21-2179

United States Court of Appeals for the Second Circuit

WE THE PATRIOTS USA, INC., DIANE BONO, MICHELLE MELENDEZ, MICHELLE SYNAKOWSKI,

Plaintiffs-Appellants,

v.

KATHLEEN HOCHUL, HOWARD A. ZUCKER, M.D.,

Defendants-Appellees.

On Appeal from the United States District Court for the Eastern District of New York

BRIEF FOR APPELLEES

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PRELIMINARY STATEMENT

The COVID-19 pandemic has imposed a deadly toll on New York, which continues to this day with the spread of the highly contagious SARS-CoV-2 Delta variant. COVID-19's impact has been particularly devastating in the healthcare sector, where already-vulnerable patients and residents are at greater risk of severe harm from any infection, and where the spread of the virus among healthcare workers can lead to a vicious cycle of staff shortages and deterioration of patient care.

In light of the distinct concerns raised by the spread of COVID-19 in the healthcare sector, the New York Department of Health (DOH) issued an emergency rule requiring COVID-19 vaccinations for certain healthcare workers: namely, any worker whose activities could potentially expose other personnel or patients to COVID-19 if he or she were infected. Like preexisting vaccination requirements for measles and rubella that have long applied to healthcare workers, DOH's emergency COVID-19 rule contains only a narrow medical exemption.

The plaintiffs here—three individual healthcare workers and an advocacy organization—seek a preliminary injunction against enforcement of the rule based on the absence of a religious exemption. The U.S.

District Court for the Eastern District of New York (Kuntz, J.) denied their request for a preliminary injunction.

This Court should affirm. For several reasons, the district court did not abuse its broad discretion in declining to issue a statewide preliminary injunction against DOH's emergency COVID-19 rule.

First, plaintiffs fail to show a likelihood of success on the merits or sufficiently serious questions going to the merits. Courts have upheld vaccination requirements for well over a century—and this Court has squarely recognized that religious exemptions are not required by the First Amendment. The presence of a limited medical exemption does not compel a different result under the Supreme Court's recent orders in cases like *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63 (2020) (per curiam). The Supreme Court's orders invalidated materially different schemes: ones that denied religious exemptions but broadly allowed comparable nonreligious exemptions that defeated the purpose of the underlying regulation at least as much as any religious exemption would have. Here, by contrast, DOH's emergency rule does not allow for broad nonreligious exemptions. And the *only* recognized exemption—to avoid medical harm—is not comparable to the nonreligious exemptions at issue

in *Roman Catholic Diocese* and its progeny because the medical exemption (1) serves rather than undermines the emergency rule's objective of protecting the health of healthcare workers, and (2) poses much more limited risks because it is tightly constrained in both scope and duration. Separately, plaintiffs' substantive due process claim is squarely foreclosed by this Court's decision in *Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015).

Second, the equities also weigh heavily in favor of allowing DOH's emergency rule to go into effect while the district court considers the merits of plaintiffs' claims. Delaying the mandatory vaccination of New York's healthcare workers—including those who seek a religious exemption—poses the risk of infection, complications, and death to both the workers themselves and the vulnerable populations that they serve. And the public at large risks receiving substandard medical care at facilities that have inadequate staffing following an outbreak among healthcare workers. By contrast, the principal harm identified by plaintiffs is their conclusory assertion that they may lose their employment if they adhere to their religious objection to the vaccine. But the emergency rule itself does not compel their termination. The evidence of such harm in this record is thin.

And in any event, it is well settled that such potential economic harm is inadequate to justify the extraordinary remedy of a preliminary injunction.

ISSUES PRESENTED

1. Whether plaintiffs have established a likelihood of success on the merits, where courts have uniformly rejected First Amendment and substantive due process challenges to compulsory vaccination laws for well over a century, including those without any religious exemption.

2. Whether the balance of the equities weighs against any preliminary injunction of DOH's emergency rule, when an injunction could potentially lead to increased risk of transmission of a potentially fatal disease among healthcare workers and the vulnerable populations they serve, whereas plaintiffs have not demonstrated that the emergency rule would lead to imminent irreparable harm.

STATEMENT OF THE CASE

A. New York's Long and Successful History of Vaccination Requirements

New York has long been a national leader in mandating vaccinations to protect against the spread of communicable disease. New York began requiring school-age children to be vaccinated against smallpox in the 1860s. *See* James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L.J. 831, 851 (2002). The Legislature has regularly updated its compulsory school vaccination laws as new vaccines have become available, and in 2019 eliminated any religious exemption from this requirement. *See* Public Health Law § 2164, *as amended by* Ch. 35, §§ 1, 2, 2019 McKinney's N.Y. Laws 153, 153-54.

New York has also regularly imposed vaccination requirements on healthcare workers. For example, DOH regulations require hospital employees who pose a risk of transmission to patients to be immunized against measles and rubella; like the emergency rule at issue here, this requirement does not contain a religious exemption. *See* 10 N.Y.C.R.R. § 405.3(b)(10)(i)-(iii). Similar rules apply to healthcare workers in long-

term care facilities and other institutions.[1] These regulations have been in place in similar form since 1980 for rubella and 1991 for measles.[2]

New York's mandatory vaccination programs reflect the consensus view that "immunizations are among the most effective preventative measures to preserve and protect the public health" and that compliance with the "childhood and adult vaccination schedules" issued by public health authorities is essential to preventing the spread of communicable diseases. Ch. 603, § 1, 2005 N.Y. Laws 3379, 3379. According to the Centers for Disease Control and Prevention (CDC), the development and spread of vaccination have brought about one of the most important public health advances in history.[3] Polio and smallpox, previously

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[1] *See* 10 N.Y.C.R.R. §§ 415.26(c)(1)(v)(a)(2)-(4) (nursing home personnel), 751.6(d)(1)-(3) (employees of diagnostic and treatment centers), 763.13(c)(1)-(3) (personnel of home health agencies, long term home health care programs, and AIDS home care programs), 766.11(d)(1)-(3) (personnel of licensed home care services agencies), 794.3(d)(1)-(3) (hospice personnel), 1001.11(q)(1)-(3) (assisted living residences personnel).

[2] *See* Health and Immunization of Employees of Medical Facilities and Certified Home Health Agencies, 3 N.Y. Reg. 6, 6 (Jan. 14, 1981) (rubella); Immunization of Health Care Workers, 13 N.Y. Reg. 16, 16 (Dec. 24, 1991) (measles).

[3] Centers for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Impact of Vaccines Universally Recommended for Children–United States, 1990-1998*, 48 Morbidity & Mortality Wkly. Rep.

(*continued on the next page*)

devastating diseases, have been essentially eliminated in the United States due to vaccination,[4] and the incidence of seven other serious diseases has similarly been reduced in the United States by nearly 100% because of compulsory vaccination.[5]

Where vaccination is not so widespread, vaccine-preventable diseases continue to cause death on a very large scale. For example, approximately 1 million people outside the United States die every year from measles.[6] Even in the United States, the incidence of various communicable diseases has grown due to a recent increase in the number of parents refusing to vaccinate their children. As a result, diseases such as measles, mumps, and whooping cough have reappeared throughout the United States, although they were once thought to be nearly eradicated here.[7]

243, 243-48 (1999) ("CDC *Achievements*"); *see also* Centers for Disease Control & Prevention, *Epidemiology and Prevention of Vaccine-Preventable Diseases* 44 (Elisha Hall et al. eds., 14th ed. 2021).

[4] CDC *Achievements*, *supra*, at 244, 246.

[5] *Id.* at 243-46.

[6] *Id.* at 247.

[7] Centers for Disease Control & Prevention, *Parent's Guide to Childhood Immunizations* 37 (2014).

B. The COVID-19 Pandemic and New York's Response

1. The COVID-19 pandemic, the invention of safe and effective vaccines, and efforts to promote their use

COVID-19 is a highly infectious and potentially deadly respiratory illness that spreads easily from person to person. It was first detected by the World Health Organization (WHO) in December 2019.[8] On March 11, 2020, the WHO declared COVID-19 a pandemic,[9] and two days later, President Trump declared a national emergency.[10] Just last week, the global death toll passed 5 million people.[11] And in the United States alone, COVID-19 has infected more than 43 million people and claimed more than 700,000 lives,[12] including at least 550,000 infections and 1,750

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[8] World Health Org., *Listings of WHO's Response to COVID-19* (last updated Jan. 29, 2021) (internet). (For internet sources, URLs are provided in the Table of Authorities.)

[9] World Health Org., *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19* (Mar. 11, 2020) (internet).

[10] Press Release, Fed. Emergency Mgmt. Agency, *COVID-19 Emergency Declaration* (Mar. 14, 2020) (internet).

[11] *See* Kavya B. & Roshan Abraham, *Global COVID-19 Deaths Hit 5 Million as Delta Variant Sweeps the World*, Reuters (Oct. 2, 2021) (internet).

[12] Centers for Disease Control & Prevention, *COVID Data Tracker: Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory* (last visited Oct. 7, 2021) (internet).

deaths among healthcare workers, who have been disproportionately harmed by the disease.[13]

In light of the harms caused by the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) issued emergency use authorizations for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines in December 2020 and February 2021.[14] On August 23, 2021, the FDA granted full regulatory approval for the Pfizer vaccine.[15]

Studies show that the vaccines are both safe and highly effective, particularly for preventing hospitalizations in vulnerable populations.

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[13] Centers for Disease Control & Prevention, *COVID Data Tracker: Cases & Deaths Among Healthcare Personnel* (last visited Oct. 7, 2021) (internet); *see* Decl. of Elizabeth Rausch-Phung, M.D., M.P.H. ("Rausch-Phung Decl.") ¶ 34, *Does v. Hochul*, No. 21-cv-5067 (E.D.N.Y. Oct. 5, 2021), ECF No. 47.

[14] Press Release, Food & Drug Admin., *FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine* (Dec. 11, 2020) (internet) (*at* Rausch-Phung Decl., Ex. JJ); Press Release, Food & Drug Admin., *FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020) (internet) (*at* Rausch-Phung Decl., Ex. KK); Press Release, Food & Drug Admin., *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine* (Feb. 27, 2021) (internet) (*at* Rausch-Phung Decl., Ex. LL).

[15] Press Release, Food & Drug Admin., *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021) (internet).

For example, among adults 65 to 74 years old, one recent study showed the efficacy for preventing hospitalizations was 96% for the Pfizer vaccine, 96% for the Moderna vaccine, and 84% for the Janssen vaccine, and concluded that increasing vaccination coverage is "critical to reducing the risk for COVID-19–related hospitalization, particularly in older adults."[16]

The COVID-19 vaccines do not contain aborted fetal cells.[17] HEK-293 cells—which are currently grown in a laboratory and are thousands of generations removed from cells collected from a fetus in 1973—were used in testing during the research and development phase of the Pfizer and Moderna vaccines.[18] But the use of HEK-293 cells for testing is

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[16] *See, e.g.*, Heidi L. Moline et al., *Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥ 65 Years – COVID-NET, 13 States, February-April 2021*, 70 Morbidity & Mortality Wkly. Rep. 1088, 1092 (2021).

[17] Los Angeles Cnty. Dep't of Pub. Health, *COVID-19 Vaccine and Fetal Cell Lines* 1 (Apr. 20, 2021) (internet).

[18] *See id.* at 1-2. PER.C6 cells—which are grown in a laboratory and thousands of generations removed from cells collected from an aborted fetus in 1985—were used during the production phase of the Janssen vaccine. *See id.*

common for a variety of everyday medications, including widely used over-the-counter drugs like Tylenol, Benadryl, and Pepto-Bismol.[19]

In light of the success of the COVID-19 vaccines, a broad coalition of healthcare professional organizations has called for healthcare employers to require their employees to be vaccinated, including the American Medical Association, American Nurses Association, American Academy of Pediatrics, Association of American Medical Colleges, National Association for Home Care and Hospice, American Academy of PAs, American Pharmacists Association, National Hispanic Medical Association, American Public Health Association, American Academy of Child and Adolescent Psychiatry, and the Infectious Diseases Society of America. As the president of the American Society of Clinical Oncology explained, "[p]atients with cancer need to know that their environment,

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[19] *See* Matthew P. Schneider, *If Any Drug Tested on HEK-293 Is Immoral, Goodbye Modern Medicine*, Through Catholic Lenses (Jan. 28, 2021) (internet) (collecting research papers); *see, e.g.*, Mirjam J. Eberhardt et al., *Reactive Metabolites of Acetaminophen Activate and Sensitize the Capsaicin Receptor TRPV1*, 7 Sci. Reps. art. no. 12775 (2017) (notes use of HEK-293 to test acetaminophen, active ingredient in Tylenol).

including the people who care for them, is as safe as possible."[20] Other organizations have noted that a vaccine requirement will prevent further harm to front line workers.[21]

In addition to the medical consensus supporting the COVID-19 vaccine, a diverse range of religious leaders has also strongly encouraged adherents to receive a COVID-19 vaccination. For example, Pope Francis, the leader of the Roman Catholic Church (a church with which two of the three plaintiffs are affiliated) has recognized that taking an approved COVID-19 vaccine is "an act of love" and "a simple yet profound way to care for one another, especially the most vulnerable."[22] The U.S. Conference of Catholic Bishops has explained that receiving the Pfizer and Moderna vaccines is consistent with the Catholic faith because the Pfizer

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[20] Press Release, Association of American Medical Colleges, *Major Health Care Professional Organizations Call for COVID-19 Vaccine Mandates for All Health Workers* (July 26, 2021) (internet) (*at* Rausch-Phung Decl., Ex. O) (quotation marks omitted).

[21] American Association of Critical-Care Nurses, *AACN Statement on Mandatory COVID-19 Vaccination* (Aug. 2, 2021) (internet) (*at* Rausch-Phung Decl., Ex. R).

[22] Devin Watkins, *Pope Francis Urges People to Get Vaccinated Against Covid-19*, Vatican News (Aug. 18, 2021) (internet) (quotation marks omitted).

and Moderna vaccines did not use fetal cell lines for their "design, development, or production," and the connection between those vaccines and abortion "is very remote."[23] More broadly, a coalition of 145 global faith leaders, representing a variety of faiths, issued a statement that the "only way to end the pandemic" is to ensure that COVID-19 vaccines "are made available to all people as a global common good."[24]

2. New York's adoption of a COVID-19 vaccination requirement for certain healthcare workers

DOH is charged with protecting the public health and, in particular, with supervising and regulating "the sanitary aspects of . . . businesses and activities affecting public health." Public Health Law § 201(1)(m). Pursuant to this broad mandate, DOH has acted swiftly to respond to the risks posed by transmission of the Delta variant in New York's healthcare sector.

