In the Supreme Court of the United States

WE THE PATRIOTS USA, INC., et al.,

Applicants,

v.

KATHY HOCHUL, Governor of New York, et al.,

Respondents.

BRIEF IN OPPOSITION TO EMERGENCY APPLICATION FOR WRIT OF INJUNCTION

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INTRODUCTION

The COVID-19 pandemic has imposed a deadly toll on New York. 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. Concerns about COVID-19 have also risen in recent months because of the alarming spread of the highly contagious SARS-CoV-2 Delta variant.

In light of these concerns, 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 patients, residents, or other personnel to COVID-19 if he or she were infected. 10 N.Y.C.R.R. § 2.61. Like preexisting vaccination requirements for measles and rubella that have been in effect for decades, DOH's emergency COVID-19 rule contains only a narrow medical exemption. Plaintiffs here sued to challenge the absence of a religious exemption in the rule on Free Exercise and substantive due process grounds. Both the district court and the Second Circuit denied plaintiffs' request for a preliminary injunction.

Plaintiffs now ask this Court for the extraordinary relief of a stay of DOH's emergency rule, based on their Free Exercise claim alone. This Court should deny the application. Under comparable circumstances, this Court recently denied a request to enjoin a Maine regulation that also requires healthcare workers to receive a COVID-19 vaccination without providing a religious exemption. See Does v. Mills, No.

21A90, 2021 WL 5027177 (U.S. Oct. 29, 2021). Like the plaintiffs in *Mills*, plaintiffs here fail to show an indisputably clear entitlement to relief on the merits of their Free Exercise claim. As the Second Circuit found, nothing in this record indicates any hostility to or singling out of religious beliefs that would render the emergency rule nonneutral. Nor does the availability of a medical exemption undercut the rule's general applicability. The rule's medical exemption is tightly constrained in both scope and duration (far more so than the medical exemption at issue in *Mills*), and it serves rather than undermines the rule's objective of protecting the health of healthcare workers. For these reasons, the medical exemption is not comparable to the religious exemption that plaintiffs seek, and thus does not support any inference that otherwise similarly situated religious interests are being disfavored.

The extraordinary relief of an interim stay is also not warranted because this Court is unlikely to grant certiorari here. There is no circuit split over the constitutionality of COVID-19 vaccination rules like the one at issue here. And the record here is unusually sparse because this appeal arose from a summary denial of plaintiffs' preliminary injunction motion; there is thus little evidence to support plaintiffs' claims, and defendants had no opportunity below to establish a full record in support of DOH's rule. These factors make this case a poor vehicle for reviewing the constitutional issues that plaintiffs have raised.

STATEMENT

A. New York's Long History of Vaccination Requirements

New York has long been a national leader in mandating vaccinations to protect against the spread of communicable disease. The State required 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). And 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. These regulations have been in place in similar form since 1980 for rubella and 1991 for measles.

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).

B. The COVID-19 Pandemic and the Development of Safe Vaccines

COVID-19 is a highly infectious and potentially deadly respiratory illness that spreads easily from person to person. In the United States alone, COVID-19 has infected more than 45 million people and claimed more than 750,000 lives,³ including almost 725,000 infections and over 2,400 deaths among healthcare workers,⁴ who have been disproportionately harmed by the disease.

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, and the FDA granted full regulatory approval for the Pfizer vaccine on August 23, 2021. Studies show that the vaccines are both safe and highly effective, particularly for preventing hospitalizations in vulnerable populations. For example, among adults 65 to 74 years old, one recent study showed the vaccines' efficacy for preventing hospitalizations ranged

³ 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. All websites last visited November 10, 2021.

⁴ Centers for Disease Control & Prevention, COVID Data Tracker: Cases & Deaths Among Healthcare Personnel.

⁵ 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); 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); Press Release, Food & Drug Admin., FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine (Feb. 27, 2021); Press Release, Food & Drug Admin., FDA Approves First COVID-19 Vaccine (Aug. 23, 2021).

from 84% to 96%, and concluded that increasing vaccination coverage is "critical to reducing the risk for COVID-19–related hospitalization, particularly in older adults."

The COVID-19 vaccines do not contain aborted fetal cells. 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. But the use of fetal cell lines for testing is common, including for the rubella vaccination, which New York's healthcare workers are already required to take. A diverse range of religious leaders has 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. The U.S. Conference of Catholic Bishops has explained that receiving the Pfizer and Moderna vaccines is consistent with the Catholic faith because those vaccines did not use fetal cell lines for their "design, development, or production," and the connection between those vaccines and abortion

⁶ 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).

⁷ Los Angeles Cnty. Dep't of Pub. Health, COVID-19 Vaccine and Fetal Cell Lines 1-2 (Apr. 20, 2021).

 $^{^8}$ Carina Storrs, How Exactly Fetal Tissue Is Used for Medicine, CNN (Dec. 8, 2017).

⁹ Devin Watkins, *Pope Francis Urges People to Get Vaccinated Against Covid-*19, Vatican News (Aug. 18, 2021) (quotation marks omitted).

"is very remote." ¹⁰ 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." ¹¹

C. New York's Response to Transmission of the Delta Variant in the Healthcare Sector

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

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 limited categories of healthcare entities—hospitals and nursing homes—to ensure that covered personnel were fully vaccinated against COVID-19. N.Y. Dep't of Health,

¹⁰ Chairmen of the Comm. on Doctrine and the Comm. on Pro-Life Activities, U.S. Conf. of Catholic Bishops, *Moral Considerations Regarding the New COVID-19 Vaccines* 4-5 (Dec. 11, 2020).

