SUPREME COURT THE STATE OF NEW YORK
COUNTY OF ONONDAGA

MEDICAL PROFESSIONALS FOR INFORMED CONSENT, INC., individually and on behalf of its Members, KRISTEN ROBILLARD, M.D., ZARINA HERNANDEZ-SCHIPPLICK, M.D., MARGARET FLORINI, A.S.C.P., OLYESYA GIRICH, RT(R), and ELIZABETH STORELLI, R.N. Individually and on behalf of others similarly situated,

Index No.: 008575/2022
Honorable Gerard J. Neri

Petitioners-Plaintiffs,

-against-

MARY T. BASSETT, in her official capacity as Commissioner of Health for the State of New York, KATHLEEN C. HOCHUL, in her official capacity as Governor of the State of New York, and the NEW YORK STATE DEPARTMENT OF HEALTH,

Respondent – Defendants.

RESPONDENTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS AND IN OPPOSITION TO PETITIONERS' MOTION FOR A PRELIMINARY INJUNCTION

LETITIA JAMES
Attorney General
State of New York
Attorney for Defendants/Respondents
300 South State Street, Suite 300
Syracuse, New York 13202

Of Counsel:

GIGI E MEYERS
Assistant Attorney General

Table of Contents

Defendant/Respondents Mary T. Bassett, in her official capacity as Commissioner of the New York State Department of Health, Kathleen C. Hochul, in her official capacity as Governor of the State of New York, and the New York State Department of Health ("DOH") (collectively, "Respondents"), respectfully submit this Memorandum of Law in opposition to the Petition, and in support of their Answer to the Petition and Motion to Dismiss the Plaintiffs/Petitioners' Medical Professionals for Informed Consent, Kristen Robillard, M.D., Zarina Hernandez-Schipplick, M.D., Margaret Florini, A.S.C.P., Olyesya Girich, RT(R), and Elizabeth Storelli, R.N. ("Petitioners") Verified Article 78 Petition (the "Petition") pursuant to CPLR §§ 3211 (a)(7), 3211 (a)(1), CPLR 506(b), and CPLR 217(1), and for such other and further relief as this Court deems just and proper, and in opposition to Petitioners' motion for a preliminary injunction.[1]

PRELIMINARY STATEMENT

Petitioners have filed the instant action in the misguided hope that this Court will rule against a growing body of precedent and belatedly upend the state-wide requirement—as well as the settled status quo since at least October 29, 2021, if not earlier—under 10 N.Y.C.R.R. § 2.61 which mandates that Petitioners are vaccinated against COVID-19. In the State of New York alone, COVID-19 has infected more than 5 million New Yorkers and has caused more than 73,000 deaths.[2]

In light of the distinct concerns raised by the spread of COVID-19 in the healthcare sector, DOH through the Public Health and Health Planning Council (PHHPC) promulgated

[1] In making this motion, Respondents are not waiving any other arguments or defenses that may exist with respect to the Petition, including, but not limited to, CPLR217(1) and/or Petitioners' failure to state any viable causes of action.

[2] Center for Disease Control & Prevention ("CDC"), *United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction* ,https://covid.cdc.gov/covid-data-tracker/#cases_totaldeaths> (Last visited November 21, 2022).

amendments to the Department's regulations, codified at N.Y. Comp. Codes R. & Regs. tit. 10, § 2.61 ("Section 2.61") to help stem the global pandemic. Section 2.61 has been successfully implemented, and permanently adopted in June of 2022. Similar actions seeking to challenge the rule have failed across the state in State and Federal Courts, and the Supreme Court has upheld identical vaccine mandates. For these reasons and the reasons discussed below, Petitioners' attempt to enjoin the application of Section 2.61 is patently meritless and should be denied. Petitioners motion for a preliminary injunction must also be denied; Petitioners not only lack any likelihood of success on the merits of their Petition, but also have not suffered irreparable harm, and the balance of equities does not weigh in their favor.

PROCEDURAL HISTORY

Petitioners commenced this action by filing a Petition on October 20, 2022. *See* ECF No. 1. The Petition sets forth three (3) causes of action alleging the enactment of §2.61 was arbitrary and capricious and/or in excess of their authority or jurisdiction, violations of the NYS Constitution warranting a declaratory judgement pursuant to CPLR Article 30 and asking for attorney's fees. The instant Answer and Motion to Dismiss follow.

ARGUMENT

POINT I

SECTION 2.61 HAS A RATIONAL BASIS AND ITS ENACTMENT WAS NOT ARBITRARY OR CAPRICIOUS

Judicial review of an agency regulation "is deferential for it is not the role of the courts to weigh the desirability of any action or choose among alternatives." *Matter of Save America's Clocks, Inc. v. City of New York*, 33 N.Y.3d 198, 207 (2019) (internal quotation marks omitted).

