22-622

United States Court of Appeals for the Second Circuit

JONATHAN ROBERTS, CHARLES VAVRUSKA,

Plaintiffs-Appellants,

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.

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

BRIEF FOR APPELLEE COMMISSIONER BASSETT

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TABLE OF CONTENTS

Page

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Cases **Page(s)**

Cases **Page(s)**

Cases **Page(s)**

Laws **Page(s)**

Miscellaneous Authorities

Federal

Miscellaneous Authorities **Page(s)**

PRELIMINARY STATEMENT

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

Plaintiffs—two non-Hispanic white individuals—sued to challenge the NYSDOH guidance as well as parallel guidance issued by New York City as purportedly violative of the Equal Protection Clause and moved

for a preliminary injunction seeking to enjoin defendants from considering race or ethnicity in connection with the allocation of COVID-19 treatments.[1] The U.S. District Court for the Eastern District of New York (Garaufis, J.) dismissed all claims for lack of standing. This Court should affirm.

Plaintiffs fail to satisfy any of the requirements for Article III standing. Plaintiffs cannot allege an injury-in-fact because the challenged guidance has never served as a barrier to COVID-19 treatment for non-Hispanic white persons and the underlying treatments are now widely available. Plaintiffs also cannot show traceability or redressability because the challenged guidance is not binding on health care professionals and largely tracks federal standards that would remain in place even if plaintiffs were to prevail in this suit. In addition, plaintiffs' challenge is moot because the challenged guidance applied only during an initial period of supply scarcity and plaintiffs' hypothetical speculation that the guidance will again come into effect does not warrant application of the

[1] New York City's Department of Health and Mental Hygiene issued similar guidance. This brief is submitted only on behalf of Mary T. Bassett, in her official capacity as NYSDOH Commissioner.

exception to mootness. A decision in the State's favor on any one of these grounds warrants affirmance.

Even if plaintiffs were somehow able to surmount all of the threshold obstacles discussed above, the proper remedy would be for this Court to remand the case to the district court for further proceedings, including resolution of plaintiffs' motion for a preliminary injunction in the first instance. There is no basis for this Court to decide the motion for the first time on appeal. Even in that circumstance there would be no basis for the Court to evaluate plaintiffs' claim that they are entitled to preliminary relief, as plaintiffs have failed to establish irreparable harm, a likelihood of success on the merits of their equal protection challenge, or that an injunction would be in the public interest.

QUESTIONS PRESENTED

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

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

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

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

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

COVID-19 is a highly infectious and potentially deadly respiratory illness that spreads easily from person to person. In the United States alone, COVID-19 has infected more than 85 million people and claimed more than 1,000,000 lives.[2] The State of New York has reported nearly 5.5 million cases[3] and over 71,000 deaths[4] attributable to COVID-19. COVID-19 remains an ongoing threat, given the periodic emergence and spread of different variants of the virus.[5]

As the record on plaintiffs' preliminary injunction motion established, COVID-19 presents demonstrably greater medical risks for persons of color. According to the U.S. Center for Disease Control and Prevention (CDC), Black Americans are equally likely to contract COVID-19 as non-Hispanic

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[2] CDC, *COVID Data Tracker* (updated June 15, 2022) (internet). (For authorities available on the internet, full URLs appear in the Table of Authorities. All URLs were last visited on June 16, 2022.)

[3] NYSDOH, *COVID-19 Testing Tracker* (updated June 15, 2022) (internet).

[4] NYSDOH, *COVID-19 Fatalities Tracker* (updated June 15, 2022) (internet).

[5] NYSDOH, *COVID-19 Variant Data: Monitoring the Prevalence of SARS-CoV-2 Variants* (internet).

whites, but are 2.5 times more likely to be hospitalized, and are 1.7 times more likely to die of the disease. Similarly, Hispanic Americans are 1.5 times as likely to contract COVID-19, 2.4 times as likely to be hospitalized, and 1.9 times as likely to die of the disease as non-Hispanic whites. (J.A. 79.) Such disparities persist even after controlling for medical comorbidities (J.A. 78, 210-220) and level of educational attainment (J.A. 78, 221-230). The CDC has hypothesized that one of the factors driving disparate COVID-19-related outcomes between non-Hispanic whites and persons of color is disparate access to available treatments. (*See* J.A. 77 n.3.)

On December 22, 2021, the FDA issued an emergency use authorization (EUA)[6] for an antiviral drug called Paxlovid for use by adults and certain pediatric patients with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19.[7] Paxlovid showed

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

[7] *See* Letter from Jacqueline A. O'Shaughnessy, Acting Chief Scientist, FDA, to Pfizer, Inc. (Karen Baker, Director, Global Regulatory Affairs) 1 (Apr. 14, 2022) (internet).

promising results in clinical testing, reducing severe outcomes (i.e., hospitalization or death) by 88 percent as compared to placebo. Paxlovid was "in very limited supply" upon its introduction and the CDC advised that "use should be prioritized for higher risk populations."[8] (*See* J.A. 75 (citing CDC health advisory).) In a Clinical Implementation Guide published around the time of Paxlovid's emergency authorization by the FDA, the CDC stated that, in addition to underlying medical conditions, factors such as race or ethnicity may "also place individual patients at high risk for progression to severe COVID-19." (J.A. 77; *see also* J.A. 135.)

