# 22-692

## United States Court of Appeals for the Second Circuit

WILLIAM A. JACOBSON, on behalf of himself and others similarly situated,

*Plaintiff-Appellant*,

v.

MARY T. BASSETT, in her official capacity as Acting Commissioner of the New York Department of Health,

*Defendant-Appellee*.

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

**BRIEF FOR DEFENDANT-APPELLEE**

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# TABLE OF CONTENTS

**Page**

**Page**

# TABLE OF AUTHORITIES

**Cases** **Page(s)**

**Cases** **Page(s)**

**Cases** **Page(s)**

**Cases** **Page(s)**

**Cases** **Page(s)**



**United States Constitution**



**Federal Statutes**



**Federal Rules and Regulations**

**New York State Statutes** **Page(s)**



**Miscellaneous Authorities**

*Federal*



*State*

**Miscellaneous Authorities** **Page(s)**

*State*



*Other*

## PRELIMINARY STATEMENT

In December 2021, the federal Food and Drug Administration (FDA) issued emergency use authorizations for COVID-19 treatments that were shown to dramatically reduce the likelihood of progression to severe disease if taken in the first five days of illness. The New York State Department of Health (NYSDOH) subsequently issued nonbinding advisory guidance to health care providers describing the new treatments and recommending criteria by which providers could prioritize the administration of the treatments during an initial period of limited supply. Specifically, the guidance advised providers to allocate the treatments to those most likely to develop severe illness associated with COVID-19 and noted that one of the many risk factors associated with development of severe illness is non-white race and Hispanic ethnicity. Two and a half months later, after initial supply shortages abated, NYSDOH issued updated guidance stating that the treatments should be prescribed without concern for availability.

Plaintiff, who is non-Hispanic white, sued NYSDOH Commissioner Mary Bassett to challenge the NYSDOH guidance on behalf of himself and similarly situated white, non-Hispanic persons. Plaintiff claimed

that the guidance violates the Equal Protection Clause, among other laws, and moved for a preliminary injunction. The U.S. District Court for the Northern District of New York (D'Agostino, J.) dismissed plaintiff's claims for lack of standing, and this Court should affirm.[1]

Plaintiff fails to satisfy any of the requirements for Article III standing. Plaintiff cannot allege an injury-in-fact because any equal protection injury he might suffer is purely speculative, and because the challenged guidance has never served as a barrier to COVID-19 treatment for white and non-Hispanic persons. Plaintiff also cannot show traceability or redressability both because the challenged guidance is not binding on health care professionals and because it largely tracks federal standards that would remain in place even if plaintiff were to prevail in this suit. In addition, plaintiff's challenge is moot because the challenged guidance applied only during an initial period of supply scarcity. A decision in the State's favor on any one of these grounds warrants affirmance or dismissal of the appeal as moot.

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[1] Another appeal currently pending before the Court, *Roberts v. Bassett* (No. 22-622), presents similar issues.

Even if plaintiff were somehow able to surmount all of the threshold obstacles discussed above, the proper remedy would be for this Court to remand the case to the district court for further proceedings, including resolution of plaintiff's motion for a preliminary injunction in the first instance. There is no reason for this Court to decide the motion for the first time on appeal, and the record before the Court provides no basis for granting preliminary relief, as plaintiff has failed to establish irreparable harm, a likelihood of success on the merits of his equal protection challenge, or that an injunction would be in the public interest.

## ISSUES PRESENTED

1. Did the district court correctly dismiss the complaint for lack of subject matter jurisdiction?

2. If this Court reinstates the complaint, should it decline to grant preliminary relief, and instead either deny the motion on the merits, or at most remand to the district court for consideration of plaintiff's preliminary injunction motion?

## STATEMENT OF THE CASE

### A. Statutory and Regulatory Background

NYSDOH is a state agency endowed by the legislature with "broad power to regulate in the public interest." *Agencies for Children's Therapy Servs., Inc. v. New York State Dep't of Health*, 136 A.D.3d 122, 129 (2d Dep't 2015). Among other things, it is empowered to "supervise the reporting and control of disease" and "promote education in the prevention and control of disease." N.Y. Pub. Health L. § 201(1)(c), (g). The NYSDOH Commissioner is charged with "exercis[ing] the functions, powers and duties of the department prescribed by law," and is empowered to "investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions, upon the public health." *Id.* § 206(1)(a), (d).

### B. The COVID-19 Pandemic and the Federal Government's Authorization of New Treatments for Patients with High Risk of Progression to Severe Disease

COVID-19 is a highly infectious and potentially deadly respiratory illness that spreads easily from person to person. In the United States alone, COVID-19 has infected more than 85 million people and claimed

more than 1,000,000 lives.[2] The State of New York has reported over 5.5 million cases[3] and over 71,000 deaths[4] attributable to COVID-19. COVID-19 remains an ongoing threat, given the periodic emergence and spread of different variants of the virus.[5]

As the record on plaintiff's preliminary injunction motion established, COVID-19 presents demonstrably greater medical risks for persons of color. According to the U.S. Centers for Disease Control and Prevention (CDC), Black Americans are as likely to contract COVID-19 as non-Hispanic whites, but are 2.5 times more likely to be hospitalized, and 1.7 times more likely to die of the disease. Similarly, Hispanic Americans are 1.5 times as likely to contract COVID-19, 2.4 times as likely to be hospitalized, and 1.9 times as likely to die of the disease as

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[2] CDC, *COVID Data Tracker*, https://covid.cdc.gov/covid-data-tracker/#datatracker-home (last visited June 21, 2022).

[3] NYSDOH, *COVID-19 Testing Tracker*, https://coronavirus.health.ny.gov/covid-19-testing-tracker (last visited June 21, 2022).

[4] NYSDOH, *COVID-19 Fatalities Tracker*, https://coronavirus.health.ny.gov/fatalities-0 (last visited June 21, 2022).

[5] NYSDOH, *COVID-19 Variant Data: Monitoring the Prevalence of SARS-CoV-2 Variants*, https://coronavirus.health.ny.gov/covid-19-variant-data (last visited June 21, 2022)

non-Hispanic whites. (JA42.) Such disparities persist even after controlling for medical comorbidities (JA41, 179-189), and level of educational attainment (JA41, 190-199). The CDC has concluded that one of the factors driving disparate COVID-19-related outcomes between non-Hispanic whites and persons of color is disparate access to available treatments. (JA40.)