The Court must ascertain whether the challenged determination had a rational basis, or whether it was arbitrary and capricious. *Peckham v. Calogero*, 12 N.Y.3d 424, 431 (2009); Nortz v. *NYS Dep't of Motor Vehicles Appeals Board*, 186 A.D.3d 977, 978 (4th Dep't 2020). A determination "'is arbitrary and capricious when it is taken without sound basis in reason or regard to the facts.'" *Thompson v. Burns*, 118 A.D.3d 1276, 1607 (4th Dep't 2014) (citation omitted). An agency's "determination will not be set aside by the courts unless it is unsupported by proof sufficient to satisfy a reasonable [person] of all the facts necessary to be proved in order to authorize the determination." *Pell v. Board of Educ.*, 34 N.Y.2d 222, 231 (1974) (quotation marks and quoted case omitted). The "Court's role in reviewing an agency action is not to determine if the agency action was correct or to substitute its judgment for that of the agency, but rather to determine if the action taken by the agency was reasonable." *Chemical Specialties Mfrs. Ass'n v. Jorling,* 85 N.Y.2d 382, 396 (1995). "If the court finds that that the determination is supported by a rational basis, it must sustain the determination even if . . . it would have reached a different result than the one reached by the agency." *Id.*

A state agency is entitled to a "high degree of judicial deference, especially when . . . act[ing] in the area of its particular expertise." *Nazareth Home of the Franciscan Sisters v. Novello*, 7 N.Y.3d 538, 544 (2006) (citation and internal quotation marks omitted). "Where the interpretation of a statute or its application involves knowledge and understanding of underlying operational practices or entails an evaluation of factual data and inferences to be drawn therefrom, the courts regularly defer to the governmental agency charged with the responsibility for administration of the statute." *Kurcsics v. Merchants Mut. Ins. Co.*, 49 N.Y.2d 451, 459 (1980). If the agency's "interpretation is not irrational or unreasonable, it will be upheld." *Id.*

Petitioners' arguments that Section 2.61 lacks a rational basis and that its enactment is arbitrary and capricious are without merit. DOH and PHHPC may promulgate regulations that "deal with any matters affecting the security of life or health or the preservation and improvement of public health in the state of New York." PHL §§ 225 (4) and (5)(a). Both DOH and PHHPC have undeniable expertise in the area of public health.

Further, Section 2.61 was promulgated to address the following legitimate State interests: fighting the spread of a dangerous virus; protecting the health and wellbeing of staff, patients and residents in healthcare and congregate care facilities, and New York State's citizenry, as a whole; preventing staffing shortages and interference with the operations of healthcare operations and congregate care facilities caused by the spread of the virus among staff and patients and residents. As recognized by the Second Circuit in its analysis of Section 2.61,

> Faced with 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, the State decided as an emergency measure to require vaccination for all employees at healthcare facilities who might become infected and expose others to the virus, to the extent they can be safely vaccinated. This was a reasonable exercise of the State's power to enact rules to protect the public health.

We the Patriots USA, Inc. v. Hochul, 17 F.4th 266, 290 (2d Cir. 2021), *op clarified*, 17 F.4th 368 (2d Cir 2021), *cert. denied sub nom. Dr. A. et al. v. Hochul*, 142 S.Ct. 552 (2021).

Indeed, as set forth in the "Regulatory Impact Statement", and "Emergency Justification" statement for Section 2.61 (Lutterloh Aff., Exhibit A), and as discussed in the accompanying Affidavit of Dr. Emily Lutterloh, Section 2.61 is the result of a comprehensive, well-reasoned plan designed to protect and improve public health across New York State, and specifically to combat the rapid and ongoing spread of COVID-19, which has included the Delta and Omicron variants and subvariants.

Moreover, this Court should only intervene upon a compelling showing that the rationale underlying Section 2.61 is unreasonable and Petitioners here wholly fail to make such a showing. *See Serafin et al. v. NYSDOH et al.*, Index No. 908296-21, *Decision and Order* (NYSCEF No. 178, December 9, 2021) (NY Sup.Ct. Albany Cnty.) at 15 ("the Court finds that respondents have demonstrated their reasoned reliance upon a multitude of documented medical studies and findings in support of the promulgation of § 2.61. Conversely, the competing analysis and credible medi[c]al studies offered by petitioners' expert were simply insufficient to demonstrate outright irrationality, arbitrariness or capriciousness in § 2.61 or its promulgation, and petitioners therefore fail to satisfy the high threshold necessary to invalidate the emergency rule under § 2.61.") (hereinafter referred to as "*Serafin*" and attached hereto as Exhibit A); and *Coalition of Citizens for Medical Choice Inc. et al. v. NYSDOH et al.*, Index No. 908359-21, *Decision, Order and Judgment* (NYSCEF No. 151, March 16, 2022) (NY Sup.Ct. Albany Cnty.) at 15 ("conflicting medical expert opinions offered by petitioners simply did not rise to the significant and compelling level necessary to afford petitioners the drastic relief sought herein") (hereinafter referred to as "*Coalition of Citizens for Medical Choice*" and attached hereto as Exhibit B); *see also Brothers of Mercy Nursing and Rehabilitation Center v. De Buono*, 292 A.D.2d 775, 776 (4th Dep't, 2002) ("the record demonstrates that respondents conducted an extensive study and arrived at a reasoned decision to implement the new methodology").

POINT II

RESPONDENTS ARE NOT REQUIRED TO INCLUDE A RELIGIOUS EXEMPTION FOR VACCINATION REQUIREMENTS

For over a century, courts have held that mandatory vaccination laws constitute a valid exercise of the States' police powers, and such laws have withstood challenges on various

constitutional grounds. *See Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905); s*ee also 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, the 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). As recently as 2015, the Second Circuit explained that mandatory vaccination "does not violate the Free Exercise Clause." *Phillips v. City of New York*, 775 F.3d 538, 543 (2d Cir. 2015).

