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February 28, 2022

Via ECF

The Honorable Katherine Polk Failla
United States District Court for the Southern District of New York
40 Foley Square, Room 618
New York, New York 10007

Re: Foundation Against Intolerance & Racism, Inc., et al. v. City of New York, et al., No. 22-CV-528 (S.D.N.Y.)

Dear Judge Failla:

This Office represents Defendant Mary T. Bassett, Commissioner of the New York State Department of Health ("DOH"), sued in her official and individual capacities ("Commissioner Bassett"), in the above-referenced action. I write pursuant to Your Honor's February 25, 2022 Order (ECF No. 29) in opposition to the motion for a temporary restraining order ("TRO") and preliminary injunction filed by Plaintiffs Foundation Against Intolerance & Racism ("FAIR") and Benjamin Stewart ("Plaintiff Stewart") (ECF Nos. 25-28).

INTRODUCTION

Plaintiffs bring this action to challenge certain guidance provided by DOH to medical providers and hospitals regarding COVID-19 drug therapies that reduce the risk of hospitalization and death in high-risk patients (the "DOH Guidance").[1] 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 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 states that providers should consider non-white race or Hispanic/Latino ethnicity as a risk factor, among a number of others. This suggestion stems from the well-documented finding that non-white race and Hispanic/Latino ethnicity are known risk factors for

[1] Plaintiffs also bring this action against the City of New York, the New York City Department of Health and Mental Hygiene ("NYCDOH"), and Dave A. Choski as Commissioner of NYCDOH (together, the "City Defendants") to challenge similar guidance issued by NYCDOH (the "NYCDOH Guidance").

developing severe illness from COVID-19 often resulting in hospitalization and death, even when controlling for other comorbidities.

Although these COVID-19 treatments are no longer in short supply, the guidance is non-mandatory, and neither Plaintiff Stewart nor any of FAIR's members currently allege that they have COVID-19, Plaintiffs nevertheless seek a TRO and preliminary injunction to "enjoin the enforcement of the [DOH Guidance] insofar as they direct that 'non-white race or Hispanic/Latino ethnicity' be considered a 'risk factor' in determining an individual's risk for severe COVID-19 illness." ECF No. 26, February 23, 2022 Memorandum of Law in Support of Plaintiffs' Motion for a TRO and Preliminary Injunction ("Pl. Br.") at 25.

Plaintiffs are not entitled to this extraordinary relief. The Court should deny Plaintiffs' motion for a TRO and preliminary injunction because (1) their claims are moot; (2) Plaintiffs lack standing; (3) 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 or federal law, and Plaintiffs' State law claim is barred by the Eleventh Amendment; (4) Plaintiffs have not demonstrated irreparable harm absent a TRO or preliminary injunction; and (5) the public interest weighs against ordering DOH to stop providing objectively true, accurate guidance to medical providers about known risk factors associated with severe illness, hospitalization and death due to COVID-19.

FACTUAL BACKGROUND

Authorization of New Oral Antiviral Therapies and Monoclonal Antibody Therapy

In December of 2021, as the Omicron variant surged in both New York and throughout the world, DOH issued the DOH 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* ECF No. 27-2, 27-3.[2] These included Paxlovid and Molnupiravir, two new oral antiviral therapies ("OAVs") that were issued Emergency Use Authorizations by the United States Food and Drug Administration ("FDA") in December 2021; and Sotrovimab, the only authorized monoclonal antibody ("mAb") therapeutic expected to be effective against the Omicron variant (collectively, "the Therapies"). ECF No. 27-3. 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* ECF No. 27-2 (DOH Guidance).

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, supply shortages of the Therapies were anticipated. *See Roberts v. Bassett*, 22-CV-00710-NGG-RML, ECF No. 23 (E.D.N.Y.) (Declaration of Eugene Heslin, MD, FAAFP,

[2] The DOH Guidance includes two documents: "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products," attached as Exhibit 3 to the February 23, 2022 Declaration of Ameer Benno ("Benno Decl.") (ECF No. 27-3); and "Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations," attached as Exhibit 2 to the Benno Declaration (ECF No. 27-2).

dated February 25, 2022 ("Heslin Decl.") ¶ 10).[3] Around this time, 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* ECF No. 27-2, 27-3 (DOH Guidance); ECF No. 27-4 (NYCDOH Guidance); *Roberts*, 22-CV-00710-NGG-RML, ECF No. 23-4 (Heslin Decl. Ex. C ("CDC Guidance")).[4] 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 the guidance documents noted that a patient's race or 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." ECF No. 27-3 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." ECF No. 27-4 at 4.

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

The finding that race or 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 reported that Black or African American, Non-Hispanic persons have been hospitalized from COVID -19 at a rate *2.5 times higher* 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 rate *2.4 times higher* than white, Non-Hispanic persons, and have suffered death at a rate *1.9 times higher*. *Id*. 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., 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 already 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 the life expectancy of Hispanic and Black

[3] The Heslin Declaration, along with nine exhibits, was submitted in opposition to a preliminary injunction filed in the Eastern District of New York which also seeks to enjoin the DOH Guidance. For the Court's convenience, a true and accurate copy of the filed Heslin Declaration, without exhibits, is attached as Exhibit A to this letter.

[4] Relevant excerpts from the CDC Guidance are attached as Exhibit B to this letter.

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") for the period 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 observed 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 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.

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. *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." ECF No. 27-3 at 1. However, there is currently no shortage of the medications in New York and no one in New York, for whom practitioners find treatment with the Therapies is appropriate based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier. Heslin Decl. ¶¶ 28, 31.

The DOH Guidance in Operation

DOH's recommendation that providers and hospitals should consider race or ethnicity as a risk factor when prescribing the Therapies is not a mandate, or a restriction of COVID-19 treatments based on 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 Plaintiff Stewart, FAIR's members, or anyone

similarly situated from receiving the Therapies in the 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.

The Current Action

Plaintiffs commenced this action by filing a complaint on January 22, 2022, against the City Defendants (ECF No. 1), then filed an Amended Complaint ("AC") on February 14, 2022, which added Commissioner Bassett as a defendant (ECF No. 21), and then moved for an *ex parte* TRO and preliminary injunction, purportedly "because of the imminent harm and life-or-death stakes that Plaintiffs face," on February 23, 2022, a full month after filing this action. ECF No. 28 ¶ 11.