The FDA has authorized several treatments for COVID-19, including monoclonal antibodies and oral antiviral drugs. In December 2021, the FDA authorized the emergency use of two oral antiviral drugs, Paxlovid and molnupiravir.[6] (*See* JA49.) The Emergency Use Authorization (EUA) for each drug limits its approved use to adults and certain pediatric patients with mild-to-moderate COVID-19 who are at

[6] Section 564 of the Food, Drug, and Cosmetic Act permits the Commissioner of the FDA "to authorize the emergency use of an unapproved medical product . . . for certain emergency circumstances" after the Secretary of Health and Human Services (HHS) "has made a declaration of emergency or threat justifying emergency use." FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* 3 (2017), https://www.fda.gov/media/97321/download; *see* 21 U.S.C. § 360bbb-3.

high risk for progression to severe COVID-19.[7] (JA129-130.) In a Clinical Implementation Guide published in December 2021, the CDC stated that, in addition to age and underlying medical conditions, other factors such as race or ethnicity may "also place individual patients at high risk for progression to severe COVID-19." (JA40, 106.) The supply of Paxlovid and molnupiravir was severely limited at the time of their emergency authorization, which coincided with the surge of the Omicron variant. (JA38, 45.)

### C. The State's Recommendation that Non-White Race or Hispanic Ethnicity Be Considered Risk Factors for Severe COVID-19 Illness

On December 27, 2021, NYSDOH issued guidance to health care providers and facilities regarding the newly approved COVID-19 treatments. NYSDOH, *COVID-19 Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment*

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[7] *See* Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to Pfizer, Inc. (Apr. 14, 2022), https://www.fda.gov/media/155049/download (last visited June 21, 2022); Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to Merck Sharp & Dohme Corp. (Mar. 23, 2022), https://www.fda.gov/media/155053/download (last visited June 21, 2022).

*Products* (Dec. 27, 2021) (JA49-56). The purpose of the guidance was to make providers and hospitals aware of the treatments and to identify factors for providers to consider when administering treatments given initially limited supply.[8] (JA38-39, 49.) "While supplies remain low," according to the guidance, health care providers should "prioritize therapies for people of any eligible age who are moderately to severely immunocompromised regardless of vaccination status or who are age 65 and older and not fully vaccinated with at least one risk factor for severe illness." (JA49.)

The guidance also describes eligibility criteria for use of Paxlovid and molnupiravir. Consistent with the FDA's EUAs for those drugs, the guidance states that they are approved for patients with mild to moderate COVID-19 symptoms and who "[h]ave a medical condition or

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[8] Additional guidance, also issued on December 27, 2021, suggests a framework for prioritizing treatments for COVID-19 patients based on their age, immunocompromised status, vaccination status, residency in a long-term care facility environment, and the presence of any "risk factors for severe illness" including various comorbidities specified by the CDC. NYSDOH, *Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations* (JA29-31). Although plaintiff referenced this guidance in his complaint, he does not allege that he has a risk factor for severe illness and raises no argument about this guidance on appeal.

other factors that increase their risk for severe illness," among other criteria. (JA50.) The guidance notes that "[n]on-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." (JA50.) A CDC resource, cited by and incorporated by hyperlink into the NYSDOH guidance, likewise includes non-white or Hispanic/Latino ethnicity as independent risk factors for severe COVID-19.[9] The NYSDOH guidance contains no enforcement mechanism, nor does it purport to supplant the clinical judgment of health care providers. (*See* JA44-45.)

By February 2022, supply shortages for the newly-approved treatments had begun to abate. (JA45.) On March 4, 2022, NYSDOH issued updated guidance advising providers that "treatment options are now widely available and there are no current shortages in supply." *See* NYSDOH, *Test Soon and Treat Early to Improve Outcomes From COVID-*

[9] CDC, *People with Certain Medical Conditions* (updated May 2, 2022), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (last visited June 21, 2022) (linked at JA49).

*19* (Mar. 4, 2022).[10] Providers are now "encourage[d] . . . to evaluate all treatment options as early as possible." *Id.* Recent data from the federal government confirms that the treatments remain widely available in New York State.[11]

### D. Procedural History and Decision Below

On January 16, 2022, plaintiff William Jacobson commenced this putative class action lawsuit in the United States District Court for the Northern District of New York. (JA12-20.) Plaintiff, who is a law professor at Cornell University, alleges that he "does not qualify" for oral antiviral therapies under the NYSDOH guidance because of his race and ethnicity. (JA16.) According to the complaint, "New York's policy creates a racial hierarchy in the distribution of life-saving COVID-19 medication." (JA15.) Specifically, while "[n]on-white and Hispanic/Latino

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[10] We are providing the Court with a copy of this memorandum in an addendum to this brief.

[11] *See* HHS, Office of the Asst. Sec'y for Preparedness & Response, *Therapeutic Distribution Locator for Provider Use*, https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com (last visited June 21, 2022) (indicating that 82,344 doses of Paxlovid and 78,088 doses of molnupiravir were available in the State of New York); *compare COVID-19 Testing Tracker* (indicating 3,596 positive tests on June 19, 2022).

individuals who test positive for COVID-19 automatically qualify for oral antiviral treatments," "an identically situated non-Hispanic/Latino white individual is ineligible unless he demonstrates a 'medical condition' or 'risk factor' that increases his risk for severe illness from COVID-19." (JA15.) The complaint further alleges that the guidance "injures Plaintiff and his fellow class members by subjecting them to an increased risk of serious illness or death when they acquire COVID-19," and "inflict[s] emotional and psychological harm on Plaintiff (and others) who are facing increased risk of harm from the pandemic on account of New York's racially discriminatory policies." (JA17.)

Plaintiff claims that the NYSDOH guidance violates (1) the Equal Protection Clause, U.S. Const. amend. XIV; (2) Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d; and (3) Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116. (JA18-19.) By way of relief, plaintiff seeks a declaratory judgment that the guidance violates these laws and an injunction restraining NYSDOH "from implementing and enforcing any discriminatory racial preferences in the Department's programs." (JA19-20.)

