect at this time~~. Such sick leave shall also include absence due to illness or death in the immediate family of the employee (per death), or with appropriate medical documentation necessary attendance upon a member of the immediate family who is ill. Such sick leave for an immediate family member shall be up to a maximum of 20 days of accrued sick leave per year. The definition of "Immediate Family" for the purposed of sick leave and bereavement leave, shall include domestic partners of the same or opposite sex who have lied in the same household for at least six (6) months and have made a commitment to continue to live as a family.

15. Article 14.5 (f): The language will read as follows: To protect employee privacy rights, all documents containing confidential medical information are maintained as confidential medical records and are kept in separate, secure medical files in the Division of Human Resources Disabilities Management Unit~~Disabilities Management Unit office~~. Access to these records is restricted as provided by law.

16. The parties agree that the Bereavement Leave section will move from Article 13 to Article 15. The parties agree to add step-mother, step-father, step-brother, and step-sister to section 15.1 (a). The parties also agree to add niece, nephew and cousin to Article 15.1(c).

17. The parties agree there will be a one year contract from July 1, 2020 – June 30, 2021. The Employees shall receive a 2.5% salary increase retroactive to June 21, 2020, which is the payroll date immediately prior to July 1, 2020.

18. The parties agree there will be a three year contract from July 1, 2021 – June 30, 2024. The Employees shall receive a 2.5% salary increase retroactive to June 20, 2021, which is the payroll date immediately prior to July 1, 2021; a 2.5% salary increase on June 19, 2022, which is the payroll date immediately prior to July 1, 2022; and a 2.5% increase on June 18, 2023, which is the payroll date immediately prior to July 1, 2023.

19. ~~The~~ To provide employees an incentive to be fully vaccinated with the COVID-19 vaccine and a retention bonus to remain employed with the State, all employees~~,~~ actively employed by the State who are fully vaccinated with the COVID-19 vaccine upon ratification of the Master Agreement, or who have been granted a medical or religious exemption by the State, shall receive a payment of $1500.00 ~~cash payment,~~ presented in a separate check. Employees actively employed by the State on July 1, 2022, who are fully vaccinated, including any required booster to be considered fully vaccinated, or who have been granted a medical or religious

exemption by the State ~~on July 1, 2022~~ shall receive an additional $1500 (or a first time payment if they were not fully vaccinated upon ratification)-~~cash payment~~, presented in a separate check. ~~Any employee who has an approved medical exemption by the State shall also receive the COVID-19 cash payment.~~

20. The parties agree to continue the provision in the health care Article, which states, "the Co-Share contribution level for full time and part time employees shall be increased based on the employee's annualized total rate of pay." The parties agree to replace the older salary numbers with the new numbers, for each agreement. Respectively, "The co-share contribution salary levels for eligible employees shall be increased by 2.5% on June 21, 2020;~~,~~ by 2.5% on June 20, 2021;-by 2.5% on June 19, 2022 and 2.5% on June 18, 2023. ~~–The co-share contribution salary levels shall be as follows:~~

Effective June 21, 2020:

For full-time employees:

Individual Plan		**Family Plan**	
Less than $105,411	20%	Less than $54,835	15%
		$54,835 less than $105,411	20%
$105,411 and above	25%	$105,411 and above	25%

For part-time employees:

Individual or Family Plan

Less than $99,360	20%
$99,360 and above	35%

Effective June 20, 2021:

For full-time employees:

Individual Plan		**Family Plan**	
Less than $108, 046	20%	Less than $56,206	15%
		$56,026 to less than $108,046	20%
$108,046 and above	25%	$108, 046 and above	25%

For part-time employees:

Individual or Family Plan

Less than $101,844	20%
$101,844 and above	35%

Effective June 19, 2022:

For full-time employees:

Individual Plan		Family Plan	
Less than $110, 747	20%	Less than $57,611	15%
		$57,611 to less than $110,747	20%
$110,747 and above	25%	$110, 747 and above	25%

For part-time employees:

Individual or Family Plan	
Less than $104, 390	20%
$104, 390 and above	35%

Effective June 18, 2023:

For full-time employees:

Individual Plan		Family Plan	
Less than $113, 516	20%	Less than $59,051	15%
		$59, 051 to less than $113, 516	20%
$113, 516 and above	25%	$113,516 and above	25%

For part-time employees:

Individual or Family Plan

Less than $107,000	20%
$107, 000 and above	35%

20. The parties agree that Article 5.7 shall state: ~~5.7 Deletion of the prior language in Article 10 shall not negate the practice of granting time off for annual employee outings.~~ Each local bargaining unit shall be granted **two** ~~four~~ hours of time off for annual employee outings. Any employee who is denied time under this provision shall be granted **two** ~~four~~ hours of time off at another time during the fiscal year.

IN WITNESS WHEREOF, the parties hereto have set their hands this 12th day of NOV 2021.

FOR THE STATE OF RHODE ISLAND

Jim Thorsen
Director
Department of Administration

FOR RHODE ISLAND COUNCIL 94 AFSMCE, AFL-CIO

J. Michael Downey
President
RI Council 94, AFSCME, AFL-CIO

Lynn Loveday
State Vice President
RI Council 94, AFSCME, AFL-CIO

Alexis Santoro
Executive Director
RI Council 94, AFSCME, AFL-CIO

Individual or Family Plan

Less than $107,000	20%
$107, 000 and above	35%

20 The parties agree that Article 5.7 shall state: ~~5.7 Deletion of the prior language in Article 10 shall not negate the practice of granting time off for annual employee outings.~~ Each local bargaining unit shall be granted **two** ~~four~~ hours of time off for annual employee outings. Any employee who is denied time under this provision shall be granted **two** ~~four~~ hours of time off at another time during the fiscal year.

IN WITNESS WHEREOF, the parties hereto have set their hands this 12th day of May 2021.

FOR THE STATE OF RHODE ISLAND

Jim Thorsen
Director
Department of Administration

FOR RHODE ISLAND COUNCIL 94 AFSMCE, AFL-CIO

J. Michael Downey
President
RI Council 94, AFSCME, AFL-CIO

Lynn Loveday
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RI Council 94, AFSCME, AFL-CIO

Alexis Santoro
Executive Director
RI Council 94, AFSCME, AFL-CIO

Exhibit K

COVID-19 Quarantine and Isolation Guidance by Population

Updated January 7, 2022

General Public	
Includes but is not limited to: • Customer/client-facing businesses, assisted living personnel, group home personnel, non-profit organizations, and office-based businesses • Institutes of higher education	Excludes: • Hospital and nursing home personnel • Congregate living residents (nursing homes, assisted livings, group homes, corrections, shelters) • Immunocompromised people • PreK-12 and childcare
Isolation and post-infection precautions (for those who have or think they have COVID-19 regardless of vaccination status) Isolation starts on the first day of symptoms (day 0) or the day of a positive test if there are no symptoms (day 0)	
• 10 days of increased precautions • Stay home and isolate for at least 5 days even if you do not have any symptoms • You may leave isolation after 5 days if: o you have no symptoms, or your symptoms have improved and; o you are fever-free for 24 hours without the use of fever-reducing medication and; o you did not have severe illness • Wear a well-fitting mask around others for 5 additional days even at home	
If you can leave isolation after 5 days, take extra precautions for an additional 5 days (day 6-10)	•Avoid places where you are unable to always wear a mask, such as **restaurants** •Avoid travel until 10 days after the day of your positive test •Avoid people who are **immunocompromised** or at high risk for severe disease, and **nursing homes** and other **high-risk settings**, until after at least 10 days
If you are not able to wear a mask or had moderate or severe illness	• Isolate for 10 days

<table>
<tr><th colspan="2">Quarantine and additional precautions - Up to date with vaccination
(For those who have come in close contact[1] with someone who tested positive for COVID-19)</th></tr>
<tr><td>You do not need to quarantine if you are up to date with your vaccination:
You are age 18 or older and have received all recommended vaccine doses, including boosters
OR
You are age 5 to 17 and have completed the primary series of a COVID-19 vaccine
OR
You had confirmed COVID-19 within the last 90 days (you tested positive using an antigen or PCR test).</td><td>Take these additional precautions:
Wear well-fitting mask around others for 10 days
If you are unable to wear a mask:
Avoid people who are immunocompromised or at higher risk for severe disease, and nursing homes and other high-risk settings.
Avoid travel for 10 days
Test on day 5, if possible
If symptoms develop, stay home and get tested</td></tr>
<tr><th colspan="2">Quarantine and additional precautions- Not up to date with vaccination
(For those who have come in close contact[2] with someone who tested positive for COVID-19)</th></tr>
<tr><td>You are not up to date with vaccination if:
You are age 18 or older and completed the primary series of recommended vaccine but have not received a recommended booster shot when eligible
OR
You received the single-dose Johnson & Johnson vaccine (completing the primary series) over 2 months ago and have not received a recommended booster shot
OR
You are not vaccinated or have not completed a primary vaccine series</td><td>Must quarantine for at least 5 days:
Continue to wear a well-fitting mask for 5 additional days after quarantine
Test on day 5 or after if possible
If symptoms develop, stay home and get tested
Days 0-10:
Avoid people who are immunocompromised or at high risk for severe disease, and nursing homes and other high-risk settings
If possible, stay away from people you live with, especially people who are at higher risk for getting very sick from COVID-19
Avoid travel for 10 days
Watch for fever (100.4◦F or greater), cough, shortness of breath, or other COVID-19 symptoms
Wear a well-fitting mask when around others at home and in public</td></tr>
<tr><td>If you are not able to wear a mask</td><td>Quarantine for 10 days</td></tr>
</table>

[1] Close contact means being within six feet of someone for a cumulative total of 15 minutes or more over a 24-hour period
[2] Close contact means being within six feet of someone for a cumulative total of 15 minutes or more over a 24-hour period

Healthcare Personnel at Hospitals and Skilled Nursing Homes

See CDC guidance document for definition of Healthcare Personnel: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Facilities may implement more restrictive quarantine and isolation policies

Work Restrictions for HCP with COVID-19 Infection

See full guidance here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Vaccination Status	Conventional	Contingency[3]	Crisis[4]
Boosted, Completed Primary Vaccine Series Only, or Unvaccinated[5]	Isolate for 10 days OR 7 days with a negative test if asymptomatic or mildly symptomatic (with improving symptoms)	Isolate for 5 days with or without negative test if asymptomatic or mildly symptomatic (with improving symptoms) and continue to wear a well-fitting mask for an additional 5 days	No restrictions with prioritization considerations (e.g., asymptomatic or mildly symptomatic)

Work Restrictions for Asymptomatic HCP with Exposures

See full guidance here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Vaccination Status	Conventional	Contingency	Crisis
Boosted	No work restrictions with negative test on day 2 and a negative test during the 5 to 7-day period	No work restrictions	No work restrictions
Completed Primary Vaccine Series Only or Unvaccinated, even if within 90 days of prior infection	Quarantine for 10 days OR 7 days with a negative test	No work restrictions with negative test on days 1, 2, 3, and a negative test during the 5 to 7-day period	No work restrictions (test if possible)

Please note: Upon changing staffing category (e.g., from "contingency" to "crisis"), healthcare facilities must notify the Rhode Island Department of Health (RIDOH) by reporting to the Center for Health Facility Regulations. Additionally, hospitals and skilled nursing facilities that shift from contingency to crisis staffing must post their staffing status and an explanation on their websites or other public-facing areas.

[3] Contingency staffing means staffing shortages are anticipated at healthcare facilities. Such facilities, in collaboration with human resources and occupational health services, should use contingency capacity strategies to plan and prepare for mitigating this problem.

[4] Crisis staffing means there are no longer enough staff to provide safe patient/resident care.

[5] All healthcare workers are required to be vaccinated against COVID-19 effective October 1, 2021, unless a medical exemption applies.

Nursing Home and Assisted Living Facility Residents	
Quarantine for 14 days	• If feasible, quarantine from last day of contact/exposure to a case in a separate room. Resident must quarantine even if COVID-19 vaccination is up to date,* after hospital discharge, or if being newly admitted to the facility • Quarantine is not necessary if resident COVID-19 vaccination is up to date* and has not had close contact exposure or travel in the past 14 days
Isolation Duration **-AND-** **End Isolation Requirements**	**Isolation starts on the first day of symptoms (day 0) or the day of a positive test if there are no symptoms (day 0)** **Not immunocompromised**** Isolate for **at least 10 days** until: • At least 10 days have passed since symptoms first appeared **AND** • At least 24 hours have passed since last fever without fever-reducing medications **AND** • Symptoms have improved **Immunocompromised** ^^** Isolate for **at least 20 days** until: • At least 20 days have passed since symptoms first appeared **AND** • At least 24 hours have passed since last fever without fever-reducing medications **AND** • Symptoms have improved
Surveillance and Outbreak Testing	• Surveillance testing and testing during an outbreak as recommended by RIDOH • After testing positive, testing again in the next 90 days is **not recommended**

* COVID-19 vaccination not up to date:

- You are ages 18 or older and completed the primary series of recommended vaccine but have not received a recommended booster shot when eligible
- You received the single-dose Johnson & Johnson vaccine (completing the primary series) over 2 months ago and have not received a recommended booster shot
- You are not vaccinated or have not completed a primary vaccine series

^ COVID-19 vaccination up to date:

- You are age 18 or older and have received all recommended vaccine doses, including boosters or;
- You are age 5 to 17 and completed the primary series of COVID-19 vaccines or;
- You had confirmed COVID-19 within the last 90 days (you tested positive using a viral test)

**The CDC defines immunocompromised as:

- Currently receiving chemotherapy for cancer
- Being within one year out from receiving a hematopoietic stem cell or solid organ transplant
- Untreated HIV infection with CD4 T lymphocyte count lower than 200
- Primary immunodeficiency (PI)
- Taking immunosuppressive medications (e.g., drugs to suppress rejection of transplanted organs or to treat rheumatologic conditions such as mycophenolate and rituximab
- Taking more than 20 mg a day of prednisone, for more than 14 days
- Other condition(s) as determined by the treating healthcare provider

^^ Consult with your healthcare provider about when you can resume being around other people

Other Congregate Care Facility Residents

(Residents of homeless shelters, group homes, correctional facilities, detention centers, and training school)

Quarantine Duration COVID-19 **(Vaccination not up to date*)**	• **5 days** from last day of contact/exposure to the case • **Always watch for symptoms for a full 14 days after exposure** • If feasible, quarantine in a separate room • Facilities may elect to quarantine newly admitted residents and residents returning after hospital or emergency department visit discharge. Fully vaccinated* residents do not need to quarantine if no close contact exposure or travel in the past 14 days. **In homeless shelters and facilities where adherence to quarantine is challenging:** • Resident must wear cloth face covering or mask at all times, as tolerated • Implement best possible physical distancing • Conduct diligent symptom monitoring
Quarantine Duration COVID-19 **(Vaccination up to date^)**	Quarantine not required but recommend additional precautions below • Wear well-fitting mask around others for 10 days • Should test on day 5, if possible • If symptoms develop, isolate and get tested
Isolation Duration **-AND-** **End Isolation Requirements**	**Isolation starts on the first day of symptoms (day 0) or the day of a positive test if there are no symptoms (day 0)** **Not immunocompromised**** Isolate for **at least 10 days** until: • At least 10 days have passed since symptoms first appeared **AND** • At least 24 hours have passed since last fever without fever-reducing medications **AND** • Symptoms have improved **Immunocompromised** ^^** Isolate for **at least 20 days** until: • At least 20 days have passed since symptoms first appeared **AND** • At least 24 hours have passed since last fever without fever-reducing medications **AND** • Symptoms have improved
Surveillance and Outbreak Testing	• Surveillance testing and testing during an outbreak as recommended by RIDOH • After testing positive, testing again in the next 90 days is **not recommended**
Where to Test	Testing may be arranged by RIDOH. Call 401-222-8022.