In December 2021, the FDA issued EUAs for two other therapeutic treatments for patients with onset of mild to moderate COVID-19 symptoms: Molnupiravir, an antiviral therapeutic found to reduce severe COVID-19 outcomes by 30 percent; and Strovimab, a monoclonal antibody product. (*See* J.A. 27, 75.)

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[8] CDC, CDCHAN-00461, *Using Therapeutics to Prevent and Treat COVID-19* (Dec. 31, 2021) (internet).

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

On December 27, 2021, NYSDOH issued two guidance documents to health care providers and facilities regarding the newly approved COVID-19 treatments.[9] The purpose of the guidance was to make providers and hospitals aware of the treatments and to identify factors for providers to consider when administering treatments given severely limited supply. (J.A. 27, 75; *see also* J.A. 36.) Neither document contained a mechanism for enforcement of the terms and neither document purported to supplant the clinical judgment of health care providers.

The guidance suggests a framework for sorting COVID-19 patients into five "risk groups" (1A through 1E) based on a patient's age, immuno-compromised status, vaccination status, residency in a long-term care facility environment, and the presence of any "risk factors for severe illness" including various comorbidities specified by the CDC. (J.A. 37.)

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[9] See J.A. 27-38, reproducing Memorandum from NYSDOH to Health Care Providers & Health Care Facilities, *COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products* (Dec. 27, 2021), and NYSDOH, *Prioritization of Anti-SARS-CoV-2 Moncolonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations*.

The framework further suggests prioritization within each group based on age and, where pertinent, the number of risk factors, whether the patient has received a vaccination booster, and the time elapsed since the patient's last vaccination. (J.A. 37.) The guidance specifies 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." (J.A. 38; *see also* J.A. 27.) CDC documents cited and hyperlinked by the NYSDOH guidance likewise include non-white or Hispanic/Latino ethnicity as risk factors for or associations with severe COVID-19.[10]

By February 2022, supply shortages for the newly approved treatments had begun to abate. (J.A. 82.) On March 4, 2022, NYSDOH issued an updated guidance advising providers that "treatment options are now widely available and there are no current shortages in supply."[11]

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[10] *See* CDC, *People with Certain Medical Conditions* (updated May 2, 2022) (internet) (hyperlinked at J.A. 37); CDC, *Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals* (internet) (hyperlinked at J.A. 38).

[11] J.A. 250, reproducing Memorandum from NYSDOH to Health Care Providers & Health Care Facilities, *Test Soon and Treat Early to Improve Outcomes from COVID-19* (Mar. 4, 2022).

Providers were encouraged "to evaluate all treatment options as early as possible." (J.A. 250.) Recent data from the federal Department of Health and Human Services confirms that the treatments remain widely available in New York State.[12]

D. Procedural History and Decision Below

On February 8, 2022, plaintiffs Jonathan Roberts and Charles Vavruska commenced this action in the U.S. District Court for the Eastern District of New York, naming as defendants Commissioner Bassett and New York City's Department of Health and Mental Hygiene. (J.A. 12.) Mr. Roberts alleges that he is 61 years old, is vaccinated against COVID-19, and has no known risk factors for the development of severe COVID-19. (J.A. 15.) Mr. Vavruska alleges that he is 55 years old, is vaccinated against COVID-19, and has at least one risk factor for the development

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[12] *See* U.S. Dep't of Health & Hum. Servs., Office of the Asst. Sec'y for Preparedness & Response, *Therapeutic Distribution Locator for Provider Use* (internet) (indicating that 85,551 doses of Paxlovid and 79,571 doses of Molnupiravir were available in the State of New York as of the date last visited); *compare COVID-19 Testing Tracker* (indicating 5,279 positive tests on June 14, 2022). On March 25, 2022, FDA issued a revised EUA limiting the use of Sotrovimab due to its lack of effectiveness against the predominant Omicron strain. *See Therapeutic Distribution Locator*, *supra*.

of severe illness that could result from COVID-19. (J.A. 15-16.) Neither plaintiff alleged that he sought and was denied any of the treatments at issue in this case. Nevertheless, plaintiffs assert that the NYSDOH guidance (and similar guidance issued by New York City) harm them by erecting a "barrier" to obtaining a benefit that is available to similarly situated persons of color, in violation of the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution. (J.A. 21-24.)

Shortly after filing their complaint, plaintiffs moved for a preliminary injunction seeking to enjoin the State from considering race in the allocation of COVID-19 treatments. (J.A. 8.) On March 15, 2022, the district court issued an opinion dismissing the complaint pursuant to Federal Rule of Civil Procedure 12(h)(3) on the ground that plaintiffs failed to establish Article III standing. (J.A. 10, 251-270.) The court "decline[d] to consider" the preliminary injunction motion given the absence of subject matter jurisdiction. (J.A. 251.)

First, the court explained that plaintiffs could not show a concrete or particularized injury-in-fact because the NYSDOH guidance did not operate as a "barrier" to the plaintiffs' receipt of any COVID-19 treatment on account of their race or ethnicity. (J.A. 262.) The court also concluded

that plaintiffs could not show actual or imminent injury because the challenged guidance applied during an initial period of limited supply, and plaintiffs' concerns about future supply shortages are speculative. (J.A. 265.)