In rejecting the plaintiffs' First Amendment claim, the *Phillips* 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. *Id.*; *see also We The Patriots, Inc. v. Hochul*, 17 F.4th 266, 293 (2d Cir. 2021) ("Both 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.").

Indeed, the absence of religious exemptions in mandatory vaccination regulations and laws is not a novel concept in New York State and Section 2.61's silence as to a religious exemption is consistent with other, pre-existing mandatory vaccination regulations for healthcare workers. Lutterloh Aff., ¶¶ 18-22. Numerous regulations requiring vaccines for healthcare workers employed by hospitals, nursing homes, diagnostic and treatment centers, home health agencies and programs and hospices, provide for medical exemptions, but do *not* provide for any religious exemption. *Id.* at ¶ 19. Further, New York State repealed the religious exemption from mandatory school entry vaccination laws for children in prekindergarten-12th grade (*see* Laws of 2019, Chapter 35, which, among other things, repealed former NYS Public Health Law § 2164(9)),

which now treat individuals with religious beliefs contrary to immunization exactly the same as individuals with non-religious beliefs contrary to immunization. *Id.*, ¶¶ 19, 22.

Ultimately, the State has no constitutional, statutory or other legal obligation to include a religious exemption in Section 2.61, and the absence of such an exemption is consistent with numerous other pre-existing regulations mandating vaccines for healthcare workers and laws mandating vaccinations for school entry. Thus, Petitioners cannot demonstrate that the absence of a religious exemption to Section 2.61's vaccine requirement was arbitrary and capricious or in any way unlawful.

Even if Respondents had an obligation to create a religious exemption, Petitioners fail to provide a single allegation of fact—much less proof—to allow the Court to believe there is any likelihood that any Petitioner would receive an exemption if one were available. Petitioners have not provided any information as to why they have a purported religious opposition to the COVID-19 vaccine. As such, the Petition fails to allege or establish an injury based on the absence of a religious exemption.

Because Petitioners cannot establish that a religious exemption is required, or that the lack of a religious exemption has impacted them, any claim related to a religious exemption must be dismissed. Petitioners' puzzling assertion that Respondents have enacted the mandate in "blatant violation of the New York State Health Law" as well as New York State Human Rights Law are unavailing and should be dismissed. See Petition NYSCEF No. 1, ¶¶ 18, 38. Section 2.61 does not require employers to violate the Human Rights Law because, although it bars an employer from granting a religious exemption, it does not prevent employers from granting an accommodation allowing them to continue working consistent with Section 2.61 while avoiding the vaccine requirement. The federal courts of the Northern District of New York and the Eastern

District of New York both examined the healthcare worker vaccine requirement and determined that it did not constitute religious discrimination under the Free Exercise Clause, the Equal Protection Clause, or Title VII of the Civil Rights Act. *See Dr. A. v. Hochul*, 586 F. Supp. 3d 136 (N.D.N.Y. 2022) and *Does 1-2 v. Hochul*, No. 21CV5067AMDTAM, 2022 WL 4637843 (E.D.N.Y. Sept. 30, 2022).

POINT III

RESPONDENTS COMPLIED WITH SAPA IN PROMULGATING SECTION 2.61

Petitioners' First cause of action also contends that the Respondents improperly assumed "legislative functions" in promulgating Section 2.61. The Petition improperly asserts that "no legislation permits the DOH to enact the mandate." *See* Petition ¶ 17. The Petition further alleges the mandate "was promulgated in blatant violation of the New York State Public Health Law ("PBH"), which specifically reserves the power to make new vaccine mandates to the Legislature." *See* Petition ¶ 18. This is a misrepresentation, as Public Health Law ("PHL") §206(1)(l) says no such thing. It merely indicates "Nothing *in this paragraph* shall authorize mandatory immunization of adults or children, except as provided in sections twenty-one hundred sixty-four and twenty-one hundred sixty-five of this chapter" (emphasis added).

The Petition's allegations on this point are meritless as §2.61 was not promulgated in reliance upon PHL § 206(1)(l). And Petitioners' citation to *Garcia* in support of their argument to the contrary is woefully misplaced—if not somewhat disingenuous—as there, the Court of Appeals held that nothing in §206(1)(l) "prohibits the adoption of mandatory immunizations if otherwise authorized by law." *Garcia v. New York City Dep't of Health & Mental* Hygiene, 31 N.Y.3d 601, 620 (2018). Petitioners' arguments fail to take into account the State Administrative Procedure Act, particularly § 202 and the process by which the legislature has granted agencies the authority

to enact rules. It also fails to take into account that §2.61 was promulgated on PHL Sections 225(5), 2800, 2803(2), 3612 and 4010(4). Primarily, the Petitioners misrepresent the timeline of events and fail to adequately grasp the rulemaking process. Secondarily, multiple courts throughout the state have upheld the same rule and the same rulemaking process. *See, e.g.*, *Serafin* ("the Court concludes that respondents have complied with SAPA and made a detailed showing of their rational basis for promulgating § 2.61"); *Coalition of Citizens for Medical Choice* ("the Court finds that Petitioner's SAPA challenge is without merit . . . respondents clearly satisfied the requirements of SAPA § 202(6)"). Petitioner's case, alleging agency overreach of a legislative process, offers no new arguments on this point, and as such the charges are easily dismissed.