Plaintiff moved for a preliminary injunction and class certification on February 4, 2022. (*See* JA8-9.) In support of his preliminary injunction motion, plaintiff stated in a declaration that when he "inevitably contract[s] COVID-19," he wants "to immediately access oral antiviral treatments to reduce [his] risk of serious illness or death." (JA34.) But because he is "of East European ancestry and not 'non-white' and not of Hispanic/Latino ethnicity," plaintiff is "not automatically eligible" for antiviral treatments. (JA33-34.) Knowing that he is "not automatically eligible" causes plaintiff to "have a heightened concern when [he] go[es] about [his] daily activities." (JA34.) The declaration notes that plaintiff is 62 years old (JA33), but does not otherwise indicate whether plaintiff is at risk of severe disease from COVID-19. NYSDOH opposed plaintiff's motions, and cross-moved to dismiss the action for lack of standing and for failure to state a claim. (*See* JA9.)

On March 25, 2022, the district court (D'Agostino, J.) granted NYSDOH's motion to dismiss and denied plaintiff's preliminary injunction and class certification motions as moot. (JA200-210.) The district court held that plaintiff lacks standing to challenge the guidance. As the court explained, "[p]laintiff's theory of future injury is too

speculative and attenuated for Article III standing." (JA207.) The court described the series of events that would have to occur before plaintiff suffered any actual injury:

> (1) Plaintiff must contract COVID-19; (2) Plaintiff must suffer mild to moderate symptoms (as opposed to being asymptomatic or hospitalized due to severe or critical symptoms); (3) Plaintiff's treating doctor must conclude that use of oral antiviral treatment is clinically appropriate for Plaintiff; and (4) there must be a shortage in oral antiviral treatment supplies at the time of Plaintiff's sickness that makes it impossible to offer the treatment to all eligible patients.

(JA208 (record citations omitted)). "In light of the discretion afforded to doctors in recommending treatment and the current lack of any shortage in oral antiviral treatment supplies," the court reasoned, plaintiff's "theory of future injury is far closer to a speculative chain of possibilities than certainly impending." (JA208-209 (citations and internal quotation marks omitted)).

The court further held that plaintiff's alleged emotional harm was not traceable to the challenged NYSDOH guidance nor redressable by a favorable decision because plaintiff is not "automatically eligible" to antiviral therapies even absent the guidance. (JA209.) As the court explained, "[e]veryone—regardless of whether race or ethnicity is

considered a risk factor—must still contract COVID-19, have an appropriate level of symptoms, and a doctor must determine oral antivirals are clinically appropriate, before they are eligible for this treatment." (JA209.) This appeal followed.

## STANDARD OF REVIEW

On appeal from a dismissal for lack of subject matter jurisdiction, this Court reviews the district court's legal conclusions *de novo*, and its factual findings for clear error. *Correspondent Servs. Corp. v. First Equities Corp. of Fla.*, 442 F.3d 767, 769 (2d Cir. 2006).

## SUMMARY OF ARGUMENT

The district court correctly determined that there is no federal subject matter jurisdiction over plaintiff's claims. First, plaintiff has failed to establish any of the elements of Article III standing. While plaintiff asserts three theories of standing—based on his alleged inability to access oral antiviral therapies under the challenged guidance, his alleged increased risk for severe COVID-19 because of this lack of access, and his resulting emotional distress—each theory relies on a chain of possibilities that is too attenuated to show any actual or imminent injury.

Most notably, the challenged guidance was in effect only during an initial period of supply shortage, and plaintiff offers only speculative assertions that he could face injury in the event of hypothetical future shortages. Plaintiff also fails to show that he will suffer a concrete and particularized injury stemming from the challenged guidance; indeed, plaintiff fails to allege that the guidance presents a barrier to any non-Hispanic white person from accessing COVID-19 treatments.

Plaintiff lacks standing for the additional reason that any injury he might suffer in the event he cannot access antiviral therapies would not be traceable to the NYSDOH guidance, nor redressable by a favorable decision here. The challenged guidance is nonbinding and does not control the medical judgment of health care providers, who must independently determine whether oral antiviral therapies are clinically appropriate. And in any event, the NYSDOH guidance sets forth the same eligibility criteria for oral antiviral therapies as those approved by the FDA and CDC. Thus, even if the guidance were declared unlawful, plaintiff still could only access oral antiviral therapies if he is at risk for severe disease from COVID-19, leaving him in the same position he is in now.

Second, plaintiff's claims are moot. The COVID-19 treatments at issue are now widely available, and the NYSDOH guidance has been updated to recommend that providers explore all options in determining a proper treatment course. Plaintiff's complaint no longer presents a live controversy, and there is no reasonable expectation that the supply shortages that prompted the challenged NYSDOH guidance are likely to recur, or that a new challenge would be unavailable to plaintiff if the guidance again takes effect.

If this Court nonetheless were to conclude that there is federal subject matter jurisdiction over plaintiff's claims, it should remand to the district court for further proceedings including consideration of plaintiff's motion for a preliminary injunction in the first instance. Or, if the Court reaches the merits of plaintiff's motion for the first time on appeal, it should deny the motion as meritless. Plaintiff cannot show that he would be irreparably harmed in the absence of injunctive relief because there is no current (or foreseeable) shortage of the oral antiviral therapies at issue. Plaintiff is also unlikely to succeed on the merits of his equal protection claim because the challenged guidance is subject to rational basis review, which it readily survives. The guidance would satisfy strict

scrutiny as well, in light of overwhelming medical evidence showing that being a member of certain racial and/or ethnic groups is a substantial and independent risk factor for severe COVID-19 illness. The guidance is narrowly tailored in permitting consideration of numerous medically substantiated risk factors, including but not limited to race and ethnicity, in the administration of COVID-19 treatments aiming to reduce the likelihood of severe illness.

## ARGUMENT

## POINT I

### FEDERAL COURTS LACK SUBJECT MATTER JURISDICTION OVER PLAINTIFF'S CLAIMS

### A. The District Court Correctly Concluded that Plaintiff Lacks Standing.

"Article III of the Constitution confines the federal courts to adjudicating actual 'cases' and 'controversies.'" *Allen v. Wright*, 468 U.S. 737, 750 (1984) (quoting U.S. Const. art. III, § 2). Article III therefore circumscribes the jurisdiction of federal courts to include only claims brought by plaintiffs who have standing to assert them. To establish Article III standing, a plaintiff must show (1) an injury in fact, which is (a) concrete and particularized, and (b) actual or imminent, not

conjectural or hypothetical; (2) that the injury is fairly traceable to the challenged action of the defendant; and (3) that it is likely the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). If the court determines at any time in the proceeding that it lacks subject matter jurisdiction, including based on matters outside the pleadings, it "must dismiss the action." Fed. R. Civ. P. 12(h)(3); *see Fountain v. Karim*, 838 F.3d 129, 133 n.5, 134 (2d Cir. 2016) (court considering its subject matter jurisdiction sua sponte may refer to evidence outside of the pleadings). The district court correctly concluded that plaintiff failed to establish his standing to sue here.