Second, the court held that plaintiffs could not show that any injuries they might have suffered were "traceable" to the NYSDOH guidance because the "nonbinding guidance has no 'determinative or coercive effect' on" health care providers making treatment decisions. (J.A. 267.) Finally, and for similar reasons, the court found that plaintiffs failed to establish redressability because any order against the state and city defendants would not bind medical providers making individual treatment decisions. In addition, the court noted that the CDC considers race and ethnicity as risk factors for severe COVID-19 illness and concluded that any order against the State and the City would not bind the CDC or preclude providers from referencing CDC guidance in making treatment decisions. (J.A. 269-270.)

STANDARD OF REVIEW

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

SUMMARY OF ARGUMENT

The district court correctly determined that there is no federal subject matter jurisdiction over plaintiffs' claims. First, plaintiffs have failed to establish any of the elements of Article III standing. Plaintiffs cannot show that they have suffered a concrete and particularized injury stemming from the challenged guidance; indeed, plaintiffs fail to allege that the guidance presents a barrier to any white and non-Hispanic person from accessing COVID-19 treatments. In addition, plaintiffs cannot show actual or imminent injury because the challenged guidance was in effect only during an initial period of supply shortage, and plaintiffs offer only speculative assertions that they might face injury in the event of hypothetical future shortages.

Plaintiffs have also failed to show that they have suffered injuries traceable to the challenged guidance and which could be redressed by a

judgment in their favor. The challenged NYSDOH guidance is nonbinding and does not control the independent medical judgment of health care providers making treatment decisions. Indeed, even if the court prohibited the state and city defendants from issuing guidance referencing race and ethnicity as risk factors for severe COVID-19 illness, nothing in that order would preclude providers from referencing similar CDC guidance and underlying scientific research.

Second, plaintiffs' complaint is moot, for many of the same reasons that they lack standing. The COVID-19 treatments at issue are now widely available, and the NYSDOH guidance has been updated to recommend that providers explore all options in determining a proper treatment course. Plaintiffs' complaint does not now present a live controversy, and there is no reasonable expectation that the supply shortages that prompted the challenged NYSDOH guidance are likely to recur, or that a new challenge would be unavailable to plaintiffs if the guidance again takes effect and also causes them harm.

If this Court nonetheless were to conclude that there is federal subject matter jurisdiction over plaintiffs' claims, it should remand to the district court for further proceedings including consideration of plaintiffs'

motion for a preliminary injunction in the first instance. Or, if the Court were to reach the merits of plaintiffs' motion for the first time on appeal, it should deny the motion as meritless. Plaintiffs cannot show that they would be irreparably harmed in the absence of injunctive relief because there is no current (or foreseeable) shortage of any of the treatments at issue. Plaintiffs are also unlikely to succeed on the merits of their equal protection claims because the challenged guidance is subject to rational basis review, which it readily survives. The guidance would satisfy strict scrutiny as well, in light of overwhelming medical evidence showing that being a member of certain racial and/or ethnic groups is a substantial and independent risk factor for severe COVID-19 illness. The guidance is narrowly tailored in permitting consideration of numerous medically substantiated risk factors, including but not limited to race and ethnicity, in the administration of COVID-19 treatments aiming to reduce the likelihood of severe illness.

ARGUMENT

POINT I

FEDERAL COURTS LACK SUBJECT MATTER JURISDICTION OVER PLAINTIFFS' CLAIMS

A. The District Court Correctly Concluded That the Plaintiffs Lacked Standing.

"Article III of the Constitution confines the federal courts to adjudicating actual 'cases' and 'controversies.'" *Allen v. Wright*, 468 U.S. 737, 750 (1984) (quoting U.S. Const. art. III, § 2, cl. 1). Article III therefore circumscribes the jurisdiction of federal courts to include only claims brought by plaintiffs who have standing to assert them. To establish Article III standing, a plaintiff must show (1) an injury in fact, which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; (2) that the injury is fairly traceable to the challenged action of the defendant; and (3) that it is likely the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). If a court determines at any time in the proceeding that it lacks subject matter jurisdiction, including based on matters outside the pleadings, it "must dismiss the action." Fed. R. Civ. P. 12(h)(3); *see Fountain v. Karim*, 838 F.3d 129, 133 n.5, 134 (2d Cir. 2016) (court considering its

subject matter jurisdiction sua sponte may refer to evidence outside of the pleadings). The district court correctly concluded that the plaintiffs had failed to satisfy any of these prerequisites in this case.

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

A plaintiff seeking to establish a concrete and particularized injury-in-fact for purposes of bringing an equal protection claim based on the government's alleged denial of a benefit must show that (i) plaintiff is a member of a disadvantaged group; (ii) the government has erected a barrier to obtaining a benefit; and (iii) the barrier causes members of one group to be treated differently from members of the other group. *See Comer v. Cisneros*, 37 F.3d 775, 793 (2d Cir. 1994) (citing *Northeastern Fla. Ch. of Assoc. Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 666 (1993)). The injury in such cases "is the denial of equal treatment resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit." *Id.*

Here, the challenged NYSDOH guidance neither erects a barrier to obtaining the treatments at issue nor causes one group to be treated differently than any other with regard to obtaining such treatments. The

challenged guidance consists of nonbinding recommendations to providers and does not supersede or supplant the professional judgment of those providers in treating individual patients. As a general matter, such voluntary guidance does not cause injury in a way that gives rise to Article III standing. *See Bear Lodge Multiple Use Ass'n v. Babbitt*, 175 F.3d 814, 821-22 (10th Cir. 1999).