¹¹ Press Release, ReliefWeb, World Religious Leaders Call for Massive Increases in Production of Covid Vaccines and End to Vaccine Nationalism (Apr. 27, 2021) (quotation marks omitted).

Order for Summary Action 3, 5 (Aug. 18, 2021). The Order also included both a medical exemption and an exemption for individuals who hold a "religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer." *Id.* at 5-6. The Order was not intended to be a permanent solution, but rather served as an immediate "stop-gap measure pending action by the Public Health and Health Planning Council," a council within DOH that consists of the Commissioner and 24 other members drawn from the public health system, healthcare providers, and elsewhere.¹²

As a result, the Order was superseded when, eight days later on August 26, 2021—three days after the FDA gave full approval to the Pfizer vaccine—the Council approved the emergency rule that is at issue in this proceeding with the benefit of fuller consideration and input by its members. Under New York law, an emergency rule may go into effect immediately and remain in effect for up to ninety days. N.Y. 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 Commissioner's Order, the emergency rule covers a broader range of healthcare entities—specifically, extending to certified home health agencies, long term home health care programs, hospices,

 $^{^{12}}$ Decl. of Vanessa Murphy, J.D., M.P.H. ("Murphy Decl.") \P 6, *Does v. Hochul*, No. 21-cv-5067 (E.D.N.Y. Oct. 5, 2021), ECF No. 48.

and adult care facilities, among others. § 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. *See* Prevention of COVID-19 Transmission by Covered Entities, 43 N.Y. Reg. 6, 6-9 (Sept. 15, 2021).

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." § 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 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, ¹³ the only "contraindications" recognized by the CDC as a ground for a medical exemption from

¹³ N.Y. Dep't of Health, Frequently Asked Questions (FAQs) Regarding the August 26, 2021 – Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation 4 ("Dep't of Health, FAQs").

COVID-19 vaccination are severe or immediate allergic reactions "after a previous dose" of the vaccine or "to a component of the COVID-19 vaccine." ¹⁴ 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 longer exists." ¹⁵ 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). ¹⁶ 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. Dep't of Health, *FAQs*, *supra*, at 4-5.

Public health experts have uniformly concurred that the number of individuals who are medically ineligible to receive a COVID-19 vaccine is very small. Data show

¹⁴ Centers for Disease Control & Prevention, Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (Nov. 5, 2021).

¹⁵ Centers for Disease Control & Prevention, Vaccine Recommendations and Guidelines of the ACIP: Contraindications and Precautions (Aug. 5, 2021).

¹⁶ *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. <u>Centers for Disease Control & Prevention</u>, <u>Safety of COVID-19 Vaccines</u> (Nov. 1, 2021). Any concerns about this unlikely risk, however, can be assuaged by receiving the Pfizer or Moderna vaccine.

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." The vaccines are safe for immunocompromised people, pregnant women, and people with underlying conditions. The primary group of people who face serious medical 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." ¹⁸

The emergency rule does not contain an exemption for those who oppose vaccination on religious or any other grounds. 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. 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 undermine a consistent approach to preventing the transmission of these particularly infectious and harmful diseases in the healthcare sector. The decision to omit a religious exemption is consistent with statements by the American Medical

¹⁷ Decl. of Elizabeth Rausch-Phung, M.D., M.P.H. (Rausch-Phung Decl.) ¶ 66, Dr. A. v. Hochul, No. 21-cv-1009 (N.D.N.Y. Sept. 22, 2021), ECF No. 16; <u>Ivan Pereira</u>, Few People Medically Exempt from Getting COVID-19 Vaccine: Experts, ABC News (Sept. 15, 2021) (quotation marks omitted).

¹⁸ Rausch-Phung Decl. ¶ 66; Pereira, Few People Medically Exempt, supra; see also Kimberly G. Blumenthal et al., Acute Allergic Reactions to mRNA COVID-19 Vaccines, 325 JAMA 1562, 1562 (2021) (rate of anaphylaxis to Pfizer and Moderna vaccinations is 2.5 to 11.1 per 1 million doses).

¹⁹ See Rausch-Phung Decl. ¶¶ 46-52.

Association that nonmedical exemptions "endanger the health of the unvaccinated individual and those whom the individual comes in contact with," and that healthcare workers in particular "have a fundamental obligation to patients [to get] vaccinated for preventable diseases." ²⁰

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 had 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 it both (a) to colleagues, thereby "exacerbating staffing shortages"; and (b) to "vulnerable patients or residents," thereby "causing [an] unacceptably high risk of complications." 43 N.Y. Reg. at 8. DOH emphasized that unvaccinated individuals have *eleven times* the risk as vaccinated individuals of being hospitalized with COVID-19.

The Council also conducted a meeting 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. 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

²⁰ American Med. Ass'n, *Audiey Kao, MD, PhD, on Mandating Vaccines for Health Care Workers* (quotation marks omitted); *see Jennifer Lubell, Why COVID-19 Vaccination Should Be Required for Health Professionals* (Am. Med. Ass'n July 27, 2021).

viruses (such as the flu) in the fall season.²¹ DOH counsel further explained that the scope of the emergency rule largely tracked preexisting 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 with the scope of DOH's regulation requiring seasonal influenza vaccination or masking for certain healthcare workers. Comm. Meeting at 10:40-11:12; 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. Comm. Meeting at 30:42-31:00; see 10 N.Y.C.R.R. §§ 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. Comm. Meeting at 14:33-15:03. 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. Id. at 37:20-37:38.

