UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JONATHAN ROBERTS AND CHARLES VAVRUSKA,

Plaintiffs,

- against -

MARY T. BASSETT, in her official capacity as Commissioner for New York State Department of Health; NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE,

Defendants.

22-CV-00710 (NGG) (RML)

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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Defendant Mary T. Bassett, Commissioner of the New York State Department of Health ("DOH"), sued in her official capacity, respectfully submits this memorandum of law, together with the accompanying Declaration of Eugene Heslin, MD, FAAFP, dated February 25, 2022, ("Heslin Decl."), and its exhibits, in opposition to Plaintiffs' motion for a preliminary injunction (ECF No. 19) ("PI Mot.").

PRELIMINARY STATEMENT

Plaintiffs bring this action seeking a court order prohibiting DOH and the New York City Department of Health ("NYCDOH") from providing certain guidance to medical providers regarding new COVID-19 drug treatments and therapies that reduce the risk of hospitalization and death in high-risk patients. Specifically, in December of 2021, when doses of the new therapies were subject to limited supply and the Omicron wave was at its peak, DOH and NYCDOH provided non-mandatory guidance to providers about how doses of the new COVID-19 treatments should be prioritized among patients most at risk of suffering hospitalization and death. The language in the guidance tracks recommendations from the Centers of Disease Control and Prevention ("CDC") and suggests that providers should consider non-white race or Hispanic/Latino ethnicity as a risk factor. This suggestion stems from the well-documented finding that non-white race and Hispanic/Latino ethnicity are known risk factors for developing severe illness from COVID-19. Although these COVID-19 treatments are no longer in short supply, Plaintiffs nevertheless seek a court order enjoining DOH and NYCDOH from advising medical providers about this clinically material information, merely because the guidance references race and ethnicity.

Plaintiffs are not entitled to this extraordinary relief. The Court should deny Plaintiffs' motion for a preliminary injunction because (1) their claims fail to raise an Article III case or

controversy; (2) Plaintiffs have not established a clear likelihood of success on the merits because the DOH guidance does not violate their rights under the Equal Protection Clause; (3) Plaintiffs have not demonstrated irreparable harm absent a preliminary injunction; and (4) the public interest weighs against ordering DOH to stop providing objectively true, accurate guidance to medical providers about known risk factors for suffering hospitalization and death due to COVID-19.

STATEMENT OF FACTS

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

Since the onset of the COVID-19 pandemic, DOH has vigorously applied all resources and taken all measures at its disposal to safeguard the safety and welfare of all New Yorkers, including closely aligning state efforts with guidance and requirements released by the Centers of Disease Control and Prevention ("CDC"). Heslin Decl. ¶ 6. The outbreak of the new Omicron variant in early December of 2021 was handled no differently. *Id.* ¶ 7. DOH ramped up testing capacity to meet demand, intensified engagement on vaccination and boosting efforts, and extended the mandatory masking protocols in public spaces. *Id.* DOH efforts have been successful in leading to a 90 percent drop in the state's positivity rate in the last month. *Id.* ¶ 8.

B. Authorization of New Oral Antiviral Therapies and Monoclonal Antibody Therapy

In December of 2021, as the Omicron variant surged, DOH issued guidance regarding several promising COVID-19 drug treatments and therapies that were found to reduce the risk of hospitalization and death in high-risk patients when taken by patients early after symptom onset. *See id.* ¶ 10; Exs. A & B ("DOH Guidance").[1] These included Paxlovid and Molnupiravir, two

[1] The DOH Guidance includes two documents: "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products," Heslin Decl., Ex. A; and "Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations," *id.*, Ex. B.

new oral antiviral therapies as to which the United States Food and Drug Administration ("FDA") issued Emergency Use Authorizations in December 2021; and Sotrovimab, the only authorized monoclonal antibody therapeutic expected to be effective against the Omicron variant (collectively, "the Therapies"). *Id*. ¶ 10. To be eligible for treatment with the Therapies, patients must have mild to moderate symptoms, test positive for COVID-19, and be within 5 days of symptom onset for oral antiviral therapies or within 10 days for the monoclonal antibody therapeutic. *See* DOH Guidance, Heslin Decl., Ex. B, at 2.

C. Temporary Shortage of Treatments and Guidance Issued by DOH, CDC, and NYCDOH

In the weeks immediately following the release of these new drug treatments, at the height of the Omicron wave, there were expected to be supply shortages of the Therapies. Heslin Decl. ¶ 10. Around this time, multiple public health agencies, including DOH, CDC, and NYCDOH, issued guidance to health care providers to inform and help guide practitioners' conversations with their patients about the risks, use, and efficacy of the Therapies. *See* DOH Guidance; Heslin Decl. Ex. C ("CDC Guidance"), & ECF No. 1-6 ("NYCDOH Guidance"). Each of these guidance documents instructed providers that—during the time that supplies were limited—treatment doses should be prioritized for those patients at the highest risk for suffering severe COVID-19 resulting in hospitalization or death, considering all known risk factors. *Id*.

All of these guidance documents noted that race and ethnicity is one of the known risk factors that may place an individual patient at a heightened risk of progression to severe COVID-19, including the risk of hospitalization or death. The DOH guidance stated: "Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19." DOH Guidance at 2. The CDC Guidance stated: "Other medical conditions or factors (for

example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 . . . ." CDC Guidance at 50. The NYCDOH Guidance stated: "Consider race and ethnicity when assessing an individual's risk. Impacts of longstanding systemic health and social inequities put Black, Indigenous, and People of Color at increased risk of severe COVID-19 outcomes and death." NYCDOH Guidance at 4.