### 1. Plaintiff failed to show that the challenged guidance imposed an injury-in-fact.

Plaintiff failed to show any injury that is both concrete and particularized and either actual or imminent.

*First theory of injury*. Plaintiff's first and chief claim of injury is that he will not have access to oral antiviral therapies because of his race and ethnicity. (JA15-16; Br. 15-19.) This prospective injury can satisfy the injury-in-fact requirement only if it is "real, immediate, and direct." *Chevron Corp. v. Donziger*, 833 F.3d 74, 121 (2d Cir. 2016) (quoting *Davis*

*v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008)). And plaintiff's alleged "threatened injury must be *certainly impending* to constitute injury in fact"; "[a]llegations of *possible* future injury" do not suffice. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). Thus, in *Clapper*, the Supreme Court held that the plaintiffs lacked standing to challenge one of the federal government's procedures for surveilling foreign communications based on speculative assertions that (1) the government would target the plaintiffs' communications with their foreign contacts; (2) the government would use the challenged method rather than rely on a different surveillance framework; and (3) an independent actor—the Foreign Intelligence Surveillance Court—would authorize such surveillance. *Id.* at 411-13.

Like the plaintiffs' alleged injury in *Clapper*, plaintiff's alleged inability to access antiviral therapies based on his race and ethnicity is too speculative to show injury-in-fact. Indeed, plaintiff's theory of standing relies on a series of events any one of which may not occur. (*See* JA208-209.) First, plaintiff must contract COVID-19. Second, plaintiff must experience mild or moderate symptoms. Third, plaintiff must seek treatment from a physician. Fourth, the physician must independently

determine that plaintiff is eligible for oral antiviral drugs under the FDA's EUA for these drugs because he is at high risk for severe disease from COVID-19—a fact that plaintiff does not plead—and that those drugs are otherwise clinically appropriate for plaintiff. (*See* JA129-130.) Fifth, those drugs must be in such short supply that the physician would have to prioritize treatment for those at higher risk for severe disease. (*See* JA49.) And finally, plaintiff must be denied access to antiviral therapies while a similarly situated non-white or Hispanic person receives such treatment. *See MGM Resorts Int'l Glob. Gaming Dev., LLC v. Malloy*, 861 F.3d 40, 50 (2d Cir. 2017) (to allege injury "based on discriminatory treatment," plaintiff must show that "he personally would have been subject to the discriminatory terms" of challenged government policy).

If any one of these events does not occur, plaintiff will not in fact suffer any equal protection injury. This "highly attenuated chain of possibilities[] does not satisfy the requirement that threatened injury must be certainly impending." *Clapper*, 568 U.S. at 410; *see also Robinson v. Sessions*, 721 F. App'x 20, 24 (2d Cir. 2018) (plaintiffs failed to show injury-in-fact where "the complaint articulate[d] a highly attenuated

chain of possibilities that could, in combination with a number of unpled facts, perpetrate the alleged constitutional harm" (citation and internal quotation marks omitted)).

Indeed, plaintiff's theorized injury is not impending at all, let alone *certainly* impending, because oral antiviral drugs are no longer in short supply. (*See* JA45.) Thus, if plaintiff contracts COVID-19 now or in the foreseeable future, the NYSDOH guidance would not even be in effect. Plaintiff cannot show an equal protection injury based on the mere possibility that there may again be a shortage in the future. *See Clapper*, 568 U.S. at 409. Additionally, that plaintiff in fact received treatment when he contracted COVID-19 in May 2022 (Br. 17) further undermines his claim of injury. Having accessed antiviral therapies in the past, plaintiff offers no reason, beyond conjecture, that he will be unable to do so in the future.

Plaintiff's reliance on *Northeastern Florida Chapter of the Associated General Contractors of America v. City of Jacksonville*, 508 U.S. 656 (1993), and its progeny is misplaced. Those cases concern a plaintiff's burden of showing a concrete and particularized injury-in-fact for purposes of bringing an equal protection claim based on the

government's alleged denial of a benefit. Such a plaintiff must establish that (i) he or she is a member of a disadvantaged group; (ii) the government has erected a barrier to obtaining a benefit; and (iii) the barrier causes members of one group to be treated differently from members of the other group. *See Comer v. Cisneros*, 37 F.3d 775, 793 (2d Cir. 1994). The injury in such cases "is the denial of equal treatment resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit." *Id.* at 791 (quoting *City of Jacksonville*, 508 U.S. at 666.)

Here, the challenged NYSDOH guidance neither erects a barrier to obtaining the treatments at issue nor causes one group to be treated differently than any other with regard to obtaining such treatments. The challenged guidance consists of nonbinding recommendations to providers and does not supersede or supplant the professional judgment of those providers in treating individual patients. As a general matter, such voluntary guidance does not cause injury in a way that gives rise to Article III standing. *See Bear Lodge Multiple Use Ass'n v. Babbitt*, 175 F.3d 814, 821-22 (10th Cir. 1999).

Nor does the NYSDOH guidance impose such barriers as have been found to cause concrete injury in the school admissions or government-contracting contexts. Thus, the guidance challenged here does not authorize providers to treat race and ethnicity as a determinative risk factor or a more significant risk factor than other markers for risk, such as age or comorbidities—indeed, as just noted, the guidance does not require the consideration of race at all. Instead, the use of race or ethnicity in treatment decisions under the challenged guidance is a voluntary undertaking by third parties. (*See* JA43-44.) In this respect, the guidance bears no resemblance to admissions programs that reserve seats for or award points in the college admissions process to members of minority groups, or affirmatively consider race and ethnicity as an unquantified factor in a holistic review of each admissions applicant's file. *Cf. Parents Involved in Cmty. Schs. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701 (2007); *Grutter v. Bollinger*, 539 U.S. 306 (2003); *Gratz v. Bollinger*, 539 U.S. 244 (2003); *Regents of Univ. of Calif. v. Bakke*, 438 U.S. 265 (1978). For the same reason, the guidance is not comparable to government programs reserving a certain percentage of contracts for minority-owned businesses or awarding extra compensation to

contractors who hire minority-owned businesses. *Cf. Adarand Constructors, Inc. v. Pena*, 515 U.S. 200 (1995); *City of Jacksonville*, 508 U.S. at 658.