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

²¹ 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) ("Comm. Meeting").

so at much lower rates than unvaccinated people.²² 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."²³

Since the emergency rule went into effect on September 27, 2021, DOH has collected preliminary data concerning the rate of vaccinations and exemptions among New York's healthcare workforce as of October 19, 2021. Because the rule has been subject to limited temporary restraining orders (TROs) preventing DOH from interfering with employers' grants of religious exemptions, this data includes some information about religious exemptions.

In the nursing home sector, 127,822 of 144,183 workers were fully vaccinated (88.7%), 12,569 had received one dose of a two-dose vaccine (8.7%), 538 were reported as currently medically ineligible for a COVID-19 vaccine (0.4%), and 2,680 were reported as "other" exemptions (1.9%), which DOH understands to refer to the

²² See Rausch-Phung Decl. ¶¶ 8-12; Centers for Disease Control & Prevention, Delta Variant: What We Know About the Science (Aug. 26, 2021); Centers for Disease Control & Prevention, Science Brief: COVID-19 Vaccines and Vaccination (Sept. 15, 2021).

²³ See Rausch-Phung Decl. ¶ 62; 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).

religious exemption preserved by the various TROs. See Decl. of Valerie A. Deetz ¶ 3, Serafin v. New York State Dep't of Health, Index No. 908296-21 (Sup. Ct. Albany County Oct. 20, 2021), NYSCEF Doc. No. 56. In the adult care facility sector, 26,449 of 29,583 workers were fully vaccinated (89.4%), 2,166 had received one dose of a two-dose vaccine (7.3%), 155 were reported as currently medically ineligible for a COVID-19 vaccine (0.5%), and 567 were reported as "other" (religious) exemptions (1.9%). See id. ¶ 4. In the hospital sector, 91.4% of workers were fully vaccinated, 4.8% had received one dose of a two-dose vaccine, 0.5% were medically ineligible for a COVID-19 vaccine, and 1.3% were reported as "other" (religious) exemptions. See Decl. of Dorothy Persico ¶ 3, Serafin, Index No. 908296-21 (Sup. Ct. Albany County Oct. 21, 2021), NYSCEF Doc. No. 57.

The disparity between medical and religious exemptions is not uniform across the State. *Cf. Does v. Mills*, No. 21-1826, 2021 WL 4860328, at *2 (1st Cir. 2021) (noting disparities in "geographic distribution of vaccination" within Maine). In Erie County, only 41 hospital workers (0.2%) were currently medically ineligible, while 740 (4%) reported "other" (religious) exemptions. And in Monroe County, only 42 (0.1%) of hospital workers were currently medically ineligible, while 977 (3.2%) reported "other" (religious) exemptions. *See* Persico Decl. ¶¶ 4-5.

D. Procedural History

On September 2, 2021, plaintiffs filed this lawsuit, challenging the omission of a religious exemption from DOH's emergency rule. The plaintiffs are We The Patriots USA, Inc., a membership organization dedicated to "promoting constitutional rights", and three individual healthcare workers allegedly subject to the emergency rule: Diane Bono, Michelle Melendez, and Michelle Synakowski. (App. 13 (¶¶ 3-6).) Plaintiffs allege that they have religious objections to receiving a vaccine that uses "a fetal cell line for development, manufacturing, or testing" (App. 14 (¶ 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. 16 (¶ 22)). They claim that the DOH emergency rule violates their rights to free exercise of religion, privacy, and medical freedom. (App. 16-18.)

Plaintiffs moved for a TRO and a preliminary injunction ten days later. According to their 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. (App. 39 (¶¶ 4, 6), 24 45 (¶¶ 4, 6), 51 (¶¶ 4, 6).) Plaintiffs stated that they believe that their employers will terminate their employment if they do not receive a COVID-19 vaccine. (App. 40 (¶ 8), 46 (¶ 8), 51 (¶ 8).) But they provided little concrete evidence to support that belief. A letter from Melendez's employer simply states that Melendez will face restrictions on her activities at work, not termination, if she does not receive a COVID-19 vaccine. (App. 48.) Synakowski does not submit any documentation from her employer corroborating her claim. And plaintiffs now

 $^{^{24}}$ The Bono affidavit bears repeated page numbers 30 and 31 but appears as the thirty-ninth and fortieth pages of the appendix.

state (Br. at 7) that Bono was terminated on September 30, 2021, but do not provide support for that statement.

The district court denied plaintiffs' motion without hearing from defendants or affording them an opportunity to develop a record. (See App. 6 (minute entry order entered September 12, 2021).) Plaintiffs appealed. (App. 36.) While plaintiffs' appeal was pending, a district court entertaining a different lawsuit entered a temporary restraining order 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. On September 30, 2021, the Second Circuit 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 (2d Cir. Sept. 30, 2021), ECF No. 65. On October 12, 2021, the Dr. A. trial court granted a preliminary injunction in that action.