Moreover, the guidance challenged here does not set aside a certain number or percentage of COVID-19 treatments for members of minority groups, nor does it authorize providers to treat race and ethnicity as a determinative risk factor or a more significant factor than other markers for risk, such as age and comorbidities. See *supra* at 8-9. The district court therefore correctly found that the challenged guidance bears no resemblance to admissions programs that reserve seats for or award points in the admissions process to members of minority groups, or affirmatively consider race and ethnicity as an unquantified factor in a holistic review of each admissions applicant's file. (J.A. 257-260 (discussing *Regents of Univ. of Calif. v. Bakke*, 438 U.S. 265 (1978), *Gratz v. Bollinger*, 539 U.S. 244 (2003), *Grutter v. Bollinger*, 539 U.S. 306 (2003), and *Parents Involved in Cmty. Schs. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701 (2007)).) Likewise,

the challenged guidance is not comparable to government programs reserving a certain percentage of contracts for minority-owned businesses or awarding extra compensation to contractors who hired minority-owned businesses. (J.A. 257-260 (discussing *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200 (1995), and *City of Jacksonville*, 508 U.S. at 658).) In those cases, race was inevitably a component of the determinations made by the respondents pursuant to the challenged admissions, school assignment, or procurement programs that they administered. Here, by contrast, the use of race in treatment decisions under the challenged guidance is a voluntary undertaking by third parties, who are not required by the guidance to prescribe medication based on considerations of race or ethnicity nor subject to any penalty for failing to consider race or ethnicity in treatment decisions.

Plaintiffs contend that even if the challenged guidance is voluntary, its "predictable effect" on the decision-making of providers has nevertheless harmed plaintiffs by creating barriers to accessing medical treatments. *See* Br. for Appellants (Br.) at 21 (quoting *New York v. United States Dep't of Homeland Security*, 969 F.3d 42, 59 (2d Cir. 2020)). But the sole authority that plaintiffs cite for this point undermines their argument.

In *DHS*, this Court considered a challenge brought by New York and other state and local entities to DHS rulemaking that would have reinterpreted the statutory "public charge" exclusion in federal immigration law. 969 F.3d at 51, 55. This Court held that plaintiffs had standing to challenge the proposed rule there because the federal government acknowledged "that expected disenrollment" by immigrants in benefit programs "will result in decreased federal funding to states, decreased revenue for healthcare providers, and an increase in uncompensated care." *Id.* at 59-60 (citations omitted). Here, by contrast, plaintiffs have pointed to no record evidence, much less a concession by the State, that the challenged NYSDOH guidance would result in predictable harms to plaintiffs or similarly situated individuals.

Moreover, even if plaintiffs could show that the guidance acts as a race-based barrier to their access of a benefit (though they cannot), they still fail to establish an actual or imminent injury—a separate and independent component of the injury-in-fact requirement—because the treatments are not subject to the supply shortages that prompted the issuance of the guidance in the first place. Plaintiffs appear to concede that they have not suffered "actual harm" and they acknowledge that the

COVID-19 treatments at issue in this case have been widely available since the spring of 2022. *See* Br. at 22, 24. Instead, plaintiffs argue that they will suffer an "imminent" injury because the challenged guidance might again take effect in the event of future hypothetical supply shortages. *Id.* at 22-23. "A party facing prospective injury has standing to sue" only "where the threatened injury is real, immediate, and direct." *Chevron Corp. v. Donziger*, 833 F.3d 74, 121 (2d Cir. 2016) (quoting *Davis v. Federal Election Comm'n*, 554 U.S. 724, 734 (2008)). Here, by contrast, the district court found that "the possibility of a future shortage appears increasingly speculative and nowhere near imminent" (J.A. 265)—factual findings which are owed deference by this Court.

Plaintiffs are also mistaken to rely on *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003), as support for a finding of injury-in-fact here. *See* Br. at 22-23. In *Baur*, the plaintiff filed suit to ban the use of "downed livestock" in food products due to the risk that such animals "are particularly likely to be infected with" certain neurological disorders that can be transmitted to humans. 352 F.3d at 627-28. The plaintiff was exposed to such meat and this Court held that he had standing to seek relief because he suffered an "*increased risk* of disease transmission

caused by exposure to a potentially dangerous food product." *Id.* at 632-33. The Court limited its ruling to "the specific context of food and drug safety suits," refusing to "decide as a matter of law whether enhanced risk generally qualifies as sufficient injury to confer standing." *Id.* at 634. The Court reasoned that such claims of injury were similar to those involving "threatened environmental harm," where the "potential harm from exposure . . . is by nature probabilistic, yet an unreasonable exposure to risk may itself cause cognizable injury." *Id.* (quotation marks omitted).

Here, the allegedly "imminent" injury to plaintiffs does not arise in "the specific context of food and drug safety," nor is such injury related to "an unreasonable exposure" to known environmental risks. *See id.* Instead, plaintiffs' hypothesized injury is contingent on a speculative series of future events: First, the plaintiffs must not only contract COVID-19 but they must also do so at a time when supply shortages counsel application of the NYSDOH guidance on treatment prioritization; next, plaintiffs must be treated by a provider who, in the provider's independent clinical judgment, considers the plaintiffs' race and ethnicity in determining whether there are risk factors that warrant administration of the treatments; and finally, the provider must then deny treatment to plaintiffs

because of the guidance's reference to race and ethnicity. The district court correctly determined that "[t]his requisite chain of events . . . is 'too speculative to satisfy the well-established requirement that threatened injury must be certainly impending.'" (J.A. 265 (citing *Clapper v. Amnesty Int'l U.S.A.*, 568 U.S. 398, 401 (2013)).)