D. The Scientific Basis for Inclusion of Race and Ethnicity as a Known Independent Risk Factor of Severe COVID-19

The finding that race and ethnicity may be an independent risk factor for severe illness and death from COVID-19 is well supported by objective data gathered by many sources during the pandemic. The CDC publishes data on the risk of COVID-19 infection, hospitalization, and death by race and ethnicity. *See* Heslin Decl. ¶ 21. As of February 1, 2022, the CDC reports that Black or African American, Non-Hispanic persons have been hospitalized from COVID -19 at a *2.5 times higher* rate than white, Non-Hispanic persons, and have suffered death at a rate *1.7 times higher*. *Id*. Hispanic or Latino persons have been hospitalized at a *2.4 times higher* rate than white, Non-Hispanic persons, and have suffered death at a *1.9 times higher* rate. *Id*.[2] As the CDC notes in reporting this data, race and ethnicity are "risk markers" for a wide variety of other conditions that may affect health and not be captured by a screening for pre-existing health conditions, including "socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g.,

[2] In the face of abundant data to the contrary, Plaintiffs claim that "the rate of death for white non-Hispanic individual exceeds the rate for any other group in New York." PI Mot. at 1. That claim is not supported, even by Plaintiffs' own source. Plaintiffs cite COVID-19 data posted on an Emory University website. *Id.* at n.5. Emory's website for outcomes in New York unambiguously shows a significantly higher rate of death per 100 thousand persons for African American and Hispanic individuals, compared to white individuals. *See* https://covid19.emory.edu/36 (last visited Feb. 25, 2022) (showing 349 deaths among African Americans per 100 thousand persons, 269 deaths among Hispanic persons per 100 thousand persons, and 155 deaths among white persons per 100 thousand persons).

frontline, essential, and critical infrastructure workers." *Id*.

Many other sources have published similar findings. For instance, an analysis of treatment data by the CDC showed that antiviral therapies are used less commonly among racial and ethnic minority groups, thus amplifying the increased risk for severe COVID-19–associated outcomes in those groups. *Id.* ¶ 16. Additionally, a National Center for Health Statistics 2020 Report demonstrated a disproportionate impact on life expectancy of Hispanic and Black people due to the COVID-19 pandemic. *Id.* ¶ 17. Further, a study published on December 10, 2020, found that people from racial and ethnic minority groups were more likely to have increased COVID-19 disease severity upon admission to the hospital when compared with non-Hispanic white people. *Id.* ¶ 18. Mortality data from CDC's National Vital Statistics System ("NVSS"), from February 1, 2020, to September 30, 2021, demonstrates that there have been an estimated 700,000 deaths in the United States, with the largest percentage increase in mortality among adults aged 25-44 years and among Hispanic or Latino people. *Id.*

An article in Scientific Reports illustrates that racial disparities continue to persist even after controlling for medical comorbidities. *Id.* ¶ 19. When compared to white patients, similarly situated Black patients showed significantly higher odds of ventilator dependence and death. *Id.* Similarly, an article in the Journal of the American Medical Association Network Open entitled "Variations in COVID-19 Mortality in the US by Race and Ethnicity" found that most racial and ethnic minority populations had higher age-adjusted mortality rates than non-Hispanic white populations. *Id.* ¶ 20.

As a result of the abundant objective data regarding outcomes during the COVID-19 pandemic, DOH, as well as the CDC, NYCDOH, and other public health agencies, have concluded that health care providers should consider non-white race or Hispanic/Latino ethnicity an

independent risk factor for severe illness and death from COVID-19. *Id.* ¶ 22.

E. No Current Shortage of Treatments in New York

The DOH Guidance was issued at a time when the Therapies were anticipated to be in short supply based upon information provided by the federal government prior to their initial distribution. *Id.* ¶ 28. The DOH Guidance expressly states that its recommendations on prioritization of the highest risk patients applies "during this time of severe resource limitations." DOH Guidance, Heslin Decl. Ex. A., at 1. However, there is currently no shortage of the medications in New York. Heslin Decl. ¶ 28

F. The DOH Guidance in Operation

DOH's recommendation that providers and hospitals should consider race and ethnicity as a risk factor when prescribing the Therapies is not a mandate, or a restriction of COVID-19 treatments by race. Heslin Decl. ¶ 24. The DOH Guidance does not replace doctors' clinical judgment and does not prevent any patient from receiving necessary treatment. *Id.* DOH expects that, in a clinical setting, a practitioner will: (1) take a detailed history and conduct a physical examination; (2) understand the risks and benefits of treatment versus nontreatment based upon the individual patient; and (3) have a discussion with the patient about risks, benefits, and alternatives. *Id.* Only then, after using appropriate clinical judgment, should a medication be prescribed. *Id.* In this context, the DOH Guidance simply provides medical practitioners with information about known risk factors for severe illness, hospitalization, and death, based on abundantly reported, objective, data. Because the DOH Guidance is not a mandate, DOH will not take any enforcement actions against practitioners or hospitals in relation to it. Heslin Decl. ¶ 27.

Nothing in the DOH Guidance prevents the Plaintiffs, or anyone similarly situated, from receiving the Therapies in the unfortunate event that they contract COVID-19, if their practitioner concludes that such treatment is clinically appropriate. *Id.* ¶ 30. No one in New York, who is

otherwise qualified for treatment based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier. *Id.* ¶ 31.