In any event, to establish standing to challenge a race-based barrier to obtaining a benefit, a plaintiff must still show that a denial of equal treatment is either actual or certainly impending. *See Malloy*, 861 F.3d at 47. Thus, for example, a plaintiff challenging "a barrier to bidding on public contracts [must] actually make a bid on the contracts at issue, or at least establish standing by proving that it very likely would have bid on the contract but for the alleged discrimination." *Id.* Plaintiff cannot challenge the barrier purportedly imposed by the NYSDOH guidance because, as explained above, plaintiff only speculates, based on an attenuated chain of possibilities, that he will be subject to unequal treatment.

*Second theory of injury*. Plaintiff's next claim of injury—that the NYSDOH guidance puts him at greater risk of severe COVID-19 (JA17; Br. 19-21)—fares no better. As an initial matter, if plaintiff were at risk for severe disease from COVID-19, then he would be eligible for oral antiviral therapies even under the challenged NYSDOH guidance. (*See*

JA50.) And while an increased risk of a bad outcome may constitute injury-in-fact in some cases, *see, e.g.*, *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003), plaintiff's unsupported allegations of increased risk here do not suffice.

Plaintiff's reliance on *Baur* in particular is misplaced. In *Baur*, the plaintiff filed suit to ban the use of "downed livestock" in food products due to the risk that such animals "are particularly likely to be infected with" certain neurological disorders that can be transmitted to humans. 352 F.3d at 627-28. This Court held that the plaintiff had standing to seek relief because he was exposed to such meat and therefore suffered an "*increased risk* of disease transmission caused by exposure to a potentially dangerous food product." *Id.* at 632-33.

But the Court refused to "decide as a matter of law whether enhanced risk generally qualifies as sufficient injury to confer standing," and limited its ruling to "the specific context of food and drug safety suits." *Baur*, 352 F.3d at 634. The Court reasoned that such claims of injury were similar to those involving "threatened environmental harm," where the "potential harm from exposure . . . is by nature probabilistic, yet an unreasonable exposure to risk may itself cause cognizable injury."

*Id.* (citation and internal quotation marks omitted); *see also Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 83 (2d Cir. 2013) (finding injury-in-fact "based on the actual, present health risk arising out of actual, present exposure" to potentially harmful chemical); *New York Pub. Int. Research. Grp. v. Whitman*, 321 F.3d 316, 325-26 (2d Cir. 2003) (finding injury-in-fact based on potential exposure to environmental pollutants).

Here, the allegedly "imminent" injury to plaintiff does not arise in "the specific context of food and drug safety," nor is such injury related to "an unreasonable exposure" to known environmental risks. *Baur*, 352 F.3d at 634. Instead, as explained above, plaintiff's hypothesized injury is contingent on a speculative series of future events. In *McMorris v. Carlos Lopez & Assocs., LLC*, 995 F.3d 295 (2d Cir. 2021), the Court regarded similarly unsupported allegations of increased risk as insufficient to show injury-in-fact. The plaintiffs in *McMorris* "failed to show that they [were] at a substantial risk of future identity theft or fraud sufficient to establish Article III standing" based on the inadvertent disclosure of personal information to the defendant company's employees. *Id.* at 303. As in this case, the plaintiffs could rely

only on "a lengthy 'chain of possibilities'" that could "result[] in injury." *Id.* at 304 (quoting *Clapper*, 568 U.S. at 410); *see also Ross v. AXA Equitable Life Ins. Co.*, 680 F. App'x 41, 46 (2d Cir. 2017) (finding that plaintiff failed to allege injury-in-fact based on alleged "increased risk" that insurers may be unable to pay out claims "in the event of an economic downturn").

*Third theory of injury*. Plaintiff's final claim of injury—that the guidance causes plaintiff emotional and psychological harm (JA17; Br. 22)—lacks merit for the same reason. A plaintiff does not have standing to sue based solely on "fears of hypothetical future harm that is not certainly impending." *Clapper*, 568 U.S. at 416. Nor is plaintiff's "heightened concern" based on his potential inability to access antiviral therapies (JA34) sufficiently concrete to show injury-in-fact. This "perfunctory allegation of emotional distress . . . is insufficient to plausibly allege constitutional standing." *Maddox v. Bank of New York Mellon Tr. Co., N.A.*, 19 F.4th 58, 66 (2d Cir. 2021); *accord Garland v. Orlans, PC*, 999 F.3d 432, 440 (6th Cir. 2021) (holding that "a general allegation of emotional harm like anxiety or distress" does not suffice to show concrete injury for purposes of Article III standing); *Pennell v. Glob.*

*Tr. Mgmt., LLC*, 990 F.3d 1041, 1045 (7th Cir. 2021) (stress alone does not "amount to a concrete harm").

In sum, none of plaintiff's three theories of injury—based on (1) his alleged inability to access oral antiviral therapies because of his race and ethnicity, (2) his alleged increased risk for severe COVID-19 because of this lack of access, and (3) his resulting emotional distress—suffices to show an injury that is both concrete and actual or imminent. Plaintiff thus fails to show any injury-in-fact.

### 2. Plaintiff failed to show that any injury is traceable to the challenged guidance.

Even if plaintiff could establish injury-in-fact, he would still lack standing because his injury would not be "fairly traceable to the challenged action of the defendant"—that is, to the nonbinding guidance distributed to providers exercising independent medical judgment across the State. *Lujan*, 504 U.S. at 560 (citation omitted). This is another independent ground for affirmance.

Traceability speaks to the "causal connection between the injury and the conduct complained of." *Lujan*, 504 U.S. at 560. Where, as here, the alleged injury is directly visited on the plaintiff by third parties (*i.e.*,

medical providers making determinations about which treatments to prescribe in individual cases), traceability "is ordinarily substantially more difficult to establish." *Id.* at 562 (citation and internal quotation marks omitted). A plaintiff lacks standing to sue a defendant based on the "independent action" of the third party unless the defendant's conduct had a "determinative or coercive effect" on the third party's actions. *Bennett v. Spear*, 520 U.S. 154, 169 (1997). In *Bennett*, for example, traceability was found based on the "powerful coercive effect" of an advisory opinion that established conditions that could ultimately result in "substantial civil and criminal penalties, including imprisonment." *Id.* at 169-70.

