

**SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF JEFFERSON**

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In the Matter of the Application of  
DARBY L. GILLESPIE, Individually, and on behalf of all  
other Individuals similarly situated,

Petitioners,

Index No.: EF2021-0003447

For a Judgment Pursuant to Article 78 of the Civil Practice  
Law and Rules

Verified Petition  
(Amended)

Against

KATHY HOCHUL, in her Official  
Capacity as Governor of the State of New York,  
HOWARD ZUCKER, in his Former Official Capacity as  
Commissioner of the New York State Department of Health,  
MARY T. BASSETT, in her Official Capacity as Acting  
Commissioner of the New York State Department of Health,  
ATTORNEY GENERAL of the State of New York,  
and STATE OF NEW YORK,

Respondents.

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Petitioner, and all other Individuals similarly situated, through their attorneys, The  
Mermigis Law Group, P.C., as and for their Article 78 Petition against KATHY HOCHUL, in her  
Official Capacity as Governor of the State of New York, HOWARD ZUCKER, in his Former  
Official Capacity as Commissioner of the New York State Department of Health, MARY T.  
BASSETT, in her Official Capacity as Acting Commissioner of the New York State Department  
of Health, ATTORNEY GENERAL of the State of New York, and STATE OF NEW YORK, as  
set forth herein, respectfully state and allege, upon information and belief, as follows:

**PRELIMINARY STATEMENT**

1. This action is brought pursuant to Article 78 of the CPLR to vacate, void and annul Respondents' decision on August 26, 2021 to remove the religious exemption from the Vaccine Mandate which ordered the COVID-19 vaccination of the "personnel" of all "covered entities" in the field of medical and health services, including the Petitioner and those similarly situated and all the hospitals, clinics, or private practices with which they are associated.

2. Respondents' Order is fundamentally unfair, arbitrary and capricious, and constitutes an abuse of discretion. The Respondents have also assumed a legislative function and are preempted by Federal Law.

3. The legislature cannot surrender its power to make law to an unelected bureaucrat, by constitutional tradition in a republican form of government. This case is about whether the New York State Department of Health and its Commissioner can abolish representative government in the creation of public health laws, and whether it can authorize the removal of a constitutional right and/or First Amendment right based on the unfettered opinion of an unelected official.

4. On June 25, 2021, two months before his last day in office, Governor Cuomo finally rescinded his declaration of a "State disaster emergency"—fifteen months after it was issued— along with all the executive orders that followed. There is no longer a public health emergency in the State of New York.

5. Just days after the end of the Cuomo administration, solely on the pretext of what the DOH's Public Health and Health Planning Council ("the Health Council") deems "a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant," Zucker and the DOH, with the assistance of defendant Attorney General Letitia James and the approval of Governor Hochul as the State's unelected chief executive, are now enforcing the Health Council's proposed COVID-19 "emergency" regulation, the aforesaid Vaccine Mandate, on August 26, 2021.

6. The Vaccine Mandate orders the COVID-19 vaccination of the "personnel" of all "covered entities" in the field of medical and health services, including the Petitioner and those similarly situated and all the hospitals, clinics, or private practices with which they are associated. *See* Exhibit A to this Complaint and NYCRR, Title 10, Part 2, § 2.61 ("the Vaccine Mandate").

7. The Amended Vaccine Mandate *excludes any religious exemption from COVID-19 vaccination but permits medical exemptions*. Yet, only days before, the superseded Public Health Order issued in the waning days of the Cuomo administration (the "prior Health Order")—one of the few things he got right—provided a broad and indeed constitutionally required religious exemption:

Religious exemption. Covered entities *shall grant a religious exemption* for COVID-19 vaccination for covered personnel if they hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer. Covered entities shall document such exemptions and such reasonable accommodations in personnel records or other appropriate records in accordance with applicable privacy laws by September 27, 2021, and continuously, as needed, thereafter.

8. As pleaded more particularly below, the “Amended” Vaccine Mandate is “Arbitrary and Capricious” and an “Abuse of Discretion.”

9. With caution thrown to the winds, everyone—the young and healthy, the old, the previously recovered and naturally immune, even pregnant and breastfeeding women—is now being pressured by governments, businesses and educational institutions to submit to COVID 19 vaccination with no assessment of the risks or benefits for each individual or any consideration of medical necessity or contraindication in each particular case. Even the smallest children, at virtually no risk from the virus, are to be vaccinated as soon as a rushed approval can be obtained from the FDA.

10. The Respondents state, “Covid-19 Vaccines are safe and effective. They offer the benefit of helping to reduce the number of covid-19 infections, which is critical to protecting public health. Unvaccinated personnel have an unacceptable high risk of transmitting the virus to colleagues and patients.” *See* Exhibit A to this Complaint and NYCRR, Title 10, Part 2, § 2.61 (“the Vaccine Mandate”).

11. On August 5, 2021, CDC Director Dr. Rochelle Walensky told CNN’s Wolf Blitzer that **the Covid-19 vaccine cannot prevent the transmission of the disease.**

<https://www.thegatewaypundit.com/2021/08/cdc-director-tells-cnn-covid-vaccines-cant-prevent-transmission-video/>

BLITZER: But what about all the fully vaccinated people who get the breakthrough infection? Can they pass it on? Could they pass it on to their children? Could they pass the virus on to older people, especially more vulnerable people with underlying health conditions?

WALENSKY: And that's exactly the point that we made in our guidance.

So, yes, they can with the delta variant. And that was the reason that we changed our guidance last Tuesday. Our vaccines are working exceptionally well. They continue to work well with delta with regard to severe illness and death. They prevent it.

But what they can't do anymore is prevent transmission. So if you are going home to somebody who has not been vaccinated to somebody who can't get vaccinated, somebody who might be immunosuppressed or a little bit frail, somebody who has co-morbidities that put them at high risk, I would suggest you wear a mask in public indoor settings.

12. The Mandate excludes personnel who are covid recovered and have natural immunity even though having SARS-CoV-2 confers much greater immunity than a vaccine.

13. A recent study showed that natural immune protection after a SARS-CoV-2 infection offers a considerably more of a shield against the variants of the pandemic coronavirus than two doses of the Pfizer vaccine. See the "Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections" Study as Exhibit B.

14. In one analysis in the aforementioned study, comparing more than 32,000 people in the health system, the risk of developing symptomatic covid-19 was 27 times higher among the vaccinated, and the risk of hospitalization was eight times higher. See Study as Exhibit B.

15. "Recovered 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 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.” (Declaration of Dr. Martin Kuldorff and Dr. Jay Bhattacharya attached as Exhibit C, ¶ 15).

16. “There is no reason to presume that vaccine immunity provides a higher level of protection than natural immunity. There is stronger evidence for long lasting immunity from natural infection than from vaccines.” (Declaration of Dr. Martin Kuldorff and Dr. Jay Bhattacharya, ¶ 15).

17. A Hearing was initially scheduled for September 2, 2021 to give Petitioner and those similarly situated an opportunity to be heard. Petitioner and those similarly situated received an email that the Hearing was cancelled. Hearing was held and Petitioner and those similarly situated were never given an opportunity to be heard.

18. There was a hearing held on September 2, 2021 without Petitioner and those similarly situated and no testimony given by Petitioner and those similarly situated because they had been told that the Hearing was cancelled. As a result, the agency decision was made with no testimony and there was no administrative record.

19. Jeff Kraut, the Chair of the PHHPC on September 2, 2021 stated that, “*we will be collecting data*” and “*get the right data.*” This admission by the Chair of the PHHPC reveals that the agency decision was not based on any data, and therefore arbitrary and capricious or an abuse of discretion.

20. An Agency decision that removed a First Amendment constitutional right which was promulgated by an unelected health care commissioner that cost 30,000 health care workers their jobs was not based on any data.

**PARTIES**

18. Petitioner Darby L. Gillespie is a medical professional whose sincere religious beliefs compel her to refuse vaccination with the available COVID-19 vaccines, all of which employ aborted fetus cell lines in their testing, development, or production. Plaintiff is also covid-recovered and has natural immunity. Plaintiff resides in Jefferson County. Petitioner and those similarly situated were terminated from their employment in health care because of Respondents' Order without an opportunity to be heard while employees with medical exemptions were allowed to continue employment. Petitioner and those similarly situated also have natural immunity which has been shown to confer much greater immunity than the vaccine.

19. Respondent Kathy Hochul (Hochul) is Governor of the State of New York who, as the State's chief executive, is responsible for the execution of its laws and regulations, including the challenged vaccine mandate, and for the approval of all executive branch policies and directives, including those of the DOH pertaining to the vaccine mandate. At all pertinent times Hochul has acted and will act under color of state law. Defendant Hochul's principal place of business is located at the State Capitol Building, Albany, New York. She is sued in her official capacity.

20. Respondent Howard A. Zucker (Zucker) is the Former Commissioner of Health for the DOH. He is responsible for promulgation and enforcement of the challenged vaccine mandate. At all pertinent times Zucker has acted and will act under color of state law.

21. Respondent Mary T. Bassett (Bassett) is the Acting Commissioner of Health for the DOH. She is responsible for enforcement of the challenged vaccine mandate. At all pertinent times Bassett has acted and will act under color of state law.

22. The Attorney General for the State of New York is the State's highest-ranking law enforcement officer charged with overall supervision of the enforcement of the challenged vaccine mandate and other laws of the State of New York.

**CLASS ACTION ALLEGATIONS**

23. This action meets all the requirements of a class action under C.P.L.R. § 901.

24. The putative Class consists of all health care employees, who have been terminated from their employment because of Respondents' Order and their sincerely held religious beliefs. The putative Class continues to be permanently removed from their employment, with no return date in sight.

25. Excluded from the Class are Respondents.

26. While Petitioner does not know the exact number of the members of the Class, Plaintiff believes there are several hundred members.