In sum, the guidance does not serve as a barrier to access to the treatments by the plaintiffs, and even if it did the plaintiffs' injury is resulting from this barrier is neither actual nor imminent so as to give them standing. The district court's dismissal can be affirmed on either of these independent grounds.

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

Assuming plaintiffs could establish an injury-in-fact, they would still lack standing because their injury would not be "fairly traceable to the challenged action of the defendant"—that is, to the nonbinding guidance distributed to providers exercising independent medical judgment across the State. *See Lujan*, 504 U.S. at 560 (alteration and quotation marks omitted). This is yet another independent ground for affirmance.

Traceability speaks to the "causal connection between the injury and the conduct complained of." *Id.* at 560. Where, as here, the alleged injury is directly visited on the plaintiff by third parties (i.e., medical providers making determinations about which treatments to prescribe in individual cases), traceability "is ordinarily substantially more difficult to establish." *Id.* at 562 (quotation marks omitted). A plaintiff lacks standing to sue a defendant based on the "independent action" of the third party unless the defendant's conduct had a "determinative or coercive effect" on the third party's actions. *Bennett v. Spear*, 520 U.S. 154, 169 (1997). In *Bennett*, for example, traceability was found based on the "powerful coercive effect" of an advisory opinion that established conditions that could ultimately result in "substantial civil and criminal penalties, including imprisonment." *Id.*

As the district court correctly found, the nonbinding guidance at issue in this case has no "determinative or coercive" effect on medical providers as "there are no penalties for failure to abide by the guidance, nor is there any enforcement mechanism in place." (J.A. 267.) And this Court and other federal appellate courts have routinely found an absence of traceability in such circumstances. *See, e.g.*, *National Council of La Raza v. Mukasey*, 283 F. App'x 848, 852 (2d Cir. 2008); *Irregulators v. Federal*

Commc'ns Comm'n, 953 F.3d 78, 83 (D.C. Cir. 2020); *Turaani v. Wray*, 988 F.3d 313, 316-17 (6th Cir. 2021); *Baccus v. Parrish*, 45 F.3d 958, 962 (5th Cir. 1995).

Plaintiffs contend that the nonbinding nature of the challenged guidance is irrelevant because the purpose of the guidance was to cause providers to discriminate based on race or ethnicity when administering COVID-19 treatments. *See* Br. at 26-27. But purpose or intent has never been the test for traceability. In *National Council of La Raza*, for example, there was no doubt that the "purpose" behind the federal government making civil immigration violation records accessible through a criminal records database was to enhance enforcement of the immigration laws. *See* 283 F. App'x at 851-52 (describing process by which database was used to identify and detain alleged immigration violators). This Court nevertheless found that plaintiffs' injuries were traceable not to the federal defendants but to state and local law enforcement officers who carried out allegedly unlawful arrests based on the availability of such records. *Id.* at 852. So, too, in *Turaani*, where the court held that a plaintiff who was denied the purchase of a firearm because of an adverse background check was not injured by the federal government, but by a gun dealer who

chose not to sell a firearm to plaintiff, based on information provided by the Federal Bureau of Investigation. *See* 988 F.3d at 316. Although the government's purpose in sharing such information is to prevent plaintiff from obtaining a firearm, there is a break in the "chain of constitutional causation" where, as here, a third party is left with "legitimate discretion" to act. *Id.* at 317 (quotation marks omitted).

3. Plaintiffs failed to show that a successful outcome in this case would redress their alleged injuries.

Plaintiffs lack standing for a third, independent reason: they failed to establish that their alleged injuries were redressable by the district court. This failure, too, is by itself sufficient grounds for affirmance of the district court's dismissal of the complaint.

As the district court explained, it was plaintiffs' burden to establish that medical providers making treatment decisions in individual cases "would behave differently in the absence of the guidance" such that a court order enjoining application of the guidance could redress plaintiffs' purported injuries. (J.A. 269.) Here, the challenged guidance was not only nonbinding, but it also paralleled guidance from the CDC, which "include[s] the consideration of race and ethnicity." (J.A. 269.) Accordingly, "it is not

clear that [providers] would behave differently in the absence of the challenged guidance" (J.A. 270); indeed, those providers may well consider race and ethnicity as risk factors based on federal guidance and overwhelming medical evidence of disparities in COVID-19 outcomes for members of racial and ethnic minority groups.

Plaintiffs argue that they were not required to show that court-ordered relief would "completely redress all [of their] injury"; instead, they simply had to show "that a favorable decision will relieve a discrete injury" to each of them. Br. at 27-28 (quotation marks omitted). But this is precisely the standard plaintiffs failed to meet. The discrete injury that plaintiffs have complained about in this proceeding is unequal access to certain COVID-19 treatments. (J.A. 21-22.) A favorable decision would do nothing to remedy that injury, because federal guidance recommending that non-white race or Hispanic ethnicity be treated as a risk factor for the development of severe COVID-19 would remain in place.[13]

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[13] Plaintiffs incorrectly suggest that "in some cases" a court order "enjoining the government from enforcing one rule will result in private actors doing the same." Br. at 28 n.21. As an initial matter, there is no "enforcement" to be enjoined in this case, and in any event, plaintiffs' argument about the future conduct of private parties is sheer speculation. *See Lujan*, 504 U.S. at 561.

