No. 22-622

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

JONATHAN ROBERTS and CHARLES VAVRUSKA,
Plaintiffs-Appellants,
v.
MARY T. BASSETT, in her official capacity as Commissioner for New York State Department of Health, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of New York
Honorable Nicholas G. Garaufis, District Judge

APPELLANTS' OPENING BRIEF

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INTRODUCTION

This case involves a clear-cut dispute between the parties: Plaintiffs Jonathan Roberts and Charles Vavruska—lifelong New York City residents—firmly believe that their race should play no part in whether they are able to obtain potentially lifesaving treatments for COVID-19 and seek equal access to that treatment without regard to their immutable characteristics. Defendants, New York State and New York City health departments, insist on using racial preferences in allocating those treatments.

Indeed, New York City proclaims that employing a race-neutral system for allocating such treatments would be "akin to intentionally maintaining a racially discriminatory policy for distributing live-saving drugs." *Roberts v. Bassett*, City Opp. to Pltfs' Mot. for Prelim. Inj., No. 22-710, ECF No. 20, at 12–13 (E.D.N.Y. filed Feb. 25, 2022). Last December, when confronted with "severe supply shortages" of the antivirals, App. 17, and "largest wave of reported cases yet," App. 52–53, Defendants issued directives to tens of thousands of individuals, including "licensed physicians, nurse practitioners, and physicians' assistants, " App. 247, instructing them to prioritize scarce COVID treatments to individuals on the basis of whether they have a chronic condition, whether they are obese or overweight, and whether they are non-white or Hispanic. App. 26–34; 39–44. Plaintiffs contend that these directives violate their equal protection rights.

The district court dismissed the case because it believed that Plaintiffs—white, non-Hispanic residents of New York City—did not have Article III standing to pursue their equal protection claims. The district court was wrong to do so. As this Court has held, "the relevant 'injury' for standing purposes may be exposure to a sufficiently serious risk of medical harm—not the anticipated medical harm itself." *Baur v. Veneman*, 352 F.3d 625, 628, 641 (2d Cir. 2003). That injury is traceable to Defendants' directives, which plainly instruct medical professionals to discriminate on the basis of race, and would be redressed by a favorable court decision.

The district court also observed that there is currently an adequate supply of COVID-19 treatments. But the State acknowledges that "supply chain disruptions can happen at any time," App. 82–83, and its race-based directive has not been superseded by another, more recent directive. App. 268. Thus, there remains a live controversy between the parties in this case.

JURISDICTIONAL STATEMENT

The district court had subject matter jurisdiction over Plaintiffs' constitutional challenge to Defendants' directives for allocating COVID-19 treatments under 28 U.S.C. §§ 1331, 1343. This appeal arises from the district court's final order dismissing the case pursuant to Federal Rule of Civil Procedure 12(b)(1) and declining to consider Plaintiffs' Motion for Preliminary Injunction. App. 251–70.

The district court's order was entered on March 15, 2022, *id.*, and Plaintiffs filed a timely notice of appeal on March 23, 2022. App. 271–72.

ISSUES PRESENTED

1. Whether Plaintiffs have Article III standing to pursue their case.

2. Whether Plaintiffs are entitled to a preliminary injunction enjoining Defendants from enforcing the race-based directives.

STATEMENT OF THE CASE

On February 8, 2022, Plaintiffs Jonathan Roberts and Charles Vavruska filed this action in the United States District Court for the Eastern District of New York. Plaintiffs challenge two similar directives, issued by the New York State Department of Health and the New York City Department of Health and Mental Hygiene,[1] which instructed providers to use race as a factor in allocating COVID-19 treatments during times of scarcity. Plaintiffs alleged that the directives violate the Equal Protection Clause of the Fourteenth Amendment, and sought injunctive relief, declaratory relief, and nominal damages. They moved for a preliminary injunction on February 18, 2022, and the district court held a hearing on the motion on March 2, 2022.

[1] For ease of reference, Plaintiffs will refer to Plaintiffs-Appellants Jonathan Roberts and Charles Vavruska as "Plaintiffs," and Defendants Mary Bassett, in her official capacity as Commissioner of the New York State Department of Health, and New York City Department of Health and Mental Hygiene collectively as "Defendants" or individually as the State or City.

On March 15, 2022, Judge Nicholas G. Garaufis issued the district court's final memorandum and order, dismissing the case for lack of jurisdiction and declining to consider Plaintiffs' Motion for Preliminary Injunction. The opinion is unreported, *see Roberts v. Bassett*, No. 22-710, 2022 WL 785167 (E.D.N.Y. Mar. 15, 2022) (Garaufis, J.), and is reproduced at App. 251–70. This appeal followed.

I. The Surge in COVID-19 Cases and Treatment Shortages

In Fall 2021, COVID-19 appeared to be behind us. Vaccinations became widely available by April 2021, and the number of cases predictably declined shortly thereafter. From a peak of more than 8,000 reported and confirmed cases per day in New York City in early January 2021, the tally had fallen to under 200 per day by late June. NYC Health, *COVID-19 Data: Trends and Tools, Long-term Trends, cases by day*.[2] But the good news was short-lived.

In November 2021, the Omicron variant of COVID-19 was identified. Centers for Disease Control and Prevention, *Potential Rapid Increase of Omicron Variant Infections in the United States* (updated Dec. 20, 2021).[3] The CDC alerted of "a rapid increase in infections" resulting from the variant's "increased transmissibility and the ability of the variant to evade immunity conferred by past infection or

[2] *Available at* https://www1.nyc.gov/site/doh/covid/covid-19-data-totals.page.
[3] *Available at* https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html.

vaccination." *Id*. Its warning proved correct. In New York City, it took only five weeks for Omicron to become the dominant variant in reported cases, compared to 20 weeks for the Delta variant. NYC Health, *Omicron Variant: NYC Report for January 13, 2022* at 2.[4] The number of cases in New York City skyrocketed—from fewer than 2,000 in November to over 40,000 per day in early January 2022. *Id.*; *see also* App. 52–53 ¶ 11 (noting that the number of new cases from November 2021 to January 2022 represented the "largest wave of reported cases yet").

Around the same time, the U.S. Food and Drug Administration issued an emergency use authorization for Paxlovid—an oral antiviral treatment for mild to moderate COVID-19 cases. U.S. FDA, *Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19*, Dec. 22, 2021.[5] The next day, the FDA also issued an emergency use authorization for another oral antiviral—molnupiravir. U.S. FDA, *Coronavirus (COVID-19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults*, Dec. 23, 2021.[6] Both drugs, along with previously approved monoclonal antibody

[4] *Available at* https://www1.nyc.gov/assets/doh/downloads/pdf/covid/omicron-variant-report-jan-13-22.pdf.
[5] *Available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19.
[6] *Available at* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain.

treatments (sotrovimab),[7] promised to bolster the availability of effective COVID-19 treatments in the United States. But the fight against Omicron was plagued by shortages of the available treatments. Both New York State and New York City noted that there were "severe supply shortages for all COVID-19 outpatient therapeutics," and that the most effective oral antiviral, Paxlovid, "go[es] out of stock frequently." App. 17 ¶ 14.

Responding to the shortage of treatments, Defendants issued directives instructing health care providers to allocate scarce treatments to those who, in Defendants' view, were most in need of them. App. 26–34, 39–44.

II. Defendants' Race-Based Directives for Allocating COVID-19 Treatments

On December 27, 2021, the New York State Department of Health published a document setting eligibility for COVID-19 treatments and directing New York health care providers and facilities to follow its guidance for prioritizing patients. *See* App. 26–34, "COVID-19 Oral Antiviral Treatments Authorized and Severe

[7] *See* GlaxoSmithKline, GSK and Vir Biotechnology announce United States government agreement to purchase additional supply of sotrovimab, authorised for the early treatment of COVID-19, Jan. 11, 2022, *available at* https://www.gsk.com/en-gb/media/press-releases/gsk-and-vir-biotechnology-announce-united-states-government-agreement-to-purchase-additional-supply-of-sotrovimab/. As of April 5, 2022, sotrovimab is no longer authorized for use in treating COVID-19 in light of data showing that it is ineffective against the new BA.2 subvariant. *See* Office of the Assistant Secretary for Preparedness and Response, *Sotrovimab*, *available at* https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Sotrovimab/Pages/default.aspx.

Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." The document, which was distributed to "health care facilities and prescribing medical professionals in New York, including licensed physicians, nurse practitioners, and physicians' assistants," App. 247, noted "severe resource restrictions" requiring providers to prioritize treatment based on a patient's risk of suffering severe illness. App. 26–34.

The document establishes eligibility criteria for oral antivirals Paxlovid and molnupiravir as follows:

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

Id. The document states that "non-white race or Hispanic/Latino ethnicity should be considered a risk factor." *Id.*

In a subsequent guidance document, the Department established five "risk groups," 1A–1E, which determine a person's priority when seeking treatment. *See* App. 35–38, "Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations." Patients assigned to Group 1A are considered the highest priority, those in Group 1B are the next highest priority, and so on. According to the Guidance, each eligible patient should be assigned to a group and then prioritized within the respective group based on age and number of risk factors. For groups 1D and 1E, providers and facilities can also prioritize based on receipt of a booster shot and time since last vaccination. *See id.*

Group 1A includes individuals of "any age with moderate to severe immunocompromise regardless of vaccine status," "[a]ge 65 and older and not fully vaccinated with at least one risk factor for severe illness," or "[a]ge 65 or older that is a resident of a long-term care facility environment." *Id.* Group 1B includes persons "under 65 years of age and not fully vaccinated with two or more risk factors for severe illness or over 65 and not fully vaccinated (no risk factors.)." *Id.* Group 1C includes persons "under 65 years of age and not fully vaccinated with at least one risk factor for severe illness." *Id.* Group 1D includes individuals "over age 65 and fully vaccinated with at least one risk factor for severe illness." *Id.* Group 1E includes persons "under 65 years of age and fully vaccinated with at least one risk

factor for severe illness or age 65 and older and fully vaccinated with no other risk factors." *Id.*

This scheme makes race determinative in two ways. First, among members in the same risk group, individuals that are non-white or of Hispanic/Latino ethnicity receive higher priority for treatment over others who are of the same age and have the same number of race-neutral risk factors. Second, because race is itself considered a risk factor, being a member of any minority group could move an individual to a higher risk group.

Aside from declaring that "[n]on-white race or Hispanic/Latino ethnicity" are to be considered risk factors, the Department's Guidance does not define "risk factors." Instead, it links to a United States Centers for Disease Control and Prevention (CDC) webpage.[8] That page lists several risk factors that may cause individuals "of any age" to be "more likely to get severely ill from COVID-19," including: cancer; chronic kidney disease; chronic liver disease; chronic lung diseases; dementia or other neurological conditions; diabetes; Down syndrome; heart conditions; HIV infection; an immunocompromised state; mental health conditions; obesity and being overweight; pregnancy; sickle cell disease or

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

thalassemia; smoking; solid organ or blood stem cell transplant; stroke or cerebrovascular disease; substance use disorders; and tuberculosis. Like the Department, the CDC also considers being non-white or Hispanic/Latino to be an independent risk factor. But the CDC does not instruct medical professionals to prioritize patients based on a rote counting of the number of risk factors they possess.