27. The legality of the enforcement of the Order and in the continued enforcement of the Order constitute questions common to the Class, and predominates over any question affecting only individual members.

28. The claim to vacate, void and annul Respondents' decision on August 26, 2021 to remove the religious exemption from the Vaccine Mandate which ordered the COVID-19 vaccination of the "personnel" of all "covered entities" in the field of medical and health services, including the Petitioner and those similarly situated and all the hospitals, clinics, or private practices with which they are associated, as the Class representative, are typical of the



claims of the members of the Class. Petitioner and all members of the Class are similarly affected by Respondents' Order and their enforcement thereof.

29. Petitioner, as a class representative, will fairly and adequately protect the interests of the Class. Petitioner's claims arise out of the same common course of conduct giving rise to the claims of other members of the Class. Petitioner's interests are coincident with, and not antagonistic to, those of the other members of the Class. Petitioner is represented by counsel who is competent and experienced in the prosecution of Article 78 claims.

30. A class action is superior to any other method for the resolution of this dispute, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured gyms and fitness centers with a method of obtaining redress for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

31. The prosecution of separate actions by individual members of the Class would create a risk of inconsistent and varying adjudications, establishing incompatible standards of conduct for Respondents.

### **JURISDICTION AND VENUE**

32. Pursuant to 42 U.S.C. § 1983, this Court has jurisdiction to enforce the provisions of the United States Constitution.

33. Pursuant to authority vested in it by state law, this Court has jurisdiction to enforce the New York State Constitution and its statutes and to find and declare any unconstitutional either on its face or as applied.

34. Venue is proper in Jefferson County because Petitioner resides in Jefferson County, State of New York.

**COUNT I - PROCEDURAL DUE PROCESS and**  
**ABUSE OF DISCRETION**

34. Petitioner incorporates paragraphs 1-33 as if fully set forth herein.

35. “Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State ... subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress.” 42 U.S.C. § 1983.

36. The Due Process Clause of the Fourteenth Amendment to the U.S. Constitution provides that no State can “deprive any person of life, liberty, or property, without due process of law.” U.S. Const. amend. XIV, § 1, cl. 3.

37. The procedural component of the Due Process Clause prohibits government from depriving Petitioner and members of the putative Class of liberty and property interests without providing any process before or after the deprivations occurred.

38. To establish a procedural due process claim under 42 U.S.C. § 1983, Plaintiff and Class member must show that (1) they had a life, liberty, or property interest protected by the

Due Process Clause; (2) they were deprived of this protected interest; and (3) the state did not afford them adequate procedural rights. See *Daily Servs., LLC v. Valentino*, 756 F.3d 893, 904 (6th Circ. 2014).

39. Petitioner and the putative Class members have a protected liberty interest in the right to live without arbitrary governmental interference with their liberty and property interests. *County of Sacramento v. Lewis*, 523 U.S. 833, 845 (1988).

40. Liberty “denotes not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized . . . as essential to the orderly pursuit of happiness by free men.” *Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 572 (1972) (emphases added).

41. Petitioner and members of the putative Class have protected liberty and property interests, which Respondents infringed through the Order:

- a. Petitioner and those similarly situated have been denied their First Amendment Free Exercise of Religion rights by Respondents.

42. Respondents did not provide any procedural due process before issuing Order. Nor do Respondents provide any mechanism for post-deprivation review.

43. Respondents acted under color of State Law in an official capacity and within the scope of their official duties when issuing the Order.

44. As a direct and proximate cause of the failure to provide any pre- or post-deprivation process, Petitioner and members of the putative class suffered prejudice and were terminated from their employment.

45. By failing to provide any pre- or post-deprivation review of the order, Petitioner and members of the putative Class are suffering substantial losses of liberty and property.

46. The prejudice that Petitioner and members of the putative Class have suffered would not have occurred but for Respondents' deprivations of their liberty and property interests.

47. Petitioner and members of the putative Class seek a declaration that the Order violates the procedural component of the Due Process Clause, and an injunction against further infringements of their rights under this Clause as described in the Prayer for Relief.

**COUNT II. - SUBSTANTIVE DUE PROCESS  
AND ABUSE OF DISCRETION**

48. Petitioner incorporates paragraphs 1-47 as if fully set forth herein.

49. "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State ... subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress." 42 U.S.C. § 1983.

50. The Due Process Clause of the Fourteenth Amendment to the U.S. Constitution provides that no State can "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1, cl. 3.

51. The substantive component of the Due Process Clause prohibits government from taking action that “shocks the conscience” or “interferes with rights implicit in the concept of ordered liberty.” *United States v. Salerno*, 481 U.S. 739, 746 (1987) (cleaned up).

52. Petitioner and members of the putative Class have a protected liberty interest in the right to live without arbitrary governmental interference with its liberty and property interests. *County of Sacramento v. Lewis*, 523 U.S. 833, 845 (1988).

53. Liberty “denotes not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized . . . as essential to the orderly pursuit of happiness by free men.” *Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 572 (1972) (emphases added).

54. The Order shocks the conscience and interferes with Petitioner’s and members of the putative Class deeply-rooted liberty and property rights, including their free exercise of religion, the right to work, right to contract, and right to engage in commerce.

55. There is no compelling reason any longer since the virus is under control and that the State of Emergency is over to deprive Petitioner and members of the putative Class of their liberty and property interests and their First Amendment rights.

56. Respondents acted under color of State law in an official capacity and within the scope of their official duties when issuing the Order.

57. Petitioner and members of the putative Class seek a declaration that the Order violates the substantive component of the Due Process Clause, and an injunction against further infringements of their rights under this Clause as described in the Prayer for Relief.

**THIRD CLAIM FOR RELIEF  
Arbitrary and Capricious Under Article 78**

58. Petitioner repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Petition as though fully set forth herein.

59. Petitioner and those similarly situated commenced this special proceeding under CPLR §§ 3001 and 7803.

60. For the reasons set forth herein above, the Respondents' Order is unquestionably arbitrary and capricious under Article 78 of the CPLR.

61. Respondents' decision is unquestionably arbitrary and capricious under Article 78 of the CPLR because Respondent has declared that the State of Emergency in New York was over on June 24, 2021.

62. Removing the Religious Exemption while allowing Medical Exemptions is unquestionably Arbitrary and Capricious under Article 78 of the CPLR.

63. Respondents' continued deprivation of Petitioner's and those similarly situated rights and continued enforcement of the Order despite Petitioner and those similarly situated having natural immunity which is greater immunity than the vaccine is also arbitrary and capricious under Article 78 of the CPLR.

64. Respondents have no scientific or other credible evidence upon which to continue to enforce the Order.

65. The only demonstrable impact from Respondents' continued implementation and enforcement of the Order has been to inflict irreparable and continuing harm upon Petitioner and those similarly situated.

66. By reason of the foregoing, Respondents should be enjoined from further implementing the Order.

**FOURTH CLAIM OF RELIEF**  
**Abuse of Discretion under Article 78**

67. Petitioner repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Petition as though fully set forth herein.

68. Petitioner and those similarly situated commenced this special proceeding under CPLR §§ 3001 and 7803.

69. Respondents have inappropriately assumed a legislative function.

70. The Respondents have acted without legislative guidance.

71. Nowhere in Public Health Law is the Respondent Zucker bestowed with the authority the authority to make Law, or preempt the Constitution.

72. To allow such agency law making would result in laws being changed at the whim of everyone Commissioner who could then be said to be beholden to their appointor but also result in a lack of representative government.

73. It is clear that the removal of the religious exemption was promulgated without any substantive justification for the emergency adoption, and the only justification that Respondents offered was entirely conclusory.

74. Jeff Kraut, the Chair of the PHHPC on September 2, 2021 stated that, “*we will be collecting data*” and “*get the right data.*” This admission by the Chair of the PHHPC reveals that the agency decision was not based on any data, and therefore arbitrary and capricious or an abuse of discretion.

<https://totalwebcasting.com/view/?func=VIEW&id=nysdoh&date=2021-09-02&seq=1>

75. The Order did not meet the minimum requirements contained in State Administrative Procedure Act §§ 202.6(d) and 202.6(e).

76. There was no notice of proposed rule making pursuant to State Administrative Procedure Act § 202.1.

77. On August 30, 2021, many health care workers affected by the mandate who wanted to be heard in the public hearing were sent an email on August 30, 2021 which announced that the public hearing on September 2, 2021 was cancelled. (See Email attached as Exhibit A.)

78. The email was a misrepresentation because the Public Health and Health Planning Council Meeting was held on September 2, 2021.

<https://totalwebcasting.com/view/?func=VIEW&id=nysdoh&date=2021-09-02&seq=1>

79. By implementation and enforcement of the Order, the Respondents have also preempted the Federal and State Constitution by removing a religious right and violating Petitioner and those similarly situated Free Exercise of Religion rights.



80. By implementation and enforcement of the Order, the Respondents have also preempted Title VII of the Civil Rights Act as well as New York State Human Rights Law.

81. Respondents have no scientific or other credible evidence upon which to continue to enforce the Order.

82. The only demonstrable impact from Respondents' continued implementation and enforcement of the Order has been to inflict irreparable and continuing harm upon Petitioner and those similarly situated.