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[23] Chairmen of the Comm. on Doctrine and the Comm. on Pro-Life Activities, *Moral Considerations Regarding the New COVID-19 Vaccines* 4-5, U.S. Conf. of Catholic Bishops (Dec. 11, 2020) (internet).

[24] Press Release, ReliefWeb, *World Religious Leaders Call for Massive Increases in Production of Covid Vaccines and End to Vaccine Nationalism* (Apr. 27, 2021) (internet).

a. The August 18, 2021, Order for Summary Action

On August 18, 2021—prior to full FDA approval of the Pfizer vaccine—the DOH Commissioner issued an Order for Summary Action under Public Health Law § 16, which allows him to "take certain action immediately" to remedy "a condition or activity which in his opinion constitutes danger to the health of the people," for a period not to exceed fifteen days. Public Health Law § 16. The Order required certain health-care entities to ensure that covered personnel were fully vaccinated against COVID-19. *See* Dep't of Health, Order for Summary Action (Aug. 18, 2021) (internet). The Order for Summary Action was narrow in scope, covering only hospitals and nursing homes. *Id.* at 3. It also included both a medical exemption and an exemption for individuals who "hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer." *Id.* at 5-6.

The Order for Summary Action was intended to serve as an immediate "stop-gap measure pending action by the Public Health and Health Planning Council," a council within DOH that consists of the DOH Commissioner and 24 other members, who are drawn from the public

health system, healthcare providers, and elsewhere.[25] As a result, the Order was superseded when—eight days later, and with the benefit of fuller consideration and input by its members—the Council approved the emergency rule that is at issue in this proceeding.

b. The August 26, 2021, Emergency Rule

On August 26, 2021—three days after the FDA gave full approval to the Pfizer vaccine—the Council issued the emergency rule at issue here. Under New York law, an emergency rule may go into effect immediately upon filing with the New York Secretary of State and remain in effect for up to ninety days, at which point it must be renewed to remain in force. State Administrative Procedure Act § 202(6)(b).

The emergency rule requires covered healthcare entities to "continuously require" employees to be fully vaccinated against COVID-19 if they "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." 10 N.Y.C.R.R. § 2.61(a)(2), (c). In contrast to the

[25] Decl. of Vanessa Murphy, J.D., M.P.H. ("Murphy Decl.") ¶ 6, *Does*, No. 21-cv-5067 (E.D.N.Y. Oct. 5, 2021), ECF No. 48.

Commissioner's Order for Summary Action, the emergency rule covers a broader range of healthcare entities—specifically, extending to certified home health agencies, long term home health care programs, AIDS home care programs, licensed home care service agencies, hospices, and adult care facilities. *See id.* § 2.61(a)(1)(ii)-(iv). Also unlike the Order, the emergency rule was formally published in the New York Register and was accompanied by a full set of required documentation, including a Regulatory Impact Statement and findings to support the need for emergency action.[26]

The rule contains only a single exception to its requirements: a narrow medical exemption that is strictly limited in duration and scope. The rule exempts employees for whom a "COVID-19 vaccine [would be] detrimental to" their health "based upon a pre-existing health condition." *Id.* § 2.61(d)(1). As to duration, the exemption applies "only until such immunization is found no longer to be detrimental to such personnel member's health," and that duration "must be stated in the personnel employment medical record." *Id.* As to scope, the exemption must be "in

[26] Murphy Decl. ¶ 12; Prevention of COVID-19 Transmission by Covered Entities, 43 N.Y. Reg. 6, 6-9 (Sept. 15, 2021).

accordance with generally accepted medical standards," such as the "recommendations of the Advisory Committee on Immunization Practices" (ACIP), a committee that operates under the auspices of the CDC. *Id.*

DOH guidance on the emergency rule makes clear that the available grounds for a medical exemption are narrow and largely temporary. As explained by DOH's Frequently Asked Questions document regarding the emergency rule,[27] the only "contraindications" recognized by the CDC as a ground for a medical exemption are severe or immediate allergic reactions "after a previous dose" of the vaccine or "to a component of the COVID-19 vaccine."[28] Even then, the CDC advises that "the majority of contraindications are temporary," such that "vaccinations often can be administered later when the condition leading to a contraindication no

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[27] Dep't of Health, *Frequently Asked Questions (FAQs) Regarding the August 26, 2021 – Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation* 4 (last visited Oct. 7, 2021) (internet) ("*FAQs*") (*at* Rausch-Phung Decl., Ex. EEE).

[28] Centers for Disease Control & Prevention, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* (last updated Sept. 27, 2021) (internet) (*at* Decl. of Emily Lutterloh MD, MPH ("Lutterloh Decl."), Ex. D, *Andre-Rodney v. Hochul*, No. 21-cv-1053 (N.D.N.Y. Oct. 1, 2021), ECF No. 10-7).

longer exists."[29] The CDC also recognizes certain "precautions"—i.e., conditions that increase the risk of a serious reaction or that interfere with the effectiveness of a vaccine—that could warrant deferring administration of the COVID-19 vaccine (such as a recent acute illness), or administering a different version of the vaccine (such as a reaction to one of the three available vaccines).[30] By contrast, less serious conditions are not a basis for a medical exemption, including common side effects to the COVID-19 vaccine like fever, headache, or fatigue; allergic reactions to other substances; or immunosuppression due to a health condition or use of another medication.[31]

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[29] Centers for Disease Control & Prevention, *Vaccine Recommendations and Guidelines of the ACIP: Contraindications and Precautions* (last visited Oct. 7, 2021) (internet) (*at* Lutterloh Decl., Ex. C).

[30] *Id.* For example, the CDC notes that a small fraction—about seven per million—of women between eighteen and forty-nine years old experience thrombosis with thrombocytopenia syndrome after receiving the Janssen vaccine. *See* Centers for Disease Control & Prevention, *Safety of COVID-19 Vaccines* (last updated Sept. 27, 2021) (internet) (*at* Rausch-Phung Decl., Ex. DD). Any concerns about this unlikely risk, however, can be assuaged by receiving the Pfizer or Moderna vaccine.

[31] *FAQs*, *supra*, at 4-5 (*at* Rausch-Phung Decl., Ex. EEE).

Consistent with the narrow criteria for medical exemptions under DOH's emergency rule, preliminary data as of September 28, 2021, indicate that only a small fraction of healthcare workers in New York have qualified. For hospitals, only 0.5% of staff have been found medically ineligible; for nursing homes, only 0.4% of staff; and for adult care facilities, only 0.6% of staff. Lutterloh Decl. ¶ 16.

These figures are consistent with the findings of other public health experts, who have uniformly concurred that the number of individuals who are medically ineligible to receive a COVID-19 vaccine is very small. According to Dr. David Dowdy, an epidemiologist at the Johns Hopkins Bloomberg School of Public Health, data show that the vaccines do not present "immediate health issues or side effects for most people with pre-existing medication conditions," and, apart from age, "there are no major exemptions that cover large groups of people."[32] The vaccines are safe for immunocompromised people, pregnant women, and people with underlying conditions. The primary group of people who face serious medical

[32] Ivan Pereira, *Few People Medically Exempt from Getting COVID-19 Vaccine: Experts*, ABC News (Sept. 15, 2021) (internet) (*at* Rausch-Phung Decl., Ex. GG) (quotation marks omitted).

risk from a COVID-19 vaccine are people who experience anaphylactic shock, but that "severe allergy is rare, and less than one in 1 million people experience it."[33] A publication earlier this year in the Journal of the American Medical Association similarly estimates that the rate of anaphylaxis to the Pfizer and Moderna vaccines is extremely small: 2.5 to 11.1 per 1 million doses.[34]

The emergency rule does not contain a religious exemption. The availability of a medical but not religious exemption is also a feature of the requirement that healthcare workers be vaccinated against measles and rubella.[35] DOH has explained that the emergency rule is consistent with these preexisting obligations and that allowing a religious exemption for the COVID-19 vaccine, but not for measles and rubella, would

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[33] *Id.*

[34] Kimberly G. Blumenthal et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*, 325 JAMA 1562, 1562 (2021).

[35] *See* 10 N.Y.C.R.R. §§ 405.3(b)(10)(iii) (hospital personnel), 415.26(c)(1)(v)(a)(4) (nursing home personnel), 751.6(d)(3) (employees of diagnostic and treatment centers), 763.13(c)(3) (personnel of home health agencies, long term home health care programs, and AIDS home care programs), 766.11(d)(3) (personnel of licensed home care services agencies), 794.3(d)(3) (hospice personnel), 1001.11(q)(3) (assisted living residences personnel).

undermine a consistent approach to preventing the transmission of these particularly infectious and harmful diseases among healthcare personnel, staff, and patients.[36] The decision to omit a religious exemption is consistent with statements by the American Medical Association that "nonmedical exemptions, such as religious or philosophic objections to vaccinations, endanger the health of the unvaccinated individual and those whom the individual comes into contact with" and that healthcare workers in particular "have a fundamental obligation to patients [to get] vaccinated for preventable diseases, such as COVID-19."[37]

In accompanying administrative materials, DOH further explained the basis for the emergency rule. It noted that the rule responded to the increasing circulation of the Delta variant, which has led to a tenfold increase in COVID-19 infections since early July 2021. DOH found that COVID-19 vaccines are safe and effective, and that the presence of unvaccinated personnel in healthcare settings poses "an unacceptably high risk" that employees may acquire COVID-19 and transmit the virus

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[36] *See* Rausch-Phung Decl. ¶¶ 71-77.

[37] American Medical Association, *Audiey Kao, MD, PhD, on Mandating Vaccines for Health Care Workers* (July 20, 2021) (internet) (*at* Rausch-Phung Decl., Ex. CC).

(a) to colleagues, thereby "exacerbating staffing shortages"; or (b) to "vulnerable patients or residents," thereby "causing [an] unacceptably high risk of complications."[38] DOH emphasized that, as compared with vaccinated individuals, unvaccinated individuals have *eleven times* the risk of being hospitalized with COVID-19.

The Council also conducted a public hearing on August 26, 2021, at which it provided further information concerning the need for the emergency rule and the scope of the obligations it imposed. Dr. Howard A. Zucker, DOH's Commissioner, explained that the emergency rule was necessary because the State was at a crucial inflection point with the increasing prevalence of the Delta variant and the heightened risk for the spread of respiratory viruses (such as the flu) in the fall season.[39]

DOH counsel further explained that the scope of the emergency rule largely tracked pre-existing vaccine requirements, including those for measles and rubella, in order to facilitate the rule's implementation and enforcement. For example, the definition of "covered personnel" aligns

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[38] 43 N.Y. Reg. at 8 (Regulatory Impact Statement).

[39] Video, Special Meeting of the N.Y. Pub. Health & Health Planning Council, Comm. on Codes, Reguls. & Legis., at 2:48-4:06 (Aug. 26, 2021) (internet) ("Comm. Meeting"); *see also* Rausch-Phung Decl. ¶ 40.

with the scope of DOH's regulation requiring seasonal influenza vaccination or masking for certain healthcare workers.[40] *See* 10 N.Y.C.R.R. § 2.59(a)(1). Counsel similarly noted that the medical exemption is consistent with the existing standards governing immunizations for students.[41] *See id.* §§ 66-1.1(*l*), 66-1.3(c). DOH's Director of Epidemiology confirmed that the medical exemption in the emergency rule is consistent with medical exemptions in other regulations and is based on generally accepted medical standards such as the recommendations of CDC's ACIP.[42] And DOH counsel also explained that the lack of a religious exemption is consistent with a variety of regulatory provisions requiring measles and rubella vaccinations for certain healthcare workers.[43] *See id.* §§ 405.3(b)(10)(i)-(iii), 415.26(c)(1)(v)(a)(2)-(4), 751.6(d)(1)-(3), 763.13(c)(1)-(3), 766.11(d)(1)-(3), 794.3(d)(1)-(3), 1001.11(q)(1)-(3).

DOH's findings about the immediate necessity for the emergency rule are supported by the CDC's conclusions that the Delta variant is

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[40] Comm. Meeting at 10:40-11:12.

[41] *Id.* at 30:42-31:00.

[42] *Id.* at 14:33-15:03.

[43] *Id.* at 37:20-37:38.

more than twice as contagious as prior variants and may cause more severe illness in unvaccinated people. Although vaccinated people may transmit the Delta variant to others, they do so at much lower rates than unvaccinated people.[44] The CDC has also recognized the importance of achieving high vaccination rates in settings where residents are at high risk of COVID-19-associated mortality, including long-term care facilities. Deaths at such facilities account for almost one third of COVID-19 related deaths in the United States, and the CDC has observed outbreaks that occurred in facilities where the "residents were highly vaccinated, but transmission occurred through unvaccinated staff members."[45]

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[44] Centers for Disease Control & Prevention, *Delta Variant: What We Know About the Science* (last updated Aug. 26, 2021) (internet) (*at* Rausch-Phung Decl., Ex. C); Centers for Disease Control & Prevention, *Science Brief: COVID-19 Vaccines and Vaccination* (last updated Sept. 15, 2021) (internet) (*at* Rausch-Phung Decl., Ex. F).

[45] James T. Lee et al., *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*, 70 Morbidity & Mortality Wkly. Rep. 1036, 1036-37 (2021) (*at* Rausch-Phung Decl., Ex. X).

3. Early implementation of the COVID-19 vaccination requirement for healthcare workers

Although the emergency rule just went into effect on September 27, 2021—subject to limited temporary restraining orders (TROs) preventing DOH from interfering with employers' grants of religious exemptions (see *infra* 29-31)—some preliminary data have emerged concerning the rate of vaccinations and exemptions among New York's healthcare workforce.