On October 29, 2021, the Second Circuit issued an order that vacated the stay pending appeal in this lawsuit, vacated the preliminary injunction in Dr. A., affirmed the trial court's order denying a preliminary injunction in this lawsuit, and reversed the trial court's order granting a preliminary injunction in Dr. A., with an opinion to follow. (App. 2-3.) Plaintiffs then filed this application for an emergency injunction.

On November 4, 2021, the Second Circuit issued its written decision. See We The Patriots USA, Inc. v. Hochul, No. 21-2179, 2021 WL 5121983 (2d Cir. Nov. 4, 2021). On plaintiffs' Free Exercise claim, the court held that plaintiffs had failed to

show that DOH's emergency rule was "likely not neutral or generally applicable." *Id.* at *8. The court explained that the rule "is facially neutral because it does not single out employees who decline vaccination on religious grounds." Id. And the court rejected plaintiffs' contention that the rule should be deemed nonneutral because it "eliminated" a religious exemption contained in the Commissioner's separate August 18 Order issued just eight days earlier, explaining that the rule was issued by different decision-makers, following a distinct procedure that "provided more process, public input, and support for a measure that would be effective" for a different duration. *Id.* at *9. As for public statements made by Governor Hochul that plaintiffs assert reflected animus, the court noted that many of those comments "did not relate to Section 2.61 or workplace vaccine requirements at all" and that the Governor's "expression of her own religious belief as a moral imperative to become vaccinated cannot reasonably be understood to imply an intent on the part of the State to target those with religious beliefs contrary to hers." Id. at *10. Otherwise, "politicians' frequent use of religious rhetoric to support their positions" would trigger heightened scrutiny for many government actions. *Id*.

The Second Circuit also concluded that the rule is likely generally applicable. The medical exemption did not render the rule underinclusive because "applying the vaccination requirement to individuals with medical contraindications and precautions would not effectively advance" the State's interest in promoting the health of healthcare workers to reduce the risk of staffing shortages. *Id.* at *12. The court also held that the evidence before it showed that the risks of a medical exemption and a

religious exemption are not comparable. The "medical exemption is defined to be limited in duration," and "[t]he statistics provided by the State further indicate that medical exemptions are likely to be more limited in number than religious exemptions, and that high numbers of religious exemptions appear to be clustered in particular geographic areas." *Id.* The court also concluded that the medical exemption does not create a mechanism for individualized exemptions because it applies to "an objectively defined category of people" and "affords no meaningful discretion to the State or employers." *Id.* at *14.

As a neutral law of general applicability, the Second Circuit assessed the rule under rational-basis review, and it concluded that the rule was a rational response to the spread of "an especially contagious variant of the virus in the midst of a pandemic that has now claimed the lives of over 750,000 in the United States and some 55,000 in New York." *Id.* at *15.

The Second Circuit also rejected plaintiffs' substantive due process claim. It explained that "[b]oth this Court and the Supreme Court have consistently recognized that the Constitution embodies no fundamental right that in and of itself would render vaccine requirements imposed in the public interest, in the face of a public health emergency, unconstitutional." *Id.* at *18. And it rejected plaintiffs' argument that this Court has overruled *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).²⁵ *Id.*

 $^{^{25}}$ The Second Circuit also rejected a Title VII preemption claim brought by a plaintiffs in the $Dr.\ A.$ action. See 2021 WL 5121983, at *16-18. Plaintiffs here did not bring such a claim.

Finally, the Second Circuit concluded that plaintiffs had also failed to show irreparable injury or a balance of the equities supporting a preliminary injunction, but noted that factual developments on remand might affect both of these factors. *Id.* at *19-21.

ARGUMENT

THE COURT SHOULD DENY PLAINTIFFS' REQUEST FOR THE EXTRAORDINARY RELIEF OF AN INTERIM STAY

Plaintiffs ask this Court to enjoin the enforcement of a duly issued emergency state health regulation—"extraordinary relief" that "does not simply suspend judicial alteration of the status quo but grants judicial intervention that has been withheld by lower courts." Respect Me. PAC v. McKee, 562 U.S. 996, 996 (2010) (quoting Ohio Citizens for Responsible Energy, Inc. v. NRC, 479 U.S. 1312, 1313 (1986) (Scalia, J., in chambers)). Such drastic relief is issued "sparingly and only in the most critical and exigent circumstances," such as when "the legal rights at issue are indisputably clear." Wisconsin Right to Life, Inc. v. Federal Election Comm'n, 542 U.S. 1305, 1306 (2004) (Rehnquist, C.J., in chambers) (quotation marks omitted). Plaintiffs do not come close to satisfying this stringent standard here.

A. This Court Is Unlikely to Grant Certiorari.

This Court's assessment of plaintiffs' likelihood of success on the merits encompasses "a discretionary judgment about whether the Court should grant review in this case." *Does v. Mills*, No. 21A90, 2021 WL 5027177, at *1 (U.S. Oct. 29, 2021) (Barrett, J., concurring); *see Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010).

Plaintiffs have failed to establish that this lawsuit is an appropriate vehicle to resolve the constitutional issues for which they seek review.