83. By reason of the foregoing, Respondents should be enjoined from further implementing the Order.

**WHEREFORE**, Petitioner and those similarly situated respectfully ask this Honorable Court to grant Petitioner and those similarly situated the following relief:

- A. Designation of this action as a class action;
- B. Designation of Petitioner as a representative Petitioner of all health care workers that have been unconstitutionally, arbitrarily and capriciously harmed by the Order; ;
- C. A declaratory judgment that the Order violates Petitioner's and Members of the Putative Class' constitutional rights as set forth in this Petition;

- D. A declaratory judgment that the Order is arbitrary and capricious and an abuse of discretion; and
- E. A declaratory judgment that Respondents' continued enforcement and extension of the Order is arbitrary and capricious under Article 78 of the C.P.L.R. and preliminarily during the pendency of this proceeding, and permanently thereafter, enjoining Respondents from enforcing the Order; and
- F. Enjoin Respondents from enforcing Order as an abuse of discretion; and
- G. Grant a preliminary injunction enjoining the enforcement and further extension of Order; and
- H. Award Petitioners their reasonable attorneys' fees, costs, and expenses under applicable state and or federal law; and
- I. Any other such further relief to which Petitioners may be entitled as a matter of law or equity, or which the Court determines to be just and proper.

Dated: Syosset, New York  
January 24, 2022

**THE MERMIGIS LAW GROUP, P.C.**  
*Attorneys for Petitioners*

/s/ James Mermigis

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**SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF JEFFERSON**

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Verification

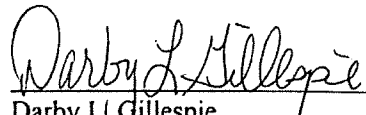
Against

KATHY HOCHUL, in her Official  
Capacity as Governor of the State of New York,  
HOWARD ZUCKER, in his Official Capacity as  
Commissioner of the New York State Department of Health,  
ATTORNEY GENERAL of the State of New York,  
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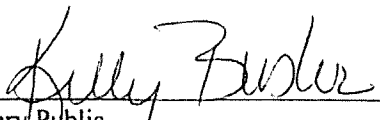
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STATE OF NEW YORK )  
COUNTY OF JEFFERSON ) ss.:

I, **DARBY L. GILLESPIE**, Petitioner, being duly sworn, deposes and says: I submit the  
attached Article 78 Petition, and know the contents thereof; that the same is true to the  
knowledge of deponent except as to the matters therein stated to be alleged upon information and  
belief, and as to those matters, I believe them to be true.

  
\_\_\_\_\_  
Darby L. Gillespie

Sworn to before me this 27<sup>th</sup> of  
January, 2022.

**KELLY BUSLER**  
NOTARY PUBLIC, STATE OF NEW YORK  
Registration No. 01BU6081449  
Qualified in Jefferson County  
My Commission Expires October 7, 2022

  
\_\_\_\_\_  
Notary Public

# **EXHIBIT “A”**

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended, to be effective upon filing with the Department of State, to read as follows:

*Part 2 is amended to add a new section 2.61, as follows:*

2.61. Prevention of COVID-19 transmission by covered entities.

(a) Definitions.

- (1) “Covered entities” for the purposes of this section, shall include:
  - (i) any facility or institution included in the definition of “hospital” in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;
  - (ii) any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;
  - (iii) hospices as defined in section 4002 of the Public Health Law; and
  - (iv) adult care facility under the Department’s regulatory authority, as set forth in Article 7 of the Social Services Law.

(2) “Personnel,” for the purposes of this section, shall mean all persons employed or affiliated with a covered entity, whether paid or unpaid, including but not limited to employees, members of the medical and nursing staff, contract staff, students, and volunteers, who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.

(3) “Fully vaccinated,” for the purposes of this section, shall be determined by the Department in accordance with applicable federal guidelines and recommendations. Unless otherwise specified by the Department, documentation of vaccination must include the manufacturer, lot number(s), date(s) of vaccination; and vaccinator or vaccine clinic site, in one of the following formats:

(i) record prepared and signed by the licensed health practitioner who administered the vaccine, which may include a CDC COVID-19 vaccine card;

(ii) an official record from one of the following, which may be accepted as documentation of immunization without a health practitioner’s signature: a foreign nation, NYS Countermeasure Data Management System (CDMS), the NYS Immunization Information System (NYSIIS), City Immunization Registry (CIR), a Department-recognized immunization registry of another state, or an electronic health record system; or

(iii) any other documentation determined acceptable by the Department.

(c) Covered entities shall continuously require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for all other covered entities absent receipt of an exemption as allowed below. Documentation of such vaccination shall be made in personnel records or other appropriate records in accordance with applicable privacy laws, except as set forth in subdivision (d) of this section.

(d) Exemptions. Personnel shall be exempt from the COVID-19 vaccination requirements set forth in subdivision (c) of this section as follows:

(1) Medical exemption. If any licensed physician or certified nurse practitioner certifies that immunization with COVID-19 vaccine is detrimental to the health of member of a covered entity's personnel, based upon a pre-existing health condition, the requirements of this section relating to COVID-19 immunization shall be inapplicable only until such immunization is found no longer to be detrimental to such personnel member's health. The nature and duration of the medical exemption must be stated in the personnel employment medical record, or other appropriate record, and must be in accordance with generally accepted medical standards, (see, for example, the recommendations of the Advisory Committee on Immunization Practices of the U.S. Department of Health and Human Services), and any reasonable accommodation may be granted and must likewise be documented in such record. Covered entities shall document medical exemptions in personnel records or other appropriate records in accordance with applicable privacy laws by: (i) September 27, 2021 for general hospitals and nursing homes; and (ii) October 7,



2021 for all other covered entities. For all covered entities, documentation must occur continuously, as needed, following the initial dates for compliance specified herein, including documentation of any reasonable accommodation therefor.

(e) Upon the request of the Department, covered entities must report and submit documentation, in a manner and format determined by the Department, for the following:

- (1) the number and percentage of personnel that have been vaccinated against COVID-19;
- (2) the number and percentage of personnel for which medical exemptions have been granted;
- (3) the total number of covered personnel.

(f) Covered entities shall develop and implement a policy and procedure to ensure compliance with the provisions of this section and submit such documents to the Department upon request.

(g) The Department may require all personnel, whether vaccinated or unvaccinated, to wear an appropriate face covering for the setting in which such personnel are working in a covered entity. Covered entities shall supply face coverings required by this section at no cost to personnel.

*Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 is added to read as follows:*

(vi) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 is added to read as follows:*

(5) collects documentation of COVID-19 or documentation of a valid medical exemption to such vaccination, for all personnel pursuant to section 2.61 of this title, in accordance with applicable privacy laws, and making such documentation immediately available upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (7) of subdivision (d) of Section 751.6 is added to read as follows:*

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (6) of subdivision (c) of Section 763.13 is added to read as follows:*

(6) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making

such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (7) of subdivision (d) of Section 766.11 is added to read as follows:*

(7) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (8) of subdivision (d) of Section 794.3 is added to read as follows:*

(8) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (v) of subdivision (q) of Section 1001.11 is added to read as follows:*

(v) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of this Title, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is added to read as follows:*

(18) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is added to read as follows:*

(14) documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

*Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is added to read as follows:*

(15) Operator shall collect documentation of COVID-19 vaccination or a valid medical exemption to such vaccination, pursuant to section 2.61 of Title 10, in accordance with applicable privacy laws, and making such documentation available immediately upon request by the Department, as well as any reasonable accommodation addressing such exemption.

## REGULATORY IMPACT STATEMENT

### Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010 (4). PHL 225(5) authorizes the Public Health and Health Planning Council (PHHPC) to issue regulations in the State Sanitary Code pertaining to any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises.

PHL Article 28 (Hospitals), Section 2800 specifies that “hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article.”

PHL Section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

PHL Section 3612 authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Section 4010 (4) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, with respect to hospice organizations.

Social Service Law (SSL) Section 461 requires the Department to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF). SSL Section 461 -e authorizes the Department to promulgate regulations to require adult care facilities to maintain certain records with respect to the facilities residents and the operation of the facility.

**Legislative Objectives:**

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL Article 40 declares that hospice is a socially and financially beneficial alternative to conventional

curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

**Needs and Benefits:**

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and 95 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide

reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

**Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:**

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, as well as any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

**Cost to State and Local Government:**

The State operates several healthcare facilities subject to this regulation. Most county health departments are licensed under Article 28 or Article 36 of the PHL and are therefore also subject to regulation. Similarly, certain counties and the City of New York operate facilities licensed under Article 28. These State and local public facilities would be required to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. They must also review and make determinations on requests for



medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations.

Although the costs to the State or local governments cannot be determined with precision, the Department does not expect these costs to be significant. State facilities should already be ensuring COVID-19 vaccination among their personnel, subject to State directives. Further, these entities are expected to realize savings as a result of the reduction in COVID-19 in personnel and the attendant loss of productivity and available staff.

**Cost to the Department of Health:**

There are no additional costs to the State or local government, except as noted above. Existing staff will be utilized to conduct surveillance of regulated parties and to monitor compliance with these provisions.

**Local Government Mandates:**

Covered entities operated by local governments will be subject to the same requirements as any other covered entity subject to this regulation.

**Paperwork:**

This measure will require covered entities to ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

**Duplication:**

This regulation will not conflict with any state or federal rules.

**Alternative Approaches:**

One alternative would be to require covered entities to test all personnel in their facility before each shift worked. This approach is limited in its effect because testing only provides a person's status at the time of the test and testing every person in a healthcare facility every day is impractical and would place an unreasonable resource and financial burden on covered entities if PCR tests couldn't be rapidly turned around before the commencement of the shift. Antigen tests have not proven as reliable for asymptomatic diagnosis to date.

Another alternative to requiring covered entities to mandate vaccination would be to require covered entities to mandate all personnel to wear a fit-tested N95 face covering at all times when in the facility, in order to prevent transmission of the virus. However, acceptable face coverings, which are not fit-tested N95 face coverings have been a long-standing requirement in these covered entities, and, while helpful to reduce transmission it does not prevent transmission

and; therefore, masking in addition to vaccination will help reduce the numbers of infections in these settings even further.

**Federal Requirements:**

There are no minimum standards established by the federal government for the same or similar subject areas.