As of October 4, 2021, 120,225 of 140,917 New York healthcare workers at nursing homes were fully vaccinated (85.3%), with an additional 17,084 having received one dose of a two-dose vaccine (12.1%), according to self-reported data from facilities. Only 674 nursing-home workers were reported as currently medically ineligible for a COVID-19 vaccine (0.5%). Another 2,934 were reported as "other" exemptions (2.1%), which DOH understands to refer to the religious exemption currently still in place due to various TROs (see *infra* at 29-31).[46]

As of the same date, 24,730 of 29,417 healthcare workers at adult care facilities were fully vaccinated (84.1%), with an additional 2,240

[46] *See* Decl. of Valerie A. Deetz ¶ 3, *Does*, No. 21-cv-5067 (E.D.N.Y. Oct. 5, 2021), ECF No. 49.

having received one dose of a two-dose vaccine (7.6%), according to self-reported data from facilities. Only 149 adult-care facility workers were reported as currently medically ineligible for a COVID-19 vaccine (0.5%). Another 399 were reported as "other" exemptions (1.36%), which DOH understands to encompass those who have claimed religious exemptions.[47]

As of September 28, 2021, 86.7% of hospital workers were fully vaccinated, according to self-reported data from facilities.[48] Only 0.5% of hospital workers were medically ineligible for a COVID-19 vaccine at that time.[49] Another 4.9% of staff are medically eligible to receive a vaccine, but are declining to do so, including (but not necessarily exclusively) for religious reasons.[50]

These data are consistent with data from other jurisdictions, which have shown that the numbers of religious exemptions significantly exceed

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[47] *Id.* ¶ 4.

[48] Decl. of Mark Hennessey ¶ 3, *Andre-Rodney*, No. 21-cv-1053 (N.D.N.Y. Oct. 1, 2021), ECF No. 10-13.

[49] Rausch-Phung Decl. ¶ 99. DOH anticipates reporting updated hospital vaccination data in the near future, and will update the Court accordingly.

[50] Press Release, Office of the Governor of N.Y., *Governor Hochul Releases Encouraging Data Showing Impact of Health Care Staff Vaccine Mandate* (Sept. 28, 2021) (internet) (*at* Rausch-Phung Decl., Ex. HHH).

medical exemptions. For instance, a survey of San Diego's healthcare providers found that most of the requests for exemptions from COVID-19 vaccines cited religious reasons, with the largest providers indicating that approximately 3% of their workforce sought religious exemption, roughly seven times the number of people who sought medical exemptions.[51] In Kentucky, a hospital reported that religious exemptions were six times larger than medical exemptions.[52] And in New Jersey, a hospital reported that 5% of its staff received a religious exemption, but only 1.2% percent received medical exemptions.[53]

C. This Lawsuit

On September 2, 2021, plaintiffs filed this lawsuit, challenging the omission of a religious exemption from DOH's emergency rule. The complaint names Howard A. Zucker, DOH's Commissioner, and Kathleen

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[51] *See* Paul Sisson, *Thousands of San Diego County Healthcare Workers Seek Vaccine Exemptions, Citing Religion*, San Diego Union-Tribune (Sept. 12, 2021) (internet).

[52] *See* Defs.' Response in Opp. to Pls.' Mot. for Restraining Order at 7, *Beckerich v. Saint Elizabeth Med. Ctr., Inc.*, No. 21-cv-105 (E.D. Ky. Sept. 14, 2021), ECF No. 15.

[53] *See* Elizabeth Llorente, *Will N.J. Hospitals Face a Nursing Shortage Under Vaccine Mandates? They Already Are*, NJ.com (Sept. 20, 2021) (internet).

Hochul, New York's Governor, as defendants in their official capacities. (Appendix (A.) 9 (¶¶ 7-8).) The plaintiffs are We The Patriots USA, Inc., a membership organization dedicated to "promoting constitutional rights" (A. 8 (¶ 3)), and three individual healthcare workers allegedly subject to the emergency rule: Diane Bono, Michelle Melendez, and Michelle Synakowski (A. 8 (¶¶ 4-6)).

Plaintiffs allege that they have religious objections to receiving a vaccine that uses "a fetal cell line for development, manufacturing, or testing" (A. 9 (¶ 10)), and that the omission of a religious exemption will require two of the plaintiffs (Melendez and Synakowski) to choose whether to take the vaccination "or lose their employment" (A. 11 (¶ 22)). They claim that the DOH emergency rule violates their rights to free exercise of religion, privacy, and medical freedom, and they seek declaratory and injunctive relief. (A. 11-14.)

Plaintiffs moved for a temporary restraining order and a preliminary injunction ten days later. The only evidence they submitted consisted of conclusory affidavits from the individual plaintiffs and letters from two of their employers. According to these submissions, Bono is "a committed and practicing member of the Christian faith"; Melendez and Synakowski

are "committed and practicing member[s] of the Roman Catholic Church"; and all three object to the use of fetal cell lines in COVID-19 vaccines. (A. 30 (¶¶ 4, 6), 34 (¶¶ 4, 6), 38 (¶¶ 4, 6).)

Plaintiffs believe that their employers will terminate plaintiffs' employment if they do not receive a COVID-19 vaccine. (A. 31 (¶ 8), 35 (¶ 8); 38 (¶ 8).) A letter from Bono's employer states that her "continued employment will be at risk" if she does not receive a COVID-19 vaccine. (A. 32.) But a letter from Melendez's employer simply states that Melendez will face restrictions on her activities at work if she does not receive a COVID-19 vaccine. (A. 36.) Synakowski does not submit any documentation from her employer corroborating her claim.

Based on these papers, the district court denied plaintiffs' motion without hearing from defendants or affording them an opportunity to develop a record supporting the denial of the preliminary injunction. (*See* Order (Sept. 12, 2021).) The next day, plaintiffs sought a stay pending appeal, which the district court also denied. (Order (Sept. 13, 2021).) Plaintiffs then filed this appeal. (A. 28-29.)

Shortly thereafter, district courts entertaining two other lawsuits challenging DOH's vaccination requirement ruled on applications for

emergency relief. In one proceeding, the U.S. District Court for the Northern District of New York (Hurd, J.), without hearing from defendants, entered a TRO barring defendants from "enforcing any requirement that employers" deny or revoke religious exemptions from COVID-19 vaccination. Order at 3, *Dr. A. v. Hochul*, No. 21-cv-1009 (N.D.N.Y. Sept. 14, 2021), ECF No. 7. That TRO was originally scheduled to expire on September 28, but the court extended it to October 12. Order at 4, *Dr. A.*, No. 21-cv-1009 (N.D.N.Y. Sept. 20, 2021), ECF No. 15. In a separate proceeding, the U.S. District Court for the Eastern District of New York (Komittee, J.) denied a request for a TRO as moot in light of the TRO already in effect in *Dr A.* Mem. & Order at 1-3, *Does*, No. 21-cv-5067 (E.D.N.Y. Sept. 14, 2021), ECF No. 35.

Several state court lawsuits have also been filed, and various courts have either denied requests for TROs or granted TROs with the same scope as the *Dr. A* TRO. *See, e.g.*, Order to Show Cause at 3, *Cattaraugus County v. New York State Dep't of Health*, Index No. 908382-21 (Sup. Ct. Albany County Sept. 29, 2021), NYSCEF Doc. No. 27; Order to Show Cause at 4, *Serafin v. New York State Dep't of Health*, Index No. 908296-21 (Sup. Ct. Albany County Sept. 24, 2021), NYSCEF Doc. No. 25. And

another lawsuit, which does not raise a Free Exercise claim, is also pending in the Northern District. *See* Compl., *Andre-Rodney*, No. 21-cv-1053 (N.D.N.Y. Sept. 22, 2021), ECF No. 1.

In these other lawsuits, unlike here, defendants have been afforded an opportunity to develop a record supporting DOH's emergency rule on plaintiffs' preliminary injunction motions, which all remain pending as of this date. For the Court's convenience, an addendum of materials publicly filed in other pending lawsuits is attached to this brief.[54]

Finally, on September 30, 2021, this Court granted in part plaintiffs' motion for a stay pending appeal, enjoining defendants from "enforcing the mandate against persons claiming religious exemptions, in a manner that would violate the terms stated" in the *Dr. A.* TRO. Order (Sept. 30, 2021).

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[54] This Court may take judicial notice of publicly filed court documents, including the fact that DOH has filed evidence supporting the emergency rule in those lawsuits where it has had an opportunity to do so. *See Communications Network International, Ltd. v. MCI WorldCom Commc'ns, Inc.*, 708 F.3d 327, 339 n.63 (2d Cir. 2013) (taking judicial notice of attorney's ECF registration information).

STANDARD OF REVIEW

A party seeking preliminary injunctive relief must establish "(1) irreparable harm; (2) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; and (3) that a preliminary injunction is in the public interest." *New York ex rel. Schneiderman v. Actavis plc*, 787 F.3d 638, 650 (2d Cir. 2015) (quotation marks omitted). This Court reviews for abuse of discretion a district court's denial of a motion for a preliminary injunction. *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005). Because a preliminary injunction is an "extraordinary and drastic remedy," *Moore v. Consolidated Edison Co. of N.Y., Inc.*, 409 F.3d 506, 510 (2d Cir. 2005) (quotation marks omitted), a district court has "considerable discretion in denying a preliminary injunction," *New York ex rel. James v. Griepp*, 11 F.4th 174, 178 (2d Cir. 2021). This Court will not reverse the denial of a preliminary injunction even if it is "doubtful about certain aspects" of such a denial. *Brennan's, Inc. v. Brennan's Rest., L.L.C.*, 360 F.3d 125, 129 (2d Cir. 2004).

SUMMARY OF ARGUMENT

Plaintiffs have failed to show that they satisfy the prerequisites for the extraordinary relief of a preliminary injunction against a duly issued state regulation.

I. Plaintiffs have failed to show a likelihood of success on the merits. Courts have long upheld mandatory vaccination requirements, including those without any religious exemption. And DOH's emergency rule satisfies rational-basis review because it reasonably serves the objective of preventing COVID-19 spread among particularly vulnerable facilities and individuals—a point that plaintiffs do not contest.

Plaintiffs' claim that the emergency rule should be subject to heightened scrutiny is meritless because the rule is a neutral, generally applicable requirement. The emergency rule is neutral because it does not expressly target religious activity for less favorable treatment and was not issued due to religious hostility. And the emergency rule is generally applicable because it extends to all covered personnel at healthcare facilities.

Contrary to plaintiffs' assertions, the presence of a narrow medical exemption does not preclude the emergency rule from being generally

applicable for purposes of a Free Exercise claim. A policy's provision of a secular but not religious exemption triggers heightened scrutiny only (a) when the secular exemption would undermine the purpose of the underlying policy to at least the same degree as any religious exemption, or (b) when a government decisionmaker has broad discretion to extend an individualized exemption to claims of religious hardship but chooses not to. Neither circumstance applies here. The medical exemption advances rather than undermines the emergency rule's objective of protecting healthcare workers and preventing them from becoming unavailable due to medical problems. The medical exemption is also tightly constrained in both scope and duration in a manner that blunts its effect on COVID-19 transmission. And the medical exemption does not confer broad discretion on any decisionmaker to consider individual circumstances but is instead limited to a small number of federally recognized contraindications and precautions. The emergency rule's provision of a medical exemption thus does not compel DOH to grant plaintiffs' request for a religious exemption that would be very different in both scope and effect.

Finally, plaintiffs have failed to show a likelihood of success on their substantive due process claims. This Court squarely rejected such a claim in *Phillips*, 775 F.3d 538, and recently declined to issue a stay in a case raising substantive due process challenges to New York City's COVID-19 vaccination requirement for schoolteachers. Plaintiffs' substantive due process claim here fails for the same reasons.

II. The equities also weigh heavily in favor of allowing DOH's emergency rule to go into effect. Delaying the mandatory vaccination of New York's healthcare workers—including those who seek a religious exemption—poses risks to the healthcare workers themselves, to their colleagues, and to the vulnerable populations that they serve, who are often at heightened risk of infection and death from COVID-19. The public at large also will suffer harm if COVID-19 outbreaks at healthcare facilities limit staffing or strain resources in a way that results in substandard medical care. By contrast, the principal harm identified by plaintiffs is their conclusory assertion that they may lose their employment if they adhere to their religious objection to the vaccine. But the emergency rule does not compel such termination. Plaintiffs' evidence that they face such harm is absent or thin. And in any event, it is well

settled that such economic harm is inadequate to justify the extraordinary remedy of a preliminary injunction.

ARGUMENT

POINT I

PLAINTIFFS HAVE NOT ESTABLISHED A LIKELIHOOD OF SUCCESS ON THE MERITS OR SUFFICIENTLY SERIOUS QUESTIONS GOING TO THE MERITS

A. Courts—Including This Court—Have Long Upheld Mandatory Vaccination Requirements, Including Those Without Religious Exemptions.

Courts have long held that mandatory vaccination laws constitute a valid exercise of the States' police powers, and such laws have withstood challenges on various constitutional grounds for more than a century. In 1905, for example, the Supreme Court held that mandatory vaccination laws do not offend "any right given or secured by the Constitution," and that the States' police powers allow imposition of "restraints to which every person is necessarily subject for the common good." *Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905). In 1922, the Court reaffirmed that settled law allowed States to use their police powers to impose compulsory vaccination. *See Zucht v. King*, 260 U.S. 174, 176 (1922).

Courts have specifically recognized that generally applicable vaccination requirements do not infringe on religious liberties. As the Supreme Court held over seventy years ago, "[t]he right to practice [one's] religion freely does not include liberty to expose the community . . . to communicable disease." *Prince v. Massachusetts*, 321 U.S. 158, 166-67 & n.12 (1944); *see also Wright v. DeWitt Sch. Dist. No. 1*, 238 Ark. 906, 913 (1965) (rejecting Free Exercise Clause challenge to school's smallpox vaccination requirement). More recently, the Court specifically identified "compulsory vaccination laws" as among the neutral, generally applicable laws that did not require religious exemptions under the First Amendment. *Employment Div., Dep't of Human Res. of Ore. v. Smith*, 494 U.S. 872, 889 (1990).

As recently as 2015, this Court similarly explained that mandatory vaccination (in that case, for schoolchildren) "does not violate the Free Exercise Clause."[55] *Phillips*, 775 F.3d at 543. In rejecting plaintiffs' First

[55] Plaintiffs are mistaken to argue (at 13-17) that the Supreme Court has overruled *Jacobson* and *Phillips*. As Justice Gorsuch noted, the Supreme Court in *Jacobson* did what this Court must do here: apply the appropriate tier of scrutiny. *Roman Catholic Diocese*, 141 S. Ct. at 70-71 (Gorsuch, J., concurring).

