

IN THE UNITED STATES DISTRICT COURT FOR THE  
NORTHERN DISTRICT OF NEW YORK

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DR. A., NURSE A., DR. C., NURSE D., DR. F., DR. G,  
THERAPIST I., DR. J., NURSE J., DR. M., NURSE N.,  
DR. O., DR. P., TECHNOLOGIST P., DR. S., NURSE S.  
and PHYSICIAN LIAISON X.,

Plaintiffs,

v.

KATHY HOCHUL, Governor of the State of New York, in  
her official capacity; HOWARD ZUCKER, M.D.,  
Commissioner of the New York State Department of  
Health, in his official capacity; and LETITIA JAMES,  
Attorney General of the State of New York, in her official  
capacity,

Defendants.

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**DECLARATION**

21 CV 1009 (DNH)(ML)

**DECLARATION OF  
ELIZABETH RAUSCH-  
PHUNG,  
M.D., M.P.H.**

**ELIZABETH RAUSCH-PHUNG, M.D., M.P.H.**, declares under penalty of perjury, pursuant  
to 28 U.S.C. § 1746, that the following is true:

1) I am the Medical Director of the Bureau of Immunization at New York State  
Department of Health (“Department” or “DOH”). I have been employed by DOH for over 11  
years. I oversee the Bureau of Immunization’s efforts to improve immunization coverage and  
prevent vaccine-preventable diseases among New Yorkers of all ages. The Bureau of  
Immunization is located within the Department’s Division of Epidemiology. I have overseen the  
Department’s role in the mass vaccination sites across the state.

2) I received my M.D. degree from the State University of New York, Upstate  
Medical University in 2003 and completed a residency in preventive medicine and a Master of  
Public Health degree in 2009. I have been licensed to practice medicine in New York State since

2008. I am currently board-certified in Preventive Medicine.

3) I make this declaration in opposition to the plaintiffs' application for a preliminary injunction. I am familiar with the facts set forth herein based on personal knowledge and expertise and DOH records. I have also reviewed guidance from the Centers for Disease Control & Prevention ("CDC") and the State, executive orders issued by the Governor, as well as studies and publications related to COVID-19.

### **Background**

4) The Department and the Commissioner of Health ("Commissioner") are charged with the overarching responsibility to protect the public health pursuant to Public Health Law ("PHL") §§ 201 and 206. Specifically, pursuant to PHL § 201(1)(m), the Department "shall ... supervise and regulate the sanitary aspects ... businesses and activities affecting public health." Pursuant to PHL § 206, the Commissioner "shall ... take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto." These statutes obligate the Department and the Commissioner to take action when the public health is put at risk by an unprecedented and unpredictable global pandemic, and the rapid outbreak of severe and fatal respiratory illnesses associated therewith.

5) On August 23, 2021, DOH published a proposed Emergency Regulation to be reviewed and adopted by the Public Health and Health Planning Council ("PHHPC").<sup>1</sup> This

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<sup>1</sup> PHHPC is a council within DOH that, in accordance with Section 225 of the Public Health Law, advises the Commissioner on issues related to the preservation and improvement of public health. PHHPC's functions include the approval of regulations related to health codes, among other things. PHHPC also has a broad array of advisory and decision-making responsibilities with respect to New York State public health and health care delivery system. See Department's *Public Health and Health Planning Council*, found at [https://www.health.ny.gov/facilities/public\\_health\\_and\\_health\\_planning\\_council/](https://www.health.ny.gov/facilities/public_health_and_health_planning_council/) (last viewed September 22, 2021).

Emergency Regulation superseded the August 18, 2021 Order for Summary Action. The Emergency Regulation expanded the scope of the Order for Summary Action to include other healthcare facilities and omitted an explicit religious exemption. The Emergency Regulation was adopted by PHHPC on August 26, 2021 and became effective August 26, 2021 for 90 days.<sup>2</sup> A copy of the Emergency Regulation is annexed hereto as **Exhibit A**.

6) This Emergency Regulation was adopted based on rational determinations by the Department and PHHPC that it was necessary to immediately address an ongoing and rapidly worsening public health crisis. The Department has accumulated, compiled and analyzed data and research regarding the nature and progression of COVID-19, its communicable nature, and the effectiveness of layered mitigation strategies to prevent community spread. These considerations provided a rational basis for the promulgation of the Emergency Regulation in question on an emergency basis and the Department complied with SAPA in doing so.