**Compliance Schedule:**

These proposed emergency regulations will become effective upon filing with the Department of State and will expire, unless renewed, 90 days from the date of filing. As the COVID-19 pandemic is consistently and rapidly changing, it is not possible to determine the expected duration of need at this point in time. The Department will continuously evaluate the expected duration of these emergency regulations throughout the aforementioned 90-day effective period in making determinations on the need for continuing this regulation on an emergency basis or issuing a notice of proposed ruling-making for permanent adoption. This notice does not constitute a notice of proposed or revised rule making for permanent adoption.

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## REGULATORY FLEXIBILITY ANALYSIS

### **Effect on Small Business and Local Government:**

This regulation will not impact local governments or small businesses unless they operate a covered entity as defined in the proposed emergency regulation. Currently, 5 general hospitals, 79 nursing homes, 75 certified home health agencies (CHHAs), 20 hospices and 1,055 licensed home care service agencies (LHCSAs), and 483 adult care facilities (ACFs) are small businesses (defined as 100 employees or less), independently owned and operated affected by this rule. Local governments operate 19 hospitals, 137 diagnostic and treatment facilities, 21 nursing homes, 12 CHHAs, at least 48 LHCSAs, 1 hospice, and 2 ACFs.

### **Compliance Requirements:**

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

### **Professional Services:**

There are no additional professional services required as a result of this regulation.

**Compliance Costs:**

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

**Economic and Technological Feasibility:**

There are no economic or technological impediments to the rule changes.

**Minimizing Adverse Impact:**

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

**Small Business and Local Government Participation:**

Due to the emergent nature of COVID-19, small businesses and local governments were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

## RURAL AREA FLEXIBILITY ANALYSIS

### Type and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), “rural area” means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as “counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population ‘rural areas’ means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein.”

The following 42 counties have an estimated population of less than 200,000 based upon 2019 United States Census projections:

Allegany County	Greene County	Schuyler County
Broome	Hamilton County	Seneca County
Cattaraugus County	Herkimer County	St. Lawrence County
Cayuga County	Jefferson County	Steuben County
Chautauqua County	Lewis County	Sullivan County
Chemung County	Livingston County	Tioga County
Chenango County	Madison County	Tompkins County
Clinton County	Montgomery County	Ulster County
Columbia County	Ontario County	Warren County
Cortland County	Orleans County	
Delaware County	Schoharie County	

Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties of have population of 200,000 or greater, and towns with population densities of 150 person or fewer per square mile, based upon 2019 United States Census population projections:

Albany County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	
Monroe County	Orange County	

**Reporting, recordkeeping, and other compliance requirements; and professional services:**

Covered entities are required to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, along with any reasonable accommodations.

Upon the request of the Department, covered entities must report the number and percentage of total covered personnel, as well as the number and percentage that have been vaccinated against COVID-19 and those who have been granted a medical exemption, along with any reasonable accommodations. Facilities and agencies must develop and implement a policy



and procedure to ensure compliance with the provisions of this section, making such documents available to the Department upon request.

**Compliance Costs:**

Covered entities must ensure that personnel are fully vaccinated against COVID-19 and document such vaccination in personnel or other appropriate records. Covered entities must also review and make determinations on requests for medical exemptions, which must also be documented in personnel or other appropriate records, along with any reasonable accommodations. This is a modest investment to protect the health and safety of patients, residents, and personnel, especially when compared to both the direct medical costs and indirect costs of personnel absenteeism.

**Minimizing Adverse Impact:**

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department's understanding that many facilities across the State have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

**EXHIBIT A**

**Rural Area Participation:**

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted. If these regulations are proposed for permanent adoption, all parties will have an opportunity to provide comments during the notice and comment period.

## JOB IMPACT STATEMENT

### **Nature of Impact:**

Covered entities may terminate personnel who are not fully vaccinated and do not have a valid medical exemption and are unable to otherwise ensure individuals are not engaged in patient/resident care or expose other covered personnel.

### **Categories and numbers affected:**

This rule may impact any individual who falls within the definition of “personnel” who is not fully vaccinated against COVID-19 and does not have a valid medical exemption on file with the covered entity for which they work or are affiliated.

### **Regions of adverse impact:**

The rule would apply uniformly throughout the State and the Department does not anticipate that there will be any regions of the state where the rule would have a disproportionate adverse impact on jobs or employment.

### **Minimizing adverse impact:**

As part of ongoing efforts to address the COVID-19 pandemic, regulated parties have been a partner in implementing measures to limit the spread and/or mitigate the impact of COVID-19 within the Department since March of 2020. Further, the Department currently has an emergency regulation in place, which requires nursing homes and adult care facilities to offer COVID-19 vaccination to personnel and residents, which has helped to facilitated vaccination of personnel. Further, it is the Department’s understanding that many facilities across the State

**EXHIBIT A**

have begun to impose mandatory vaccination policies. Lastly, on August 18, 2021, President Biden announced that as a condition of participating in the Medicare and Medicaid programs, the United States Department of Health and Human Services will be developing regulations requiring nursing homes to mandate COVID-19 vaccination for workers.

## EMERGENCY JUSTIFICATION

The Centers for Disease Control and Prevention (CDC) has identified a concerning national trend of increasing circulation of the SARS-CoV-2 Delta variant. Since early July, cases have risen 10-fold, and 95 percent of the sequenced recent positives in New York State were the Delta variant. Recent New York State data show that unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have over 11 times the risk of being hospitalized with COVID-19.

The COVID-19 vaccines are safe and effective. They offer the benefit of helping to reduce the number of COVID-19 infections, including the Delta variant, which is a critical component to protecting public health. Certain settings, such as healthcare facilities and congregate care settings, pose increased challenges and urgency for controlling the spread of this disease because of the vulnerable patient and resident populations that they serve. Unvaccinated personnel in such settings have an unacceptably high risk of both acquiring COVID-19 and transmitting the virus to colleagues and/or vulnerable patients or residents, exacerbating staffing shortages, and causing unacceptably high risk of complications.

In response to this significant public health threat, through this emergency regulation, the Department is requiring covered entities to ensure their personnel are fully vaccinated against COVID-19, and to document evidence thereof in appropriate records. Covered entities are also required to review and make determinations on medical exemption requests, and provide reasonable accommodations therefor to protect the wellbeing of the patients, residents and personnel in such facilities. Documentation and information regarding personnel vaccinations as well as exemption requests granted are required to be provided to the Department immediately upon request.

Based on the foregoing, the Department has determined that these emergency regulations are necessary to control the spread of COVID-19 in the identified regulated facilities or entities. As described above, current circumstances and the risk of spread to vulnerable resident and patient populations by unvaccinated personnel in these settings necessitate immediate action and, pursuant to the State Administrative Procedure Act Section 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

# **EXHIBIT “B”**

## Title page

### **Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections**

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**The authors declare they have no conflict of interest.**

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## Abstract

### Background:

Reports of waning vaccine-induced immunity against COVID-19 have begun to surface. With that, the comparable long-term protection conferred by previous infection with SARS-CoV-2 remains unclear.

### Methods:

We conducted a retrospective observational study comparing three groups: (1) SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, (2) previously infected individuals who have not been vaccinated, and (3) previously infected *and* single dose vaccinated individuals. Three multivariate logistic regression models were applied. In all models we evaluated four outcomes: SARS-CoV-2 infection, symptomatic disease, COVID-19-related hospitalization and death. The follow-up period of June 1 to August 14, 2021, when the Delta variant was dominant in Israel.

### Results:

SARS-CoV-2-naïve vaccinees had a 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant ( $P < 0.001$ ) for symptomatic disease as well. When allowing the infection to occur at any time before vaccination (from March 2020 to February 2021), evidence of waning natural immunity was demonstrated, though SARS-CoV-2 naïve vaccinees had a 5.96-fold (95% CI, 4.85 to

7.33) increased risk for breakthrough infection and a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalizations compared to those that were previously infected.

### **Conclusions:**

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. Individuals who were both previously infected with SARS-CoV-2 and given a single dose of the vaccine gained additional protection against the Delta variant.

## Introduction

The heavy toll that SARS-CoV-2 infection has been taking on global health and healthcare resources has created an urgent need to estimate which part of the population is protected against COVID-19 at a given time in order to set healthcare policies such as lockdowns and to assess the possibility of herd immunity.

To date, there is still no evidence-based, long-term correlate of protection<sup>1</sup>. This lack of correlate of protection has led to different approaches in terms of vaccine resource allocation, namely the need for vaccine administration in recovered patients, the need for booster shots in previously vaccinated individuals or the need to vaccinate low-risk populations, potentially previously exposed.

The short-term effectiveness of a two-dose regimen of the BioNTech/Pfizer BNT162b2 mRNA COVID-19 vaccine was demonstrated in clinical trials<sup>2</sup> and in observational settings<sup>3,4</sup>. However, long term effectiveness across different variants is still unknown, though reports of waning immunity are beginning to surface, not merely in terms of antibody dynamics over time<sup>5-7</sup>, but in real-world settings as well<sup>8</sup>. Alongside the question of long-term protection provided by the vaccine, the degree and duration to which previous infection with SARS-CoV-2 affords protection against repeated infection also remains unclear. Apart from the paucity of studies examining long-term protection against reinfection<sup>9</sup>, there is a challenge in defining reinfection as opposed to prolonged viral shedding<sup>10</sup>. While clear-cut cases exist, namely two separate clinical events with two distinct sequenced viruses, relying solely on these cases will likely result in an under-estimation of the incidence of reinfection. Different criteria based on more widely-available information have been suggested<sup>11</sup>, the Centers for Disease Control and Prevention's (CDC) guidelines refer to two positive SARS-CoV-2 polymerase chain reaction (PCR) test results at least 90 days

apart.<sup>12</sup> Using similar criteria, population-based studies demonstrated natural immunity<sup>13,14</sup> with no signs of waning immunity for at least 7 months, though protection was lower for those aged 65 or older<sup>9</sup>.