* COVID-19 vaccination not up to date:
- You are age 18 or older and completed the primary series of recommended vaccine but have not received a recommended booster shot when eligible
- You received the single-dose Johnson & Johnson vaccine (completing the primary series) over 2 months ago and have not received a recommended booster shot
- You are not vaccinated or have not completed a primary vaccine series

^ COVID-19 vaccination up to date
- You are age 18 or older and have received all recommended vaccine doses, including boosters or;
- You are age 5 to 17 and completed the primary series of COVID-19 vaccines or;
- You had confirmed COVID-19 within the last 90 days (you tested positive using a viral test)

** The CDC defines immunocompromised as:
- Currently receiving chemotherapy for cancer
- Being within one year out from receiving a hematopoietic stem cell or solid organ transplant
- Untreated HIV infection with CD4 T lymphocyte count lower than 200
- Primary immunodeficiency (PI)
- Taking immunosuppressive medications (e.g., drugs to suppress rejection of transplanted organs or to treat rheumatologic conditions such as mycophenolate and rituximab
- Taking more than 20 mg a day of prednisone for more than 14 days
- Other condition(s) as determined by the treating healthcare provider

^^ Consult with your healthcare provider about when you can resume being around other people

Exhibit L

The Providence Journal

POLITICS

COVID-positive employees can work after Eleanor Slater Hospital declares staffing 'crisis'

Katherine Gregg The Providence Journal

Published 10:52 a.m. ET Jan. 3, 2022 | Updated 5:25 p.m. ET Jan. 3, 2022

PROVIDENCE — The state-run Eleanor Slater Hospital has declared a staffing crisis and notified employees with "mild symptoms" of the virus that causes COVID-19 that they can work.

A memo obtained by The Journal on Monday advised employees that: "We have officially notified [the Rhode Island Department of Health] that we are in such a staffing situation."

The memo went out on New Year's Day, at a point when the Department of Health was publicly stating that no hospital in the state had declared the need to bring back infected employees.

"No, no facility has reported to us yet that they are in a position that requires COVID-19 positive healthcare providers to be working. If a facility does reach that point, that information would be posted publicly so patients and families would be aware," Health Department spokesman Joseph Wendelken told The Journal over the weekend.

On Monday, Wendelken told The Journal that information was accurate at that point, but fluid.

When Monday began, for example, he reported the Respiratory and Rehabilitation Center of Rhode Island, a nursing home in Coventry, was "using asymptomatic staff that recently tested positive." By mid-morning, he said, the nursing home was no longer in "crisis."

Elaborating, Lori Mayer, a spokeswoman for the 134-resident respiratory and rehabilitation center, said the home had "one asymptomatic COVID+ employee working on the Center's COVID+ Unit [over the weekend]...A number of staff members were out with COVID but have since recovered and returned to work."

Of the state hospital, Wendelken said: "Eleanor Slater Hospital had one asymptomatic staff person who recently tested positive on site on Saturday, and one worker on site on Sunday." He said none were there on Monday.

"These people on Saturday and Sunday were masked," Wendelken said, "and facility administrators communicated that they would try to have them only caring for COVID-19 positive patients."

Despite that assurance, Pam Costello, the mother of one long-term patient on the Zambarano campus, was upset that she was not notified of the new policy and deeply concerned for her son, Jason Gagnon.

"What a dangerous situation to expose patients who are already compromised," she told The Journal. "I know in my son Jason's case who is very prone to severe lung infections, if he was to contract COVID from one of these workers, it could KILL him.

"Not only are patients in danger, but the workers who are healthy are being put in danger of contracting COVID and possible bringing it home to their families," she said. . "I was not allowed to even visit my son...over the holidays because I was exposed to a friend who may have been exposed to COVID but tested negative."

Lynn Blais, president of the United Nurses and Allied Professionals (UNAP), said her union, representing more than 7,000 nurses and health professionals, "is unequivocally opposed" to the state's decision to allow COVID-19 positive health care workers to work.

"First and foremost, we believe that it's critically important to ensure a healthy workforce in which health care workers are not spreading the virus to other workers and, more importantly, to at-risk patients who are susceptible to the most harmful effects of the virus."

"Second, this policy will likely come with the unintended consequence of exacerbating staffing shortages when more workers in hospitals become infected with COVID-19, get sick, and are forced to quarantine."

"The UNAP believes that only health care workers who are asymptomatic, have a negative test, and continue to wear a mask should be returning to the workforce after 5 days." .

More: RI Health Dept. opens door for COVID-infected staff to work at hospitals, nursing homes

Eleanor Slater Hospital, with 200 medical and psychiatric patients on two campuses in Cranston and Burrillville, has been on the verge of a staffing crisis for some time.

It had not, as of Monday morning, posted the required notice on its website that it had any COVID-infected employees taking care of any patients.

The state agency that runs Eleanor Slater Hospital has not responded to inquiries.

But the memo follows a Journal news report over the weekend about the new crisis-staffing policy posted quietly by health officials late last week.

Mirroring guidance from the CDC, the new Rhode Island policy allows hospitals and nursing homes to bring asymptomatic and "mildly symptomatic" employees back to work – without any waiting period – if they reach a point where the facilities are in a staffing crisis situation.

Wendelken, the Health Department spokesman, said the new CDC guidance "is reflective of science that indicates that most SARS-CoV-2 transmission occurs early in the course of illness."

"For healthcare providers, the CDC is recognizing that states across the country are experiencing healthcare worker shortages. If a facility is experiencing a significant staffing challenge, facility administrations may make a determination on the need to have ... COVID-19 positive healthcare providers work.

"However, asymptomatic or mildly symptomatic workers should be considered first in these instances, and of course masks are required."

"Also, facility administrators should be using their clinical judgement in making staffing decisions. For example, a facility may opt for a COVID-19 positive worker to only care for COVID-19 positive patients."

After the Health Department posting came to light over the weekend, Twitter lit up with questions, statements of concern and in some cases condemnation.

Republican state Sen. Jessica de la Cruz Tweeted: "RIDOH will allow healthcare staff who test positive w/COVID to work but not unvaxxed healthcare staff who test negative?! Its time for the state to admit its mistake. We need all hands on deck to address the healthcare crisis. Rehire these qualified & experienced professionals."

Why not bring back "healthy, unvaccinated workers" before employees with known COVID infections?

On Sunday night, Wendelken provided this answer: "An unvaccinated healthcare worker is at greater individual risk, given how many COVID-19 positive patients are in facilities.

"Additionally, someone who is vaccinated and who tested positive for COVID-19 has a much lower viral load, compared to someone who is COVID positive and unvaccinated. This means that the likelihood of transmission is much less."

A spokeswoman for Care New England said its hospitals, which include Butler, Kent, and Women & Infants Hospitals, are not using COVID positive workers at this time.

But "this may change in the future, due to the rising number of COVID infections and hospitalizations throughout the state of Rhode Island," spokeswoman Raina Smith said.

A spokeswoman for the Lifespan network spelled out the tiered rules, none of which allow an infected employee, symptomatic or asymptomatic, to return to work for at least five days.

Tier One: "Lifespan employees who test positive for COVID-19 and are asymptomatic must stay home for five days and then can return to work." Tier Two: "If they have symptoms they must isolate...at home for the five days" and only return "if their symptoms have improved and they have been [without a fever] for 24 hours."

Tier Three: "Lifespan employees who have been exposed to COVID-19 but are asymptomatic, may continue to work," spokeswoman Kathleen Hart said.

John Gage of the Rhode Island Health Care Association, which represents the majority of nursing homes in the state, said he was unaware of any using COVID infected staff "at this time."

"That said, RI nursing homes are in the midst of a critical staff shortage," he said. "There simply are not enough applicants to fill vacant positions.

"Facilities have quadrupled their use of staffing agencies...[Many] charge exorbitant rates that, in some cases, amounts to price gouging – i.e. charging a $30/hour premium if staffing a facility with any covid cases for the duration of the "outbreak" or else they will pull their staff altogether to send them elsewhere for the premium. It is out of control."

Exhibit M

The Vaccine Adverse Event Reporting System (VAERS) Results

Data current as of 12/31/2021

Vaccine	VAERS ID	Adverse Event Description
COVID19 (COVID19 (JANSSEN)) (1203)	1410359-1	"1pm on 06/11/2021 I experienced stroke symptoms. was rushed by ambulance to Hospital. CAT scan, MRI were done and TPA was given. No large blood clots were found but meds were used as precaution for smaller clots. Was transferred to Hospital to Neurological Stroke Unit ICU was there for 4 days. I was tested for various viruses and shingles they were negative including the Covid test. They found a problem with 7th nerve bundle . Bell""s Palsy was diagnosed . They are researching how and why this occurred. I am home resting and recuperating."
COVID19 (COVID19 (MODERNA)) (1201)	1117439-1	Right-sided facial numbness and slight facial drooping right after receiving vaccine. Tingling and pins/needles sensation. Numbness has prolonged up til this day. Received medical treatment from physician who mentioned bells palsy and prescribed Prednisone 20mg take 3 tablets by mouth everyday for 7 days and Valacyclovir 1 gram 3x a day for 7 days.
	1197618-1	It swells my face; I have numbness; Tingling of the whole thing in my lip; pins and needles in the left side of my mouth/sometimes it goes across my lip and into my right side; she did not get the second dose because her face is bad/more than 36 days after the first dose without receiving the second dose; hair loss; a hole in her hair; bells palsy; This spontaneous case was reported by a nurse and describes the occurrence of FACIAL PARALYSIS (bells palsy) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 030L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included COVID-19 in 2020. Previously administered products included for an unreported indication: ZOSTAVAX (Shingles vaccine). On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In February 2021, the patient experienced FACIAL PARALYSIS (bells palsy) (seriousness criterion medically significant). On an unknown date, the patient experienced SWELLING FACE (It swells my face), HYPOAESTHESIA (I have numbness), PARAESTHESIA ORAL (Tingling of the whole thing in my lip), ORAL PAIN (pins and needles in the left side of my mouth/sometimes it goes across my lip and into my right side), PRODUCT DOSE OMISSION ISSUE (she did not get the second dose because her face is bad/more than 36 days after the first dose without receiving the second dose), ALOPECIA (hair loss) and HAIR INJURY (a hole in her hair). At the time of the report, FACIAL PARALYSIS (bells palsy), SWELLING FACE (It swells my face), HYPOAESTHESIA (I have numbness), PARAESTHESIA ORAL (Tingling of the whole thing in my lip) and ORAL PAIN (pins and needles in the left side of my mouth/sometimes it goes across my lip and into my right side) had not resolved and PRODUCT DOSE OMISSION ISSUE (she did not get the second dose because her face is bad/more than 36 days after the first dose without receiving the second dose), ALOPECIA (hair loss) and HAIR INJURY (a hole in her hair) outcome was unknown. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. She stated that on the third week after the vaccine, she experienced bells palsy.; Sender's Comments: This case concerns a 71-year-old female with a serious unexpected event of facial paralysis, along with nonserious unexpected swelling face, oral paraesthesia, hypoesthesia, oral pain, alopecia, hair injury and product dose omission issue. Based on current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
	1788364-1	Bells palsy with muscle control loss and taste loss on left side of face. Wrote a long description but lost everything with the 20 minute time limit.
	1813668-1	Site: Bruising at Injection Site-Mild, Site: Itching at Injection Site-Mild, Site: Pain at Injection Site-Severe, Site: Redness at Injection Site-Mild, Site: Swelling at Injection Site-Mild, Systemic: Allergic: Anaphylaxis-Mild, Systemic: Allergic: Difficulty Breathing-Mild, Systemic: Allergic: Difficulty Swallowing, Throat Tightness-Mild, Systemic: Allergic: Itch (specify: facial area, extremeties)-Mild, Systemic: Allergic: Itch Generalized-Mild, Systemic: Allergic: Rash (specify: facial area, extremeties)-Mild, Systemic: Allergic: Rash Generalized-Mild, Systemic: Allergic: Swelling of Face / Eyes / Mouth / Tongue-Mild, Systemic: Abdominal Pain-Mild, Systemic: Autoimmune Disease (diagnosed by MD)-Mild, Systemic: Bell's Palsy-Mild, Systemic: Blood Disorder (diagnosed by MD)-Mild, Systemic: Body Aches Generalized-Mild, Systemic: Cardiac Disorder (diagnosed by MD)-Mild, Systemic: Chest Tightness / Heaviness / Pain-Mild, Systemic: Chills-Mild, Systemic: Confusion-Mild, Systemic: Diarrhea-Mild, Systemic: Dizziness / Lightheadness-Severe, Systemic: Exhaustion / Lethargy-Severe, Systemic: Fainting / Unresponsive-Mild, Systemic: Fever-Mild, Systemic: multiple prominent lymph nodes (thyroid/neck) demonstrating loss of normal fatty hila-Mild, Systemic: Flushed / Sweating-Mild, Systemic: Headache-Mild, Systemic: Heart Attack-Mild, Systemic: Hypertension-Mild, Systemic: Hyperventilation-Mild, Systemic: Hypotension-Mild, Systemic: Joint Pain-Mild, Systemic: Lymph Node Swelling-Severe, Systemic: MIS (Multisystem Inflammatory Syndrome)(diagnosed by MD)-Mild, Systemic: Nausea-Mild, Systemic: Neurological Disorder (diagnosed by MD)-Mild, Systemic: Numbness (specify: facial area, extremities)-Mild, Systemic: Seizure-Mild, Systemic: Shakiness-Mild, Systemic: Stroke-Mild, Systemic: Tachycardia-Mild, Systemic: Tingling (specify: facial area, extemities)-Mild, Systemic: Tinnitus-Mild, Systemic: Unable to Sleep-Mild, Systemic: Visual Changes/Disturbances-Mild, Systemic: Vomiting-Mild, Systemic: Weakness-Mild, Additional Details: extreme fatigue, swollen/sore neck area. sent for ultrasound which presented with 'multiple mildly prominent lymph nodes that are demonstrating loss of normal fatty hila'. Did not present immediately, approx 7 days after 1st dose.
	1949032-1	Bell's palsy right side
COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	0956275-1	left facial palsy
	0958926-1	Patient developed right facial numbness and facial droop on 1/7/21. She came to the TMH ED and was admitted. She was afebrile; neurologic exam was consistent with a peripheral facial palsy on the right.
	1238444-1	Bell's palsy diagnosed, left side facial paralysis, treated w/ prednisone and acyclovir. Still affected. Previous history of Bell's palsy on opposite side (2014).
	1241935-1	Droopy right eye- Bell?s palsy. Eye tearing. Treatment- Retain- mgd
	1289407-1	Bell's Palsy noted on 5/4/21. Did have some mouth pain on 5/3 that was attributed to potential wisdom tooth eruption, then cranial nerve 7 palsy noted on 5/4/21.
	1327664-1	1/20/21 CVS administered the vaccine at the center. 1/21/21 Employee called out for her shift, reporting left face drooping and has reached out to her PCP. Diagnosed by urgent care doctor with Bell's Palsy, taken out of work 1/21 through 1/24.