7) Namely, despite the ending of the state disaster emergency on June 25, 2021, “[w]ith the emergence of the Delta variant, a strain twice as transmissible as the SARS-CoV-2 strain, this does not mean that COVID-19 is gone. Cases have risen 10-fold since early July, with the Delta variant accounting for 95% of recent sequenced positives in New York State.” See **Exhibit A**.

**COVID-19 Variants Continue to Present a Grave Threat to Health and Safety**

8) Despite the gains that New York has made, the pandemic is not over as numbers

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<sup>2</sup> In accordance with SAPA § 202(6)(b), the Emergency Regulation went into effect immediately upon filing. In accordance with SAPA § 202, emergency regulations are effective for 90 days, subject to renewal.

have continued to increase. The COVID-19 variants discovered in New York and around the world create an increased risk for transmission and exacerbate the danger in situations that are already considered risky by their nature.

9) The CDC conducts surveillance on SARS-CoV-2 strains to create a library of the various specimens and sequences to better assist in the public health response.<sup>3</sup> A copy of the CDC Scientific Brief: *Emerging SARS-CoV-2 Variants* is attached hereto as **Exhibit B**. Some notable emerging variants were discovered in the United Kingdom (Alpha), South Africa (Beta), and Brazil (Gamma), all of which spread easier than the original virus. *Id.* The current predominant variant in the United States is the Delta variant, which is more than twice as transmissible as these previous variants. A copy of the CDC's *Delta Variant: What We Know About the Science* is attached hereto as **Exhibit C**.

10) Indeed, in May 2021, only 1% of cases in New York were from the Delta variant. A copy of news article *University at Buffalo Researchers Taking a Closer Look at the Delta Variant* is attached hereto as **Exhibit D**. By July 2021, however, despite all of the predominant COVID-19 variants found in New York; every new case except one that was genome sequenced by scientists at the University of Buffalo was the Delta variant. A copy of Local Buffalo News article, *Every case except one was delta: NY scientists urge vaccines, masking as delta variant rages* is attached hereto as **Exhibit E**. The CDC variant proportions tracker for the region that includes New York, New Jersey, Puerto Rico, and the Virgin Islands indicates that for the week

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<sup>3</sup> On May 31, 2021, The World Health Organization (“WHO”) announced new naming labels for the variants of interest and concern. *See Tracking SARS-CoV-2 Variants, World Health Organization*, found at <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/> (last viewed September 9, 2021).

of September 12 to September 18, 2021, 98.4% of cases were Delta.<sup>4</sup> Based on data collected for a 4-week period up to August 28, 2021, in New York State, 97.8% of cases were Delta.<sup>5</sup>

11) Globally, scientists are seeking to understand the ease of the variants' transmission and the efficacy of existing vaccines against them. See Exhibit B. A great deal of new information about the variants' "virologic, epidemiologic, and clinical characteristics" is developing. Id.

12) According to the CDC, the Delta variant is more than two times more contagious than previous variants and may cause more severe illness than previous variants in unvaccinated people. See Exhibit C. "[D]ata show fully vaccinated persons are less likely than unvaccinated persons to acquire SARS-CoV-2, and infections with the Delta variant in fully vaccinated persons are associated with less severe clinical outcomes." A copy of the CDC's *Science Brief: COVID-19 Vaccines and Vaccination* is attached hereto as **Exhibit F**. Although vaccinated people can become infected and have the potential to spread the virus to others, they do so at much lower rates than unvaccinated people. Id.; **Exhibit C**. SARS-CoV-2 transmission between unvaccinated persons is the primary cause of continued spread. **Exhibit F**.

13) Additionally, all of the abovementioned variants have been characterized by the CDC as variants of concern. A "variant of concern" is one "for which there is evidence of an increase in transmissibility, more severe disease (e.g., increase hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures." A

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<sup>4</sup> See Variant Proportions, CDC, found at <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (last viewed September 22, 2021).

<sup>5</sup> Id.

copy of the CDC's *SARS-CoV-2 Variant Classifications and Definitions* is attached hereto as **Exhibit G**.

14) One of the key concerns in this regard is to ensure that New York State does not return to the infection levels experienced during the spring of 2020 when the hospitals were overwhelmed, which can lead to further unnecessary deaths. During the spring 2020, many doctors and nurses came to help New York, as it had become the epicenter for the pandemic. As the entire nation has now, at one point or another, faced high infection rates, New York can no longer rely on the reserve of the additional volunteers.