The Delta (B.1.617.2) Variant of Concern (VOC), initially identified in India and today globally prevalent, has been the dominant strain in Israel since June 2021. The recent surge of cases in Israel<sup>15</sup>, one of the first countries to embark on a nationwide vaccination campaign (mostly with the BioNTech/Pfizer BNT162b2 vaccine), has raised concerns about vaccine effectiveness against the Delta variant, including official reports of decreased protection<sup>16</sup>. Concomitantly, studies have demonstrated only mild differences in short-term vaccine effectiveness<sup>17</sup> against the Delta variant, as well as substantial antibody response<sup>18</sup>. Apart from the variant, the new surge was also explained by the correlation found between time-from-vaccine and breakthrough infection rates, as early vaccinees were demonstrated to be significantly more at risk than late vaccinees<sup>8</sup>. Now, when sufficient time has passed since both the beginning of the pandemic and the deployment of the vaccine, we can examine the long-term protection of natural immunity compared to vaccine-induced immunity.

To this end, we compared the incidence rates of breakthrough infections to the incidence rates of reinfection, leveraging the centralized computerized database of Maccabi Healthcare Services (MHS), Israel's second largest Health Maintenance Organization.

## Methods

### *Study design and population*

A retrospective cohort study was conducted, leveraging data from MHS' centralized computerized database. The study population included MHS members aged 16 or older who were vaccinated prior to February 28, 2021, who had a documented SARS-CoV-2 infection by February 28, 2021, or who had both a documented SARS-CoV-2 infection by February 28, 2021 *and* received one dose of the vaccine by May 25, 2021, at least 7 days before the study period. On March 2, 2021, The Israeli Ministry of Health revised its guidelines and allowed previously SARS-CoV-2 infected individuals to receive one dose of the vaccine, after a minimum 3-month-interval from the date of infection

### *Data Sources*

Anonymized Electronic Medical Records (EMRs) were retrieved from MHS' centralized computerized database for the study period of March 1, 2020 to August 14, 2021.

MHS is a 2.5-million-member, state-mandated, non-for-profit, second largest health fund in Israel, which covers 26% of the population and provides a representative sample of the Israeli population. Membership in one of the four national health funds is mandatory, whereas all citizens must freely choose one of four funds, which are prohibited by law from denying membership to any resident. MHS has maintained a centralized database of EMRs for three decades, with less than 1% disengagement rate among its members, allowing for a comprehensive longitudinal medical follow-up. The centralized dataset includes extensive demographic data, clinical measurements, outpatient and hospital diagnoses and procedures, medications

dispensed, imaging performed and comprehensive laboratory data from a single central laboratory.

### *Data extraction and definition of the study variables*

#### *COVID-19-related data*

COVID-19-related information was captured as well, including dates of the first and second dose of the vaccine and results of any polymerase chain reaction (PCR) tests for SARS-CoV-2, given that all such tests are recorded centrally. Records of COVID-19-related hospitalizations were retrieved as well, and COVID-19-related mortality was screened for. Additionally, information about COVID-19-related symptoms was extracted from EMRs, where they were recorded by the primary care physician or a certified nurse who conducted in-person or phone visits with each infected individual.

#### *Exposure variable: study groups*

The eligible study population was divided into three groups: (1) fully vaccinated and SARS-CoV-2-naïve individuals, namely MHS members who received two doses of the BioNTech/Pfizer mRNA BNT162b2 vaccine by February 28, 2021, did not receive the third dose by the end of the study period and did not have a positive PCR test result by June 1, 2021; (2) unvaccinated previously infected individuals, namely MHS members who had a positive SARS-CoV-2 PCR test recorded by February 28, 2021 and who had not been vaccinated by the end of the study period; (3) previously infected *and* vaccinated individuals, including individuals who had a positive SARS-CoV-2 PCR test by February 28, 2021 and received one dose of the vaccine by May 25, 2021, at least 7 days before the study period. The fully vaccinated group was the comparison (reference) group in our study. Groups 2 and 3, were matched to the

comparison group 1 in a 1:1 ratio based on age, sex and residential socioeconomic status.

### *Dependent variables*

We evaluated four SARS-CoV-2-related outcomes, or second events: documented RT-PCR confirmed SARS-CoV-2 infection, COVID-19, COVID-19-related hospitalization and death. Outcomes were evaluated during the follow-up period of June 1 to August 14, 2021, the date of analysis, corresponding to the time in which the Delta variant became dominant in Israel.

### *Covariates*

Individual-level data of the study population included patient demographics, namely age, sex, socioeconomic status (SES) and a coded geographical statistical area (GSA, assigned by Israel's National Bureau of Statistics, corresponds to neighborhoods and is the smallest geostatistical unit of the Israeli census). The SES is measured on a scale from 1 (lowest) to 10, and the index is based on several parameters, including household income, educational qualifications, household crowding and car ownership. Data were also collected on last documented body mass index (BMI) and information about chronic diseases from MHS' automated registries, including cardiovascular diseases<sup>19</sup>, hypertension<sup>20</sup>, diabetes<sup>21</sup>, chronic kidney disease<sup>22</sup>, chronic obstructive pulmonary disease, immunocompromised conditions, and cancer from the National Cancer Registry<sup>23</sup>.

### *Statistical analysis*

Two multivariate logistic regression models were applied that evaluated the four aforementioned SARS-CoV-2-related outcomes as dependent variables, while the study groups were the main independent variables.

*Model 1—previously infected vs. vaccinated individuals, with matching for time of first event*

In model 1, we examined natural immunity and vaccine-induced immunity by comparing the likelihood of SARS-CoV-2-related outcomes between previously infected individuals who have never been vaccinated and fully vaccinated SARS-CoV-2-naïve individuals. These groups were matched in a 1:1 ratio by age, sex, GSA and time of first event. The first event (the preliminary exposure) was either the time of administration of the second dose of the vaccine *or* the time of documented infection with SARS-CoV-2 (a positive RT-PCR test result), both occurring between January 1, 2021 and February 28, 2021. Thereby, we matched the “immune activation” time of both groups, examining the long-term protection conferred when vaccination or infection occurred within the same time period. The three-month interval between the first event and the second event was implemented in order to capture reinfections (as opposed to prolonged viral shedding) by following the 90-day guideline of the CDC.

*Model 2*

In model 2, we compared the SARS-CoV-2 naïve vaccinees to unvaccinated previously infected individuals while intentionally *not* matching the time of the first event (i.e., either vaccination or infection), in order to compare vaccine-induced immunity to natural immunity, regardless of time of infection. Therefore, matching



was done in a 1:1 ratio based on age, sex and GSA alone. Similar to the model 1, either event (vaccination or infection) had to occur by February 28, to allow for the 90-day interval. The four SARS-CoV-2 study outcomes were the same for this model, evaluated during the same follow-up period.

### *Model 3*

Model 3 examined previously infected individuals vs. previously-infected-and-once-vaccinated individuals, using “natural immunity” as the baseline group. We matched the groups in a 1:1 ratio based on age, sex and GSA. SARS-CoV-2 outcomes were the same, evaluated during the same follow-up period.

In all three models, we estimated natural immunity vs. vaccine-induced immunity for each SARS-CoV-2-related outcome, by applying logistic regression to calculate the odds ratio (OR) between the two groups in each model, with associated 95% confidence intervals (CIs). Results were then adjusted for underlying comorbidities, including obesity, cardiovascular diseases, diabetes, hypertension, chronic kidney disease, cancer and immunosuppression conditions.

Analyses were performed using Python version 3.73 with the stats model package.

$P < 0.05$  was considered statistically significant.

### *Ethics declaration*

This study was approved by the MHS (Maccabi Healthcare Services) Institutional Review Board (IRB). Due to the retrospective design of the study, informed consent was waived by the IRB, and all identifying details of the participants were removed before computational analysis.

*Data availability statement*

According to the Israel Ministry of Health regulations, individual-level data cannot be shared openly. Specific requests for remote access to de-identified community-level data should be directed to KSM, Maccabi Healthcare Services Research and Innovation Center.

*Code availability*

Specific requests for remote access to the code used for data analysis should be referred to KSM, Maccabi Healthcare Services Research and Innovation Center.

## Results

Overall, 673,676 MHS members 16 years and older were eligible for the study group of fully vaccinated SARS-CoV-2-naïve individuals; 62,883 were eligible for the study group of unvaccinated previously infected individuals and 42,099 individuals were eligible for the study group of previously infected and single-dose vaccinees.

### *Model 1 – previously infected vs. vaccinated individuals, with matching for time of first event*

In model 1, we matched 16,215 persons in each group. Overall, demographic characteristics were similar between the groups, with some differences in their comorbidity profile (Table 1a).

During the follow-up period, 257 cases of SARS-CoV-2 infection were recorded, of which 238 occurred in the vaccinated group (breakthrough infections) and 19 in the previously infected group (reinfections). After adjusting for comorbidities, we found a statistically significant 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection as opposed to reinfection ( $P < 0.001$ ). Apart from age  $\geq 60$  years, there was no statistical evidence that any of the assessed comorbidities significantly affected the risk of an infection during the follow-up period (Table 2a).

As for symptomatic SARS-COV-2 infections during the follow-up period, 199 cases were recorded, 191 of which were in the vaccinated group and 8 in the previously infected group. Symptoms for all analyses were recorded in the central database within 5 days of the positive RT-PCR test for 90% of the patients, and included chiefly fever, cough, breathing difficulties, diarrhea, loss of taste or smell, myalgia, weakness, headache and sore throat. After adjusting for comorbidities, we found a 27.02-fold risk (95% CI, 12.7 to 57.5) for symptomatic breakthrough infection as

opposed to symptomatic reinfection ( $P<0.001$ ) (Table 2b). None of the covariates were significant, except for age  $\geq 60$  years.