FAIR claims to be a "membership-based organization dedicated to advancing civil rights and liberties for all Americans." AC ¶ 16. FAIR alleges it has members in New York City who are white and non-Hispanic/Latino ("members classified as white"), who will seek treatment with the Therapies if they develop symptoms and test positive for COVID-19. Id. ¶¶ 17, 19. Similarly, Plaintiff Stewart claims that if he were to test positive for COVID-19 and develop symptoms, he would seek treatment with the Therapies. ECF No. 27-6 ¶ 8. Notably, FAIR does not claim to have any members who currently have COVID-19, have ever sought COVID treatments, or have ever been denied COVID treatments due to their race or ethnicity, or for any other reason. Plaintiff Stewart also does not allege that he has COVID-19, that he has ever sought antiviral treatment for COVID-19, or that he has ever been denied antiviral treatment due to his race or ethnicity, or for any other reason. AC ¶¶ 29-31. In addition, although FAIR submitted declarations from two of its white, non-Hispanic members, neither of them claims to have or have had COVID-19 or to have been denied treatment based on their race. ECF No. 27-7 ¶ 8; ECF No. 27-8 ¶ 9.

STANDARD OF REVIEW

The standard for determining whether to grant a motion for a TRO is identical to the standard for a preliminary injunction, *Local 1814, Int'l Longshoreman's Ass'n, AFL-CIO v. N.Y. Shipping Ass'n*, 965 F.2d 1224, 1228 (2d Cir. 1992), which is "an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 24 (2008). Plaintiffs bear the burden of establishing (1) that they are likely to succeed on the merits, (2) that they are likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in their favor, and (4) that an injunction is in the public interest. *Id*. at 20. The final two factors – the balance of the equities and the public interest, "merge when the Government is the opposing party." *L&M Bus Corp. v. Bd. of Educ.*, 2018 WL 2390125, at *13 (E.D.N.Y. May 25, 2018) (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

ARGUMENT

I. 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*. "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*.

Even if Plaintiffs could have stated a claim based on the circumstances that were in effect when the DOH Guidance was first issued—and they have not—those circumstances are no longer in effect. Plaintiffs' motion for a TRO and preliminary injunction is based on their allegation that if scarce treatments are prioritized based on the known risk factors, Plaintiff Stewart and FAIR's members classified as white might be denied access to the Therapies based on their race. The DOH Guidance was issued in late December 2021, when the new OAV and mAbs therapies at issue had just been authorized, and when the unprecedented Omicron wave of COVID-19 cases was just peaking. That unique confluence of circumstances led to a temporary shortage of available OAV and mAbs treatments. Heslin Decl. ¶ 28. As the DOH Guidance expressly stated, its guidance regarding prioritization of high-risk patients applied only "during this time of severe resource limitations." ECF No. 27-3 at 1. Since then, production of OAV and mAbs 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' claims also cannot be saved by the capable-of-repetition-yet-evading-review doctrine, which 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)). It is Plaintiffs' burden to establish that the two exceptional circumstances simultaneously apply. They have not and cannot do so here, not least because since late December, manufacturers have significantly ramped up production of the treatments in response to government orders for millions of doses.[5] In the face of these dramatically changed circumstances, any speculation about the possibility of future events is plainly insufficient.

II. 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). An individual 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

[5] *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.").

likely to be redressed by a favorable judicial decision.'" *Id.* (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)).

An organization can establish standing in one of two ways. First, an organization may have standing to sue on behalf of its members if they would have standing to sue in their own right; the interests it seeks to protect are germane to the organization's purpose; and the participation of individual members in the lawsuit is not required. *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock*, 477 U.S. 274, 282 (1986). Second, an organization may "have standing in its own right to seek judicial relief from injury to itself." *Warth v. Seldin*, 422 U.S. 490, 511 (1975). To establish standing in its own right, the organization must demonstrate the requirements for Article III standing: injury, causation, and redressability. *See Friends of the Earth v. Laidlaw Envt'l Services, Inc.*, 528 U.S. 167, 181-88 (2000). Under this theory, "an organization must show actual or threatened injury-in-fact that is 'fairly traceable to the alleged action and likely to be redressed by a favorable court decision.'" *Ragin v. Harry Macklowe Real Estate Co*., 6 F.3d 898, 904 (2d Cir. 1993) (internal citation omitted). In addition, "the injury or threat of injury must be both real and immediate, not conjectural or hypothetical." *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983) (citations and quotations omitted). This is a "requirement that cannot be met where there is no showing of any real or immediate threat that the plaintiff will be wronged again." *Id.* at 111.

It is plaintiffs' burden to establish that they have established each element standing. *See Spokeo*, 578 U.S. at 338. As to relief, a plaintiff must demonstrate standing separately for each form of relief sought. *Lyons*, 461 U.S. at 109 (notwithstanding the fact that plaintiff had standing to pursue damages, he lacked standing to pursue injunctive relief); *see also Lewis v. Casey*, 518 U.S. 343, 358, n.6 (1996) ("Standing is not dispensed in gross.").

Neither Plaintiff Stewart nor FAIR has standing to seek injunctive relief against Commissioner Bassett through their current motion, and Plaintiffs are unlikely to succeed on their claims because they do not have standing to seek any relief in this lawsuit.

A. Plaintiff Stewart Lacks Standing and FAIR Lacks Standing on Behalf of Its Members

In cases alleging an equal protection violation, 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*, 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.*

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*, 528 U.S. at 180-81 (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, 743-44 (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.* (quoting *Allen v. Wright*, 468 U.S. 737, 755 (1984)) (internal quotation marks omitted).

1. Neither Plaintiff Stewart Nor FAIR's Members Have an Injury-in-Fact

Plaintiffs claim that Plaintiff Stewart and FAIR members classified as white 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* Pl. Br. at 11-13. It is not alleged that Plaintiff Stewart or any of FAIR members classified as white have COVID-19; that they have ever sought the Therapies; or that they have ever been denied the Therapies due to their race or ethnicity, or for any reason. *Id*. 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 acts as a barrier.

Plaintiffs' allegations are insufficient to establish an injury in fact for Plaintiff Stewart or FAIR's members. 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 race and ethnicity as a risk factor when prescribing [the Therapies] is in no way meant to be read as a mandate, or a restriction of COVID-19 treatments by race." *Id.* ¶ 24. The DOH Guidance does not replace "doctors' clinical judgment, and does not prevent any patient from receiving necessary treatment." *Id.* In the event that Plaintiff Stewart or a FAIR member classified as white contracted COVID-19, they would have the opportunity to be evaluated by their medical providers. DOH expects that those providers would determine what course of treatment is clinically appropriate, based upon a conversation with their patient, and a review of their patient's medical history, risk factors, and circumstances. Ultimately, "[n]othing in the Guidance prevents [Plaintiff Stewart or FAIR members classified as white], 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, Plaintiff Stewart and

members of FAIR will be entitled to receive the treatment that their doctor concludes is clinically appropriate, regardless of their race or ethnicity.