For one thing, there is no circuit split over the constitutionality of COVID-19 vaccination requirements for healthcare workers. The only other court of appeals to have addressed such a rule upheld it on grounds similar to those given by the Second Circuit below. See Does, 2021 WL 4860328. And although the Sixth Circuit upheld a preliminary injunction against a university's COVID-19 vaccination requirement for student-athletes, see Dahl v. Board of Trs. of W. Mich. Univ., 15 F.4th 728 (6th Cir. 2021) (per curiam), that case involved "a factual setting significantly different from that presented here": namely, a scheme under which the university's grant of exemptions was subject to no meaningful standards. We The Patriots, 2021 WL 5121983, at *15 n.29. See infra at 25-26.

In addition, as the Second Circuit repeatedly noted, the "record before the district court[] was sparse." We The Patriots, 2021 WL 5121983, at *14. The district court summarily denied plaintiffs' preliminary injunction motion before defendants could file a response, and without conducting any hearing. As result, plaintiffs never fully developed their claims of irreparable harm or proved the actual practices of their employers, which are not parties here. And defendants never had the opportunity to create a detailed record supporting this emergency rule, including facts showing the narrowness of the medical exemption.

For these reasons, this Court should reject plaintiffs' invitation to "use the emergency docket to force the Court to give a merits preview in cases that it would

be unlikely to take—and to do so on a short fuse without benefit of full briefing and oral argument." *Mills*, 2021 WL 5027177, at *1 (Barrett, J., concurring).

B. Plaintiffs Have Not Shown an Indisputably Clear Right to Relief.

Plaintiffs' request for relief should also be denied because they have failed to make a "strong showing" of likely success on the merits of their appeal, see Nken v. Holder, 556 U.S. 418, 426 (2009) (quotation marks omitted), let alone an "indisputably clear" constitutional violation, Wisconsin Right to Life, 542 U.S. at 1306 (Rehnquist, C.J., in chambers) (quotation marks omitted).

1. Plaintiffs are unlikely to succeed on their Free Exercise claim.

Under this Court's precedents, "laws incidentally burdening religion are ordinarily not subject to strict scrutiny under the Free Exercise Clause so long as they are neutral and generally applicable." Fulton v. City of Philadelphia, 141 S. Ct. 1868, 1876 (2021). This Court has specifically identified "compulsory vaccination laws" as among the neutral, generally applicable laws that do 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). Here, as the Second Circuit correctly held, plaintiffs' Free Exercise claim fails because DOH's emergency rule is a neutral law of general applicability that is subject to rational-basis review—a bar that it readily clears.

a. DOH's emergency rule is neutral.

DOH's emergency rule is neutral because it does not "target[] religious conduct for distinctive treatment," Church of the Lukumi Babalu Aye, Inc. v. Hialeah, 508 U.S. 520, 533-34 (1993). On its face, the rule does not mention religious activity at all—in contrast to the COVID-19 executive orders at issue in Roman Catholic Diocese of Brooklyn v. Cuomo, which expressly "single[d] out houses of worship" for distinctive treatment. 141 S. Ct. 63, 66 (2020). Nor does the history or administration of DOH's emergency rule reveal any "subtle departures from neutrality" reflecting hostility or animus towards religion. See Lukumi, 508 U.S. at 534 (quotation marks omitted).

Plaintiffs raise two grounds to question the emergency rule's neutrality, but the Second Circuit correctly found both of them unavailing. First, plaintiffs infer religious hostility from the August 26 emergency rule's supposedly "sudden reversal" (Br. at 22) of the Commissioner's earlier August 18 Order for Summary Action, which contained a religious exemption. But "Plaintiffs misconstrue the connection between the August 18 Order and the August 26 Rule." We The Patriots, 2021 WL 5121983, at *9. As DOH has explained, the Commissioner issued the Order under his sole authority as an immediate, temporary, and narrow "stop-gap measure"—in effect for only fifteen days, see Public Health Law § 16. Murphy Decl. ¶ 6. And the Commissioner's Order was intended to be effective only "pending action by the Public Health and Health Planning Council," an expert body within DOH composed of two dozen healthcare professionals that considered and issued the more comprehensive and longer-term emergency rule at issue here. Id. Thus, "[t]he Council did not amend

the August 18 Order: rather, it independently promulgated a new Rule" pursuant to an independent administrative process. We The Patriots, 2021 WL 5121983, at *9. On the limited record presented in this case, plaintiffs have failed to show that any change between the Commissioner's August 18 Order and the Council's August 26 emergency rule reflected religious intolerance, rather than the Council's more extended consideration of public-health policy based on input from its two dozen members. See id. at *9-10 & n.20.

In any event, plaintiffs are wrong to suggest that the mere removal of an exemption is necessarily nonneutral—and thus subject to heightened scrutiny under the Free Exercise Clause. A policy is not neutral when it "single[s] out the religious for disfavored treatment," Trinity Lutheran Church of Columbia, Inc. v. Comer, 137 S. Ct. 2012, 2020 (2017). But here, the emergency rule restores equality rather than subjecting religious beliefs to distinctive burdens. Specifically, the emergency rule treats religious exemptions the same as any other type of claim for an exemption—with the sole exception of the narrow medical exemption, which is unique for reasons explained below. And the emergency rule also brings COVID-19 vaccination in line with longstanding measles and rubella vaccination requirements, as DOH officials explained at the August 26 meeting—requirements that have been in effect for decades and that have never been held to violate the Free Exercise Clause. In comparable circumstances, courts have declined to apply heightened scrutiny even when an agency or legislature has deliberately eliminated longstanding religious exemptions. See Mills, 2021 WL 4860328, at *1.