Nine cases of COVID-19-related hospitalizations were recorded, 8 of which were in the vaccinated group and 1 in the previously infected group (Table S1). No COVID-19-related deaths were recorded in our cohorts.

*Model 2 –previously infected vs. vaccinated individuals, without matching for time of first event*

In model 2, we matched 46,035 persons in each of the groups (previously infected vs. vaccinated). Baseline characteristics of the groups are presented in Table 1a. Figure 1 demonstrates the timely distribution of the first infection in reinfected individuals.

When comparing the vaccinated individuals to those previously infected at any time (including during 2020), we found that throughout the follow-up period, 748 cases of SARS-CoV-2 infection were recorded, 640 of which were in the vaccinated group (breakthrough infections) and 108 in the previously infected group (reinfections). After adjusting for comorbidities, a 5.96-fold increased risk (95% CI, 4.85 to 7.33) increased risk for breakthrough infection as opposed to reinfection could be observed ( $P<0.001$ ) (Table 3a). Apart from SES level and age  $\geq 60$ , that remained significant in this model as well, there was no statistical evidence that any of the comorbidities significantly affected the risk of an infection.

Overall, 552 symptomatic cases of SARS-CoV-2 were recorded, 484 in the vaccinated group and 68 in the previously infected group. There was a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic breakthrough infection than symptomatic reinfection (Table 3b). COVID-19 related hospitalizations occurred in 4 and 21 of the reinfection and breakthrough infection groups, respectively. Vaccinated

individuals had a 6.7-fold (95% CI, 1.99 to 22.56) increased to be admitted compared to recovered individuals. Being 60 years of age or older significantly increased the risk of COVID-19-related hospitalizations (Table S2). No COVID-19-related deaths were recorded.

***Model 3 - previously infected vs. vaccinated and previously infected individuals***

In model 3, we matched 14,029 persons. Baseline characteristics of the groups are presented in Table 1b. Examining previously infected individuals to those who were both previously infected and received a single dose of the vaccine, we found that the latter group had a significant 0.53-fold (95% CI, 0.3 to 0.92) (Table 4a) decreased risk for reinfection, as 20 had a positive RT-PCR test, compared to 37 in the previously infected and unvaccinated group. Symptomatic disease was present in 16 single dose vaccinees and in 23 of their unvaccinated counterparts. One COVID-19-related hospitalization occurred in the unvaccinated previously infected group. No COVID-19-related mortality was recorded.

We conducted a further sub-analysis, compelling the single-dose vaccine to be administered *after* the positive RT-PCR test. This subset represented 81% of the previously-infected-and-vaccinated study group. When performing this analysis, we found a similar, though not significant, trend of decreased risk of reinfection, with an OR of 0.68 (95% CI, 0.38 to 1.21,  $P$ -value=0.188).

## Discussion

This is the largest real-world observational study comparing natural immunity, gained through previous SARS-CoV-2 infection, to vaccine-induced immunity, afforded by the BNT162b2 mRNA vaccine. Our large cohort, enabled by Israel's rapid rollout of the mass-vaccination campaign, allowed us to investigate the risk for additional infection – either a breakthrough infection in vaccinated individuals or reinfection in previously infected ones – over a longer period than thus far described.

Our analysis demonstrates that SARS-CoV-2-naïve vaccinees had a 13.06-fold increased risk for breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for a symptomatic disease as well.

Broadening the research question to examine the extent of the phenomenon, we allowed the infection to occur at any time between March 2020 to February 2021 (when different variants were dominant in Israel), compared to vaccination only in January and February 2021. Although the results could suggest waning natural immunity against the Delta variant, those vaccinated are still at a 5.96-fold increased risk for breakthrough infection and at a 7.13-fold increased risk for symptomatic disease compared to those previously infected. SARS-CoV-2-naïve vaccinees were also at a greater risk for COVID-19-related-hospitalization compared to those who were previously infected.

Individuals who were previously infected with SARS-CoV-2 seem to gain additional protection from a subsequent single-dose vaccine regimen. Though this finding corresponds to previous reports<sup>24,25</sup>, we could not demonstrate significance in our cohort.

The advantageous protection afforded by natural immunity that this analysis demonstrates could be explained by the more extensive immune response to the SARS-CoV-2 proteins than that generated by the anti-spike protein immune activation conferred by the vaccine<sup>26,27</sup>. However, as a correlate of protection is yet to be proven<sup>1,28</sup>, including the role of B-Cell<sup>29</sup> and T-cell immunity<sup>30,31</sup>, this remains a hypothesis.

Our study has several limitations. First, as the Delta variant was the dominant strain in Israel during the outcome period, the decreased long-term protection of the vaccine compared to that afforded by previous infection cannot be ascertained against other strains. Second, our analysis addressed protection afforded solely by the BioNTech/Pfizer mRNA BNT162b2 vaccine, and therefore does not address other vaccines or long-term protection following a third dose, of which the deployment is underway in Israel. Additionally, as this is an observational real-world study, where PCR screening was not performed by protocol, we might be underestimating asymptomatic infections, as these individuals often do not get tested.

Lastly, although we controlled for age, sex, and region of residence, our results might be affected by differences between the groups in terms of health behaviors (such as social distancing and mask wearing), a possible confounder that was not assessed. As individuals with chronic illness were primarily vaccinated between December and February, confounding by indication needs to be considered; however, adjusting for obesity, cardiovascular disease, diabetes, hypertension, chronic kidney disease, chronic obstructive pulmonary disease, cancer and immunosuppression had only a small impact on the estimate of effect as compared to the unadjusted OR. Therefore, residual confounding by unmeasured factors is unlikely.

This analysis demonstrated that natural immunity affords longer lasting and stronger protection against infection, symptomatic disease and hospitalization due to the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity. Notably, individuals who were previously infected with SARS-CoV-2 and given a single dose of the BNT162b2 vaccine gained additional protection against the Delta variant. The long-term protection provided by a third dose, recently administered in Israel, is still unknown.



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## Tables and figures

**Table 1a.** Characteristics of study population, model 1 and 2.

Characteristics	Model 1 – with matching of time of first event		Model 2 – without matching of time of first event	
	Previously infected (n=16,215)	Vaccinated individuals (n=16,215)	Previously infected (n=46,035)	Previously infected and vaccinated (n =46,035)
<b>Age years, mean (SD)</b>	36.1 (13.9)	36.1 (13.9)	36.1 (14.7)	36.1 (14.7)
<b>Age group – no. (%)</b>				
16 to 39 yr	9,889 (61.0)	9,889 (61.0)	28,157 (61.2)	28,157 (61.2)
40 to 59 yr	5,536 (34.1)	5,536 (34.1)	14,973 (32.5)	14,973 (32.5)
≥60 yr	790 (4.9)	790 (4.9)	2,905 (6.3)	2,905 (6.3)
<b>Sex – no. (%)</b>				
Female	7,428 (45.8)	7,428 (45.8)	22,661 (49.2)	22,661 (49.2)
Male	8,787 (54.2)	8,787 (54.2)	23,374 (50.8)	23,374 (50.8)
<b>SES, mean (SD)</b>	5.5 (1.9)	5.5 (1.9)	5.3 (1.9)	5.3 (1.9)
<b>Comorbidities – no. (%)</b>				
Hypertension	1,276 (7.9)	1,569 (9.7)	4,009 (8.7)	4,301 (9.3)
CVD	551 (3.4)	647 (4.0)	1,875 (4.1)	1,830 (4.0)
DM	635 (3.9)	877 (5.4)	2,207 (4.8)	2,300 (5.0)
Immunocompromised	164 (1.0)	420 (2.6)	527 (1.1)	849 (1.8)
Obesity (BMI ≥30)	3,076 (19.0)	3,073 (19.0)	9,117 (19.8)	8,610 (18.7)
CKD	196 (1.2)	271 (1.7)	659 (1.4)	814 (1.8)
COPD	65 (0.4)	97 (0.6)	218 (0.5)	292 (0.6)
Cancer	324 (2.0)	636 (3.9)	1,044 (2.3)	1,364 (3.0)

SD – Standard Deviation; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD – Cardiovascular Diseases; DM – Diabetes Mellitus; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

**Table 1b.** Characteristics of study population, model 3.

Characteristics	Previously infected (n=14,029)	Previously infected and single dose vaccinated (n=14,029)
<b>Age years, mean (SD)</b>	33.2 (14.0)	33.2 (14.0)
<b>Age group – no. (%)</b>		
16 to 39 yr	9543 (68.0)	9543 (68.0)
40 to 59 yr	3919 (27.9)	3919 (27.9)
≥60 yr	567 (4.0)	567 (4.0)
<b>Sex – no. (%)</b>		
Female	7467 (53.2)	7467 (53.2)
Male	6562 (46.8)	6562 (46.8)
<b>SES, mean (SD)</b>	4.7 (1.9)	4.7 (1.9)
<b>Comorbidities</b>		
Hypertension	892 (6.4)	1004 (7.2)
CVD	437 (3.1)	386 (2.8)
DM	529 (3.8)	600 (4.3)
Immunocompromised	127 (0.9)	145 (1.0)
Obesity (BMI ≥30)	2599 (18.5)	2772 (19.8)
CKD	137 (1.0)	162 (1.2)
COPD	30 (0.2)	53 (0.4)
Cancer	241 (1.7)	267 (1.9)

SD – Standard Deviation; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD – Cardiovascular Diseases; DM – Diabetes Mellitus; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

**Table 2a. OR for SARS-CoV-2 infection, model 1, previously infected vs. vaccinated**

Variable	Category	$\beta$	OR	95%CI	P-value
<b>Induced Immunity</b>	Previously infected	Ref			
	Vaccinated	2.57	13.06	8.08 – 21.11	<0.001
<b>SES</b>		0.04	1.04	0.97 – 1.11	0.251
<b>Age group, yr.</b>	16-39	Ref			
	40-59	0.05	1.05	0.78 - 1.4	0.751
	≥60	0.99	2.7	1.68 – 4.34	<0.001
<b>Sex</b>	Female	Ref			
	Male	-0.03	0.97	0.76 – 1.25	0.841
<b>Comorbidities</b>	Obesity (BMI≥30)	0.01	1.01	0.73 – 1.39	0.967
	Diabetes mellitus	-0.36	0.7	0.39 – 1.25	0.229
	Hypertension	0.1	1.11	0.72 – 1.72	0.641
	Cancer	0.37	1.44	0.85 – 2.44	0.171
	CKD	0.53	1.7	0.83 – 3.46	0.146
	COPD	-0.46	0.63	0.15 – 2.66	0.529
	Immunosuppression	-0.1	0.91	0.42 – 1.97	0.803
	Cardiovascular diseases	0.26	1.3	0.75 – 2.25	0.343

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.