This Court's decision in *Town of Babylon v. Federal Housing Finance Agency*, 699 F.3d 221 (2d Cir. 2012), is directly on point. In that case, the plaintiff sued the Office of the Comptroller of Currency (OCC), alleging that nonbinding guidance issued by OCC to national banks adversely affected the operation of locally operated programs designed to encourage homeowners to make energy efficient home improvements. 699 F.3d at 225-26. This Court concluded that the plaintiffs failed to show redressability because even in the absence of nonbinding OCC guidance, the national banks "would remain entirely free to treat" the underlying programs unfavorably. *Id.* at 228-29. Here too, the elimination of NYSDOH's nonbinding guidance would leave unaffected federal government guidelines and medical evidence supporting a provider's decision to consider race and ethnicity as independent risk factors for severe COVID-19 illness.

Finally, the alleged injuries suffered by plaintiff Jonathan Roberts are not redressable for the additional reason that the treatments at issue were not authorized for patients with his risk profile, irrespective of the consideration of race or ethnicity. As the district court noted, the FDA's EUAs were "limited to individuals with a high risk of developing severe COVID-19, as defined by the CDC's risk factors," and "Roberts alleges

that he has none of these risk factors." (J.A. 269.) Plaintiffs contend that "under the challenged directives, Mr. Roberts would be eligible for the treatments if he were non-white or Hispanic" (*see* Br. at 28-29 n.22), but he is not seeking relief in the form of being treated as though he were non-white or Hispanic. Instead, Roberts is asking this Court to order defendants to refrain "from using race in determining which patients receive priority for" certain COVID-19 treatments. (J.A. 24.) Such relief would not make Roberts eligible to receive the underlying treatments.

B. Plaintiffs' Challenge Is Moot.

As explained above, plaintiffs lack standing for four independent reasons: the guidance does not erect a barrier to plaintiffs' access of a benefit; any injury suffered by plaintiffs is not actual or imminent; any such injury is not traceable to the guidance; and any such injury is not redressable by a successful outcome in this case. Even if plaintiffs could overcome *all* of these standing-related hurdles, the Court still lacks subject matter jurisdiction because plaintiffs' challenge to the guidance is moot for the reason that the circumstances giving rise to their alleged injury are no longer present.

"A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982)). Here, the challenged recommendations apply only during supply shortages, which have now dissipated. *See supra* at 9-10. The treatments at issue are now widely available and NYSDOH has encouraged providers "to evaluate all treatment options as early as possible" without regard to availability. (J.A. 250.) Thus, plaintiffs' challenge to NYSDOH's prioritization guidance is moot.

Plaintiffs are mistaken to argue that their complaint satisfies the "capable of repetition yet evading review exception to mootness." Br. at 30. This exception "applies only in exceptional situations." *Spencer v. Kemna*, 523 U.S. 1, 17 (1998); *accord Lillbask ex rel. Mauclaire v. State of Conn. Dep't of Educ.*, 397 F.3d 77, 85 (2d Cir. 2005). For the exception to apply, there must be "a reasonable expectation that the same complaining party will be subject to the same alleged action again." *Id. Spencer*, 523 U.S. at 17 (quotation & alteration marks omitted); *accord Lillbask*, 397 F.3d at 85. "[M]ere speculation that the parties will be involved in a dispute over

the same issue does not rise to the level of a reasonable expectation or demonstrated probability of recurrence." *Dennin v. Connecticut Interscholastic Athletic Conf., Inc.*, 94 F.3d 96, 101 (2d Cir. 1996) (quotation marks omitted). Here, plaintiffs' claims of future injury are built on speculation: nothing in the record points to any reasonable expectation that the supply shortages are likely to recur.

Nor is the challenged action "in its duration too short to be fully litigated prior to its cessation or expiration," even if supply shortages were to recur. *Spencer*, 523 U.S. at 17 (quotation marks omitted); *accord Lillbask*, 397 F.3d at 85. Future supply shortages are likely to be accompanied by significant media attention, and any direction from NYSDOH to providers about how to allocate treatments during periods of shortages will necessarily be publicly available. (*See, e.g.*, J.A. 75.) Plaintiffs will have ample opportunity to bring their challenge and seek emergency relief if necessary at that time. *See, e.g.*, *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 273, 277-79 (2d Cir. 2021) (describing procedural history of six weeks between filing of motion for preliminary injunction and resolution of appeal).

Finally, plaintiffs' request for nominal damages (*see* Br. at 31) does not preclude the dismissal of their claim against Commissioner Bassett,

because claims for money damages against state officials in their official capacities are barred by Eleventh Amendment sovereign immunity. *See, e.g.*, *National Rifle Ass'n of Am. v. Hochul*, No. 21-3187, 2021 WL 5313713, at *2 (2d Cir. 2021) (summary order); *Simmons v. Conger*, 86 F.3d 1080, 1086 (11th Cir. 1996).