The standard of review in matters regarding the State Administrative Procedure Act ("SAPA") is one of substantial agency compliance. *See* SAPA § 202(8); *see also, Medical Society of the State of N.Y. v. Serio*, 100 N.Y.2d 854, 869 (2003) (each rule or regulation proposed by an agency must be promulgated "in substantial compliance"). "[T]he determination of an agency acting pursuant to its authority and within its area of expertise is . . . entitled to judicial deference." *Entergy Nuclear Indian Point 2, LLC v. N.Y. State Dep't of State*, 130 A.D.3d 1190, 1192 (3d Dep't 2015).

When an agency adopts a regulation not "so lacking in reason for its promulgation that it is essentially arbitrary (*Matter of Bernstein v. Toia*, 43 N.Y.2D 437, 448, (1977)), the "rule has the full force and effect of law." *Molina v. Games Mgt. Servs.*, 58 N.Y.2d 523, 529 (1983). SAPA §202(5)(a) simply requires that an agency promulgating a rule comply with the provisions of this section and submit a notice of adoption to the secretary of state for publication in the state register. It was published in the State Register on December 15, 2021, with the public comment period expiring on February 14, 2022. Riegert Aff. ¶ 10. The Petitioners fail to mention whether they took

part in this public comment period while the regulation was being promulgated, arguing that their "democratic rights are being violated." *See* Petition ¶ 60. One cannot argue an inability to partake in the democratic process while simultaneously refusing to participate.

Respondents have clearly complied with SAPA in promulgating Section 2.61.

POINT IV

THE BOREALI FACTORS FAVOR RESPONDENTS

Petitioners claims that Respondents "from the executive branch violated the separation of powers doctrine by issuing a permanent regulation on June 22, 2022, mandating COVID-19 vaccines for healthcare workers in violation of state law" *See* Petition at ¶ 5. Petitioners are incorrect. As discussed in the "Regulatory Impact Statement" for Section 2.61, Lutterloh Aff., Ex. A, pp. 8 – 9, and *supra*, there is ample statutory authority for Respondents' promulgation of Section 2.61.

The Court of Appeals in *Boreali v. Axelrod*, 71 N.Y.2d 1 (1987), articulated four factors to determine whether agency rulemaking exceeded legislative fiat:

> whether (1) the agency did more than balanc[e] costs and benefits according to preexisting guidelines, but instead made value judgments entail[ing] difficult and complex choices between broad policy goals to resolve social problems; (2) the agency merely filled in details of a broad policy or if it wrote on a clean slate, creating its own comprehensive set of rules without benefit of legislative guidance; (3) the legislature has unsuccessfully tried to reach agreement on the issue, which would indicate that the matter is a policy consideration for the elected body to resolve; and (4) the agency used special expertise or competence in the field to develop the challenged regulation.

NYC C.L.A.S.H., 27 N.Y.3d at 179-80 (internal quotation marks and citations omitted). Importantly, these considerations, known as the *Boreali* factors, "are not to be applied rigidly." *Id*. at 180. "In fact, they are not mandatory, need not be weighed evenly, and are essentially

guidelines for conducting an analysis of an agency's exercise of power." *Id*. (citing *Greater New York Taxi Ass'n*, 25 N.Y.3d at 612). Here, all of the *Boreali* factors weigh in favor of the Respondents. *See Serafin* ("the Court concludes that all four factors proffered and discussed in Boreali support the legality of respondents' promulgation of § 2.61 and finds that the doctrine of separation of powers has not been violated here."); *Coalition of Citizens for Medical Choice* (same).

A. The First Boreali Factor

Petitioners make a conclusory assertion that Respondents "have violated the separation of powers doctrine by issuing a permanent regulation in violation of state law," adding that "the NYSDOH exceeded its field of competence by making value judgements entailing difficult and complex choices between broad policy goals to resolve social problems." Petition, ¶¶ 5, 20.

In considering the first factor, the Court should review whether Respondents "did more than balance the costs and benefits according to pre-existing guidelines, but instead made value judgments entailing difficult and complex choices between broad policy goals to resolve social problems." *NYC C.L.A.S.H.*, 27 N.Y.3d at 181. "*Boreali* specifically described this factor as whether the agency has 'constructed a regulatory scheme laden with exceptions based solely upon economic and social concerns.'" *NYC C.L.A.S.H.*, 27 N.Y.3d at 181.

The "focus" of the first factor analysis "must be on whether the challenged regulation attempts to resolve difficult social problems" by "making choices among competing ends." *Nat'l Rest. Ass'n v. New York City Dep't of Health & Mental Hygiene*, 148 A.D.3d 169, 174 (1st Dep't 2017) (citing *New York Statewide Coalition of Hispanic Chambers of Commerce v. New York City Dep't of Health & Mental Hygiene*, 23 N.Y.3d 681, 697 (2014)). Such improper "choices" or "value judgments" are evidenced by the adoption of exceptions which attempt to balance the policy

goal (*i.e*. public health) with economic concerns that are unrelated to the policy goal. *See, e.g.*, *NYC C.L.A.S.H.*, 27 N.Y.3d at 181 n.5.