The nonbinding guidance at issue in this case has no coercive effect on medical providers because there is no mechanism for enforcing the guidance. (*See* JA45.) This Court and other federal appellate courts have routinely found an absence of traceability in such circumstances. *See, e.g.*, *Nat'l Council of La Raza v. Mukasey*, 283 F. App'x 848 (2d Cir. 2008); *Irregulators v. Fed. Commc'ns Comm'n*, 953 F.3d 78, 83 (D.C. Cir. 2020); *Turaani v. Wray*, 988 F.3d 313, 316-17 (6th Cir. 2021).

Additionally, as the district court held (JA209), plaintiff failed to show the requisite causal connection between the challenged guidance and his alleged emotional and psychological harm from not being automatically eligible for COVID-19 treatments. It is true that plaintiff is not automatically eligible for oral antiviral therapies under the NYSDOH guidance. But that is because the FDA has approved Paxlovid and molnupiravir only for patients who are at high risk for progression to severe COVID-19 (JA129-130)—and plaintiff has not alleged that he is at such risk. Moreover, even for such patients, physicians must independently determine whether those drugs are clinically appropriate for an individual patient. (JA44.) Any "heightened concern" plaintiff may experience from not knowing whether he will be able to access COVID-19 treatment (*see* JA34) is traceable to these independent actors, not to NYSDOH.

### 3. Plaintiff failed to show that a successful outcome in this case would redress his alleged injury.

Plaintiff lacks standing for a third, independent reason: he failed to establish that his alleged injury is redressable by the district court. This

failure, too, is by itself sufficient grounds for affirmance of the district court's dismissal of the complaint.

"Redressability is the non-speculative likelihood that the injury can be remedied by the requested relief." *Coal. of Watershed Towns v. U.S. Envtl. Prot. Agency*, 552 F.3d 216, 218 (2d Cir. 2008) (citation and internal quotation marks omitted). Any injury-in-fact would not be redressable here because even if the challenged guidance were invalidated, plaintiff would still have to be at high risk for progression to severe COVID-19 in order to access oral antiviral therapies. As noted, the FDA has approved these therapies for patients with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19. (JA129-130.) And the FDA's criteria for high risk are the same as those contained in the NYSDOH guidance. (JA50.) Thus, the relief plaintiff seeks here would have no bearing on plaintiff's eligibility to receive the underlying treatments. Because plaintiff would be in the same position he is in now even if he received a favorable decision in this case, he has failed to satisfy the redressability requirement. *See Lujan*, 504 U.S. at 561; *Coal. of Watershed Towns*, 552 F.3d at 218.

Plaintiff also has not shown that health care providers would make different treatment decisions if the guidance were invalidated. Here, the challenged guidance was not only nonbinding, but it also paralleled guidance from the CDC, which calls for consideration of race and ethnicity in assessing risk for progression to severe COVID-19. (JA40, 106.) Thus, even if the guidance were invalidated, health care providers may well consider race and ethnicity as risk factors based on federal guidance and overwhelming medical evidence of disparities in COVID-19 outcomes for members of racial and ethnic minority groups.

This Court's decision in *Town of Babylon v. Federal Housing Finance Agency*, 699 F.3d 221 (2d Cir. 2012), is instructive. In that case, the plaintiff sued the Office of the Comptroller of the Currency (OCC), alleging that nonbinding guidance issued by OCC to national banks adversely affected the operation of locally operated programs designed to encourage homeowners to make energy efficient home improvements. *Town of Babylon*, 699 F.3d at 225-26. This Court concluded that the plaintiffs failed to show redressability because even in the absence of nonbinding OCC guidance, the national banks "would remain entirely free to treat" the underlying programs unfavorably. *Id.* at 229. Here too,

the elimination of NYSDOH's nonbinding guidance would leave unaffected federal government guidelines and medical evidence supporting providers' consideration of race and ethnicity as independent risk factors for severe COVID-19 illness.

### B. Plaintiff's Challenge Is Moot.

As explained above, plaintiff lacks standing for four independent reasons: plaintiff failed to show any equal protection injury that is actual or imminent; the guidance does not erect a barrier to plaintiff's access to a benefit; any injury plaintiff might suffer would not be traceable to the guidance; and any such injury would not be redressable by a favorable decision in this case. Even if plaintiff could overcome *all* of these standing-related hurdles, the Court still lacks subject matter jurisdiction because plaintiff's claims are now moot in light of changed circumstances.

"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." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982)). Here, the challenged recommendation applies only during a supply shortage. (JA49.) While a

shortage existed in December 2021, when the FDA first approved oral antiviral therapies for emergency use (and when the Omicron variant surged), that shortage dissipated in February 2022, shortly after plaintiff commenced this action. (*See* JA45; Addendum.) The treatments at issue are now widely available, and NYSDOH has encouraged providers "to evaluate all treatment options as early as possible" without regard to availability. (*See* Addendum.) These changed circumstances render plaintiff's challenge to the NYSDOH guidance moot. And NYSDOH need not show that "it will never declare a new shortage of oral antiviral treatments," as plaintiff argues. (Br. 19.) That kind of showing is required only when a defendant asserts mootness based on "voluntary cessation of a challenged practice," *Trinity Lutheran Church of Columbia, Inc. v. Comer*, 137 S. Ct. 2012, 2019 n.1 (2017)—not when mootness is based on a change of circumstances, like the resolution of the supply shortage here.

Nor does this case present an "exceptional situation[]" warranting an exception to the mootness doctrine. *Lillbask ex rel. Mauclaire v. State of Conn. Dep't of Educ.*, 397 F.3d 77, 85 (2d Cir. 2005) (quoting *Spencer v. Kemna*, 523 U.S. 1, 17 (1998)). For the exception to apply, there must be "a reasonable expectation that the same complaining party would be

subjected to the same action again." *Id.* (quoting *Spencer*, 523 U.S. at 17). "[M]ere speculation that the parties will be involved in a dispute over the same issue does not rise to the level of a reasonable expectation or demonstrated probability of recurrence." *Dennin v. Conn. Interscholastic Athletic Conf., Inc.*, 94 F.3d 96, 101 (2d Cir. 1996) (citation and internal quotation marks omitted). Here, plaintiff's claims of future injury are built on speculation: nothing in the record points to any reasonable expectation that the supply shortages are likely to recur.