15) On September 22, 2021, Johns Hopkins reported that globally, 229,698,682 individuals to date had tested positive for COVID-19, and a total of 4,711,795 confirmed COVID-19 deaths worldwide.<sup>6</sup> In addition, 42,420,384 individuals in the United States had tested positive for COVID-19 to date, and total 678,584 had died of COVID-19. Id.

16) The first surge of COVID-19 in New York was March-April-May 2020 and a resurgence of the COVID-19 pandemic swept through the New York in November-December-January 2020-2021, with previous variants. Now we are in the midst of another resurgence, presently with highly transmittable Delta variant.

17) In New York, looking at testing data as of September 20, 2021, the total number of individuals to date who had tested positive for COVID-19 was 2,363,842,<sup>7</sup> and as reported to

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<sup>6</sup> See COVID-19 Dashboard, John Hopkins University of Medicine, found at <https://coronavirus.jhu.edu/map.html> (last viewed September 22, 2021).

<sup>7</sup> See NYSDOH COVID-19 Tracker, found at <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Map?%253Aembed=yes&%253Atoolbar=no&%3AisGuestRedirectFromVizportal=y&%3Aembed=y> (last viewed September 22, 2021).

and compiled by the CDC, the number of individuals who had died of COVID-19 was 56,309.<sup>8</sup>

18) On September 20, 2021, 143,765 were tested for COVID-19 and there were 5,242 new positive COVID-19 cases in New York State. This is a total positivity rate of 3.64%.<sup>9</sup>

Despite the gains that New York has made, the pandemic is not over as numbers have continued to increase.

19) Governor Cuomo ended the state disaster emergency to fight COVID-19 on June 25, 2021, citing declining hospitalization and positivity statewide, as well as success in vaccination rates. A copy of the Governor's June 23, 2021 Press Release is attached hereto as **Exhibit H**.

20) However, with the emergence of the Delta variant, a strain twice as transmissible as the SARS-CoV-2 strain, this does not mean that COVID-19 is gone. See Exhibit A.

21) With the state disaster emergency ended but the with the continuing need to control the spread of the prevalent Delta variant, Commissioner Zucker "recommend[ed] following guidance from the CDC and local health departments." A copy of the August 5, 2021 Press Release "Statement from New York State Department of Health Commissioner Dr. Howard Zucker" is attached hereto as **Exhibit I**.

### **The Importance of Vaccinations**

22) Fully vaccinated individuals are less likely to spread infectious diseases to

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<sup>8</sup> See NYSDOH, COVID-19 Tracker, Fatalities by County, found at <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-Fatalities?%253Aembed=yes&%253Atoolbar=no&%3AisGuestRedirectFromVizportal=y&%3Aembed=y> (last viewed September 22, 2021).

<sup>9</sup> See NYSDOH, COVID-19 Tracker, Daily Totals: Persons Tested and Persons Tested Positive, found at <https://covid19tracker.health.ny.gov/views/NYS-COVID19-Tracker/NYSDOHCOVID-19Tracker-DailyTracker?%253Aembed=yes&%253Atoolbar=no&%3AisGuestRedirectFromVizportal=y&%3Aembed=y> (last viewed September 22, 2021).

other people, including people who cannot get vaccinated because they are too young, or they have a weakened immune system.

23) COVID-19 is not the only serious preventable disease that is of concern. The CDC declared vaccination to be one of the ten greatest public health achievements of the twentieth century. The introduction and widespread use of vaccines have profoundly reduced the occurrence of many serious infectious diseases. Prior to vaccines, thousands of children each year, living in the United States, could expect to die or be left with life-long disabilities as a result of contracting diseases that are now preventable by vaccination, such as smallpox, poliomyelitis, rubella, measles, diphtheria and pertussis. If enough people stop getting vaccinated, outbreaks of now-rare, preventable diseases would return, as happened with the 2018-2019 measles outbreak in New York State – the worst measles outbreak in the United States in more than 25 years.

24) For instance, rubella and polio have both been declared eliminated from the United States, however they both have occurred in other countries and therefore, unvaccinated New Yorkers remain at risk of those diseases if they either travel to those countries or have contact with people sick with rubella or polio visiting from or returning from travel to countries in which they are circulating.