G. The Current Action

Plaintiffs commenced this action by filing a complaint on February 8, 2022, (ECF No. 1) ("Compl."), and filed this motion for a preliminary injunction on February 18, 2022, (ECF No. 19). Notably, Plaintiffs, who self-identify as white, non-Hispanic individuals under age 65, do not allege that they have COVID-19, that they have ever sought the Therapies to treat for COVID-19, or that they have ever been denied treatment with the Therapies due to their race or ethnicity, or for any other reason. Compl. ¶¶ 39-40; *see* Declaration of Jonathan Roberts in Support of PI Mot. (ECF 19-1) ("Roberts Decl.") ¶¶ 3-5; Declaration of Charles Vavruska in Support of PI Mot. (ECF 19-2) ("Vavruska Decl.") ¶¶ 3-6.

STANDARD OF REVIEW

"Preliminary injunctive relief . . . is an 'extraordinary and drastic remedy' that is 'unavailable except in extraordinary circumstances.'" *Murray v. Cuomo*, No. 20-CV-03571, 2020 WL 2521449, at *8 (S.D.N.Y. May 18, 2020) (quoting *Moore v. Consol. Edison Co.*, 409 F.3d 506, 511 (2d Cir. 2005)). Where "a preliminary injunction will affect government action taken in the public interest pursuant to a statute or regulatory scheme, the moving party must demonstrate (1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction." *Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 143 (2d Cir. 2016) (internal quotation marks omitted). Where a plaintiff "seeks a mandatory injunction against the government that would change the status quo existing when the case was filed," a heightened standard applies in which the plaintiff "must show "a clear or substantial likelihood of success on the merits." *Murray*, 2020 WL

2521449, at *8 (internal quotation marks omitted).

ARGUMENT

I. PLAINTIFFS' CLAIMS DO NOT RAISE AN ARTICLE III CASE OR CONTROVERSY

A. Plaintiffs Lack Standing to Pursue Their Claims

Article III of the Constitution "limits the federal courts' power to the resolution of 'Cases' and 'Controversies.'" *Dhinsa v. Krueger*, 917 F.3d 70, 77 (2d Cir. 2019) (citing U.S. Const. art. III, § 2). A litigant who invokes federal jurisdiction therefore "must demonstrate standing to sue," consisting of three elements: "the individual initiating the suit 'must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Id.* (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). The Plaintiffs bear the burden of establishing each element of these elements. *See Spokeo*, 578 U.S. at 338 (citing *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990)).

In cases claiming a violation of the Equal Protection Clause of the Fourteenth Amendment, a plaintiff can show standing "[w]hen the government erects a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group . . . ." *Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 666 (1993). In this context, the alleged injury is "the denial of equal treatment resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit." *Id.*; *see also Comer v. Cisneros*, 37 F.3d 775, 793 (2d Cir. 1994) (stating that "to show Article III standing for constitutionally-protected equal protection claims, a plaintiff must allege that (1) there exists a reasonable likelihood that the plaintiff is in the disadvantaged group, (2) there exists a government-erected barrier, and (3) the barrier causes members of one group to be treated differently from members of the other group.").

"Although the injury-in-fact requirement is not as stringent in Equal Protection cases, a plaintiff must still establish that she [or he] suffered *some* sort of identifiable harm. . . . Whether it's a barrier or an unequal playing field that affects a plaintiff's pursuit, she must identify some disadvantage to meet the constitutional requirement for standing." *Youth Alive v. Hauppauge Sch. Dist.*, No. 08-CV-1068, 2012 WL 4891561, at *3 (E.D.N.Y. Oct. 15, 2012) (emphasis in original). "The mere allegation of unequal treatment, absent some kind of actual injury, is insufficient to create standing" on an equal protection claim. *Johnson v. U.S. Off. of Pers. Mgmt.*, 783 F.3d 655, 665 (7th Cir. 2015).

Moreover, "[t]o seek injunctive relief, a plaintiff must show that [she or] he is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical[.]" *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009) (quoting *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 180–181 (2000)). Significantly, no Article III standing exists if a plaintiff's theory of injury rests on an "attenuated chain of inferences necessary to find harm." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013). Rather, the plaintiff "bear[s] the burden of pleading and proving concrete facts showing that the defendant's actual action has caused the substantial risk of harm," and may not "rely on speculation about 'the unfettered choices made by independent actors not before the court.'" *Id.* (quoting *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 562 (1992)).

Further, "[t]he rule against generalized grievances applies with as much force in the equal protection context as in any other." *United States v. Hays*, 515 U.S. 737, 743 (1995). The Supreme Court has made clear that even if a plaintiff alleges that "a governmental actor is discriminating on the basis of race, the resulting injury 'accords a basis for standing only to those persons who are personally denied equal treatment' by the challenged discriminatory conduct.'" *Id.* at 743-44

(quoting *Allen v. Wright*, 468 U.S. 737, 755 (1984)) (internal quotation marks omitted); *see Vaughn v. Consumer Home Mortg. Co.*, 297 F. App'x 23, 26 (2d Cir. 2008) (summary order) (stating that in equal protection cases in which plaintiffs facing a government-erected barrier, standing is afforded "only to those persons who are 'personally denied equal treatment by the challenged discriminatory conduct'") (quoting *In re U.S. Catholic Conference*, 885 F.2d 1020, 1025 (2d Cir. 1989)).