Vaccine	VAERS ID	Adverse Event Description
	1413579-1	On June 16 when I got the shot, about an hour later I started getting a headache that started in the back of my head. When I woke up on June 17 at 7:45AM I had a slamming headache that again started from the back of my head and radiated both upward and downward into my neck and shoulders. The headache was there all day and all of the following day, June 18. Then on June 19 I woke up at 7:45AM with the headache significantly decreased. In place of the headache I had numbness on the left side of my face. I was unable to move the left side of my face at all. The left side of my tongue was numb. The numbness and tingling goes to my left ear and the left side of my neck. On June 20 I had all the same symptoms with the left side of my face. I called my PCP who told me it sounded like Bell's Palsy and that I needed to go to the hospital. At the hospital they ruled out any neurological issues. I was diagnosed with Bell's Palsy (which I have NEVER had before). They ordered Prednisone which I will start taking tomorrow since my pharmacy was already closed. They also took bloodwork testing for lyme disease which there are no results for yet. As for pregnancy, there is no history to share beside me being 23 weeks pregnant and I am due October 15.
	1522227-1	Burning sensation in neck for 24 hours tapered slowly.; Back pain.; Sore armpits for 1 week; Tender breast for 1 week; This is a spontaneous report from a contactable consumer, the patient. A 39-year-old non-pregnant female patient received the first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN) via an unspecified route of administration in the right arm on 25Apr2021 at 14:45 (at the age of 39-years-old) as a single dose for COVID-19 immunisation. Medical history included bell's palsy on left side 2 years ago and the patient was still dealing with synkinesis. Concomitant medications were not reported. Prior to the vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. The patient did not receive any other vaccines within four weeks prior to the vaccination. On 25Apr2021 at 14:45, the patient experienced burning sensation in neck for 24 hours tapered slowly, back pain, sore armpits and tender breast for 1 week. The clinical outcome of the events burning sensation in neck for 24 hours tapered slowly, back pain, sore armpits and tender breast for 1 week was resolving at the time of this report. No follow-up attempts are needed; information about lot/batch number cannot be obtained.
	1971575-1	Bell's Palsy
COVID19 (COVID19 (UNKNOWN)) (1202)	1115991-1	Bell's palsy, left-side facial droop

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more than 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 12/31/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

About COVID19 vaccines:

- For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/).
- One report may state that the patient received more than one brand of COVID-19 vaccine on the same visit. This is a reporting error, but explains why the total number of reports may not equal the total number of COVID-19 vaccine doses.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Jan 9, 2022 4:53:49 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 12/31/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Jan 9, 2022 4:53:49 PM

Query Criteria:

Adverse Event Description:	palsy
Date of Onset:	2021
Date Report Completed:	2021
Date Report Received:	2021
Date Vaccinated:	2021
State / Territory:	Rhode Island
Vaccine Products:	COVID19 VACCINE (COVID19)
VAERS ID:	All
Group By:	Vaccine; VAERS ID
Show Totals:	False
Show Zero Values:	False

Exhibit N

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF TEXAS
CORPUS CHRISTI DIVISION

JAMES RODDEN, *et. al.*, *Plaintifs,* v. ANTHONY FAUCI, *et. al.,* *Defendants,*	Civil Action No. : 3 :21-cv-00317

Joint Declaration of Dr. Jayanta Bhattacharya and Dr. Martin Kulldoff

We, Drs. Jayanta ("Jay") Bhattacharya and Martin Kulldorff provide the following Joint Declaration and hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct:

Background

1. Dr. Jay Bhattacharya is a Professor of Medicine at Stanford University and a research associate at the National Bureau of Economic Research. He is also Director of Stanford's Center for Demography and Economics of Health and Aging. He holds an M.D. and Ph.D. from Stanford University. He has published 152 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. His research has been cited in the peer-reviewed scientific literature more than 11,000 times.

2. Dr. Martin Kulldorff is a Professor of Medicine at Harvard Medical School, and he is a biostatistician and epidemiologist at Brigham and Women's Hospital. He holds a Ph.D. from Cornell University. He is the author of 237 published articles in leading medical, epidemiological, statistics, and science journals, cited over 25,000 times in peer-reviewed scientific journals. Dr. Kulldorff is recognized internationally for his foundational research on the detection and monitoring of disease outbreaks and on the monitoring and evaluation of vaccine safety issues. His epidemiological methods are routinely used by the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA") and other public health agencies around the world.

3. Both of us have dedicated our professional careers to the analysis of public health data, including infectious disease epidemiology and policy, and the efficacy and safety of medical interventions.

4. We have both studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). We are intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

5. Our assessment of vaccine immunity is based on studies related to the efficacy and safety of the three vaccines that have received Emergency Use Authorization ("EUA") from the Food and Drug Administration (FDA) for use in the United States. These include two mRNA technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus vector vaccine technology (manufactured by Johnson & Johnson).

6. Neither of us has received any financial or other compensation to prepare this Declaration. Nor have we ever received any personal or research funding from any pharmaceutical company. In writing this, we are motivated solely by our commitment to public health.

7. Neither of us has an existing doctor-patient relationship with Jeanna Norris.

8. We have been asked to provide our opinion on several matters related to Michigan State University ("MSU" or "University") vaccine policy for faculty and staff (the "mandatory vaccination" directive), including the following:

a. Whether, based on the current medical and scientific knowledge, natural immunity is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;

b. Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity; and

c. An assessment of the comparative safety to recipients of administering vaccines to those who have natural immunity relative to immunologically naïve recipients with no prior history of COVID infection.

9. Our opinions are summarized in a recent article we published and which we reaffirm here: "[R]ecovered COVID patients have strong, long-lasting protection against severe disease if reinfected, and evidence about protective immunity after natural infection is stronger than the evidence from the vaccines. Hence, it makes no sense to require vaccines for recovered COVID patients. For them, it simply adds a risk, however small."[1]

[1] Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

Mortality Risk from COVID-19 Infection and Corresponding Marginal Benefit From Vaccination Varies By Orders of Magnitude Based on Age

10. The mortality risk posed by COVID infection is a basic parameter necessary to understand the public health benefits from vaccines. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or a positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts; these both miss infected people who are not identified by the public health authorities or do not volunteer for RT-PCR testing. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports or positive test counts are substantially biased upwards. According to a meta-analysis (published by the World Health Organization) by Dr. John Ioannidis of every seroprevalence study conducted with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%.[2] A newly released meta-analysis by scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.[3]

11. The mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at higher risk of death if infected, while younger patients face a

[2] Ioannidis JPA, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, BULL WORLD HEALTH ORGAN (Jan 1, 2021).
[3] Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications*, MEDRXIV (Aug. 14, 2020), https://bit.ly/3gpIoIV.

vanishingly small risk.[4] The same is true for hospitalization risk, which is similarly age-dependent. The best evidence on age-specific infection fatality rates comes again from seroprevalence studies.

12. The CDC's best estimate of the infection fatality ratio for people ages 0-19 years is 0.00002, meaning infected children have a 99.998% infection survivability rate.[5] The CDC's best estimate of the infection fatality rate for people ages 20-49 years is 0.0005, meaning that young adults have a 99.95% survivability rate. The CDC's best estimate of the infection fatality rate for people age 50-64 years is 0.006, meaning this age group has a 99.4% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 65+ years is .09, meaning seniors have a 91.0% survivability rate.

13. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the *Lancet*)[6] provides a detailed age breakdown of the infection survival rate in a preprint companion paper[7]: 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65 years old.

14. In summary, the mortality risk posed by COVID infection in the young is vanishingly small, while the threat posed to the elderly is orders of magnitude higher. One direct corollary of this point is that the corresponding personal benefit from vaccination, at least as far as mortality risk is concerned, is orders of magnitude lower for the young relative to the elderly.

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[4] Kulldorff M., *COVID-19 Counter Measures Should Be Age-Specific*, LINKEDIN (Apr. 10, 2020), https://www.linkedin.com/pulse/covid-19-counter-measures-should-age-specific-martin-kulldorff/.

[5] Centers for Disease Control and Prevention, *COVID-19 Pandemic Planning Scenarios*, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

[6] Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study*,THE LANCET (June 11, 2020), https://bit.ly/3l87S13.

[7] Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland*, OSF PREPRINTS (June 15, 2020), https://osf.io/wdbpe/.

Another corollary is that the community benefit from vaccines mandates is orders of magnitude lower for a university compared to say a nursing home, whee the average age is much higher.

Both Vaccine Immunity and Natural Immunity Provide Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected

15. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There has never been a reason to presume that vaccine immunity provides a higher level of protection than natural immunity, and there is now evidence that natual immunity is stronger than vaccine immunity. Since vaccines arrived one year after the disease, there is also stronger evidence for long lasting immunity from natural infection than from the vaccines.

16. Both types are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibodies level in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.[8,9] A Phase III trial showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.[10]

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[8] Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T., *COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, N ENGL J MED (Feb. 4, 2021).

[9] Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC, *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*, N ENGL J MED. (Dec. 31, 2020).

[10] Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, Goepfert PA, Truyers C, Fennema H, Spiessens B, Offergeld K, Scheper G, Taylor KL, Robb ML, Treanor J, Barouch DH, Stoddard J, Ryser MF, Marovich MA, Neuzil KM, Corey L, Cauwenberghs N, Tanner T, Hardt K, Ruiz-Guiñazú J, Le Gars M, Schuitemaker H, Van Hoof J, Struyf F, Douoguih M, *Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19*, N ENGL J MED (June 10, 2021), 2187-2201.

17. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells[11], bone marrow plasma cells[12], spike-specific neutralizing antibodies [13], and IgG+ memory B cells[14] following naturally acquired immunity.

18. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies show that natural immunity provides greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

19. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19[15] and show that the vast majority of reinfections are less severe than first-time

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[11] Jennifer M. Dan, et al., *Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection*, SCIENCE (Feb. 5, 2021) (finding that memory T and B and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility for most individuals").

[12] Jackson S. Turner, et al., *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, NATURE (May 24, 2021) (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Ewen Callaway, *Had COVID? You'll probably make antibodies for a lifetime*, NATURE (May 26, 2021), https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

[13] Tyler J. Ripperger, et al., *Orthogonal SARS-Cov-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humor Immunity*, 53 IMMUNITY, Issue 5, pp. 925-933 E4 (Nov. 17, 2020) (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

[14] Kristen W. Cohen, et al., *Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells*, MEDRXIV (Apr. 27, 2021), https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v1 (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

[15] Nabin K. Shrestha, et al., *Necessity of COVID-19 vaccination in previously infected individuals*, MEDRXIV (preprint), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3. ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study "and concluded that those with natural immunity are "unlikely to benefit from covid-19 vaccination"); Galit Perez, et al., *A 1 to 1000 SARS-CoV-2 reinfection proporation in members of a large healthcare provider in Israel: a preliminary report*, MEDRXIV (Mar. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1 (Israeli study finding that approximately 1/1000 of participants were reinfected); Roberto Bertollini, et al,. *Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar*, JAMA (June 9, 2021), https://jamanetwork.com/journals/jama/fullarticle/2781112?resultClick=1 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Stefan Pilz, et al., *SARS-CoV-2 re-infection risk in Austria*, EUR. J. CLIN. INVEST. (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988582/(previous

infections.[16] For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided excellent protection in preventing COVID-19 infection, morbidity, and mortality.[17] Of the 187,549 unvaccinated persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age.

20. A more recent study from Israel directly compare natual immunity with vaccine immunity.[18] The study compares previously infected and recovered individuals who did not receive a vaccine after their recovery against individuals who received the Pfizer vaccine without having had the disease. The study considered four primary endpoints: a positive COVID test (a surrogate endpoint of limited value); symptomatic COVID-19 disease, hospitalization for COVID-

SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Aodhan Sean Breathnach, et al., *Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies*, 82 J. OF INFECTION e11-e12 (2021) https://doi.org/10.1016/j.jinf.2021.05.024 (.0.86% of previously infected population in London became reinfected); Alison Tarke, *Negligible impact of SARS0CoV-2 variants on CD4 and CD8 T cell reactivity in COVID-19 exposed donors and vaccines*, BIORXIV (Mar. 1, 2021), https://www.biorxiv.org/content/10.1101/2021.02.27.433180v1 (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered Covid patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

[16] Laith J. Abu-Raddad, et al., *SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals followed for up to 35 weeks*, MEDRXIV (Feb. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.01.15.21249731v2 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Victoria Jane Hall, et al., *SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study*, 397 LANCET: 1459-69 (Apr. 9, 2021), https://pubmed.ncbi.nlm.nih.gov/33844963/ (finding "a 93% lower risk of COVID-19 symptomatic infection… [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Aidan T. Hanrah, et al., *Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection*, 82 JOURNAL OF INFECTION, Issue 4, E29-E30 (Apr. 1, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832116/ (Apr. 1, 2021) (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

[17] Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2. vaccine protection: A three-month nationwide experience from Israel*, MEDRXIV (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

[18] Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. *medRxiv*. August 25, 2021. doi: https://doi.org/10.1101/2021.08.24.21262415.

19 disease, and COVID-19 associated mortality (all recorded in the months after recovery or vaccination). The study adjusts for age, demographic variables, patient comorbidities, and the timing of the disease/vaccine. The primary findings are that vaccinated individuals had 13.1 times higher risk of testing positive [95% CI: 8.08-21.1], 27 times higher risk of symptomatic disease [95% CI: 12.7-57.5], ~8.1 times higher risk of COVID-related hospitalization [95% CI: 1.01-64.55]. None of the patients in the study died due to COVID-related mortality. The vaccinated individuals were also at higher risk compared to those that had COVID diseas before the vaccines became available. The authors concluded:

> This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity.

21. Based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting.[19]

22. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 epidemic.[20] A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.[21]

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[19] Chris Baranjuk, *How long does covid-19 immunity last?* 373 BMJ (2021) (emphasis added).
[20] Nina Le Bert, *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control*, NATURE (Aug. 2020).
[21] Xiaocong Yu, et al., *Neutralizing antibodies derived form the B cells of 1918 influenze pandemic survivors*, NATURE (2008).

23. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, researchers have argued that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.[22]

24. In short, there is no medical or scientific reason to believe that vaccine immunity is superior to or will prove longer-lasting than natural immunity, much less that all currently approved vaccines will be expected to prove more durable than natural immunity despite their different technological foundations and dosing protocols.

Vaccine Side Effects Do Occur, Including Rare But Deadly Side Effects

25. Though the COVID vaccines are safe by the standards of many other vaccines approved for use in the population, like all medical interventions, they have side effects. In summarizing the evidence on vaccine side effects, the CDC lists both common side effects, at least one of which occurs in over half of all people who receive the vaccines, as well as deadly side effects that occur rarely in demographic subsets of the vaccinated population.

26. The common side effects include pain and swelling at the vaccination site and fatigue, headache, muscle pain, fever, and nausea for a limited time after vaccination.[23] Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur within 30 minutes after vaccination, which can typically be treated with an epinephrine injection if it occurs.[24] Finally, the CDC's vaccine safety committee has identified

[22] Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses hove taught scientists*, 594 NATURE 164 (June 10, 2021), https://www.nature.com/articles/d41586-021-01505-x (study notes that "Six months is not much time to collect data on how durable vaccine responses will be…. In the meantime some researchers are looking to natural immunity as a guide.").
[23] Centers for Disease Control, *Possible Side Effects After Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.
[24] Centers for Disease Control, *What to Do If You Have an Allergic Reaction after Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.

rare but deadly side effects, including a heightened risk of clotting abnormalities[25] in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis[26] in young people — but especially young men — after mRNA vaccination, and higher risk of Guillane-Barre Syndrome[27] after the J&J vaccine. There is still the possibility of severe side effects that have yet to be identified as the vaccines have been in use in human populations for less than a year. Active investigation to check for safety problems is still ongoing.

27. Though the CDC[28] still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts[29] have objected to overly rosy assumptions made in the CDC analysis about vaccine side effects. They suggest that the recommendation is fragile to minor perturbation in their assumptions. The critical point for our analysis – undisputed in the scientific literature – is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known at this point in time.

28. While uncertain, some clinical evidence indicates that those who have recovered from COVID-19 could potentially have a *heightened* risk of adverse effects compared with those

[25] Martin Kulldorff, *The Dangers of Pausing the J&J Vaccine*, THE HILL (April 17, 2021), https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine.
[26] Centers for Disease Control, *Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults* (May 28, 2021), https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.
[27] LaFranier and Weiland, *FDA Attaches Warning of Rare Nerve Syndrome to Johnson & Johnson Vaccine,* NEW YORK TIMES (July 12, 2021), https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html.
[28] Walensky, *CDC Director Statement on Pfizer's Use of COVID-19 Vaccine in Adolescents Age 12 and Older* (May 12, 2021), https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html.
[29] Pegden, *Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses* (June 24, 2021), https://medium.com/@wpegden?p=d7d6b3df7cfb.

who have never had the virus.[30] [31] This may be because vaccine reactogenicity after the first dose is higher among those with prior natural immunity.[32]

Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

29. Since its spread through the human population, the SARS-CoV-2 virus – an RNA virus – has been mutating, including some forms that are likely more transmissible than the original wild-type virus that emerged from Wuhan, China, in 2019. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that a vaccine mandate is unwarranted.

30. First, the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.[33,34,35] Although reinfection can occur, people who have been previously infected by the wild-type (non-variant) virus are unlikely to have a severe outcome

[30] Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).
[31] Cristina Menni, *Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study*, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021) (finding that "Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 [i.e., AstraZeneca vaccine] and 2.9 times after the first dose of BNT162b2 [i.e., Pfizer/BioNTech vaccine]) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2).").
[32] Florian Krammer, et al., *Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a singe dose of SARS-CoV-2 mRNA vaccine*, MEDRXIV (Feb. 1, 2021), https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1 (concluding that "vaccine reactogenicity after the first dose is substantially more pronounced in individuals with pre-existing immunity." The authors note that "quantitative serological assays that measure antibodies to the spike protein could be used to screen individuals prior to vaccination," which would "limit the reactogenicity experienced by COVID-19 survivors.).
[33] Alison Tarke, A., Sidney, J., Methot, N., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., da Silva Antunes, R., Frazier, A., Rawlings, S. A., Smith, D. M., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A., & Sette, A., *Negligible impact of SARS-CoV-2 variants on CD4 + and CD8 + T cell reactivity in COVID-19 exposed donors and vaccinees*, BIORXIV, 2021.02.27.433180 (2021), https://doi.org/10.1101/2021.02.27.433180.
[34] Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A., & Edwards, D. K., *mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants*, BIORXIV : THE PREPRINT SERVER FOR BIOLOGY, 2021.01.25.427948 (2021), https://doi.org/10.1101/2021.01.25.427948.
[35] Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T. C., & Tobian, A. A., *CD8+ T cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants*, MEDRXIV : THE PREPRINT SERVER FOR HEALTH SCIENCES, 2021.02.11.21251585 (2021), https://doi.org/10.1101/2021.02.11.21251585.

(hospitalization or death) after exposure to a variant virus. A variant circulating in the population thus poses little additional risk of hospital overcrowding or excess mortality due to viral infection.

31. Second, theoretical work suggests that lockdowns place selective pressure that promotes the development and establishment of more deadly variants. This, in part, may explain why the most concerning variants have emerged in places like the U.K., South Africa, and California, where severe lockdowns have been imposed for extended periods.[36] While this hypothesis awaits a definitive empirical test, it is consistent with the *prima facie* evidence on mutant variants' development.

32. Third, the variants have been widely spreading in many countries these past months, even as cases have dropped. This is true, for instance, in Florida, where the U.K. variant B.1.1.7 was widespread this past winter[37], but cases fell sharply over the same period that the variant has been spreading. That variants with an infectivity advantage – but no more lethality – make up a larger fraction of a smaller number of cases is an interesting scientific observation but not crucial for public health policy.

33. Fourth, the dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still perhaps be infected but rarely have severe symptoms in response to infection. Throughout last year, a rise in cases was inevitably accompanied by an increase in deaths with a two-to-three-week lag. However, during this most recent wave, there has been little rise in daily deaths to accompany the rise in cases because of the deployment of the vaccine in the vulnerable older population in the

[36] Moran J., *Mutant variations and the danger of lockdowns*, THE CRITIC MAGAZINE (March 2, 2021), https://thecritic.co.uk/mutant-variations-and-the-danger-of-lockdowns/.

[37] US Centers for Disease Control, *US COVID-19 Cases Caused by Variants* (2021), https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html.

United States. The same is true in Sweden and the U.K., where vaccines have been provided to the entirety of the vulnerable elderly population and more.[38] Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are now effectively decoupled.

The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID patients ("Long COVID") Does Not Alter The Conclusion that Vaccine Mandates Are Unwarranted

34. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify vaccine mandates and lockdown measures. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.[39] One cross-sectional study found that about 30% of recovered COVID patients reported at least one symptom months after recovery, with fatigue and anosmia (loss of sense of smell) by far the most common.[40] A separate study with a more convincing longitudinal methodology, by contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.[41] Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.[42] A study of children who recovered from

[38]Jay Bhattacharya, Martin Kulldorff, and Sunetra Gupta, *Sweden's Lessons for the UK's Third Wave*, THE SPECTATOR (July 12, 2021), https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting.
[39] Nalbandian, A., Sehgal, K., Gupta, A. et al., *Post-acute COVID-19 syndrome*, NAT MED 27, 601–615 (2021), https://doi.org/10.1038/s41591-021-01283-z.
[40] Logue JK, Franko NM, McCulloch DJ, et al., *Sequelae in Adults at 6 Months After COVID-19 Infection*, JAMA NETW OPEN (2021);4(2):e210830, doi:10.1001/jamanetworkopen.2021.0830.
[41] Sudre, C.H., Murray, B., Varsavsky, T. et al., *Attributes and predictors of long COVID*, NAT MED 27, 626–631 (2021), https://doi.org/10.1038/s41591-021-01292-y.
[42] Arnold DT, Hamilton FW, Milne A, et al., *Patient outcomes after hospitalisation with COVID-19 and implications for follow-up: results from a prospective UK cohort*, THORAX, 76:399-401 (2021).

COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.[43] Some analysts have noted the similarity between "long COVID" symptoms and other functional somatic syndromes that sometimes occur after other viral infections and other triggers (and sometimes with no identifiable etiology).[44]

35. To summarize, as with other viruses, long COVID symptoms occur in a minority of patients who recover from COVID and pose a real burden on patients who suffer from it. However, this fact does not alter the logic of our argument. On the countrary. After suffering through COVID, with or without long COVID, such individuals should not be forces to also endure common but mild vaccine adverse reactions or risk rare but serious adverse reactions. Moreover, the successful vaccine rollout in the United States – where every teenager and adult has free access to the vaccines – addresses the problem of long COVID, just as it addresses COVID-associated mortality.

CDC Recommendation for Vaccination of Recovered COVID Patients Applies With Equal Force to Previously Vaccinated

36. Written before the Israel study, the CDC, in a frequently asked questions section of a website encouraging vaccination, provided the following advice to previously recovered patients in July 2021:[45]

> Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn

[43] Thomas Radtke, Agne Ulyte, Milo A Puhan, Susi Kriemler, *Long-term symptoms after SARS-CoV-2 infection in school children: population-based cohort with 6-months follow-up*, MEDRXIV (2021), https://doi.org/10.1101/2021.05.16.21257255.
[44] Ballering A, Olde Hartman T, Rosmalen J Long COVID-19, *persistent somatic symptoms and social stigmatization,* J EPIDEMIOL COMMUNITY HEALTH (2021).
[45] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (accessed July 30, 2021)

> more about why getting vaccinated is a safer way to build protection than getting infected.

37. The last sentence is true but irrelevant for people with natural immunity. The statement on CDC's website that "studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19," is incorrect. As one would expect, people with prior COVID-19 disease have increased levels of antibodies after receiving the vaccine, leading to fewer positive tests, just as if they are re-exposed to the disease. This does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths. In an update to the website[46] on August 19, 2021, the CDC links to a single study from Kentucky.[47] That study showed fewer positive tests among those who had both natural immunity and a vaccine, but the study did not evaluate the relevant outcomes of symptomatic disease, hospitalizations, deaths or transmission. Like the Kentucky study, the Israel study also found that those with both natural immunity and a vaccine were less likely to test positive compared with those with natural immunity but no vaccine. The Israel study also evaluated other outcomes, and did not find any statistically significant difference with respect to symptomatic disease, hospitalizations or deaths, all of which were very low in both groups (e.g. no deaths in either group).

38. The text of this advice by the CDC also does not address any of the scientific evidence we have provided in our declaration, herein, about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that we do not know how long natural immunity

[46] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (accessed August 26, 2021)
[47] Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1081-1083. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e1

after recovery lasts, in terms of 5, 10, or 20 years from now, the immunological evidence to date suggests that protection against disease will last for years.[48]

39. That is because, with exceedingly few reinfections among millions of recovered COVID-19 patients, we know that there is excellent protection for at least 18 months, and that protection is not suddenly going to disappear after exactly 18 months.

40. Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID recovered patients from vaccination mandates, since the same is true to an even highe degree about vaccine mediated immunity. We do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

41. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine breakthrough infections itself recognizes.[49] On the same CDC FAQ webpage we cite above[50], the CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

42. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who already has been infected and recovered will benefit on net from the additional protection provided by vaccination.

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[48] Patel N (2021) Covid-19 Immunity Likely Lasts for Years. MIT Technology Review. January 6, 2021. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/

[49] CDC COVID-19 Vaccine Breakthrough Case Investigations Team (2021) COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. May 28, 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm

[50] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

On this point, the CDC's statement in the FAQ is non-responsive, and ignores the scientific evidence.

Conclusion

43. A fundamental ethical principle guiding the practice of medicine is that any medical intervention, whether surgical, pharmacological, or a vaccine, should be recommended and undertaken only if it is deemed medically necessary. Any medical procedure, including vaccination, involves risk. No medical procedure is 100% safe, especially those involving a new vaccine which by definition has not been studied for long-term adverse side effects. For this reason, it is a fundamental principle of medical ethics that the risks of the procedure be balanced against the potential benefits.

44. As we established earlier, based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable as that acquired through vaccination. In Jeanna Norris' case, there is no doubt that, based on recent measures of her antibody levels, she is protected by natural immunity (Dr. Bhattacharya has examined the results from Ms. Norris' laboratory tests). The results indicate the presence of both spike-protein and nucleocapsid protein antibodies; the latter is a reliable sign of previous natural infection (the former turns positive after either previous natural infection or vaccination). The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date. From the point of view of Ms. Norris' personal health, there is no good reason that she should be vaccinated. At the very least, the decision should be left to Ms. Norris and her doctors without coercion applied by the University.

45. There is also no community health reason for the University to mandate vaccinations since she already has stonge immunity than those that ae vaccinated, and the vaccine is available to all teens and adults who want it. Indeed, based on our analysis of the existing medical and scientific literature, any policy mandating vaccinations that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.[51]

46. As we wrote in the *Wall Street Journal* this spring, "[t]he idea that everybody needs to be vaccinated is as scientifically baseless as the idea that nobody does. Covid vaccines are essential for older, high-risk people and their caretakers and advisable for many others. But those who've been infected are already immune . . . .If authorities mandate vaccination of those who don't need it, the public will start questioning vaccines in general . . . . Coercive vaccination policies would erode trust even further."[52]

47. We criticized those pushing for and implementing vaccine mandates as "undermining public trust in vaccines. In this sense, they are more dangerous than the small group of so-called anti-vaxxers have ever been."

48. It is unethical to coerce low-risk Americans to take the vaccine, such as low-risk students and those with natual immunity, while older high-risk individuals in Asia, Africa and Latin America are dying from COVID19 because there are not enough vaccines available in those countries.

49. Now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is even weaker than it was in the spring when we wrote that *Wall Street*

[51] Jay Bhattacharya, Sunetra Gupta, and Martin Kulldorff, *The Beauty of Vaccines and Natural Immunity*, SMERCONISH NEWSLETTER (June 4, 2021), https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity.

[52] Martin Kulldorff and Jay Bhattacharya, *Vaccine Passports Prolong Lockdowns*, WALL STREET JOURNAL (Apr. 6, 2021), https://www.wsj.com/articles/vaccine-passports-prolong-lockdowns-11617726629.

Journal piece. There is no good public health case for MSU to require proof of vaccination for employees and students to participate in University activities that do not involve care for high-risk patients. And, since those recovered from COVID19 has better protection than vaccinated individuals, there are no public health reasons to impose different mask requirements for the two groups.

50. Since the successful vaccination campaign already protects the vulnerable population, even the unvaccinated who have not had COVID disease –pose a vanishingly small threat to the vaccinated o those with natual immunity. They are protected by an effective vaccine, that dramatically reduces the likelihood of hospitalization or death after infections to near zero, o by natural immunity.