Amendment claim in *Phillips*, this Court reasoned that "New York could constitutionally require that all children be vaccinated in order to attend public school" without any religious exemption at all, and that such an exemption "goes beyond what the Constitution requires."[56] *Id.* In short, "it has been settled law for many years that claims of religious freedom must give way in the face of the compelling interest of society in fighting the spread of contagious diseases through mandatory inoculation programs." *Sherr v. Northport–E. Northport Union Free Sch. Dist.*, 672 F. Supp. 81, 88 (E.D.N.Y. 1987); *see id.* at 83 (citing cases).[57]

The absence of a religious exemption in DOH's emergency rule is not an outlier. Comparable immunization laws also contain no such exemption. For example, New York's immunization requirement for schoolchildren no longer contains a religious exemption. *See* Public Health Law § 2164; *F.F. v. State*, 194 A.D.3d 80, 88 (3d Dep't 2021) (rejecting Free Exercise challenge to removal of religious exemption). As discussed,

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[56] Plaintiffs argue (at 36-37) that *Lawrence v. Texas*, 539 U.S. 558 (2003), somehow undermined *Jacobson*, but fail to address the holding in *Phillips* that *Jacobson* remains good law.

[57] *See McCarthy v. Boozman*, 212 F. Supp. 2d 945, 948 (W.D. Ark. 2002).

New York's requirement that healthcare workers be vaccinated against measles and rubella does not allow for religious exemptions either. See *supra* at 5-6. And several other States have similarly declined to permit religious exemptions from their immunization laws. *See* Cal. Health & Safety Code § 120325 et seq. (Westlaw 2021); Conn. Gen. Stat. Ann. § 10-204a (Westlaw 2021) (except for preschool or prekindergarten students previously entitled to a religious exemption); Me. Rev. Stat. Ann. tit. 20-A, § 6355 (Westlaw 2021) (religious exemption repealed effective September 1, 2021); Miss. Code Ann. § 41-23-37 (Westlaw 2021); W. Va. Code Ann. § 16-3-4 (Westlaw 2021). Indeed, the Fourth Circuit rejected a Free Exercise challenge to West Virginia's mandatory childhood vaccination statute, which, like DOH's emergency rule, recognized only medical but not religious exemptions. *See Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App'x 348, 353-54 (4th Cir. 2011).

In light of this settled law upholding vaccination requirements, including those without religious exemptions, plaintiffs fail to show a likelihood of success on the merits or sufficiently serious questions going to the merits. Plaintiffs' Free Exercise claim fails because, as explained

further below, DOH's emergency rule is a neutral law of general applicability that is subject to rational-basis review—a bar that it readily clears. And plaintiffs' substantive due process claim fails under this Court's decision in *Phillips*. Plaintiffs are thus not entitled to a preliminary injunction.

B. DOH's Emergency Rule Comports with the Free Exercise Clause.

1. DOH's emergency rule is subject to rational-basis review because it is neutral and generally applicable.

It is well-established that the right to free exercise of religion does not relieve an individual of the obligation to comply with a "valid and neutral law of general applicability." *Smith*, 494 U.S. at 879 (quotation marks omitted). Rational-basis review is all that is required to uphold neutral laws of general applicability—i.e., laws that do not target, disapprove of, or single out religious groups or practices, even if the law "proscribes (or prescribes) conduct that [one's] religion prescribes (or proscribes)." *Id.* at 889 (quotation marks omitted). Here, rational-basis review applies because DOH's emergency rule is both neutral and generally applicable.

a. DOH's emergency rule is neutral.

DOH's emergency rule is neutral because it does not target practices based on "their religious motivation." *See New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 162 (2d Cir. 2020) (quotation marks omitted). On its face, the rule does not mention religious activity at all—in sharp contrast to the COVID-19 executive orders reviewed by the Supreme Court in *Roman Catholic Diocese*, which expressly "single[d] out houses of worship" for distinctive treatment. 141 S. Ct. at 66; *see also Agudath Israel of Am. v. Cuomo*, 980 F.3d 222, 229 (2d Cir. 2020) (Park, J., dissenting) (noting that orders' restrictions on "houses of worship" evidenced "disparate treatment of religious and secular institutions [that] is plainly not neutral").

Nor does the history or administration of DOH's emergency rule reveal any "subtle departures from neutrality" reflecting hostility or animus towards religion. *See Church of the Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 534 (1993) (quotation marks omitted); *see also Masterpiece Cakeshop, Ltd. v. Colorado Civil Rts. Comm'n*, 138 S. Ct. 1719, 1731 (2018); *New Hope Fam. Servs.*, 966 F.3d at 163. In assessing whether animus animated a government action, courts look to "the

historical background of the decision under challenge, the specific series of events leading to the enactment or official policy in question, and the legislative or administrative history, including contemporaneous statements made by members of the decisionmaking body." *New Hope Fam. Servs.*, 966 F.3d at 163 (quotation marks omitted).

In *Roman Catholic Diocese*, for example, the Supreme Court was troubled by public statements by the Governor that appeared to criticize the Orthodox Jewish community; the Court noted the observation by a judge of this Court that such statements could be "viewed as targeting" that community. 141 S. Ct. at 66 (quotation and alteration marks omitted) (citing *Agudath*, 980 F.3d at 229 (Park, J., dissenting)). Similarly, in *New Hope Family Services*, this Court held that plaintiffs had plausibly pleaded religious animus based in part on public statements by agency officials suggesting that they "did not think [plaintiff's] religious beliefs about family and marriage could legitimately be carried into the public sphere." 966 F.3d at 168 (quotation marks omitted). This Court further found "a suspicion of religious animosity" based on the agency's departure from its statutory mandate and a history of agency inaction. *Id.* at 166.

This case does not present any similar circumstances that would plausibly suggest that religious animus motivated DOH's emergency rule. Plaintiffs have identified no statements from DOH or its officials suggesting that they were "intolerant of religious beliefs." *See Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1877 (2021). Instead, plaintiffs rely heavily (Br. for Pls.-Appellants (Br.) at 22-23) on remarks made by Governor Hochul at a church service, nearly three weeks *after* the emergency rule's adoption, in which she argued that accepting the COVID-19 vaccine was consistent with her Christian faith. Assuming that those statements bear on DOH's issuance of the emergency rule at all, *cf. Barber v. Thomas*, 560 U.S. 474, 486 (2010) (when interpreting legislative history, "the Court normally gives little weight to statements . . . made *after* the [enactment] in question has become law"), they do not display hostility to religion in a way that would undermine the emergency rule's neutrality. Instead, Governor Hochul's statements reflected an attempt to portray religion in a positive light and vaccination as consistent with religious principles—the same message that many faith leaders have also propounded. See *supra* at 12-13. Her statements are thus not remotely comparable to the statements that courts described as criticizing

disfavored religions or religious views in *Roman Catholic Diocese* and *New Hope Family Services*.

Plaintiffs are also wrong to assert (at 21-24) that any religious animus can be inferred from the fact that the Commissioner's earlier August 18 Order for Summary Action contained a religious exemption. DOH has explained that the Order for Summary Action was intended as an immediate, temporary "stop-gap measure"—one that was narrower than the emergency rule at issue here in several respects—"pending action by the Public Health and Health Planning Council," which issued the more comprehensive emergency rule at issue here to cover a broader range of facilities and workers. Murphy Decl. ¶ 6. DOH officials also explained at the August 26 public hearing that the emergency rule is silent on a religious exemption in order to provide healthcare employers with standards consistent with the longstanding measles and rubella vaccination requirements. See *supra* at 22-23. Thus, the changes between the Order for Summary Action and the emergency rule do not reflect religious hostility, but rather the inherently temporary and limited nature of the Order, and DOH's attempt in the emergency rule to follow the model already established by preexisting vaccination requirements.

b. DOH's emergency rule is generally applicable.

As relevant here, courts have identified two circumstances under which a policy can fail to be generally applicable. *See generally Fulton*, 141 S. Ct. at 1877. The first is if the policy "is substantially underinclusive such that it regulates religious conduct while failing to regulate secular conduct that is *at least as harmful* to the legitimate government interests purportedly justifying it." *Central Rabbinical Cong. v. New York City Dep't of Health & Mental Hygiene*, 763 F.3d 183, 197 (2d Cir. 2014) (emphasis added). The second is if the policy "invites the government to consider the particular reasons for a person's conduct by providing a mechanism for individualized exemptions." *Fulton*, 141 S. Ct. at 1877 (quotation and alteration marks omitted). Neither circumstance applies to DOH's emergency rule.

i. The rule is not substantially underinclusive.

On its face, DOH's emergency rule is generally applicable because it covers all healthcare workers at covered entities 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." 10 N.Y.C.R.R. § 2.61(a)(2). The only exception to this requirement is a narrow

medical exemption for workers who would currently suffer specific contra-indications if they were to receive the COVID-19 vaccine or are otherwise subject to specific "precautions." *See id.* § 2.61(d)(1). Plaintiffs claim (Br. at 24-26) that, under the Supreme Court's recent orders on COVID-19 assembly restrictions, this medical exemption precludes the emergency rule from being generally applicable and thus compels DOH to offer a religious exemption as well. This argument misconstrues the Supreme Court's recent orders as well as settled case law on general applicability.

As this Court has explained, it is simply not the case that a religious exemption is required whenever a policy offers *any* nonreligious exemption. Instead, the Free Exercise Clause subjects a policy to strict scrutiny only when it denies a religious exemption while at the same time offering a nonreligious exemption that is "at least as harmful" to the objectives of the underlying policy. *Central Rabbinical Cong.*, 763 F.3d at 197. In other words, what the Free Exercise Clause bars is "disparate treatment" of otherwise comparable exemption claims that differ only in their religious or non-religious motivation. *Agudath*, 980 F.3d at 229 (Park, J., dissenting); *see also Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021) (per curiam)

(strict scrutiny applies only when a policy treats "*comparable* secular activity more favorably than religious exercise" (emphasis added)).

In *Roman Catholic Diocese*, for example, the Supreme Court found that COVID-19 executive orders were not generally applicable when, on the record before the Court, they appeared to impose more stringent assembly restrictions on religious services than on a broad range of comparable secular businesses that "contributed to the spread of COVID-19" more than religious congregations would. 141 S. Ct. at 67. The Court reached the same conclusion in *Tandon*, holding that heightened scrutiny applied because, according to the record in that case, California appeared to treat a vast range of secular activities—including "hair salons, retail stores, personal care services, movie theaters, private suites at sporting events and concerts, and indoor restaurants"—more leniently than religious practices without any showing that the secular activities "pose[d] a lesser risk of [COVID-19] transmission than applicants' proposed religious exercise." 141 S. Ct. at 1297 (emphasis omitted).

The lower-court cases cited by plaintiffs similarly recognize that strict scrutiny applies only when a policy denies religious exemptions while granting nonreligious exemptions that are equally or more harmful

to the claimed government interest. For example, in *Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, the Third Circuit applied strict scrutiny to a municipal policy allowing medical but not religious exemptions from a rule prohibiting police officers from wearing beards. 170 F.3d 359, 360, 365-66 (3d Cir. 1999) (Alito, J.). The court noted that the asserted government interest was in maintaining a uniform appearance for law enforcement personnel and that the medical exemption directly undercut that interest in the same manner as any religious exemption would. Given that comparability, the availability of the medical exemption alone raised the concern that the municipality had "made a value judgment that secular (i.e., medical) motivations for wearing a beard are important enough to overcome its general interest in uniformity but that religious motivations are not." *Id.* at 366.

Similarly, in *Blackhawk v. Pennsylvania*, the Third Circuit applied strict scrutiny to a state law that forbade religious exemptions from restrictions on keeping wildlife in captivity while categorically exempting zoos and circuses from such restrictions. 381 F.3d 202, 210 (3d Cir. 2004) (Alito, J.). Noting that the purpose of the underlying state law was to raise revenue (from charging permit fees) and to "discourage the keeping

of wild animals in captivity," *id.* at 211, the Third Circuit found that the nonreligious exemptions for zoos and circuses "undermine[d] the purpose of the law *to at least to the same degree* as the covered conduct that is religiously motivated," *id.* at 209 (emphasis added).

In sharp contrast, the medical exemption in DOH's emergency rule is not comparable to the religious exemption requested by plaintiffs, for at least two reasons. *First*, far from "undermin[ing] the interests served by" the emergency rule, *id.* at 211, the medical exemption *advances* the underlying rule's objective of protecting the health of healthcare workers and preventing them from becoming unavailable to work for medical reasons. Denying an exemption to workers for whom a "COVID-19 vaccine [would be] detrimental to" their health, 10 N.Y.C.R.R. § 2.61(d)(1), on the other hand, would exacerbate one of the very risks that DOH is attempting to address, and conflict with healthcare providers' ethical obligations to "do no harm." *See Jacobson*, 197 U.S. at 39 (it "would be cruel and inhuman" to require vaccination of a person if "he is not at the time a fit subject of vaccination, or that vaccination, by reason of his then condition, would seriously impair his health").

The medical exemption is thus unlike the secular exemptions criticized by the Supreme Court in *Roman Catholic Diocese* and *Tandon*, and more similar to an exemption in the Oregon law that the Supreme Court found to be generally applicable in *Smith*. The Oregon law prohibited possession of peyote "unless the substance has been prescribed by a medical practitioner." *Smith*, 494 U.S. at 874. But this "prescription exception" did not preclude the Oregon law from being generally applicable for purposes of a Free Exercise claim because it did "not necessarily undermine Oregon's interest in curbing the unregulated use of dangerous drugs." *Fraternal Order*, 170 F.3d at 366. To the contrary, the prescription exception was consistent with the underlying drug law's objective of "protect[ing] public health and welfare" because "when a doctor prescribes a drug, the doctor presumably does so to serve the patient's health and in the belief that the overall public welfare will be served." *Blackhawk*, 381 F.3d at 211. The medical exemption here similarly serves rather than undercuts an important purpose of DOH's emergency rule.

Second, although the medical exemption does raise the risk of COVID-19 transmission from medically ineligible staff, its extremely narrow scope and limited duration means that the medical exemption

does not risk such harm "to *at least the same degree* as would" plaintiffs' proffered religious exemption. *Id.* at 211. As explained above, the medical exemption is available only when a worker can demonstrate a small number of specific contraindications—essentially, a severe or immediate allergic reaction to the COVID-19 vaccine or one of its components—or certain "precautions" recognized by CDC and DOH guidance. See *supra* at 16-20. By contrast, our country's respect for diverse religious views, including individualized beliefs that may not reflect any institutionalized creed, make it both legally and practically difficult to limit the scope of any religious exemption in a similar manner. *See Gillette v. United States*, 401 U.S. 437, 457 (1971).