Under the State's directive, a white non-Hispanic person with cancer is treated the same as a non-white or a Hispanic person who is disease-free. Two 66-year-old vaccinated individuals with diabetes who would otherwise have equal standing in Group 1D would see a person of "[n]on-white race or Hispanic/Latino ethnicity" receive priority over a white non-Hispanic person. Race can also determine whether a person is even eligible for oral antivirals or whether similarly situated individuals are put into different risk groups.

New York City follows the state guidance. On December 27, 2021, the City published a health advisory that sets out eligibility criteria for New York City patients who wish to receive oral antiviral treatments and instructs providers on how to prioritize access. App. 39–44, "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products" (Health Advisory #39). Health Advisory #39 instructs health care providers to "[a]dhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies

during this time of severe resource limitations," and instructs providers to "consider race and ethnicity when assessing an individual's risk." *Id.* The City distributed the guidance to "75,000 email addresses aimed at medical providers and other registered individuals." App. 55 ¶ 22.

These directives were part of the government's broader scheme to curate the allocation of COVID treatments. In November 2021, the federal government announced the purchase of 10 million courses of Paxlovid and 3 million courses of Lagevrio (molnupiravir), pending subsequent emergency use authorizations. U.S. Dep't of Health and Human Services, *Biden Administration Secures 10 Million Courses of Pfizer's COVID-19 Oral Antiviral Medicine as Additional Tool to Reduce Hospitalizations and Save Lives*, Nov. 18, 2021;[9] Office of the Assistant Secretary for Preparedness and Response, *Lagevrio*.[10] In turn, the federal government allocated the courses to the various state health departments for distribution. Office of the Assistant Secretary for Preparedness and Response, *Paxlovid*;[11] Office of the Assistant, *Lagevrio*. As a result, the Department was the exclusive supplier of the treatments in New York. And although supplies are now

[9] *Available at* https://www.hhs.gov/about/news/2021/11/18/biden-administration-secures-10-million-courses-pfizers-covid-19-oral-antiviral-medicine-as-additional-tool-reduce-hospitalizations-save-lives.html.
[10] *Available at* https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Lagevrio/Pages/default.aspx.
[11] *Available at* https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Paxlovid/Pages/default.aspx.

available more broadly, both the State and the City initially contracted with select pharmacies to supply the treatments to eligible patients. *See* App. 26–34. For instance, Rite Aid was the only provider in Niagara County, *id*., Kinney Drugs was the only provider in Onondaga County, *id.*, and Alto Pharmacy was the only provider in the City of New York. *See* App. 39–44. The State also reminded individuals that the oral antivirals "may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under New York State law to prescribe drugs in the therapeutic class to which Paxlovid and molnupiravir belong (i.e., anti-infectives)." App. 29.

According to a *New York Post* article published soon after the directives went into effect, the "race-based approach in treatment" soon began "to have real-world consequences." *See* Jon Levine, *NYC will consider race when distributing life-saving COVID treatments*, New York Post, Jan. 1, 2022.[12] A Staten Island doctor filling two prescriptions for Paxlovid claimed that, for the first time in 30 years, he was asked by a pharmacist to disclose the race of his patients before the treatment was authorized.

Although supply shortages of Paxlovid have largely eased in the last few months, doubts linger as to whether shortages could return in the event of another

[12] *Available at* https://nypost.com/2022/01/01/nyc-considering-race-in-distributing-life-saving-covid-treatment/.

spike in cases like that seen in December 2021 given the uncertainty of continued funding for the acquisition of the treatments. *See* Zeke Miller, *White House expands availability of COVID antiviral treatment amid ample supply*, Associated Press, Apr. 26, 2022.[13] At the same time, cases in New York City have increased five-fold since March 2022 from a low of around 600 per day to over 3,000 per day as of May 3, 2022, *supra* n.2, triggering an elevated alert level that could result in a return of public health restrictions, Ralph Ellis, *NYC Raises COVID Alert Level to Medium*, WebMD, May 2, 2022.[14]

III Plaintiffs Jonathan Roberts and Charles Vavruska

Jonathan Roberts was born and raised in New York City. App. 45 ¶ 2. Mr. Roberts tested into the prestigious Bronx High School of Science and from there earned a math degree at Harvard—the only four years of his life in which he lived outside of New York. *Id.* He now lives in Manhattan with his wife of over 30 years. *Id.* Mr. Roberts is 61 years old, white and not Hispanic, and fully vaccinated against COVID-19 with no known risk factors for severe illness that could result from COVID-19. *Id.* ¶ 3. He does not therefore qualify for inclusion in any tier of the "risk groups" established by the State or the City for prioritization of COVID-19

[13] *Available at* https://www.pbs.org/newshour/health/white-house-expands-availability-of-covid-antiviral-treatment-amid-ample-supply.
[14] *Available at* https://www.webmd.com/vaccines/covid-19-vaccine/news/20220502/nyc-raises-covid-alert-level-to-medium.

treatments. App. 46 ¶ 4. If he were any race but white, he would qualify for the last tier (1E) of the risk groups.

Charles Vavruska is an electrical engineer and a resident of Queens. App. 47 ¶ 2. A lifelong resident of New York, Mr. Vavruska is 55 years old, white and not Hispanic, and vaccinated against COVID-19. *Id.* ¶ 3. In March 2020, Mr. Vavruska contracted COVID-19 and was hospitalized for 10 days. *Id.* He has at least one risk factor (overweight and obesity) for severe illness that could result from another bout with COVID-19. *Id.* ¶ 4. He therefore qualifies for inclusion in the last tier (1E) of the risk groups for prioritization of the COVID-19 treatments at issue in this case.

Mr. Roberts and Mr. Vavruska remain at risk for contracting COVID-19. The number of cases in New York City has increased over the last two months, and "the state of emergency to address the threat and impacts of COVID-19 in the City of New York . . . remains in effect." City of New York, Executive Order No. 83 (Apr. 28, 2022).[15]

IV. Proceedings Below

Plaintiffs initiated this civil rights lawsuit in the United States District Court for the Eastern District of New York on February 8, 2022, against Defendant Mary T. Bassett in her official capacity as Commissioner for the New York State

[15] *Available at* https://www1.nyc.gov/office-of-the-mayor/news/083-003/emergency-executive-order-83.

Department of Health and Defendant Department of Health and Mental Hygiene of the City of New York. Plaintiffs allege that Defendants' directives, which instruct medical providers to provide a racial preference when allocating COVID-19 treatments in times of scarcity, violate the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution.

Plaintiffs promptly requested a pre-motion conference, as required by the district court judge's rules, and filed their motion for preliminary injunction soon after. After full briefing and a hearing on the preliminary injunction motion, Defendants submitted information regarding changes to the directives since they were issued in December 2021. The State Defendant asserted that it planned to issue updated guidance noting that "there is currently no shortage of the COVID-19 therapies at issue in this case" and that all patients are eligible to receive it if their practitioners deemed it appropriate. App. 247. But the State acknowledged that the updated guidance did not supersede the December 2021 directive (which continues to govern in times of scarcity), and instead acts as an update to it. App. 248. The City claims that the case is moot because its earlier-issued directive is no longer in effect, *see Roberts*, 22-710, ECF No. 33 at 2. As support, the City points to a subsequently issued directive that provides notice that one of the antivirals is

"currently in stock." *See* NYC Health, "Paxlovid is Available for COVID-19 Treatment in New York City" (2022 Health Advisory #2).[16]

The district court issued its opinion on March 15, 2022. The court dismissed the case because it concluded that Plaintiffs have not demonstrated Article III standing. App. 251–70. Plaintiffs filed a timely notice of appeal on March 23, 2022. App. 271–72.

STANDARD OF REVIEW

This Court reviews the legal questions of whether a plaintiff has standing *de novo*. *See Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011). The district court's denial of preliminary injunctive relief is reviewed for abuse of discretion, which occurs when the district court bases its ruling on an incorrect legal standard or on a clearly erroneous assessment of the facts. *See New York Progress and Protection PAC v. Walsh*, 733 F.3d 483, 486 (2d Cir. 2013).

SUMMARY OF ARGUMENT

The district court erred in dismissing the case for lack of jurisdiction. Under the familiar three-part test set forth by the Supreme Court in *Lujan*, a plaintiff has standing to raise his claims if he suffers an "injury in fact" that is both "fairly

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

traceable" to a defendant's actions and redressable by a favorable decision from the court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992).

In this case, Plaintiffs have satisfied all three of the *Lujan* factors. As the district court acknowledged, the directives facially disadvantage Plaintiffs on the basis of their membership in a racial and ethnic group (i.e., white and non-Hispanic). App. 256–57. The injury-in-fact in an equal protection case is not the ultimate denial of the benefit, but the erection of "a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group." *Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 666 (1993). Moreover, Plaintiffs seek equal access to oral antivirals that must be taken within five days of symptom onset to treat a disease that is unpredictable and ubiquitous in nature. Thus, there is no question that the denial of equal access increases Plaintiffs' risk of illness and constitutes a concrete injury-in-fact.

Plaintiffs have satisfied their "relatively modest" burden of demonstrating that their injury is "fairly traceable" to Defendants' directives. *Rothstein v. UBS AG*, 708 F.3d 82, 92 (2d Cir. 2013) (quoting *Bennett v. Spear*, 520 U.S. 154, 171 (1997)). Defendants acknowledge that they distributed the guidance to roughly 75,000 individuals, including physicians and other medical professionals. App. 55 ¶ 22. Given that Defendants are government entities that regulate the physicians and supply the treatments, it is a matter of common sense that the directives produce a

coercive effect on medical professionals who prescribe the COVID-19 treatments at issue. Plaintiffs' injury is also redressable by a favorable court decision. There is no evidence that providers would use race in the same way absent the directives, and in any case, "the redressability prong does not demand that court-ordered relief completely redress all injury." *Dean v. Town of Hempstead*, 527 F.Supp.3d 347, 406 (E.D.N.Y. 2021) (citing cases). Finally, the current supply of COVID-19 treatments does not render the case moot. The State acknowledges that supply shortages can occur at any time, App. 82–83 ¶ 28, and neither defendant has taken the simple step of disavowing the use of race in allocating treatments during times of scarcity. At a minimum, Plaintiffs are entitled to nominal damages against the City for subjecting them to heightened risk of illness during the months of limited supply.