This factor weighs in favor of the agency when the rule does not include an attempt to compromise with concerns that are unrelated to the policy goal. *See, e.g.*, *Garcia*, 31 N.Y.3d at 612-13 ("There is no indication that the Board limited the scope of its rules [requiring flu vaccination] based on financial considerations of special or business interests."); *NYC C.L.A.S.H.*, 27 N.Y.3d at 181, n.5 (no evidence of economic considerations where regulation "merely prohibits smoking in designated outdoor areas under the jurisdiction of" the agency). Similarly, the first *Boreali* factor weighs in favor of the agency when the rule includes exceptions that are designed to further the legislative interests. *See, e.g.*, *LeadingAge*, 32 N.Y.3d at 265 ("[I]nstead of improperly weighing competing special interests against the public health goal, the waiver provisions of the hard cap regulations are designed to *further* the legislative goal." (emphasis in original)).

Here, Section 2.61—unlike the rule at issue in *Boreali*—does not include any attempt to weigh competing or special interests which are unrelated to the public health goal through exceptions to the rule. It is simply an across-the-board requirement mandating COVID-19 vaccinations for all employees of healthcare facilities (within DOH's jurisdiction) who are "engage[d] 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 NYCRR § 2.61. The Regulation only provides for a limited medical exemption clearly related to the public health goal articulated, 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 on a pre-existing health condition," in "accordance with generally accepted medical standards." Lutterloh Aff. ¶24.

Requiring healthcare workers to be vaccinated against COVID-19 is consistent with longstanding vaccination requirements for other healthcare professionals. Existing New York regulations already require that all persons who work at hospitals, nursing homes, diagnostic and treatment centers, home health agencies and programs, assisted living residences, and hospices be vaccinated for measles and rubella. Lutterloh Aff. ¶19; *see, e.g.,* 10 N.Y.C.R.R. § 405.3(b)(10)(i)-(ii). Like Section 2.61, the regulations requiring measles and rubella vaccinations contain a medical exemption, but do not contain a religious exemption. *Id.* at ¶19. Section 2.61 is consistent with these pre-existing regulations.

Petitioners' claims that Respondents' "have acted with animus in removing a religious exemption from the Mandate, which is an abuse of discretion." Petition ¶102. However, there is no suggestion that the omission of a religious exemption was based on economic or special interests or entailed an inappropriate value judgment. As previously discussed at Point II, *supra*, a lack of religious exemption is consistent with other, prior mandatory vaccination regulations for health care workers in New York State and laws requiring vaccines for schoolchildren. Lutterloh Aff., ¶¶ 18-22. Indeed, including a religious exemption in Section 2.61 would itself have been a "value judgment" which favored certain religious beliefs opposed to immunization over other non-religious beliefs opposed to immunization.

Section 2.61 does not include any exceptions that are unrelated to the policy goal of public health. By omitting a religious exemption, Respondents avoided carving out an exception that was unrelated to the policy goal of public health.

Thus, Petitioners fail to set forth sufficient evidence demonstrating that exceptions to Section 2.61 were based solely upon economic and social concerns unrelated to the policy goal of public health, and the first *Boreali* factor favors Respondents.

B. The Second Boreali Factor

The second *Boreali* factor is called the "tabla rasa" or clean slate consideration, where the court assesses "whether the agency merely filled in details of a broad policy or if it wrote on a clean slate, creating its own comprehensive set of rules without benefit of legislative guidance." *NYC C.L.A.S.H.*, 27 N.Y.3d at 182 (internal citations and quotation marks omitted). If an agency writes on a "clean slate," it can run afoul of the separation of powers. Where, as here, an agency has a longstanding history of regulating in a particular subject area, or has set forth policy by a statutory scheme, the agency is not writing on a clean slate. *See, e.g.*, *Garcia*, 31 N.Y.3d at 613-14 ("long history of mandating immunization" supported agency action under the clean slate factor); *Greater N.Y. Taxi Ass'n*, 25 N.Y.3d at 611 (finding taxi and limousine commission "has always regulated the taxi industry as to almost every detail of its operation"); *LeadingAge N.Y., Inc. v. Shah*, 32 N.Y. at 265 (legislature created a "statutory framework directing" the agency to use state health funds in the most efficient manner possible); *Kerri W.S. v. Zucker*, 202 A.D.3d 143 (4th Dep't 2021) (finding no "blank slate" in realm of mandatory child vaccines).

Here, Respondents are not regulating on a "clean slate"; instead, they are executing policy decisions articulated by the Legislature through a comprehensive statutory scheme. *See, e.g.*, *Spence v. Shah*, 136 A.D.3d 1242, 1245 (3d Dep't 2016) (rejecting a hospital worker's challenge to a regulatory vaccine requirement because "the Legislature has granted broad authority to DOH to consider and implement regulations regarding the preservation and improvement of public health, as well as establishing standards in health care facilities") (citing Pub. Health L. §§ 225,

2800, 2803, 3612, 4010); *see also* 10 N.Y.C.R.R. § 405.3(b)(10)(i)–(ii) (requiring that hospital employees—without a religious exemption—who pose a risk of transmission to patients must be immunized against measles and rubella). Indeed, the State Legislature has accepted that vaccinations are a viable method of curbing the spread of disease. *See* Public Health Law ("PHL") §§ 2164, 2165.