Plaintiffs nevertheless allege that Plaintiff Stewart and Plaintiff FAIR's members classified as white cannot obtain oral antiviral treatments "unless they demonstrate a 'medical condition or other factors that increase their risk for severe illness'" while non-white or Hispanic individuals "are not required to make such a showing." AC ¶ 33. Plaintiffs' claim misconstrues the DOH Guidance, which is not a treatment policy dictating which patients can and cannot receive the Therapies, but guidance documents that provide 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 of 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. Thus, contrary to Plaintiffs' claim, the DOH Guidance does not dictate whether any patient "qualifies" to receive antiviral treatment based on their race or ethnicity. AC ¶ 30; Pl. Br. at 13; *see* Heslin Decl. ¶ 9 ("There is no 'scoring system' and you do not have to 'get enough points' in order to receive the medication.").

Indeed, DOH does not dictate the 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 a 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 v. Hauppauge Sch. Dist.*, No. 08-CV-1068 NGG VMS, 2012 WL 4891561, at *3 (E.D.N.Y. Oct. 15, 2012) (holding plaintiffs had no 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.*, 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 all have to occur for them to suffer an injury. Plaintiff Stewart and FAIR's members classified as white do not have COVID-19, they may never contract it, and if they do contract it, they may be asymptomatic. *See, e.g.*, ECF No. 27-6 (Stewart Declaration); No. 27-7 & 27-8 (Member Declarations). If they do contract it and develop symptoms, their physicians may or may not deem their medical condition suitable for treatment with the Therapies. If their physicians do determine that their conditions warrant treatment with the Therapies, based upon a full review of their medical histories and discussions of any possible contraindications, they may or may not be eligible for the therapy for reasons unrelated to their race or ethnicity. And if they

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

Like the plaintiffs in *Clapper*, the harm alleged 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).

2. Any Alleged Injury Is Not Traceable to DOH and Is Not Redressable by the Court

In addition to alleging an injury in fact, in order 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 of these 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, Plaintiff Stewart and the FAIR members' alleged injury is that they believe their doctors might not write them a prescription for the Therapies, even if they were to contract COVID-19. If that outcome were to occur, 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 Therapies, Plaintiff Stewart and FAIR members would only be denied access to those Therapies if their doctor independently concluded that such treatments were not clinically appropriate, given their 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 Roberts*, 22-CV-00710-NGG-RML, ECF No. 23-4 (Heslin Decl. Ex. C, CDC Guidance at 50). The CDC guidance would remain in effect, even in the absence of the DOH Guidance.

B. FAIR Lacks Standing on Its Own Behalf

1. FAIR Cannot Demonstrate an Injury-in-Fact

FAIR's "formulaic recitation" of the standing elements is insufficient for it to maintain its

claims against Commissioner Bassett. *In re Facebook, Inc., Initial Pub. Offering Derivative Litig.*, 797 F.3d 148, 159 (2d Cir. 2015) ("A formulaic recitation of the derivative standing requirements will not suffice."). Although FAIR alleges it suffered an "opportunity cost" by "expending resources . . . that could have been allocated elsewhere" to research, provide education, maintain a website, organize, advertise, and lobby against the DOH and NYCDOH Guidance, FAIR does not explain what activities they were diverted from or what financial impact this had on its mission. Further, FAIR does not adequately allege that DOH caused it to divert resources. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (finding "perceptible impairment" exists where organization diverts resources from its other activities as a result of the challenged conduct). The Amended Complaint alleges that FAIR's mission is "to promote equal protection under the law and to advocate for individuals who [allegedly] suffer discrimination." AC ¶ 16. Thus, far from burdening it, the activities that FAIR claims it undertook in response to the allegedly discriminatory guidance were done in furtherance of its mission, i.e., its usual activities.

Moreover, it is well settled that a plaintiff cannot manufacture standing. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) ("[P]laintiff cannot achieve standing to litigate a substantive issue . . . for the cost of bringing suit."). Here, most if not all of the activities FAIR allegedly undertook concerning the guidance was simply preparation for litigation. *See* AC ¶ 26-27 (researching the guidance, "shar[ing] analyses regarding their lawfulness," reaching out to members, "lobbying," and "of course, Plaintiff FAIR has expended substantial time, resources, and money to challenge these policies in court"). Although FAIR cites to *Nnebe v. Daus*, 644 F.3d 147, 156 (2d Cir. 2011), to argue it has standing, the court in *Nnebe* only found standing after determining that plaintiff was not simply "trolling for grounds to litigate." *Id*. at 157-58. In so holding, the court distinguished the plaintiff, who stood to obtain a permanent benefit for itself through the suit, from an organization "which presumably could have continued to seek out new, [allegedly] discriminatory [conduct] and bring additional suits." *Id.* at 158. Here, FAIR does not explain any benefit it would obtain on its own behalf if the Court were to issue an injunction.

2. Any Alleged Injury Is Not Traceable to DOH and Is Not Redressable by the Court

None of FAIR's alleged injury is fairly traceable to the DOH Guidance and FAIR's alleged injury is not redressable by the Court. Indeed, as explained above, even if the DOH Guidance was never issued and 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. Indeed, practitioners were likely already aware of the plethora of widely publicized, objective data showing that race and ethnicity are risk factors for hospitalization and death from COVID-19 prior to the issuance of the DOH Guidance. Regardless, practitioners are now even more likely to be aware of this widely publicized, objective data, and an injunction against the DOH Guidance will not erase that knowledge. Further, the CDC Guidance has been in effect since December 29, 2021, and it would remain in effect even if the Court issued an injunction against Commissioner Bassett. Finally, Plaintiffs seek to "enjoin *the enforcement of* the [DOH Guidance] insofar as they direct that 'non-white race or Hispanic/Latino ethnicity' be considered a 'risk factor,'" (Pl. Br. at 25 (emphasis added)), but as explained above, DOH does not "enforce" the DOH Guidance. Heslin Decl. ¶ 27.

III. Plaintiffs Cannot Establish a Clear or Substantial Likelihood of Success on their Claims

A. The Guidance Does Violate The Equal Protection Clause

To state a claim under the Equal Protection clause, a plaintiff 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). If the law does not target a suspect class, then 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," and "'[t]he burden is on the one attacking the [governmental action] to negative every conceivable basis which might support it.'" *Id*. (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)). On the other hand, if the challenged distinction 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).

1. 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 Vt. & State Agric. Coll.*, 56 F. Supp. 2d 419, 427-28 (D. Vt. 1999) (citing *Adarand Constructors, Inc.*, 515 U.S. at 222, 224) (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 Plaintiff Stewart or FAIR's members, 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 on cases where the government has made race an express factor in an otherwise race-neutral decision. For example, *Bush v. Vera*, 517 U.S. 952, 971 (1996) involved a challenge to redistricting that used "racial classification in the drawing of" the district lines. By contrast, the DOH Guidance does not create a racial classification, or confer a benefit or impose a burden, and hence, it does not provoke strict scrutiny review.[6] Indeed, as held in *Vera*, "[s]trict scrutiny does not apply merely because [a government action] is performed with consciousness of race." *Id*. at 958.