51. With widespread vaccination of the vulnerable, asymptomatic people pose even less risk to the vulnerable than before the vaccine became available. At the same time, the requirement for a vaccine passport or other type of proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice that caution against warrantless discrimination against segments of the population (in this case, the unvaccinated).

52. We recently observed that "[u]niversities used to be bastions of enlightenment. Now many of them ignore basic benefit-risk analyses, a staple of the toolbox of scientists; they deny immunity from natural infection; they abandon the global international perspective for narrow nationalism; and they replace trust with coercion and authoritarianism. Mandating the COVID-19 vaccine thus threatens not only public health but also the future of science."[53]

[53] Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

53. Universities can be leaders in developing sensible policies grounded in sound scientific evidence and abide by the fundamental principles of medical ethics. Individuals who have recovered from COVID-19 should be exempt from any vaccine mandates and treated as in an identical position to those who have been vaccinated.

Respectfully submitted,

Dr. Jay Bhattacharya, MD, Ph.D.
Professor of Medicine
Stanford University

Dr. Martin Kulldorff, Ph.D.
Professor of Medicine
Harvard University

Exhibit O

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

JEANNA NORRIS, KRAIG EHM, and D'ANN ROHRER, individually and on behalf of all others similarly situated, *et al.*, *Plaintiffs,* v. SAMUEL STANLEY, et al. *Defendants*.	Civil Action No.: 21-cv-00756-PLM

DECLARATION OF DR. JAYANTA BHATTACHARYA SUPPORTING PLAINTIFFS

I, Dr. Jayanta Bhattacharya, declare as follows:

1. I am an adult of sound mind and make this statement voluntarily, based upon my own personal knowledge, education, and experience.

2. Based on my training and experience, I have formed an opinion on the reasonableness of the requested accommodations and on the possibility of other accommodations not listed to a reasonable degree of scientific certainty.

EXPERIENCE & CREDENTIALS

3. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine and a research associate at the National Bureau of Economic Research. I am also Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 154 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed

scientific literature more than 11,600 times. My curriculum vitae is attached to this declaration as Exhibit A.

4. I have dedicated my professional career to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions. I have both studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). I am intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

5. My assessment of vaccine immunity is based on studies related to the efficacy and safety of the one vaccine to receive full approval from the Food and Drug Administration (FDA) and the two vaccines that the FDA has granted Emergency Use Authorization (EUA) for use in the United States. These include two mRNA-technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus-vector vaccine technology (manufactured by Johnson & Johnson). Of those, the Pfizer vaccine, also known as Comirnaty, has full FDA approval.

6. I have not and will not receive any financial or other compensation to prepare this Declaration or to testify in this case. Nor have I received compensation for preparing declarations or reports or for testifying in *any* other case related to the COVID-19 pandemic, or any personal or research funding from any pharmaceutical company. My participation here has been motivated solely by my commitment to public health, just as my participation in other cases has been.

7. I have no prior relationship with any of the plaintiffs.

8. I have been asked to provide my opinion on several matters related to Michigan State University's vaccine policy for its employees, including the following:

- Whether, based on the current medical and scientific knowledge, immunity after COVID recovery (sometimes referred to as natural immunity) is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;
- Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity;
- An assessment of the comparative safety to recipients of administering vaccines to those who have natural immunity relative to immunologically naïve recipients with no prior history of COVID infection;
- Whether vaccines pose any risks to individuals with certain medical conditions;
- The safety of providing accommodations to those who have recovered from COVID; and
- What those accommodations could look like in practice.

9. My opinions are partly summarized in a recent article I published and which I reaffirm here: "[R]ecovered COVID patients have strong long-lasting protection against severe disease if reinfected, and evidence about protective immunity after natural infection is at least as good as from the vaccines. Hence, it makes no sense to require vaccines for recovered patients. For them, it simply adds a risk, however small, without any benefit."[1]

10. I also offer my opinion that certain individuals may face heightened risk of vaccine side effects. Though the vaccines are safe for most patients, the FDA has identified a heightened risk of myocarditis and pericarditis after vaccination with the mRNA vaccines – especially for

[1] Kulldorff, M., & Bhattacharya, J. (2021, June 17). The ill-advised push to vaccinate the young. *The Hill.*

young men. It has also identified a heightened risk of clotting abnormalities in young women taking the adenovirus vector vaccine. Even more importantly, the vaccine has not been thoroughly tested for safety and efficacy in patients with certain chronic conditions such as Multiple Sclerosis, so there is still considerable scientific uncertainty about these heightened risks for some patients.

11. I also conclude that MSU can safely accommodate COVID-recovered employees by exempting them from vaccine requirements since they possess better immunity via prior infection than a vaccinated worker who never had COVID possesses from vaccination. MSU could also safely accommodate those employees who have not previously been infected with from COVID-19 but have religious or medical reasons for not wanting the vaccine by requiring daily symptom checking paired with rapid antigen tests to confirm if a worker is infectious. To reduce the risk from asymptomatically infected workers, MSU can require workers to conduct weekly PCR or antigen tests, though if it adopts this accommodation, it would be best practice to require it of both vaccinated and unvaccinated employees since both groups can spread the virus asymptomatically. If implemented, these accommodations would keep MSU's campus as safe as possible from the risk of COVID infection, while preserving the employment of numerous MSU employees.

OPINIONS

I. Natural Immunity Provides Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected; COVID-19 Vaccines Provide Limited Protection Against Infection but Durable Protection Against Severe Outcomes if Infected.

12. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There is no reason to presume that vaccine immunity provides a higher level of protection than natural immunity. Since vaccines arrived one year after the disease, there is stronger evidence for long lasting immunity from natural infection than from the vaccines.

13. Both types are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibody levels in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.[2, 3] A Phase III trial showed 85% efficacy for the Johnson & Johnson adenovirus-based vaccine against severe disease.[4]

14. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells[5], bone marrow plasma cells[6], spike-specific neutralizing

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[2] Baden, L. R., El Sahly, H. M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S. A., Rouphael, N., Creech, C. B., McGettigan, J., Khetan, S., Segall, N., Solis, J., Brosz, A., Fierro, C., Schwartz, H., Neuzil, K., Corey, L., Zaks, T. for the COVE Study Group (2021). Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine*, *384*(5), 403-416. doi: 10.1056/NEJMoa2035389

[3] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W. Jr., Hammitt, L. L., Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine*, *387*(27), 2603-2615. doi: 10.1056/NEJMoa2034577

[4] Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P. A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K. L., Robb, M. L., Treanor, J., Barouch, D. H., Stoddard, J., Ryser, M. F., Marovich, M. A., Douoguih, M. for the ENSEMBLE Study Group. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *The New England Journal of Medicine*, *384*(23), 2187-2201. doi: 10.1056/NEJMoa2101544

[5] Dan, J. M., Mateus, J., Kato, Y., Hastie, K. M., Yu, E. D., Faliti, C. E., Grifoni, A., Ramirez, S. I., Haupt, S., Frazier, A., Nakao, C., Rayaprolu, V., Rawlings, S. A., Peters, B., Krammer, F., Simon, V., Saphire, E. O., Smith, D. M., Weiskopf, D., Crotty, S. (2021). Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science*, *371*, 1-13. doi: 10.1126/science.abf4063 (finding that memory T and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility in most individuals").

[6] Turner, J. S., Kim, W., Kalaidina, E., Goss, C. W., Rauseo, A. M., Schmitz, A. J., Hansen, L., Haile, A., Klebert, M. K., Pusic, I., O'Halloran, J. A., Presti, R. M. & Ellebedy, A. H. (2021). SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. *Nature*, *595*(7867), 421-425. doi: 10.1038/s41586-021-03647-4 (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Callaway, E. (2021, May 26). Had COVID? You'll probably make antibodies for a lifetime. *Nature*. https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

antibodies[7], and IgG+ memory B cells[8] following naturally acquired immunity.

15. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies overwhelmingly conclude that natural immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

16. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19[9] and show that the vast majority of reinfections are less severe than first-time

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[7] Ripperger, T. J., Uhrlaub, J. E., Watanabe, M., Wong, R., Castaneda, Y., Pizzato, H. A., Thompson, M. R., Bradshaw, C., Weinkauf, C. C., Bime, C., Erickson, H. L., Knox, K., Bixby, B., Parthasarathy, S., Chaudhary, S., Natt, B., Cristan, E., El Aini, T., Rischard, F., Bhattacharya, D. (2020). Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humor immunity. *Immunity*, *53*(5), 925-933. doi: 10.1016/j.immuni.2020.10.004 (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

[8] Cohen, K. W., Linderman, S. L., Moodie, Z., Czartoski, J., Lai, L., Mantus, G., Norwood, C., Nyhoff, L. E., Edara, V. V., Floyd, K., De Rosa, S. C., Ahmed, H., Whaley, R., Patel, S. N., Prigmore, B., Lemos, M. P., Davis, C. W., Furth, S., O'Keefe, J., McElrath, M. J. (2021). Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *medRxiv*, Preprint. (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

[9] Shrestha, N. K., Burke, P. C., Nowacki, A. S., Terpeluk, P. & Gordon, S. M. (2021). Necessity of COVID-19 vaccination in previously infected individuals. *medRxiv*, Preprint. doi: 10.1101/2021.06.01.21258176 ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study" and concluded that those with natural immunity are "unlikely to benefit from COVID-19 vaccination"); Perez, G., Banon, T., Gazit, S., Moshe, S. B., Wortsman, J., Grupel, D., Peretz, A., Tov, A. B., Chodick, G., Mizrahi-Reuveni, M., & Patalon, T. (2021). A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: A preliminary report. *medRxiv*, Preprint. doi: 10.1101/2021.03.06.21253051 (Israeli study finding that approximately 1/1000 of participants were reinfected); Bertollini, R., Chemaitelly, H., Yassine, H. M., Al-Thani, M. H., Al-Khal, A., & Abu-Raddad, L. J. (2021). Associations of vaccination and of prior infection with positive PCR test results for SARS-CoV-2 in airline passengers arriving in Qatar. *JAMA*, *326*(2), 185-188. doi: 10.1001/jama.2021.9970 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Pilz, S., Chakeri, A., Ioannidis, J. P. A., Richter, L., Theiler-Schwetz, V., Trummer, C., Krause, R., Allerberger, F. (2021). SARS-CoV-2 re-infection risk in Austria. *European Journal of Clinical Investigation*, *51*(4), 1-7. doi: 10.1111/eci.13520 (previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Breathnach, A. S., Duncan, C. J. A., El Bouzidi, K., Hanrath, A. T., Payne, B. A. I., Randell, P. A., Habibi, M. S., Riley, P. A., Planche, T. D., Busby, J. S., Sudhanva, M., Pallett, S. J. C. & Kelleher, W. P. (2021). Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies. *The Journal of Infection*, *83*(2), 237-279. doi: 10.1016/j.jinf.2021.05.024 (0.86% of previously infected population in London became reinfected); Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2*(7), 100355

infections.[10] For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided equivalent if not better protection than vaccine immunity in preventing COVID-19 infection, morbidity, and mortality.[11] Of the 187,549 unvaccinated persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age. Another study, analyzing data from Italy, found that only 0.31% of COVID-recovered patients experienced a reinfection within a year after the initial infection, despite the circulation of the Delta variant.[12] In summary, the overwhelming conclusion of the pertinent scientific literature is that natural immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

(an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered COVID patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

[10] Abu-Raddad, L. J., Chemaitelly, H., Coyle, P., Malek, J. A., Ahmed, A. A., Mohamoud, Y. A., Younuskunju, S., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Butt, A. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Yassine, H. M., Al Kuwari, M. G., Al Romaihi, H. E., Al-Thani, M. H., Al Khal, A., Bertollini, R. (2021). SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. *EClinicalMedicine*, *35*, 1-12. doi: 10.1016/j.eclinm.2021.100861 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Hall, V. J., Foulkes, S., Charlett, A., Atti, A., Monk, E. J. M., Simmons, R., Wellington, E., Cole, M. J., Saei, A., Oguti, B., Munro, K., Wallace, S., Kirwan, P. D., Shroti, M., Vusirikala, A., Rokadiya, S., Kall, M., Zambon, M., Ramsay, M., Hopkins, S. (2021). SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study. *The Lancet*, *397*(10283), 1459-1469. doi: 10.1016/S0140-6736(21)00675-9 (finding "a 93% lower risk of COVID-19 symptomatic infection… [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Hanrath, A. T., Payne, B., A., I., & Duncan, C. J. A. (2021). Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection. *The Journal of Infection*, *82*(4), e29-e30. doi: 10.1016/j.jinf.2020.12.023 (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

[11] Goldberg, Y., Mandel, M., Woodbridge, Y., Fluss, R., Novikov, I., Yaari, R., Ziv, A., Freedman, L., & Huppert, A. (2021). Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2.vaccine protection: A three-month nationwide experience from Israel. *medRxiv*, Preprint. doi: 10.1101/2021.04.20.21255670

[12] Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

17. Based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting. A survey article published on June 30, 2021, in the *British Medical Journal* concluded, "[t]here is reason to think that immunity could last for several months *or a couple of years*, at least, given what we know about other viruses and what we have seen so far in terms of antibodies in patients with COVID-19 and in people who have been vaccinated."[13]

18. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 epidemic.[14] A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.[15]

19. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, the researchers argue that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.[16]

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[13] Baraniuk, C. (2021). How long does covid-19 immunity last? *The British Medical Journal*, *373*, 1-3. doi: 10.1136/bmj.n1605 (emphasis added).

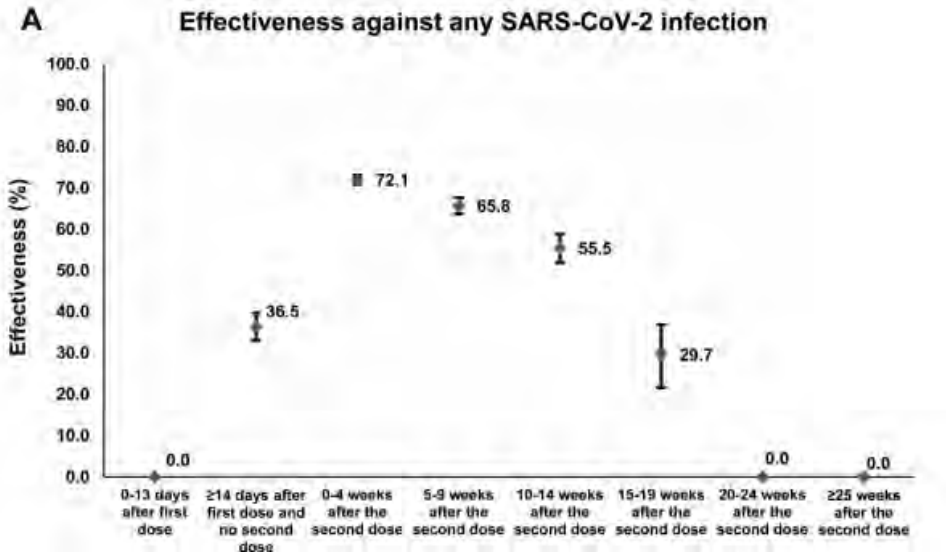
[14] Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. *Nature*, *584*, 457-462. doi: 10.1038/s41586-020-2550-z

[15] Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, *455*, 532-536. doi: 10.1038/nature07231

[16] Ledford, H. (2021). Six months of COVID vaccines: What 1.7 billion doses have taught scientists. *Nature*, *594*(7862), 164-167. doi: 10.1038/d41586-021-01505-x (study notes that "Six months is not much time to collect data on how durable vaccine responses will be. . . . In the meantime some researchers are looking to natural immunity as a guide.").