Pursuant to PHL § 201(1)(m), the Department "shall . . . supervise and regulate the sanitary aspects . . . businesses and activities affecting public health." And, 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." Accordingly, these statutes obligate DOH and the Commissioner to take action when the public health is put at risk, such as by an unprecedented and unpredictable global pandemic, and the rapid outbreak of severe and fatal respiratory illnesses associated therewith.

Moreover, PHL § 225 gives the PHHPC authority to issue regulations pertaining to any "matters affecting the security of life or health or the preservation and improvement of public health in the state of New York", which has been broadly interpreted to include the designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises, as well as other public health dilemmas. *See, e.g., Spence* at 1245; *Vapor Technology Assoc. et al., v. Cuomo et al.*, 203 A.D.3d 1516 (3d Dep't 2022) (holding that emergency regulations banning the manufacture and sale of flavored vaping liquids contributing to the youth vaping epidemic and associated health impacts were within the grant of authority under PHL §225).. This authority certainly includes the authority to issue regulations regarding healthcare entities subject to Respondents' regulatory authority in order to mitigate a global pandemic surging across the State.

Notably, PHL § 2800 explicitly states that "[i]n order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, [DOH] shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article." Further, PHL §§ 2803(2), 3612 and 4010(4) authorize the PHHPC to adopt and amend rules and regulations, subject to DOH approval, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing entities covered by Section 2.61, including standards for the provision of care and services and staff qualifications. Finally, Social Service Law ("SSL") § 461 requires DOH to promulgate regulations establishing standards applicable to Adult Care Facilities ("ACF"), and SSL § 461-e authorizes DOH to promulgate regulations to require ACFs to maintain records with respect to facility residents and operations.

Respondents were acting within the statutory scheme outlined above, and pursuant to pre-existing legislative policy decisions, when they promulgated Section 2.61. Thus, they have not exceeded their authority in doing so, and the second *Boreali* factor weighs in their favor. *See, e.g., Serafin; Coalition of Citizens for Medical Choice.*

C. <u>The Third Boreali Factor</u>

The third *Boreali* factor has been called the "consensus consideration," pursuant to which courts asses "whether the legislature has unsuccessfully tried to reach agreement on the issue, which would indicate that the matter is a policy consideration for the elected body to resolve."

NYC C.L.A.S.H., 27 N.Y.3d at 183. The Court of Appeals has warned that "Legislative inaction, because of its inherent ambiguity, affords the most dubious foundation for drawing positive inferences." *Id*. at 184. For this reason, courts have repeatedly found that the existence of prior unsuccessful legislation—even in greater amounts than present here—does not indicate that an agency has exceeded its mandate. *See, e.g.*, *Rent Stabilization Ass'n of N.Y.C. v. Higgins*, 83 N.Y.2d 156, 170 (1993); *N.Y. State Health Facilities Ass'n v. Axelrod*, 77 N.Y.2d 340, 348 n.2 (1991), *rev'g* 155 A.D.2d 208 (3d Dep't 1990). Furthermore, unsuccessful bills—such as those which do not make it out of committee—do not favor the Petitioners because such bills were not "the subject of vigorous debate." *See Nat'l Rest. Ass'n*, 148 A.D.3d at 178 ("However, on each occasion, the proposed legislation was sent to committee, and no further action was taken, so there is no indication that it was the subject of vigorous debate."); *LeadingAge*, 32 N.Y.3d at 265 ("While bills have been introduced in the legislature relating to executive compensation caps, they never made it out of committee", and "a single unsuccessful proposal is not in the same class as the repeated unsuccessful legislative efforts we have deemed indicative of the type of broad public policy issue reserved exclusively to the legislature").

Here, Petitioners fail to point to even one legislative bill regarding a vaccine mandate for healthcare workers, much less one that made it out of committee, was voted on by the Legislature and failed to pass such a vote. Instead, Petitioners merely note that the Legislature has not acted at all. Petitioners' inference that this discredits the mandate is baseless, and in making it, they disregard the case law to the contrary - including the Court of Appeals' holding that legislative inaction "affords the most dubious foundation for drawing positive inferences." *NYC C.L.A.S.H.*, 27 N.Y.3d at 184.

Further, the "mere fact that the Legislature has enacted specific legislation in a particular field does not necessarily lead to the conclusion that broader agency regulation of the same field is foreclosed." *Consol. Edison Co. of New York v. Dep't of Envtl. Conservation*, 71 N.Y.2d 186, 193, 519 N.E.2d 320 (1988). If anything, by leaving intact Respondents' broad discretion over protecting the public health, ensuring the welfare and safety of the covered entities' patients/residents, and regulating the covered entities' standards and quality of care, operations and staffing, the Legislature signaled its intent to defer to Respondents' expertise in addressing such issues. *See Med. Soc'y of State v. Serio*, 100 N.Y.2d 854, 865-66 (2003). As noted above, Respondents have repeatedly promulgated regulations requiring vaccinations for staff of entities subject to their regulatory oversight (including ones that lacked any religious exemption, and in the absence of any "state of emergency") and the Legislature has not acted to curtail that authority.