25) The worldwide eradication of smallpox and the near-eradication of poliomyelitis can be directly attributed to vaccination. Similarly, once commonly encountered and often deadly diseases such as diphtheria and rubella are becoming a rarity in the United States as a result of the routine use of vaccination against these and other infectious diseases



26) When immunization coverage rates drop, even in only localized or isolated communities, the risk of vaccine preventable disease outbreaks rises, as we saw in the 2018-2019 measles outbreak, which resulted in a large number of cases spreading quickly in relatively small communities that had very low rates of MMR vaccination coverage (within a state that had a high overall MMR vaccine coverage). Vaccination mandates are in place not only to protect, for instance, children in close proximity in a classroom setting or patients and staff in close hospital quarters, but more importantly, the public at large. There remains a risk to the public if unimmunized individuals in the community begin to grow in number. If immunization rates for vaccine-preventable diseases begin to drop, New York State could face the precarious scenario of dealing with multiple outbreaks of communicable diseases at the same time. To risk another serious wave of the COVID-19 pandemic outbreak, during a time when New York State's public health resources are already incredibly strained, would be extremely irresponsible.

#### **History of COVID-19 Vaccinations**

27) The United States Food and Drug Administration ("FDA") may issue an Emergency Use Authorization ("EUA") to facilitate the availability of vaccinations during public health emergencies, such as the COVID-19 pandemic. This allows an unapproved medical product to prevent serious life-threatening diseases in an emergency when certain criteria have been met and there are no adequate or approved alternatives. A copy of the FDA's *Emergency Use Authorization for Vaccines Explained* is attached hereto as **Exhibit J**.

28) On December 11, 2020, the FDA issued its first EUA for the Pfizer COVID-19 vaccine for those ages 16 and older. A copy of the FDA's December 11, 2020 News Release is attached hereto as **Exhibit K**.

29) On December 18, 2020, the FDA issued an EUA for the Moderna COVID-19 vaccine for use by those ages 18 and older. A copy of the FDA's December 18, 2020 News Release is attached hereto as **Exhibit L**.

30) On February 27, 2021, the FDA issued an EUA Janssen COVID-19 Vaccine for use in ages 18 or older. A copy of the FA's February 27, 2021 News Release is attached hereto as **Exhibit M**.

31) On May 10, 2021, the FDA expanded the EUA for the Pfizer COVID-19 vaccination to include individuals ages 12-15 years of age. A copy of the FDA's May 10, 2021 News Release is attached hereto as **Exhibit N**.

32) On August 12, 2021, the FDA amended the EUAs for the Pfizer and Moderna vaccination for use of an additional dose in immunocompromised individuals. A copy of the FDA's August 12, 2021 News Release is attached hereto as **Exhibit O**.

33) On August 23, 2021, the FDA approved the first COVID-19 vaccine – the Pfizer-BioNTech COVID-19 Vaccine – for the prevention of COVID-19 in those ages 16 and older. The vaccine continues to be made available under emergency use authorization (EUA) for those aged 12-15. A copy of the FDA's *Comirnaty and Pfizer-BioNTech COVID-19 Vaccine* is attached hereto as **Exhibit P**.

34) On September 17, 2021, the FDA voted to recommend EUA for a booster dose of the Pfizer vaccine in individuals 65 years of age or older and for individuals at high risk of severe COVID-19, to be administered at least six months after the two-dose series. The panel agreed that healthcare workers and others at high risk of occupational exposure should be included in this EUA. A copy of the September 17, 2021 Press Release is attached hereto as

**Exhibit Q.**

**The Development of COVID-19 Vaccines**

35) There is an important distinction between what is in the actual makeup of the vaccines versus what was used in the research and development of the vaccines. None of the FDA approved final COVID-19 vaccine products contain any fetal cells.

36) Each of the manufacturers of COVID-19 vaccines currently authorized for use in the U.S. have statements on their websites that they do not contain fetal cell lines nor human-derived materials.

37) The Moderna website states “[t]he Moderna COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or materials of human or animal origin. The Moderna COVID-19 vaccine does not use fetal cell lines during the vaccine manufacturing or lot testing.” A copy of the Moderna website text is attached hereto as **Exhibit R**.

38) The Pfizer website states that “[a]nimal or human fetal-derived cell lines are not used to produce Comirnaty (also known as Pfizer-BioNTech COVID-19 Vaccine), which consists of synthetic and enzymatically produced components.” A copy of the Pfizer website text is attached hereto as **Exhibit S**.