i. Plaintiffs Have Not Alleged an Injury in Fact

Plaintiffs claim they have been injured by the DOH Guidance's recommendation that healthcare providers consider non-white race or Hispanic/Latino ethnicity a risk factor for developing severe COVID-19 when prescribing the Therapies, including in making decisions about prioritizing high-risk patients during a shortage that no longer exists. *See* PI Mot. at 8; Compl. ¶¶ 37-40. Plaintiffs, who self-identify as white, non-Hispanic individuals under the age of 65, do not allege that they have COVID-19; that they have ever sought the Therapies to treat COVID-19; or that they have ever been denied treatment with the Therapies due to their race or ethnicity, or for any reason. Compl. ¶¶ 39-40; *see* Roberts Decl. ¶¶ 3-5; Vavruska Decl.¶¶ 3-6. Plaintiffs nevertheless contend that, by recommending that health care providers consider non-white race and Hispanic/Latino ethnicity as an independent risk factor for developing serious illness, the DOH Guidance "disadvantage[s]" them as white people and imposes a "barrier" to their access to antiviral treatments by making it more difficult for them access to the treatments due to their race. *See* PI Mot. at 8.

Plaintiffs' allegations are insufficient to establish an injury in fact. First, Plaintiffs fail to show that the DOH Guidance creates a "barrier" preventing white persons from receiving the Therapies. The DOH Guidance merely states that during times of severe resource limitations,

medical providers should prioritize treatment doses for those patients at the highest risk of severe illness and death. It then provides accurate information about multiple known factors for severe illness and death due to COVID-19, including race and ethnicity. DOH's recommendation that medical providers can and should consider accurate information about all known risk factors when evaluating each individual patient is not a race-based "barrier," nor does it "create a racial hierarchy in the delivery of care." Heslin Decl. ¶ 25. Importantly, [t]he recommendation that providers and hospitals should consider non-white race and Hispanic/Latino ethnicity as a risk factor when prescribing the Therapies is not a mandate, or a restriction of COVID-19 treatments by race." *Id.* ¶ 24. The DOH Guidance does not replace practioners' "clinical judgment, and does not prevent any patient from receiving necessary treatment." *Id.* In the event that the Plaintiffs unfortunately contracted COVID-19, they would have the opportunity to be evaluated by their medical providers. DOH expects those medical providers would determine what course of treatment is clinically appropriate, based upon a conversation with their Plaintiff patient, and a review of their patient's medical history, risk factors, and circumstances. Ultimately, "[n]othing in the Guidance prevents the Plaintiffs, or anyone similarly situated, from receiving treatment with oral antivirals in the unfortunate event that they contract COVID-19," *id.* ¶ 30, and "[n]o one in New York, who is otherwise qualified based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier." *Id.* ¶ 31. Especially considering that there is no longer a shortage of the Therapies in New York, Plaintiffs will be entitled to receive the treatment their doctor concludes is clinically appropriate, regardless of their race or ethnicity.

Plaintiffs nevertheless allege that the DOH Guidance creates a "barrier" by requiring white individuals only to demonstrate a medical condition or other factor that increases their risk for

severe illness to be eligible for the Therapies. PI Mot. at 8. Specifically, Plaintiffs claim that Plaintiff Roberts is "categorically ineligible" to receive oral antiviral therapies under the DOH Guidance "[g]iven his age, vaccination status, and current health," and the fact that he is white rather than non-white or Hispanic, while Plaintiff Vavruska will inevitably receive the therapies "after non-white or Hispanic individuals with the exact same age, vaccination status, and health condition [who] receive them first." *Id.* Plaintiffs' claims misconstrue the DOH Guidance, which is not "a 'treatment policy'" dictating which patients can and cannot receive the Therapies, but guidance documents that provides healthcare providers with accurate information to make those decisions based on their clinical judgment and considering the circumstances unique to each patient. Heslin Decl. ¶ 9. While the DOH Guidance lists "medical condition[s] or other factors that increase their risk for severe illness" as one of the eligibility criteria for the Therapies, the determination whether a patient has a medical condition or other risk factors that make the Therapies an appropriate treatment resides with the healthcare provider. Heslin Decl. ¶¶ 24-25. Contrary to Plaintiffs' claims, the DOH Guidance does not dictate that any patient is "categorically" eligible or ineligible to receive antiviral treatment based on their race or ethnicity, nor does it require that people of non-white or Hispanic/Latino ethnicity receive antiviral treatment "before non-white or Hispanic individuals with the exact same age, vaccination status, and health condition." Pls.' Mem. at 8; *see* Heslin Decl. ¶ 9 ("There is no 'scoring system' and you do not have to 'get enough points' in order to receive the medication.").

To that end, Plaintiffs' claim that "under the State's directive, a white, non-Hispanic person with cancer is treated the same as a non-white or a Hispanic person who is disease free," PI Mot. at 5, is a gross oversimplification and distortion of the DOH Guidance. Nothing in the DOH Guidance dictates a specific course of treatment for any individual patient. The DOH Guidance

merely recommends that each patient should be independently examined by their doctor for risk factors of hospitalization and death from COVID-19, to determine what course of treatment is appropriate. The fact that the doctor of a non-white or Hispanic patient considers *accurate* information, supported by abundant objective data, about that patient's risk of suffering severe illness does not create a "barrier" to the white, non-Hispanic patient receiving his or her own individualized treatment. Plaintiffs therefore fail to establish standing on this basis. *See, e.g.*, *MGM Resorts Int'l Glob. Gaming Dev., LLC v. Malloy*, No. 15-CV-1182, 2016 WL 9446646, at *6 (D. Conn. June 23, 2016) (holding that the statute at issue did not impose a "barrier" to a benefit and distinguishing classes of cases to the contrary), *aff'd*, 861 F.3d 40 (2d Cir. 2017), *as amended* (Aug. 2, 2017); *Youth Alive*, 2012 WL 4891561, at *3 (holding that the plaintiffs had not proven injury where they "operate on the same, if not an advantageous, playing field and do not face any barrier that impedes their ability to obtain any benefit") (citing *Vaughn v. Consumer Home Mortg. Co., Inc.*, 470 F. Supp. 2d 248, 266 (E.D.N.Y. 2007)) (dismissing plaintiffs' claims for lack of standing absent proof of "a barrier in any real sense to any plaintiff's ability to obtain [a] benefit"), *aff'd*, 297 F. App'x 23 (2d Cir. 2008).