Second, plaintiffs argue that statements by Governor Hochul—made nearly three weeks after the issuance of the emergency rule here—reflect animus towards religion and a lack of neutrality. But those statements do not bear the weight that plaintiffs place on them. As the Second Circuit noted, many of the Governor's statements, including a speech at a church service, "did not relate to Section 2.61 or workplace vaccine requirements at all"; instead, those statements reflected the Governor's attempt to encourage the general public to become vaccinated. We The Patriots, 2021 WL 5121983, at *10. Nor did any of the Governor's statements express "intoleran[ce] of religious beliefs," see Fulton, 141 S. Ct. at 1877; to the contrary, the Governor spoke positively of her own religious principles as being compatible with receiving the COVID-19 vaccine, We The Patriots, 2021 WL 5121983, at *10-11. And finally, plaintiffs identify no troubling statements by members of the decision-making body—the Council—that actually considered and issued this emergency rule. The circumstances here thus contrast sharply with those that troubled the Court in Roman Catholic Diocese, in which the same government official that had issued the executive orders under review had made critical statements specifically about religious congregations' compliance with those orders. See 141 S. Ct. at 66.

b. DOH's emergency rule is generally applicable.

This Court has identified two circumstances under which a policy can fail to be generally applicable. The first 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).

The second is if the policy is substantially underinclusive because it "prohibits religious conduct while permitting secular conduct that undermines the government's interests in a similar way." *Id.* (quotation and alteration marks omitted). Neither circumstance applies here.

i. DOH's emergency rule does not vest any government official or agency with broad discretion to grant individualized exemptions. This Court recently held that a scheme for granting foster care contracts was not generally applicable because it allowed a state official to grant exceptions "in his/her sole discretion" from applications of an antidiscrimination statute. *Id.* at 1878 (quotation marks omitted). Similarly, *Smith* explained that the scheme at issue in *Sherbert v. Verner*, 374 U.S. 398 (1963), was not generally applicable because it allowed exceptions for "good cause," which was an undefined standard under that scheme. 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 ACIP standards. *Id.* Healthcare providers lack discretion to grant exemptions

outside of these federally recognized, health-based criteria. Thus, unlike the schemes at issue in *Fulton* and *Sherbert*, the medical exemption does not authorize discretionary exemptions, and it tightly constrains healthcare providers even as to their application of medical criteria for excusing workers from receiving the COVID-19 vaccine. *See We The Patriots*, 2021 WL 5121983, at *14-15.

Indeed, the medical exemption in DOH's emergency rule is even narrower than the exemption in the Maine statute considered in *Mills*. The dissenting opinion there noted that strict scrutiny should apply to Maine's vaccination requirement because "employees can avoid the vaccine mandate if they produce a written statement from a doctor or other care provider indicating that immunization *may be* medically inadvisable," or that an employee has "mere *trepidation* over vaccination" for medical reasons. *Mills*, 2021 WL 5027177, at *2 (Gorsuch, J., dissenting) (quotation marks omitted and emphasis added in part). DOH's emergency rule does not provide anything like this type of discretion to grant a medical exemption. To the contrary, the rule contains only a narrow and clearly defined medical exemption, constrained by federal standards. 10 N.Y.C.R.R. § 2.61(d); *see* Dep't of Health, *FAQs*, *supra*, at 4-5. Accordingly, the regulation at issue here does not trigger the same concerns identified in the dissenting opinion in *Mills*. *See We The Patriots*, 2021 WL 5121983, at *14 n.28.

ii. Plaintiffs have also failed to show a likelihood of success on their claim that the medical exemption renders the emergency rule underinclusive. As this Court has explained, the Free Exercise Clause bars disparate treatment of otherwise comparable exemption claims that differ only in their religious or nonreligious motivation. See 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)). Strict scrutiny thus applies to a policy that offers a secular exemption that "undermines the purposes of the law to at least the same degree as the covered conduct that is religiously motivated." Blackhawk v. Pennsylvania, 381 F.3d 202, 209 (3d Cir. 2004).

In Roman Catholic Diocese, for example, this 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" possibly more than safety-conscious religious congregations would. 141 S. Ct. at 67; see Tandon, 141 S. Ct. at 1297 (secular activities regulated more leniently than religious practices without any showing that secular activities "pose[d] a lesser risk of [COVID-19] transmission than applicants' proposed religious exercise" (emphasis omitted)). Similarly, in *Blackhawk*, 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 at 210. 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 purposes of the law to at least to the same degree as the covered conduct that is religiously motivated," id. at 209 (emphasis added). See also Central Rabbinical Cong. v. New York City Dep't of Health & Mental Hygiene, 763 F.3d 183, 197 (2d Cir. 2014) (underinclusiveness if policy "regulates religious conduct while failing to regulate secular conduct that is at least as harmful to the legitimate government interests purportedly justifying it"); Fraternal Order of Police Newark Lodge No. 12 v. City of Newark, 170 F.3d 359, 360, 365-66 (3d Cir. 1999) (applying strict scrutiny to a municipal policy prohibiting police officers from wearing beards because available medical exemption undermined government interest in maintaining a uniform appearance as much as any religious exemption would).