This practical reality is confirmed by preliminary data showing that as much as four to six times the number of healthcare workers have claimed religious exemptions as have claimed medical exemptions. See *supra* at 25-27. Reports from other jurisdictions implementing COVID-19 vaccine requirements for healthcare workers are in accord—for example, San Diego's largest healthcare providers received seven times the number of requests for religious exemptions compared to medical exemptions. See *supra* at 26-27. And a similar disparity existed when

New York previously allowed religious exemptions from the vaccine requirements for public school children: in 2017 to 2018, for example, there were 4,571 medical exemptions but nearly six times as many religious exemptions (26,627).[58]

The medical exemption in DOH's emergency regulation is not only strictly limited in scope, but also in duration. It applies "only until [COVID-19] immunization is found no longer to be detrimental to such personnel member's health," and such duration "must be stated in the personnel employment medical record." 10 N.Y.C.R.R. § 2.61(d)(1). And CDC and DOH guidance note that the majority of contraindications and precautions will be temporary, meaning that most medical exemptions will simply defer the administration of the COVID-19 vaccine rather than permanently excusing a worker from being vaccinated.[59] For example, individuals suffering from an acute illness may need to defer vaccination,

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[58] Aff. of Debra Blog ¶ 15, *F.F. v. State*, Index No. 04108/2019 (Sup. Ct. Albany County July 29, 2019).

[59] For example, while those who have experienced anaphylactic shock from taking a vaccine might qualify for an indefinite exemption, that "severe allergy is rare, and less than one in 1 million people experience it." Pereira, *supra* (*at* Rausch-Phung Decl., Ex. GG); *see* Blumenthal, *supra*, at 1562 (2.5 to 11.1 instances of anaphylaxis per 1 million doses of mRNA vaccines).

but may receive a vaccination after recovering from the illness. See *supra* at 16-20. By contrast, plaintiffs have not suggested that any religious exemption would be limited in time or periodically reassessed, as the medical exemption must be under the emergency rule.

The strictly limited scope and duration of any medical exemption thus precludes the conclusion that the medical exemption will be "at least as harmful" to the underlying objectives of DOH's emergency rule as plaintiffs' requested religious exemption. *See Central Rabbinical Cong.*, 763 F.3d 197. In sharp contrast, the Supreme Court found that the secular activities permitted by the exemptions in *Roman Catholic Diocese* and *Tandon* were *riskier* than religious congregation, in light of various churches' and synagogues' larger physical venues and "admirable safety records." *Roman Catholic Diocese*, 141 S. Ct. at 67; *see also Tandon*, 141 S. Ct. at 1297 (noting that California had failed to "show that the religious exercise at issue is more dangerous"). And the Third Circuit similarly concluded in *Blackhawk* that the secular zoos-and-circuses exemption, which permitted large numbers of wild animals to be held in captivity, caused far greater harm than the plaintiff's religiously motivated request there to keep just two black bears. 381 F.3d at 211.

Accordingly, because the medical exemption here advances rather than undermines the objectives of DOH's emergency rule, and because it poses less of a risk than plaintiffs' requested religious exemption would, its presence here does not preclude the emergency rule from being generally applicable for purposes of a Free Exercise claim. Put simply, the medical exemption bears no similarity to the broad secular exemptions that the Supreme Court and other courts have found to raise concerns about discriminatory treatment against similarly situated religious concerns. Instead, the medical exemption is a singular and strictly limited exception that is not comparable in purpose or effect to any other exemption—religious or nonreligious alike.

ii. The rule does not provide for discretionary, individualized exemptions.

DOH's emergency rule is also generally applicable because it does not vest any government official or agency with broad discretion to grant individualized exemptions. A law that has such exemptions must satisfy strict scrutiny "because such a regime creates the opportunity for a facially neutral and generally applicable standard to be applied in practice in a

way that discriminates against religiously motivated conduct." *Blackhawk*, 381 F.3d at 209.

The Supreme Court recently applied this principle to hold that Philadelphia's scheme for granting foster care contracts was not generally applicable because it allowed a state official to grant an exception "in his/her sole discretion" to particular applications of Philadelphia's prohibition on sexual-orientation discrimination. *Fulton,* 141 S. Ct. at 1878 (quotation marks omitted). Similarly, *Smith* explained that the unemployment-compensation scheme at issue in *Sherbert v. Verner*, 374 U.S. 398 (1963), was not generally applicable because it allowed exceptions for "good cause," an undefined standard. 494 U.S. at 884. "[W]here the State has in place a system of individual exemptions, it may not refuse to extend that system to cases of 'religious hardship' without compelling reason." *Id.*

Here, by contrast, the emergency rule does not lay out any similarly broad discretionary scheme of individualized exemptions under which DOH could consider claims of religious hardship. Instead, the emergency rule contains only a single, limited exemption for employees for whom a "COVID-19 vaccine [would be] detrimental to" their health "based upon

a pre-existing health condition." 10 N.Y.C.R.R. § 2.61(d)(1). The scope of the exemption is narrow and clearly defined: it must be "in accordance with generally accepted medical standards," and it specifically references the "recommendations of the Advisory Committee on Immunization Practices." *Id.* And healthcare providers lack discretion to grant exemptions outside of these federally recognized criteria. Thus, unlike the schemes at issue in *Fulton* and *Sherbert*, the medical exemption does not authorize consideration of religious concerns at all. And it tightly constrains healthcare providers even as to their application of medical criteria for excusing workers from receiving the COVID-19 vaccine. The medical exemption thus bears no similarity to the broad discretionary schemes that have triggered heightened scrutiny in other cases.

2. DOH's emergency rule has a rational basis and would survive heightened scrutiny in any event.

As a neutral law of general applicability, the DOH emergency rule easily satisfies rational-basis review because it demonstrates a "reasonable fit" between the State's purpose and "the means chosen to advance that purpose." *Leebaert v. Harrington*, 332 F.3d 134, 139 (2d Cir. 2003) (quotation marks omitted). New York seeks to protect public health and

safety by reducing the incidence of COVID-19 in particularly vulnerable facilities that have borne the brunt of COVID-19 infections. The emergency rule reasonably serves this objective by vaccinating healthcare workers whose responsibilities require them to directly interact with patients, residents, and other personnel—thereby both protecting the workers themselves, and preventing them from being vectors of transmission to their colleagues and the vulnerable populations that they serve. These protections also prevent staffing shortages that could follow an outbreak among staff, and strains on limited healthcare resources that could follow an outbreak among patients or residents. *See* 43 N.Y. Reg. at 8. Indeed, plaintiffs do not purport to contest the rationality of DOH's emergency rule.

Instead, plaintiffs argue only that the emergency rule fails to satisfy heightened scrutiny. For the reasons given above, no heightened scrutiny applies to DOH's neutral and generally applicable policy. But even if some form of heightened scrutiny did apply here, DOH's emergency rule would satisfy it as well. As the Supreme Court has made clear, promoting public health by preventing the spread of COVID-19 is "unquestionably a compelling interest." *Roman Catholic Diocese*, 141 S.

Ct. at 67. And DOH's emergency rule is narrowly tailored to that end. *See id.*

First, there is "a very direct connection" between vaccination requirements and "the preservation of health and safety." *Garcia v. New York City Dep't of Health & Mental Hygiene*, 31 N.Y.3d 601, 612 (2018). See *supra* at 5-7. DOH specifically noted that the COVID-19 vaccines are safe and effective, and that unvaccinated individuals have eleven times the risk of being hospitalized with COVID-19. *See* 43 N.Y. Reg. at 8.

Second, the emergency rule focuses narrowly on specific workers in a discrete sector where COVID-19 transmission poses heightened and unacceptable risks: employees in healthcare settings who directly interact with patients and personnel in a way that would expose them to infection. Transmission of COVID-19 by healthcare workers in these facilities thus raises particular risks to (1) their own personal safety; (2) the safety of their colleagues; (3) the safety of the vulnerable populations they serve; and (4) the safety of the public at large, which could be threatened by staffing shortages or resource strains at healthcare facilities where there are COVID-19 outbreaks. *See id.* The rule does not apply to individuals working outside of enumerated entities in the healthcare

sector, and it does not apply to employees who pose no risk of exposing colleagues or patients to COVID-19. 10 N.Y.C.R.R. § 2.61(a)(2). Like long-standing regulations governing measles and rubella vaccinations for healthcare workers, the emergency rule is thus narrowly drawn to address the particular concerns raised by specific vulnerable settings and populations.

Third, contrary to plaintiffs' claim (Br. at 27), DOH considered but rejected alternative approaches to vaccination because they would not adequately achieve DOH's goal of promoting public health by preventing COVID-19 transmission in healthcare settings. DOH concluded that a testing requirement, for example, would be impracticable due to its expense and the unreasonable burden of requiring near-daily testing for employees. Testing is also limited in its effectiveness because existing tests are imperfect, and healthcare personnel could contract and spread COVID-19 between tests. Similarly, a masking requirement, while "helpful to reduce transmission . . . does not prevent transmission." 43 N.Y. Reg. at 8. DOH thus reasonably concluded that masking should be required *in addition to* vaccination, not in place of it.

In addition, a policy allowing private healthcare employers to decide on their own whether to require vaccinations would be inadequate to address the harms that DOH has identified. For example, a recent study showed that vaccination rates among nursing home staff were lagging before DOH issued the emergency rule: only 60% were fully vaccinated as of July 2021.[60] DOH also has an interest in ensuring uniformity across New York's healthcare system to protect patients or residents who transfer between facilities.

Contrary to plaintiffs' argument (Br. at 29-30), heightened scrutiny would not require defendants to show that the omission of a religious exemption in particular serves a compelling interest. Applying that analysis here would improperly import the analysis required in the Religious Land Use and Institutionalized Persons Act, *see* 42 U.S.C. § 2000cc-1(a), and the Religious Freedom Restoration Act, *see id.* § 2000bb-1(b), which do not apply here to claims against the State outside the context of land use and prisons, *see City of Boerne v. Flores*, 521 U.S. 507, 511

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[60] Brian E. McGarry et al., *Association of Nursing Home Characteristics with Staff and Resident COVID-19 Vaccination Coverage* 2, JAMA Internal Med. (Sept. 16, 2021) (internet).

(1997). But even if that analysis did apply here, the emergency rule would still withstand scrutiny.[61]

As explained above, a religious exemption would lead to significantly more unvaccinated healthcare workers for longer periods of time than are currently permitted by the emergency rule's narrow medical exemption. Heightened scrutiny would not preclude DOH from responding to the qualitatively higher risks posed by a religious exemption in the way that it chose. The "mere fact that a law contains some secular exceptions" is not in of itself sufficient to prove that "the government lacked a compelling interest in avoiding another exception to accommodate a claimant's religious exercise." *Yellowbear v. Lampert*, 741 F.3d 48, 61 (10th Cir. 2014) (Gorsuch, J.). Courts look for "a qualitative or quantitative difference between the particular religious exemption requested and other secular exceptions already tolerated." *Id.* Here, the significant differences between the narrow medical exemption and the religious

[61] Plaintiffs are also wrong to claim (Br. at 30-34) that New York's healthcare sector has reached herd immunity and the emergency rule is unnecessary. DOH relied on ample evidence (see *supra* at 21-24) that the Delta variant still remains a threat, and plaintiffs' speculation to the contrary is unable to overcome that reasoned decision-making.

exemption requested by plaintiffs justify DOH's decision to allow only tightly constrained medical exemptions to its emergency rule.

DOH's reasons for rejecting less restrictive alternatives than vaccination, such as masking and testing, also justify the absence of such alternatives for workers claiming a religious exemption. Although testing and masking would certainly reduce the risk of COVID-19 transmission and infection by unvaccinated workers, they are not as effective as vaccination. And these alternatives' reduced efficacy is particularly troubling in light of the Delta variant's markedly higher transmissibility and lethality. By contrast, the COVID-19 vaccines are not only highly effective at reducing infection and transmission, but also safe, free, and easily available.

Accordingly, DOH's emergency rule would withstand heightened scrutiny even if such scrutiny applied.

C. Compulsory Vaccination Does Not Violate Substantive Due Process.

Finally, plaintiffs have also failed to show a likelihood of success on their substantive due process claim. This Court's decision in *Phillips*, which held that there was no substantive due process right to resist New

York's vaccination requirement for schoolchildren, forecloses plaintiffs' claim. *See* 775 F.3d at 542-43.

Substantive due process protects with heightened scrutiny only "those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition." *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (quotation marks omitted); *accord Leebaert*, 332 F.3d at 140. Because the Supreme Court has "always been reluctant to expand the concept of substantive due process," it has stressed the need to first carefully and narrowly define the interests at issue before looking to see if they are deeply rooted in law, practices, and traditions. *Glucksberg*, 521 U.S. at 720 (quotation marks omitted).

Applying this framework, plaintiffs' substantive due process claim amounts to the claim that they have a right to work at healthcare facilities in positions where they could expose themselves and others to infection without receiving a vaccination. As in *Phillips*, this asserted right is not "objectively, deeply rooted in this Nation's history and tradition." *Id.* at 720-21 (quotation marks omitted). To the contrary, the only deeply rooted history here supports New York's policy of requiring COVID-19 vaccinations for healthcare workers. See *supra* at 5-7. This

Court recently recognized as much when it denied without comment a stay of the vaccination requirement for New York City teachers that was predicated on a substantive due process claim. *See* Order, *Maniscalco v. New York City Dep't of Educ.*, No. 21-2343 (2d Cir. Sept. 27, 2021), ECF No. 28.

Accordingly, plaintiffs' claim is evaluated under the deferential standards of rational-basis review. *See Beatie v. City of New York*, 123 F.3d 707, 711 (2d Cir. 1997). And, as explained above (see *supra* at 56-57), DOH's emergency rule is plainly rational.

POINT II

THE BALANCE OF THE EQUITIES TIPS DECIDEDLY IN FAVOR OF DENYING A PRELIMINARY INJUNCTION HERE

Plaintiffs have failed to establish that they will suffer irreparable harm, "[p]erhaps the single most important prerequisite for the issuance of a preliminary injunction." *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002) (alteration in original) (quotation marks omitted). The principal harm asserted by plaintiffs is a potential loss of their employment due to the DOH emergency rule (*see* Br. at 7-8, 41). But plaintiffs

have failed to establish that any such harm is either imminent or irreparable.