On the merits, it is not close. Despite Defendants' efforts to portray their directives as suggesting that medical professionals conduct a holistic review of each patient, the directives apply race as a mechanical plus factor—in direct contravention of Supreme Court precedent. *Compare* App. 38 (using race as a risk factor for every non-white or Hispanic individual), *with Gratz v. Bollinger*, 539 U.S. 244, 271–72 (2003) (invalidating admissions policy that awarded "20 points to every single applicant from an 'underrepresented minority' group"). The violation of Plaintiffs' fundamental right to be free from racial discrimination would be itself enough to warrant a preliminary injunction. But preliminary relief is doubly warranted here

given the rapidly evolving and unpredictable nature of the Coronavirus pandemic and the fact that Plaintiffs' requested relief would impose minimal burdens on Defendants. Plaintiffs do not ask that Defendants refrain from instructing medical professionals to distribute COVID-19 treatments on the basis of risk factors, such as age, vaccination status, or chronic conditions. Plaintiffs simply ask that Defendants follow in the footsteps of other government entities and refrain from using race. *See, e.g.*, Utah Dep't of Health, *UDOH announces changes to risk assessment process for accessing scarce COVID-19 treatments* (Jan. 21, 2022).[17]

ARGUMENT

I. Plaintiffs Have Article III Standing to Raise Their Claim in Federal Court

A. Plaintiffs Are Injured by Defendants' Directives

The directives injure Plaintiffs by denying them equal access to potentially life-saving medical treatments and increasing their risk of suffering from serious illness. The injury-in-fact in an equal protection case involving racial discrimination is not the ultimate denial of the benefit, but the erection of "a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group." *Ne. Fla. Ass'n of Gen. Contractors*, 508 U.S. at 666. In the Second Circuit, a plaintiff "must allege that (1) there exists a reasonable likelihood that the

[17] *Available at* https://health.utah.gov/featured-news/udoh-announces-changes-to-risk-assessment-process-for-accessing-scarce-covid-19-treatments.

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 district court accepted that there was a reasonable likelihood that Plaintiffs were members of the disadvantaged group. App. 256–57. Nonetheless, it concluded that it lacked jurisdiction because it was "not convinced that Plaintiffs have shown the challenged guidance either constitutes a barrier or causes one group to be treated differently from another." App. 257. It was wrong to do so.

The plain text of the directives shows that they impose a barrier to access on the basis of race. Because non-white race or Hispanic ethnicity is considered an independent risk factor and because patients seeking treatments are prioritized, in part, according to the number of risk factors they possess, the directives prioritize a non-white individual over a white individual who is identically situated in terms of age, vaccination status, and number of race-neutral risk factors.[18] In the district court, the State asserted that it is unlikely that two individuals will be competing for the

[18] The district court suggested that a barrier to equal treatment can only come in the form of a set-aside, *see* App. 257–58, but that is not so. *See Grutter v. Bollinger*, 539 U.S. 306, 317 (2003) (noting that the plaintiff "clearly had standing" in a case involving "holistic review" of applicants on factors including their race). In any event, because the directives at issue here involve the rote assignment of a risk factor solely on the basis of race, it is more akin to the program considered in *Gratz*, which the district court considered a barrier sufficient to establish an injury in fact. App. 258–59.

last remaining pill. App. 278 (contending that "[d]octors aren't lining up their patients and deciding who gets one last pill"). But that example is an illustration of Defendants' scheme for prioritization during times of scarcity which, by definition, means that many individuals will be competing for a fewer number of treatments.

In fact, the whole point of Defendants' directives was to funnel scarce COVID-19 treatments to those who needed it the most. App. 36 (noting that treatments "should be prioritized for patients with the highest risk of hospitalization and death"). Defendants cannot say, on one hand, that to eliminate the consideration of race would be akin to maintaining a racially discriminatory system, *Roberts*, No. 22-710, ECF No. 20, at 12–13, and on the other, suggest that their directives have little to no effect, App. 260 (proclaiming that "the guidance merely advises providers to consider race and ethnicity"); *cf. Stilwell v. Office of Thrift Supervision*, 569 F.3d 514, 518 (D.C. Cir. 2009) (finding it "more than a little ironic that [the agency] would suggest [the plaintiff] lack[s] standing and then, later in the same brief, label [the plaintiff] as a prime example of . . . the very problem the Rule was intended to address") (alterations and citation omitted). Defendants have gone to lengths in curating the distribution of COVID-19 treatments. *See supra* Statement of the Case at II. "When an agency action has a predictable effect . . . on the decisions of third parties, the consequences of those third party decisions may suffice to establish standing." *New York v. Dep't of Homeland Security*, 969 F.3d 42, 59 (2d Cir. 2020).

It is of little relevance that Plaintiffs have "never contracted COVID-19 nor sought out the Treatments during the period of shortage." App. 262. Plaintiffs are requesting prospective relief. As experience from the last two years has taught, COVID-19 can strike at unpredictable times. The treatments at issue here must be taken within five days of symptom onset, which would require an individual who has recently been diagnosed with COVID-19 to obtain a lawyer, file a lawsuit, seek preliminary relief, and receive a favorable decision from a court—all in less than a week. As the district court acknowledged, the time period is too fleeting for an individual to obtain meaningful relief in court after he has been infected with COVID-19. App. 264. Requiring an individual to contract COVID-19 and seek treatment before he may challenge the directives would essentially shield the directives from review.[19]

That the district court would require individuals to seek treatment to establish their standing also ignores the fact that the directives injure Plaintiffs by subjecting them to an increased risk of suffering the negative effects of COVID-19. In *Baur v. Veneman*, 352 F.3d 625, 628 (2d Cir. 2003), this Court reviewed a district court's dismissal of a citizen's lawsuit on the basis that "exposure to meat products from downed livestock was insufficient to establish a cognizable Article III injury-in-

[19] Further, given that there is some period of heightened immunity after contracting COVID-19, Plaintiffs have a *better* claim to prospective relief than an individual who sought treatment since the directives were published in late December.

fact." This Court reversed, holding that "exposure to an enhanced risk of disease transmission may qualify as injury-in-fact in consumer food and drug safety suits." *Id.* As particularly relevant here, this Court noted "the relevant 'injury' for standing purposes may be exposure to a sufficiently serious risk of medical harm—not the anticipated medical harm itself—thus only the exposure must be imminent, not the actual onset of disease." *Id.* at 641. Many other cases in the Second Circuit recognize that an injury-in-fact can be contingent. *See, e.g.*, *Carter v. HealthPort Technologies, LLC*, 822 F.3d 47, 55 (2d Cir. 2016) ("[A] liability, including a contingent liability, may be a cognizable legal injury.") (collecting cases).

The district court also dismissed Plaintiffs' claims as a generalized grievance. App. 261–62. But as this Court noted in *Baur*, a concrete harm can be "widely shared," and "[t]he fact that many other citizens could assert the same injury, by itself, is not sufficient to defeat standing." *Baur*, 352 F.3d at 635 & n.9. Just as the consumption of downed livestock increased the risk of disease to all would-be beef eaters in *Baur*, Defendants' directives increase the risk of medical illness to white, non-Hispanic residents of New York such as Mr. Roberts and Mr. Vavruska. Just as this Court held that Baur suffered a concrete, though widely shared, injury-in-fact in his case, it should reverse the district court and hold that Plaintiffs have suffered a cognizable injury here.

The district court concluded that Plaintiffs did not suffer an "actual or imminent harm." App. 263–65. Although the Court agreed with Plaintiffs that "it is impractical to wait until a person has tested positive for COVID-19 to file suit," App. 265, it concluded that Plaintiffs' injury was not imminent because the federal government has announced that the manufacturer for one of these treatments has announced plans to provide millions of pills, App. 264–65. Yet, as the State acknowledged, supply chain disruptions can occur at any time. App. 82–83. And the uncertainty of federal funding places doubts on whether supplies will remain adequate during another surge in COVID-19 cases. *See supra* n.13.

B. Plaintiffs' Injury Is "Fairly Traceable" to Defendants' Race-Based Directives

Plaintiffs' injury is fairly traceable to Defendants' COVID-19 directives. At the pleading stage of litigation, the plaintiffs' "burden . . . of alleging that their injury is 'fairly traceable' to" the challenged act "is relatively modest." *Rothstein*, 708 F.3d at 92 (quoting *Bennett*, 520 U.S. at 171). This Court has reiterated that the requirement is not onerous. *Carter*, 822 F.3d at 55–56. As the Supreme Court has admonished, it is "wrong[ ]" to "equate[ ] injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation." *Bennett*, 520 U.S. at 168–69.

Even at this preliminary stage, the record shows that the City issued the directives to 75,000 providers, App. 55 ¶ 22, and the State distributed the directives

to "health care facilities and prescribing medical professionals in New York, including licensed physicians, nurse practitioners, and physicians' assistants." App. 247.[20] And beyond regulating the practice of prescribing physicians, Defendants here are the sole suppliers of the COVID-19 treatments at issue. Common sense thus dictates that the unequal treatment of Plaintiffs is fairly traceable to the directives, which instruct medical professionals to treat patients differently on the basis of race. As Defendants acknowledge elsewhere, differential treatment is the whole point of the exercise. The City contends that its failure to consider race in distributing COVID-19 treatments would be akin to maintaining a racially discriminatory enterprise. *Roberts*, No. 22-710, ECF No. 20, at 12–13. Both Defendants similarly acknowledge that the directives aim to get COVID-19 treatments to patients that—in Defendants' view—need them the most. Plaintiffs have sufficiently alleged some causal connection between their injury and Defendants' directives.

The district court's holding to the contrary rested on the fact that the directives do not expressly provide penalties for medical professionals who refuse to follow them. But whether Plaintiffs' injury is fairly traceable to Defendants' directives does

[20] The State issued a subsequent letter informing medical professionals that they need not apply the previous guidance because there was now adequate supply of the treatments. App. 247. But as the State acknowledged, the subsequently issued guidance does not supersede the directive challenged in this case, but acts as an update to it. App. 248. The challenged directive remains operative during times in which there is scarcity, which the State concedes can occur at any time. App. 82–83.

not hinge on whether the directives carry express penalties for noncompliance. If that were the law, then no one would have standing to challenge any sort of directive not backed by express penalties—even ones that instructed physicians not to treat individuals on the basis of race.

The district court also relied upon *Nat'l Council of La Raza v. Mukasey*, 283 Fed. Appx. 848, 851 (2d Cir. 2008) (summary order). Yet the Court's holding in that case was not based on the lack of express penalties, but on the plaintiffs' failure to make "any allegations supporting a reasonable inference that [the federal] defendants' actions have a determinative or coercive effect on the state and local law enforcement officers who carry out the arrests" of which the plaintiffs complain. *Id.* at 852. On the contrary, the *La Raza* plaintiffs alleged both that federal officials merely requested assistance from state and local law enforcement and that "a number of state and local authorities [chose] not to comply" with those requests "for policy reasons." *Id.* at 851–52. The Second Circuit's analysis in *La Raza* is thus unhelpful to Defendants. The court reiterated what the Supreme Court stated in *Bennett*: even an "advisory" opinion can produce a coercive effect on a third-party actor. *See id.* at 3 (quoting *Bennett*, 520 U.S. at 169).