20. A recent study from Qatar by Chemaitelly and colleagues, which tracked 927,321 individuals for six months after vaccination, concluded that the Pfizer vaccine's "induced protection against infection appears to wane rapidly after its peak right after the second dose, but it persists at a robust level against hospitalization and death for at least six months following the second dose."[17]

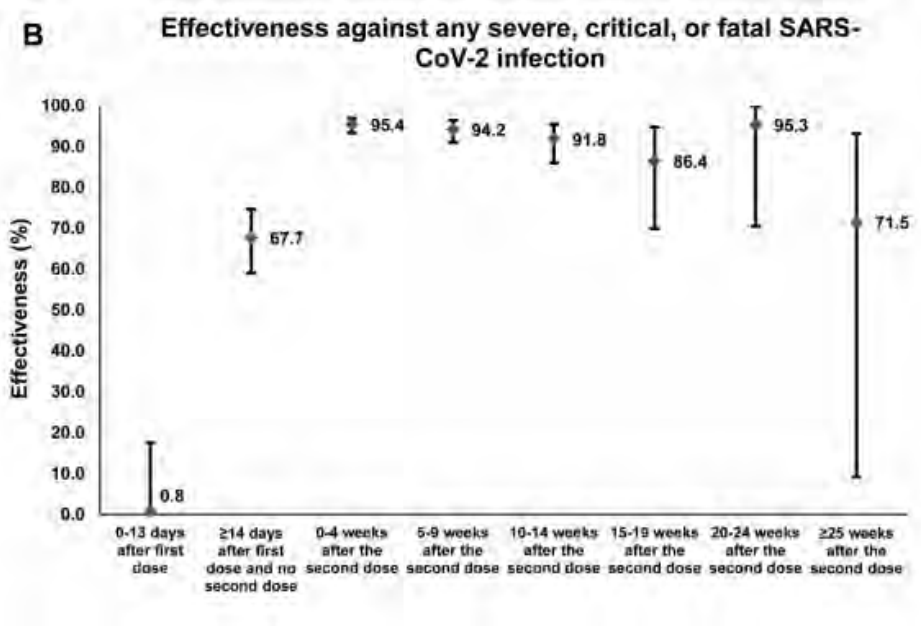
21. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine mediated protection against infection peaks at 72.1% zero to four weeks after the second dose, and then declines to 0%, 20 weeks after the second dose. According to this result, vaccines only protect against infection (and therefore disease spread) for a short period of time after the second dose of the mRNA vaccines.



22. On the other hand, Panel B shows that protection versus severe disease is long lasting after vaccination—even though the person will no longer be fully protected against infection and,

[17] Chemaitelly, H., Tang, P., Hasan, M. R., Al Mukdad, S., Yassine, H. M., Benslimane, F. M., Khatib, H. A. A., Coyle, P., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Kuwari, M. G. A., Romaihi, H. E. A., Abu-Raddad, L. J. (2021). Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar. *medRxiv*, Preprint. doi: 10.1101/2021.08.25.21262584

presumably, disease spread. At 20-24 weeks after the second dose, the vaccine remains 95.3% efficacious versus severe disease. While it appears to dip after 25 weeks to 71.5% efficacy, the confidence interval is so wide that it is consistent with no decrease whatsoever even after 25 weeks.



23. The Qatari study is no outlier. Another recent study documented declining vaccine efficacy in the first three months after vaccination against disease transmission in the era of the Delta variant.[18] Yet another study, conducted in Wisconsin, confirmed that vaccinated individuals can shed infectious SARS-CoV-2 viral particles.[19] The authors analyzed nasopharyngeal samples to check whether patients showed evidence of infectious viral particles. They found that vaccinated individuals were at least as likely as unvaccinated individuals to be shedding live virus. They concluded:

[18] Eyre, D. W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K. B., Walker, A. S. & Peto, T. E. A. (2021). The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *medRxiv*, Preprint. doi: 10.1101/2021.09.28.21264260

[19] Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Halfmann, P. J., Segaloff, H. E., Kocharian, A., Florek, K. R., Westergaard, R., Bateman, A., Jeppson, G. E., Kawaoka, Y., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Shedding of infectious SARS-CoV-2 despite vaccination. *medRxiv*, Preprint. doi: 10.1101/2021.07.31.21261387

> Combined with other studies these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons.

24. In summary, the evidence to date strong suggests that while vaccines—like natural immunity—provide protection against severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread. In short, there is no medical or scientific reason to believe that vaccine immunity will prove longer lasting than natural immunity, much less that all currently approved vaccines will be expected to prove more durable than natural immunity despite their different technological foundations and dosing protocols.

II. The Named Plaintiffs Have Naturally Acquired Immunity to COVID-19

25. I have examined the SARS-CoV-2 specific antibody lab results of Jeanna Norris, Kraig Ehm, and D'Ann Rohrer. There is no doubt that, based on recent testing, Ms. Norris, Mr. Ehm, and Ms. Rohrer show evidence of positive SARS-CoV-2 antibodies to both the spike protein and the nucleocapsid protein. The latter is not found in vaccinated individuals, but rather only in those who have previously been infected with the SARS-CoV-2 virus. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date (as I discuss in the previous section). From the point of view of Plaintiffs' personal health, there is no good reason that they should be vaccinated. At the very least, the decision should be left to Plaintiffs and their doctors without coercion applied by the University.

III. Vaccine Side Effects, Though Rare, Do Occur and Can Be Deadly.

26. Though the COVID vaccines are safe by the standards of many other vaccines approved for use in the population, like all medical interventions, they have side effects. In summarizing the evidence on vaccine side effects, the CDC lists both common side effects, at least one of which occurs in over half of all people who receive the vaccines, as well as deadly side effects that occur rarely in demographic subsets of the vaccinated population.

27. The common side effects include pain and swelling at the vaccination site and fatigue, headache, muscle pain, fever, and nausea for a limited time after vaccination.[20] Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur immediately after vaccination, which can typically be treated with an epinephrine injection.[21] Finally, the CDC's vaccine safety committee has identified rare but deadly side effects, including a heightened risk of clotting abnormalities[22] in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis[23] in young people—but especially young men—after mRNA vaccination, and higher risk of Guillane-Barre Syndrome[24] after the J&J vaccine. There is still the possibility of severe side-effects that have yet to be identified as the

[20] Centers for Disease Control and Prevention. (2021, September 30). *Possible side effects after getting a COVID-19 vaccine*. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

[21] Centers for Disease Control and Prevention. (2021, August 30). *What to do if you have an allergic reaction after getting a COVID-19 vaccine*. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html

[22] Kulldorff, M. (2021, April 17). The dangers of pausing the J&J vaccine. *The Hill*. https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine

[23] National Center for Immunization & Respiratory Diseases, Centers for Disease Control and Prevention. (2021, August 23). *Clinical considerations: Myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines among adolescents and young adults*. Retrieved October 1, 2021 from https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

[24] LaFraniere, S. & Weiland, N. (2021, July 12). FDA attaches warning of rare nerve syndrome to Johnson & Johnson vaccine. *The New York Times*. https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html

vaccines have been in use in human populations for less than a year. Active investigation to check for safety problems is still ongoing.

28. Though the CDC[25] still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts[26] have objected to overly rosy assumptions made in the CDC analysis about vaccine side effects. Those analysts suggest that the CDC's recommendation is fragile to minor perturbation in their assumptions. The critical point for my analysis—undisputed in the scientific literature—is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known now.

IV. The Risk of Those Side Effects Is Heightened In Certain Groups & Clinical Data on Vaccine Safety and Efficacy are Not Available for Patients with Certain Chronic Diseases.

29. The CDC lists two primary contraindications to COVID vaccination: (1) "severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine"; and (2) "immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine."[27] Among the inactive ingredients of the COVID vaccines, polyethylene glycol (PEG)—which is used in other drugs and vaccines—is most likely to induce an allergic reaction. In addition to contraindications, the CDC lists several precautions to vaccination, including known allergic reactions to polysorbate or PEG or to other

[25] Walensky, R. (2021, May 12). CDC director statement on Pfizer's use of COVID-19 vaccine in adolescents age 12 and older. *Center for Disease Control and Prevention*. Retrieved October 1, 2021 from https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html

[26] Pegden, W. (2021, June 24). Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses. *Medium.* https://medium.com/@wpegden?p=d7d6b3df7cfb

[27] National Center for Immunization & Respiratory Diseases, Centers for Disease Control and Prevention. (2021, September 27). *Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States*. Retrieved October 1, 2021 from https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

non-COVID vaccines and injectable therapies. Patients with precautions are encouraged to consult with an allergist or immunologist and to conduct an individualized risk assessment by the vaccination provider before getting the vaccine [28]

30. Some clinical evidence indicates that those who have recovered from COVID-19 could be at a *heightened* risk of adverse effects compared with those who have never had the virus.[29, 30] This may be because vaccine reactogenicity after the first dose is higher among those with prior immunity.[31] Despite this evidence, the CDC does not list prior immunity as a contraindication to vaccination, though it does recommend waiting 90 days after recovering before vaccination.

31. Though the CDC recommends the COVID vaccines for all adults, because they are novel—available for use in the population for only 9-10 months—there remain open questions about their use in special populations because they have not been tested in subgroups of patients with particular clinical conditions. For instance, in a comprehensive discussion of the biology of

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[28] Centers for Disease Control and Prevention. (2021, September 27). *Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States: Contraindications and precautions*. Retrieved Oct. 1, 2021 from https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#Contraindications

[29] Mathioudakis, A. G., Ghrew, M., Ustianowski, A., Ahmad, S., Borrow, R., Papavasileiou, L. P., Petrakis, D., & Bakerly, N. D. (2021). Self-reported real-world safety and reactogenicity of COVID-19 vaccines: A vaccine recipient survey. *Life*, *11*(3), 249. doi: 10.3390/life11030249

[30] Menni, C., Klaser, K., May, A., Polidori, L., Capdevila, J., Louca, P., Sudre, C. H., Nguyen, L. H., Drew, D. A., Merino, J., Hu, C., Selvachandran, S., Antonelli, M., Murray, B., Canas, L. S., Molteni, E., Graham, M. S., Modat, M., Joshi, A. D., Spector, T. D. (2021). Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: A prospective observational study. *The Lancet Infectious Diseases*, *21*(7), 939-949. doi: 10.1016/S1473-3099(21)00224-3 (finding that "Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 [i.e., AstraZeneca vaccine] and 2.9 times after the first dose of BNT162b2 [i.e., Pfizer/BioNTech vaccine]) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2).").

[31] Krammer, F., Srivastava, K., the PARIS team & Simon, V. (2021). Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a single dose of SARS-CoV-2 mRNA vaccine. *medRxiv*, Preprint. https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1 (concluding that "vaccine reactogenicity after the first dose is substantially more pronounced in individuals with pre-existing immunity." The authors note that "quantitative serological assays that measure antibodies to the spike protein could be used to screen individuals prior to vaccination," which would "limit the reactogenicity experienced by COVID-19 survivors.").

immune responses to vaccination (including COVID-19 vaccination) for patients with Multiple Sclerosis published in June 2021, Coyle et al. emphasize the lack of high-quality evidence available to guide recommendations for MS patients. They point out that three of six medical societies that focus on MS patients have failed to make a recommendation on whether MS patients should receive the COVID-19 vaccines. They and other authorities[32] emphasize the need for personalized decision making based on the clinical condition of the MS patient:[33]

> Currently, three COVID-19 vaccines have been granted emergency use authorization in the USA on the basis of promising interim findings of ongoing trials. Because analyses of these vaccines in people with MS are not available, decisions regarding COVID-19 vaccination and DMT choice should be informed by data and expert consensus, and personalized with considerations for disease burden, risk of infection, and other factors.

32. The paucity of data on the COVID-19 vaccine on patients with particular conditions is not limited to Multiple Sclerosis. Pregnant women were excluded from participating in the COVID-19 vaccination trials, consequently only limited randomized trial data are available about COVID-19 vaccine safety for that group.[34] Though the CDC and obstetrics focused specialty organizations nevertheless recommend COVID vaccination for pregnant women, many authors in peer reviewed journal articles have pointed to the lack of scientific data regarding vaccine safety in this group a problem for clinicians providing accurate advice to pregnant women.[35] Given this

[32] Ciotti, J. R., Valtcheva, M. V. & Cross, A. H. (2020). Effects of MS disease-modifying therapies on responses to vaccinations: A review. *Multiple Sclerosis Related Disorders*, *45*, 1-11. doi: 10.1016/j.msard.2020.102439

[33] Coyle, P. K., Gocke, A., Vignos, M. & Newsome, S. D. (2021). Vaccine considerations for multiple sclerosis in the COVID-19 era. *Advances in Therapy*, *38*(7), 3550-3588. doi:10.1007/s12325-021-01761-3

[34] Rasmussen, S. A., Kelley, C. F., Horton, J. P., & Jamieson, D. J. (2021). Coronavirus disease 2019 (COVID-19) vaccines and pregnancy: What obstetricians need to know. *Obstetrics & Gynecology*, *137*(3), 408-414. doi: 10.1097/AOG.0000000000004290 Erratum in: *Obstetrics & Gynecology*, *137*(5), 962. doi: 10.1097/AOG.0000000000004379

[35] Holness, N. A., Powell-Young, Y. M., Torres, E., DuBois, S., & Giger, J. N. (2021) Covid-19, pregnancy, and vaccinations. *Journal of National Black Nurses Association*, *32*(1), 1-9..

uncertainty, Nicola Volpe and her colleagues[36] writing in the *Journal of Perinatal Medicine* explicitly recommend that "Women should discuss with healthcare professionals about the benefits and risks of having the vaccine, allowing an informed decision." In recent months some observational studies have shown reassuring results, including that pregnant woman face no greater risk of complications during pregnancy or delivery,[37] or of spontaneous abortion or miscarriage after vaccination.[38] Nevertheless, there is still an area of active research where safety signals may still emerge. A large French study of vaccine safety in pregnancy expects to report complete results in late 2022.[39] After a thorough review of mostly reassuring data on the safety of the vaccine for pregnant women, Lydia Shook and some of her colleagues at Massachusetts General Hospital write that – given the recent introduction of the vaccine into use by pregnant women – it may be some time before full safety data become available:[40]

> Complete pregnancy outcomes data from people vaccinated in the first and early second trimesters are not yet available as most of these pregnancies are ongoing. Durability of IgG in the blood of neonates born to vaccinated mothers has not yet been defined, nor has whether the anti-SARS-CoV-2 IgG generated influences the response to other childhood vaccines. Information on postnatal outcomes and offspring development will require long term follow-up of children born to individuals who received the vaccine during pregnancy.