2. 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. N.Y.C. 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 observed during the COVID-19 pandemic show 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 as an independent risk factor for severe illness and death from COVID-19 when considering whether to prescribe the

[6] Plaintiffs also cite to *Vera* to argue that strict scrutiny applies even when the government employs such classifications for "benign" reasons, such as for "race-targeted medical outreach programs." Pl. Br. at 17. However, this discussion in *Vera* was dicta discussing a hypothetical raised by Justice Stevens, and the hypothetical assumed that the outreach program involved "racial classifications" which imposed a benefit. *Vera*, 517 U.S. at 984. DOH is not conferring any benefit to any specific class of people here; it is only providing guidance to medical practitioners.

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. The DOH Guidance therefore survives rational basis review and Plaintiffs' Equal Protection claim cannot succeed.

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

Even if the Court were to apply strict scrutiny, 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 Cal. 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 Vera*, 517 U.S. at 984 (stating in dicta that a racial classification in "Justice Stevens' hypothetical of a targeted outreach program to protect victims of sickle cell anemia" would "no doubt" be benign); *Mitchell v. Washington*, 818 F.3d 436, 446 (9th Cir. 2016) ("It 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 generally 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. As discussed above, the 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*, 3-4.

In an attempt to establish otherwise, Plaintiffs submit an "Expert Declaration" from Carrie D. Mendoza, M.D., a physician licensed to practice medicine in three states, but not in New York. Dr. Mendoza proports to specialize in Emergency Medicine, but does not claim to specialize in treating COVID-19 patients nor that she has any involvement with COVID-19 patients once they leave the emergency room. ECF No. 27-5 ("Mendoza Decl.") ¶¶ 1, 3. Dr. Mendoza incorrectly claims that "there is no known medical basis for concluding that a specific skin color, race, or ethnicity itself places a patient at higher risk of severe illness or death from COVlD-19." *Id.* ¶ 16. This assertion is contradicted by all of the objective data and medical studies cited above, none of which Dr. Mendoza addresses in her declaration. *See id.* Further, although Dr. Mendoza claims that "a patient's race and ethnicity do not, by themselves, put that patient at a higher risk of severe illness or death from COVID-19," she cites to no objective data or medical studies to support this assertion. *Id.* Dr. Mendoza's unsupported opinion runs counter to the overwhelming data indicating that race and ethnicity is clearly a risk factor for severe disease for COVID-19, and accordingly, her declaration bears no weight and should be disregarded.

The DOH Guidance is 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). Importantly, the objective data shows race or ethnicity acts as an *independent* risk factor, separate and apart from a patient's medical history. To reiterate, racial disparities continue to persist in COVID-19 outcomes *even after* controlling for medical comorbidities. Heslin ¶ 19. 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.

Plaintiffs also argue that the DOH Guidance is not narrowly tailored because it does not specifically carve out Asian Americans from what counts as "non-white," Asian Americans would "presumably" be considered non-white, and "data shows that Asian Americans have better outcomes from COVID-19 than any other racial group for which data is available." Pl. Br. at 21. First, Plaintiffs cite to only limited information for the assertion that Asian Americans have better COVID outcomes, by claiming that "while persons of Asian descent constitute 14% of New York City's population, they represent only 7% of COVID-19 deaths." *Id*. However, these statistics do not take other factors into account, such as the number of Asian Americans who contract COVID-19, the vaccination rates within the Asian American community, or the levels of other comorbidities in this community. Moreover, the fact that the DOH Guidance does not provide a detailed breakdown of risk factors by each race does not mean that it is not narrowly tailored. Plaintiffs cite to nothing to support their argument that to solve what they claim is an impermissible racial classification, the DOH Guidance should have contained more granular racial classifications. Indeed, "[n]arrow tailoring does not require exhaustion of every conceivable race-neutral alternative," and it certainly does not require the exhaustion of every conceivable race-*based* alternative. *See Grutter*, 539 U.S. at 339. Further, as previously noted, the DOH Guidance is not mandatory and merely permits health care providers to *consider* a patient's non-white race or Hispanic ethnicity as one of many risk factors.

In sum, by advising doctors to consider all clinically relevant 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.

B. Plaintiffs' Section 1981 Claim Will Not Succeed

"Section 1981, like the Equal Protection Clause, only prohibits intentional racial discrimination." *Brown v. City of Oneonta*, 221 F.3d 329, 339 (2d Cir. 2000). "To state a claim under § 1981, a plaintiff must allege facts showing that (1) the plaintiff is a member of a racial minority; (2) the defendant intentionally discriminated on the basis of race; and (3) the discrimination concerned one of the statute's enumerated activities." *Weiss v. City Univ. of N.Y.*, No. 17-CV-3557 (VSB), 2019 WL 1244508, at *10 (S.D.N.Y. Mar. 18, 2019) (citing *Brown*, 221 F.3d at 339). Section 1981 provides, in pertinent part, that "[a]ll persons . . . shall have the same right . . . to make and enforce contracts, to sue, be parties, give evidence, and to the full and equal

benefit of all laws and proceedings for the security of persons and property."

As an initial matter, Plaintiffs do not identify which "of the statute's enumerated activities" the alleged discrimination concerns. The DOH Guidance does not concern the right "to sue, be parties, give evidence, and to the full and equal benefit of all laws and proceedings." Plaintiffs have made no allegations or arguments that the DOH Guidance "is sufficiently contractual in nature" to otherwise fall within the purview of § 1981. *Cf. Weiss*, 2019 WL 1244508, at *10 (finding admission to educational program sufficiently contractual in nature).

Second, as discussed above, the Guidance does not exclude anyone from receiving the Therapies on the basis of race. Instead, it merely permits health care providers to consider a patient's non-white race or Hispanic ethnicity as a risk factor that a particular patient is more likely to suffer severe illness as a result of COVID-19. The Guidance does not prevent a white patient from receiving antiviral therapies and does not automatically qualify a non-white or Hispanic patients for such therapies. Instead, whether a patient receives the Therapies rests in health care providers' medical judgment.

Third, the intent of the DOH Guidance is not to discriminate based on race, but to advise health care providers about antiviral therapies and to review/discuss with health care providers the recommended parameters, and clinical considerations, for use of antiviral treatments. Heslin Decl. ¶ 12.