First, plaintiffs' threadbare evidence fails to establish that they face any imminent threat of future loss of employment. As an initial matter, and contrary to plaintiffs' repeated mischaracterizations (*e.g.*, A. 38 (¶ 8)), DOH's emergency rule does not say anything about whether unvaccinated healthcare workers should or should not be retained. To comply with the emergency rule's requirement that certain healthcare workers be vaccinated, an employer can reassign such workers to activities where, if they were infected, they would not pose a risk of transmitting COVID-19 to patients, residents, or other workers. *See* 10 N.Y.C.R.R. § 2.61(a)(2). DOH's emergency rule thus does not, on its face, require any employer to terminate unvaccinated workers, including plaintiffs. And plaintiffs fail to describe either the functions they perform at work or whether they have sought (or been denied) reassignment to activities that would place them outside the scope of the emergency rule.

Nor have plaintiffs shown that their particular employers are choosing to implement DOH's emergency rule by terminating them. Although plaintiffs' complaint alleges that two of the plaintiffs (Melendez

and Synakowski) will "lose their employment" if they remain unvaccinated (A. 11 (¶ 22)), Synakowski has offered no evidence to support that conclusory assertion (A. 38 (¶ 8)). The letter from Melendez's employer, in turn, does not threaten termination at all, but simply lists restrictions on her work activities if she does not receive a COVID-19 vaccine. (A. 36.) Plaintiffs' appellate brief asserts that the last plaintiff, Bono, has already been terminated (Br. at 6 n.2, 43), but provides no support for this assertion. In any event, if she has indeed been fired, that past injury would not support a preliminary injunction here because no relief that this Court could issue against DOH would compel Bono's former employer to rehire her. *See Garcia v. Google, Inc.*, 766 F.3d 929, 938 (9th Cir. 2014) ("past injuries aren't sufficient to establish irreparable harm for purposes of an injunction"), *on reh'g en banc*, 786 F.3d 733 (9th Cir. 2015). Courts routinely deny injunctive relief when presented with similarly threadbare claims of irreparable harm. *See, e.g.*, *Baker's Aid v. Hussmann Foodservice Co.*, 830 F.3d 13, 16 (2d Cir. 1987).

Second, even if plaintiffs did face the imminent threat of being terminated, it is well-established that the loss of employment, and the resulting financial loss, do not constitute "irreparable harm" because

plaintiffs can be fully compensated by reinstatement or with money damages. *See Sampson v. Murray*, 415 U.S. 61, 90-92 (1974); *Hyde v. KLS Pro. Advisors Grp., LLC*, 500 F. App'x 24, 25 (2d Cir. 2012); *Savage v. Gorski*, 850 F.2d 64, 67 (2d Cir. 1988). This principle is independently fatal to plaintiffs' request for a preliminary injunction.

Plaintiffs also assert irreparable injury from an imminent deprivation of their First Amendment right to free exercise. *See Roman Catholic Diocese*, 141 S. Ct. at 67. But plaintiffs do not allege—much less prove—that DOH's emergency rule will compel them to act in violation of their religious beliefs. They remain free to refuse a COVID-19 vaccine, and if they do so, they may need to find a new position that falls outside the scope of DOH's emergency rule (whether with their current employer or a new employer).

In sharp contrast to plaintiffs' failure to show imminent irreparable harm, the public would suffer serious harms if DOH's emergency rule were stayed. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). As discussed above (see *supra* at 21-24), achieving high vaccination rates in particularly vulnerable settings is of the utmost importance. Those vulnerable populations include immunocompromised patients

especially susceptible to viral infections and people who cannot receive the COVID-19 vaccine because they are too young or have contraindications. The COVID-19 vaccines are extremely safe and effective at protecting healthcare workers themselves and the populations they serve from suffering severe complications from COVID-19. And the vaccination requirement will also protect others who need emergency medical treatment—for example, individuals suffering heart attacks, strokes, or appendicitis—from the consequences of staffing shortages and overstrained emergency rooms that could follow a COVID-19 outbreak among healthcare workers.[62]

These concerns are especially urgent now in light of the uncertainty surrounding the scope of future COVID-19 outbreaks. The emergence and prevalence of the Delta variant have led experts to predict that there will be a fall surge in COVID-19 infections.[63] And limited healthcare resources will soon face additional strains due to seasonal influenza and

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[62] *See, e.g.*, Jenny Deam, *A Boy Went to a COVID-Swamped ER. He Waited for Hours. Then His Appendix Burst*, ProPublica (Sept. 15, 2021) (internet).

[63] Jeanne Whalen, *Models Predict U.S. Coronavirus Infections Could Surge This Fall If Vaccination Rates Lag, Former FDA Chief Says*, Wash. Post (June 20, 2021) (internet).

other diseases that accompany the onset of fall and winter.[64] Vaccination of healthcare workers will help to prevent additional burdens from being inflicted on the healthcare sector at the precise moment when it is already at threat of becoming overtaxed.

Accordingly, the balance of the equities tips decidedly in favor of defendants. This Court may affirm the district court's denial of a preliminary injunction on that ground alone.

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[64] Centers for Disease Control & Prevention, *Influenza (Flu)* (last visited Oct. 7, 2021) (internet).

CONCLUSION

For the foregoing reasons, this Court should affirm the district court's denial of plaintiffs' motion for a preliminary injunction.

Dated: New York, New York
October 7, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Kelly Cheung, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 13,294 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7) and Local Rule 32.1.

/s/ *Kelly Cheung*

Addendum

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JOHN DOES 1–2, JANE DOES 1–3,
JACK DOES 1–1750, JOAN DOES 1–750,

Plaintiffs,

v.

KATHY HOCHUL, in her official capacity as Governor of the State of New York, HOWARD A. ZUCKER, in his official capacity as Commissioner of the New York State Department of Health, TRINITY HEALTH, INC., NEW YORK-PRESBYTERIAN HEALTHCARE SYSTEM, INC., WESTCHESTER MEDICAL CENTER ADVANCED PHYSICIAN SERVICES, P.C.,

Defendants.

No. 21-cv-5067 AMD-TAM

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) The Department of Health and the Public Health and Health Planning Council ("PHHPC") have utilized their authority in recent years to promulgate emergency regulations. Examples include:

a) Requiring standards for operation of "cooling towers" that can harbor legionella bacteria and spread disease (NY Reg, Sept. 2, 2015 at 14-17; 10 NYCRR Part 4);

b) Creating civil penalties for possession of "bath salts" and synthetic marijuana (NY Reg, Aug. 26, 2015 at 8-11; 10 NYCRR Subpart 9-1);

c) Requiring local health department to develop action plans to address the potential spread of the Zika virus (NY Reg, Apr. 6, 2016 at 23-24; 10 NYCRR § 40-2.24);

d) Facilitating the prescribing and dispensing of controlled substances, administering treatment for narcotics addiction, and creating an opioid overdose program (NY Reg, Aug. 27, 2014 at 11-13, and Oct. 18, 2017 at 16-17; 10 NYCRR §§ 80.136 and 80.138).

6) On August 23, 2021, DOH published a proposed Emergency Regulation to be reviewed and adopted by the Public Health and Health Planning Council ("PHHPC").[1] The Emergency Regulation was adopted by PHHPC on August 26, 2021 and became effective August 26, 2021 for 90 days.[2] A copy of the Emergency Regulation is annexed hereto as **Exhibit A**.

7) This Emergency Regulation provided that "[c]overed entities shall continuously require [covered] personnel to be fully vaccinated against COVID-19". The "personnel" covered under this Emergency Regulation are "all persons employed [by] or affiliated with a covered entity, whether paid or unpaid . . . who engage in activities such that if they were infected with

[1] 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-marking 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/ (last viewed September 22, 2021).

[2] 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.

COVID-19, they could potentially expose other covered personnel, patients, or residents to the disease." Id.

8) 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, the rise of the Delta variant, 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.

9) Namely, despite the ending of the state disaster emergency on June 25, 2021, data available before the Emergency Regulation was adopted suggested that "[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

10) Despite the gains that New York has made, numbers 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.

11) 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.[3] 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 now known to be 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**.

12) 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 of September 19 to September 25, 2021, 99.1% of cases were Delta.[4] Based on data collected, in New York State for a four-week period ending September 11, 2021, 98.54% of cases were Delta.[5]

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[3] 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).
[4] See *Variant Proportions*, CDC, found at https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last viewed October 5, 2021).
[5] Id.

13) 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.

14) 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**.

15) Additionally, the Delta variant has 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 copy of the CDC's *SARS-CoV-2 Variant Classifications and Definitions* is attached hereto as **Exhibit G**.

16) One of the key concerns in this regard is to ensure that New York State does not return to the severity of the pandemic 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.

17) On October 5, 2021, Johns Hopkins reported that globally, 235,495,429 individuals to date had tested positive for COVID-19, and a total of 4,811,281 confirmed COVID-19 deaths worldwide.[6] In addition, 43,853,214 individuals in the United States had tested positive for COVID-19 to date, and total 703,402 had died of COVID-19. Id.

18) 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. We are now in the midst of another resurgence, with highly transmissible Delta variant.

19) In New York, as of October 3, 2021, the total number of individuals to date who had tested positive for COVID-19 was 2,424,368,[7] and as reported to and compiled by the CDC, the number of individuals who had died of COVID-19 was 56,917.[8]

20) On October 3, 2021, out of 122,193 COVID-19 tests, there were 2,896 new positive COVID-19 cases in New York State. This is a total positivity rate of 2.37%.[9] By

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[6] See COVID-19 Dashboard, John Hopkins University of Medicine, found at https://coronavirus.jhu.edu/map.html (last viewed October 5, 2021).

[7] 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 October 5, 2021).

[8] 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 October 5, 2021).

[9] 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

comparison, a year ago, on October 3, 2020, out of 110,329 COVID-19 tests, there were 1,222 positive COVID-19 cases in New York State. This was a positivity rate of 1.10%.[10] Despite the gains that New York has made, the pandemic is not over as numbers have continued to increase.

21) 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**.

22) 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**.

23) With the state disaster emergency ended but 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**.

Basis for Mandating COVID-19 Vaccines for Health Care Personnel

24) 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 J.** The mortality rate of COVID-19 is

viewed October 5, 2021).
[10] Id.

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 K**. 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 L**.

25) This emergency regulation focuses on the vaccination of healthcare workers in the already highly-regulated covered entities under the Department's direct statutory and regulatory authority as a means to protect the public health and reduce the incidence of COVID-19 during a time when the Delta variant is causing a surge in COVID-19 cases. This regulation will protect both the State's frontline healthcare workers and the vulnerable patient populations in the healthcare sector where COVID-19 transmission poses heightened risks.

26) The regulation is tailored to focus on healthcare facilities as settings that pose a unique risk of COVID-19 transmission, as compared to other settings. For example, it is difficult for healthcare workers who practice hands-on patient care to achieve the same types of social distancing measures that are put in place in other settings. There is also an increased risk of severe illness associated with COVID-19 transmission in healthcare or long-term care settings due to the vulnerable patient or elderly populations that healthcare providers are serving, particularly those with underlying conditions.[11]

27) Patient facing healthcare professionals and their household members have threefold and twofold increased risks, respectively, of COVID-19. A copy of the *Risk of*

[11] CDC, People with Certain Medical Conditions, found at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last viewed September 29, 2021).

Hospital Admission with Coronavirus Disease 2019 in Healthcare Workers and their Households: Nationwide Linkage Cohort Study is attached hereto as **Exhibit M**. According to the CDC, to date, 569,147 US health care personnel have contracted COVID-19 and 1,828 have died of COVID-19.[12]

28) Further, health care workers tend to care for persons who are elderly, sick, and vulnerable, who might not be vaccinated because they have contraindications, or who might not gain sufficient immunity from the vaccine to provide adequate protection from severe 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 N.** Vaccinating healthcare workers would protect even the unvaccinated patients because COVID-19 vaccines are associated with fewer infections overall and less risk of transmission.

29) 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

[12] Cases & Deaths Among Healthcare Personnel, CDC, found at https://covid.cdc.gov/covid-data-tracker/#health-care-personnel (last viewed October 5, 2021).

copy of *Major Health Care Professional Organizations Call for COVID-19 Vaccine Mandates for All Health Workers* is attached hereto as **Exhibit O.**

30) 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 P.** 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 O.** 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.

31) 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 Q-T**. 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 R.** 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 T.**

32) 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 U**. 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 V**. 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.

33) 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 W.**

34) 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 X.**

35) The CDC has expressed concern that "COVID-19 outbreaks have occurred in LTCFs 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 Y.** 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.

36) The vaccination requirement is imperative to protect those who need medical treatment during this pandemic from potentially devastating staffing shortages and overstrained hospitals that could follow a COVID-19 outbreak among our frontline healthcare workers. The pandemic has already caused staffing challenges in New York State because of the increase in COVID-19 cases due to the Delta variant. A COVID-19 outbreak among healthcare workers would exacerbate these challenges.

37) There have been recent concerns that the vaccination mandate could inadvertently cause staffing shortages due to healthcare worker resignations. However, this pales in comparison to the potential staffing shortages that could be caused by a deadly and disruptive outbreak among unvaccinated healthcare personnel.

38) Governor Hochul has put measures put in place to address any potential healthcare worker staffing shortages. Among other measures, Executive Order No. 4 authorizes out-of-state and retired professionals and recent graduates to practice in New York, and allows additional healthcare workers to administer COVID-19 testing and vaccinations. A copy of Executive Order No. 4 is attached hereto as **Exhibit Z**. Governor Hochul also "directed a 24/7 Operations Center, led by the New York State Department of Health, to constantly monitor staffing operations and trends statewide, provide guidance to healthcare facilities and help troubleshoot acute situations with providers as necessary." A copy of the September 27, 2021 Press Release is attached hereto as **Exhibit AA**.

39) Thus far, the vaccination mandate has proven to be successful. Per the Emergency Regulation, current personnel were 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. On September 28, 2021, Governor Hochul announced that the percentage of nursing home staff receiving at least one COVID-19 vaccine dose increased to 92% as of September 27th, up from 71% on August 24th and 82% on September 20th. The percentage of adult care facilities staff receiving at least one COVID-19 vaccine dose similarly increased to 89% as of September 27th, up from 77% on August 24th and 85% on September 20th. The percentage of hospital staff receiving at least one dose is 92% based on preliminary self-reported data. The percentage of

fully vaccinated hospital staff is 85% as of September 27th, up from 84% as of September 22nd and 77% as of August 24th.[13] A copy of the September 28, 2021 Press Release is attached hereto as **Exhibit BB**.

40) Time is of the essence. The Department is concerned that the numbers of COVID-19 cases will continue to increase, especially with the coming 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. Vaccination of healthcare workers will help to prevent additional burdens from being inflicted on the healthcare sector at a point in time when it is already threatened with being overtaxed.