[36] Volpe, N., Luca Schera, G. B., Dall'Asta, A., Di Pasquo, E., & Ghi, T. (2021) COVID-19 in pregnancy: Where are we now? *Journal of Perinatal Medicine*, *49*(6), 637-642. doi: 10.1515/jpm-2021-0309.

[37] Theiler, R. N., Wick, M., Mehta, R., Weaver, A. L., Virk, A., & Swift, M. (2021). Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. *American Journal of Obstetrics & Gynecology MFM*, *3*(6), 100467. doi: 10.1016/j.ajogmf.2021.100467 Online ahead of print.

[38] Kharbanda, E. O., Haapala, J., DeSilva, M., Vazquez-Benitez, Vesco, K. K., Naleway, A. L., & Lipkind, H. S. (2021). Spontaneous abortion following COVID-19 vaccination during pregnancy. *JAMA*, e2115494. Online ahead of print. doi:10.1001/jama.2021.15494

[39] Cottin, J., Benevent, J., Khettar, S., & Lacroix, I. (2021). COVID-19 vaccines and pregnancy: What do we know? *Therapie*, *76*(4), 373-374. doi: 10.1016/j.therap.2021.05.011

[40] Shook, L. L., Fallah, P. N., Silberman, J. N., & Edlow, A. G. (2021) COVID-19 vaccination in pregnancy and lactation: Current research and gaps in understanding. *Frontiers in Cellular and Infection Microbiology*, *11*, 735394. doi: 10.3389/fcimb.2021.735394

33. There are also patients with particular genetic conditions where vaccine safety data are not adequate. For instance, for patients with alpha-1 antitrypsin deficiency (AATD), an inherited disorder that predisposes a patient to enzymatic tissue injuries and inflammation—especially in the lungs— there are no clinical data whatsoever regarding the safety and efficacy of the COVID-19 vaccines. Writing in *Lancet Respiratory Medicine*, Yang and Zhao hypothesize "individuals with AATD might derive limited benefit from the current COVID-19 vaccines." They note that "even though vaccination has been prioritised to more vulnerable populations (such as people with AATD), individuals with AATD are usually not included in clinical trials (as reported in ClinicalTrials.gov), and thus the effectiveness and adverse event profile of vaccination in this population are unknown."[41] The same can be said for other patients with many other chronic diseases, for whom the decision whether to vaccinate should be an individual decision made in consultation with their physicians, rather than coerced by a firm or the government.

V. Asymptomatic Disease Spread is Rare.

34. In this section, I discuss the evidence regarding the asymptomatic transmission of disease. This is important because if asymptomatic disease spread is rare, MSU can keep its campus safe from COVID disease spread by the simple expedient of requiring those who have not been vaccinated (and even those who have been) to report daily through an online app whether they are experiencing symptoms consistent with COVID-19. Those who are experiencing symptoms would be asked to stay at home from work or class and get tested; returning to campus only if the test is negative.

[41] Yang, C. & Zhao, H. (2021) COVID-19 vaccination in patients with α1-antitrypsin deficiency. *The Lancet, Respiratory Medicine*, *9*(8), 818-820. doi:10.1016/S2213-2600(21)00271-X

35. The best evidence on how frequently asymptomatic disease spread occurs comes from a large meta-analysis of 54 studies from around the world of within-household spread of the virus—that is, from an infected person to someone else living in the same home (Madewell et al. 2020). This study represents the most comprehensive survey of the vast empirical literature on asymptomatic spread. At home, *of course*, none of the safeguards often recommended in public spaces outside of home (such as masking and social distancing) are typically applied. Because the study focuses on a single setting (household transmission), it is not subject to the same problems that other studies on this topic might have. In particular, by focusing on a homogenous setting where few safeguards exist, the estimate represents an upper bound on the frequency that someone positive for the virus but with no symptoms (and hence either pre-symptomatic or asymptomatic) may spread the virus to close contacts. The primary result is that symptomatic patients passed on the disease to household members in 18% of instances. In comparison, those infected but without symptoms (asymptomatic and pre-symptomatic patients) passed on the infection to household members in only 0.7% of instances.[42]

36. There is some additional evidence on how frequently asymptomatic disease spread occurs. A large study of 10 million residents of Wuhan, China, all tested for the presence of the virus, found a total of 300 cases, all asymptomatic. A comprehensive contact tracing effort identified 1,174 close contacts of these patients, none of whom tested positive for the virus.[43] This is consistent with a vanishingly low level of asymptomatic spread of the disease. Given the late

[42] Madewell, Z. J., Yang, Y., Longini, I. M., Halloran, M. E. & Dean, N. E. (2020). Household transmission of SARS-CoV-2: A systematic review and meta-analysis. *JAMA Network Open*, *3*(12), 1-17. doi:10.1001/jamanetworkopen.2020.31756

[43] Cao, S., Gan, Y., Wang, C., Bachmann, M., Wei, S., Gong, J., Huang, Y., Wang, T., Li, L., Lu, K., Jiang, H., Gong, Y., Xu, H., Shen, X., Tian, Q., Lv, C., Song, F., Yin, X. & Lu, Z. (2020). Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. *Nature Communications*, *11*(1), 5917. doi: 10.1038/s41467-020-19802-w

date of the study relative to the date of the large first wave of infections in Wuhan, it is likely that none of the 300 asymptomatic cases were likely ever to develop symptoms. A separate, smaller meta-analysis similarly found that asymptomatic patients are much less likely to infect others than symptomatic patients.[44]

37. By contrast with asymptomatic patients, symptomatic patients are very likely to infect others with the virus during extended interactions, especially in the initial period after they develop symptoms. A careful review of 79 studies on the infectivity of COVID-19 patients found that even symptomatic patients are infectious for only the first eight days after symptom onset, with no evidence of live virus detected beyond day nine of illness.[45]

38. Much of the support for the idea that asymptomatic disease spread is common comes from theoretical modeling work from earlier in the epidemic (including some of my own published research[46]), predicting some level of asymptomatic disease spread. However, this sort of modeling work does not represent actual evidence that asymptomatic spread is common in the real world, since they rely on many modeling assumptions that are impossible to check.

39. There is at least one prominent real-world study that some have used to argue that asymptomatic disease spread is common. A meta-analytic study by Qiu et al. (2021) distinguishes the likelihood of disease spread by a pre-symptomatic individual from the likelihood of spread by

[44] Buitrago-Garcia, D., Egli-Gany, D., Counotte, M. J., Hossmann, S., Imeri, H., Ipekci, A. M., Salanti, G. & Low, N. (2020). Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: A living systematic review and meta-analysis. *PLOS Medicine*, *17*(9), e1003346. doi: 10.1371/journal.pmed.1003346

[45] Cevik, M., Tate, M., Lloyd, O., Maraolo, A. E., Schafers, J. & Ho, A. (2021). SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: A systematic review and meta-analysis. *The Lancet, Microbe*, *2*(1), e13-e22. doi: 10.1016/S2666-5247(20)30172-5

[46] Peirlinck, M., Linka, K., Costabal, F. S., Bhattacharya, J., Bendavid, E., Ioannidis, J. P. A. & Kuhl, E. (2020). Visualizing the invisible: The effect of asymptotic transmission on the outbreak dynamics of COVID-19. *Computer Methods in Applied Mechanics and Engineering*, *372*(1), 113140. doi: 10.1016/j.cma.2020.113410

an asymptomatic individual who never develops symptoms.[47] A primary finding of this study is that, while an asymptomatic individual who never develops symptoms is exceedingly unlikely to spread the disease, individuals who are not symptomatic now but will eventually develop symptoms are efficient at infecting others during their pre-symptomatic state.

40. Distinguishing between an infected individual who will eventually develop symptoms and an infected individual who will never develop symptoms is difficult without the passage of time. Infected individuals who will develop symptoms tend to do so within a very short interval (two to three days) after first becoming infected. Meanwhile, infected individuals who never develop symptoms may test positive with the PCR test for the virus for an extended period. These two groups of observationally identical individuals are mixed in the population in some unknown frequency that may change over time. Given this information constraint, from a policy point of view, the relevant question is how likely it is that an infected individual without symptoms (whether pre-symptomatic or purely asymptomatic) will spread the disease to close contacts. The Madewell et al. (2020) study provides an answer (less than 0.7% secondary attack rate in household settings), while the Qiu et al. (2021) study does not. Additionally, unlike the Madewell et al. (2020) study, the Qiu et al. (2021) study does not concentrate its focus on a homogenous environment (households), which makes the results it reports harder to interpret.

41. In summary, asymptomatic individuals are an order of magnitude less likely to infect others than symptomatic individuals, even in intimate settings such as people living in the same household where people are much less likely to follow social distancing and masking practices that they follow outside the household. Spread of the disease in less intimate settings by

[47] Qiu, X., Nergiz, A. I., Maraolo, A. E., Bogoch, I. I., Low, N. & Cevik, M. (2021). The role of asymptomatic and pre-symptomatic infection in SARS-CoV-2 transmission-A living systematic review. *Clinical Microbiology and Infection*, *27*(4), 511-519. doi: 10.1016/j.cmi.2021.01.011

asymptomatic individuals—including in the context of the MSU campus environment—is likely to be even less likely than in the household.

VI. There Are Multiple Safe Alternatives to Indefinite Leave or Termination that Can Be Offered to MSU Employees.

42. Can MSU keep those on campus safe if it does not mandate that all its employees (and students) be vaccinated? The answer is a definitive yes.

43. First and most obviously, MSU could adopt a robust sick policy, requiring that those who have not been vaccinated and who show symptoms consistent with COVID-19 infection stay at home from work, returning to work only once they have had a negative COVID-19 PCR or antigen test result. This could be implemented, for instance, by requiring workers to complete a symptom self-check each day before coming to work. MSU would provide employees and students with a supply of inexpensive rapid antigen tests, which are easy to self-administer at home, provide results within 30 minutes, and are highly accurate for detecting whether a patient is infectious.[48, 49] A large number of lateral flow antigen tests have received Emergency Use Authorization (EUA) by the US Food and Drug Administration.[50] Alternatively, MSU could require that any unvaccinated members of its campus obtain those tests themselves to keep its own costs down. Employees who report COVID-19 like symptoms would be asked to send a picture of their positive test result to their manager by phone or email to verify their result.[51] A system that required the

[48] Surasi, K., Cummings, K. J., Hanson, C., Morris, M. K., Salas, M., Seftel, D., Ortiz, L., Thilakaratne, R., Stainken, C. & Wadford, D. A. (2021). Effectiveness of Abbott BinaxNOW rapid antigen test for detection of SARS-CoV-2 infections in outbreak among horse racetrack workers, California, USA. *Emerging Infectious Diseases*, *27*(11).

[49] Homza, M., Zelena, H., Janosek, J., Tomaskova, H., Jezo, E., Kloudova, A., Mrazek, J., Svagera, Z. & Pymula, R. (2021). Covid-19 antigen testing: Better than we know? A test accuracy study. *Infectious Diseases*, *53*(9), 661-668. doi: 10.1080/23744235.2021.1914857

[50] US FDA. (2021) In-Vitro Diagnostics EUA – Antigen Diagnostic Tests for SARS-CoV-2. Oct. 4, 2021. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2 Accessed Oct. 10, 2021

[51] Indeed, if United's goal is really to prevent the spread of COVID-19 as much as reasonably possible, symptom checking should be required of all workers, whether vaccinated or not, since the evidence shows that vaccination

few employees who seek the vaccine exemption to provide this information to their manager each day before coming to work would be inexpensive – no online reporting system would be necessary.

44. For this symptom checking policy to be effective in reducing the risk of disease spread, it must be the case that symptomatic workers are substantially more likely to infect others than workers who are infected (that is, have evidence of the virus in the nasopharynx), but who have no symptoms. Fortunately, as we have seen in the previous section, the best empirical evidence shows that the probability that an asymptomatic individual will spread the disease is very low. And because the overwhelming majority of MSU employees will themselves be vaccinated, they face even less risk from any of their asymptomatic, unvaccinated coworkers who receive an accommodation from MSU for religious or medical reasons (including on the basis of naturally acquired immunity) of developing severe COVID symptoms.

45. Second, MSU could implement a program of weekly PCR or antigen testing as a condition of an employee's receiving an exemption. Many other organizations have implemented a testing regimen like this for all employees, including my home institution, Stanford University. Workers receiving an exemption could take the test in the workplace—there are versions of the test available that can be self-administered. Or workers could be required to purchase and take the test at home.[52]

46. Third, MSU could simply exempt from its vaccine requirement all employees who legitimately claim an exemption and have recovered from COVID infection. The evidence provided in this declaration shows that such employees pose at least as little—and likely less—

does not eliminate the possibility of infection and may provide less protection versus infection than immunity induced by prior COVID infection.

[52] Indeed, the safest option would be for both vaccinated and unvaccinated workers to be required to provide a weekly test, since both can have asymptomatic SARS-CoV-2 infections.

risk of spreading the SARS-CoV-2 virus than fully vaccinated workers who are not among the set of COVID-recovered patients.

47. While it is true that those who have recovered from COVID could incrementally reduce the infection risk they pose to other employees by *also* receiving the vaccine, it would make no sense for MSU to make this a requirement. For one thing, the incremental safety benefit of such a requirement would be vanishingly small. A study analyzing 738 patients in Kentucky and published in the CDC's journal (MMWR), estimated that the odds that COVID-recovered patients who are vaccinated are 2.34 [95% CI: 1.58-3.47] times lower for reinfection than COVID-recovered patients who are not vaccinated.[53] However, this reduction in the relative risk of reinfection represents a vanishingly small absolute risk reduction. Recall the study of Italian COVID-recovered patients that I cite above reported a reinfection rate of 0.3%, or 3 out of 1,000 after one year.[54] If the Kentucky study is right, vaccinating COVID recovered patients prevents on the order 2 infections out of a 1,000 people. This reduction can easily be replicated and improved upon without forced vaccination but with the symptom checking and regular testing solutions I suggest.

48. Moreover, the proper baseline for assessing the reasonableness of an exemption policy is not what kind of policy would produce the *maximum* reduction in risk, but rather what exemption options would reduce the risk posed by those receiving an exemption to a level below that posed by those complying with MSU's vaccination requirement. After all, MSUU is willing to tolerate the risk of infection posed by those who have received the vaccine—a risk that increases

[53] Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1081-1083. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e1

[54] Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

substantially a few months after vaccination, or those who have received vaccines such as the Sinovac vaccine, for which no phase 3 randomized clinical trial study has been published (a Sinovac randomized trial is due to be completed in February 2022.[55] If the objective were to reduce infection risk as much as humanly possible, MSU would have to require its *vaccinated* employees to find a way to contract COVID (and stay home until they recover)—since the combination of a vaccination and a prior COVID reduces infection risk compared to either alone. But MSU could not reasonably impose such a requirement, since an actual COVID infection would pose additional health risks to those who have been vaccinated. By the same risk/benefit logic—in light of the health risks posed by the vaccine itself—MSU cannot reasonably require those seeking an exemption who have recovered from COVID to also be vaccinated.