Plaintiffs' pleadings give rise to a "reasonable inference" of a coercive effect in this case. As noted above, Defendants are regulators of the third-party medical professionals and suppliers of the COVID-19 treatments at issue in this case.

Defendants published the directives and distributed them to medical professionals across the state precisely to ensure that the treatments would be distributed to those who—in Defendants' view—were most at risk of suffering severe consequences from COVID-19. App. 36 (noting that treatments "should be prioritized for patients with the highest risk of hospitalization and death"); App. 252 (noting that "providers are instructed to adhere to the NYS DOH guidance on prioritization") (internal quotation marks deleted). Plaintiffs have met their "relatively modest" burden of alleging that Defendants' efforts to direct the distribution of COVID-19 treatments was not an exercise in futility.

C. Plaintiffs' Injury Is Redressable by a Favorable Court Decision

It is "likely, as opposed to merely speculative, that the [Plaintiffs'] injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561 (internal quotation marks omitted). The district court acknowledged that the directives placed Plaintiffs in a disfavored group for receiving COVID-19 treatments. App. 257–58. A decision enjoining Defendants from enforcing the directives will therefore necessarily redress Plaintiffs' injury by placing them on equal footing with other New Yorkers with the same medical conditions.

The fact that there are third parties involved here does not make Plaintiffs' injury any less redressable. "The redressability prong does not demand that court-ordered relief completely redress all injury." *Dean*, 527 F.Supp.3d at 406 (collecting

cases).[21] The district court was therefore incorrect to hold that Plaintiffs' injury was not redressable because of similar CDC Guidance and because Plaintiffs have "not alleged how practitioners would act in the absence of the guidance." App. 270. Instead, "a plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his *every* injury." *Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982). In all events, the CDC guidance does not instruct providers to prioritize COVID-19 treatments based on a crude counting of the number of risk factors. *See supra* n.8. Although Defendants have widely shared their directives, App. 55 ¶ 22, App. 247, there is no evidence that the CDC distributed its guidance to medical professionals across New York. And it is Defendants, not the CDC, that directly regulate medical professionals and distribute the COVID-19 treatments in New York.[22] There is similarly no support for the counterintuitive proposition that,

[21] In some cases, a court order enjoining government from enforcing one rule will result in private actors doing the same. In one recent case, a federal court vacated a mask requirement for airlines, Amtrak, and other forms of public transportation. Private rideshare companies soon followed by repealing their own requirements. Jessica Flores, *Uber and Lyft have dropped their mask mandates*, SF Chronicle, Apr. 19, 2022, https://www.sfchronicle.com/bayarea/article/Uber-drops-mask-mandate-17090505.php.

[22] The district court also believed that "Plaintiff Roberts would be in the exact same situation in the absence of the" challenged directives because FDA's Emergency Use Authorization is "limited to individuals with a high risk of developing severe COVID-19, as defined by the CDC's risk factors." App. 269. Yet under the challenged directives, Mr. Roberts would be eligible for the treatments if he were

absent the directives, medical professionals will nonetheless allocate COVID-19 treatments in the way prescribed by the directives.[23]

D. Plaintiffs' Challenge to the Directives Is Not Moot

This case is not moot. "A case becomes moot when interim relief or events have eradicated the effects of the defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur." *Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 647 (2d Cir. 1998); *see also Am. Freedom Def. Initiative v. Metro. Transp. Auth.*, 815 F.3d 105, 109 (2d Cir. 2016) (noting that relevant question is whether the defendant's conduct has been "sufficiently altered so as to present a substantially different controversy from the one that existed when . . . suit was filed") (internal quotation marks omitted).

Here, Defendants have not chosen to alter their conduct in any meaningful respect. The State admits that although its challenged directive is not in effect while current supplies of COVID-19 treatments are sufficient, the directive has not been superseded. App. 249. In other words, the directive—and its use of racial

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non-white or Hispanic. *See* App. 37 (establishing that individuals who are under 65 and fully vaccinated are eligible in Group 1E if they possess at least one risk factor for severe illness).

[23] *Town of Babylon v. Federal Housing Finance Agency*, 699 F.3d 221, 224 (2d Cir. 2012), is not to the contrary. The directive challenged in that case did not dictate the injury of which the plaintiff complained. Therefore, the record was clear that "even if the [directive] were vacated," the injury to the plaintiff would "remain in force." *Id.* at 230.

preferences—will dictate providers' behavior as soon as treatments become scarce. It is the same with the City's directive. Although the City contends that directive is no longer in effect, *Roberts*, 22-710, ECF No. 33 at 2, a closer examination reveals that the most recent City directive says nothing about superseding the challenged City directive in this case, and instead only provides notice that one of the antivirals is "currently in stock." *See* NYC Health, "Paxlovid is Available for COVID-19 Treatment in New York City" (2022 Health Advisory #2).[24] But as the State itself noted, supply shortages can occur at any time. App. 82–83. The City similarly acknowledges that "community transmission remains an ongoing public health concern, App. 53 ¶ 11, and cases in New York City have already increased five-fold since March. The fact that Defendants' directives will continue to apply during future shortages means the case is not moot.

At the very least, this case falls within the capable of repetition yet evading review exception to mootness. *See Irish Lesbian & Gay Org.*, 143 F.3d at 647–49. Unpredictable surges in COVID-19 cases make the dispute in this case capable of repetition. Yet, in a case like this one, fluctuations in case numbers can easily allow a dispute to evade review. *See id.* at 648 (citing cases for the proposition that "a few weeks" was "clearly insufficient for full litigation of [plaintiff's] claims").

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

Finally, with respect to the City, Plaintiffs' request of nominal damages precludes mootness. *Van Wie v. Pataki*, 267 F.3d 109, 115 & n.4 (2d Cir. 2001). The district court's denial of nominal damages was based on its view that Plaintiffs have not been injured. But the directives increased the risk of illness to Plaintiffs in the months in which treatments were scarce. Nominal damages are therefore proper.

II. Plaintiffs Are Entitled to Preliminary Relief

While the district court only analyzed the question of whether Plaintiffs have standing in this action when it considered the motion for preliminary injunction, full consideration of the motion is still proper in this Court. *See Cacchillo*, 638 F.3d at 405 (considering merits of preliminary injunction appeal in case in which the district court dismissed on standing).

A party seeking a preliminary injunction must establish "that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008).[25]

[25] Second Circuit precedents "suggest that the Plaintiffs may be able to show that a preliminary injunction is warranted on the strength of the[ ] first two factors alone." *New York*, 969 F.3d at 86 & n.38.

A. Plaintiffs Are Likely to Succeed on the Merits

Plaintiffs are likely to succeed on their claim that the State's and City's race-based allocations of COVID-19 treatments violate the Equal Protection Clause of the Fourteenth Amendment. All racial classifications are subject to strict scrutiny because they are "simply too pernicious to permit any but the most exact connection between justification and classification." *Parents Involved in Cmty. Schs. v. Seattle Sch. Dist. No. 1*, 551 U.S. 701, 720 (2007) (internal quotations omitted).

The directives at issue contain racial classifications that "distribute[] burdens or benefits on the basis of [race]." *Id*. at 721 (citations omitted). The directives instruct health care providers to prioritize COVID-19 treatments to individuals on the basis of age, vaccination status, and risk factors such as chronic kidney disease, heart disease, cancer, and "[n]on-white race or Hispanic/Latino ethnicity." *See* App. 35–38. Because race is an independent risk factor, the directives instruct providers to allocate treatments to non-white individuals over identically situated white individuals who are the same age, have the same vaccination status, and the same number of risk factors apart from race. The directives are therefore subject to strict scrutiny. *See Mitchell v. Washington*, 818 F.3d 436, 444–46 (9th Cir. 2016) (consideration of race-related success rate of treatment as one of many factors in decision not to recommend patient for the treatment is subject to strict scrutiny).

Under strict scrutiny, "the government has the burden of proving that racial classifications 'are narrowly tailored measures that further compelling governmental interests.'" *Johnson v. California*, 543 U.S. 499, 505 (2005) (quoting *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 227 (1995)). Defendants must show that the directives both: (1) further a compelling interest; and (2) are narrowly tailored to further those interests. They cannot do either.

1. Race-Based COVID-19 Directives Do Not Further a Compelling Interest

Furthering a compelling interest is necessary to "assur[e] that the legislative body is pursuing a goal important enough to warrant use of a highly suspect tool." *City of Richmond v. J.A. Croson Co.*, 488 U.S. 469, 493 (1989) (plurality op.). The Supreme Court has recognized only two compelling interests sufficient to justify racial classifications: (1) remedying the past effects of de jure discrimination; and (2) diversity in higher education. *Parents Involved*, 551 U.S. at 720–22. Neither applies here. Instead, Defendants' use of racial classifications is based on the assertion that "longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19." App. 35–38. But neither the City nor the State have come close to establishing the "factual predicate" for their race-based directives. *See Croson*, 488 U.S. at 498. In the district court, Defendants proffered evidence in an attempt to sustain the race-based directives. Yet the State's own evidence suggests that its race-based directive is at best overbroad.

For instance, the State asserts that "[p]erhaps the most convincing data point" is a chart compiled by the CDC. *See* App 79 ¶ 21. But that chart reveals that race and ethnicity are risk markers for *other* conditions or behavior that affects health, such as "socioeconomic status, access to health care, and exposure to the virus related to occupation." *Id.* And it shows that Asians whose race is considered a risk factor fare better on every measure—cases, hospitalizations, and deaths. *Id.* Other studies cited by the State suffer from similar flaws. *See* App. 77 ¶ 16 (citing CDC data that "health care and social inequities," not biological differences due to race, result in worse COVID-19 outcomes); App. 190 (not controlling for race-neutral factors in changes in life expectancy and concluding that Hispanic whites have a higher life expectancy than non-Hispanic whites despite its "disadvantaged socioeconomic profile"); App. 199 (stating that race-neutral factors such as "access to quality healthcare, general health status, education, economic stability," contribute to an increased likelihood of severe illness from members of minority racial groups); App. 216 (acknowledging that previous studies suggest disparities can be explained by factors such as socioeconomic status, lack of testing for SARS-CoV-2 infection, and virus exposure due to employment in essential-worker occupations).

2. Race-Based COVID-19 Directives Are Not Narrowly Tailored

Narrow tailoring requires this Court to scrutinize "the means chosen" by the government, and to ensure that they "fit th[e] compelling goal so closely that there

is little or no possibility that the motive for the classification was illegitimate racial prejudice or stereotype." *Croson*, 488 U.S. at 493. The Supreme Court has established several benchmarks for determining whether a law is narrowly tailored. For example, narrow tailoring requires individualized consideration. *Grutter*, 539 U.S. at 334. Using race in a rigid, mechanical way does not suffice. Narrow tailoring also demands a close fit between the ends sought by the government and the means chosen to advance those ends. For instance, race-based decision-making is unconstitutional where it is overinclusive by providing gratuitous benefits to individuals due to their race. In addition, government must engage in "serious, good faith consideration of workable race-neutral alternatives" that would allow it to achieve a compelling interest. *Id*. at 339. Race must be used only as a last resort. The directives fail on all these counts.