Nor is the challenged action "in its duration too short to be fully litigated prior to its cessation or expiration," even if supply shortages were to recur. *Lillbask*, 397 F.3d at 85 (quoting *Spencer*, 523 U.S. at 17). Future supply shortages are likely to be accompanied by significant media attention, and any direction from NYSDOH to providers about how to allocate treatments during periods of shortages will necessarily be publicly available. Plaintiff will have ample opportunity to bring his challenge and seek emergency relief if necessary at that time. *See, e.g.*, *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 273, 277-79 (2d Cir. 2021) (describing procedural history of six weeks between filing of motion for preliminary injunction and resolution of appeal).

## POINT II

### PLAINTIFF IS NOT ENTITLED TO A PRELIMINARY INJUNCTION EVEN IF HE CAN ESTABLISH SUBJECT MATTER JURISDICTION

### A. This Court Should Not Decide Plaintiff's Motion for a Preliminary Injunction in the First Instance.

It is well-settled that the decision of whether to enter a preliminary injunction "remains within the sound discretion of the district court." *American Express Fin. Advisors Inc. v. Thorley*, 147 F.3d 229, 232 (2d Cir. 1998). Without a district court ruling as to the preliminary injunction factors, a reviewing court is "unable to determine whether the district court properly carried out this function." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 305 (D.C. Cir. 2006).

Accordingly, if this Court concludes that there is federal subject matter jurisdiction over plaintiff's complaint, it should remand for further proceedings in the district court, including the adjudication of plaintiff's preliminary injunction motion. *See Salinger v. Colting*, 607 F.3d 68, 83 (2d Cir. 2010) (remanding for consideration by the district court of the remaining three preliminary injunction factors, where the district court had considered only the first of the four factors). "The district court is in the best position to evaluate all of the evidence and

weigh the factors to determine whether the injunction should issue." *Home Instead, Inc. v. Florance*, 721 F.3d 494, 500 (8th Cir. 2013) (citation omitted).

### B. Plaintiff's Motion for a Preliminary Injunction Fails on the Merits.

If this Court were to reach the merits of plaintiff's motion for a preliminary injunction for the first time on an appeal—contrary to typical appellate practice—it should deny the motion as meritless.

Preliminary injunctive relief is an "extraordinary and drastic remedy" that is "unavailable except in extraordinary circumstances." *Moore v. Consol. Edison Co. of N.Y., Inc.*, 409 F.3d 506, 510 (2d Cir. 2005) (citation omitted). 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) (citation and internal quotation marks omitted). Where, as here, the government is a party to the suit, the "public interest"

and the "balance of equities" merge into a single factor. *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 58-59 (2d Cir. 2020). Plaintiff has failed to make these showings and thus is not entitled to a preliminary injunction.

### 1. Plaintiff cannot establish irreparable harm given the surplus of available treatments.

"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) (citation and internal quotation marks omitted). While "a presumption of irreparable injury flows from a violation of constitutional rights," *We the Patriots USA, Inc.*, 17 F.4th at 294 (citation omitted), that presumption can be overcome when there is "no showing of any real or immediate threat that the plaintiff will be wronged again," *Levin v. Harleston*, 966 F.2d 85 (2d Cir. 1992) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 111, 103 (1983)).

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." *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007) (citation and internal quotation marks omitted). Even if plaintiff were able to establish injury for purposes of Article III standing, it remains the case that there are no *current* shortages of any of the COVID-19 treatments at issue. At this time, providers are "encourage[d] . . . to evaluate all treatment options as early as possible." (*See* Addendum.) Accordingly, plaintiff is not threatened by any actual or imminent injury that requires extraordinary injunctive relief.

**2. Plaintiff is unlikely to succeed on the merits of his claims against Commissioner Bassett.**

Plaintiff is also unlikely to succeed on the merits of his equal protection claim.[12] To establish an equal protection violation, a plaintiff must identify (1) "a law or policy that expressly classifies persons on the

[12] To the extent that the NYSDOH guidance is subject to Title VI and Section 1557 of the Affordable Care Act, plaintiff's claims under those laws are adjudicated under the same constitutional standard as his equal protection claim, *see* 42 U.S.C. §§ 2000d, 18116; *Bakke*, 438 U.S. at 287, and fail for the same reasons.

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) (citations and internal quotation marks omitted). If the challenged law or policy does not "target[] a suspect class," it is subject to "highly deferential" rational basis review, where the classification "'is presumed constitutional,' and 'the burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it.'" *Winston v. City of Syracuse*, 887 F.3d 553, 560 (2d Cir. 2018) (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)). Otherwise, a law or policy employing a racial classification will be upheld if it satisfies strict scrutiny—that is, if it implements "narrowly tailored measures that further compelling governmental interests." *Adarand*, 515 U.S. at 227.

**a. NYSDOH's guidance is subject to rational basis review and easily meets that standard.**

Contrary to plaintiff's argument (Br. 24-25), the challenged guidance does not establish a racial classification triggering the

application of strict scrutiny. "The term racial classification normally refers to a governmental standard, preferentially favorable to one race or another, for the distribution of benefits." *Hayden v. County of Nassau*, 180 F.3d 42, 49 (2d Cir. 1999) (citation omitted). As the Supreme Court has explained, "any person, of whatever race, has the right to demand that any governmental actor subject to the Constitution justify any racial classification subjecting that person to unequal treatment under the strictest judicial scrutiny." *Adarand*, 515 U.S. at 224. But "a racial classification that *does not* confer a benefit or impose a burden on an individual would not implicate the equal protection clause." *Honadle v. Univ. of Vermont & State Agric. Coll.*, 56 F. Supp. 2d 419, 428 (D. Vt. 1999) (emphasis added).

Here, the challenged guidance does not confer a benefit or impose a burden based on a racial classification. The guidance does not require that any action be taken with respect to any individual based on their race or ethnicity. *Cf. Lewis v. Ascension Par. Sch. Bd.*, 662 F.3d 343, 361 (5th Cir. 2011) (King, C.J., concurring in part) ("In every case in which the 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."). And the guidance does not prevent any patient from receiving COVID-19 treatment due to their race or ethnicity. The guidance instead provides accurate information about multiple known risk factors for severe illness and death due to COVID-19, including race and ethnicity. "[T]he mere awareness or consideration of race should not be mistaken for racially discriminatory intent or for proof of an equal protection violation." *Doe ex rel. Doe v. Lower Merion Sch. Dist.*, 665 F.3d 524, 548 (3d Cir. 2011).