Here, 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, Blackhawk, 381 F.3d at 211, the medical exemption advances the underlying rule's objective of "protecting the health of healthcare employees" in order to "reduce the risk of staffing shortages that can compromise the safety of patients and residents even beyond a COVID-19 infection," We The Patriots, 2021 WL 5121983, at *12. The medical exemption is thus unlike the secular exemptions criticized by this Court in Roman Catholic Diocese and Tandon, and more similar to an exemption in the Oregon law that the Court nonetheless 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 may raise the risk of COVID-19 infection of and 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. (emphasis added). As explained above, the medical exemption is available only when a worker can demonstrate a specific contraindication—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. The number of medical exemptions will thus necessarily be quite limited. And because the most significant contraindication is an adverse reaction to a prior dose of the COVID-19 vaccine, many of the workers who receive medical exemptions will already have received at least

partial protection.²⁶ Religious exemptions do not face similar limitations. Indeed, preliminary data show that "medical exemptions are likely to be more limited in number than religious exemptions, and that high numbers of religious exemptions appear to be clustered in particular geographic areas." We The Patriots, 2021 WL 5121983, at *12.

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." § 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. For example, individuals suffering from an acute illness may need to defer vaccination, but may receive a vaccination after recovering from the illness. By contrast, any religious exemption would not be similarly limited in time or periodically reassessed. See We The Patriots, 2021 WL 5121983, at *12.

The strictly limited scope and duration of any medical exemption thus precludes the conclusion that the medical exemption will "undermine[] the purposes

Mark G. Thompson et al., Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021, 70 Morbidity & Mortality Wkly. Rep. 495, 495 (2021) (showing 80% effectiveness for partial immunization).

of the law to at least the same degree as the covered conduct that is religiously motivated." *Blackhawk*, 381 F.3d at 209. In sharp contrast, this Court found that the secular activities permitted by the exemptions in *Roman Catholic Diocese* and *Tandon* were *riskier* than religious congregation, in light of 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").

Plaintiffs' speculation that the limited number of individuals that receive medical exemptions will pose a similar risk of infecting patients and other personnel is entirely unsupported by the record. As the Second Circuit explained, "it may be feasible for healthcare entities to manage the COVID-19 risks posed by a small set of objectively defined and largely time-limited medical exemptions," as opposed to the risks posed by "a much greater number of permanent religious exemptions, which, according to the State's evidence, appear more commonly sought in certain locations."

We The Patriots, 2021 WL 5121983, at *12. At minimum, "[w]ith a record as undeveloped on the issue of comparability as that presented here," id. at *13, plaintiffs have failed to establish that the risks are sufficiently comparable to allow the mere availability of a narrow medical exemption to defeat the emergency rule's general applicability.

c. 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 satisfies rational-basis review because it demonstrates a "reasonable fit" between the State's purpose and "the means chosen to advance that purpose." *Reno v. Flores*, 507 U.S. 292, 305 (1993) (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 interact directly 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.

Even if some form of heightened scrutiny did apply, DOH's emergency rule would satisfy it as well. Promoting public health by preventing the spread of COVID-19 is "unquestionably a compelling interest." *Roman Catholic Diocese*, 141 S. Ct. at 67. That interest remains compelling today, notwithstanding advances in treating and preventing COVID-19. The COVID-19 vaccines are extraordinarily effective at mitigating the spread of COVID-19—but only to the extent people use them, an objective that DOH is attempting to further with the emergency rule. And despite plaintiffs' speculation to the contrary, there is no evidence that New York (or

anywhere else in the United States) has reached levels of immunization sufficient to create herd immunity. Notwithstanding the recent decline in transmission after the Delta variant tore through the country this summer, community transmission of COVID-19 remains "high" or "substantial" in over 90% of counties in the United States, including *all* of the counties in New York.²⁷ Nor does the potential *future* availability of additional treatment options mitigate DOH's compelling interest in combatting COVID-19 *now*. Although several experimental treatments are being considered, they have not yet received FDA approval, and scientists do not know how quickly the virus may adapt to develop resistance to antiviral medications.²⁸

DOH's emergency rule is also narrowly tailored to preventing the spread of COVID-19. See Roman Catholic Diocese, 141 S. Ct. at 67; Lukumi, 508 U.S. at 531-32. There is no serious dispute that vaccination is a safe and highly effective method for preventing the spread of COVID-19 and mitigating the seriousness of any infection. See 43 N.Y. Reg. at 8. And 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 "most likely to come into regular contact with [individuals] for whom the consequences of contracting COVID-19 are likely to be most severe," Mills, 2021 WL 4860328, at *8. The rule does not apply to individuals working outside of enumerated entities in the healthcare sector, and it

²⁷ Centers for Disease Control & Prevention, COVID Data Tracker: COVID-19 Integrated County View.

²⁸ See Grace Browne, Merck's Antiviral Could Be Just What COVID Was Waiting For, Wired (Nov. 1, 2021).

does not apply to employees who pose no risk of exposing colleagues or patients to COVID-19. See § 2.61(a)(2). Like longstanding 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.

DOH also 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. A testing requirement, for example, would be not only burdensome but ineffective: antigen tests have not proven sufficiently reliable for asymptomatic diagnosis; and PCR tests (which are slower) would allow healthcare personnel to contract and spread COVID-19 between tests or while awaiting results. 43 N.Y. Reg. at 8. DOH also rejected a masking alternative, noting that masks, while "helpful to reduce transmission . . . do[] not prevent transmission." *Id*. Maine similarly concluded that the use of personal protective equipment, including masks, "reduced but did not eliminate the possibility of spreading COVID-19 in healthcare facilities." *Mills*, 2021 WL 4860328, at *3. DOH thus reasonably concluded that masking should be required *in addition to* vaccination, not in place of it.