Plaintiffs also have not shown actual or imminent injury necessary to establish standing. Plaintiffs' theory of standing relies on a hypothetical, highly attenuated series of multiple contingent events that would have to occur for them to suffer an injury. Plaintiffs do not have COVID-19 and may never contract it. Compl. ¶¶ 39-40. If they do contract it, their practitioners may or may not deem their medical condition suitable for treatment with the Therapies. If their practitioners do determine that Plaintiffs' conditions warrant treatment with the Therapies, based upon a full review of their medical histories and discussions of any possible contraindications, Plaintiffs may or may not be eligible for the therapy for reasons unrelated to their race or ethnicity.

If Plaintiffs are eligible, there is no shortage of the Therapies such that the guidance would be invoked.

Like the plaintiffs in *Clapper*, the harm that Plaintiffs allege is contingent on a chain of attenuated hypothetical events and actions by third parties independent of DOH, which is insufficient to show injury in fact. 568 U.S. at 410; *see also SC Note Acquisitions, LLC v. Wells Fargo Bank, N.A.*, 934 F. Supp. 2d 516, 526 (E.D.N.Y. 2013), *aff'd*, 548 F. App'x 741 (2d Cir. 2014) (no standing where the plaintiff's alleged harm was "contingent on a future event that may not occur as anticipated, or indeed may not occur at all") (internal quotation marks and alterations omitted). Plaintiffs do not even allege that they *would* take the Therapies if available to them, only that they "want the ability to access any medication that would be beneficial" for them to take if they were to contract COVID-19 in the future. Roberts Decl. ¶ 5; Vavruska Decl. ¶ 6. "Such some day intentions—without any description of concrete plans, or indeed even any specification of when the some day will be—do not support a finding of the actual or imminent injury" to establish standing. *Summers*, 555 U.S. at 496 (internal quotation marks omitted).

ii. Plaintiffs' Alleged Injury Is Not Traceable to Defendant and Is Not Redressable by the Court

In addition to alleging an injury in fact, to achieve Article III standing a plaintiff must also demonstrate that the injury is fairly traceable to the challenged conduct of the defendants, and that the injury is likely to be redressed by a favorable judicial decision. *See Spokeo,* 578 U.S. at 338. Plaintiffs fail on both additional grounds.

First, Plaintiffs' alleged injury is not traceable to DOH. To satisfy the traceability bar, a plaintiff must show "a causal connection between the injury and the conduct complained of—the injury has to be fairly trace[able] to the challenged action of the defendant, and not th[e] result [of] the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560 (internal

citation omitted). Here, Plaintiffs' alleged injury is that they believe their practitioners might not write them a prescription for the Therapies even if they were to contract COVID-19. If that outcome occurred, it would not be fairly traceable to the information provided in the non-mandatory DOH Guidance. Especially given that there is no longer a shortage of the treatments, Plaintiffs would only be denied access to those treatments if their practitioners independently concluded that such treatments were not clinically appropriate, given each Plaintiff's own unique medical history, risk factors, and circumstances. That hypothetical outcome would not be traceable to the DOH Guidance, and the relief they seek is therefore not appropriate.

Likewise, Plaintiffs' alleged injury is not redressable by the judicial decision they seek. Even if the Court were to issue an order instructing DOH to strike any mention of race or ethnicity from the non-mandatory DOH Guidance, practitioners must still make clinical decisions based on all available medical evidence. Practitioners are not likely to simply ignore the widely publicized, objective data showing that race and ethnicity is a risk factor for hospitalization and death from COVID-19, even if the disputed language in the DOH Guidance were to be stricken. Moreover, Plaintiffs fail to address the independent guidance from the CDC, which also advises healthcare providers that race and ethnicity are risk factors for severe COVID-19. *See* CDC Guidance at 50. The CDC guidance would remain in effect, even in the absence of the DOH Guidance.

B. Plaintiffs' Claims Are Moot

"Article III of the Constitution grants the Judicial Branch authority to adjudicate 'Cases' and 'Controversies.'" *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90 (2013). "In our system of government, courts have no business deciding legal disputes or expounding on law in the absence of such a case or controversy." *Id*. (internal citations omitted). "[A]n actual controversy must exist not only at the time the complaint is filed, but through all stages of the litigation." *Id*. (internal

citations omitted). "A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Id*. (internal citations omitted).