That the guidance also *recommends* that providers consider race and ethnicity as risk factors in making treatment decisions does not mean that the guidance triggers strict scrutiny. Like "race-conscious yet nonpreferential activities such as recruiting or other forms of outreach," NYSDOH's recommendation neither requires any action with respect to the race-based risk factors nor disadvantages anyone. *Honadle*, 56 F. Supp. 2d at 428; *see also Allen v. Alabama State Bd. of Educ.*, 164 F.3d 1347, 1352 (11th Cir. 1999) (vacated on joint motion of the parties) ("where the government does not exclude persons from benefits based on race, but chooses to undertake outreach efforts to persons of one race,

broadening the pool of applicants, *but disadvantaging no one*, strict scrutiny is generally inapplicable" (emphasis added)). Thus, the guidance does not trigger strict scrutiny.

Accordingly, plaintiff's challenge to the guidance is subject to rational basis review. Under this standard, the Court asks whether there is a "rational relationship between the [policy] and a legitimate [governmental] purpose." *Molinari v. Bloomberg*, 564 F.3d 587, 606 (2d Cir. 2009) (citation omitted). Plaintiff's burden under this standard is a heavy one: "rational basis review contemplates 'a strong presumption of validity, and those attacking the rationality of the legislative classification have the burden to negative every conceivable basis which might support it.'" *Progressive Credit Union v. City of New York*, 889 F.3d 40, 49 (2d Cir. 2018) (quoting *F.C.C. v. Beach Commc'ns*, 508 U.S. 307, 314-15 (1993)).

Plaintiff fails to meet that heavy burden here. Medical research has demonstrated that non-white and Hispanic individuals have suffered severe illness and death from COVID-19 in disproportionately higher numbers than white persons. (JA41-42.) Accordingly, the inclusion of race and ethnicity as an independent risk factor for the development of

severe COVID-19 in NYSDOH's 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.

**b. NYSDOH's guidance would satisfy strict scrutiny, in any event.**

Plaintiff's equal protection claim would fail even if the NYSDOH guidance were subject to review under the strict scrutiny standard because the inclusion of race and ethnicity as a risk factor for severe disease is narrowly tailored to achieve a compelling state interest. *Adarand*, 515 U.S. at 227. "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." *Bakke*, 438 U.S. at 310; *see also 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."). Indeed, there is significant, peer-reviewed medical research that "explore[s] possible racial connections with diseases and treatments." Erik Lilliquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in*

*Medicine*, 39 Harv. C.R.-C.L.L. Rev. 391, 393 (2004); *see also* Scarlett S. Lin & Jennifer L. Kelsey, *Use of Race and Ethnicity in Epidemiologic Research: Concepts, Methodological Issues, and Suggestions for Research*, 22 Epidemiologic Rev. 187, 191-92 (2000).

The challenged NYSDOH guidance serves the State's compelling interest in protecting public health and preventing severe illness and death from COVID-19. The guidance provides accurate information about multiple known risk factors for severe COVID-19 illness to encourage providers to consider whether their patients are at a high risk of developing severe illness or dying from COVID-19 when considering treatment options during periods of limited supply. (JA49-50.) These racial and ethnic disparities in COVID-19 outcomes persist even after controlling for medical comorbidities and educational attainment. (JA41, 179-189, 190-199.)

The NYSDOH 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.

Here, the guidance references race and ethnicity as part of an overall clinical assessment aimed at evaluating a patient's risk for developing severe COVID-19. And there is no race-neutral alternative that would account for the medically proven fact that non-white race or Hispanic ethnicity is an independent risk factor for severe COVID-19 illness. Plaintiff suggests that the NYSDOH guidance could have determined eligibility for treatments according to "objective medical criteria or risk factors for *all* patients regardless of race," such as "advanced age, obesity, a weakened immune system, and several other chronic medical conditions." (Br. 26.) But these risk factors are already considered. (*See* JA49-50.) And plaintiff has provided no evidence that, contrary to multiple studies (*supra* at 5-6), the heightened risk observed in non-white and Hispanic persons can be largely explained by differences in comorbidities or chronic medical conditions between them and non-Hispanic white persons, and therefore no reason to think his preferred factors can simply be substituted for the use of race or ethnicity in assessing risk. An exclusive focus on the factors preferred by plaintiff would simply disregard information about a different medically known risk.

### 3. The public interest supports denial of the preliminary injunction.

Finally, the public interest weighs 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." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982). The injunction requested by plaintiff would serve only to limit the government from issuing guidance citing to known risk factors for severe COVID-19. The public interest would not be served by such an outcome.

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Dated: Albany, New York
June 21, 2022

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Beezly J. Kiernan, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains **8,964** words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7).

*/s/ Beezly J. Kiernan*

# ADDENDUM

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Date: March 4, 2022
To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

**TEST SOON AND TREAT EARLY**
**TO IMPROVE OUTCOMES FROM COVID-19**

Summary:

- Don't delay. Test soon and treat early to improve outcomes from COVID-19.
- COVID-19 treatment options are available and there are no current shortages.

As we continue to combat COVID-19 infections throughout the state, we want to remind you that there are treatment options available. Each of these treatments have proven to be effective against COVID-19 and are available throughout New York State. Treatments can be organized into three categories which are outline below.

- **Pre-exposure Prophylaxis.** To be given to those who are immunocompromised or otherwise unable to get the COVID-19 vaccine prior to being diagnosed. Product: Evusheld.
- **Monoclonal Antibody Treatment.** Provided via IV soon after diagnosis (within 7 days of symptom onset). Currently authorized products include: sotrovimab & bebtelovimab (ONLY if none of the preferred therapies are available, feasible to deliver, or clinically appropriate)
- **Antivirals.** Administered soon after diagnosis either via IV (within 7 days of symptom onset) or orally (within 5 days of symptom onset). Products include: remdesivir (IV), Paxlovid (oral) & molnupiravir (oral).

Since treatment options are now widely available and there are no current shortages in supply if a person tests positive for SARS-CoV-2 we encourage you to evaluate all treatment options as early as possible. Availability of these medications (all except remdesivir) can be found using the COVID-19 Therapeutics Locator.

Starting the week of March 7th, we anticipate new sites will open in New York State through President Biden's Test to Treat program. These Test to Treat sites will provide increased availability of immediate testing and early treatment and will also be displayed on the COVID-19 Therapeutics Locator.

Additional questions about COVID-19 treatment options or availability can be sent to COVID19Therapeutics@health.ny.gov.