2. Plaintiffs have not sought emergency relief on their substantive due process claim, and could not likely obtain it in any event.

Plaintiffs acknowledge (at 9 n.7) that their claim that the emergency rule violates their rights to "privacy, medical freedom, and bodily autonomy under the Fourteenth Amendment" is "an unsuitable ground for granting extraordinary relief" and that they are proceeding solely on their First Amendment claim for purposes of this application. Plaintiffs nonetheless devote a substantial portion of their brief to arguing that this Court has overruled *Jacobson*. That argument is irrelevant to plaintiffs' First Amendment claim, and this Court should accordingly disregard it in resolving this stay application.

The argument is also mistaken. As the Second Circuit observed, this Court did not overrule Jacobson in Roman Catholic Diocese given that the Court "did not even mention Jacobson." We The Patriots, 2021 WL 5121983, at *18. And this Court has expressly recognized that "an individual's liberty interest in declining an unwanted smallpox vaccine" was outweighed by "the State's interest in preventing disease" in Jacobson. Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 278 (1990). Finally, plaintiffs' argument (at 15-19) that Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992), and other substantive due process precedents overruled Jacobson is wrong. As the Second Circuit held, those cases did not establish a broad fundamental privacy right for medical decisions that have "such broad community consequences as declining vaccination against a highly contagious disease while working in contact with vulnerable people in healthcare facilities." We The

Patriots, 2021 WL 5121983, at *18 n.35. In any event, as plaintiffs acknowledge, their arguments concerning Jacobson are, at a minimum, insufficiently clear to grant the extraordinary relief sought here.

C. The Absence of Irreparable Injury and the Balance of the Equities Weigh Heavily Against an Injunction.

The extraordinary relief of an emergency stay is also unwarranted here for the additional reason that these plaintiffs have failed to establish either irreparable injury or a balance of the equities in their favor.

1. Plaintiffs have failed to establish that they will suffer any harms that are either imminent or irreparable. *First*, plaintiffs' threadbare evidence fails to establish that they face any imminent threat of adverse employment actions. Nothing in the emergency rule requires employers to terminate or otherwise take adverse employment actions against unvaccinated healthcare workers. Rather, employers can comply with the emergency rule by reassigning unvaccinated 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* § 2.61(a)(2). Plaintiffs have not proffered any evidence that they have sought (or been denied) such a reassignment.

Nor have plaintiffs shown that they are at risk of termination because their particular employers are choosing to implement DOH's emergency rule by terminating them. Synakowski has offered no evidence to support her conclusory

claim that she faces termination.²⁹ Melendez now acknowledges (Br. at 3, 8) that she is on an unrelated medical leave and thus is not currently subject to the emergency rule. And the letter that she submitted from her employer did not threaten termination at all, only restrictions on her work activities. (App. 48.) As for the last individual plaintiff, plaintiffs' brief asserts (at 7) that Bono has already been terminated but provides no support for this assertion. In any event, if Bono has indeed been fired, that past injury would not support an injunction here because no relief that the Court could issue against DOH would compel Bono's former employer to rehire her. *Cf. City of Los Angeles v. Lyons*, 461 U.S. 95, 103 (1983) ("past wrongs" insufficient to warrant prospective injunctive relief).

Second, even if plaintiffs did face the imminent harms they allege, it is well-established that loss of employment, and the resulting financial loss, do not constitute "irreparable harm" because plaintiffs can be fully compensated by reinstatement or money damages, including in claims against their employers. See Sampson v. Murray, 415 U.S. 61, 90-92 (1974). 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 have not established that DOH's emergency rule directly compels them to act in violation of their religious beliefs. They remain free to refuse a COVID-19 vaccine, subject to potential employment

 $^{^{29}}$ Synakowski claimed that she would be terminated by September 21, but has not provided further information on her employment status. *See We The Patriots*, 2021 WL 5121983, at *5 n.9.

consequences. This purported harm bears no resemblance to the harm in *Roman Catholic Diocese*, where this Court found that the executive orders under review directly interfered with religious exercise by barring "the great majority of those who wish[ed] to attend" religious services from doing so. 141 S. Ct. at 67-68.

In contrast to plaintiffs' failure to show imminent irreparable harm, the public faces the risk of imminent irreparable harm if DOH's emergency rule were stayed. See Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 24 (2008). 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 have been proven to be extremely safe and effective at protecting healthcare workers themselves and the populations they serve from suffering severe complications from COVID-19. See supra at 4-5. And the vaccination requirement will also protect others who need emergency medical treatment from the consequences of staffing shortages and overstrained emergency rooms that could follow a COVID-19 outbreak among healthcare workers.

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. And limited healthcare resources will soon face additional strains due to seasonal influenza and other diseases that accompany the onset of fall

and winter. Vaccination of healthcare workers will help to prevent additional burdens from being inflicted on the healthcare sector at the precise moment when it is at risk of becoming overtaxed. Accordingly, the balance of the equities tips decidedly in favor of defendants.

CONCLUSION

The emergency application for a writ of injunction should be denied.

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Respectfully submitted,

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