Even if Plaintiffs had stated a valid Equal Protection claim based on the circumstances that were in effect when the DOH Guidance was first issued—and they do not—those circumstances are no longer in effect, and their claims are now moot. Plaintiffs' motion for a preliminary injunction is based on their allegation that if scarce treatments are prioritized based on the known risk factors, they might be denied access to certain COVID-19 therapies based on their race. The DOH Guidance was issued in late December 2021, when the new antiviral oral therapies had just been authorized by the FDA; Sotovimab was the only authorized monoclonal antibody therapeutic effective against the Omicron variant of COVID-19; and the unprecedented Omicron wave of COVID-19 cases was just peaking. That unique confluence of circumstances led to a temporary shortage of available doses of the Therapies. Heslin Decl. ¶ 28. As the DOH Guidance expressly stated, its recommendation regarding prioritization of high-risk patients applied only "during this time of severe resource limitations." DOH Guidance, Heslin Decl., Ex. A, at 1. Since then, production of the Therapies has increased supply, and the number of positive COVID-19 cases in New York has drastically decreased. Heslin Decl. ¶¶ 8, 28. There is no current shortage of the Therapies in New York, and DOH has encouraged *any* individual who believes they may need the treatments to contact to their doctor to have the appropriate clinical discussion. *Id*. at ¶¶ 28-29.

Plaintiffs argue that their claims are nevertheless not moot because "COVID-19 creates unpredictable scenarios" and "Defendants do no, and cannot, represent that supplies of COVID-19 treatments will outnumber demand indefinitely." PI Mot. at 9. This argument distorts the relevant standard. The capable-of-repetition doctrine is a "severely circumscribed" exception to

mootness that "'applies only in exceptional situations, where the following two circumstances are simultaneously present: (1) the challenged action is in its duration too short to be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again.'" *Knaust v. City of Kingston*, 157 F.3d 86, 88 (2d Cir. 1998) (quoting *Spencer v. Kemna*, 523 U.S. 1, 17 (1998)). Contrary to Plaintiffs' contention, this standard does not place the burden on DOH to guarantee that treatment supply will outnumber demand "indefinitely." PI Mot. at 9. Rather, Plaintiffs must establish that the two exceptional circumstances simultaneously apply. They cannot do so, not least because between late December and the present, manufacturers have drastically ramped up production of the treatments in response to government orders for millions of doses.[3] In the face of these dramatically changed circumstances, Plaintiffs' speculation about the possibility of future events is insufficient to implicate the capable-of-repetition doctrine. Nor have Plaintiffs identified facts establishing that a future hypothetical shortage would be too short in duration for them to bring a new challenge.[4]

II. PLAINTIFFS HAVE NOT ESTABLISHED A CLEAR LIKELIHOOD OF SUCCESS BECAUSE THE DOH GUIDANCE DOES NOT VIOLATE THE EQUAL PROTECTION CLAUSE

To state a claim under the Equal Protection clause of the Fourteenth Amendment, a plaintiff

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[3] *See, e.g.*, Bloomberg, "Game-Changer Pfizer Pill Is Easier to Find as Omicron Fades Away" (Feb. 16, 2022), *available at* https://www.bloomberg.com/news/articles/2022-02-16/-game-changer-pfizer-pill-easier-to-get-as-omicron-fades-away ("Now, as cases plummet nationwide and the company continues to deliver hundreds of thousands of doses ordered by the federal government to pharmacies, Paxlovid is starting to look downright plentiful. Doctors and health officials in New York, Boston, Colorado and other areas where the omicron wave has receded report that supply seems to be meeting the softening demand.").

[4] Likewise, the voluntary cessation doctrine does not apply here because it is not DOH's voluntary conduct alone that has made Plaintiffs' claims moot. Rather, external events have "completely and irrevocably eradicated the effects of the alleged violation," *Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 815 F.3d 105, 109 (2d Cir. 2016), because Plaintiffs will have access to the treatments if their doctors prescribe it.

must identify (1) "a law or policy that expressly classifies persons on the basis of race;" (2) "a facially neutral law or policy that has been applied in an intentionally discriminatory manner;" or (3) "a facially neutral statute or policy [that] has an adverse effect and . . . was motivated by discriminatory animus." *Brown v. City of Oneonta*, 221 F. 3d 329, 337 (2d Cir. 2000). The level of review a court must apply to an Equal Protection claim "depends on the nature of the class of individuals the state or local government treats differently or the rights at issue." *Winston v. City of Syracuse*, 887 F.3d 553, 560 (2d Cir. 2018). "'[I]f a law neither burdens a fundamental right nor targets a suspect class,'" the governmental classification need only "'bear[] a rational relation to some legitimate end.'" *Id.* (quoting *Romer v. Evans*, 517 U.S. 620, 631 (1996)). Rational basis review "is highly deferential." *Id*. The governmental classification "is presumed constitutional, and '[t]he burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it.'" *Id*. (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)). By contrast, if the challenged governmental distinction "either (1) burdens a fundamental right or (2) targets a suspect class," strict scrutiny analysis applies. *Friedman v. Bloomberg L.P.*, 884 F.3d 83, 92 (2d Cir. 2017). Under strict scrutiny, governmental classifications survive "if they are narrowly tailored measures that further compelling governmental interests." *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 227 (1995).

A. The DOH Guidance Does Not Create a Racial Classification Requiring Strict Scrutiny Review

"The term racial classification normally refers to a governmental standard, preferentially favorable to one race or another, for the distribution of benefits." *Hayden v. Cty. of Nassau*, 180 F.3d 42, 49 (2d Cir. 1999) (citing *Raso v. Lago*, 135 F.3d 11, 16 (1st Cir. 1998), *cert. denied*, 525 U.S. 811 (1998)) (alteration omitted). "In every case in which the [Supreme] Court has applied strict scrutiny to a 'racial classification' a racial preference or classification appeared on the face

of the government decision *and* required that action be taken with respect to an individual based on the classification." *Lewis v. Ascension Par. Sch. Bd.*, 662 F.3d 343, 361–62 (5th Cir. 2011) (King, C.J., concurring in part) (collecting cases) (emphasis in original). While the Supreme Court has "not precisely define[d] the term 'racial classification' for equal protection purposes," it has "described such classifications as burdening or benefiting individuals on the basis of race, or subjecting individuals to unequal treatment." *Honadle v. Univ. of Vermont & State Agric. Coll.*, 56 F. Supp. 2d 419, 427–28 (D. Vt. 1999) (citing *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 222, 224 (1995)) (internal citation omitted). "According to this description, a racial classification that does not confer a benefit or impose a burden on an individual would not implicate the equal protection clause." *Honadle*, 56 F. Supp. 2d at 428.