First, a narrowly tailored law provides "individualized consideration" and uses race "in a flexible, nonmechanical way." *Id*. at 334. The directives, however, use race in a rigid, mechanical manner. App. 35–38. They treat race as one risk factor for every individual who is not white—regardless of whether that person is likely to suffer adverse effects from COVID-19.

The directives' mechanical application of a racial preference is not narrowly tailored. It is instead like the unconstitutional admissions policy in *Gratz*, 539 U.S. at 271–72, which was invalidated because it automatically awarded "20 points to

every single applicant from an 'underrepresented minority' group." Similarly, the directives use race as one risk factor for *every* non-white or Hispanic individual in New York. The mindless assignment of a value to race is antithetical to narrow tailoring.

Second, "the means chosen [must] 'fit' th[e] compelling goal so closely that there is little or no possibility that the motive for the classification was illegitimate racial prejudice or stereotype." *Croson*, 488 U.S. at 493. Yet the State's and City's use of race is overinclusive because it gives a preference to non-white individuals who are perfectly healthy. *See* App. 79 ¶ 21.

The government's use of race is also overinclusive because it grants a racial preference to every non-white racial group. Thus, even if it produced evidence to support its claim that "longstanding systemic health and social inequities" leads to "increased risk of severe illness" for members of some racial groups, it strains credulity to believe the government can do so for every non-white racial group. *See* App. 35–38. On the contrary, the "random inclusion of racial groups" for which there is no evidence of "longstanding systemic health and social inequities" demonstrates that a program is not narrowly tailored. *See Croson*, 488 U.S. at 506.

Third, the State and City failed to engage in "serious, good faith consideration of workable race-neutral alternatives" that would allow them to achieve a compelling interest. *Grutter*, 539 U.S. at 339. This is particularly concerning here

because such alternatives are readily available. For example, the government could have distributed COVID-19 treatments to those who are more likely to contract COVID-19 (e.g., those who use public transportation to commute to work or those who work in high-contact environments like grocery stores). They could also employ the same set of race-neutral risk factors already in use, including chronic diseases and obesity. Indeed, shortages in COVID-19 treatments have not been confined to New York. Most other states have not used race in allocating COVID-19 treatments, *see, e.g.*, Wash. Dep't of Health, *Interim-DOH Guidance on Prioritization for Use of AntiSARS-CoV-2 Monoclonal Antibodies* (Apr. 18, 2022),[26] and the ones that did have since reversed course, *see, e.g.*, Utah Dep't of Health, *UDOH announces changes to risk assessment process for accessing scarce COVID-19 treatments* (Jan. 21, 2022).[27] There is no reason the State and City cannot similarly disengage from the "sordid business" of "divvying us up by race." *League of United Latin Am. Citizens v. Perry*, 548 U.S. 399, 511 (2006) (Roberts, C.J., concurring in part, concurring in the judgment in part, and dissenting in part).

[26] *Available at* https://doh.wa.gov/sites/default/files/2022-02/821-155-InterimMonoclonalAntibodyGuidance.pdf.

[27] *Available at* https://health.utah.gov/featured-news/udoh-announces-changes-to-risk-assessment-process-for-accessing-scarce-covid-19-treatments.

B. The Remaining Preliminary Injunction Factors Are Satisfied

The other preliminary injunction factors are also satisfied in this case. That the directives violate Plaintiffs' fundamental right to equal protection under the Fourteenth Amendment is enough to establish irreparable harm. *Conn. Dep't of Envtl. Prot. v. OSHA*, 356 F.3d 226, 231 (2d Cir. 2004) (noting that a violation of constitutional rights is presumed to cause irreparable harm); *Diaz v. N.Y.C. Bd. of Elections*, 335 F.Supp.2d 364, 367 (E.D.N.Y. 2004) (alleging violation of Equal Protection Clause of Fourteenth Amendment satisfies "irreparable harm" standard).

In addition, the directives increase the risk of medical illness to Plaintiffs in times of scarcity—which Defendants concede can occur at any time. App. 82–83. No amount of monetary compensation can mitigate the inability to seek potentially lifesaving medical treatment on equal footing—treatment that must be received within days of the onset of COVID-19 symptoms. *See* App. 28 (directing patients to start treatment within five days of symptom onset).

The balance of hardships and public interest factors merge in cases where the government is the opposing party. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Both factors counsel in favor of preliminary relief. Absent a preliminary injunction, Plaintiffs are not assured equal access to COVID-19 treatments during a rapidly evolving pandemic. By contrast, a preliminary injunction will allow Defendants to allocate treatments on the basis of any factor except race. Finally, a preliminary

injunction is in the public interest, which "requires obedience to the Constitution." *Carey v. Klutznick*, 637 F.2d 834, 839 (2d Cir. 1980).

CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the district court and remand with instructions to enter the preliminary injunction requested by the plaintiffs.

Dated: May 12, 2022.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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and Type-Style Requirements

This document complies with the type-volume limitation of Local Rule 32.1(a)(4), excluding the parts of the document exempted by Fed. R. App. P. 32(f), because this document contains 8,980 words.

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Dated: May 12, 2022.

/s/ Wencong Fa
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Attorney for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Wencong Fa
WENCONG FA
Attorney for Plaintiffs-Appellants

No. 22-622

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

JONATHAN ROBERTS and CHARLES VAVRUSKA,
Plaintiffs-Appellants,
v.
MARY T. BASSETT, in her official capacity as Commissioner for New York State Department of Health, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of New York
Honorable Nicholas G. Garaufis, District Judge

JOINT APPENDIX
VOLUME 1 OF 1

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APPEAL,ACO

U.S. District Court
Eastern District of New York (Brooklyn)
CIVIL DOCKET FOR CASE #: 1:22-cv-00710-NGG-RML

Roberts et al v. Bassett et al
Assigned to: Judge Nicholas G. Garaufis
Referred to: Magistrate Judge Robert M. Levy
Cause: 28:1983 Civil Rights

Date Filed: 02/08/2022
Jury Demand: None
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: Federal Question

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Date Filed	#	Docket Text
02/08/2022	1	COMPLAINT *for Declaratory and Injunctive Relief* against Mary T. Bassett, Department of Health and Mental Hygiene of the City of New York filing fee $ 402, receipt number ANYEDC-15270804 Was the Disclosure Statement on Civil Cover Sheet completed -YES,, filed by Charles Vavruska, Jonathan Roberts. (Attachments: # 1 Civil Cover Sheet, # 2 Proposed Summons to Mary T. Bassett, # 3 Proposed Summons

		to Dep't of Health and Mental Hygiene, # 4 Exhibit A to Complaint, # 5 Exhibit B to Complaint, # 6 Exhibit C to Complaint) (Houghton, Jonathan) (Entered: 02/08/2022)
02/08/2022	2	NOTICE of Change of firm, mailing address, and email address *of Attorney Jonathan Houghton.* Once the filing has been made, you must login to www.pacer.gov and update your account. (Houghton, Jonathan) (Entered: 02/08/2022)
02/08/2022		Case Assigned to Judge Nicholas G. Garaufis and Magistrate Judge Robert M. Levy. Please download and review the Individual Practices of the assigned Judges, located on our website. Attorneys are responsible for providing courtesy copies to judges where their Individual Practices require such. (Neptune, Pierre) (Entered: 02/09/2022)
02/09/2022	3	Summons Issued as to Mary T. Bassett, Department of Health and Mental Hygiene of the City of New York. (Attachments: # 1 Summons - Mary T. Bassett) (Neptune, Pierre) (Entered: 02/09/2022)
02/09/2022	4	In accordance with Rule 73 of the Federal Rules of Civil Procedure and Local Rule 73.1, the parties are notified that ***if*** all parties consent a United States magistrate judge of this court is available to conduct all proceedings in this civil action including a (jury or nonjury) trial and to order the entry of a final judgment. Attached to the Notice is a blank copy of the consent form that should be filled out, signed and filed electronically **only if all** parties wish to consent. The form may also be accessed at the following link: http://www.uscourts.gov/uscourts/FormsAndFees/Forms/AO085.pdf. **You may withhold your consent without adverse substantive consequences**. **Do NOT return or file the consent unless all parties have signed the consent.** (Neptune, Pierre) (Entered: 02/09/2022)
02/09/2022	5	This attorney case opening filing has been checked for quality control. See the attachment for corrections that were made, if any. (Neptune, Pierre) (Entered: 02/09/2022)
02/09/2022		Notice of Related Case: **The Civil Cover Sheet filed in this civil action indicates a related case.** (Neptune, Pierre) (Entered: 02/09/2022)
02/09/2022	6	MOTION to Appear Pro Hac Vice Filing fee $ 150, receipt number ANYEDC-15276972. by Jonathan Roberts, Charles Vavruska. (Attachments: # 1 Affidavit in Support of Motion, with Certificates of Supreme Courts of California and Texas annexed thereto) (Fa, Wencong) (Entered: 02/09/2022)
02/10/2022		ORDER granting 6 Motion for Leave to Appear Pro Hac Vice. The attorney shall register for ECF, registration is available online at www.pacer.gov. Once registered, the attorney shall file a notice of appearance and ensure that s/he receives electronic notification of activity in this case. Also, the attorney shall ensure the 150 admission fee be submitted to the Clerks Office via filing the event *Pro Hac Vice Filing Fee*. Ordered by Magistrate Judge Robert M. Levy on 2/10/2022. (Marino, Janine) (Entered: 02/10/2022)
02/11/2022	7	SUMMONS Returned Executed by Charles Vavruska, Jonathan Roberts. Department of Health and Mental Hygiene of the City of New York served on 2/9/2022, answer due 3/2/2022. (Attachments: # 1 Exhibit - Email to Department) (Fa, Wencong) (Entered: 02/11/2022)
02/11/2022	8	NOTICE of Appearance by Wencong Fa on behalf of Jonathan Roberts, Charles Vavruska (notification declined or already on case) (Fa, Wencong) (Entered: 02/11/2022)