C. The Guidance Does Violate Title VI

Title VI provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." 42 U.S.C. § 2000d. In other words, "[r]ace cannot be the basis of excluding anyone from participation in federally funded program." *Regents of Univ. of Cal.*, 438 U.S. at 418.

"To state a claim for a violation of Title VI, a plaintiff must show, through specific factual allegations, that (1) the defendant discriminated on a prohibited basis; (2) the discrimination was intentional; and (3) the discrimination was a substantial or motivating factor for the defendant's action." *Joseph v. Metro. Museum of Art*, No. 15-CV-9358-GHW, 2016 WL 3351103, at *3 (S.D.N.Y. June 15, 2016), *aff'd*, 684 F. App'x 16 (2d Cir. 2017) (quotations omitted). "In order to establish intentional discrimination, Plaintiff 'must show that the decisionmaker selected or reaffirmed a particular course of action at least in part 'because of' not merely 'in spite of' its adverse effects upon an identifiable group.'" *Id.* (quoting *Soberal-Perez v. Heckler*, 717 F.2d 36, 42 (2d Cir. 1983)).

Neither the Amended Complaint nor the Declarations submitted in support of Plaintiffs' motion include facts sufficient to state a claim under Title VI. First, once again, the Guidance does not exclude anyone from receiving the Therapies on the basis of race, as it merely permits health care providers to consider a patient's non-white race or Hispanic ethnicity as a risk factor. Second, as also explained above, the intent of the Guidance was not to discriminate based on race, but to advise health care providers about the Therapies and review/discuss with providers the recommended parameters, and clinical considerations, for use and eligibility for antiviral

treatments. Heslin Decl. ¶ 12.

Third, the Amended Complaint does not sufficiently allege that Plaintiff Stewart or FAIR's members classified as white are excluded from any "program or activity receiving Federal financial assistance." Instead, it only alleges, in conclusory fashion, that DOH "receive[s] federal financial assistance to provide therapies, including mAb products and OAVs, for the treatment of COVID-19." AC ¶ 112. Plaintiff fails to articulate any facts that the Therapies at issue in the DOH Guidance are associated with any federal source of funding received by DOH.[7] Since Plaintiffs fail to allege any facts to support the essential elements of a Title VI claim, they cannot succeed on such claim.

D. The Guidance Does Violate ACA

"A race-discrimination claim under the ACA has the same elements as a Title VI claim." *Prather v. Mirkil*, No. 217-CV-00183 GMN VCF, 2020 WL 1862692, at *2 (D. Nev. Apr. 14, 2020) (citing 42 U.S.C. § 18116). Therefore, for the same reasons that Plaintiffs cannot succeed on their Title VI claim, Plaintiffs cannot succeed on their claim under the ACA.

E. Plaintiffs' State Law Claim Against Commissioner Bassett Is Barred By The Eleventh Amendment

Plaintiffs' fifth cause of action – which seeks to enjoin the DOH Guidance by alleging that it violates Article I, § 11 of the New York State Constitution – is barred by Eleventh Amendment immunity. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 103-06 (1984) (Eleventh Amendment prevents suit requiring state official to follow state law). The Eleventh Amendment prohibits lawsuits against a state without that state's unambiguous consent or an act of Congress. *See Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 54-55 (1996). A narrow exception to Eleventh Amendment immunity exists under the *Ex parte Young* doctrine, which permits "suits against state officers acting in their official capacities that seek prospective injunctive relief to prevent a continuing violation of federal law," but "*Young* does not allow a federal court to issue an injunction for a violation of state law." *Kelly v. N.Y. Civil Serv. Comm'n*, 632 F. App'x 17, 18 (2d Cir. 2016) (summary order); *accord Treistman v. McGinty*, 804 F. App'x 98, 99 (2d Cir. 2020) (summary order) ("A claim that state officials violated state law in carrying out their official responsibilities is a claim against the State that is protected by the Eleventh Amendment.").[8] Accordingly, Plaintiffs' State law claim necessarily fails.

IV. Plaintiffs Have Not Demonstrated Irreparable Harm Absent an 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

[7] Plaintiffs also allege that *medical providers* receive federal funds (AC ¶ 113), but this allegation has no relevance to a Title VI claim brought against Commissioner Bassett as opposed to these unidentified *medical providers*.

[8] The fact that Plaintiff has also alleged federal causes of action is of no moment, because "[t]his constitutional bar applies to pendent claims as well." *Pennhurst*, 465 U.S. at 120. Indeed, Plaintiffs seem to acknowledge that their claim for injunctive relief under State law fails against Commissioner Bassett, as they only argue that "the 11th Amendment does not bar suits against state officials in their official capacities where, as here, the suit seeks prospective injunctive or declaratory relief for violations of *federal* law." Pl. Br. at 16 n.7 (emphasis added).

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 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 claims that is redressable by an injunction by this Court, 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 the Therapies in New York, and the evidence before the Court establishes that the Therapies are available for any patient, including Plaintiff Stewart and FAIR's purported members, upon a medical determination by a healthcare provider. *See* Heslin Decl. ¶¶ 28-31.

V. The Balance of Equities and Public Interest Weighs Against the Requested Injunction

The balance of the equities and the consideration of the public interest weigh strongly 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 suffering 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 the doctors of Plaintiff Stewart or FAIR's members classified as white will prescribe them the Therapies, should such treatment be clinically appropriate in the event that they contract COVID-19. The only result of such an order is that medical providers in New York may be less well informed about actual risk factors for severe COVID-19 illness. The public interest would not be served by such an outcome.

Plaintiffs have not shown that they are entitled to the extraordinary relief of a TRO or preliminary injunction, and, accordingly, their motion should be denied.

Thank you for Your Honor's consideration of this matter.

Respectfully submitted,

/s/ Erin R. McAlister

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Attorney for Commissioner Bassett

cc: All counsel of record (via ECF)

E IBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE 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; and the DEPARTMENT OF HEALTH AND MENTAL HYGIENE OF THE CITY OF NEW YORK,

Defendants.

DECLARATION OF EUGENE HESLIN, M.D., FAAFP

Case No. 1:22-cv-00710 (NGG) (RML)

EUGENE HESLIN, M.D., FAAFP, declares under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true:

1. I am the First Deputy Commissioner at the New York State Department of Health. I have served in this capacity since July 13, 2017. My duties and responsibilities in this position involve supporting the Commissioner of Health. Prior to assuming this position, I was a primary care clinician in clinical practice for 25 years.

2. I am a Medical Doctor and received my M.D. from University of Texas Health Science Center in Houston.

3. During the COVID-19 pandemic I have supported the response, initially working with a testing site in New Rochelle, subsequently working with hospitals and alternative care

sites most recently working with the vaccination site opening at the Javits Center, providing support for the Commissioner and for the Office of Primary Care Health Systems Management ("OPCHSM"), projects and working with supporting the Covid therapeutics.