Here, the DOH Guidance does not create a racial classification that implicates the Equal Protection Clause. *See id.* at 427-28. As discussed above and in Dr. Heslin's declaration, the DOH Guidance provides accurate information about multiple known risk factors for severe illness and death due to COVID-19 that may make a patient an appropriate candidate for treatment with the Therapies, particularly during the time when there was a severe supply shortage of these medications. The fact that the DOH Guidance notes that race and ethnicity are known, independent risk factors for severe COVID-19 is not tantamount to a "racial classification" erected by the government. Importantly, the DOH Guidance does not require that any action be taken with respect to any individual based on their race or ethnicity. Nor does it prevent any patient, including Plaintiffs, from receiving necessary treatment for COVID-19 due to their race or ethnicity. *See Lewis*, 662 F.3d at 361–62. The DOH Guidance does not mandate who can and cannot receive the Therapies, Heslin Decl. ¶ 9; it simply notes the scientifically established fact that persons of non-white race or Hispanic/Latino ethnicity may have a higher risk of suffering severe illness and death

due to COVID-19. By acknowledging this fact, the DOH Guidance does not confer a benefit or impose a burden on any individual due to their race or ethnicity. *See Honadle*, 56 F. Supp. 2d at 428.

Plaintiffs fail to cite any cases holding that a government public health agency has erected a "racial classification" subject to strict scrutiny, merely for sharing clinically relevant and objectively well supported information about risk factors for disease—just because the clinical risk factors are associated with race or ethnicity. Rather, Plaintiffs rely solely on cases where the government has made race an express factor in an otherwise race-neutral decision. For example, *Parents Involved in Cmty. Sch. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701 (2007) – a case relied on heavily by Plaintiffs – involved a challenge to student assignment plans that used race to allocate slots in oversubscribed high schools and determine which public schools certain children may attend. By contrast, the DOH Guidance does not create a racial classification, and it does not provoke strict scrutiny review.

B. The DOH Guidance Is Rationally Related to a Legitimate Government Interest in Preventing Severe Illness and Death From COVID-19

State action that does not provoke strict scrutiny review "will ordinarily survive an equal protection attack so long as the challenged classification is rationally related to a legitimate governmental purpose.'" *Maniscalco v. New York City Dep't of Educ.*, No. 21-CV-5055, 2021 WL 4344267, at *5 (E.D.N.Y. Sept. 23, 2021), *aff'd*, No. 21-2343, 2021 WL 4814767 (2d Cir. Oct. 15, 2021) (quoting *Kadrmas v. Dickinson Pub. Sch.*, 487 U.S. 450, 457-58 (1988)). A plaintiff challenging state action subject to rational basis review bears a "heavy burden" of showing that "the varying treatment of different groups or persons is so unrelated to the achievement of any combination of legitimate purposes" that the treatment is "irrational." *Id.* (quoting *Kadrmas*, 487 U.S. at 462-63).

Plaintiffs fail to meet that heavy burden here. As discussed above, abundantly reported, objective data regarding outcomes during the COVID-19 pandemic shows that non-white and Hispanic/Latino individuals have suffered severe illness and death from COVID-19 in disproportionately higher numbers than white individuals. Heslin Decl. ¶¶ 13-22. Based on this information, many public health agencies, including DOH, have concluded that healthcare providers should consider non-white race or Hispanic/Latino ethnicity an independent risk factor for severe illness and death from COVID-19 when considering whether to prescribe the Therapies. *Id.* ¶ 22. The inclusion of this independent risk factor in the DOH Guidance is rationally related to the State's legitimate interest in preventing severe illness and death from COVID-19, and in giving medical providers accurate, comprehensive information about known risk factors for developing severe disease so that they can make informed treatment decisions for their patients. The DOH Guidance therefore survives rational basis review and Plaintiffs' Equal Protection Claim cannot succeed.

C. Even If Strict Scrutiny Applied, the DOH Guidance Would be Valid

Even if the Court were to apply strict scrutiny—which it should not do—the DOH Guidance would be valid because its inclusion of race and ethnicity as a risk factor for severe disease is narrowly tailored to achieve a compelling state interest. *See Grutter v. Bollinger*, 539 U.S. 306, 343 (2003). "It may be assumed that in some situations a State's interest in facilitating the health care of its citizens is sufficiently compelling to support the use of a suspect classification." *Regents of Univ. of California v. Bakke*, 438 U.S. 265, 310 (1978) (stating that a State may have compelling interests "in safeguarding health, [and] in maintaining medical standards"); *see also Mitchell v. Washington*, 818 F.3d 436, 446 (9th Cir. 2016) (stating that "[i]t is not difficult to imagine the existence of a compelling justification [to consider race] in the