02/11/2022	9	Letter MOTION for pre motion conference *re Preliminary Injunction* by Jonathan Roberts, Charles Vavruska. (Fa, Wencong) (Entered: 02/11/2022)
02/14/2022		ORDER: Plaintiffs' 9 application for a pre-motion conference regarding a preliminary injunction is GRANTED. The parties are DIRECTED to contact the court's Deputy promptly at Joseph_Reccoppa@nyed.uscourts.gov to schedule a pre-motion conference on February 15, 2022. Ordered by Judge Nicholas G. Garaufis on 2/14/2022. (Katz, Jennifer) (Entered: 02/14/2022)
02/15/2022	10	MOTION to Appear Pro Hac Vice *of Attorney Caleb Trotter* Filing fee $ 150, receipt number ANYEDC-15292630. by Jonathan Roberts, Charles Vavruska. (Attachments: # 1 Affidavit in Support of Motion, with Certificate of Supreme Court of California annexed thereto) (Trotter, Caleb) (Entered: 02/15/2022)
02/15/2022		ORDER granting 10 Motion for Leave to Appear Pro Hac Vice. The attorney shall register for ECF, registration is available online at www.pacer.gov. Once registered, the attorney shall file a notice of appearance and ensure that s/he receives electronic notification of activity in this case. Also, the attorney shall ensure the 150 admission fee be submitted to the Clerks Office via filing the event *Pro Hac Vice Filing Fee*. Ordered by Magistrate Judge Robert M. Levy on 2/15/2022. (Marino, Janine) (Entered: 02/15/2022)
02/15/2022	11	NOTICE of Appearance by Samantha Michelle Schonfeld on behalf of Department of Health and Mental Hygiene of the City of New York (aty to be noticed) (Schonfeld, Samantha) (Entered: 02/15/2022)
02/15/2022	12	NOTICE of Appearance by Caleb Randall Trotter on behalf of Jonathan Roberts, Charles Vavruska (notification declined or already on case) (Trotter, Caleb) (Entered: 02/15/2022)
02/16/2022	13	NOTICE of Appearance by Erin P. Kandel on behalf of Mary T. Bassett (aty to be noticed) (Kandel, Erin) (Entered: 02/16/2022)
02/16/2022	14	MOTION to Appear Pro Hac Vice Filing fee $ 150, receipt number ANYEDC-15295568. by Jonathan Roberts, Charles Vavruska. (Attachments: # 1 Affidavit in Support of Motion, with Certificate of Supreme Court of California annexed thereto) (Boden, Anastasia) (Entered: 02/16/2022)
02/16/2022		ORDER granting 14 Motion for Leave to Appear Pro Hac Vice. The attorney shall register for ECF, registration is available online at www.pacer.gov. Once registered, the attorney shall file a notice of appearance and ensure that s/he receives electronic notification of activity in this case. Also, the attorney shall ensure the 150 admission fee be submitted to the Clerks Office via filing the event *Pro Hac Vice Filing Fee*. Ordered by Magistrate Judge Robert M. Levy on 2/16/2022. (Marino, Janine) (Entered: 02/16/2022)
02/16/2022	15	NOTICE of Appearance by Anastasia P. Boden on behalf of Jonathan Roberts, Charles Vavruska (notification declined or already on case) (Boden, Anastasia) (Entered: 02/16/2022)
02/16/2022	16	MOTION for Refund of Fees Paid Electronically *in error related to Motion to Appear Pro Hac Vice of Anastasia P. Boden* by Jonathan Roberts, Charles Vavruska. (Attachments: # 1 Exhibit A - Notice of Electronic Filing and Fee Payment, # 2 Exhibit B - Receipt for Erroneous Fee Payment) (Boden, Anastasia) (Entered: 02/16/2022)

02/17/2022		Minute Entry for proceedings held before Judge Nicholas G. Garaufis: Pre-motion conference held on February 16, 2022. Counsel for Plaintiffs and counsel for Defendants present via videoconference. The court DIRECTED Plaintiffs to file their motion for a preliminary injunction by February 18, 2022, Defendants to file their response by February 25, 2022, and Plaintiffs to file their reply, if any, by March 1, 2022 at 12PM. The court DIRECTED the parties to to address Article III standing in the briefing. The court DIRECTED the parties to appear for oral argument on March 2, 2022 at 11AM in Courtroom 4D South. (Court Reporter Michele Lucchese) (Katz, Jennifer) (Entered: 02/17/2022)
02/17/2022	17	APPROVAL of 16 Motion for Refund of Fees Paid Electronically. Signed Tiffeny Lee-Harris, Case Processing Supervisor on 2/17/2022. (forwarded for processing) (Lee, Tiffeny) (Entered: 02/17/2022)
02/17/2022	18	SUMMONS Returned Executed by Charles Vavruska, Jonathan Roberts. Mary T. Bassett served on 2/15/2022, answer due 3/8/2022. (Fa, Wencong) (Entered: 02/17/2022)
02/18/2022	19	MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* by Jonathan Roberts, Charles Vavruska. (Attachments: # 1 Declaration of Plaintiff Jonathan Roberts in Support of Motion, # 2 Declaration of Plaintiff Charles Vavruska in Support of Motion) (Fa, Wencong) (Entered: 02/18/2022)
02/25/2022	20	MEMORANDUM in Opposition re 19 MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* filed by Department of Health and Mental Hygiene of the City of New York. (Schonfeld, Samantha) (Entered: 02/25/2022)
02/25/2022	21	AFFIDAVIT/DECLARATION in Opposition re 19 MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* filed by Department of Health and Mental Hygiene of the City of New York. (Attachments: # 1 Exhibit State Guidance, # 2 Exhibit DOHMH Guidance) (Schonfeld, Samantha) (Entered: 02/25/2022)
02/25/2022	22	MEMORANDUM in Opposition re 19 MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* filed by Mary T. Bassett. (Kandel, Erin) (Entered: 02/25/2022)
02/25/2022	23	AFFIDAVIT/DECLARATION in Opposition re 19 MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* filed by Mary T. Bassett. (Attachments: # 1 Exhibit AA - Statewide Cluster Dashboard, # 2 Exhibit A - DOH Guidance: COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products, # 3 Exhibit B - DOH Guidance: Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral Antivirals for the Treatment of COVID-19 During Times of Resource Limitations, # 4 Exhibit C - CDC Guidance, # 5 Exhibit D - National Center for Health Statistics 2020 Report, # 6 Exhibit E - CDC December 10, 2020 Study, # 7 Exhibit F - Mortality data from CDCs National Vital Statistics System, # 8 Exhibit G - Scientific Reports Article, # 9 Exhibit H - Journal of the American Medical Association Network Open Article) (Kandel, Erin) (Entered: 02/25/2022)
02/28/2022	24	NOTICE of Appearance by Rachel Fried on behalf of National Medical Association, American Medical Association, Medical Society of the State of New York, American College of Physicians, American Public Health Association, Council of Medical Specialty Societies, 1199SEIU United Healthcare Workers East, Community Service

		Society of New York, Inc., Housing Works, Callen-Lorde Community Health Center, medical and health equity professionals and academics (aty to be noticed) (Fried, Rachel) (Entered: 02/28/2022)
02/28/2022	25	Letter MOTION for Leave to File Document *Amici Curiae Brief* by 1199SEIU United Healthcare Workers East, American College of Physicians, American Medical Association, American Public Health Association, Callen-Lorde Community Health Center, Community Service Society of New York, Inc., Council of Medical Specialty Societies, Housing Works, Medical Society of the State of New York, National Medical Association, medical and health equity professionals and academics. (Attachments: # 1 Proposed Amicus Brief) (Fried, Rachel) (Entered: 02/28/2022)
02/28/2022	26	MOTION to Appear Pro Hac Vice Filing fee $ 150, receipt number ANYEDC-15329059. by 1199SEIU United Healthcare Workers East, American College of Physicians, American Medical Association, American Public Health Association, Callen-Lorde Community Health Center, Community Service Society of New York, Inc., Council of Medical Specialty Societies, Housing Works, Medical Society of the State of New York, National Medical Association, medical and health equity professionals and academics. (Attachments: # 1 Affidavit, # 2 Certificate of Good Standing, # 3 Certificate of Good Standing) (Lewis, John) (Entered: 02/28/2022)
02/28/2022		ORDER: 25 Application to file Amici Curiae Brief by medical and health equity professionals and academics is GRANTED. The parties have not objected to the court's consideration of this brief. Ordered by Judge Nicholas G. Garaufis on 2/28/2022. (Katz, Jennifer) (Entered: 02/28/2022)
02/28/2022	27	REPLY in Support re 19 MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* filed by Jonathan Roberts, Charles Vavruska. (Fa, Wencong) (Entered: 02/28/2022)
02/28/2022	28	AFFIDAVIT/DECLARATION in Support re 19 MOTION for Preliminary Injunction *and Memorandum of Law in Support of Motion* filed by Jonathan Roberts, Charles Vavruska. (Attachments: # 1 Exhibit 1 - Emory University Covid-19 Health Dashboard, # 2 Exhibit 2 - CDC Covid Data Tracker, # 3 Exhibit 3 - NY State Covid-19 Guidance Repository) (Fa, Wencong) (Entered: 02/28/2022)
03/01/2022	29	NOTICE of Appearance by Jessica Lynn Katzen on behalf of Department of Health and Mental Hygiene of the City of New York (aty to be noticed) (Katzen, Jessica) (Entered: 03/01/2022)
03/03/2022		Minute Entry for proceedings held before Judge Nicholas G. Garaufis: Oral argument on Plaintiffs' 19 motion for a preliminary injunction. Counsel for Plaintiffs and counsel for Defendants present in person. The court DIRECTED the parties to promptly submit any supplemental materials requested by the court during the hearing. The court RESERVED decision on the motion for a preliminary injunction. (Court Reporter Avery Armstrong) (Katz, Jennifer) (Entered: 03/03/2022)
03/04/2022	30	Letter *Re: Information Requested by the Court during Oral Argument on Plaintiffs' Motion for a Preliminary Injunction* by Mary T. Bassett (Kandel, Erin) (Entered: 03/04/2022)
03/04/2022		ORDER: The court is in receipt of Defendant Commissioner Bassett's 30 Letter regarding information requested by the court during oral argument on Plaintiffs' motion for a preliminary injunction. Defendant Commissioner Bassett is DIRECTED to promptly provide a date by which the new guidance will be issued and whether it will