4. I am familiar with the facts set forth herein based upon personal knowledge, discussions with Department staff, and Department records. I have also reviewed guidance from the Centers for Disease Control & Prevention ("CDC") and studies and publications related to COVID-19, particularly studies related to the disproportionate impact and health care disparities of COVID-19 on racial and ethnic groups and minority groups.

5. I make this affidavit in opposition to Plaintiffs' Motion for a Preliminary Injunction.

BACKGROUND ON COVID-19

6. The history of the COVID-19 pandemic requires no introduction. The lives of individuals around the world, including New York State, have been impacted by the virus and measures enacted to prevent its spread. The New York State Department of Health ("DOH"), since the onset of the pandemic, has vigorously applied all resources and taken all measures legally at its disposal to ensure the safety and welfare of all New Yorkers. The DOH has closely aligned state efforts with guidance and requirements released by the CDC.

7. The outbreak of the new Omicron variant, in early December was handled no differently. The full weight of resources available to the DOH were immediately brought to bear on the issue. Testing capacity was ramped up to meet demand, engagement on vaccination and boosting efforts intensified, and the mandatory masking protocols in public spaces were

extended.

8. As Commissioner Bassett stated in her testimony on February 8, 2022, at the Joint Legislative Public Hearing on the State Fiscal Year 2022-2023 Executive Budget Proposal ("Joint Public Hearing")[1], DOH efforts have been successful in leading to a 90 percent drop in the state's positivity rate in the last month. The February 17, 2022 state-wide cluster dashboard attached hereto as **Exhibit AA** identified one new cluster in the State with 4 associated cases.

9. It is my understanding that Plaintiffs brought this litigation challenging specific portions of the guidance issued by DOH entitled "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products" and "Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations" ("Guidance"). A copy of the Guidance is attached hereto as **Exhibit A** and **Exhibit B**. These publications are guidance and are not a "treatment policy". They do not create a "scoring system" and you do not have to "get enough points" in order to receive the medication as Plaintiffs asserts. The Guidance was issued by the DOH, to health care providers and health care facilities on December 27, 2021, and December 29, 2021, respectively to help guide and focus busy clinicians through conversations with their patients about treatment and risk factors. The Guidance among other things, discusses the treatment and prevention of severe COVID-19 with oral antivirals within certain categories,

[1] Joint Legislative Public Hearing on 2022 Executive Budget Proposal: Topic Health/Medicaid | NY State Senate (nysenate.gov), *available at* https://www.nysenate.gov/calendar/public-hearings/february-08-2022/joint-legislative-public-hearing-2022-executive-budget.

including those with risk factors for severe illness.

THE GUIDANCE AND ITS SCIENTIFIC BASIS

10. In December of 2021, as the Omicron variant began to surge, the Food and Drug Administration ("FDA") issued Emergency Use Authorizations for a number of drug treatments and therapies that were found to reduce the risk of hospitalization and death in high-risk patients when taken by the patients early after symptom onset. These include Paxlovid and Molnupiravir, two antiviral therapies, and Sotrovimab, a monoclonal antibody product. Shortly after their release, supply shortages of these drug treatments and therapies began to present. *See* https://emergency.cdc.gov/han/2021/han00461.asp, https://time.com/6139151/covid-drug-shortages/; and https://www.forbes.com/sites/saibala/2021/12/28/theres-a-shortage-of-monoclonal-antibody-treatments-for-covid-19-heres-how-they-work/?sh=1798a70637f7.

11. As a result, the DOH released the December 27, 2021, Guidance to make providers and hospitals aware of the newly authorized treatments. A copy of the Guidance is attached hereto **Exhibit A.** Additionally, the Guidance was meant to address factors to be considered when administering therapies amongst tranches of patients considering supply shortages.

12. Broadly the Guidance (1) summarizes the antiviral treatment modalities; (2) reviews the recommended parameters for use and eligibility for antiviral treatments; (3) discusses the clinical considerations for antiviral treatments; (4) reviews the process for referring patients for antiviral treatment within and outside New York City to ensure equitable access; and (5) reviews changes in the use of monoclonal antibodies.

13. The language at issue in this litigation falls within the eligibility section of the Guidance, which was meant to advise about health-based risk factors to consider when providing treatment. Specifically, Plaintiff takes issue with the portion of the Guidance advising providers and hospitals that they should consider race and ethnicity as a risk factor when making decisions as to whether an individual meets the criteria for oral antiviral treatment:

> "Oral antiviral treatment is authorized for patients who meet all the following criteria:
> - Age 12 years and older weighing at least 40 kg (88 pounds) for Paxlovid, or 18 years and older for molnupiravir
> - Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
> - Have mild to moderate COVID-19 symptoms
>   - Patient cannot be hospitalized due to severe or critical COVID-19
> - Able to start treatment within 5 days of symptom onset
> - Have a medical condition or other factors that increase their risk for severe illness.
>   - ***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"***

See Exhibit A (emphasis added).

14. Both the State and City of New York coordinated on the issuance of this Guidance, and the New York City Department of Health issued almost identical guidance in its "2021 Health Advisory #39."[2]

[2] *See* New York City Department of Health and Mental Hygiene 2021 Health Advisory #39, *available at* https://www1.nyc.gov/assets/doh/downloads/pdf/han/advisory/2021/covid-19-oral-treatments-authorized-shortage.pdf.

15. The language at issue tracks CDC guidance published in the "Federal Response to COVID-19 Therapeutics Clinical Implementation Guide," *see* **Exhibit C**. Specifically, the guidance says, "Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of monoclonal antibody treatments "mAb" therapy is not limited to the medical conditions or factors listed above . . . ." *See Id.* at p. 50

16. Further, a CDC Morbidity and Mortality Weekly Report analyzed treatment data of over 800,000 patients with a positive COVID-19 test result, which showed that a larger percentage of patients who received mAbs had high-risk medical conditions, in accordance with current treatment guidelines. However, this study also found mAb treatments have been used less commonly among racial and ethnic minority groups, thus amplifying the increased risk for severe COVID-19–associated outcomes in those groups. This inclusion is one of many risk factors to be considered, and is based on data that indicates COVID-19 mortality rates are higher among certain demographic groups namely non-white/Hispanic communities.[3]

17. Additional evidence supports these findings. A National Center for Health Statistics 2020 Report showed a disproportionate impact on life expectancy due to the COVID-19 pandemic. From 2019 to 2020, Hispanic people experienced the greatest drop in life expectancy — three years — and Black Americans saw a decrease of 2.9 years. White people

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[3] *See* CDC, "Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19 — United States, March 2020–August 2021", *available at* https://www.cdc.gov/mmwr/volumes/71/wr/mm7103e1.htm?s_cid=mm7103e1_w.

experienced the smallest decline, of 1.2 years. A copy of the National Center for Health Statistics 2020 Report is attached hereto as **Exhibit D**.