Far from creating new public policy, the mandate is a quintessential example of interstitial rulemaking. It implements legislatively-expressed policies and responds to a rapidly developing and expanding public health crisis (and its effect on entities subject to Respondents' regulatory authority and their patients/residents), filling in the gaps in the statutory enforcement scheme. Thus, the third *Boreali* factor also weighs in favor of Respondents.

D. The Fourth Boreali Factor

The fourth factor "turns on agency knowledge, and specifically whether the agency used special expertise or competence in the field to develop the challenged regulation." *NYC C.L.A.SH.*, 27 N.Y.3d at 184.

Clearly this factor weighs in favor of the Respondents and no substantial discussion of this factor is necessary. *See, e.g.* Serafin; Coalition of Citizens for Medical Choice.

POINT V

PRELIMINARY INJUNCTION MUST ALSO BE DENIED

A preliminary injunction is a "drastic" remedy, "which should be used sparingly" to "preserve the status quo pending a trial." *Soundview Cinemas, Inc. v. AC I Soundview, LLC*, 149 A.D.3d 1121, 1123 (2d Dep't 2017). When deciding whether to issue a preliminary injunction, courts "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24, 129 S.Ct. 365, 172 L.E.2d 249 (2008). To obtain such drastic relief, the movant must show "(1) a likelihood of success on the merits, (2) irreparable harm in the absence of an injunction, and (3) a balance of the equities in favor of the injunction." Id. A preliminary injunction "will not be granted unless a clear right thereto is established under the law and the undisputed facts upon the moving papers, and the burden of showing an undisputed right rest upon the movant." *Saran v. Chelsea GCA Realty P'ship, L.P.*, 148 A.D.3d 1197, 1199 (2d Dep't 2017). Finally, "absent extraordinary circumstances, a preliminary injunction will not issue where to do so would grant the movant the ultimate relief to which he or she would be entitled in a final judgment." *Berman v. TRG Waterfront Lender, LLC*, 181 A.D.3d 783, 784–85 (2d Dep't 2020).

The legality and constitutionality of §2.61 has been exhaustively litigated since shortly after it was first promulgated as an emergency measure; a point which Petitioners conspicuously fail to mention in any of their submissions to this Court. Although very limited injunctive relief was initially granted against the State, courts—including the Second Circuit, federal district courts, and various State Supreme Courts—have more recently repeatedly denied requests for injunctive relief identical to that sought here. *See e.g. We the Patriots USA, Inc. v. Hochul*, Nos. 21-2179, 21-2566, 2021 U.S. App. LEXIS 32880, at *13-15 (2d Cir. Nov. 4, 2021)("WTP I"), (Second Circuit

decision affirming ruling by E.D.N.Y. denying injunctive relief against § 2.61 and reversing injunction issued by N.D.N.Y. against §2.61); *Andre-Rodney v. Hochul*, 1:21-cv-1053 (BKS/CFH), 2021 U.S. Dist. LEXIS 210105 (N.D.N.Y Nov. 1, 2021) (denying injunctive relief against § 2.61); *Kinsley v. Zucker*, Index No. E2021-0983, NYSCEF Nos. 133-134 (Sup. Ct. Cayuga Cnty. Nov. 8, 2021) (vacating previous TRO and denying preliminary injunction against § 2.61); *Cattaraugus County v. N.Y.S. Dep't of Health*, Index No. 9098382-21, NYSCEF No. 41 (Sup. Ct. Albany Cnty. Oct. 8, 2021) (same). At present, any injunction against the enforcement of § 2.61 has been lifted as of October 29, 2021, *We the Patriots USA, Inc. v. Hochul*, Nos. 21-2179, 21-2566, 2021 U.S. App. LEXIS 32921 (2d Cir. Oct. 29, 2021), and the requirement that "healthcare facilities 'continuously require' that certain medically eligible employees—those covered by the Rule's definition of 'personnel'—are vaccinated against COVID-19, is currently in effect." *We the Patriots USA, Inc. v. Hochul*, Nos. 21-2179, 21-2566, 2021 U.S. App. LEXIS 33691, at *4 (2d Cir. Nov. 12, 2021). Here, Plaintiffs offer no new evidence or arguments that would indicate a likelihood of success on the merits.

Regardless of the Petition's complete and utter lack of merit, Petitioners' claims of irreparable harm—premised on purported constitutional violations, the loss of their jobs, and their inability to collect unemployment benefits—are equally unpersuasive, and again, identical claims have been rejected by other courts in the context of § 2.61. First, any assertion of irreparable harm premised on a purported constitutional violation fails, because Petitioners have not and cannot establish any constitutional violation in connection with § 2.61. Supra; *see also WTP I*, at *53–54 ("[B]ecause [plaintiffs] have failed to demonstrate a likelihood of success on their First Amendment or other constitutional claims, their asserted harm is not of a constitutional dimension. Thus, [p]laintiffs fail to meet the irreparable harm element simply by alleging an impairment of

their Free Exercise right."); *Andre-Rodney*, at *21–22 (same). Any claim of irreparable harm caused by their suspensions without pay, eventual termination, and the inability to collect unemployment benefits due to their refusal to comply with § 2.61 is also insufficient to constitute irreparable harm. *WTP I*, at *54–56 ("It is well settled, however, that adverse employment consequences are not the type of harm that usually warrants injunctive relief[.]"); *Andre-Rodney*, at *22–23 (same); *see also Broecker*, at *25–26 ("[T]he Court is compelled to note that the harms resulting from noncompliance with the NYC DOE Vaccination Mandate identified by Plaintiff are by no means *irreparable*." (emphasis in original)).