context of medical treatment"); *Pietrangelo v. Sununu*, No. 2021 DNH 067, 2021 WL 1254560, at *1-*4 (D.N.H. Apr. 5, 2021), *appeal dismissed*, 15 F.4th 103 (1st Cir. 2021) (discussing the sources of scientific data relied upon in determining what groups have been disproportionately affected by COVID-19 in the creation of state's COVID-19 vaccination prioritization plan). Here, the DOH Guidance serves the State's compelling interest in protecting the public health of its citizens and preventing severe illness and death from COVID-19. The DOH Guidance furthers these interests by giving medical providers accurate, comprehensive information about known risk factors so that they can make appropriate treatment decisions and ensure that patients with the highest risk of developing severe illness or dying from COVID-19 receive the Therapies when they are in short supply. *See* Heslin Decl. ¶¶ 13-21. Plaintiffs' argument that the DOH Guidance fails to further a compelling government interest seems to be based on their incorrect claim that the rate of death for white individuals exceeds the rate for other groups in New York. PI Mot. at 1. As noted above, Plaintiffs fail to support that incorrect contention, as abundant objective evidence published by many sources during the pandemic conclusively shows a much higher rate of hospitalization and death for non-white and Hispanic individuals. *See supra* 4-6.

The DOH Guidance is also narrowly tailored. "Narrow tailoring does not require exhaustion of every conceivable race-neutral alternative," but requires consideration of "the importance and the sincerity of the reasons advanced by the governmental decisionmaker for the use of race in that particular context." *Grutter*, 539 U.S. at 327, 339 (holding that a race-sensitive admissions program was narrowly tailored because the consideration of race was merely one factor in the decision-making process and individualized consideration was given to each applicant). Plaintiffs argue that the DOH Guidance is not narrowly tailored because DOH could simply advise medical providers to ignore a patient's race and ethnicity and limit their review to a patient's

history of chronic diseases or obesity. PI Mot. at 15. That argument misses the point that the objective data shows that race and ethnicity act as an *independent* risk factor, separate and apart from a patient's medical history. As the CDC has advised, race and ethnicity are "risk markers" for a wide variety of other conditions that may affect health and not be captured by a screening for pre-existing health conditions, including "socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers." Heslin Decl. ¶ 21; *see also id*. at ¶ 19.[5] Plaintiffs' proposed alternative would therefore have practitioners ignore relevant independent risk factors. By advising practitioners to consider all clinically relevant risk factors, the DOH Guidance is the narrowest way in which the State can ensure that the Therapies are available to those most at risk of severe illness or death from COVID-19.

III. PLAINTIFFS HAVE NOT DEMONSTRATED IRREPARABLE HARM ABSENT A PRELIMINARY INJUNCTION

Plaintiffs will not suffer irreparable harm absent a preliminary injunction. "A showing of irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction." *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (internal quotation marks omitted). While "[g]enerally an alleged violation of a constitutional right creates a presumption of irreparable harm," a plaintiff seeking "prospective injunctive relief . . . must show a likelihood of either future harm or continuing harm." *Krull v. Oey*, 19-CV-0142, 2019 WL 1207963, at *10 (N.D.N.Y. Mar. 14, 2019). A plaintiff seeking to satisfy the irreparable harm

[5] This CDC explanation of the data on race and ethnicity also shows that Plaintiffs miss the mark when they argue that there is no evidence of biological factors making non-white or Hispanic persons more likely to contract severe COVID-19. PI Mot. at 1. Plaintiffs provide no support for their contention that a patient's risk of disease must be biological in nature in order for it to be material to a medical decision.

requirement must demonstrate that "absent a preliminary injunction [he or she] will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." *Bisnews AFE (Thailand) Ltd. v. Aspen Research Group Ltd.*, 437 F. App'x 57, 58 (2d Cir. 2011) (summary order). As discussed above, Plaintiffs do not allege any Article III injury as to their Equal Protection claims, much less an injury causing irreparable harm. *See Amidax Trading Grp. v. S.W.I.F.T. SCRL*, No. 08-CV-5689, 2012 WL 868691, at *2 (S.D.N.Y. Mar. 13, 2012) ("because . . . the plaintiff lacks standing, the plaintiff also has failed to establish irreparable harm"). Moreover, there is no current shortage of oral antiviral medications in New York, and the evidence before the Court establishes that antiviral therapies are available for any patient, including Plaintiffs, upon a medical determination by a healthcare provider. *See* Heslin Decl. ¶¶ 28-31.

IV. THE PUBLIC INTEREST WEIGHS AGAINST ISSUING THE REQUESTED INJUNCTION

The balance of the equities and the consideration of the public interest weigh against issuing the requested injunction. In exercising their discretion in whether to enter an injunction, courts "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *N.Y.S. Rifle & Pistol Ass'n v. City of N.Y.*, 86 F. Supp. 3d 249, 258 (S.D.N.Y. 2015), *aff'd*, 883 F. 3d 45 (2d Cir. 2018) (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). Here, Plaintiffs ask the Court to order DOH to stop providing objectively true and accurate guidance to medical providers about known risk factors for hospitalization and death due to COVID-19—merely because that information happens to mention race and ethnicity. Achieving that outcome will not make it any more likely that Plaintiffs' own practitioners will prescribe them the Therapies, should such treatment be clinically appropriate in the event they contract COVID-19. The only result of such an order is that medical providers in New York will

likely be less well informed about the risk factors for severe COVID-19. The public interest would not be served by such an outcome.

CONCLUSION

For the reasons set forth above, Defendant Mary T. Bassett respectfully requests that the Court deny Plaintiffs' motion for a preliminary injunction, together with such other and further relief as the Court deems just and proper.

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Respectfully submitted,

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