**Table 2b. OR for Symptomatic SARS-CoV-2 infection, model 1, previously infected vs. vaccinated**

Variable	Category	$\beta$	OR	95%CI	P-value
<b>Induced Immunity</b>	Previously infected	Ref			
	Vaccinated	3.3	27.02	12.7 – 57.5	<0.001
<b>SES</b>		0.04	1.04	0.96 – 1.12	0.312
<b>Age group, yr.</b>	16-39	Ref			
	40-59	0.19	1.21	0.88 – 1.67	0.25
	≥60	1.06	2.89	1.68 – 4.99	<0.001
<b>Sex</b>	Female	Ref			
	Male	-0.19	0.82	0.62 – 1.1	0.185
<b>Comorbidities</b>	Obesity (BMI≥30)	0.02	1.02	0.71 – 1.48	0.899
	Diabetes mellitus	-0.31	0.73	0.37 – 1.43	0.361
	Hypertension	0.12	1.13	0.69 – 1.85	0.623
	Cancer	0.37	1.45	0.8 – 2.62	0.217
	CKD	0.1	1.1	0.42 – 2.87	0.846
	COPD	-0.78	0.46	0.06 – 3.41	0.445
	Immunosuppression	-0.37	0.69	0.25 – 1.89	0.468
	Cardiovascular diseases	0.03	1.03	0.52 – 2.03	0.941

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

**Table 3a. OR for SARS-CoV-2 infection, model 2, previously infected vs. vaccinated**

Variable	Category	$\beta$	OR	95%CI	P-value
<b>Induced Immunity</b>					
	Previously infected	Ref			
	Vaccinated	1.78	5.96	4.85 – 7.33	<0.001
<b>SES</b>		0.07	1.07	1.03 – 1.11	<0.001
<b>Age group, yr.</b>					
	16-39	Ref			
	40-59	0.06	1.06	0.9 – 1.26	0.481
	≥60	0.79	2.2	1.66 – 2.92	<0.001
<b>Sex</b>					
	Female	Ref			
	Male	-0.01	0.99	0.85 - 1.14	0.842
<b>Comorbidities</b>					
	Obesity (BMI≥30)	0.12	1.13	0.94 – 1.36	0.202
	Diabetes mellitus	-0.15	0.86	0.61 – 1.22	0.4
	Hypertension	-0.12	0.89	0.67 – 1.17	0.402
	Cancer	0.2	1.22	0.85 – 1.76	0.283
	CKD	0.3	1.35	0.85 – 2.14	0.207
	COPD	0.48	1.62	0.88 – 2.97	0.121
	Immunosuppression	-0.03	0.98	0.57 – 1.66	0.925
	Cardiovascular diseases	0.08	1.09	0.77 – 1.53	0.638

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary

Disease.

**Table 3b. OR for Symptomatic SARS-CoV-2 infection, model 2, previously infected vs. vaccinated**

Variable	Category	$\beta$	OR	95%CI	P-value
<b>Induced Immunity</b>					
	Previously infected	Ref			
	Vaccinated	1.96	7.13	5.51 – 9.21	<0.001
<b>SES</b>		0.07	1.07	1.02 – 1.12	0.003
<b>Age group, yr.</b>					
	16-39	Ref			
	40-59	0.09	1.1	0.9 – 1.33	0.35
	≥60	0.8	2.23	1.61 – 3.09	<0.001
<b>Sex</b>					
	Female	Ref			
	Male	-0.02	0.98	0.82 – 1.16	0.785
<b>Comorbidities</b>					
	Obesity (BMI≥30)	0.16	1.18	0.95 – 1.46	0.133
	Diabetes mellitus	-0.11	0.89	0.61 – 1.32	0.571
	Hypertension	-0.01	0.99	0.72 – 1.35	0.943
	Cancer	0.08	1.09	0.7 – 1.69	0.71
	CKD	0.13	1.14	0.65 – 1.98	0.654
	COPD	0.5	1.65	0.82 – 3.31	0.162
	Immunosuppression	0	1	0.54 – 1.85	0.999
	Cardiovascular diseases	0	1	0.67 – 1.5	0.99

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10; CVD –

Cardiovascular Diseases; CKD – Chronic Kidney Disease; COPD – Chronic Obstructive Pulmonary Disease.

**Table 4a.** OR for SARS-CoV-2 infection, model 3, previously infected vs. previously infected and single-dose-vaccinated

Variable	Category	$\beta$	OR	95%CI	P-value
<b>Induced Immunity</b>					
	Previously infected	Ref			
	Previously infected and vaccinated	-0.64	0.53	0.3 – 0.92	0.024
<b>SES</b>		0.11	1.12	0.98 – 1.28	0.096
<b>Age group, yr.</b>					
	16-59	Ref			
	$\geq 60$	-0.81	0.44	0.06 – 3.22	0.422
<b>Comorbidities</b>					
	Immunosuppression	0.72	2.06	0.28 – 15.01	0.475

SES – Socioeconomic status on a scale from 1 (lowest) to 10

**Table 4b.** OR for Symptomatic SARS-CoV-2 infection, model 2, previously infected vs. previously infected and vaccinated

Variable	Category	$\beta$	OR	95%CI	P-value
<b>Induced Immunity</b>					
	Previously infected	Ref			
	Previously infected and vaccinated	-0.43	0.65	0.34 – 1.25	0.194
<b>SES</b>		0.06	1.06	0.9 – 1.24	0.508
<b>Age group, yr.</b>					
	16-59	Ref			
	$\geq 60$	-16.9	0	0.0 – inf	0.996
<b>Comorbidities</b>					
	Immunosuppression	1.15	3.14	0.43 – 23.01	0.26

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10.

**Table S1. OR for COVID-19-related hospitalizations, model 1, previously infected vs. vaccinated**

Variable	Category	$\beta$	OR hospitalized	95%CI	P-value
<b>Induced Immunity</b>					
	Previously infected	Ref			
	Vaccinated	2.09	8.06	1.01 – 64.55	0.049
<b>SES</b>		0.05	1.05	0.72 – 1.53	0.81
<b>Age <math>\geq 60</math> yrs (16-39, ref)</b>		5.08	160.9	19.91 – 1300.44	<0.001

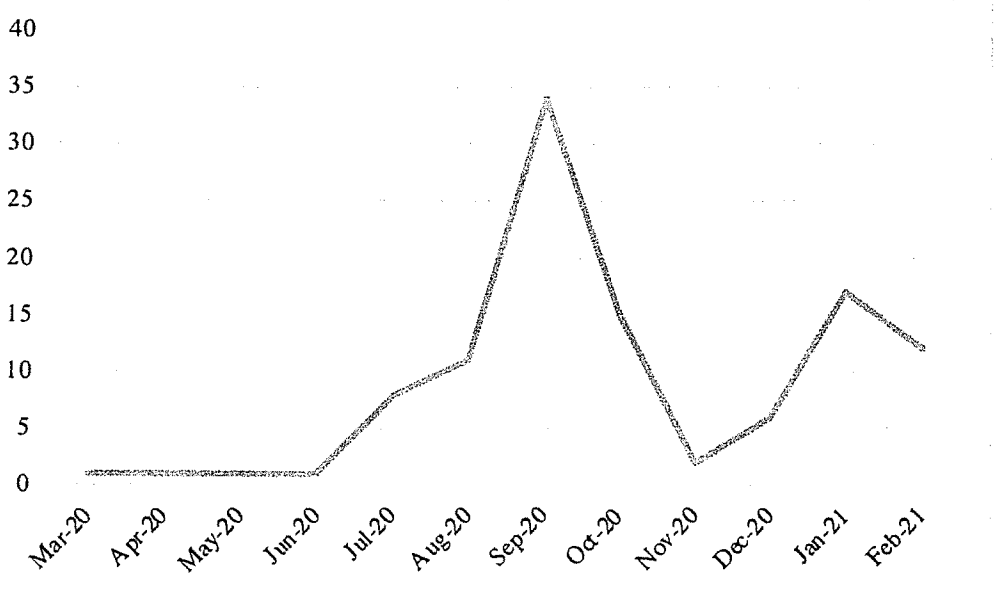
OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10

**Table S2. OR for COVID-19-related hospitalizations, model 2, previously infected vs. vaccinated**

Variable	Category	$\beta$	OR hospitalized	95%CI	P-value
<b>Induced Immunity</b>					
	Previously infected	Ref			
	Vaccinated	1.95	7.03	2.1 – 23.59	0.002
<b>SES</b>		-0.07	0.93	0.74 – 1.17	0.547
<b>Age <math>\geq 60</math> yrs (16-39, ref)</b>		4.3	73.5	25.09 – 215.29	<0.001

OR – Odds Ratio; SES – Socioeconomic status on a scale from 1 (lowest) to 10

Figure 1. Time of first infection in those reinfected between June and August 2021, model 2.