POINT II

PLAINTIFFS ARE NOT ENTITLED TO A PRELIMINARY INJUNCTION EVEN IF THEY CAN ESTABLISH STANDING AND JUSTICIABILITY

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

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

Accordingly, if this Court concludes that there is federal subject matter jurisdiction over plaintiffs' complaint, it should remand for further

proceedings in the district court, including the adjudication of plaintiffs' preliminary injunction motion. *See Salinger v. Colting*, 607 F.3d 68, 83 (2d Cir. 2010) (remanding for consideration by the district court of the remaining three preliminary injunction factors, where the district court had considered only the first of the four factors). "The district court is in the best position to evaluate all of the evidence and weigh the factors to determine whether the injunction should issue."[14] *Home Instead, Inc. v. Florance*, 721 F.3d 494, 500 (8th Cir. 2013) (quotation marks omitted).

B. Plaintiffs' Motion for a Preliminary Injunction Fails on the Merits.

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

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[14] Plaintiffs contend that "full consideration of the motion is . . . proper in this Court" (Br. at 31), but the only authority they cite for this proposition holds that this Court "may affirm" the district court's decision "on any ground supported by the record," *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 405 (2d Cir. 2011) (quotation marks omitted). Plaintiffs, of course, are seeking reversal of the district court's ruling. Moreover, unlike in this case, both parties in *Cacchillo* "pressed the Court at oral argument to consider Cacchillo's entitlement to a preliminary injunction rather than remand the case to the district court." *Id.* at n.2.

Preliminary injunctive relief is an "extraordinary and drastic remedy" that is "unavailable except in extraordinary circumstances." *Moore v. Consolidated Edison Co. of N.Y., Inc.*, 409 F.3d 506, 510 (2d Cir. 2005) (quotation marks omitted). Where "a preliminary injunction will affect government action taken in the public interest pursuant to a statute or regulatory scheme, the moving party must demonstrate (1) irreparable harm absent injunctive relief, (2) a likelihood of success on the merits, and (3) public interest weighing in favor of granting the injunction." *Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 143 (2d Cir. 2016) (quotation marks omitted). Where, as here, the government is a party to the suit, the "public interest" and the "balance of equities" merge into a single factor. *DHS*, 969 F.3d at 58-59. Plaintiffs must demonstrate each of these factors; the failure as to any one is fatal to the motion. *Cf. Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 68 (2d Cir. 2007) (per curiam).

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

"A showing of irreparable harm is the single most important prerequisite for the issuance of a preliminary injunction." *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (quotation marks omitted). While "a presumption of irreparable injury flows from a violation of constitutional rights," *We the Patriots USA, Inc.*, 17 F.4th at 295, that presumption can be overcome when there is "no showing of any real or immediate threat that the plaintiff will be wronged again." *Levin v. Harleston*, 966 F.2d 85, 90 (2d Cir. 1992) (quotation marks omitted).

A plaintiff seeking to satisfy the irreparable harm requirement must demonstrate that "absent a preliminary injunction they will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." *Grand River*, 481 F.3d at 66 (quotation marks omitted). Even if plaintiffs are able to establish injury for the purposes of Article III standing, it remains the case that there are no *current* shortages of any of the COVID-19 treatments at issue. At this time, providers have been "encourage[d] . . . to evaluate all treatment options as early as

possible." (J.A. 250.) Accordingly, plaintiffs are not threatened by any actual or imminent injury that requires extraordinary injunctive relief.

2. Plaintiffs are unlikely to succeed on the merits of their equal protection claim against Commissioner Bassett.

Plaintiffs are also unlikely to succeed on the merits of their claims. To state a claim under the Equal Protection Clause of the Fourteenth Amendment, a plaintiff must identify (1) "a law or policy that expressly classifies persons on the basis of race"; (2) "a facially neutral law or policy that has been applied in an intentionally discriminatory manner"; or (3) "a facially neutral statute or policy [that] has an adverse effect and . . . was motivated by discriminatory animus." *Brown v. City of Oneonta*, 221 F.3d 329, 337 (2d Cir. 2000) (quotation marks omitted). If the challenged law or policy does not "target[] a suspect class," it is subject to a "highly deferential" rational basis review, where the classification "is presumed constitutional, and 'the burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it.'" *Winston v. City of Syracuse*, 887 F.3d 553, 560 (2d Cir. 2018) (cleaned up); *see Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973). Otherwise, a law or policy employing a racial classification

will be upheld if it satisfies strict scrutiny—that is, if it implements "narrowly tailored measures that further compelling governmental interests." *Adarand*, 515 U.S. at 227.

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

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

Here, the challenged guidance does not confer a benefit or impose a burden based on a racial classification. The guidance does not require that any action be taken with respect to any individual based on their race or ethnicity. *Cf. Lewis v. Ascension Par. Sch. Bd.*, 662 F.3d 343, 361-62 (5th Cir. 2011) ("In every case in which the Court has applied strict scrutiny to a 'racial classification,' a racial preference or classification appeared on the face of the government decision and required that action be taken with respect to an individual based on the classification.") (King, J., concurring in part). And the guidance does not prevent any patient from receiving COVID-19 treatment due to their race or ethnicity. The guidance instead provides accurate information about multiple known risk factors for severe illness and death due to COVID-19, including race and ethnicity. "[T]he mere awareness or consideration of race should not be mistaken for racially discriminatory intent or for proof of an equal protection violation." *Doe ex rel. Doe v. Lower Merion Sch. Dist.*, 665 F.3d 524, 548 (3d Cir. 2011). However, that the guidance also *recommends* that providers consider race and ethnicity as risk factors in making treatment decisions does not make it a classification based on race. "[R]ace-conscious yet non-preferential activities such as recruiting or other forms of outreach" do

not trigger strict scrutiny. *Honadle*, 56 F. Supp. 2d at 428; *see also Allen v. Alabama State Bd. of Educ.*, 164 F.3d 1347, 1352 (11th Cir.1999) (vacated on joint motion of the parties) ("where the government does not exclude persons from benefits based on race, but chooses to undertake outreach efforts to persons of one race, broadening the pool of applicants, *but disadvantaging no one*, strict scrutiny is generally inapplicable" (emphasis added)). The guidance does not require any action with respect to the race-based risk factors; it is "non-preferential" and "disadvantage[s] no one," and, as a result, does not create a classification on the basis of race.