And critically, Petitioners' significant delays in seeking to protect their purported constitutional rights and ensure their continued employment/recourse to unemployment benefits—injuries that they have known about and actually suffered for months—cuts sharply against their present claims of irreparable harm. *See Broecker*, at *26–27 (delay of forty-four days in seeking relief against termination caused by mandatory vaccination policy "does not convey a looming, irreparable harm, and does not invoke the urgent need for speedy action to protect the plaintiffs' rights[,] as is typical when injunctions are sought on an expedited basis" (internal quotation marks omitted)); *see also Hirschfeld v. Bd. of Elections in City of New York*, 984 F.2d 35, 39 (2d Cir. 1993); M.F. v. Cuomo, Index No. 607277/21, NYSCEF No. 63, at p.10 (Sup. Ct. Nassau Cnty. June 28, 2021) (refusing to find irreparable harm in another action filed by Petitioners' counsel, Finn, where the petitioners had long been subjected to the allegedly objectionable policy and waited months before seeking relief). Petitioners, therefore, have not—and cannot—demonstrate irreparable harm, and their request for a TRO should be denied on this basis alone.

Finally, it cannot reasonably be argued that the equities tip in their favor. As the Second Circuit explained specifically with respect to § 2.61, "the State has an indisputably compelling

interest in ensuring that the employees . . . are vaccinated against COVID-19, not just to protect them and those with whom they come into contact from infection, but also to prevent an overburdening of the healthcare system. Although Plaintiffs undoubtedly face a difficult choice, . . . such hardships are outweighed by the State's interest[.]" WTP I, at *56–59. Thus, in contrast to the non-irreparable harm suffered by Petitioners, the harm posed by enjoining Respondents—who have acted reasonably and lawfully to safeguard and protect the lives of this State's residents—is truly irreparable, particularly because it would apply on a State-wide basis.[3] *See Hopkins Hawley LLC v. Cuomo*, 20-cv-10932(PAC), 2021 U.S. Dist. LEXIS 3961, at *3 (S.D.N.Y. Jan. 8, 2021) ("As the Supreme Court recently explained, '[s]temming the spread of COVID-19 is unquestionably a compelling interest.'" (quoting *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020))); *Columbus Ale House, Inc. v. Cuomo*, 495 F. Supp. 3d 88, 94 (E.D.N.Y. 2020) ("[E]njoining the actions of state elected officials in matters that affect public safety also constitutes an irreparable harm."); *Luke's Catering Serv., LLC v. Cuomo*, 485 F. Supp. 3d 369, 388 (W.D.N.Y. 2020) ("Weakening the State's response to a public-health crisis by enjoining it from enforcing measures employed specifically to stop the spread of COVID-19 is not in the public interest."). Indeed, the staffing shortages that are cited by Plaintiffs as a result of the vaccine mandate "pales in comparison to the potential staffing shortages that could be caused by a deadly and disruptive outbreak among unvaccinated healthcare personnel." Madden Aff., ¶ 14. The balance of the equities, therefore, does not favor Petitioners' request for a TRO or preliminary injunction, providing yet another reason why their application should be denied.

[3] Notwithstanding Petitioners' claim that injunctive relief against § 2.61 would lessen the burden on the State caused by labor shortages, serving to promote the safety of the public and therefore weighing in favor of Petitioners' request for a TRO, § 2.61 was enacted specifically to help combat the risk of staffing shortages caused by the potential transmission of COVID-19 between unvaccinated workers and their colleagues. See WTP I, at *11, 33–34. Petitioners' argument in this respect, therefore, is without merit.

CONCLUSION

For the foregoing reasons, Respondents respectfully request that the Court dismiss all causes of action and deny all requests for relief asserted in the Petition, in their entirety and with prejudice; dismiss the Complaint portion of the Petition and Complaint along with all non-Article 78 portions of the Petition and Complaint and/or portions of same that seek a declaratory judgment, in their entirety; and grant such other and further relief as the Court deems just and proper.

DATED: December 22, 2022
Syracuse, New York

LETITIA JAMES
Attorney General
State of New York
Attorney for State Defendant

Gigi E. Meyers

GIGI E. MEYERS
Assistant Attorney General
New York State Office of the Attorney General
300 South State Street, Suite 300
Syracuse, New York 13202
Telephone: 315-448-4800

TO: Gibson Law Firm, PLLC
Sujata Sidhu Gibson
832 Hanshaw Rd., Suite A
Ithaca, New York 14850

CERTIFICATION

In accordance with 22 NYCRR § 202.8-b (c), the undersigned certifies that the word count in this memorandum of law (excluding the caption, table of contents, table of authorities, signature block and this certification) as established using the word count of the word-processing system used to prepare it, is 6,959 words.

Dated: Syracuse, New York
December 22, 2022

Respectfully submitted,

By: /s/Gigi E. Meyers