39) The Janssen website states that “[t]here is no fetal tissue nor any human cells present in the Janssen COVID-19 Vaccine (Ad26.COV2.S; JNJ-78436735).” A copy of the Janssen website text is attached hereto as **Exhibit T**.

40) In sum, while none of the FDA approved COVID-19 vaccines contain any fetal cells, fetal cell lines were only “used in testing during research and development of the mRNA vaccines [Moderna or Pzifer], and during production of the Johnson and Johnson [Janssen]

vaccine.” A copy of the Nebraska Medicine’s *You asked, we answered: Do the COVID-19 Vaccines Contain Aborted Fetal Cells* is attached hereto as **Exhibit U**.

41) A North Dakota Department of Health COVID-19 vaccine handout also notes that “[h]istorical fetal cell lines were derived in the 1960’s and 1970’s from two elective abortions and have been used to create vaccines for diseases such as hepatitis A, rubella, and rabies.” The North Dakota Department of Health handout *COVID-19 Vaccines & Fetal Cell Lines* is attached hereto as **Exhibit V**.

42) Further, fetal cell lines have been used in other medical technologies. This process is not new.

43) For instance, fetal cell lines have been used to develop Rubella, hepatitis A and varicella-containing vaccines. A copy of CNN’s *How Exactly Fetal Tissue is Used for Medicine* is attached hereto as **Exhibit W**.

44) Importantly, the Rubella vaccination, developed using the same fetal cell lines, is already required of healthcare workers in New York State.

45) Fetal cells have also been used in “hundreds of thousands of other research projects” including the improvement of techniques for and the study of in vitro fertilization, “birth defects, eye diseases, Parkinson’s Alzheimer’s disease, AIDS, and spinal cord injuries.” A copy of NBC News *What is fetal tissue research? And why is it important to medicine?* is attached hereto as **Exhibit X**.

**Religious Exemption to COVID-19 Vaccinations**

46) The absence of religious exemptions in mandatory vaccination laws is not a novel concept in New York State and the Emergency Regulation's silence as to a religious exemption is consistent with other mandatory vaccination laws for healthcare workers.

47) Existing regulations require that all persons who work at hospitals, nursing homes, diagnostic and treatment centers, home health agencies and programs and hospices be immune to measles and rubella. While these regulations all provide for a medical exemption, *none* of these regulations provide for a religious exemption. See 10 NYCRR § 405.3 (requiring measles and rubella immunizations for all hospital personnel with an exception for physicians practicing medicine from remote location); 10 NYCRR § 415.26 (requiring measles and rubella immunizations for all nursing home personnel except for those with no clinical or patient contact responsibilities and who are located in a building with no patient care services); 10 NYCRR § 751.6 (requiring measles and rubella vaccinations for all employees of diagnostic and treatment centers); 10 NYCRR § 763.13 (requiring measles and rubella vaccinations prior to patient care duties, for all personnel of certified home health agencies, long term home health care programs, and AIDS home care programs); 10 NYCRR § 766.11 (requiring measles and rubella vaccinations for all health care personnel of licensed home care services agencies who have direct patient contact); and 10 NYCRR § 794.3 (requiring measles and rubella vaccinations for all hospice personnel, including direct employees, contract staff, and volunteers who have direct patient or family contact); 10 NYCRR § 1001.11 (requiring measles and rubella vaccinations for all assisted living residences personnel, including all direct care staff).

48) The absence of a religious exemption in 10 NYCRR § 2.61 is consistent with all of the above pre-existing regulations relevant to healthcare workers. To provide otherwise for solely the COVID-19 vaccination mandate would be inconsistent with similar regulations, which all seek to advance similar goals of preventing the transmission of infectious diseases among health care personnel, staff, and patients.

49) Similar to the majority of the above regulations, 10 NYCRR § 2.61 recognizes that the greatest threat of transmission is posed by healthcare personnel who have direct contact with other staff and patients. Therefore, the vaccination mandate in 10 NYCRR § 2.61 is appropriately limited to only those personnel “who engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients, residents to the disease.”

50) Mandatory school entry vaccination laws similarly do not provide for a religious exemption.

51) As part of the multi-faceted approach to addressing the 2018-2019 measles outbreak, on June 13, 2019, New York State signed into law legislation which removed religious exemptions from school vaccination requirements for children in prekindergarten-12<sup>th</sup> grade (“religious exemption repeal”). (Laws of 2019, Chapter 35, which, among other things, repealed former NYS Public Health Law § 2164(9)). The law now treats individuals with religious beliefs contrary to immunization exactly the same as individuals with non-religious beliefs contrary to immunization.

52) Chapter 35 of the Laws of 2019 eliminated non-medical (i.e., religious) exemptions to vaccination requirements.

**Basis for Mandating COVID-19 Vaccines for Health Care Personnel**

53) As set forth above, the highly contagious Delta Variant is spreading across the nation and across New York. Delta is currently the predominant variant of the virus in the United States. **Exhibit C.** Health care workers have higher rates of infection than people in other fields. A copy of the *Annals of Internal Medicine*, *The Case for Mandating COVID-19 Vaccines for Health Care Workers* is attached hereto as **Exhibit Y.** The mortality rate of COVID-19 is estimated to be 1 in 100 to 250. A copy of *SARS-CoV-2 Antibody Prevalence in England Following the First Peak of the Pandemic* is attached hereto as **Exhibit Z.** In 2020 alone, SARS-CoV-2 is estimated to have caused more than 522,000 excess deaths in the United States. A copy of *Excess Deaths from COVID-19 and Other Causes in the US, March 1, 2020 to January 2, 2021* is attached hereto as **Exhibit AA.**

54) Patient facing healthcare professionals and their household members have threefold and twofold increased risks of admission with COVID-19. A copy of the *Risk of Hospital Admission with Coronavirus Disease 2019 in Healthcare Workers and their Households: Nationwide Linkage Cohort Study* is attached hereto as **Exhibit BB.** According to the CDC, to date, 557,585 US health care personnel have contracted COVID-19 and 1,768 have died of COVID-19.<sup>10</sup>

55) Further, health care workers tend to persons who are elderly, sick, and vulnerable, who might not be vaccinated because they are either too young or have contraindications, or who might not gain sufficient immunity from the vaccine to provide adequate protection from severe

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<sup>10</sup> Cases & Deaths Among Healthcare Personnel, CDC, found at <https://covid.cdc.gov/covid-data-tracker/#health-care-personnel> (last viewed September 22, 2021).

illness, such as immunocompromised individuals. A copy of the *Safety and Immunogenicity of Anti-SARS-CoV-2 Messenger RNA Vaccines in Recipients of Solid Organ Transplants* is attached hereto as **Exhibit CC**. Vaccinating healthcare workers would protect even the unvaccinated patients because COVID-19 vaccines are associated with fewer infections overall and less risk of transmission.

56) More than “50 health care professional societies and organizations [have] called for all health care employers to require their employees to be vaccinated against COVID-19 in a joint statement released” on July 26, 2021. These include, but are not limited to, the “American Medical Association, American Nurses Association, American Academy of Pediatrics, Association of American Medical Colleges, and National Association for Home Care and Hospice”, as well as the American Academy of PAs, American Pharmacists Association, the National Hispanic Medical Association, the American Public Health Association, American Academy of Child and Adolescent Psychiatry and the Infectious Diseases Society of America. A copy of *Major Health Care Professional Organizations Call for COVID-19 Vaccine Mandates for All Health Workers* is attached hereto as **Exhibit DD**.

57) Dr. Audiey Kao, MD, PhD, the American Medical Association’s Vice President of Ethics, made it clear that “Do no harm is a core ethic for all those who care for the sick and injured. . . . [A]ll those working in the health care system have a fundamental obligation to patients by getting vaccinated for preventable diseases such as COVID-19.” A copy the American Medical Association’s *Why COVID-19 Vaccination Should be Required for Health Professionals* is attached hereto as **Exhibit EE**. Dr. Ezekiel Emanuel, the vice provost for global initiatives at the University of Pennsylvania, also emphasized that ““No patient should have to



worry that they could become infected by one of their care providers, and no provider should put their patient at risk.” **Exhibit DD.** For example, the president of the American Society of Clinical Oncology stated that “[p]atients with cancer need to know that their environment, including the people who care for them, is as safe as possible.” Id. This collective statement unequivocally supports the requirement for universal vaccination of health workers.

58) Other organizations have separately stated their support for healthcare worker vaccination requirements. For example, the American Association of Nurse Anesthesiology, American Association of Critical-Care Nurses, National Association of Neonatal Nurses, and the American College of Occupational and Environmental Medicine. A copy these statements are attached hereto as **Exhibits FF-II.** These organizations have stated that vaccinations to health care team members will not only reduce the burden of this disease on acute and critical -care units and communities, but will prevent further harm to front line workers. **Exhibit GG.** Further, healthcare workers and their employers benefit from required vaccinations because “COVID-19 is more disruptive to the workforce and hospital/health care operations than any disease encountered in the last century due to required quarantining and potential length of illness.” **Exhibit II.**

59) On July 26, 2021, the Department of Veterans Affairs mandated COVID-19 vaccines for health care personnel who work in Veterans Health Administration facilities, visit those facilities or provide direct care to those the VA serves. A copy of the July 26, 2021 News Release is attached hereto as **Exhibit JJ.** On August 12, 2021, the Department of Health and Human Services Secretary announced that “more than 25,000 members of its health care workforce [will be required] to be vaccinated against COVID-19.” A copy of the August 12,

2021 Press Release is attached hereto as **Exhibit KK**. This includes staff at the Indian Health Service and National Institutes of Health who either “interact with, or have the potential to come into contact with, patients.” Id. The U.S. Surgeon General also immediately required “members of the U.S. Public Health Service Commissioned Corps” to be vaccinated. Id.

60) The CDC has also recommended that healthcare personnel all receive the COVID-19 vaccination, as they “continue to be on the front line of the nation’s fight against COVID-19,” by “providing critical care to those who are or might be infected with the virus that causes COVID-19.” A copy of the CDC’s *COVID-19 Vaccines for Healthcare Personnel* is attached hereto as **Exhibit LL**.

61) The CDC has also recognized that achieving high vaccination rates in particularly vulnerable settings, such as long-term care facilities (“LTCF”), is of the utmost importance, since residents of these facilities are at high risk for COVID-19 associated mortality. “As of March 2021, deaths among LTCF residents and HCP have accounted for almost one third . . . of COVID-19 associated deaths in the United States.” This is why early vaccination of these groups were prioritized. A copy of the CDC’s *Disparities in COVID-19 Vaccination Coverage Among Health Care Personnel Working in Long-Term Care Facilities, by Job Category, National Healthcare Safety Network – United States, March 2021* is attached hereto as **Exhibit MM**.

62) The CDC has expressed concern that “COVID-19 outbreaks have occurred in LTCF in which residents were highly vaccinated, but transmission occurred through unvaccinated staff members.” Id. Partial vaccination of staff provides insufficient protection. For example, in Kentucky, an outbreak occurred in a skilled nursing facility with 90.4% of its

residents vaccinated, after introduction from “an unvaccinated, symptomatic” healthcare provider. A copy of the CDC’s *COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program – Kentucky, March 2021* is attached hereto as **Exhibit NN**. The CDC’s study found that “[a]ttack rates were three to four times as high among unvaccinated residents and HCP as among those who were vaccinated; vaccinated persons were significantly less likely to experience symptoms or require hospitalization.” Id. Ultimately, 46 residents and HCP were infected. Id.

63) Per the Emergency Regulation, current personnel are set to receive their first dose by September 27, 2021 for general hospitals and nursing homes, and by October 7, 2021 for all other covered entities. Time is of the essence. The Department is concerned that the numbers of COVID-19 cases will continue to increase, especially given the fall and winter seasons. The cold weather and upcoming holiday gatherings are likely to keep people indoors together, increasing the likelihood that COVID-19 can spread from person to person, given the highly contagious nature of the disease. Additionally, as cold and flu season has arrived, the varying symptoms of COVID-19 (i.e. cough, fever, fatigue, muscle or body aches, headache, sore throat, congestion or runny nose, among others) could easily be mistaken for a cold or the flu. Again, this will increase the likelihood the people with COVID-19 will go untreated for longer and in the interim, potentially spread the disease to others.

64) Reducing the number of unvaccinated personnel who can expose vulnerable patients to the potentially deadly disease in the healthcare setting is of utmost importance. To accomplish this goal, it is imperative that the regulation limit the allowed exemptions. According to Dr. Kao “AMA's position is that nonmedical exemptions, such as religious or philosophic

objections to vaccinations, endanger the health of the unvaccinated individual and those whom the individual comes in contact with, so the AMA supports legislation eliminating nonmedical exemptions from immunizations.” A copy of the AMA’s *Audiey Kao, MD, PhD, on Mandating Vaccines for Health Care Workers* is attached hereto as **Exhibit OO**.