VII. Variants Do Not Alter the Conclusion that Accommodations Can Be Allowed Without Risk to Public Safety.

49. Since its spread through the human population, the SARS-CoV-2 virus—an RNA virus—has been mutating, including some forms that are likely more transmissible than the original wild-type virus that emerged from Wuhan, China, in 2019. As of the date of this declaration, the Delta variant is the dominant form of the SARS-CoV-2 virus worldwide. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that accommodations can be allowed without risk to public safety.

50. For one thing, the first two accommodations discussed above would be equally effective against variants as they are against the original Wuhan version. That is because all variants to arise thus far produce symptoms that can be checked for, and can be identified through standard COVID testing. So regular symptom-checking and/or testing for those receiving medical

[55] US National Library of Medicine. Clinical Trials.gov. An Effectiveness Study of the Sinovac's Adsorbed COVID-19 (Inactivated) Vaccine (Projeto S). https://clinicaltrials.gov/ct2/show/NCT04747821. Accessed 10/18/2021

or religious accommodations.

51. Variants likewise do not affect the reasonableness of the COVID-recovery alternative discussed above. The key point is that the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.[56, 57, 58] This is true of the Delta variant as well. In a study of a large population of patients in Israel, *vaccinated* people who had not been previously infected were 13 times more likely to experience a breakthrough infection with the Delta variant than patients who had recovered from COVID.[59] Although reinfection can occur, people who have been previously infected by the virus are unlikely to have a severe outcome (hospitalization or death) after exposure to a variant virus (see section I above for citations). A variant circulating in the population thus poses little additional risk of excess mortality due to viral infection.

52. The dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has partially decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still be infected but much less commonly have severe symptoms in response to infection. Throughout last year, a rise in cases was inevitably accompanied by an increase in deaths with a two-to-three-week lag.

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[56] Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2,* 100355.

[57] Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A. & Edwards, D. K. (2021). mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. *bioRxiv*, Preprint. doi: 10.1101/2021.01.25.427948

[58] Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T.C. & Tobian, A. A. (2021). $CD8^+$ T-cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants. *Open Forum Infectious Diseases 8*(7), ofab143.

[59] Gazit, S., Shlezinger, R., Perez, G., Lotan, R., Peretz, A., Ben-Tov, A., Cohen, D., Muhsen, K., Chodick, G. & Patalon, T. (2021). Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections. *medRxiv*, Preprint. doi: 10.1101/2021.08.24.21262415

However, during this most recent wave, in Sweden and the U.K., where vaccines have been provided to a large portion of the vulnerable elderly population and more, there have been "relatively few hospitalisations and deaths" in those countries.[60] Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are at least partially decoupled, so the public danger from the continuing spread of COVID-19 disease is less than it was last year when the vaccine was not available.

VIII. The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID Patients ("Long COVID") Does Not Alter the Conclusion that Accommodations Pose No Threat to Public Safety.

53. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify unyielding vaccine mandates. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.[61] One cross-sectional study found that about 30% of recovered COVID patients reported at least one symptom months after recovery, with fatigue and anosmia (loss of sense of smell) by far the most common.[62] A separate study with a more convincing longitudinal methodology, by contrast, concluded that only 2.3% of patients experienced such symptoms three months after recovery.[63] Patients who suffered a more severe

[60] Bhattacharya, J., Kulldorff, M. & Gupta, S. (2021, July 12). Sweden's lessons for the UK's third wave. *The Spectator*. https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting

[61] Nalbandian, A., Sehgal, K., Gupta, A., Madhavan, M. V., McGroder, C., Stevens, J. S., Cook, J. R., Nordvig, A. S., Shalev, D., Sehrawat, T. S., Ahluwalia, N., Bikdeli, B., Dietz, D., Der-Nigoghossian, C., Liyanage-Don, N., Rosner, G. F., Bernstein, E. J., Mohan, S., Beckley, A. A. & Wan, E. Y. (2021). Post-acute COVID-19 syndrome. *Nature Medicine*, *27*(4), 601-615. doi: 10.1038/s41591-021-01283-z

[62] Logue, J. K., Franko, N. M., McCulloch, D. J., McDonald, D., Magedson, A., Wolf, C. R., & Chu, H. Y. (2021). Sequelae in adults at 6 months after COVID-19 infection. *JAMA Network Open, 4*(2), e210830. doi: 10.1001/jamanetworkopen.2021.0830

[63] Sudre, C. H., Murray, B., Varsavsky, T., Graham, M. S., Penfold, R. S., Bowyer, R. C., Pujol, J. C., Klaser, K., Antonelli, M., Canas, L. S., Molteni, E., Modat, M., Cardoso, M. J., May, A., Ganesh, S., Davies, R., Nguyen, L. H., Drew, D. A., Astley, C. M., Steves, C. J. (2021). Attributes and predictors of long COVID. *Nature Medicine*, *27*(4), 626-631. doi: 10.1038/s41591-021-01292-y

acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.[64] A study of children who recovered from COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.[65] Some analysts have noted the similarity between "long COVID" symptoms and other functional somatic syndromes that sometimes occur after other viral infections and other triggers (and sometimes with no identifiable etiology).[66]

54. To summarize, as with other viruses, long COVID symptoms occur in a minority of patients who recover from COVID and pose a real burden on patients who suffer from it. However, this fact does not alter the logic of my point about accommodations. On the contrary. After suffering through a COVID infection, with or without long COVID, such individuals should not be forced to also endure common, but mild, vaccine adverse reactions or risk rare—but serious—adverse reactions. Moreover, the successful vaccine rollout in the United States—where every teenager and adult now have free access to the vaccines—addresses the problem of long COVID, just as it addresses COVID-associated mortality.

IX. The CDC's Recommendation for Vaccination of Recovered COVID Patients Applies with Equal Force to Those Who Have Been Previously Vaccinated, Whose Protection Against Infection Wanes Within a Few Months After Vaccination.

55. The CDC, in the Frequently Asked Questions (FAQ) section of its website encouraging

[64] Arnold, D. T., Hamilton, F. W., Milne, A., Morley, A. J., Viner, J., Attwood, M., Noel, A., Gunning, S., Hatrick, J., Hamilton, S., Elvers, K. T., Hyams, C., Bibby, A., Moran, E., Adamali, H. I., Dodd, J. W., Maskell, N. A., Barratt, S. L. (2021). Patient outcomes after hospitalisation with COVID-19 andimplications for follow-up: Results from a prospective UK cohort. *Thorax*, *76*, 399-401. doi: 10.1136/thoraxjnl-2020-216086

[65] Radtke, T., Ulyte, A., Puhan, M. A. & Kriemler, S. (2021). Long-term symptoms after SARS-CoV-2 infection in school children: Population-based cohort with 6-months follow-up. *JAMA*, *326*(9), 869-871. doi: 10.1001/jama.2021.11880

[66] Ballering, A., Olde Hartman, T. & Rosmalen, J. (2021). Long COVID-19, persistent somatic symptoms and social stigmatization. *Journal of Epidemiology and Community Health*, *75*, 603-604. doi: 10.1136/jech-2021-216643

vaccination, provides the following advice to previously recovered patients:[67]

> Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

56. The text of this advice by the CDC does not address any of the scientific evidence included here about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that I do not know how long natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will last for years.[68] Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID-recovered patients from vaccination mandates, since the same can be said about vaccine mediated immunity. I do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

57. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine breakthrough infections itself recognizes.[69] On the same CDC FAQ webpage I cite above,[70] the

[67] Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2019 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

[68] Patel, N. V. (2021, January 6). *Covid-19 immunity likely lasts for years*. MIT Technology Review. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/

[69] CDC COVID-19 Vaccine Breakthrough Case Investigations Team. (2021). COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. *Morbidity and Mortality Weekly Report (MMWR)*, *70*(21), 792-793. doi: http://dx.doi.org/10.15585/mmwr.mm7021e3

[70] Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

58. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who *already* has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the CDC's statement in the FAQ is irrelevant. Here again, the possibility of reinfection does not alter the conclusion that, especially for those who have already recovered from COVID, accommodations can be allowed without threatening public safety.

X. Conclusion

59. A fundamental ethical principle guiding the practice of medicine is that any medical intervention, whether surgical, pharmacological, or a vaccine, should be recommended and undertaken only if it is deemed medically necessary. Any medical procedure, including vaccination, involves risk. No medical procedure is 100% safe, especially those involving a new vaccine, which by definition has not been studied for long-term adverse side effects. For this reason, it is a fundamental principle of medical ethics that the risks of the procedure be balanced against the potential benefits.

60. As I established earlier, based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable (or more) as that acquired through vaccination. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date. There is no good reason for those who have such protection and who have sincere medical or religious objections to be

vaccinated. At the very least, the decision should be left to them, in conjunction with their doctors, and without coercion from their employers.

61. In sum, based on my analysis of the existing medical and scientific literature, any exemption policy that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.[71]

62. Indeed, now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is weaker than it once was. There is no good public health case for United Airlines to require proof of vaccination for employees who have recovered from COVID-19 and have a sincere medical or religious objection to vaccination. Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero. At the same time, natural immunity provides benefits that are at least as strong and may well be stronger than those from vaccines.

63. In conclusion, the emerging evidence from the medical literature finds that COVID-recovered patients have robust and long lasting immunity against SARS-CoV-2 reinfection; that this immunity against infection is better than vaccinated patients who have never had COVID; that the vaccines—though safe for most people—do sometimes cause known severe side effects; that for patients with particular chronic conditions, including Multiple Sclerosis, the data on the safety and efficacy of the vaccine is still uncertain; and finally, that there exist inexpensive safe

[71] Bhattacharya, J., Gupta, S. & Kulldorff, M. (2021, June 4). *The beauty of vaccines and natural immunity.* Smerconish Newsletter. https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity

accommodations that MSU can adopt which would protect both employees and customers against SARS-CoV-2 infection without terminating unvaccinated employees.

64. I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct this 18th day of October, 2021, at Stanford, California.

Respectfully submitted,

Dr. Jay Bhattacharya, MD, Ph.D.
Professor of Health Policy
Stanford University

EXHIBIT P

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 05, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

2nd Letter Subject: Final Response Letter

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 02, 2021, Freedom of Information Act (FOIA) request on September 02, 2021, seeking:

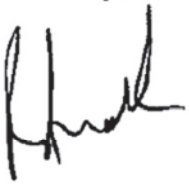
> "Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that this information is not collected.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by February 03, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

#21-02152-FOIA

Exhibit Q

STATE OF RHODE ISLAND
DEPARTMENT OF HEALTH

IN RE STEPHEN T. SKOLY, JR., DMD

DEPARTMENT OF HEALTH RESPONSE OT REQUEST FOR PRODUCTION BY RESPONDENT

The Rhode Island Department of Health provides the following response to Respondent's Request for Production of Documents:

1. All documents relied upon by the Director in her issuance of the Notice of Violation and Compliance Order dated October 1, 2021.

https://www.providencejournal.com/story/news/local/2021/09/30/cranston-dentist-defy-ri-vaccination-mandate/5934167001/

https://oceanstatecurrent.com/doctor-puts-it-all-on-the-line/

2. All documents of the Department of Health referencing Respondent from October 1, 2021 to present.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Without waiving this objection, the Department states that after internal inquiry, all documents and communications regarding Respondent after issuance of the Notice of Violation and Compliance Order were related to the legal proceeding and either generated by or directed to counsel. These materials are protected by the work product and/or attorney-client privilege. Without waiving this objection, Respondent is directed to the following:

https://www.providencejournal.com/story/news/local/2021/10/01/ri-dentist-nurse-who-defied-vaccine-mandate-still-had-jobs-friday/5948625001/

https://oceanstatecurrent.com/breaking-news-quick-pitch-update-doc-skoly-seeks-legal-action-on-ridoh-tyranny/

https://oceanstatecurrent.com/inthedugout-when-cancel-culture-intersects-with-politicized-pandemic-science/

3. All documents of the RI Department of any instance in which a person contracted and recovered from Covid, became re-infected with Covid, and, while reinfected, transmitted Covid to another person.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case.

4. All documents of the RI Department of Health of any instance in which a person received a Covid vaccine approved by the Department of Health, and, after receiving the vaccine, contracted Covid and transmitted Covid to another person.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case.

5. All documents of the RI Department of Health of any instance in which a person received a Covid vaccine approved by the RI Department of Health, and, subsequent to the vaccination, exhibited symptoms of Bells' Palsy or Guillain Barre.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Without waiving this objection, the Department is not aware of any Rhode Island resident reporting such symptoms to the

Department after vaccination.

6. All documents of the RI Department of Health, of anyone in Rhode Island been given a religious exemption from a Rhode Island Covid-vaccine mandate.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Without waiving this objection the Department states that Landmark Medical Center sought to allow unvaccinated health care workers into its facility and ceased doing so upon service of a Compliance Order by the Department.

7. All documents referencing compliance actions taken against any other health care worker or facility pursuant to the Emergency Regulation.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Furthermore, it calls for internal communications related to disciplinary actions, all of which include consultation with legal counsel and are protected by attorney client privilege. Without waiving this objection, see attached Notices of Violation and Compliance Orders.

8. All documents upon which you rely in denying an exemption for natural immunity to the vaccine mandate contained in the Emergency Regulation.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Without waiving this objection, the Department attaches the CDC MMWR Release of August 6, 2021, which provides evidence of the increased efficacy of vaccination as opposed to "acquired immunity."

9. All documents on the Department reflecting the infection rate of COVID-19 in dental

offices. Specifically included should be all documents relied upon by the Director to support her public statement that dental practices were lower priority on the vaccination list under the phase one of vaccination, and there was no significant spread in dental offices.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Specifically, the circumstances in August 2021 (no shortage of vaccines and the anticipated surge of the Delta variant) render any prior statements irrelevant.

10. Al documents referencing the "Advisory Committee on Immunization Practices (ACIP) guidelines and determined as acceptable by the facility," as reference in the Emergency Regulation.

Answer: The Department objects to this request on the grounds that it is not relevant to the subject matter involved in the pending action, it is unduly burdensome, and cannot lead to the discovery of admissible evidence in this case. Without waiving this objection, Respondent is referred to the Covid-19 Vaccination Guidance set forth at https://www.immunize.org/acip/#covid , all of which was consulted and adopted by the Department.

Rhode Island Department of Health
By its Attorney,

Bruce Todesco 12-31-21

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Rhode Island Department of Health
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bruce.todesco@health.ri.gov

CERTIFICATION OF SERVICE

I hereby certify that I transmitted the within document to Christy B. Durant, Esq., cdurant@qdlawri.com and Gregory P. Piccirilli, Esq., gregory@splawri.com on this 31st day of December, 2021.

Bruce Todesco