**EXHIBIT “C”**



**Joint Declaration of Dr. Jayanta Bhattacharya and Dr. Martin Kulldorff**

We, Drs. Jayanta (“Jay”) Bhattacharya and Martin Kulldorff provide the following Joint Declaration:

**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 monitoring of vaccines and other medical health and safety issues. His methods are routinely used by the Centers for Disease Control and Prevention (“CDC”) and other public health agencies around the world.

3. Both of us have dedicated our professional careers to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy 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 Professor Zywicki.

8. We have been asked to provide our opinion on several matters related to George Mason University’s (GMU or University) vaccine policy for faculty and staff (the “mandatory vaccination” policy), 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 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.”<sup>1</sup>

**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 fundamental parameter necessary to understand the lack of net public health benefits from vaccine mandates and passports. 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

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<sup>1</sup> Martin Kulldorff 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?r=1>.

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%.<sup>2</sup> A newly released meta-analysis by scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.<sup>3</sup>

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 vanishingly small risk.<sup>4</sup> 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.<sup>5</sup> 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*)<sup>6</sup> provides a detailed age breakdown of the infection survival rate in a preprint

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<sup>2</sup> Ioannidis JPA, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, BULL WORLD HEALTH ORGAN (Jan 1, 2021).

<sup>3</sup> 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/3gpIolV>.

<sup>4</sup> 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/>.

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

<sup>6</sup> 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/3187S13>.

companion paper<sup>7</sup>: 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.

#### **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 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.

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.<sup>8,9</sup> A Phase III trial

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<sup>7</sup> 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/>.

<sup>8</sup> 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).

<sup>9</sup> 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,

showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.<sup>10</sup>

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<sup>11</sup>, bone marrow plasma cells<sup>12</sup>, spike-specific neutralizing antibodies<sup>13</sup>, and IgG+ memory B cells<sup>14</sup> following naturally acquired immunity.

18. 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).

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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).

<sup>10</sup> 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.

<sup>11</sup> 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”).

<sup>12</sup> 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”).

<sup>13</sup> 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).

<sup>14</sup> 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”).

19. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19<sup>15</sup> and show that the vast majority of reinfections are less severe than first-time infections.<sup>16</sup> 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.<sup>17</sup> 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

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<sup>15</sup> 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 proportion 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 Bertolini, 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 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> (.086% of previously infected population in London became reinfected); Alison Tarke, *Negligible impact of SARS-CoV-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).

<sup>16</sup> 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. Hanrahan, 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).

<sup>17</sup> 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>.

over 80 years of age. 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.

20. 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.”<sup>18</sup>

21. 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.<sup>19</sup> 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.<sup>20</sup>

22. 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.<sup>21</sup>

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<sup>18</sup> Chris Baranjk, *How long does covid-19 immunity last?* 373 *BMJ* (2021) (emphasis added).

<sup>19</sup> Nina Le Bert, *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control*, *NATURE* (Aug. 2020).

<sup>20</sup> Xiaocong Yu, et al., *Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors*, *NATURE* (2008).

<sup>21</sup> Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses have 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. 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.

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

24. 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.

25. 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.<sup>22</sup> 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 if it occurs.<sup>23</sup> Finally, the CDC's vaccine safety committee has identified rare but deadly side effects, including a heightened risk of clotting abnormalities<sup>24</sup> in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis<sup>25</sup> in young people — but especially young men — after mRNA vaccination, and higher risk of

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<sup>22</sup> 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>.  
<sup>23</sup> 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>.  
<sup>24</sup> 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>.  
<sup>25</sup> 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>.

Guillane-Barre Syndrome<sup>26</sup> 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.

26. Though the CDC<sup>27</sup> still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts<sup>28</sup> 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.

27. Some clinical evidence indicates that those who have recovered from COVID-19 could have a *heightened* risk of adverse effects compared with those who have never had the virus.<sup>29 30</sup> This may be because vaccine reactogenicity after the first dose is higher among those with prior immunity.<sup>31</sup>

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<sup>26</sup> LaFraniar 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>.

<sup>27</sup> 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>.

<sup>28</sup> Pegden, *Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses* (June 24, 2021), <https://medium.com/@wpegden?p=d7d6b3df7cfc>.

<sup>29</sup> 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).

<sup>30</sup> 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).”).

<sup>31</sup> Florian Krammer, et al., *Robust spike antibody responses and increased reactogenicity in seropositive individuals after a single 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.”).

## Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

28. 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 for young people is unwarranted.

29. First, the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.<sup>32,33,34</sup> Although reinfection can occur, people who have been previously infected by the wild-type (non-variant) virus are unlikely to have a severe outcome (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.

30. 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.<sup>35</sup> While this hypothesis awaits a definitive empirical test, it is consistent with the *prima facie* evidence on mutant variants' development.

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<sup>32</sup> 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>.

<sup>33</sup> 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>.

<sup>34</sup> 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>.

<sup>35</sup> 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/>.

31. 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<sup>36</sup>, 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.

32. 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 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.<sup>37</sup> Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are now effectively decoupled.

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<sup>36</sup> US Centers for Disease Control, *US COVID-19 Cases Caused by Variants* (2021), <https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html>.

<sup>37</sup>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>.

**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**

33. 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.<sup>38</sup> 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.<sup>39</sup> A separate study with a more convincing longitudinal methodology, by contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.<sup>40</sup> Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.<sup>41</sup> 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.<sup>42</sup> 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).<sup>43</sup>

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<sup>38</sup> 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>.

<sup>39</sup> 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.

<sup>40</sup> 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>.

<sup>41</sup> 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).

<sup>42</sup> 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>.

<sup>43</sup> Ballering A, Olde Hartman T, Rosmalen J Long COVID-19, *persistent somatic symptoms and social stigmatization*, J EPIDEMIOLOG COMMUNITY HEALTH (2021).

34. 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 contrary. After suffering through COVID, 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 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**

35. The CDC, in a frequently asked questions section of a website encouraging vaccination, provides the following advice to previously recovered patients:<sup>44</sup>

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.

36. The text of this advice by the CDC does not address any of 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 lasting natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will

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<sup>44</sup> US Centers for Disease Control (2021) Frequently Asked Questions About COVID-19 Vaccination. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

last for years.<sup>45</sup> 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. 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.

37. 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.<sup>46</sup> On the same CDC FAQ webpage we cite above<sup>47</sup>, the CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

38. 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 non-responsive, and ignores the scientific evidence.

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<sup>45</sup> 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/>

<sup>46</sup> 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>

<sup>47</sup> US Centers for Disease Control (2021) Frequently Asked Questions About COVID-19 Vaccination. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

## Conclusion

39. 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.

40. 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 Professor Zywicki's case, there is no doubt that, based on recent measures of his antibody levels and his history of prior COVID infection, he is protected by natural immunity (Dr. Bhattacharya has examined the results from Prof. Zywicki's laboratory tests). 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 from the point of view of Professor Zywicki's personal health that he should be vaccinated. At the very least, the decision should be left to Professor Zywicki and his doctors without coercion applied by the University.

41. There is also no community health reason for the University to mandate vaccinations since 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.<sup>48</sup>

42. 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.”<sup>49</sup>

43. 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.”

44. It is unethical to coerce low-risk Americans to take the vaccine, such as students and those with natural 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.

45. 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 Journal* piece. There is no good public health case for GMU to require proof of vaccination for employees and students to participate in University activities that do not involve care for high-risk patients. Since the successful vaccination campaign already protects the vulnerable population, the

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<sup>48</sup> 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>.

<sup>49</sup> 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>.

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 and natural immunity, which provides benefits that are at least as strong.

46. 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).

47. 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.”<sup>50</sup>

48. 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,

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<sup>50</sup> 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>.

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Exhibit "AA"



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**Fwd: Patricia King. Denial Summary. Fwd: Order for summary Action in the Matter of Covered Entities the Prevention and Control of the 2019 Novel Corona Virus**

i message

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**Heather Speciale** <nursespeciale@gmail.com>  
To: MermigisLaw@gmail.com, jamie@myerandscher.com

Sun, Nov 14, 2021 at 6:18 PM

Sent from my iPhone

Begin forwarded message:

**From:** Heather <chas9567@verizon.net>  
**Date:** September 13, 2021 at 9:39:28 AM EDT  
**To:** nursespeciale@gmail.com  
**Subject:** **Fwd: Patricia King. Denial Summary. Fwd: Order for summary Action in the Matter of Covered Entities the Prevention and Control of the 2019 Novel Corona Virus**

Sent from my iPad

Begin forwarded message:

**From:** Patricia King <pking9219@icloud.com>  
**Date:** September 11, 2021 at 8:21:33 PM EDT  
**To:** Heather <chas9567@verizon.net>  
**Subject:** **Patricia King. Denial Summary. Fwd: Order for summary Action in the Matter of Covered Entities the Prevention and Control of the 2019 Novel Corona Virus**

Sent from my iPhone

Begin forwarded message:

**From:** "doh.sm.Vaccine.Order.Hearing" <Vaccine.Order.Hearing@health.ny.gov>  
**Date:** September 7, 2021 at 8:38:31 AM EDT  
**To:** pking9219@icloud.com  
**Subject:** **RE: Order for summary Action in the Matter of Covered Entities the Prevention and Control of the 2019 Novel Corona Virus**

On August 26, 2021, the Department of Health filed an Emergency Regulation (codified as Section 2.61 of Title 10 of the Official Compilation of Codes, Rules, and Regulations of the State of New York [10 NYCRR]), which supersedes and renders moot the Order for Summary Action ("Order") that was served on affected entities on August 19, 2021. The Order is therefore vacated and the hearing, required under the Order, which was scheduled for September 2, 2021, has been canceled.

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