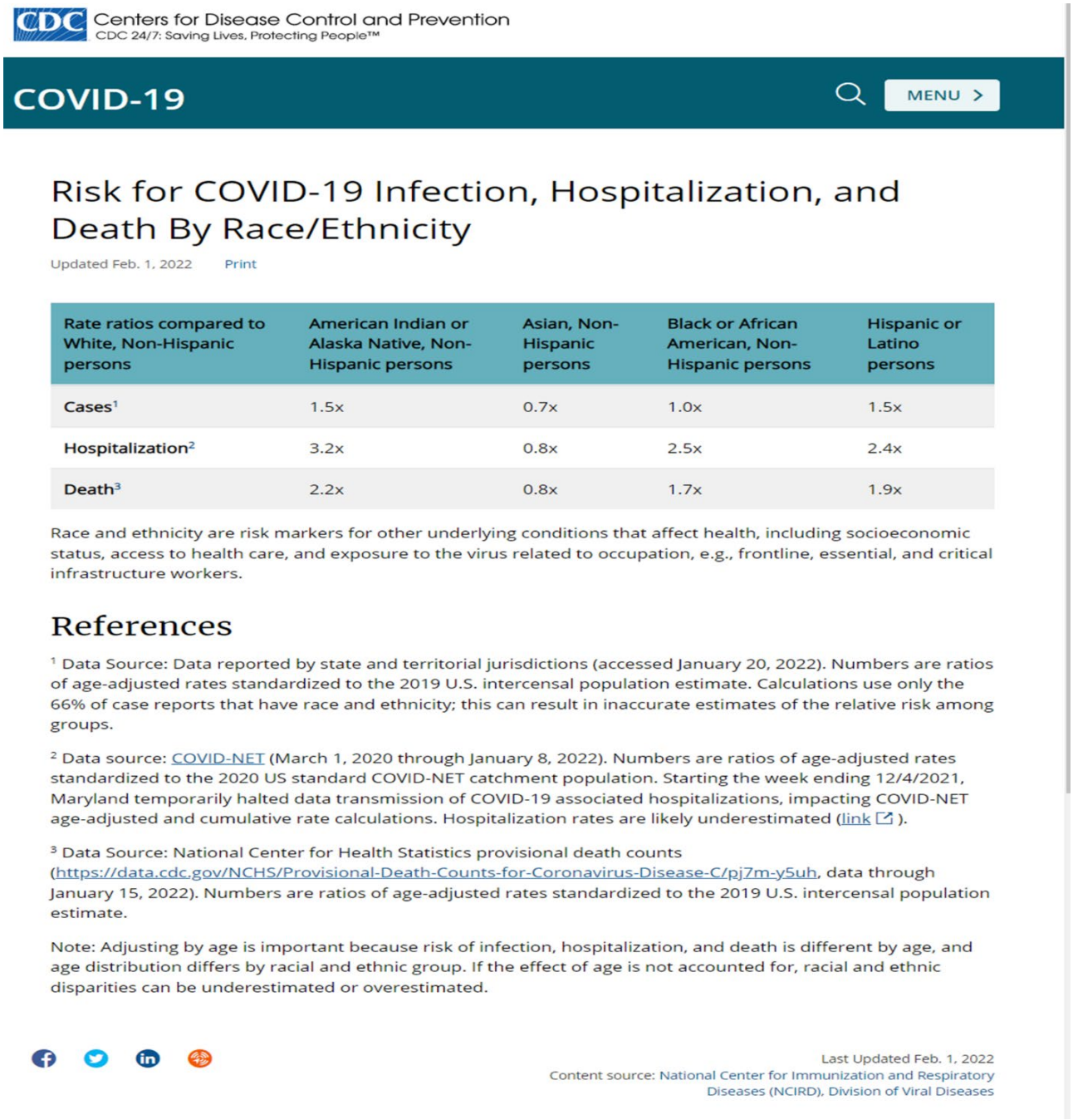
18. A study published on December 10, 2020, found that people from racial and ethnic minority groups were more likely to have increased COVID-19 disease severity upon admission to the hospital when compared with non-Hispanic white people. A copy of the December 10, 2020 study is attached here to as **Exhibit E**. Mortality data from CDC's National Vital Statistics System ("NVSS"), from February 1, 2020, to September 30, 2021, shows there have been an estimated 700,000 excess deaths in the United States. The largest percentage increase in mortality occurred among adults aged 25–44 years and among Hispanic or Latino people. A copy of the mortality data from the CDC's National Vital Statistics System from February 1, 2020, to September 30, 2021, is attached hereto as **Exhibit F**.

19. An article in Scientific Reports illustrates that racial disparities continue to persist even after controlling for medical comorbidities. A copy of "Racial disparities in COVID-19 outcomes exist despite comparable Elixhauser comorbidity indices between Blacks, Hispanics, Native Americans, and Whites" is attached hereto as **Exhibit G**. This article finds when compared to white patients, similarly situated Black patients showed significantly higher odds of ventilator dependence and death.

20. DOH's Commissioner Mary T. Bassett recently contributed to an article in the Journal of the American Medical Association Network Open article entitled "Variations in COVID-19 Mortality in the US by Race and Ethnicity", which found most racial and ethnic minority populations had higher age-adjusted mortality rates than non-Hispanic White

populations. A copy of the article is attached hereto as **Exhibit H**.

21. Perhaps the most convincing data point can be found in this simple chart compiled by the



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

COVID-19 MENU >

Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity

Updated Feb. 1, 2022 Print

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases[1]	1.5x	0.7x	1.0x	1.5x
Hospitalization[2]	3.2x	0.8x	2.5x	2.4x
Death[3]	2.2x	0.8x	1.7x	1.9x

Race and ethnicity are risk markers for other underlying conditions that affect health, including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.

References

[1] Data Source: Data reported by state and territorial jurisdictions (accessed January 20, 2022). Numbers are ratios of age-adjusted rates standardized to the 2019 U.S. intercensal population estimate. Calculations use only the 66% of case reports that have race and ethnicity; this can result in inaccurate estimates of the relative risk among groups.

[2] Data source: COVID-NET (March 1, 2020 through January 8, 2022). Numbers are ratios of age-adjusted rates standardized to the 2020 US standard COVID-NET catchment population. Starting the week ending 12/4/2021, Maryland temporarily halted data transmission of COVID-19 associated hospitalizations, impacting COVID-NET age-adjusted and cumulative rate calculations. Hospitalization rates are likely underestimated (link).

