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 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.*)

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[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.

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 supplies and do not supplant the judgment of a medical provider. (State's Opp. at 3.)

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[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://www1.nyc.gov/assets/doh/downloads/pdf/han/advisory/2022/covid-paxlovid-available.pdf.

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

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

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 injury in fact, which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) that the injury is fairly traceable to the challenged action of the defendant; and (3) that it is likely the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

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.

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 Su-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 III 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 "underrepresented minority freshman applicants receive 20 points" of the 100 points needed to guarantee admission. *Id.* at

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[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.*

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 "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

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[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 if 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.

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), 2017 WL 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 plaintiff's 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 plaintiff's "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

[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-union-address-as-delivered/; *see also* Press Release, *Pfizer to Provide U.S. Government with an Additional 10 Million Treatment Courses of its Oral Therapy to*

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 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

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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).

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 plaintiff's 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. Sec'y 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."), *aff'd & 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
NICHOLAS G. GARAUFIS
United States District Judge