		supersede the guidance Plaintiffs seek to enjoin. Ordered by Judge Nicholas G. Garaufis on 3/4/2022. (Katz, Jennifer) (Entered: 03/04/2022)
03/07/2022		ORDER: Defendant Commissioner Bassett is DIRECTED to provide a date by which the New York State Department of Health will issue new guidance and whether it will supersede the guidance Plaintiffs seek to enjoin by Tuesday March 8, 2022 at 12pm. Ordered by Judge Nicholas G. Garaufis on 3/7/2022. (Katz, Jennifer) (Entered: 03/07/2022)
03/07/2022	31	Letter *in Response to the Court's March 4, 2022 Electronic Order re: New DOH Guidance* by Mary T. Bassett (Attachments: # 1 Exhibit A - March 4, 2022 DOH Guidance) (Kandel, Erin) (Entered: 03/07/2022)
03/08/2022	32	MOTION for pre motion conference *re Defendant Commissioner Bassett's Proposed Motion to Dismiss the Complaint Pursuant to Fed. R. Civ. P. 12(b)(1) & 12(b)(6)* by Mary T. Bassett. (Kandel, Erin) (Entered: 03/08/2022)
03/08/2022	33	MOTION for pre motion conference by Department of Health and Mental Hygiene of the City of New York. (Schonfeld, Samantha) (Entered: 03/08/2022)
03/09/2022		ORDER: Defendants' 32 33 applications for a pre-motion conference regarding a motion to dismiss and for an extension of the time to answer the Complaint until 45 days after the court has ruled on the motion to dismiss are GRANTED. The parties are DIRECTED to contact the court's Deputy at Joseph_Reccoppa@nyed.uscourts.gov to schedule the pre-motion conference. Ordered by Judge Nicholas G. Garaufis on 3/9/2022. (Katz, Jennifer) (Entered: 03/09/2022)
03/09/2022		ORDER granting 26 Motion for Leave to Appear Pro Hac Vice. The attorney shall register for ECF, registration is available online at www.pacer.gov. Once registered, the attorney shall file a notice of appearance and ensure that s/he receives electronic notification of activity in this case. Also, the attorney shall ensure the 150 admission fee be submitted to the Clerks Office via filing the event *Pro Hac Vice Filing Fee*. Ordered by Magistrate Judge Robert M. Levy on 3/9/2022. (Levy, Robert) (Entered: 03/09/2022)
03/09/2022	34	Letter *in Response to Defendants Requests for a Pre-Motion Conference, ECF Nos. 32, 33* by Jonathan Roberts, Charles Vavruska (Fa, Wencong) (Entered: 03/09/2022)
03/15/2022	35	MEMORANDUM & ORDER, 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. So Ordered by Judge Nicholas G. Garaufis on 3/15/2022. (fwd'd for jgm) (Lee, Tiffeny) (Entered: 03/15/2022)
03/23/2022	36	NOTICE OF APPEAL as to 35 Order on Motion to Certify FLSA Collective Action,, Order on Motion for Preliminary Injunction, by Jonathan Roberts, Charles Vavruska. Filing fee $ 505, receipt number ANYEDC-15403994. Appeal Record due by 4/6/2022. (Fa, Wencong) (Entered: 03/23/2022)
03/24/2022		Electronic Index to Record on Appeal sent to US Court of Appeals. 36 Notice of Appeal, Documents are available via Pacer. For docket entries without a hyperlink or for documents under seal, contact the court and we'll arrange for the document(s) to be made available to you. (Jones, Vasean) (Entered: 03/24/2022)

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APP 11

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JONATHAN ROBERTS and CHARLES VAVRUSKA,

Plaintiffs,

v.

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

Defendants.

Case No. 1:22-cv-00710

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Amidst a surge in cases involving the Omicron variant of COVID-19 in December 2021, the U.S. Food and Drug Administration granted emergency approval for an oral antiviral hailed as "the biggest advance in the pandemic since the vaccines."[1] The antiviral has been in development since March 2020, when Pfizer sent chemist Dafydd Owen home with instructions to develop an oral drug to fight the emerging pandemic. For the next 13 months, Owen worked in a makeshift office in his home to develop the drug—building on the work his colleagues had produced nearly two decades earlier in the fight against SARS. In December 2021, the FDA

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

finally granted emergency use authorization for his brainchild: Paxlovid. An "antiviral superstar," the drug "reduces the rate of hospitalizations by around 90%" with "no safety issue beyond placebo."[2] By interfering with the virus's ability to replicate, the drug could "prevent more than a million hospitalizations," and has potential to reduce transmission, which would avert "myriad disruptions such as medical professional shortages, school closings and flight cancellations."[3]

2. Despite plans to ramp up production, supplies are currently scarce. Thus, both the State of New York and New York City instruct providers to follow the state's directive for allocating scarce COVID-19 treatments—oral antivirals Paxlovid and Molnupiravir as well as monoclonal antibodies. The directives require providers to prioritize treatment to individuals based on age, vaccination status, and a number of risk factors. Risk factors include medical conditions such as cancer, chronic disease, diabetes, and obesity. The directives also state that, apart from any medical condition, non-white race or Hispanic/Latino ethnicity must be considered as an independent risk factor. As a result, an unvaccinated 64-year-old African American with diabetes receives priority over an unvaccinated white 64-year-old with diabetes. A vaccinated 66-year-old who is Hispanic receives priority over a vaccinated 66-year-old who is not.

3. New York's designation of race as an independent risk factor has no basis in science. Although race may be associated with different risk factors, New York has cited no evidence that race—on its own—makes an individual more

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

susceptible to suffering adverse effects from COVID-19. Indeed, that evidence does not exist, because race does not connote any attribute inherent to any individual. It is instead an arbitrary classification that lumps in many different individuals with different attributes and different needs.

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

5. Plaintiffs are New York residents who object to differential treatment on the basis of race and seek access to treatment on a race-neutral basis. Plaintiff Jonathan Roberts' mother immigrated from Hungary to escape antisemitic sentiments prevalent in Europe at the time. Mr. Roberts has lived in New York for almost his entire life and happily calls New York City "home" with his wife of over thirty years. Plaintiff Charles Vavruska is vaccinated and wishes not to repeat his experience in March 2020 when he was hospitalized for ten days with COVID-19. Plaintiffs are all Americans. Plaintiffs are all New Yorkers. As then-Mayor-elect Eric Adams stated in December 2020: "We are in this together."[4] Not so, under New York's directives. "It is a sordid business, this divvying us up by race." *League of United Latin Am. Citizens v. Perry*, 548 U.S. 399, 511 (2006) (Roberts, C.J., concurring in part, concurring in the judgment in part, and dissenting in part).

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

JURISDICTION AND VENUE

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

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

PARTIES

8. Plaintiff Jonathan Roberts is a resident of Manhattan, New York. He is white and not Hispanic, 61 years old, vaccinated against COVID-19, and has no known risk factors for severe illness that could result from COVID-19. Mr. Roberts does not therefore qualify for inclusion in any tier of the "risk groups" established by the New York State Department of Health or New York City's Department of Health and Mental Hygiene for prioritization of certain COVID-19 treatments. If he were any race but white, he would qualify for the last tier (1E) of the risk groups.

9. Plaintiff Charles Vavruska is a resident of Queens, New York. A lifelong resident of New York, Mr. Vavruska is white and not Hispanic, 55 years old, and vaccinated against COVID-19. In March 2020, Mr. Vavruska contracted COVID-19 and was hospitalized for 10 days. He has at least one risk factor (overweight and

obesity) for severe illness that could result from another bout with COVID-19. Mr. Vavruska therefore qualifies for inclusion in the last tier (1E) of the risk groups for prioritization of certain COVID-19 treatments.

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

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

12. Defendant Department of Health and Mental Hygiene of the City of New York ("NYC Health") is sued pursuant to 42 U.S.C. § 1983 for its policy directing New York City health care providers and facilities to use a patient's race as a factor in prioritizing the administration of certain COVID-19 treatments. *See Pizarro v. Ponte*, No. 17-cv-4412, 2019 WL 568875, at *7 n.11 (S.D.N.Y. Feb. 11, 2019) ("[Department of Health and Mental Hygiene] is a suable entity."); *Monell v. Dep't of Social Servs*, 436 U.S. 658, 694 (1978).

FACTUAL ALLEGATIONS

State Directive

13. On January 11, 2022, New York was in the middle of a surge in COVID-19 cases prompted by the new Omicron variant. Acting Commissioner Janet

Woodcock of the United States Food and Drug Administration stated that "most people are going to get covid." Aaron Blake, *"Most people are going to get covid": A momentous warning at a Senate hearing*, Washington Post (Jan. 11, 2022).[5]

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

15. Pursuant to its statutory authority, N.Y. Pub. Health Law § 201(1), (3), on December 27, 2021, the New York Department of Health published a document directed to New York health care providers and health care facilities titled, "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." Exh. A. The document was published on the Department's website on a page dedicated to the Department's "COVID-19 Guidance Documents." *See* https://coronavirus.health.ny.gov/covid-19-guidance-repository.

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

[5] *Available at* https://www.washingtonpost.com/politics/2022/01/11/most-people-are-going-get-covid-momentous-warning-senate-hearing/.
[6] https://coronavirus.health.ny.gov/monoclonal-antibody-therapeutics (State website); https://www1.nyc.gov/site/doh/covid/covid-19-providers-treatments.page#refer (City website).
[7] https://www1.nyc.gov/site/doh/covid/covid-19-providers-treatments.page#refer.

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

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

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

20. The Guidance sets out five "risk groups" (1A-1E), with "[p]atients assigned to 1A [ ] be[ing] considered the highest priority, with 1B being the next highest priority and so on."

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

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

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

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

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

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

27. As a result, two 66-year-old vaccinated individuals with diabetes who would otherwise have equal standing in tier 1D would see a person of "[n]on-white race of Hispanic/Latino ethnicity" receive priority over a white non-Hispanic person.

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

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

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

30. The Mayo Clinic has determined that "there's no evidence that people of color have genetic or other biological factors that make them more likely to be affected by COVID-19."[9]

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

City Directive

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

[9] *See* https://www.mayoclinic.org/diseases-conditions/coronavirus/expert-answers/coronavirus-infection-by-race/faq-20488802 (last visited Feb. 7, 2022).
[10] *See* https://covid19.emory.edu/ (last visited Feb. 7, 2022).

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

34. Specifically, in setting out eligibility criteria for New York City patients to receive oral antiviral treatments, Health Advisory #39 instructs providers to "consider race and ethnicity when assessing an individual's risk. Impacts of longstanding systemic health and social inequities put Black, Indigenous and People of Color at increased risk of severe COVID-19 outcomes and death."

35. In an effort "[t]o ensure equitable access to oral antivirals," NYC Health has selected only one provider, Alto Pharmacy, to fill all oral antiviral prescriptions for patients in New York City.

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

The State and City Directives Injure Plaintiffs

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

38. The erection of "a barrier that makes it more difficult for members of one group to obtain a benefit than it is for members of another group" is a cognizable

injury in an equal protection case alleging racial discrimination. *Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 666 (1993).

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

40. Because Plaintiff Vavruska is white and not Hispanic, 55 years old, and vaccinated against COVID-19 with at least one risk factor (overweight and obesity), he qualifies for tier 1E. The Guidance provides that, for persons in the same tier seeking limited COVID-19 treatments, priority should be given to persons with the highest number of risk factors. As Mr. Vavruska does not possess the additional risk factor of being non-white or Hispanic/Latino, he would receive COVID-19 treatment after an individual in tier 1E who is non-white or Hispanic/Latino with the same number of other risk factors.

CLAIM FOR RELIEF
(Against All Defendants)

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

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

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

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

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

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An entry of a judgment declaring that Defendants' use of race in determining which patients receive priority for oral antiviral and monoclonal antibody treatments for COVID-19 is unconstitutional because it violates the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution;

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

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

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

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

Respectfully submitted this 8th day of February, 2022.

s/ Jonathan M. Houghton
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**Pro Hac Vice Pending*

EXHIBIT A

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

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

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Date: December 27, 2021
To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

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

Summary:

- Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).
  - Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 when started early after symptom onset.
  - Paxlovid is the preferred product and is available for patients age 12 years and older.
  - Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA- authorized COVID-19 treatment options are not accessible or clinically appropriate.
- At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.
  - There will be a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV beginning 1/3/2022.
- Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.