41) 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

[13] On September 29, 2021, Governor Hochul announced that the percentage of fully vaccinated hospital staff had increased to 87%. *Governor Hochul Provides Update on Health Care Staffing Following First-in-Nation Vaccine Mandate Implementation*, found at https://www.governor.ny.gov/news/governor-hochul-provides-update-health-care-staffing-following-first-nation-vaccine-mandate (last viewed September 30, 2021). As of September 29, 2021, in the Capital Region, 94% of hospital workers were reported as fully vaccinated. In Central New York, 88% of hospital workers were fully vaccinated. In the Finger Lakes region, 90% of hospital workers were fully vaccinated. In Long Island, 82% of hospital workers were fully vaccinated. In the Mid-Hudson region, 87% of hospital workers were fully vaccinated. In Mohawk Valley, 82% of hospital workers were fully vaccinated. In New York City, 87% of hospital workers were fully vaccinated. In the North County region, 87% of hospital workers were fully vaccinated. In the Southern Tier region, 86% of hospital workers were fully vaccinated. Finally, in Western New York, 87% of hospital workers were fully vaccinated. *Hospital Worker Vaccinations*, found at https://covid19vaccine.health.ny.gov/hospital-worker-vaccinations (last viewed September 30, 2021).

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 CC**.

42) 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 Unites States. A copy of the CDC's *Safety of COVID-19 Vaccines* is attached hereto as **Exhibit DD**. 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 EE**. 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 DD.** Additionally, the vaccines are proven effective at protecting against severe disease and death from Delta and other currently known variants. A copy of the CDC's *Key Things to Know* is attached hereto as **Exhibit FF**.

43) 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 GG**. 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 HH.** 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 EE**. 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.

44) Alternatives to the healthcare worker vaccination mandate were considered and rejected as insufficient to protect against the increased risk of COVID-19 transmission in healthcare settings. As set forth in the regulatory impact statement for the subject regulation, acceptable 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 vaccinations will help reduce the numbers of infections in these settings even further." Additionally, another alternative to require healthcare facilities to test *all* personnel in their facility before each shift was rejected as ineffective and burdensome. It might be difficult for entities to turn around PCR test results quickly before the commencement of each workers'

shift, especially given the number of workers in larger facilities; additionally, it would place an "unreasonable resource and financial burden" on these facilities. Finally, 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." See **Exhibit A.**

The Importance of Vaccinations

45) Fully vaccinated individuals are less likely to spread infectious diseases to other people, including people cannot get vaccinated because they are too young, or have a weakened immune system.

46) 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.

47) 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.

48) 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

49) 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 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

50) 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 II**.

51) 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 JJ**.

52) 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 KK**.

53) 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 LL**.

54) 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 MM**.

55) 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 NN**.

56) 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 OO**.

57) 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 PP**.

58) On September 22, 2021, the FDA amended the EUA for the Pfizer-BioNTech's COVID-19 vaccine to be administered as boosters to certain groups of individuals, including but not limited to "individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19." A copy of the September 22, 2021 FDA News Release is attached hereto as **Exhibit QQ**.

59) On September 23, 2021, the CDC's Advisory Committee on Immunization Practices ("ACIP") met to discuss recommendations on booster shots. The ACIP only recommended boosters for the elderly population, long-term care residents, and those with some underlying medical conditions. On September 24, 2021, the CDC provided recommendations that ultimately differed from the ACIP's recommendations by also recommending the booster for workers in high-risk settings (explicitly naming healthcare workers), as well as those 65 and older, those with underlying medical conditions, and those in long-term care settings, aligning their recommendations with the FDA's EUA amendment. A copy of the CDC's *Who is Eligible for a COVID-19 Vaccine Booster Shot?* is attached hereto as **Exhibit RR**.

The Development of COVID-19 Vaccines

60) 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.

61) 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.

62) 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 SS**.

63) 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 TT**.

64) 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 UU**.

65) 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 VV**.

66) 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 WW.**

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

68) 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 XX**.

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

70) 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 YY**.

Religious Exemption to COVID-19 Vaccinations

71) 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.

72) 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).

73) 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.

74) 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."

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

76) 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-12th 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.

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

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

78) 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 ZZ.** 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 form SARS-CoV-2 Infection* is attached hereto as **Exhibit AAA.** This means that vaccine-induced antibodies appear to be better able than infection-induced antibodies to bind to variant strains. Id.

79) 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 BBB.**

80) 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 CCC.** The risk of severe illness and death from COVID-19 far outweighs any benefits of natural immunity. **Exhibit ZZ.** To reduce the likelihood of future infection, health care personnel should be vaccinated, even if they were previously infected with COVID-19.

Breakthrough Infections

81) Vaccine breakthrough cases are "instances in which an individual tested positive for COVID-19 after being fully-vaccinated." There have been breakthrough cases and associated hospitalizations in fully-vaccinated people reported in New York State. However, these cases occur "at levels substantially lower than among unvaccinated people" due to COVID-19 vaccine effectiveness.[14]

82) As of September 26, 2021, the Department is aware of 86,860 laboratory-confirmed breakthrough cases of COVID-19 in New York State, which corresponds to .7% of the fully-vaccinated population. There have only been 6,083 hospitalizations with COVID-19 among fully-vaccinated people in New York State, which correspondents to .05% of the population of fully-vaccinated people.[15]

83) Breakthrough infections do not mean that vaccines are not working; the breakthrough cases are uncommon events among the fully vaccinated because the vaccinations *do* work. However, no vaccination is 100% effective.[16]

84) It is also important to consider these rates in the context of cases and hospitalizations in unvaccinated individuals, which are substantially higher. New York State data available before the emergency regulation was adopted shows that "unvaccinated individuals are approximately 5 times as likely to be diagnosed with COVID-19 compared to vaccinated individuals. Those who are unvaccinated have more than11 times the risk of being

[14] NYS DOH, COVID-19 Breakthrough Data Report, found at https://covid19vaccine.health.ny.gov/covid-19-breakthrough-data-report (last viewed September 30, 2021).
[15] Id.
[16] Id.

hospitalized with COVID-19." See **Exhibit A**. In the week of September 6, 2021, data shows that fully-vaccinated New Yorkers had a 77.2% "lower chance of becoming a COVID-19 case compared to unvaccinated New Yorkers." Fully vaccinated New Yorkers had between 89.7% and a 95.2% "lower chance of being hospitalized with COVID-19, compared to unvaccinated New Yorkers." [17]

85) These findings align with clinical and population studies being conducted worldwide.

86) For example, a study published in the New England Journal of Medicine conducted of 11,453 fully-vaccinated health-care workers at a medical center in Israel showed that the most breakthrough infections that occurred were mild or asymptomatic. Of the workers that were tested for COVID-19 during the study, only 39 breakthrough cases were detected. 26 had mild symptoms and none required hospitalizations. Notably, for the 37 patients for whom data was available about the source of infection, the suspected source was an unvaccinated person. A copy of *Covid-19 Breakthrough Infections in Vaccinated Health Care Workers* is attached hereto as **Exhibit DDD**.

Medical Exemptions

87) The Emergency Regulation provides for a medical exemption for those personnel who have a "licensed physician or certified nurse practitioner [certify] 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 medical exemption must be "in accordance with

[17] NYS DOH, COVID-19 Breakthrough Data Report, found at https://covid19vaccine.health.ny.gov/covid-19-breakthrough-data-report (last viewed September 30, 2021).

generally accepted medical standards" such as the recommendations of the Advisory Committee on Immunization Practices ("ACIP") of the U.S. Department of Health and Human Services, upon which the CDC guidance on use of the COVID-19 vaccine is based. **Exhibit A**.

88) In practice, there are likely few instances that would result in the granting of a valid medical exemption to the COVID-19 vaccination. Based on currently applicable accepted medical standards, there are only a narrow set of contraindications and, in some cases, additional precautions to the COVID-19 vaccinations.

89) The Department issued a "Frequently Asked Questions (FAQs) Regarding the August 26, 2021-Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation". The FAQs confirmed that the applicable ACIP COVID-19 vaccination contraindications and precautions are available on the Centers for Disease Control and Prevention's ("CDC") website. A copy of the FAQs is attached hereto as **Exhibit EEE**.

90) In general, the CDC defines "contraindications" as conditions under which a vaccine should not be administered because of the increased risk for a serious adverse reaction. As indicated by the CDC, "the majority of contraindications are temporary" and vaccines can often be administered when the contraindication no longer exists. A "precaution" is a "condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity." When a precaution is present, the vaccination should be deferred, but a vaccination might be indicated even in the face of a precaution if the benefit from the vaccine outweighs the risk. A copy of the CDC's *Contraindications and Precautions* is attached hereto as **Exhibit FFF**.

91) The CDC considers there to be only very narrow contraindications to the COVID-

19 vaccines, limited to "[s]evere allergic reaction (e.g. anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine" or "[i]mmediate (within 4 hours) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine." A copy of the CDC's *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* is attached hereto as **Exhibit GGG**. The CDC defines "immediate allergic reaction" as "any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g. wheezing, stridor), or anaphylaxis that occur within four hours following administration." See **Exhibit EEE; Exhibit GGG**.

92) The CDC confirms that "most people deemed to have a precaution to a COVID-19 vaccine at the time of their vaccination appointment can and should be administered [the] vaccine." **Exhibit GGG**. For example, a mere history of an immediate allergic reaction to any other vaccine or injectable therapy is a precaution, but not a contraindication to the vaccine. Other recognized precautions include: 1) a history of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine; 2) current moderate to severe acute illness (which is a temporary precaution until the individual has recovered); and 3) "[a] contraindication to one type of COVID-19 vaccine (e.g., mRNA COVID-19 vaccines) have precautions to another type of COVID-19 vaccine (e.g., Janssen/Johnson vaccine)." **Exhibit EEE**.

93) Those with a medical exemption are not required to be vaccinated until the immunization "is found no longer to be detrimental to such personnel member's health." **Exhibit A**. Many medical exemptions are merely temporary; however, there are some exceptions. For instance, an individual may have a serious allergic to the first dose of a mRNA COVID-19 vaccine and would thereafter have a contraindication to receiving additional doses of

the mRNA vaccine. **Exhibit GGG**.

94) Conversely, while a precaution exists for those with a prior or current SARS-CoV-2 infection or a history of multisystem inflammatory syndrome in children ("MIS-C") or adults ("MIS-A") caused by SARS-CoV-2 infection, these precautions are recommended by the CDC to be strictly temporary in nature. Id. The CDC recommends that those with a history of symptomatic or asymptomatic SARS-CoV-2 infection should be offered the vaccine regardless of this history, including those with long-term post- COVID-19 symptoms. The vaccination should only be deferred until the person has recovered from symptomatic, acute illness, and they have met criteria to discontinue isolation. There is no recommended interval before the vaccination can occur. For those with a history of MIS-C or MIS-A, they should consider only "delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing . . . the risk of reinfection and therefore, the benefit from vaccination, might increase with time following initial infection." Id.

95) In both of the above cases, while recent COVID-19 infection may be a reason to delay vaccination temporarily, it is not a permanent contraindication to the vaccine. The risk of SARS-CoV-2 reinfection might be low after the period of initial infection due to natural immunity, but the CDC notes that over time, this immunity wanes. Id.

96) Similarly, for those receiving "monoclonal antibodies or convalescent plasma as part of COVID-19 treatment" vaccination should be only temporarily deferred for at least 90 days after receiving the antibodies or plasma for treatment as a precautionary measure to ensure there is no interference with the vaccine-induced immune response. Id.

97) Local or systemic post-vaccination symptoms following the first dose of the

COVID-19 vaccine (e.g., pain, swelling, localized axillary lymphadenopathy, fever, fatigue, headache, chills, myalgia, arthralgia) are not a contraindication to the second dose of the vaccine. Id.

98) Practitioners should follow the generally accepted medical standards to appropriately grant legitimate medical exemptions to those with valid contraindications and, in some cases, precautions. In practice, given the narrow breadth of the currently known limited contraindications and precautions, this generally results in few valid medical exemptions.

99) Preliminary data available as of September 28, 2021 suggest that for hospitals statewide, only 0.5% of staff are medically ineligible (with 0.4% of direct care workers being medically ineligible). For nursing homes, only 0.4% of the staff were considered medically ineligible (with 0.5% of direct care workers being medically ineligible). Finally, for adult care facilities, only 0.6% of staff were considered medically ineligible (identical for direct care workers). A copy of *Governor Hochul Releases Encouraging Data Showing Impact of Health Care Staff Vaccine Mandate* is attached hereto as **Exhibit HHH**.

Dated: October 5, 2021

ELIZABETH RAUSCH-PHUNG

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JOHN DOES 1–2, JANE DOES 1–3,
JACK DOES 1–1750, JOAN DOES 1–750,

Plaintiffs,

v.

KATHY HOCHUL, in her official capacity as Governor of the State of New York, HOWARD A. ZUCKER, in his official capacity as Commissioner of the New York State Department of Health, TRINITY HEALTH, INC., NEW YORK-PRESBYTERIAN HEALTHCARE SYSTEM, INC., WESTCHESTER MEDICAL CENTER ADVANCED PHYSICIAN SERVICES, P.C.,

Defendants.

No. 21-cv-5067 AMD-TAM

DECLARATION OF VALERIE DEETZ

VALERIE A. DEETZ, declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true:

1) I am the Deputy Director of the Center for Health Care Provider Services and Oversight, Office of Primary Care and Health Systems Management at the New York State Department of Health ("Department" or "DOH"). I have worked for the Department since 2005 and held this position since March 2019. In this position I am responsible for providing leadership, direction and management for the surveillance and oversight of New York's hospitals, diagnostic and treatment centers, organ transplant centers, nursing homes, home health care providers, hospice providers, adult care facilities, Intermediate Care Facilities (ICFs), Emergency Medical Services (EMS), and funeral directors. Prior to holding this position, I served as the Director of the Division of Adult Care Facilities and Assisted Living Surveillance, the Deputy Director of Nursing Homes and Intermediate Care Facility Surveillance, and the

Director of the Community Transition Program.

2) 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 a review of DOH records.