[3] Data Source: National Center for Health Statistics provisional death counts (https://data.cdc.gov/NCHS/Provisional-Death-Counts-for-Coronavirus-Disease-C/pj7m-y5uh, data through January 15, 2022). Numbers are ratios of age-adjusted rates standardized to the 2019 U.S. intercensal population estimate.

Note: Adjusting by age is important because risk of infection, hospitalization, and death is different by age, and age distribution differs by racial and ethnic group. If the effect of age is not accounted for, racial and ethnic disparities can be underestimated or overestimated.

Last Updated Feb. 1, 2022
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

CDC. [4]

22. All of this data supports that 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.

HOW THE GUIDANCE OPERATES

23. While the data overwhelmingly supports the fact that communities of color are at greater risk when it comes to the impact of COVID and thus the DOH's desire to level the playing field, it is also important to understand the DOH's intent as to how the guidance should operate in practice rather than in theory.

24. The recommendation that providers and hospitals should consider race and ethnicity as a risk factor when prescribing oral antiviral treatments is in no way meant to be read as a mandate, or a restriction of COVID-19 treatments by race. The Guidance does not replace doctors' clinical judgment, and does not prevent any patient from receiving necessary treatment. Rather, the Guidance is intended to address the well documented reality that communities of color have been disproportionately impacted by the COVID-19 pandemic. This has been reiterated publicly in discussion about using these medications and I have personally, publicly spoken to this in multiple venues including: (1) a widely publicized and attended New York State New York City webinar[5]; (2) monthly calls held by the New York State Medical Society

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[4] CDC, Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity (updated Feb. 1, 2022), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html.

[5] *See* DOH & NYCDOHMH Healthcare Provider Webinar on COVID-19, *available at* https://www.youtube.com/watch?v=jm7-BQ0RvHQ.

and New York State Association of County Health Officials (attended by public health directors of any county that chooses to participate) and (3) weekly regional calls with hospitals, county officials, and advocacy organizations.

25. Despite Plaintiff's provocations, the Guidance does not, nor is it intended to, operate as a barrier to care for white people or create a racial hierarchy in the delivery of care. To provide an example at the extremes, as contemplated by Plaintiffs: a white person and person of color both present to a treating doctor; only one oral antiviral treatment is available; the white person has various comorbidities and is in a seriously medically compromised state; the person of color presents as asymptomatic with no comorbidities. In this situation the DOH would expect the physician, using her or his medical judgment, to prescribe the one antiviral treatment available to the white person. Please keep in mind I offer this simple explanation for the court's benefit. In reality conjecture at the extremes often oversimplifies matters. In a clinical setting, pursuant to my training and experience I would expect a practitioner should: (1) take a detailed history and conduct a physical examination, (2) understand the risks and benefits of treatment versus non treatment based upon the person presented in front of you, 3) have a discussion with the patient about risk, benefits, and alternatives especially since these medications are only approved for use pursuant to emergencies authorizations and thus have not received full FDA approval. Only then after using appropriate medical clinical judgment should a medication be prescribed. These decisions should always be based upon the physician-patient relationship and a shared decision-making process that is part and parcel to patient care. Guidance issued by the DOH is simply a suggestion to help focus the thoughts of practitioners and inform reasonable

discussion.

26. In short, the Guidance is just that -- guidance. It is not a substitute for the use of sound clinical judgment by practitioners or hospitals[6]. It merely points to one of many factors to be considered when prescribing treatment. All things being equal among patients, the Guidance is meant to allow the flexibility for health care providers to consider persons of color as being at an increased risk due to the disproportionate impact of COVID-19 on communities of color.

27. It is also important to note, because the Guidance is not a mandate, the DOH will not take enforcement actions against practitioners or hospitals in relation to it.

NO CURRENT SHORTAGE OF MEDICATIONS

28. It is also important to note this Guidance was issued at a time when oral antiviral treatments were anticipated to be in short supply based upon information provided by the federal government prior to their initial distribution. That is not the current situation.[7] As Commissioner Bassett testified at the Joint Public Hearing on February 8, 2022, there is currently no shortage of the medications in New York. *See* footnotes 5 and 6 above. Even though there is

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[6] *See* Joint Legislative Public Hearing on 2022 Executive Budget Proposal: Topic Health/Medicaid | NY State Senate (nysenate.gov) at 2 hours 13 minutes in response to a question posed by Assemblyman Colin Schmitt, *available at* https://www.nysenate.gov/calendar/public-hearings/february-08-2022/joint-legislative-public-hearing-2022-executive-budget.

[7] *See* Erie County Department of Health Announcement, *available at* https://www2.erie.gov/health/index.php?q=press/erie-county-department-health-highlights-availability-covid-19-oral-antiviral-medications; "Press Release: New York City announces the availability of Paxlovid COVID-19 oral treatment", *available at* http://outbreaknewstoday.com/new-york-city-announces-the-availability-of-paxlovid-covid-19-oral-treatment-50398/.

not currently a shortage of oral antiviral treatments, the pandemic has taught us that supply chain disruptions can happen at any time.

29. Any individual in need of the medications has been encouraged by the DOH to reach out to their treating clinician to have the appropriate discussion about treatment options. This was publicly stated on February 15, 2022, by Governor Hochul.

CONCLUSION

30. Nothing in the Guidance prevents the Plaintiff, or anyone similarly situated, from receiving treatment with oral antivirals in the unfortunate event that they contract COVID-19.

31. The Guidance is based on data that shows COVID-19 mortality rates are higher among certain demographic groups, including non-white/Hispanic communities. No 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.

Dated: February 25, 2022

EUGENE HESLIN, M.D., FAAFP

E IBIT B

Federal Response to COVID-19: Therapeutics Clinical Implementation Guide

Outpatient administration guide for healthcare providers

12/29/2021

Table of Contents

HIGH RISK FACTORS FOR TREATMENT AND POST-EXPOSURE PROPHYLAXIS WITH mAbs INCLUDE, BUT ARE NOT LIMITED TO:

- Older age (for example ≥ 65 years of age)
- Less than 1 year of age (bamlanivimab/etesevimab only)
- Obesity or being overweight (for example, adults with BMI ≥ 25, or if age 12-17, have BMI ≥ 85th percentile for their age and gender based on CDC growth charts)
- Pregnancy
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital abnormalities)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and **authorization of mAb therapy is not limited to the medical conditions or factors listed above**. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, visit the CDC website:

- CDC Underlying Medical Conditions Associated with High Risk for Severe COVID-19: Information for Healthcare Providers (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html)
- CDC's Clinical Growth Charts (https://www.cdc.gov/growthcharts/clinical_charts.htm)
- The COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints