TABLE OF CONTENTS

22-622-cv; 22-692-cv

Roberts v. Bassett; *Jacobson v. Bassett*

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

SUMMARY ORDER

*** * * * ***

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 15th day of November, two thousand twenty-two.

PRESENT: JOSÉ A. CABRANES,

GERARD E. LYNCH,

BETH ROBINSON,

Circuit Judges.

JONATHAN ROBERTS and CHARLES VAVRUSKA,

Plaintiffs-Appellants, 22-622-cv

v.

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

Defendants-Appellees.

* * * * *

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

Plaintiff-Appellant, 22-692-cv

v.

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

Defendant-Appellee.

* * * * *

Appeals from a March 15, 2022 order of the United States District Court for the Eastern District of New York (Nicholas G. Garaufis, *Judge*) and an April 1, 2022 judgment of the United States District Court for the Northern District of New York (Mae A. D'Agostino, *Judge*).

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment and order of the District Courts be and hereby are **AFFIRMED**.

Plaintiffs Jonathan Roberts and Charles Vavruska sued the Commissioner of the New York State Department of Health ("State Defendant") and the New York City Department of Health and Mental Hygiene ("City Defendant"), alleging that Defendants' guidance on how to prioritize patients eligible for specified new COVID-19 treatments violates the Fourteenth Amendment. Plaintiff William A. Jacobson alleges the same of State Defendant's guidance and, further, that it violates Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d and Title I of the Affordable Care Act, 42 U.S.C. § 18116. The

District Courts dismissed both cases for lack of standing. Plaintiffs appeal.

We assume the parties' familiarity with the underlying facts, the procedural history of the cases, and the issues on appeal.

I. Background

In late 2021, the U.S. Food and Drug Administration ("FDA") authorized several new COVID-19 treatments for high-risk patients: a monoclonal antibody product, Sotrovimab, and two antiviral therapies, Paxlovid and Molnupiravir. These medications, the latter two of which must be taken within five days of symptom onset, were initially and briefly in short supply.

Soon after the FDA's authorizations, State Defendant published "guidance" instructing health-care providers on how to prioritize patients eligible for the new treatments during the supply shortage. It directed providers to assign patients to one of five descending risk groups depending on their vaccination status, age, and risk factors for severe COVID-19. Generally, patients with more risk factors were to be placed in a higher priority risk group and to receive priority within their respective risk groups. The guidance noted that "[n]on-white race or Hispanic/Latino ethnicity should be considered a risk factor." 22-692 J.A. 29–31. City Defendant issued and distributed to 75,000 email addresses an "advisory" instructing providers to follow State Defendant's guidance while a supply shortage persisted. Plaintiffs, who are white and not of Hispanic/Latino ethnicity, did not contract COVID-19 while the shortage continued and the guidance remained operative.

Plaintiffs allege three injuries. First, they allege that the guidance denies them equal access to the new COVID-19 treatments. Second, they contend that it increases their risk of severe illness.

Third, Plaintiff Jacobson argues that it harms him emotionally because the denial of automatic eligibility for treatment due to his race and ethnicity causes him heightened concern. Each alleged injury requires its own standing analysis, and we address each in turn.

II. Alleged Denial of Equal Access to Treatment

To establish constitutional standing, a plaintiff must demonstrate an (1) injury in fact that is (a) concrete and particularized and (b) actual or imminent, (2) fairly traceable to the challenged action of the defendant, and (3) likely to be redressed by a favorable decision. *See Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 560–61 (1992). We review *de novo* a district court's decision to grant a motion to dismiss for lack of standing. *See Chabad Lubavitch of Litchfield Cnty., Inc. v. Litchfield Historic Dist. Comm'n*, 768 F.3d 183, 191 (2d Cir. 2014). And "we 'accept [ ] all well-pleaded allegations in the complaint as true [and] draw [ ] all reasonable inferences in the plaintiff's favor.'" *Id.* (quoting *Bigio v. CocaCola Co.*, 675 F.3d 163, 169 (2d Cir. 2012)).

Upon review of the records, we conclude that Plaintiffs lack standing based on their alleged denial of equal access to treatment because they have not demonstrated an imminent injury in fact.

When the government "erects a barrier . . . mak[ing] it more difficult for members of one group to obtain a benefit than [another]," the "injury in fact . . . is the denial of equal treatment resulting from the

imposition of the barrier, not the ultimate inability to obtain the benefit." *Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 666 (1993). We have identified three elements necessary for standing under *Northeastern Florida Chapter*: "that (1) there exists a reasonable likelihood that the plaintiff is in the disadvantaged group, (2) there exists a government-erected barrier, and (3) the barrier causes members of one group to be treated differently from members of the other group." *Comer v. Cisneros*, 37 F.3d 775, 793 (2d Cir. 1994).

We assume *arguendo* that Plaintiffs have met their burden under *Comer*. But satisfying *Comer* does not mean Plaintiffs have demonstrated *all* that is required to establish an injury in fact. *Comer* helps define the contours of an injury in fact in the equal protection context. It does not, however, eliminate the requirement that the injury be "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)); *see also MGM Resorts Int'l Glob. Gaming Dev., LLC v. Malloy*, 861 F.3d 40, 47 (2d Cir. 2017).

Plaintiffs fail to satisfy the requirement that an injury in fact be actual or imminent. They suffered no actual injury because a provider neither delayed nor denied their COVID-19 treatment because of the guidance, which operated during the supply shortage. Their alleged denial of equal access to treatment, then, must be imminent. Imminent injuries cannot be "too speculative." *Lujan*, 504 U.S. at 564 n.2. And although "[a]n allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur," *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158

(2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 & n.5 (2013)), "a highly attenuated chain of possibilities[ ] does not satisfy the requirement that [a] threatened injury must be certainly impending," *Clapper*, 568 U.S. at 410.

A highly attenuated chain of possibilities is precisely what we have here. Plaintiffs must (1) test positive for COVID-19 (2) while there is a shortage of treatments specified by the guidance, (3) experience mild to moderate symptoms, (4) seek treatment, (5) within the appropriate time of symptom onset, (6) from a health-care provider (7) who adheres to the guidance and (8) resultingly declines or delays a specified treatment (9) because of Plaintiffs' race or ethnicity. The alleged injury in fact is not impending let alone "certainly impending," especially given the undisputed widespread availability of the specified treatments. *Clapper*, 568 U.S. at 410. Plaintiffs therefore lack standing to challenge the guidance they allege denies them equal access to treatment.

III. Alleged Increased Risk of Suffering Severe Illness

Plaintiffs also fail to demonstrate an injury in fact based on their alleged increased risk of severe COVID-19 because of the guidance. Plaintiffs rely primarily on *Baur v. Veneman*, which held that "exposure to an enhanced risk of disease transmission may qualify as injury-in-fact in consumer food and drug safety suits." 352 F.3d 625, 628 (2d Cir. 2003). We assume *arguendo* that *Baur* extends beyond such suits.[1]

---

[1] Like *Baur*, these cases involve probabilistic harm in a public health context. We have demonstrated a willingness to extend

The *Baur* plaintiffs faced an actual, increased risk of mad cow disease because they were exposed to potentially unsafe meat in the food supply. 352 F.3d at 640. Here, Plaintiffs would face an actual, increased risk of severe COVID-19 only once a provider denied or delayed treatment because of the guidance. No provider delayed or denied treatment, so the alleged *Baur* injury, if one exists, must be imminent.

An imminent *Baur* injury may arise when a plaintiff is imminently exposed to "a sufficiently serious [enhanced] risk of medical harm." *Id.* at 641. But to be imminently exposed to an enhanced risk of severe COVID-19, the attenuated chain of events listed above must occur. Because Plaintiffs cannot rely on an attenuated chain of possibilities to demonstrate an injury in fact, they again fail to establish standing.

IV. Plaintiff Jacobson's Alleged Emotional Injury

Plaintiff Jacobson further fails to establish standing based on his alleged emotional harm because it is not traceable to the guidance. To establish standing, "there must be a causal connection between

---

Baur to a non-consumer food and drug safety suit, but only in a non-precedential order. *See United States v. Evseroff*, 528 Fed. App'x 75, 77 (2d Cir. 2013) (summary order). Yet the cases before us do not present a "tight connection between the type of injury . . . allege[d] and the fundamental goals of the statutes" sued under—a factor that reinforced the *Baur* Court's conclusion that the plaintiff had alleged a cognizable injury. 352 F.3d at 635. For that reason, *Baur* does not determine the outcome here, even if that case extends beyond the food-and-drug context. Accordingly, we need not address the scope of the *Baur* holding here.

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 (quoting *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976)). Jacobson alleges that he experiences heightened daily concern because he is not automatically eligible for treatment solely because of his race and ethnicity. But the reason Jacobson, as a white, non-Hispanic/Latino man, lacks automatic eligibility for treatment is that the FDA—as informed by the Centers for Disease Control and Prevention—does not consider him a high-risk patient. In other words, it is the FDA's authorization, not State Defendant's guidance, that precludes his automatic eligibility on the basis of race and ethnicity. Absent traceability, Jacobson's alleged emotional injury is insufficient to establish standing.

CONCLUSION

We hold that Plaintiffs fail to establish standing to challenge State and City Defendants' December 2021 guidance on how to prioritize patients for specified COVID-19 treatments during a supply shortage. They fail to demonstrate an imminent injury in fact regarding their alleged denial of equal treatment and increased risk of severe illness. And Plaintiff Jacobson fails to demonstrate that his alleged emotional injury is traceable to the challenged guidance.

In reaching our conclusion, we emphasize that we have not considered the merits of Plaintiffs' appeals.[2]

---

[2] Judge Cabranes joins the judgment of the Court in full, but takes this opportunity to state his personal view: government "guidance" effectively directing health-care providers to

In sum, we have reviewed all of the arguments raised by Plaintiffs Roberts, Vavruska, and Jacobson on appeal and find them to be without merit. For the foregoing reasons, we **AFFIRM** the March 15, 2022 order of the U.S. District Court for the Eastern District of New York and the April 1, 2022 judgment of the U.S. District Court for the Northern District of New York.

FOR THE COURT:

Catherine O'Hagan Wolfe, Clerk of Court

s/ Catherine O'Hagan Wolfe

---

prioritize the treatment of patients based on race or ethnicity may indeed present portentous legal issues if challenged by plaintiffs with standing.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JONATHAN ROBERTS and CHARLES VAVRUSKA,

Plaintiffs,

-against-

MARY T. BASSETT, in her official capacity as Commissioner for NEW YORK STATE DEPARTMENT OF HEALTH, and the DEPARTMENT OF HEALTH AND MENTAL HYGIENE OF THE CITY OF NEW YORK,

Defendants.

MEMORANDUM & ORDER
22-CV-710 (NGG) (RML)

NICHOLAS G. GARAUFIS, United States District Judge.

Plaintiffs Jonathan Roberts and Charles Vavruska request that this court issue a preliminary injunction to enjoin Mary T. Bassett, the Commissioner of the New York State Department of Health (the "State Defendant") and the Department of Health and Mental Hygiene of the City of New York ("DOHMH" or the "City Defendant," collectively, "Defendants") from distributing COVID-19 treatments on the basis of race. For the reasons explained below, this court lacks subject matter jurisdiction over this dispute because Plaintiffs have not demonstrated Article III standing. Thus, as there is no case or controversy before this court, the court declines to consider

Plaintiffs' motion for a preliminary injunction, and the case is DISMISSED.

I. BACKGROUND

In December 2021, the Food and Drug Administration ("FDA") issued Emergency Use Authorization ("EUA") for several promising new oral antiviral therapies, including Paxlovid, Molnupiravir, and Sotrovimab (the "Treatments"), to treat COVID-19.[1] (State Def.'s Mem. in Opp. to Pl.'s Mot. for Prelim. Inj. at 2–3 (State's Opp.) (Dkt. 22).) The FDA authorized the Treatments for individuals "who are at high risk for progression to severe COVID-19."[2] The EUA provides that "information on medical conditions and factors associated with increased risk for progression to severe COVID-19" can be found on the "People with Certain Medical Conditions" page of the United States Centers for Disease Control and Prevention ("CDC") website.[3] During the Omicron surge this winter, there were shortages of the

---

[1] Sotromivab was the only authorized monoclonal antibody therapeutic expected to be effective against the Omicron variant.

[2] Food & Drug Admin., Emergency Use Authorization for Paxlovid (Dec. 22, 2021), https://www.fda.gov/media/155049/download; *see also* Food & Drug Admin., Emergency Use Authorization for Molnupiravir (Feb. 4, 2022), https://www.fda.gov/media/155053/download; Food & Drug Admin., Emergency Use Authorization for Sotrovimab (Feb. 23, 2022), https://www.fda.gov/media/149532/download; Food & Drug Admin., Frequently Asked Questions on the Emergency Use Authorization of Sotrovimab (Feb. 23, 2022), https://www.fda.gov/media/149535/ download.

[3] Ctrs. for Disease Control & Prevention, People With Certain Medical Conditions (Feb. 25, 2022), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

Treatments in New York. (Pl's Mem. in Supp. of. Mot. for Prelim. Inj. at 1 (Mot.) (Dkt. 19); State's Opp. at 3.) Given the limited supply of the Treatments, on December 27, 2021, the State Defendant and City Defendant published guidance for allocating them.

The State's guidance ("State Guidance"), which is addressed to "Health Care Providers and Health Care Facilities," informs providers that "[s]upplies of oral antivirals will be extremely limited initially." (Dec. 27, 2020 Mem. to Providers at 2 (Dkt. 1-4).) As a result, "[w]hile supplies remain low," providers are instructed to "adhere to the NYS DOH guidance on prioritization" and "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." (*Id.*)

The State Guidance provides that the Treatments are authorized for patients who (i) are twelve or older, (ii) test positive for COVID-19, (iii) have mild to moderate symptoms, (iv) are able to start treatment within five days of symptom onset, and (v) have a medical condition or other factors that increase risk for severe illness. (*Id.* at 3.) With respect to risk factors, the State Guidance explains that "[n]on-white 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." (*Id.*)

The State Guidance also includes a table that delineates how to prioritize distribution of the Treatments during "times of resource limitations." (Prioritization Guidance at 2 (Dkt. 1-5).) The table creates risk groups based on vaccination, age,

immunocompromised status, and a number of "risk factors for severe illness." (*Id.* at 3.) The Guidance provides a recommended approach and notes of prioritization for each risk group. At issue here is a note that provides 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." (*Id.* at 4.) Though the guidance does not explicitly define "risk factors for severe illness," it cites to the same CDC webpage with risk factors referenced in the FDA's EUAs. (*Id.*) Those federal risk factors include "racial and ethnic minority groups."

On March 4, 2022, the State Defendant issued new guidance, which advises that the Treatments are now ("widely available" and that the federal government's Test to Treat program, which began the week of March 7, 2022, "will provide increased availability of immediate testing and early treatment." (Mar. 4, 2022 State Guidance (Dkt. 31-1).)

The City's Health Advisory #39 (the "City Guidance") directs health care providers to "adhere to the New York State Department of Health . . . guidance on prioritization of high-risk patients . . . during this time of severe resource limitations." (Health Advisory #39 at 2 (Dkt. 1-6).) The City Guidance reiterates the eligibility criteria from the State Guidance and adds: "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." (*Id.* at 4.)

On February 1, 2022, the City Defendant issued Health Advisory #2, which superseded the challenged guidance. (March 2, 2022 Tr. 32:16–23.) The new advisory notes that the treatments are in stock, but that "supplies remain limited."[4]

Plaintiff Jonathan Roberts is a vaccinated 61-year-old non-Hispanic and white resident of Manhattan with no known risk factors; his co-Plaintiff Charles Vavruska is a vaccinated 55-year-old non-Hispanic and white resident of Queens, and is overweight or obese, which is considered a risk factor. (Mot. at 6.) Plaintiffs assert that they are entitled to access to the Treatments on an equal basis, without regard to their race. Roberts, who does not meet the eligibility requirements, contends that he is entirely denied access to the drugs. (*Id.* at 8.)

Plaintiffs allege that this scheme makes race determinative in two ways. First, among members in the same risk group, individuals who are non-white or Hispanic receive higher priority for treatment over those who are of the same age and have the same race neutral risk factors. (*Id.* at 4.) Second, being a member of any minority group could move an individual to a higher risk group. (*Id.*) On this basis, Plaintiffs contend that Defendants have violated the equal protection clause of the Fourteen Amendment in issuing the challenged guidance.

Defendants assert that the directives are merely guidance to be used in emergency periods of limited

---

[4] N.Y.C . Dep't of Health & Mental Hygiene, *Health Advisory #2: Paxlovid is Available for COVID-19 Treatment in New York City* (Feb. 1, 2022), https ://wwwl.nyc.gov /assets/ doh/ downloads/pdf/han/ advisory/ 2022/ covid-paxlovid-available. pdf.

supplies and do not supplant the judgment of a medical provider. (State's Opp. at 3.) They argue the guidance "simply provides medical practitioners with information about known risk factors for severe illness, hospitalization, and death, based on abundantly reported, objective, data." (*Id.* at 6.) Although Plaintiffs state that Roberts is categorically ineligible for the medication, Defendants maintain that "[n]othing in the . . . Guidance prevents the Plaintiffs . . . from receiving the Therapies . . . if their practitioner concludes that such treatment is clinically appropriate." (*Id.*)

Defendants further contend that there is no longer a shortage of the Treatments, and the guidance applied only "during [a past] *time* of severe resource limitations." (*Id.* at 16.) Plaintiffs counter that providers frequently report low stock and, given the unpredictability of the COVID-19 pandemic and the likelihood of future variants, a future shortage is not unlikely. (Mot. at 7, 9.)

On February 18, 2022, Plaintiffs moved for a preliminary injunction, seeking to enjoin Defendants from distributing the Treatments in accordance with the above guidance.

II. LEGAL STANDARD

"It is axiomatic that federal courts are courts of limited jurisdiction and may not decide cases over which they lack subject matter jurisdiction," *Lyndonville Sav. Bank & Tr. v. Lussier*, 211 F.3d 697, 700 (2d Cir. 2000), and "standing is perhaps the most important of the jurisdictional doctrines." *FW/PBS,*

Inc. v. City of Dallas, 493 U.S. 215, 231 (1990).[5] If a court does not have subject matter jurisdiction, the action must be dismissed. Fed. R. Civ. P. 12(h)(3); *Cave v. E. Meadow Union Free Sch. Dist.*, 514 F.3d 240, 251 (2d Cir. 2008) ("Appellants' motion for a preliminary injunction should therefore have been dismissed for lack of jurisdiction, rather than on the ground that appellants are unlikely to succeed on the merits of their action."). The party "invoking the authority of the court bears the burden of proof on the issue of standing." *Lee v. Bd. of Governors of the Fed. Reserve Sys.*, 118 F.3d 905, 910 (2d Cir. 1997).

To establish Article III standing, a plaintiff must show (1) an **i**njury 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).

III. DISCUSSION

A. Article III Standing

1. Injury in Fact

There are two components to establishing an "injury in fact." First, a plaintiff must show that the harm was concrete and particularized; and second, a plaintiff must show that the harm was actual or imminent. *See id.* at 560.

---

[5] When quoting cases, and unless otherwise noted, all citations and quotation marks are omitted, and all alterations are adopted.

a. Concrete and Particularized

The parties submit that in the equal protection context, the injury in fact "is the denial of equal treatment resulting from the imposition of [a] barrier," which "makes it more difficult for members of one group to obtain a benefit than it is for members of another group." *Ne. Fla. Chap. of Assoc. Gen. Contractors of Am. v. City of Jacksonville,* 508 U.S. 656, 666 (1993). The injury is not "the ultimate inability to obtain the benefit." *Id.* The Second Circuit has set forth the following criteria for establishing standing under the "barrier" standard, that: "(1) there exists a reasonable likelihood that the plaintiff is in the disadvantaged group, (2) there exists a government-erected barrier, and (3) the barrier causes members of one group to be treated differently from members of the other group." *Comer v. Cisneros,* 37 F.3d 775, 793 (2d Cir. 1994).

The court accepts that to the extent there is a group that is "disadvantaged" by Defendants' guidance, there is a reasonable likelihood that Plaintiffs, as white and non-Hispanic individuals, are members of the group. But the court is not convinced that Plaintiffs have shown the challenged guidance either constitutes a barrier or causes one group to be treated differently from another.

b. Existence of a Government-Erected Barrier

The "barrier" concept described in *City of Jacksonville* has its roots in *Regents of University of California v. Bakke*, in which the Supreme Court explained that, in the affirmative action context, a plaintiff's injury was his inability "to compete for all 100 places in the class." 438 U.S. 265, 280 n.14 (1978).

The impetus behind this standard was to save those plaintiffs from having to affirmatively show that they would have obtained the benefit but for the barrier—in *Bakke*, that the applicant would have otherwise been admitted to medical school. However, the barrier standard does not dispense with the Article ill injury requirement; a policy or program is only a "barrier" if it denies plaintiffs equal treatment in some manner.

In *Bakke* and *City of Jacksonville*, the Court found that a barrier existed because the policies at issue set aside a predetermined number of spots or amount of funding for individuals from underrepresented groups; in effect, they created quotas. *See City of Jacksonville*, 508 U.S. at 658 (10% of amount spent on city contracts set aside for "Minority Business Enterprises"); *Bakke*, 438 U.S. at 266 (16 out of 100 places in the medical school class reserved for "minority" students). Thus, these barriers denied plaintiffs equal treatment because fewer spots or less funding were accessible to them than a similarly situated underrepresented candidate.

The Court has explicitly employed the barrier approach to standing on only a few occasions in majority opinions since *City of Jacksonville.* First, in *Adarand Constructors, Inc. v. Pena,* a subcontractor alleged racial discrimination stemming from a government program, which provided compensation to contractors if they hired small businesses controlled by "socially and economically disadvantaged individuals," defined as "Black Americans, Hispanic Americans, Native Americans, Asian Pacific Americans, and other minorities, or any other individual found to be disadvantaged by the Small Business Administration." 515 U.S. 200, 205

(1995).[6] The Court found that the plaintiff had standing to seek prospective relief because the ((discriminatory classification prevents the plaintiff from competing on an equal footing." *Id.* at 211. Like the *City of Jacksonville* scheme, which rendered a pot of funds accessible to underrepresented candidates but entirely inaccessible to the plaintiffs, the government program in *Adarand* awarded funds only to members of disadvantaged groups.

A decade after *City of Jacksonville,* in *Gratz v. Bollinger,* the Court revisited the barrier standard. 539 U.S. 244 (2003).[7] The relevant University of Michigan admission policy provided that

---

[6] Other regulations provided for the inclusion of women and other socially or economically disadvantaged individuals in this program. *See id.* at 208.

[7] Plaintiffs note *Gratz*'s companion case, *Grutter v. Bollinger,* as support for their conception of standing in the context of the equal protection clause. 539 U.S. 306 (2003). In *Grutter,* the Court noted that the plaintiff "clearly has standing" and cited *City of Jacksonville*, but it neither mentioned the barrier standard nor provided further analysis, and standing was not addressed in by the lower court decisions. *Id.* at 317. Without more from the Court, it is difficult to know whether the decision to find standing rested on the barrier standard or some other standard and why the Court determined there was standing. Undoubtedly, the permissible race-conscious law school admissions policy in *Grutter* is more similar to the challenged guidance in this case than the other barrier cases that the Court has considered. Still, the court is not troubled by any apparent similarities in the nature of the barrier. Even if the challenged guidance did constitute a "barrier," Plaintiffs' claim is neither concrete and particularized nor actual or imminent, whereas Grutter's injury clearly was: She had personally been rejected from the University of Michigan Law School and sought, among other relief, compensatory and punitive (rather than nominal) damages in addition to an order requiring the institution to offer her, personally, admission. *See id.*

"underrepresented minority freshman applicants receive 20 points" of the 100 points needed to guarantee admission. *Id.* at 266.[8] This undergraduate admission policy was similar to the scheme in *Adarand* in that 20 points, or 20% of the total points needed to gain admittance, were offered *only* to underrepresented minorities. Because the points were completely unavailable to applicants who were not underrepresented minorities, the Court held that plaintiffs were denied equal treatment in the admissions process.

Finally, in *Parents Involved in Community Schools v. Seattle School District 1*, the Court again alluded to *City of Jacksonville*'s barrier standard in holding that

---

[8] The standing analysis was complicated in this case because the class representative, after being rejected from the University of Michigan, alleged in the complaint that he intended to transfer jf the "discriminatory" admissions policy was eliminated. *Gratz,* 539 U.S. at 283 (Stevens, J., dissenting). But the transfer policy, which the Court summarized as "all minimally qualified minority transfer applicants [we]re admitted outright," *id.* at 266, was not before the Court. (Nor was it discussed in the lower court opinions). The Court found that the transfer student had standing to request prospective relief as it related to the undergraduate policy because it was so similar to the transfer policy. *Id.* (explaining that the sole differences between the two processes were the fact that the freshman program used the 20-point system, whereas "virtually all . . . minimally qualified" underrepresented transfer students were admitted). Thus, the fact that the class representative was a transfer student seeking prospective relief as it related to the undergraduate admissions policy "clearly ha[d] no effect on petitioners' standing to challenge the University's use of race in undergraduate admissions." *Id.* While the Court's barrier analysis focused more on the actual or imminent prong, it is clear that the barrier for standing purposes was the undergraduate admission policy, not the transfer policy.

"being forced to compete in a race-based system that may prejudice the plaintiff" can constitute an equal protection injury. 551 U.S. 701, 719 (2007). The scheme in *Parents Involved* classified children based on their race, which the school districts "relie[d] upon . . . in assigning [the] student to a particular school, so that the racial balance at the school [fell] within a predetermined range based on the racial composition of the school district as a whole." *Id.* at 709. In effect, the school district again had created racial quotas along the lines of the scheme challenged in *Bakke,* making certain spots *completely unavailable* to white students, thus denying them equal treatment.

This review of the Court's racial discrimination jurisprudence under the barrier standard makes clear that the types of policies and programs previously found to be barriers are different than the State and City Guidance at issue in this case. Here, the guidance does not set aside a predetermined number of pills for nonwhite and Hispanic New Yorkers. The guidance does not advise providers to automatically dispense pills to nonwhite and Hispanic patients on the basis of race or ethnicity. Nor does it set a threshold—or even target—number of points in order to obtain the Treatments or give some predetermined percentage of such points to nonwhite and Hispanic patients. It is, rather and emphatically, *guidance*. Defendants' documents are nonbinding and have no mechanism for present or future enforcement. The guidance merely advises providers to consider race and ethnicity as one of many factors in assessing the patient before them, consistent with medical evidence and with the limited FDA EUAs for the Treatments. Nor are medical practitioners akin to educational institutions or governmental agencies reviewing a

total set of applicants and comparing them to one another to determine who qualifies for a benefit. Instead, *individual practitioners*, third parties otherwise unconnected to Defendants, make individualized assessments of each of *their own* patients and decide on an appropriate course of treatment. The court is skeptical that the injury alleged here constitutes a barrier under the Supreme Court's previous decisions given these important distinctions. However, even if it did, *City of Jacksonville* emphasizes the importance of finding that a barrier impacted the plaintiffs personally, and as discussed in the following sections, Plaintiffs have alleged neither a concrete and particularized nor actual or imminent injury.

c. *Impact of the Alleged Barrier on Different Groups*

As to the third element set forth in *Cisneros*, Plaintiffs also must show that the challenged guidance causes them to be treated differently than members of other groups. But Plaintiffs fail to show that their injury is anything more than a generalized grievance.

Although the court acknowledges that the injury in fact requirement "is not as stringent in Equal Protection cases, a plaintiff still must establish that she has suffered *some* sort of identifiable harm." *Youth Alive v. Hauppauge Sch. Dist.*, No. 08-CV-1068 (NGG) (VMS), 2012 WL 4891561, at *2 (E.D.N.Y. Oct. 15, 2012). This is particularly true in light of the Supreme Court's recent decision in *Spokeo v. Robins,* which emphasized the "concreteness" and "particularization" elements of an injury in fact. As Justice Alito explained for the Court, an injury "must affect the plaintiff in a personal and individual way"

and must also be concrete, "that is, it must actually exist." 578 U.S. 330, 339–340 (2016). Thus, for example, the Court has declined to find standing where plaintiffs alleged an injury based on the IRS's grant of a tax-exemption to a racially discriminatory school. *See Allen v. Wright*, 468 U.S. 737, 755–56 (1984). The court explained that there had been merely an "abstract stigmatic injury," and were the court to permit plaintiffs to proceed on that basis, "[a] black person in Hawaii could challenge the grant of a tax exemption to a racially discriminatory school in Maine." *Id.* at 756.

Consistent with this requirement, the Court has "refused to recognize a generalized grievance against allegedly illegal governmental conduct as sufficient for standing." *United States v. Hays*, 515 U.S. 737, 743 (1995). This rule that generalized grievances cannot satisfy Article III standing "applies with as much force in the equal protection context as in any other." *Id.* Where the government allegedly discriminates on the basis of race, "the resulting injury accords a basis for standing only to those persons who are *personally denied* equal treatment by the challenged discriminatory conduct." *Id.* at 743–744 (emphasis added); *see also Carney v. Adams*, 141 S.Ct. 493, 502 (2020) ("[Plaintiff] has not sufficiently differentiated himself from a general population of individuals affected in the abstract by the legal provision he attacks."). In accordance with the Court's generalized grievance jurisprudence, courts in this district applying the barrier standard have looked for some type of identifiable harm. *See, e.g.*, *Evans v. Port Auth. of N.Y. & N.J.*, 15-CV-3942 (MKB), 2017WL 3396444, at *5–6 (E.D.N.Y. Aug. 8, 2017) (holding that plaintiffs did not show "that they have been injured in

a personal and individual way" where employing the barrier standard); *Credico v. N.Y. State Bd. of Elections*, No. 10-CV-4555 (RJD) (CLP), 2013 WL 3990784, at *8–*9 (E.D.N.Y. Aug. 5, 2013) (analyzing whether the alleged barrier imposed a concrete injury on plaintiffs); *Youth Alive*, 2012 WL 4891561, at *3 (finding that the the challenged practice "had no discernible impact on Plaintiffs' ability to exercise their First Amendment rights").

Plaintiffs have not explained how nonbinding guidance that directs medical practitioners to consider race and ethnicity as one factor in prescribing the Treatments impacts them in some concrete and particularized manner. Plaintiffs never contracted COVID-19 nor sought out the Treatments during the period of shortage. Plaintiffs have proffered no evidence beyond the mere existence of the nonbinding guidance to demonstrate that Plaintiffs or any other white, non-Hispanic person (who, in any event, is not before this court) have faced a barrier "that actually exists" to obtaining the Treatments on the basis of their race. Plaintiffs have not even alleged that during the period of shortage that any person whatsoever was denied the Treatments. This action, then, "resembles a complaint asserting that the plaintiffs chances of winning the lottery were reduced, filed by a plaintiff who never bought a lottery ticket, or who tore it up before the winner was announced." *Clinton v. City of N.Y.,* 524 U.S. 417, 458 (1998) (Scalia, J., concurring). Indeed, it is not clear the lottery ever took place.

At this stage, any "injury" is, at most, the type of "abstract stigmatic harm" that the Court rejected in *Allen*. That conclusion is buttressed by Plaintiffs'

request for only nominal damages. If the court were to accept this conception of an injury in fact, it would be opening its doors to the type of generalized grievances that "transform the federal courts into no more than a vehicle for the vindication of the value interests of concerned bystanders." *Allen*, 468 U.S. at 756. It would be permitting millions of not-yet-injured New Yorkers to sue Defendants.

Without evidence of the impact of this alleged barrier in practice and how it has denied these particular Plaintiffs equal treatment, the court is unable to find that this injury is sufficiently concrete or particularized to constitute an Article III injury.

d. Actual or Imminent

Even if this court were to find that Plaintiffs' alleged barrier was sufficiently concrete and particularized, the injury must also be actual or imminent to constitute an injury in fact. *See Lujan,* 504 U.S. at 560. Plaintiffs are not permitted to rely on a "speculative chain of possibilities," particularly where they involve "the unfettered choices made by independent actors not before the court." *Clapper v. Amnesty Int'l USA,* 568 U.S. 398, 414 & n.5 (2013). Instead, the injury must be "certainly impending." *Id.* at 410. Plaintiffs appear to argue that somehow the Court's holding in *Clapper* cannot apply in the equal protection context, because the injury "is not the ultimate denial of the treatments, but the government-imposed barriers to obtaining those treatments." (Pl.'s Reply in Supp. of Mot for Prelim. Inj. at 5 ("Reply") (Dkt. 27).) But even in barrier cases, courts must still inquire into whether the injury is "imminent" or "certainly impending." *MGM Resorts*

Int't Glob. Gaming Dev., LLC v. Malloy, 861 F.3d 40, 46–47 (2d Cir. 2017).

In *City of Jacksonville*, the Court found that the barrier injury was sufficiently actual or imminent where plaintiffs "regularly bid on contracts in Jacksonville and would bid on those that the city's ordinance makes unavailable to them." 508 U.S. at 668. Likewise, in *Adarand*, the Court accepted the imminence of the injury because the plaintiff's general manager testified that the company had bid on every guardrail project in the state. 515 U.S. at 212. Conversely, the Second Circuit did not find imminence where a plaintiff was merely "interested" in exploring an opportunity and "made initial studies of . . . viability." *Malloy*, 861 F.3d at 47. This is because the competition was "purely abstract," and there was not yet an "uneven playing field." *Id.* at 51; *see also Carney*, 141 S.Ct. at 501–03 (contrasting the plaintiffs "few words of general intent" about applying for a judgeship with "similar cases . . . contain[ing] more evidence that the plaintiff was 'able and ready'" to apply, including *Adarand*, *City of Jacksonville*, and *Gratz*). The lesson from these cases is plain: A plaintiff is not injured by the mere existence of a barrier denying equal treatment, but must also show that the barrier threatens to wreak harm that is actual or imminent *to them*. Unlike the plaintiffs in the Supreme Court's barrier cases, Plaintiffs' attempts here to "compete" for the benefit of the Treatments are "still entirely conjectural." *Malloy*, 861 F.3d at 51.

With respect to Plaintiffs' request for prospective relief, the court agrees with Plaintiffs that it is impractical to wait until a person has tested positive for COVID-19 to file suit challenging the guidance.

(Mot. at 9.) But in order to justify injunctive relief, even assuming they were injured in the past, Plaintiffs must at very least be able to establish a likelihood they will be subject to the same treatment in the future. *See City of Los Angeles v. Lyons,* 461 U.S. 95, 111 (1983). In this period of surplus, however, the State Guidance is not in effect, and the City Guidance has been superseded. Although Plaintiffs argue that a future shortage is likely in light of the unpredictability of the COVID-19 virus and possible variants, a possibility the court acknowledges, the federal government has announced that Pfizer alone-the manufacturer of only one of the three Treatments-will provide "1 Million pills this month and more than double that next month."[9] At this rate of production, as compared to the current COVID-19 case counts, the possibility of a future shortage appears increasingly speculative and nowhere near imminent. Further, there is no indication that future variants will be responsive to the Treatments. There would at least have to be a future shortage; the State Guidance would have to come back into effect; and the City would have to issue new guidance using race and

---

[9] The White House, Remarks of President Joe Biden - State of the Union Address As Prepared for Delivery (Mar. 1, 2022), https:// www.whitehouse.gov/briefing-room/speeches-remarks/ 2022/03/01/remarks-of-president-joe-biden-state-of-the-unionaddress-as-delivered/; *see also* Press Release, *Pfizer to Provide U.S. Government with an Additional 10 Million Treatment Courses of its Oral Therapy to Help Combat COVID-19* (Jan. 4, 2022), https://www .pfizer.com/news/press-release/press-release-detail/pfizer-provide-us-government-additional-10-million (announcing that Pfizer will supply the federal government with 20 million Paxlovid treatment courses, half of which will be delivered by the end of June 2022).

ethnicity in a similar manner to the superseded guidance. None of these events are imminent.

Turning to Plaintiffs' request for retrospective relief for the period in which the challenged guidance was in place, to incur even nominal damages, the Plaintiffs would have had to actually run up against the alleged barrier and experience a denial of equal treatment. *See City of Jacksonville*, 508 U.S. at 666 (injury is "the denial of equal treatment *resulting from* the imposition of the barrier" (emphasis added)). First, Plaintiffs, who are both vaccinated, would have needed to contract COVID-19. Second, they would have needed to seek out the Treatments from a medical provider. Third, the medical provider would have needed to rely on the nonbinding guidance to determine whether to prescribe the Treatments. Fourth, and finally, that provider would have needed to apply the guidance in such a manner so as to deny Plaintiffs equal treatment. This requisite chain of events demonstrates that Plaintiffs' allegation of injury is "too speculative to satisfy the well-established requirement that threatened injury must be certainly impending." *See Clapper*, 568 U.S. at 401. Plaintiffs have not yet come anywhere close to arriving at the "uneven playing field," let alone attempted to compete on it. *Malloy*, 861 F.3d at 51. This is not to say that Plaintiffs would have to show they had laced up for a game they were destined to lose, but the game itself would have had to at least been played. Because it never was, Plaintiffs fail to allege an injury that is actual or imminent.

Since Plaintiffs fail to allege an injury that is concrete and particularized and actual or imminent, Plaintiffs cannot satisfy the injury in fact

requirement. Accordingly, the court finds that Plaintiffs lack standing on this ground.

2. Traceability

Even assuming Plaintiffs could establish an injury in fact, they would need to establish traceability-that there be a "causal connection between the injury and the conduct complained of," which should not be "the result of the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560. The "line of causation" between the allegedly unconstitutional conduct and the plaintiffs injury may not be "too attenuated." *Allen*, 468 U.S. at 752, 759; *see also Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 42–43 (1976) ("It is purely speculative whether the denials of service specified in the complaint fairly can be traced to [IRS] 'encouragement' or instead result from decisions made by the hospitals without regard to the tax implications."). Although a plaintiff "need not allege that a defendant's challenged actions were the very last step in a chain of events leading to an alleged injury," they must at least "plead facts indicating that a defendant's actions had a determinative or coercive effect upon the action of someone else who directly caused the alleged injury." *Nat'l Council of La Raza v. Mukasey*, 283 F. App'x 848, 851 (2d Cir. 2008) (summary order) (citing *Bennett v. Spear,* 520 U.S. 154 (1997)). In *La Raza,* the Second Circuit found that the federal government's policy and practice of entering civil immigration records into criminal records databases, which were then accessible by state and local law enforcement agencies, was not sufficiently "determinative or coercive" where no "adverse consequences" resulted from resistance to the policy. *Id.* at 852. In reaching

this decision, the *La Raza* panel distinguished the Supreme Court's decision in *Bennet*, 520 U.S. at 170, where a Fish and Wildlife Services opinion by contrast could result in "substantial civil and criminal penalties." *Id.*

Because the injury alleged here is unequal treatment *as a result* of the nonbinding guidance, the hypothetical injury occurs at the point that medical practitioners make decisions in reliance on the guidance. The traceability question—insofar as the injury traces back to Defendants—then hinges upon whether the challenged guidance had a "determinative or coercive effect" upon medical practitioners. Plaintiffs contend that even if the challenged guidance "do[es] not expressly provide for a penalty . . . the Supreme Court 'appears willing to presume that the government will enforce the law as long as the relevant statute is recent and not moribund.'" (Mot. at 10 (*quoting Hedges v. Obama*, 724 F.3d 170, 197 (2d Cir. 2013)).) While conceding that the injury may also be attributable to providers, Plaintiffs maintain that the injury is still "fairly traceable" to Defendants. (*Id.*) In response, State Defendant explains that practitioners make independent judgments, so any hypothetical scenario in which Plaintiffs were unable to get a prescription for the Treatments would not be traceable to the challenged guidance. (State Opp. at 15.) Plaintiffs counter that the State "cannot blame physicians or practitioners if they follow the government-created guidance." (Reply at 5.)

Hedges, however, describes the Court's approach to pre-enforcement challenges to laws. This case, by contrast, challenges nonbinding guidance, not law,

and it does not do so in a pre-enforcement posture. The court is therefore unwilling to presume, as in *Hedges*, that a law is likely to soon be enforced when it is not even clear whether the challenged guidance ever will be, or ever *can* be. Indeed, there are no penalties for failure to abide by the guidance, nor is there any enforcement mechanism in place. Given that practitioners ultimately impose any alleged denial of equal treatment, and the nonbinding guidance has no "determinative or coercive effect" on these practitioners, the court finds that Plaintiffs lack standing on this alternative ground.

3. Redressability

The final element of standing is redressability. Plaintiffs must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561. The Supreme Court has distinguished between redressability in the context of "identifiable Government violations of law" and lawsuits "challeg[ing] a more generalized level of Government action." *Id.* at 568 (distinguishing between challenging "decisions to fund particular projects allegedly causing [plaintiffs] harm" and an agency regulation). Where, as here, plaintiffs elect to challenge the latter, the Court has expressed that "[s]uch suits, even when premised on allegations of several instances of violations of law, are rarely if ever appropriate for federal-court adjudication." *Allen*, 468 U.S. at 759–60. This is particularly true in cases where the individual or entity directly inflicting the injury, *i.e.* the medical provider, is not a party. The court can "accord relief only against" parties to the suit. *Lujan*, 504 U.S. at 568.

Courts in the Second Circuit have put the onus on Plaintiffs to show that withdrawing guidance impacting third parties would redress their injuries. In *Town of Babylon v. Federal Housing Finance Agency*, the Town of Babylon and the National Resources Defense Council alleged that a Federal Housing Finance Agency directive and Office of Comptroller of the Currency ("OCC") bulletin adversely impacted certain clean energy programs. 699 F.3d 221, 224 (2d Cir. 2012). The court assessed whether plaintiffs had standing to challenge the OCC Bulletin for allegedly altering the lending practices of national banks, which were not party to the litigation. *Id.* at 229–30. Focusing on the fact that "[n]othing in the OCC Bulletin compelled national banks to take any action," and that it was "Supervisory Guidance," the court found that plaintiffs failed to show that the "national banks regulated by the OCC would act differently were the OCC Bulletin vacated." *Id.* Lower courts in the Second Circuit have taken a similar approach. *See, e.g.*, *Doe v. U.S. Secy of Transp.*, No. 17-CV-7868 (CS), 2018 WL 6411277, at *6 (S.D.N.Y. Dec. 4, 2018) ("Plaintiffs . . . allege that airlines and hotels have explained that they are required to allow dogs on their premises due to federal regulations, but that does not equate to an allegation that, absent the regulations, the regulated entities would exclude service animals."); *Town of Southold v. Town of E. Hampton*, 406 F. Supp. 2d 227,236 (E.D.N.Y. 2005) ("Since ferry operators rather than the Town Plaintiffs are the objects of the Ferry Law, and the Town Plaintiffs can show neither that the Ferry Law caused their alleged injury nor that these alleged injuries would be redressed by a favorable decision, they do not satisfy the Article III standing

requirements."), *affd & rev'd on other grounds*, 477 F.3d 38, 46 (2d Cir. 2007).

Here, Plaintiffs challenge broad nonbinding guidance rather than an "identifiable Government violation of the law." *See Lujan*, 504 U.S. at 568. The "regulated parties" under the guidance are medical providers in New York who implement the guidance and thereby inflict the alleged injury. These providers are not before this court, and as a result, the court is not able to control their activities. Thus, Plaintiffs must show the court that providers would behave differently in the absence of the guidance. Plaintiffs have not done so.

Moreover, as the State Defendant has pointed out, in the absence of the State and City guidance, many elements of the guidance would *certainly* remain in place. *Cf. Town of Babylon,* 699 F.3d at 230. Based on the court's understanding of the FDA's EUAs, Plaintiff Roberts would be in the exact same situation in the absence of the guidance. The EUAs for the Treatments are limited to individuals with a high risk of developing severe COVID-19, as defined by the CDC's risk factors. Roberts alleges that he has none of these risk factors. (Compl. ¶ 39.) Thus, with or without this policy, Roberts faces a complete barrier to obtaining the Treatments. Even if he were eligible under the EUAs, Plaintiffs have not alleged how practitioners would act in the absence of the guidance. They allege that the "CDC Guidance does not employ race in the same way as the directives" without explaining further. (Reply at 5.) As the court sees it, though, the EUAs directly point providers to the CDC risk factors, which themselves include the consideration of race and ethnicity. Providers could be

expected to follow the CDC guidance and other available scientific and medical research about the nature of race and ethnicity as risk factors. Thus, it is not clear that they would behave differently in the absence of the challenged guidance.

Plaintiffs have not shown it is likely that that their injuries will be redressed by a favorable decision. Thus, the court finds yet another reason that they do not have standing.

IV. CONCLUSION

For the reasons explained above, all claims against Defendants are DISMISSED without prejudice.

SO ORDERED.

Dated: Brooklyn, New York
March 15, 2022

s/ Nicholas G. Garaufis
United States District Judge

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

JONATHAN ROBERTS and CHARLES VAVRUSKA,

Plaintiffs,

v.

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.

Case No. 1:22-cv-00710

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Amidst a surge in cases involving the Omicron variant of COVID-19 in December 2021, the U.S. Food and Drug Administration granted emergency approval for an oral antiviral hailed as "the biggest advance in the pandemic since the vaccines."[1] The antiviral has been in development since March 2020, when Pfizer sent chemist Dafydd Owen home with instructions to develop an oral drug to fight the emerging pandemic. For the next 13 months, Owen

[1] Andrea Kane and Nadia Kounang, *Pfizer's Covid-19 antiviral pill was hailed as a game-changer, but supplies are scarce*, CNN, Jan. 12, 2022, https://www.cnn.com/2022/01/12/health/paxlovid-pfizerantiviral- scarce/index.html.

worked in a makeshift office in his home to develop the drug—building on the work his colleagues had produced nearly two decades earlier in the fight against SARS. In December 2021, the FDA finally granted emergency use authorization for his brainchild: Paxlovid. An "antiviral superstar," the drug "reduces the rate of hospitalizations by around 90%" with "no safety issue beyond placebo."[2] By interfering with the virus's ability to replicate, the drug could "prevent more than a million hospitalizations," and has potential to reduce transmission, which would avert "myriad disruptions such as medical professional shortages, school closings and flight cancellations."[3]

2. Despite plans to ramp up production, supplies are currently scarce. Thus, both the State of New York and New York City instruct providers to follow the state's directive for allocating scarce COVID-19 treatments—oral antivirals Paxlovid and Molnupiravir as well as monoclonal antibodies. The directives require providers to prioritize treatment to individuals based on age, vaccination status, and a number of risk factors. Risk factors include medical conditions such as cancer, chronic disease, diabetes, and obesity. The directives also state that, apart from any medical condition, non-white race or Hispanic/Latino ethnicity must be considered as an independent risk factor. As a result, an unvaccinated 64-year-old African American with diabetes receives priority over an unvaccinated white 64-year-old with diabetes. A vaccinated 66-year-old who is Hispanic

---

[2] *Id.*
[3] *Id.*

receives priority over a vaccinated 66-year-old who is not.

3. New York's designation of race as an independent risk factor has no basis in science. Although race may be associated with different risk factors, New York has cited no evidence that race—on its own—makes an individual more susceptible to suffering adverse effects from COVID-19. Indeed, that evidence does not exist, because race does not connote any attribute inherent to any individual. It is instead an arbitrary classification that lumps in many different individuals with different attributes and different needs.

4. New York's designation of race as an independent risk factor deprives deserving individuals of much-needed medical treatments solely due to their race. A white, non-Hispanic person with cancer is treated the same as a non-white or a Hispanic person who is disease-free.

5. Plaintiffs are New York residents who object to differential treatment on the basis of race and seek access to treatment on a race-neutral basis. Plaintiff Jonathan Roberts' mother immigrated from Hungary to escape antisemitic sentiments prevalent in Europe at the time. Mr. Roberts has lived in New York for almost his entire life and happily calls New York City "home" with his wife of over thirty years. Plaintiff Charles Vavruska is vaccinated and wishes not to repeat his experience in March 2020 when he was hospitalized for ten days with COVID-19. Plaintiffs are all Americans. Plaintiffs are all New Yorkers. As then-Mayor-elect Eric Adams stated in December

2020: "We are in this together."[4] Not so, under New York's directives. "It is a sordid business, this divvying us up by race." *League of United Latin Am. Citizens v. Perry*, 548 U.S. 399, 511 (2006) (Roberts, C.J., concurring in part, concurring in the judgment in part, and dissenting in part).

JURISDICTION AND VENUE

6. This action arises under the Fourteenth Amendment to the United States Constitution and 42 U.S.C. § 1983. This Court has jurisdiction over this federal claim under 28 U.S.C. §§ 1331 (federal question) and 1343(a) (redress for deprivation of civil rights). Declaratory relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

7. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) on the grounds that a substantial part of the acts giving rise to Plaintiffs' claim occurred in New York, and because one of the Defendants resides in this district and all Defendants are residents of the state in which the district is located.

PARTIES

8. Plaintiff Jonathan Roberts is a resident of Manhattan, New York. He is white and not Hispanic, 61 years old, vaccinated against COVID-19, and has no known risk factors for severe illness that could result from COVID-19. Mr. Roberts does not therefore qualify for inclusion in any tier of the "risk groups" established by the New York State Department of Health or New York City's Department of Health and

[4] City of New York, Transcript: Mayor de Blasio Holds Media Availability (Dec. 19, 2021), https://www1.nyc.gov/office-of-the-mayor/news/842-21/transcript-mayor-de-blasio-holds-media-availability

Mental Hygiene for prioritization of certain COVID-19 treatments. If he were any race but white, he would qualify for the last tier (1E) of the risk groups.

9. Plaintiff Charles Vavruska is a resident of Queens, New York. A lifelong resident of New York, Mr. Vavruska is white and not Hispanic, 55 years old, and vaccinated against COVID-19. In March 2020, Mr. Vavruska contracted COVID-19 and was hospitalized for 10 days. He has at least one risk factor (overweight and obesity) for severe illness that could result from another bout with COVID-19. Mr. Vavruska therefore qualifies for inclusion in the last tier (1E) of the risk groups for prioritization of certain COVID-19 treatments.

10. Both Plaintiffs want the ability to access oral antiviral or monoclonal antibody treatments on an equal basis, without regard to their race, if they contract COVID-19.

11. Defendant Mary T. Bassett is sued in her official capacity as Commissioner for the New York State Department of Health, pursuant to *Ex parte Young*, 209 U.S. 123 (1908), for acting under color of state law in directing New York State health care providers and facilities to use a patient's race as a factor in prioritizing the administration of certain COVID-19 treatments.

12. Defendant Department of Health and Mental Hygiene of the City of New York ("NYC Health") is sued pursuant to 42 U.S.C. § 1983 for its policy directing New York City health care providers and facilities to use a patient's race as a factor in prioritizing the administration of certain COVID-19 treatments. *See Pizarro v. Ponte*, No. 17-cv-4412, 2019

WL 568875, at *7 n.11 (S.D.N.Y. Feb. 11, 2019) ("[Department of Health and Mental Hygiene] is a suable entity."); *Monell v. Dep't of Social Servs*, 436 U.S. 658, 694 (1978).

FACTUAL ALLEGATIONS

State Directive

13. On January 11, 2022, New York was in the middle of a surge in COVID-19 cases prompted by the new Omicron variant. Acting Commissioner Janet Woodcock of the United States Food and Drug Administration stated that "most people are going to get covid." Aaron Blake, *"Most people are going to get covid": A momentous warning at a Senate hearing*, Washington Post (Jan. 11, 2022).[5]

14. At about the same time, New York noted that there were "severe supply shortages for all COVID-19 outpatient therapeutics."[6] The most effective oral antiviral, Paxlovid, "go[es] out of stock frequently."[7]

15. Pursuant to its statutory authority, N.Y. Pub. Health Law § 201(1), (3), on December 27, 2021, the New York Department of Health published a document directed to New York health care providers and health care facilities titled, "COVID-19 Oral Antiviral Treatments Authorized and Severe

---

[5] *Available at* https://www.washingtonpost.com/politics/2022/01/11/most-people-are-going-get-covid-momentous-warning-senate-hearing/.

[6] https://coronavirus.health.ny.gov/monoclonal-antibody-therapeutics (State website); https://www1.nyc.gov/site/doh/covid/covid-19-providers-treatments.page#refer (City website).

[7] https://www1.nyc.gov/site/doh/covid/covid-19-providers-treatments.page#refer.

Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." Exh. A. The document was published on the Department's website on a page dedicated to the Department's "COVID-19 Guidance Documents." *See* https://coronavirus.health.ny.gov /covid-19-guidancerepository.

16. The purpose of the document is to apprise health care providers and facilities of approved, highly effective oral antiviral and monoclonal antibody treatments for COVID-19, *see supra* ¶ 1, and to direct them to prioritize administration of those treatments due to supply shortages.

17. In setting out the eligibility criteria for the oral antiviral treatments, the Department lists a number of risk factors. Among the risk factors listed are age, vaccination status, chronic kidney disease, heart disease, cancer, and "[n]on-white race or Hispanic/Latino ethnicity."

18. The Department states that "[n]on-white race or Hispanic/Latino ethnicity" is a risk factor because "longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19."

19. The Department further directs health care providers and facilities to prioritize their use of COVID-19 treatments according to the Department's prioritization guidance, which is contained in a document titled, "Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations." Exh. B ("Guidance").

20. The Guidance sets out five "risk groups" (1A-1E), with "[p]atients assigned to 1A [ ] be[ing]

considered the highest priority, with 1B being the next highest priority and so on."

21. Group 1A includes individuals of "any age with moderate to severe immunocompromise regardless of vaccine status," or "Age 65 and older and not fully vaccinated with at least one risk factor for severe illness," or "Age 65 or older that is a resident of a long-term care facility environment."

22. Group 1B includes persons "under 65 years of age and not fully vaccinated with two or more risk factors for severe illness or over 65 and not fully vaccinated (no risk factors.)."

23. Group 1C includes persons "under 65 years of age and not fully vaccinated with at least one risk factor for severe illness."

24. Group 1D includes individuals "over age 65 and fully vaccinated with at least one risk factor for severe illness."

25. Group 1E includes persons "under 65 years of age and fully vaccinated with at least one risk factor for severe illness or age 65 and older and fully vaccinated with no other risk factors."

26. The Guidance also provides for prioritizing within each risk group based on age and number of risk factors. In addition, for groups 1D and 1E, providers and facilities can also prioritize based on receipt of a booster shot and time since last vaccination.

27. As a result, two 66-year-old vaccinated individuals with diabetes who would otherwise have equal standing in tier 1D would see a person of "[n]on-

white race of Hispanic/Latino ethnicity" receive priority over a white non-Hispanic person.

28. Aside from declaring that "[n]on-white race or Hispanic/Latino ethnicity" are to be considered "risk factors," the Department's Guidance does not itself define "risk factors." Instead, it links to a United States Centers for Disease Control and Prevention (CDC) webpage last updated on December 14, 2021, titled, "People With Certain Medical Conditions."[8]

29. The CDC webpage lists several risk factors that may cause individuals "of any age" to be "more likely to get severely ill from COVID-19": cancer; chronic kidney disease; chronic liver disease; chronic lung diseases; dementia or other neurological conditions; diabetes; Down syndrome; heart conditions; HIV infection; an immunocompromised state; mental health conditions; obesity and being overweight; pregnancy; sickle cell disease or thalassemia; smoking; solid organ or blood stem cell transplant; stroke or cerebrovascular disease; substance use disorders; and tuberculosis. The CDC also considers being non-white or Hispanic/Latino to be an independent risk factor.

30. The Mayo Clinic has determined that "there's no evidence that people of color have genetic or other

[8] The webpage is available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extraprecautions/ people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html.

biological factors that make them more likely to be affected by COVID-19."[9]

31. CDC data compiled by Emory University shows that in New York, the rate of deaths due to COVID-19 for white non-Hispanic individuals exceeds the death rate for any other group.[10]

City Directive

32. On December 27, 2021, NYC Health published 2021 Health Advisory #39 titled, "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." Exh. C.

33. Health Advisory #39 instructs health care providers to "[a]dhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations."

34. Specifically, in setting out eligibility criteria for New York City patients to receive oral antiviral treatments, Health Advisory #39 instructs providers to "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."

35. In an effort "[t]o ensure equitable access to oral antivirals," NYC Health has selected only one

---

[9] *See* https://www.mayoclinic.org/diseases-conditions/coronavirus/expert-answers/coronavirusinfection-by-race/faq-20488802 (last visited Feb. 7, 2022).

[10] *See* https://covid19.emory.edu/ (last visited Feb. 7, 2022).

provider, Alto Pharmacy, to fill all oral antiviral prescriptions for patients in New York City.

36. NYC Health also instructs health care providers administering monoclonal antibodies to "adhere" to the New York State Health Department's Guidance.

The State and City Directives Injure Plaintiffs

37. As a result of both the State Department of Health's and NYC Health's directives prioritizing administration of oral antivirals and monoclonal antibodies, Plaintiffs are disadvantaged in receiving potentially life-saving oral antiviral and monoclonal antibody treatments for COVID-19 based on their race.

38. The erection of "a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group" is a cognizable injury in an equal protection case alleging racial discrimination. *Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 666 (1993).

39. Because Plaintiff Roberts is white and not Hispanic, 61 years old, vaccinated against COVID-19, and has no known risk factors for severe illness that could result from COVID-19, he is not eligible for any of the risk groups identified by the State. If he were any race but white, he would qualify for tier 1E.

40. Because Plaintiff Vavruska is white and not Hispanic, 55 years old, and vaccinated against COVID-19 with at least one risk factor (overweight and obesity), he qualifies for tier 1E. The Guidance provides that, for persons in the same tier seeking

limited COVID-19 treatments, priority should be given to persons with the highest number of risk factors. As Mr. Vavruska does not possess the additional risk factor of being non-white or Hispanic/Latino, he would receive COVID-19 treatment after an individual in tier 1E who is non-white or Hispanic/Latino with the same number of other risk factors.

CLAIM FOR RELIEF

(Against All Defendants)

Racial Discrimination in Violation of the Equal Protection Clause of the Fourteenth Amendment

41. Plaintiffs repeat and reallege each and every allegation contained in the preceding allegations of the Complaint.

42. Defendants' directives prioritize individuals on the basis of race for individuals in the same risk tier.

43. Defendants' directives consider race itself as a risk factor. A person's race can be used to move that person to a higher risk tier.

44. Defendants' directives for COVID-19 oral antiviral and monoclonal antibody treatments "distribute[] burdens or benefits on the basis of individual racial classifications." *See Parents Involved in Community Schools v. Seattle Sch. Dist. No. 1*, 551 U.S. 701, 720 (2007).

45. Defendants' directives discriminate on the basis of race and are subject to "strict scrutiny." *See Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 227 (1995).

46. Under strict scrutiny, the Equal Protection Clause of the Fourteenth Amendment prohibits the government from discriminating based on race unless its means are narrowly tailored to a compelling governmental interest. *See Adarand Constructors*, 515 U.S. at 220.

47. Defendants' use of race as a risk factor in their directives does not further a compelling interest.

48. Defendants' use of race as a risk factor in their directives does not remedy current or past racial discrimination by the government.

49. Defendants' use of race as a risk factor in their directives is not narrowly tailored to any interests the Defendants might assert.

50. Defendants consider race as a risk factor for every non-white or Hispanic/Latino individual. For those individuals, race is afforded the same weight as one risk factor.

51. Defendants did not give serious consideration to workable race-neutral alternatives. Risk factors besides race can ensure that COVID-19 treatments are allocated according to individual need.

52. Defendants' enforcement of their directives denies Plaintiffs equal protection under the law in violation of the Fourteenth Amendment to the United States Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An entry of a judgment declaring that Defendants' use of race in determining which patients

receive priority for oral antiviral and monoclonal antibody treatments for COVID-19 is unconstitutional because it violates the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution;

B. An entry of a permanent injunction against Defendants prohibiting them from using race in determining which patients receive priority for oral antiviral and monoclonal antibody treatments for COVID-19;

C. An award of attorneys' fees, costs, and expenses in this action pursuant to 42 U.S.C. § 1988;

D. An award to Plaintiffs of $1.00 in nominal damages; and

E. Any further relief as the Court may deem just, necessary, or proper.

Respectfully submitted this 8th day of February, 2022.

s/ Jonathan M. Houghton
JONATHAN M. HOUGHTON
* * * * *

Counsel for Plaintiffs

EXHIBIT A

New York Department of Health

Date: December 27, 2021

To: Health Care Providers and Health Care Facilities

From: New York State Department of Health

COVID-19 ORAL ANTIVIRAL TREATMENTS AUTHORIZED AND SEVERE SHORTAGE OF

ORAL ANTIVIRAL AND MONOCLONAL ANTIBODY TREATMENT PRODUCTS

Summary:

•Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).

•Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 when started early after symptom onset.

•Paxlovid is the preferred product and is available for patients age 12 years and older.

•Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate.

•At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.

•There will be a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV beginning 1/3/2022.

•Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.

The announcement is to make you aware of information about available COVID-19 outpatient

therapeutics, including newly authorized oral antiviral treatments.

While the availability of oral antivirals for treatment of COVID-19 is an important milestone, it comes at a time of a significant surge in cases and reduced effectiveness of existing therapeutics due to the omicron variant, which is now the predominant variant nationally and estimated by the Centers of Disease Control and Prevention (CDC) to account for over 90% of cases in New York. Supplies of oral antivirals will be extremely limited initially, and there is now only one monoclonal antibody product that is effective for treatment of infection caused by the omicron variant. While supplies remain low, adhere to the NYS DOH guidance on prioritization of anti-SARS-CoV-2 therapies for treatment and prevention of severe COVID-19 and 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.

COVID-19 Oral Antiviral Treatment

The FDA authorized the first oral antiviral therapies, Paxlovid from Pfizer and molnupiravir from Merck, to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, regardless of vaccination status. The oral antivirals work by interfering with several steps in the reproductive process of SARS-CoV-2 to prevent efficient replication of the virus in host cells. The U.S. Department of Health and Human Services (HHS) provides oral antivirals at no cost to patients.

Paxlovid is the preferred product, and molnupiravir can be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate. Prior to initiating treatment, providers and patients should carefully consider the known and potential risks and benefits. Limited supply will require providers to prioritize treatment for patients at highest risk for severe COVID-19 until more product becomes available.

Paxlovid clinical trials among 2,246 high-risk patients showed an 88% reduction in the risk for hospitalization and death among people taking paxlovid compared to those taking placebo. Paxlovid is a combination treatment with PF-07321332 (or nirmatrelvir) and ritonavir. PF-07321332 inhibits the main protease of SARS-CoV-2 virus, the 3CL-like protease, that impedes synthesis of other non-structural proteins and ultimately inhibits viral replication. Ritonavir is a protease inhibitor (also used in HIV treatment) that acts as a pharmacokinetic enhancer of protease inhibitors.

Molnupiravir clinical trials among 1,433 high-risk patients showed a 30% reduction in the risk for hospitalization and death among people taking molnupiravir compared to those taking placebo. Molnupiravir is the pro-drug of a nucleoside analog that competes with the viral RNA polymerase and induces RNA mutations that ultimately have an antiviral effect.

Eligibility

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

Under the authorizations, paxlovid and molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under New York State law to prescribe drugs in the therapeutic class to which paxlovid and molnupiravir belong (i.e., anti-infectives).

For Paxlovid only:

•Therapy is contraindicated for patients (1) with a history of clinically significant hypersensitivity reactions to its active ingredients or any other

components of the product; (2) treating with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or (3) treating with drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.

•Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.

•Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

•Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

•Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the

duration of treatment and for 4 days after the last dose of molnupiravir.

• Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.

• Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

• For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

Treatment is most effective when given as soon as possible and no more than 5 days after symptom onset. High-risk patients who present within 6 to 10 days of symptoms onset should be referred for monoclonal antibody therapy.

The most common side effects reported during treatment and within 14 days after the last dose of molnupiravir were mild or moderate diarrhea, nausea, and dizziness. For Paxlovid, mild or moderate dysgeusia, diarrhea, hypertension, and myalgia were reported.

Oral antivirals are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19. Oral antivirals should not be used for longer than 5 consecutive days.

Referring Patients for Oral Antivirals Outside of NYC

To ensure equitable access to oral antivirals, the New York State Department of Health has worked in partnership with local jurisdictions to identify 1–2 pharmacies within each jurisdiction (where possible). As supplies increase, additional pharmacies will be added. A list of participating pharmacies is provided in Appendix A at the end of this message.

Product is expected to ship on Tuesday 12/28/2021 and the earliest orders will be able to be filled is estimated to be Wednesday 12/29/2021. Please contact the local pharmacy to confirm availability or if your local pharmacy is Walmart, go to www.walmart.com/covidmedication to inquire about product availability at each store.

Referring Patients for Oral Antivirals in NYC

To ensure equitable access to oral antivirals, the NYC Department of Health and Mental Hygiene (Health Department) has partnered with Alto Pharmacy, a pharmacy delivery service. At this time, this is the only way NYC patients can receive oral antivirals. As supplies increase, additional pharmacies will be added.

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and through a language line in Russian, Mandarin, Vietnamese, Arabic, and Korean. Prescriptions confirmed by 5 p.m. on weekdays or 1p.m. on weekends will be delivered

the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

Providers who would like to automatically have molnupiravir substituted when Paxlovid is unavailable must submit two prescriptions, one for each medication, with a comment in the notes section of the molnupiravir prescription which reads "to be used in case Paxlovid prescription cannot be filled because of supplies limitation". Substituting with molnupiravir can only be done for patients meeting eligibility criteria and with no contraindications for either product.

Changes to Monoclonal Antibody Use

At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody therapeutic that is expected to be effective against the omicron variant of SARS-CoV-2. Supplies of Sotrovimab are extremely limited and providers should adhere to NYS DOH prioritization guidance.

As of December 23, 2021, there is a pause on further allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV beginning 1/3/2022. Bamlanivimab with etesevimab and REGEN-COV do not retain activity against omicron. NYC providers should refer to NYC's Letter to Providers: Omicron and Monoclonal Antibodies. Monoclonal antibody treatment can no longer be used as post-exposure prophylaxis.

Please continue to monitor our website regularly for updated guidance, including on treatment supply

and prioritization: COVID-19 Monoclonal Antibody (mAb) Therapeutics: Information for Providers | Department of Health (ny.gov).

Appendix A: List of Participating Pharmacies outside of New York City by County

* * * * *

EXHIBIT B

New York Department of Health

Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations

Introduction

In times of limited supplies of monoclonal antibodies (mAbs) and oral antivirals (OAVs), providers should prioritize patients eligible for treatment based on their level of risk for progressing to severe COVID-19. In addition, the most efficacious products should be prioritized for patients with the highest risk for hospitalization and death.

According to the NIH COVID-19 Treatment Guidelines, triage and prioritization should only be implemented when logistical or supply constraints make it impossible to offer the therapy to all eligible patients. During periods of limited resources, the Panel suggests:

- Prioritizing the **treatment** of COVID-19 **and**

- Prioritizing anti-SARS-CoV-2 mAbs and OAVs for **unvaccinated or incompletely vaccinated** individuals and **vaccinated individuals who are not expected to mount an adequate immune**

response (e.g., individuals with moderate to severe immunocompromise or individuals aged ≥65 years).

As reminder, Monoclonal antibodies and oral **therapeutics are <u>not</u> a substitute for vaccination** in individuals for whom vaccination is recommended. Providers should continue recommending COVID-19 vaccination as the best strategy to prevent COVID-19 severe disease, hospitalizations, and deaths.

Patients who have moderate to severe immune compromise (due to a medical condition or receipt of immunosuppressive medications or treatments) or are unable to receive COVID-19 vaccines due to a history of a severe adverse reaction to a COVID-19 vaccine should be considered for pre-exposure prophylaxis with a long-acting monoclonal antibody (Evusheld).

How to use this framework

Each patient should be assigned to a group within Tier 1 and then prioritized within the respective group. Patients assigned to 1A should be considered the highest priority, with 1B being the next highest priority and so on. The recommended therapy section notes which groups should receive therapy without exception and which groups may need to be put on a wait list if supplies of a given therapeutic are limited.

Tier 1: Prioritization Groups for the Treatment of COVID-19

For treatment, patients must have mild to moderate symptoms, test positive for SARS-CoV-2, and be within 10 days of symptom onset for mAbs or within 5 days for oral antivirals

Appendix 59a

Risk Groups	Recommended Therapy / Approach	Notes on prioritiza-tion
1A. Any age with moderate to severe immunocompromise regardless of vaccine status **or** Age 65 and older and not fully vaccinated with at least one risk factor for severe illness **or** Age 65 or older that is a resident of a long-term care facility environment	**Refer for monoclonal antibody therapy** (mAb) or prescribe Paxlovid, ideally within 24 hours of positive test Consider molnupiravir if the options above are not available	If needed, prioritize patients based on •Age •Number of risk factors
1B. Under 65 years of age and not fully vaccinated with two or more risk factors for severe illness or over 65 and not fully vaccinated (no risk factors)	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on •Age •Number of risk factors
1C. Under 65 years of age and not fully vaccinated with at least one risk factor for severe illness	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on •Age

Appendix 60a

1D. Over age 65 and fully vaccinated with at least one risk factor for severe illness	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on •Age •Number of risk factors •Receipt of booster •Time since last vaccination
1E. Under 65 years of age and fully vaccinated with at least one risk factor for severe illness **or** Age 65 and older and fully vaccinated with no other risk factors	Consider mAbs or OAVs if supplies allow	If needed, prioritize patients based on •Age •Number of risk factors •Receipt of booster •Time since last vaccination

Notes

•We recommend using BMI ≥30 as a cutoff for weight-based risk factor

•The risk of severe disease increases with the number of comorbidities, even among fully vaccinated individuals

•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 CDC guidance for further information on specific medical conditions and associated risk

•Fully vaccinated is currently defined as having received two doses of an mRNA vaccine, or a single dose of the Johnson & Johnson vaccine

EXHIBIT C

NYCHealth

2021 HEALTH ADVISORY #39

COVID-19 ORAL ANTIVIRAL TREATMENTS AUTHORIZED AND SEVERE SHORTAGE OF ORAL ANTIVIRAL AND MONOCLONAL ANTIBODY TREATMENT PRODUCTS

•Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).

•Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 disease when started early after symptom onset.

•Prescriptions in New York City (NYC) will be filled by Alto Pharmacy to provide free, same day home delivery regardless of insurance or immigration status.

•Paxlovid is the preferred product and is available for patients age 12 years and older.

•Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate.

•At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.

•There is a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. These products do not retain activity against omicron and should not be used.

•Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.

•While therapeutic shortages continue, off-label use of remdesivir on an outpatient basis may be an option.

• Check nyc.gov/health/covidprovidertreatments regularly for updates.

December 27, 2021

Dear Colleagues,

This HAN includes information about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatment.

While the availability of oral antivirals for treatment of COVID-19 is an important milestone, it comes at a time of a significant surge in cases and reduced effectiveness of existing therapeutics due to the omicron variant, which is now the predominant variant nationally and estimated by the Centers of Disease Control and Prevention (CDC) to account for over 90% of cases in New York. Supplies of oral antivirals will initially be extremely limited, and there is now only one monoclonal antibody product that is effective for treatment of infection caused by the omicron variant. While supplies remain low, adhere to the NYS DOH guidance on prioritization of anti-SARS-CoV-2 therapies for treatment and prevention of severe COVID-19 and prioritize therapies for people of any eligible age with moderate to severe immunocompromise regardless of vaccination status or who are age 65 and older and not fully vaccinated with at least one risk factor for severe illness.

COVID-19 Oral Antiviral Treatment

The FDA authorized the first oral antiviral therapies, Paxlovid from Pfizer and molnupiravir from Merck, to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, regardless of vaccination status. The oral antivirals work by interfering with several steps in the reproductive process of SARS-CoV-2 to prevent efficient replication of the virus in host cells. The U.S. Department of Health and Human Services (HHS) provides oral antivirals at no cost to patients.

Paxlovid is the preferred product, and molnupiravir can be considered for patients age 18 years and older for whom alternative FDA-authorized COVID-19 treatment options are not accessible or clinically appropriate. Limited supply will require providers to prioritize treatment for patients at highest risk for severe COVID-19 until more product becomes available.

Paxlovid clinical trials among 2,246 high-risk patients showed an 88% reduction in the risk for hospitalization and death among people taking Paxlovid compared to those taking placebo. Paxlovid is a combination treatment with PF-07321332 (or nirmatrelvir) and ritonavir. PF-07321332 inhibits the main protease of SARS-CoV-2 virus, the 3CL-like protease, that impedes synthesis of other non-structural proteins and ultimately inhibits viral replication. Ritonavir is a protease inhibitor (also used in HIV treatment) that acts as a pharmacokinetic enhancer of protease inhibitors.

Molnupiravir clinical trials among 1,433 high-risk patients showed a 30% reduction in the risk for hospitalization and death among people taking molnupiravir compared to those taking placebo. Molnupiravir is the pro-drug of a nucleoside analog that competes with the viral RNA polymerase and induces RNA mutations that ultimately have an antiviral effect.

Eligibility

Oral antiviral treatment is authorized for patients who meet all the following criteria:

•Age 12 years and older for Paxlovid, or 18 years and older for Molnupiravir

• Weigh at least 40 kg (88 pounds)

• 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 or receiving oxygen therapy due to COVID-19

• Are able to start treatment within 5 days of symptom onset

• Have a medical condition or other factors that increase their risk for severe COVID-19 illness.

• 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.

For Paxlovid only:

• Therapy is contraindicated for patients with history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; are on drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or are on drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.

•Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.

•Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

•Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.

•Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.

•Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.

•Males of reproductive potential who are sexually active with females of childbearing potential should

use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.

• For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

Treatment is most effective when given as soon as possible and no more than 5 days after symptom onset. High-risk patients who present within 6 to 10 days of symptoms onset should be referred for monoclonal antibody therapy.

The most common side effects reported during treatment and within 14 days after the last dose of molnupiravir were mild or moderate diarrhea, nausea, dizziness, and headache. For Paxlovid, mild or moderate dysgeusia, diarrhea, hypertension, and myalgia were reported.

Oral antivirals are not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19 and should not be used for longer than 5 consecutive days.

Referring Patients for Oral Antivirals

To ensure equitable access to oral antivirals, the NYC Department of Health and Mental Hygiene (Health Department) has partnered with Alto Pharmacy, a pharmacy delivery service. At this time, this is the only way NYC patients can receive oral antivirals. As supplies increase, additional pharmacies will be added.

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule

their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and support in numerous other languages through language line. Prescriptions confirmed by 5 p.m. on weekdays or 1 p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

Providers who would like to automatically have molnupiravir substituted when Paxlovid is unavailable must submit two prescriptions, one for each medication, and state in the notes section of the molnupiravir prescription, "to be used in case Paxlovid prescription cannot be filled because of supply limitation." Substituting with molnupiravir can only be done for patients meeting eligibility criteria and with no contraindications for either product.

Changes to Monoclonal Antibody Use

At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody therapeutic that is expected to be effective against the omicron variant of SARS-CoV-2. Supplies of Sotrovimab are extremely limited and providers should adhere to NYS DOH prioritization guidance, and refer to the NYC Health Department's Letter to Providers: Omicron and Monoclonal Antibodies.

As of December 23, 2021, there is a pause on further allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. Bamlanivimab with etesevimab and

REGEN-COV do not retain activity against omicron and should not be used. Monoclonal antibody treatment can no longer be used as post-exposure prophylaxis.

Outpatient Use of Remdesivir

The National Institute of Health (NIH) has issued treatment recommendations given therapeutics shortages and inactivity of some therapeutics against the omicron variant. This includes the use of remdesivir via IV infusion on an outpatient basis. Remdesivir is FDA approved for hospitalized patients only; use of the drug for outpatient treatment would be an off-label indication. It is currently unknown if this treatment option will be available for patients in NYC. Do not send patients to the hospital to request treatment unless first identifying a facility and making arrangements in advance. See NIH COVID-19 Treatment Guidelines for more information.

Providers not offering treatment can refer patients to NYC Health + Hospitals. Patients can be connected to a health care provider by calling 212-COVID19 (212-268-4319). Treatment is available regardless of immigration status or ability to pay.

Thank you for all you are doing to help support the safety of your patients and our city. Please check nyc.gov/health/covidprovidertreatments regularly for updated guidance, including on treatment supply and prioritization.

Sincerely,

s/ Celia Quinn
Celia Quinn MD, MPH
Deputy Commissioner

Appendix 70a

Division of Disease Control

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jonathan Roberts and Charles Vavruska, Plaintiffs, -against- Mary T. Bassett, in her official capacity as Commissioner for New York State Department of Health; New York City Department of Health and Mental Hygiene, Defendants.	Case No. 1:22-cv-00710-NGG-RML **Declaration of Charles Vavruska in Support of Plaintiffs' Motion for Preliminary Injunction**

I, Charles Vavruska, declare as follows:

1. The facts set forth in this declaration are based on my personal knowledge, and if called as a witness, I could and would competently testify thereto under oath. As to those matters which reflect a matter of opinion, they reflect my personal opinion and judgment upon the matter.

2. I am an electrical engineer and a lifelong resident of Queens, New York, where I currently reside.

3. I am white and not Hispanic, 55 years old, and fully vaccinated against COVID-19. In March 2020, I

contracted COVID-19 and was hospitalized for 10 days.

4. I reviewed the list of risk factors on a CDC website entitled "Persons with Certain Medical Conditions," that I have one of the risk factors (overweight and obesity) listed on the website. The link to the website appears on footnote 8 to the complaint in this case. I have reviewed the New York guidelines attached as Exhibit B to the complaint in this case. According to the guidelines, I qualify for inclusion in the last tier (1E) of the risk groups established by the New York State Department of Health and New York City's Department of Health and Mental Hygiene for prioritization of certain COVID-19 treatments. But an otherwise identical situated person who is either non-white or Hispanic would be prioritized for COVID-19 treatment over me.

5. I engage in activities that subject me to an increased risk of contracting Coronavirus. For example, I regularly meet with people for work and for social reasons. In addition, I frequently take public transportation such as the subway in New York City.

6. I want the ability to access any medication that would be beneficial for me to take. I want equal access to COVID-19 treatments such as Paxlovid, Molnupiravir, and monoclonal antibodies if I were to contract COVID-19.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on February 18, 2022.

s/ Charles Vavruska
CHARLES VAVRUSKA

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jonathan Roberts and Charles Vavruska, Plaintiffs, -against- Mary T. Bassett, in her official capacity as Commissioner for New York State Department of Health; New York City Department of Health and Mental Hygiene, Defendants.	Case No. 1:22-cv-00710-NGG-RML **Declaration of Jonathan Roberts in Support of Plaintiffs' Motion for Preliminary Injunction**

I, Jonathan Roberts, declare as follows:

1. The facts set forth in this declaration are based on my personal knowledge, and if called as a witness, I could and would competently testify thereto under oath. As to those matters which reflect a matter of opinion, they reflect my personal opinion and judgment upon the matter.

2. I was born in Manhattan and raised in the Flushing area of Queens in New York City. My mother immigrated to the United States from Hungary as a child, where her family faced anti-Semitism that prevailed in Europe at that time. For high school, I

tested into Bronx High School of Science. After high school I attended Harvard where I earned a math degree. My time at Harvard was the only time of my life in which I lived outside of New York. I currently reside in Manhattan.

3. I am 61 years old and fully vaccinated against COVID-19. I reviewed the list of risk factors on a CDC website entitled "Persons with Certain Medical Conditions," and confirmed that I have none of the risk factors listed on the website. The link to the website appears on footnote 8 to the complaint in this case.

4. I identify as white and non-Hispanic. I have reviewed the New York guidelines attached as Exhibit B to the complaint in this case. I do not qualify for inclusion in any tier of the "risk groups" established by the New York State Department of Health or New York City's Department of Health and Mental Hygiene for prioritization of certain COVID-19 treatments. If I were any race but white or if I were Hispanic, I would qualify for the last tier (1E) of the risk groups.

5. I want the ability to access any medication that would be beneficial for me to take. I am especially interested in Paxlovid and have been fascinated by the science of the drug from videos I have watched. I would seek the drug as a possible treatment if I were to contract COVID-19.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on February 17, 2022.

s/ Jonathan Roberts
JONATHAN ROBERTS

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 MICHELLE E. MORSE, M.D., MPH

Dr. Michelle E. Morse, declares pursuant to 28 U.S.C. § 1746, under penalty of perjury, that the following is true and correct:

1. I am the Chief Medical Officer of the Department of Health and Mental of Hygiene ("DOHMH" or "the Health Department") of the City of New York.

2. I received my BA from the University of Virginia in 2003, my MD from the University of Pennsylvania in 2008, and an MPH from Harvard School of Public Health in 2012.

3. Prior to working at the Health Department, I served as a Health Policy Fellow at the international Academy of Medicine; Assistant Professor at Harvard Medical School; Assistant Program Director of the Internal Medicine Residency Program at Brigham

and Women's Hospital; and Deputy Chief Medical Officer at Partners In Health.

4. The information provided in this declaration is based on my personal knowledge and professional expertise.

5. For the reasons discussed herein, DOHMH's Health Advisory # 39, which was created to inform hospitals and medical care providers of newly authorized COVID-19 treatments, furthers the public health goals of minimizing the hospitalization and morbidity rates due to COVID-19 in New York City.

COVID-19 Background

6. Coronavirus disease, or COVID-19, is an infectious disease caused by the SARSCoV-2 virus. COVID-19 most commonly spreads between people who are in close proximity, i.e., within approximately 6 feet of one another for at least 15 minutes either consecutively or cumulatively within a 24-hour period. It is spread primarily when someone infected with the virus releases droplets or particles when talking, coughing, sneezing, or singing, and the droplets or particles are breathed in by another individual or land in another individual's eyes, nose, or mouth.

7. In indoor settings, the virus can also travel through the air and infect people who are much further than 6 feet away. It is also possible for people to become infected by touching a surface that has the virus on it, and then touching their eyes, nose or mouth with unwashed hands, though this is thought to be less common than other forms of transmission. There is significant evidence that people can transmit the virus whether or not they have symptoms; while

people with symptoms are likely more contagious than people without symptoms, the number of people infected, on average, by people without symptoms may be greater, because they continue to conduct activities with others and do not know to isolate themselves. Based on current knowledge, the time between virus exposure and the onset of illness (the incubation period) can range from 2−14 days with most people developing symptoms 4−6 days after exposure. There is some evidence that the Omicron variant incubation is shorter than prior strains, with one study estimating the average incubation period as 3 days.[1]

8. COVID-19 has affected the lives of hundreds of millions of people worldwide and remains a serious threat all over the world, including New York City residents. As of February 17, 2022, there have been over 418 million reported cases of COVID-19 worldwide,[2] including over 77 million in the United States,[3] of which over 1.9 million have been in New York City.[4] There have been over 5.85 million

---

[1] See Lin T. Brandal et al. Outbreak caused by the SARS-CoV-2 Omicron variant in Norway, November to December 2021, Eurosurveillance (Dec. 15, 2021), https://www.eurosmveillance.org/content/10.2807/1560-7917.ES.2021.26.50.2101147.

[2] See COVID19 Dashboard Johns Hopkins, https://www.arcgis.com/apps/dashboards/bda7594 740fd 40299423467b48e9ecf6 (last accessed Feb. 17, 2022).

[3] See COVID-19 Data Tracker, CDC.gov, https://covid.cdc.gov/covid-datatracker/#trendsdailycases (last accessed Feb. 17, 2022).

[4] See COVID-19: Data NYC Health, https:/www1.nyc.gov/site/doh/covid/covid-19-data-totals page (last accessed Feb. 17 , 2022).

reported deaths from COVID-19 worldwide,[5] with more than 923,000 reported deaths in the United States[6] and 39,503 confirmed and probable deaths in New York City alone.[7]

9. On January 31, 2020, the United States Department of Health and Human Services declared the COVID-19 virus a public safety emergency, and on March 11, 2020, the World Health Organization declared it to be a global pandemic.

10. In the late winter/spring of 2020, New York City was the epicenter of the COVID-19 pandemic in the United States. It suffered from a shortage of medical equipment, personal protective equipment, intensive care unit beds, and medical personnel. Accordingly, on March 12, 2020, Mayor Bill de Blasio issued Emergency Executive Order No. 98, which remains in effect today, declaring a state of emergency in New York City. On March 25, 2020, the Commissioner of Health declared COVID-19 a public health emergency within the City. That declaration remains in effect today.

COVID-19 in NYC Today

11. While New York City is no longer experiencing the widespread crisis that marked the winter/spring of 2020, there have been new variants and surges, meaning that community transmission remains an ongoing public health concern. The Centers for Disease Control and Prevention (CDC) reports that

---

[5] See COVID-19 Dashboard, supra note 2.
[6] See COVID-19 Data Tracker supra note 3.
[7] See COVID-19: Data supra note 4.

New York City is experiencing a substantial level[8] of community transmission.[9] From the end of November, 2021 through the end of January, 2022, New York City experienced the largest wave of reported cases yet during the pandemic. As of February 17, 2022, over the last 28 days in New York City, there was an average of 3,296 reported new cases per day, with a peak 7-day average of 43,636 reported new cases on January 4, 2022.[10] This surge was driven by the highly transmissible Omicron variant, which more easily infected persons who had existing immunity from previous infection or vaccination than previous variants of the virus.

12. In New York City, those most likely to be hospitalized are people who are not vaccinated, and a higher proportion of Black New Yorkers and people age 75 and older were hospitalized during the Omicron surge.[11]

13. As of the date of this declaration, New York City still is battling COVID-19 but the surge in positive cases has fallen dramatically. For the week ending February 19, 2022, there were an average of

---

[8] "Substantial" community transmission indicates a county with 50–99.9 or more new cases of COVID-19 per 100,000 people in a seven-day period, or a county with 8–9.99% or more positive COVID-19 tests in a seven-day period. See COVID-19 Data Tracker supra note 3.

[9] As of February 13, 2022, three boroughs are still considered as having a "high" level of community transmission, or more than 100 new cases of COVID-19 per 100,000 people.

[10] See COVID-19: Data, supra note 4.

[11] See Omicron Variant: NYC Report for January 13, 2022, NYC Health, https://www1.nyc.gov/assets/doh/downloads/pdf/covid/omicron-variant-report-jan-13-22.pdf (last visited Feb 24, 2022).

790 new cases reported in New York City daily, compared with 2,000 cases reported daily over the previous 28 days.[12]

The State's December 27, 2021 Guidance

14. As the Omicron variant began to surge throughout the country, the Food and Drug Administration ("FDA") issued Emergency Use Authorizations for several drug treatments and therapies found to be effective in reducing the risk of hospitalizations and deaths in high-risk individuals. These treatments include two antiviral therapies (Paxlovid and Molnupiravir) and one monoclonal antibody product (Sotrovimab). Shortly after the release of these treatments, the Omicron surge in New York State caused supply shortages.

15. As a result of supply shortages, on December 27, 2021, the New York State Department of Health issued "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products" ("State Guidance"). A copy of the State Guidance is annexed hereto as Exhibit "A." [*see* Pet. App. 48a, *supra*]

16. The State Guidance was created to inform hospitals and medical providers of the newly available treatments and to address certain factors to be considered when administering these limited therapies among infected individuals.

17. The "Eligibility" section of the State's Guidance sets forth health-based risk factors to consider when determining courses of treatment in times of supply shortages. One of the risk factors to consider is race

---

[12] See COVID-19: Data, supra note 4.

and ethnicity. Indeed, evidence-based studies and data have shown that there has been longstanding inequality in impact of COVID-19, including treatment, in non-white and Hispanic/Latino communities.[13]

18. Specifically, the State Guidance provides "Oral antiviral treatment is authorized for patients who meet all of the following criteria: . . . 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 inequalities have contributed to an increase risk of severe illness and death from COVID-19."

DOHMH's December 27, 2021 Guidance

19. In light of the State's Guidance and CDC data showing that treatments were being underutilized by non-white and Hispanic/Latino communities, on December 27, 2021, DOHMH issued "2021 Health Advisory #39 COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." ("City Guidance"). A copy of the City Guidance is annexed hereto as Exhibit "B." [*see* Pet. App. 57a, *supra*]

20. The City Guidance closely mirrors the State Guidance and similarly informs hospitals and medical providers of the newly available treatments (along

---

[13] See Health Equity Considerations & Racial& Ethnic Minority Groups, CDC.gov (updated Jan 25, 2022) https://www.cdc.gov/coronavirus/2019-ncov/communitv/health-equity/race-ethnicity.html; Underlying Medical Conditions, CDC.gov (updated Feb. 15 , 2022) https://www.cdc.gov/corona virus/2019-ncov/hcp/clinicalcare/underlvingconditions.html.

with their scarcity at the time) and to address certain factors to be considered when administering these therapies among infected individuals.

21. Specifically, the City Guidance provides that hospitals and medical providers "[c]onsider 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."

22. DOHMH distributed the City Guidance by posting it to its website as well as sending it via email as a Health Alert to approximately 75,000 email addresses aimed at medical providers and other registered individuals via the Health Alert Network ("HAN"). DOHMH's HAN regularly delivers up-to-date health alert information to medical providers and maintains an online document library on public health topics.[14]

23. The City Guidance is not a mandate, law, or order restricting COVID-19 treatment by race or any other single factor. The City Guidance is not meant to replace a medical provider's sound clinical judgment of what course of treatment is best for patients. Rather, the City Guidance is intended to address evidence-based data that Black, Indigenous, Latinx, and other people of color communities have been disproportionally impacted by COVID-19, and to remind providers to consider all factors that have been shown to contribute to poor outcomes from

---

[14] See Health Alert Network (HAN), NYC Health, https://www1.nyc.gov /site/doh/providers/resources/health-alert-network.page (last accessed Feb. 24, 2022).

COVID-19, including social determinants of health like race and ethnicity.

24. As noted by the CDC, five key areas of social determinants of health contribute to marginalized racial and ethnic groups being disproportionately affected by COVID-19: neighborhood and physical environment, health and healthcare, occupation and job conditions, income and wealth, and education. Discrimination, which includes racism and associated chronic stress, influences each of these key topic areas.[15] Exposure to racism has biological consequences.[16] Specific to COVID-19, one large-scale study found that, compared with non-Hispanic White patients of similar ages with similar comorbidities, non-Hispanic Black patients had significantly higher length of hospital stay and odds of ventilator dependence and death.[17] A study of 219.1 million adults aged 25 years or older, found that racial disparities persisted in age adjusted COVID mortality rates in 2020 when comparing within levels of education, stating "If all racial and ethnic populations

---

[15] See COVID-19 Racial and Ethnic Health Disparities, CDC.gov (Dec. 10, 2022)

[16] See Dimsdale JE. Psychological stress and cardiovascular disease, J. Am. Coll. Cardiol. 51:1237–1246 (2008); Arline T. Geronimus et al., "Weathering" and Age Patterns of Allostatic Load Scores Among Blacks and Whites in the United States, 96 Am. J. Pub. Health 826 (2006), doi.org/10.2105 /AJPH.2004.060749; Yin Paradies, A systematic review of empirical research on self-reported racism and health 35 Int'l J. Epidemiology 888, 888 (2006), bit.ly/3IX87qS

[17] See Fares Qeadan et al., Racial disparities in COVID-19 outcomes exist despite comparable Elixhauser comorbidity indices between Blacks Hispanics. Native Americans and Whites, Scientific Reports (Apr. 22, 2021), https://www.nature.com/articles/s41598-021-88308-2.

had experienced the same mortality rates as college-educated non-Hispanic White populations, 71% fewer deaths among racial and ethnic minority populations would have occurred."[18] Other studies have found that, after adjusting for various socioeconomic measures, significant racial disparities remained in COVID disease severity[19] and hospitalization.[20]

25. The City Guidance reminder to consider race among the factors in treatment decisions was a continuation of the work of the City's Taskforce on Racial Inclusion & Equity (TRIE) launched in April 2020 in response to the disproportionate impact of COVID-19 on communities of color. Via TRIE, City agency leaders monitor and tailor the COVID-19 response in 33 highly affected neighborhoods, including vaccination messaging and specific services.[21]

26. The City's Guidance does not prevent any individual from receiving treatments should they

---

[18] See Justin M. Feldman and Mary T. Bassett, Variation in COVID-19 Mortality in the US by Race and Ethnicity and Educational Attainment, JAMANetwork, (Nov. 23, 2021), https://jamanetwork.com/joumals/jamanetworkopen/fullarticle/2786466.

[19] See Shruti Magesh, et al. Disparities in COVID-19 Outcomes by Race Ethnicity and Socioeconomic Status: A Systematic Review and Meta-analysis, JAMA Network (Nov. 1, 2021), https://pubmed.ncbinhn.nih.gov/34762110/.

[20] See Nicholas E. Ingraham, et al, Racial and Ethnic Disparities in Hospital Admissions from COVID-19: Determining the Impact of Neighborhood Deprivation and Primacy Language, 36(11) J. Gen. Internal Med. 3462 (Nov. 2021), https://pubmed.ncbi.nlm.nih.2ov/34003427/.

[21] See About Taskforce on Racial Inclusion & Equity, NYC.gov, https://www1.nyc.gov/site/Inc/about/about.page (last accessed Feb. 25, 2022).

contract COVID-19. Individuals who are qualified based on risk factors will not be turned away from necessary treatment based on race.

27. Because the City Guidance is not a mandate, the City will not take any enforcement actions against hospitals or medical care providers in relation to it. In fact, there are no mechanisms in place to track how the City Guidance has been used by providers or to enforce it in any way.

There is No Longer a Shortage of These Treatments in New York City

28. As stated above, the City Guidance was issued during a surge in Omicron variant cases in New York City.

29. As of the date of this declaration, there is no longer a shortage of oral antivirals or monoclonal antibody treatment products. In fact, there is a surplus. Indeed, on February 2, 2022, DOHMH distributed a HAN notice[22] entitled "Paxlovid is Available for COVID-19 Treatment in New York City" to alert providers of this fact.

Dated: New York, New York

February 25, 2022

s/ Michelle E. Morse
Michelle E. Morse, M.D., MPH

[22] See 2022 Health Advisory #2: Paxlovid is Available for COVID-19 Treatment in New York, NYC Health (Feb. 1, 2022), https://www1.nyc.gov/assets/doh/downloads/pdf/han/advisory/2022/covid-paxlovid-available.pdf.

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

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 statewide 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

---

[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/publichearings/february-08-2022/joint-legislative-public-hearing-2022-executive-budget.

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, 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-drugshortages/; and https://www.forbes.com/sites/saibala/2021/12/28/theres-a-shortage-ofmonoclonal-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 <u>mild to moderate COVID-19 symptoms</u>
>
> • 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]

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,

---

[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-oraltreatments-authorized-shortage.pdf.

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 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

---

[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.

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 CDC.[4]

---

[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-

CDC 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

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

---

ncov/coviddata/investigations-discovery/hospitalization-death-by-race-ethnicity.html.

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 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

---

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

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

---

[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

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 not currently a shortage of oral antiviral treatments, the

---

posed by Assemblyman Colin Schmitt, *available at* https://www.nysenate.gov/calendar/public-hearings/february-08-2022/joint-legislative-publichearing-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-highlightsavailability-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/.

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

s/ Eugene Heslin
Eugene Heslin, M.D., FAAFP

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

* * * * *

March 4, 2022

By ECF

Honorable Nicholas G. Garaufis
United States District Judge
United States District Court for the Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

RE: *Roberts et al. v, Bassett et al.*, 22-CV-710

Dear Judge Garaufis:

This Office represents defendant Mary T. Bassett, Commissioner of the New York State Department of Health ("DOH"), in the above-captioned matter. I am writing to provide information the Court requested during oral argument on Plaintiffs' motion for a preliminary injunction regarding two issues: (1) DOH's distribution of the DOH Guidance; and (2) whether DOH plans to issue updated guidance in light of evolving events.

DOH uses the Health Commerce System ("HCS"), an online portal and secure website, to facilitate web-based interactions and secure communications with health care facilities, providers, and practitioners in New York. The Integrated Health Alerting and Notification System ("IHANS") is a communications application within the HCS. DOH used IHANS to

distribute the DOH Guidance via email to health care facilities and prescribing medical professionals in New York, including licensed physicians, nurse practitioners, and physicians' assistants. DOH did not distribute the DOH Guidance to pharmacies.

DOH plans to imminently issue updated guidance via IHANS to inform health care facilities, providers, and practitioners that there is currently no shortage of the COVID-19 therapies at issue in this case, and every patient is eligible to receive the therapies if their practitioner determines the treatment is clinically appropriate. DOH will provide the updated guidance to the Court and parties as soon as it is issued.

Respectfully submitted,

/s/
Erin Kandel
Assistant Attorney General

cc: All counsel via ECF

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

* * * * *

March 7, 2022

By ECF

Honorable Nicholas G. Garaufis
United States District Judge
United States District Court for the Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

RE: *Roberts et al. v. Bassett et al.*, 22-CV-710

Dear Judge Garaufis:

This Office represents defendant Mary T. Bassett, Commissioner of the New York State Department of Health ("DOH"), in the above-captioned matter. I am writing in response to the Court's March 4, 2022 electronic Order directing DOH to provide a date by which the new guidance referenced in DOH's March 4, 2022 letter to the Court will be issued, and to indicate whether it will supersede the DOH guidance issued in late December 2021 that Plaintiffs seek to enjoin ("December 2021 Guidance").

DOH issued new guidance, entitled "Test Soon And Treat Early To Improve Outcomes From COVID-19," on March 4, 2022 (hereinafter, "March 4, 2022 Guidance") to health care facilities, providers, and practitioners in New York using DOH's Integrated Health Alerting and Notification System. A copy of the March 4, 2022 Guidance is attached as Exhibit A to this letter.

The March 4, 2022 Guidance does not supersede the December 2021 Guidance but acts an update to it, informing practitioners that there is currently no shortage of supplies constraining their ability to prescribe the antiviral and monocloncal antibody treatment therapies at issue in this case ("the Therapies") if they determine that treatment is clinically appropriate. The purpose of the March 4, 2022 Guidance is to remind practitioners of the COVID-19 treatment options available, including the Therapies; to inform practitioners that "COVID-19 treatment options are available and there are no current shortages"; and to encourage practitioners "to evaluate all treatment options as early as possible." *See* Ex. A. The March 4, 2022 Guidance further states: "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." *Id.*

The Therapies remain subject to the Emergency Use Authorizations issued by the United States Food and Drug Administration ("FDA"). At present, the FDA has authorized the Therapies to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease. Thus, the December 2021 Guidance advises that practitioners consider patients' risk factors for severe disease when determining whether to prescribe the Therapies. Moreover, although the Therapies "are now widely available and there are no current shortages in supply," *id.*, the December 2021 Guidance recommends the prioritization of patients based on

their level of risk of progressing to severe COVID-19 during times of resource limitations.

Respectfully submitted,

/s/
Erin Kandel
Assistant Attorney General

cc: All counsel via ECF

EXHIBIT A

New York Department of Health

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.