3) According to facility self-reported data reported on October 4, 2021 for all nursing homes statewide 120,225 out of the 140,917 healthcare workers ("HCW") were reported as fully vaccinated (85.3%), with an additional 17,084 (12.1%) receiving one dose only. Only 674 total HCW were reported as medically ineligible. 2,934 reported "other" exemptions.[1]

4) According to facility self-reported data reported on October 4, 2021 for all adult care facilities statewide 24,730 out of the 29,417 healthcare workers ("HCW") were reported as fully vaccinated (84.1%), with an additional 2,240 (7.6%) receiving one dose only. Only 149 total HCW were reported as medically ineligible. 399 were reported in "other" status.[2]

Dated: October 5, 2021

Valerie A. Deetz

VALERIE A. DEETZ

[1] The question posed to the facilities asked for "other exemptions." However, the Department is unaware of an exemption other than medical or religious.

[2] This number encompasses those who have not yet gotten vaccinated, but were not otherwise reported as medically ineligible. This may include those who have claimed a religious exemption.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JOHN DOES 1–2, JANE DOES 1–3,
JACK DOES 1–1750, JOAN DOES 1–750,

Plaintiffs,

v.

KATHY HOCHUL, in her official capacity as Governor of the State of New York, HOWARD A. ZUCKER, in his official capacity as Commissioner of the New York State Department of Health, TRINITY HEALTH, INC., NEW YORK-PRESBYTERIAN HEALTHCARE SYSTEM, INC., WESTCHESTER MEDICAL CENTER ADVANCED PHYSICIAN SERVICES, P.C.,

Defendants.

DECLARATION

No. 21-cv-5067 AMD-TAM

DECLARATION OF VANESSA MURPHY, J.D. M.P.H.

VANESSA MURPHY, J.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 Emergency Preparedness Associate Attorney at the New York State Department of Health ("Department" or "DOH"), a position I have held for over five years. I am responsible for addressing all legal issues related to actual or potential public health emergencies. I work within the Bureau of Program Counsel, which is located within the Department's Division of Legal Affairs.

2) My responsibilities as they relate to COVID-19, include but are not limited to, advising on a variety of issues related to the Department's pandemic response and drafting COVID-19 related regulations.

Statutory Background

3) 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.

4) The Department may 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 on multiple separate tracks: two examples are the development of emergency regulations and a Summary Order.

PHL § 16 Summary Order Background

4) One way that the Department can take action to address dangers to the public health is found in PHL § 16. This section was enacted to address emergent situations threatening the health of the people of the state of New York where it would be prejudicial to the interests of the people to wait until after a hearing has been conducted to address the situation. It provides the Commissioner with authority to order immediate remediation and provides the party upon whom such an order is served an opportunity to appear before the Department to present evidence in opposition to the order.

5) PHL § 16 states:

> Whenever the commissioner, after investigation, is of the opinion that any person is causing, engaging in or maintaining a condition or activity which in his opinion constitutes danger to the health of the people, and that it therefore appears to be prejudicial to the interests of the people to delay action for fifteen days until an opportunity for a hearing can be provided in accordance with the provisions of section twelve-a of this chapter, the commissioner shall order the person, including any state agency or political subdivision having jurisdiction, by written notice to discontinue such dangerous condition or activity or take certain action immediately or within a specified period of less than fifteen days. As promptly as possible thereafter, within not to exceed fifteen days, the commissioner shall provide the person an opportunity to be heard and to present any proof that such condition or activity does not constitute a danger to the health of the people.

6) In this case, a Summary Order served as a stop-gap measure pending action by the Public Health and Health Planning Council (PHHPC).

The August 18, 2021 PHL § 16 Summary Order

7) On August 18, 2021, New York State Health Commissioner Howard A. Zucker signed such a PHL § 16 Summary Order (hereinafter, the August 18 Summary Order) directing general hospitals and nursing homes to require most personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021. The August 18 Summary Order also provided parties bound by it an opportunity to be heard on September 2, 2021, via videoconference, to present any proof that failure to implement and comply with the requirements of the Order would not constitute a danger to the health of the people of the State of New York.

8) This August 18 Summary Order was based upon a recent increase in COVID-19 cases where since early July 2021, cases had risen 10-fold, and 95 percent of sequenced recent

positives in New York State were of the Delta variant. Although New York State had aggressively promoted vaccination since COVID-19 vaccines first became available in December 2020, current vaccination rates were clearly not high enough to prevent the spread of the more transmissible Delta variant.

Emergency Regulation Background

9) Another tool afforded the Department to address emergent situations are emergency regulations. The State Administrative Procedure Act ("SAPA") § 202(6)(a) states that:

> [I]f an agency finds that the immediate adoption of a rule is necessary for the preservation of the public health, safety or general welfare and that compliance with the requirements of [the proposed rule making process in SAPA §202(1)] would be contrary to the public interest, the agency may dispense with all or part of such requirements and adopt the rule on an emergency basis.

10) The Department of Health and the Public Health and Health Planning Council ("PHHPC") have utilized their authority in recent years to promulgate emergency regulations. Examples include:

1. Requiring standards for operation of "cooling towers" that can harbor legionella bacteria and spread disease (NY Reg, Sept. 2, 2015 at 14-17; 10 NYCRR Part 4);
2. Creating civil penalties for possession of "bath salts" and synthetic marijuana (NY Reg, Aug. 26, 2015 at 8-11; 10 NYCRR Subpart 9-1);
3. Requiring local health department to develop action plans to address the potential spread of the Zika virus (NY Reg, Apr. 6, 2016 at 23-24; 10 NYCRR § 40-2.24);

4. Facilitating the prescribing and dispensing of controlled substances, administering treatment for narcotics addiction, and creating an opioid overdose program (NY Reg, Aug. 27, 2014 at 11-13, and Oct. 18, 2017 at 16-17; 10 NYCRR §§ 80.136 and 80.138).

The August 26, 2021 Emergency Regulation

11) On August 23, 2021, DOH published a proposed Emergency Regulation to be reviewed and adopted by the Public Health and Health Planning Council ("PHHPC").[1] The Emergency Regulation was adopted by PHHPC on August 26, 2021 and became effective August 26, 2021 for 90 days.[2] A copy of the Emergency Regulation is annexed hereto as **Exhibit A**.

12) In accordance with SAPA § 202(6)(d), the notice of emergency adoption:

1. Cited the statutory authority under which the rule was adopted, including particular sections and subdivisions;
2. Stated that the notice does not constitute a notice of proposed or revised rulemaking for permanent adoption;
3. Included findings supporting the need for immediate adoption as being necessary for the preservation of public health, including a description of why

[1] 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-marking 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/ (last viewed September 22, 2021).

[2] 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.

any delay in the issuance of this Emergency Regulation would be contrary to public interest;

4. Stated that Emergency Regulation would be effective immediately upon filing with the Department of State;
5. Stated that the Emergency Regulation would expire 90 days from the date of filing, unless renewed;
6. Contained the complete text of the Emergency Regulation, as adopted;
7. Included a Regulatory Impact Statement;
8. Included a Regulatory Flexibility Analysis; and
9. Provided the name, public office address, and telephone number of Department Representative, knowledgeable on the rule.

13) 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, the rise of the Delta variant, 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.

Dated: October 5, 2021

Vanessa Murphy
VANESSA MURPHY

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

DAPHNEE JANE ANDRE-RODNEY; et al.,

Plaintiffs,

v.

KATHY HOCHUL, in her official capacity as Governor of New York State; et al.,

Defendants.

DECLARATION

1:21 CV 1053 (BKS)(CFH)

DECLARATION OF EMILY LUTTERLOH MD, MPH,

EMILY LUTTERLOH MD, MPH, declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true:

1. I am the Director of the Division of Epidemiology at the New York State Department of Health ("DOH" or the "Department"). Before taking my current position in July 2021, I was the Director of the Bureau of Healthcare Associated Infections, a position I held since 2011; I have been employed by the Department since 2010. In my position, I coordinate the Department's efforts to investigate, reduce, and prevent outbreaks and transmission of infectious diseases.

2. In 1998, I received my MD degree from Indiana University School of Medicine. In 2010, I received my Master of Public Health ("MPH") degree from Johns Hopkins University. Before joining the Department in 2010, I served as an attending physician in pediatric infectious disease, and then as a Lieutenant Commander and Epidemic Intelligence Service Officer in the United States Public Health Service. I have been licensed to practice

medicine in New York State since 2010, and I am Board Certified in Infectious Disease and Pediatric Infectious Disease.

3. My responsibilities as they relate to COVID-19 include oversight of Department epidemiologists who advise local health departments, healthcare facilities, and other internal and external partners about the pandemic response. Additionally, my responsibilities include writing guidance related to epidemiology and the pandemic response and advising other groups within the Department and other State agencies about issues related to epidemiology.

1) 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

2) On August 23, 2021, DOH published a proposed Emergency Regulation to be reviewed and adopted by the Public Health and Health Planning Council ("PHHPC"). The Emergency Regulation was adopted by PHHPC on August 26, 2021 and became effective August 26, 2021 for 90 days. A copy of the Emergency Regulation is annexed hereto as **Exhibit A**.

3) This Emergency Regulation provided that "[c]overed entities shall continuously require [covered] personnel to be fully vaccinated against COVID-19". The "personnel" covered under this Emergency Regulation are "all persons employed [by] or affiliated with a covered entity, whether paid or unpaid . . . 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." Id.

4) The Emergency Regulation provides for a medical exemption for those personnel who have a "licensed physician or certified nurse practitioner [certify] 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 medical exemption must be "in accordance with generally accepted medical standards" such as the recommendations of the Advisory Committee on Immunization Practices ("ACIP") of the U.S. Department of Health and Human Services, upon which the CDC guidance on use of the COVID-19 vaccine is based. Id.

5) In practice, there are likely few instances that would result in the granting of a valid medical exemption to the COVID-19 vaccination. Based on currently applicable accepted medical standards, there are only a narrow set of contraindications and, in some cases, additional precautions to the COVID-19 vaccinations.

6) The Department issued a "Frequently Asked Questions (FAQs) Regarding the August 26, 2021-Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation". The FAQs confirmed that the applicable ACIP COVID-19 vaccination contraindications and precautions are available on the Centers for Disease Control and Prevention's ("CDC") website. A copy of the FAQs is attached hereto as **Exhibit B**.

7) In general, the CDC defines "contraindications" as conditions under which a vaccine should not be administered because of the increased risk for a serious adverse reaction. As indicated by the CDC, "the majority of contraindications are temporary" and vaccines can often be administered when the contraindication no longer exists. A "precaution" is a "condition

in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity." When a precaution is present, the vaccination should be deferred, but a vaccination might be indicated even in the face of a precaution if the benefit from the vaccine outweighs the risk. A copy of the CDC's *Contraindications and Precautions* is attached hereto as **Exhibit C**.

8) The CDC considers there to be only very narrow contraindications to the COVID-19 vaccines, limited to "[s]evere allergic reaction (e.g. anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine" or "[i]mmediate (within 4 hours) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine." A copy of the CDC's *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* is attached hereto as **Exhibit D**. The CDC defines "immediate allergic reaction" as "any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g. wheezing, stridor), or anaphylaxis that occur within four hours following administration." See **Exhibit B; Exhibit D**.

9) The CDC confirms that "most people deemed to have a precaution to a COVID-19 vaccine at the time of their vaccination appointment can and should be administered [the] vaccine." **Exhibit D**. For example, a mere history of an immediate allergic reaction to any other vaccine or injectable therapy is a precaution, but not a contraindication to the vaccine. Other recognized precautions include: 1) a history of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine; 2) current moderate to severe acute illness (which is a temporary precaution until the individual has recovered); and 3) "[a] contraindication to one type of COVID-19 vaccine (e.g., mRNA COVID-19 vaccines) have precautions to another type of

COVID-19 vaccine (e.g., Janssen/Johnson vaccine)." **Exhibit B**.

10) Those with a medical exemption are not required to be vaccinated until the immunization "is found no longer to be detrimental to such personnel member's health." **Exhibit A**. Many medical exemptions are merely temporary; however, there are some exceptions. For instance, an individual may have a serious allergic to the first dose of a mRNA COVID-19 vaccine and would thereafter have a contraindication to receiving additional doses of the mRNA vaccine. **Exhibit D**.

11) Conversely, while a precaution exists for those with a prior or current SARS-CoV-2 infection or a history of multisystem inflammatory syndrome in children ("MIS-C") or adults ("MIS-A") caused by SARS-CoV-2 infection, these precautions are recommended by the CDC to be strictly temporary in nature. Id. The CDC recommends that those with a history of symptomatic or asymptomatic SARS-CoV-2 infection should be offered the vaccine regardless of this history, including those with long-term post- COVID-19 symptoms. The vaccination should only be deferred until the person has recovered from symptomatic, acute illness, and they have met criteria to discontinue isolation. There is no recommended interval before the vaccination can occur. For those with a history of MIS-C or MIS-A, they should consider only "delaying vaccination until they have recovered from their illness and for 90 days after the date of diagnosis of MIS-C or MIS-A, recognizing . . . the risk of reinfection and therefore, the benefit from vaccination, might increase with time following initial infection." Id.

12) In both of the above cases, while recent COVID-19 infection may be a reason to delay vaccination temporarily, it is not a permanent contraindication to the vaccine. The risk of SARS-CoV-2 reinfection might be low after the period of initial infection due to natural

immunity, but the CDC notes that over time, this immunity wanes. Id.

13) Similarly, for those receiving "monoclonal antibodies or convalescent plasma as part of COVID-19 treatment" vaccination should be only temporarily deferred for at least 90 days after receiving the antibodies or plasma for treatment as a precautionary measure to ensure there is no interference with the vaccine-induced immune response. Id.

14) Local or systemic post-vaccination symptoms following the first dose of the COVID-19 vaccine (e.g., pain, swelling, localized axillary lymphadenopathy, fever, fatigue, headache, chills, myalgia, arthralgia) are not a contraindication to the second dose of the vaccine. Id.

15) Practitioners should follow the generally accepted medical standards to appropriately grant legitimate medical exemptions to those with valid contraindications and, in some cases, precautions. In practice, given the narrow breadth of the currently known limited contraindications and precautions, this generally results in few valid medical exemptions.

16) Preliminary data available as of September 28, 2021 suggest that for hospitals statewide, only 0.5% of staff are medically ineligible (with 0.4% of direct care workers being medically ineligible). For nursing homes, only 0.4% of the staff were considered medically ineligible (with 0.5% of direct care workers being medically ineligible). Finally, for adult care facilities, only 0.6% of staff were considered medically ineligible (identical for direct care workers). A copy of *Governor Hochul Releases Encouraging Data Showing Impact of Health Care Staff Vaccine Mandate* is attached hereto as **Exhibit E**.

Dated: October 1, 2021

Emily Lutterloh

EMILY LUTTERLOH