65) According to the CDC, the COVID-19 vaccines are safe for almost all patients. To date, more than 380 million doses of COVID-19 vaccine have been administered in the United States. A copy of the CDC’s *Safety of COVID-19 Vaccines* is attached hereto as **Exhibit PP**. Despite the exceedingly large number of vaccinations, serious side effects have been extremely rare. A recent analysis by the CDC’s Advisory Committee on Immunization Practices found that the known and projected benefits of COVID-19 vaccines far outweigh potential risks. A copy of the CDC’s *COVID-19 Vaccines in Adults: Benefit-Risk Discussion* is attached hereto as **Exhibit QQ**. In addition to being evaluated in tens of thousands of participants in clinical trials, the vaccines met the FDA’s rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support authorization of the vaccine. **Exhibit PP**.

66) According to Dr. David Dowdy, an epidemiologist at the Johns Hopkins Bloomberg School of Public Health, there are no immediate health issues or side effects for most people with pre-existing medical conditions and the data so far shows that less than one in one million people experience the rare side effect of anaphylaxis. A copy of ABC News’ *Few People Medically Exempt from Getting COVID-19 Vaccine: Experts* is attached hereto as **Exhibit RR**. The incidence of vaccine-induced Thrombosis with Thrombocytopenia Syndrome, another rare side effect, is about .9 per million people after the Johnson & Johnson Vaccine. A copy of the American College of Cardiology’s *Vaccine-Induced thrombotic Thrombocytopenia*

*(VITT) and COVID-19 Vaccines: What Cardiovascular Clinicians Need to Know* is attached hereto as **Exhibit SS**. Vaccine-induced Thrombosis with Thrombocytopenia Syndrome has not been reported in patients who received the Moderna or Pfizer COVID-19 vaccines. Id. According to the CDC's analysis of the risks and benefits of each of the U.S. COVID-19 vaccines, for every million doses of mRNA vaccine given to adults, there were only 3.5 reported cases of myocarditis. **Exhibit QQ**. And for every million doses of Janssen vaccine given to adults, there were only 3 reported cases of Thrombosis with Thrombocytopenia Syndrome and 7.8 cases of Guillain-Barre Syndrome. Id.

**COVID-19 Vaccine for Persons Who Have Recovered from COVID-19**

67) While being infected with COVID-19 may offer some immunity, and reinfection is unlikely in the 90 days after initial infection, experts do not know how long that protection lasts. A copy of the CDC's *Answering Patients' Questions About COVID-19 Vaccine and Vaccination* is attached hereto as **Exhibit TT**. Multiple studies have shown, however, that the vaccine is more effective at protecting against COVID-19 than natural immunity. According to a recent report, neutralizing antibodies from people vaccinated with the Moderna COVID-19 vaccine bind more broadly to the SARS-CoV-2 receptor binding domain than antibodies from people with prior COVID-19 infection. A copy of *Antibodies Elicited by mRNA-1273 Vaccination Bind More Broadly to the Receptor Binding Domain Than do Those from SARS-CoV-2 Infection* is attached hereto as **Exhibit UU**. This means that vaccine-induced antibodies appear to be better able than infection-induced antibodies to bind to variant strains. Id.

68) A cross-sectional study that monitored antibody and memory B-cell levels among 63 people who had recovered from COVID-19 found that, although in the absence of

vaccination, both antibody and memory B-cell levels persisted through 12 months after infection, vaccination increased antibody and memory B-cell levels above those induced by infection, and resulted in greater neutralizing antibody activity against COVID-19 variants of concern compared to that elicited by prior infection alone. A copy of *Naturally Enhanced Neutralizing Breadth Against SARS-CoV-2 One Year After Infection* is attached hereto as **Exhibit VV**.

69) Further, the risk of getting reinfected with symptomatic disease is about 2.5-fold higher among unvaccinated persons who have recovered from COVID-19 than for those who are vaccinated. A copy of *Vaccines Beat Natural Immunity in Fight Against COVID-19* is attached hereto as **Exhibit WW**. The risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity. **Exhibit TT**. To reduce the likelihood of future infection, health care personnel should be vaccinated, even if they were previously infected with COVID-19.

Dated: September 22, 2021

  
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