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

Plaintiffs fail to meet that heavy burden here. Medical research has demonstrated that non-white and Hispanic individuals have suffered severe illness and death from COVID-19 in disproportionately higher numbers than white persons. (J.A. 76-80.) Accordingly, the inclusion of race and ethnicity as an independent risk factor for the development of severe COVID-19 in NYSDOH's guidance is rationally related to the State's legitimate interest in preventing severe illness and death from COVID-19, and in giving medical providers accurate, comprehensive information about known risk factors for developing severe disease.

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

Plaintiffs' equal protection claim would fail even if the NYSDOH guidance was subject to review under the strict scrutiny standard because the inclusion of race and ethnicity as a risk factor for severe disease is narrowly tailored to achieve a compelling state interest. *See Adarand*, 515 U.S. at 227. "It may be assumed that in some situations a State's interest in facilitating the health care of its citizens is sufficiently compelling to support the use of a suspect classification." *Bakke*, 438 U.S. at 310; *see also Mitchell v. Washington*, 818 F.3d 436, 446 (9th Cir. 2016) ("It is

not difficult to imagine the existence of a compelling justification [to consider race] in the context of medical treatment."). Indeed, there is significant, peer-reviewed medical research that "explore[s] possible racial connections with diseases and treatments." Erik Lilliquist & Charles A. Sullivan, *The Law and Genetics of Racial Profiling in Medicine*, 39 Harv. C.R.-C.L.L. Rev. 391, 393 (2004); *see also* Scarlett S. Lin & Jennifer L. Kelsey, *Use of Race and Ethnicity in Epidemiologic Research: Concepts, Methodological Issues, and Suggestions for Research*, 22 Epidemiologic Rev. 187, 191-92 (2000).

The challenged NYSDOH guidance serves the State's compelling interest in protecting public health and preventing severe illness and death from COVID-19. As stated above (at 38-39), the guidance provides accurate information about multiple known risk factors for severe COVID-19 illness to encourage providers to consider whether their patients are at a high risk of developing severe illness or dying from COVID-19 when determining treatment options during periods of limited supply. (J.A. 27, 75; *see* J.A. 76-80.) Plaintiffs suggest (Br. at 34) that the undisputed racial disparities in COVID-19 outcomes are attributable to factors other than race, such as socioeconomic status, access to health

care, and education, but the record evidence below showed that racial and ethnic disparities in COVID-19 outcomes persist even after controlling for medical comorbidities and educational attainment. (J.A. 78, 210-220 (comorbidities), 221-230 (educational attainment).)

The NYSDOH guidance is also narrowly tailored. "Narrow tailoring does not require exhaustion of every conceivable race-neutral alternative," but requires consideration of "the importance and the sincerity of the reasons advanced by the governmental decisionmaker for the use of race in that particular context." *Grutter*, 539 U.S. at 327, 339. Here, the guidance references race and ethnicity as part of an overall clinical assessment aimed at evaluating a patient's risk for developing severe COVID-19. Plaintiffs are simply wrong to suggest that the guidance reduces race and ethnicity to a "mindless assignment of a value." Br. at 36. Moreover, the record includes copious evidence indicating that race and ethnicity are clinically relevant risk factors for the development of severe COVID-19. (*See, e.g.*, J.A. 224-25 ("Nearly all racial and ethnic minority subgroups . . . experienced higher mortality . . . than their non-Hispanic White counterparts.").)

There is no race-neutral alternative that would account for the medically proven fact that non-white race or Hispanic ethnicity is an independent risk factor for severe COVID-19 illness. Plaintiffs suggest that the NYSDOH guidance could have prioritized treatments according to "race-neutral risk factors" such as "chronic diseases and obesity," but as plaintiffs concede, these classifications are "already in use." Br. at 37. An exclusive focus on comorbidities would simply disregard a different medically known risk. Plaintiffs also note that a number of other states do not "use[] race in allocating COVID-19 treatments." *Id*. Again, the guidance does not reference race or ethnicity to "allocate" treatments. See *supra* at 8-9. In any event, the fact that other States choose not to include certain risk factors in medical guidance does not preclude New York from making an independent judgment on the issue.

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

Finally, the public interest weighs against issuing the requested injunction. In exercising their discretion in whether to enter an injunction, courts "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *New York State Rifle & Pistol Ass'n v. City of New York*, 86 F. Supp. 3d 249, 258 (S.D.N.Y. 2015), *aff'd*, 883 F.3d 45 (2d Cir. 2018) (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). The injunction requested by plaintiffs would serve only to limit the government from issuing guidance citing to objectively true and accurate information about known risk factors for severe COVID-19 illness. The public interest would not be served by such an outcome.

CONCLUSION

The district court's judgment should be affirmed.

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June 16, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Alenette B. Jordan, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 8,592 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7) and Local Rule 32.1.

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