The announcement is to make you aware of information about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatments.

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

COVID-19 Oral Antiviral Treatment

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

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

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

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

Eligibility

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

- Age 12 years and older weighing at least 40 kg (88 pounds) for Paxlovid, or 18 years and older for molnupiravir
- Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
- Have mild to moderate COVID-19 symptoms
    - Patient cannot be hospitalized due to severe or critical COVID-19
- Able to start treatment within 5 days of symptom onset
- Have a medical condition or other factors that increase their risk for severe illness.
    - Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19

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

- Therapy is contraindicated for patients (1) with a history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; (2) treating with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or (3) treating with drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.
- Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.
- Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

- Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.
- Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
- For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

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

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

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

Referring Patients for Oral Antivirals Outside of NYC

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

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

Referring Patients for Oral Antivirals in NYC

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

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and through a language line in Russian, Mandarin, Vietnamese, Arabic, and Korean. Prescriptions confirmed by 5 p.m. on weekdays or 1p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

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

Changes to Monoclonal Antibody Use

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

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

Please continue to monitor our website regularly for updated guidance, including on treatment supply and prioritization: COVID-19 Monoclonal Antibody (mAb) Therapeutics: Information for Providers | Department of Health (ny.gov).

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

County Name	Store #	Store Name	City	Zip
Albany	417	CVS	ALBANY	12205
Albany	2702	CVS	COLONIE	12205
Albany		CENTRAL AVE PHARMACY	ALBANY	12206
Broome	1835	Walmart	VESTAL	13850
Cayuga	62	Kinney Drugs	AUBURN	13021
Cayuga	73	Kinney Drugs	MORAVIA	13118
Chautauqua	10870	Rite Aid	JAMESTOWN	14701
Chautauqua	10811	Rite Aid	DUNKIRK	14048
Chemung	10880	Rite Aid	HORSEHEADS	14845
Chemung	260	Rite Aid	ELMIRA	14901
Chenango	2120	Walmart	NORWICH	13815
Clinton		Condo Pharmacy	PLATTSBURGH	12901
Clinton		Cornerstone Drug & Gift	ROUSES POINT	12979
Columbia	242	CVS	HUDSON	12534
Cortland	7	Kinney Drugs	CORTLAND	13045
Delaware	19432	Walgreens	STAMFORD	12167
Dutchess	418	CVS	POUGHKEEPSIE	12601
Dutchess		Beekman pharmacy	POUGHQUAG	12570
Erie		Tile Pharmacy	CHEEKTOWAGA	14225
Erie		Kenmore Rx Center	KENMORE	14217
Erie		Wanakah Pharmacy	HAMBURG	14075
Erie		Larwood Pharmacy, Inc.	EAST AURORA	14052
Erie		Cy's Elma Pharmacy	ELMA	14059
Erie	3288	Walgreens	BUFFALO	14215
Essex	95	Kinney Drugs	LAKE PLACID	12946
Essex		Moriah Pharmacy	PORT HENRY	12974
Essex		Willsboro Pharmacy	WILLSBORO	12996
Franklin	10591	Walgreens	MALONE	12953
Fulton	18296	Walgreens	JOHNSTOWN	12095
Genesee	10807	Rite Aid	BATAVIA	14020
Hamilton		NATHAN LITTAUER HOSPITAL	SPECULATOR	12164
Herkimer	27	Kinney Drugs	ILION	13357
Jefferson		BOLTONS PHARMACY	WATERTOWN	13601
Jefferson	42	Kinney Drugs	ALEXANDRIA BAY	13607
Lewis	20	Kinney Drugs	LOWVILLE	13367
Livingston	5072	CVS	DANSVILLE	14437
Madison		Dougherty Pharmacy	MORRISVILLE	13408
Madison	46	Kinney Drugs	CHITTENANGO	13037

County Name	Store #	Store Name	City	Zip
Monroe	5123	CVS	BROCKPORT	14420
Monroe	831	CVS	WEBSTER	14580
Monroe	10512	Walgreens	ROCHESTER	14621
Montgomery	25	Kinney Drugs	ST. JOHNSVILLE	13452
Nassau	997	CVS	GLEN COVE	11542
Nassau	2028	CVS	HEMPSTEAD	11550
Nassau	1084	CVS	FREEPORT	11520
Niagara	10817	Rite Aid	LOCKPORT	14094
Niagara	3600	Rite Aid	NIAGARA FALLS	14301
Oneida	639	Rite Aid	UTICA	13502
Oneida	610	Rite Aid	ROME	13440
Oneida		Bassett Medical Center OP Pharmacy	COOPERSTOWN	13326
Onondaga	43	Kinney Drugs	BALDWINSVILLE	13027
Onondaga	79	Kinney Drugs	LIVERPOOL	13088
Onondaga	108	Kinney Drugs	SYRACUSE	13206
Onondaga	64	Kinney Drugs	EAST SYRACUSE	13057
Ontario	10846	Rite Aid	GENEVA	14456
Ontario	10842	Rite Aid	CANANDAIGUA	14564
Orange	10688	CVS	NEWBURGH	12550
Orange	2908	CVS	MONROE	10950
Oswego		Wayne Drug- Oswego	OSWEGO	13126
Otsego	2262	Walmart	ONEONTA	13820
Putnam		COMMUNITY PHARMACY INC	BREWSTER	10509
Putnam	5054	CVS	CARMEL	15012
Rensselaer	906	CVS	TROY	12182
Rensselaer	2137	CVS	WYNANTSKILL	12198
Rockland	2205	CVS	SPRING VALLEY	10977
Saratoga	10384	Walgreens	WILTON	12866
Saratoga	5046	CVS	CLIFTON PARK	12065
Schenectady	2340	CVS	SCHENECTADY	12304
Schenectady	5385	CVS	SCOTIA	12302
Schoharie	7326	CVS	COBLESKILL	12043
Schuyler	3221	Walmart	WATKINS GLEN	14891
Seneca	65	Kinney Drugs	SENECA FALLS	13148
St. Lawrence	1	Kinney Drugs	GOUVERNEUR	13642
St. Lawrence		The Medicine Place-KimRos Inc.	OGDENSBURG	13669
St. Lawrence		Adk Pharmacy COVID-19	STAR LAKE	13690
Steuben	2326	Walmart	HORNELL	14830
Steuben	2992	Walmart	PAINTED POST	14810

County Name	Store #	Store Name	City	Zip
Suffolk	3099	CVS	BAY SHORE	11706
Suffolk	6026	CVS	RIVERHEAD	11901
Suffolk	1271	CVS	ROCKY POINT	11778
Suffolk	2961	CVS	HUNTINGTON STATION	11746
Sullivan		Rock Hill Healthmart Pharmacy	ROCK HILL	12775
Sullivan		K & K Pharmacy	LIBERTY	12754
Tompkins	80	Kinney Drugs	ITHACA	14850
Ulster	8945	CVS	KINGSTON	12401
Ulster	323	CVS	SAUGERTIES	12477
Warren	419	CVS	QUEENSBURY	12804
Washington	2685	CVS	HUDSON FALLS	12839
Wayne	66	Kinney Drugs	LYONS	14489
Westchester	5048	CVS	PEEKSKILL	10566
Westchester	5350	CVS	PORT CHESTER	10573
Westchester	4539	CVS	YONKERS	10701
Wyoming		Sinclair Pharmacy	WARSAW	14569
Yates	442	Rite Aid	PENN YAN	14527

EXHIBIT B

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

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

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

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

Introduction

In times of limited supplies of monoclonal antibodies (mAbs) and oral antivirals (OAVs), providers should prioritize patients eligible for treatment based on their level of risk for progressing to severe COVID-19. In addition, the most efficacious products should be prioritized for patients with the highest risk for hospitalization and death.[1]

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

- Prioritizing the **treatment** of COVID-19 **and**
- Prioritizing anti-SARS-CoV-2 mAbs and OAVs for **unvaccinated or incompletely vaccinated** individuals and **vaccinated individuals who are not expected to mount an adequate immune response** (e.g., individuals with moderate to severe immunocompromise or individuals aged ≥65 years).

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

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

How to use this framework

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

[1] In clinical trials, Paxlovid demonstrated an 88% reduction in hospitalizations and death in high-risk unvaccinated adults vs. 85% for Sotrovimab vs. 30% for Molnupiravir

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

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

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Tier 1: Prioritization Groups for the Treatment of COVID-19
For treatment, patients must have mild to moderate symptoms, test positive for SARS-CoV-2, and be within 10 days of symptom onset for mAbs or within 5 days for oral antivirals

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

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

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

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Notes

- We recommend using BMI ≥30 as a cutoff for weight-based risk factor
- The risk of severe disease increases with the number of comorbidities, even among fully vaccinated individuals[2]
- Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19
- See CDC guidance for further information on specific medical conditions and associated risk
- Fully vaccinated is currently defined as having received two doses of an mRNA vaccine, or a single dose of the Johnson & Johnson vaccine

[2] Bierle *et al*, mAb Treatment of Breakthrough COVID-19 in Fully Vaccinated Individuals with High-Risk Comorbidities. *JID* 2021

EXHIBIT C

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD, MSc
Commissioner

2021 HEALTH ADVISORY #39

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

- **Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).**
  - **Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 disease when started early after symptom onset.**
  - **Prescriptions in New York City (NYC) will be filled by Alto Pharmacy to provide free, same day home delivery regardless of insurance or immigration status.**
  - **Paxlovid is the preferred product and is available for patients age 12 years and older.**
  - **Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA- authorized COVID-19 treatment options are not accessible or clinically appropriate.**
- **At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.**
  - **There is a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. These products do not retain activity against omicron and should not be used.**
- **Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.**
- **While therapeutic shortages continue, off-label use of remdesivir on an outpatient basis may be an option.**
- **Check nyc.gov/health/covidprovidertreatments regularly for updates.**

December 27, 2021

Dear Colleagues,

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

While the availability of oral antivirals for treatment of COVID-19 is an important milestone, it comes at a time of a significant surge in cases and reduced effectiveness of existing

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Dave A. Chokshi, MD, MSc
Commissioner

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

COVID-19 Oral Antiviral Treatment

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

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

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

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

Eligibility

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

- Age 12 years and older for Paxlovid, or 18 years and older for Molnupiravir
- Weigh at least 40 kg (88 pounds)

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- Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
- Have mild to moderate COVID-19 symptoms
    - Patient cannot be hospitalized or receiving oxygen therapy due to COVID-19
- Are able to start treatment within 5 days of symptom onset
- Have a medical condition or other factors that increase their risk for severe COVID-19 illness.
    - Consider race and ethnicity when assessing an individual's risk. Impacts of longstanding systemic health and social inequities put Black, Indigenous, and People of Color at increased risk of severe COVID-19 outcomes and death.

For Paxlovid only:

- Therapy is contraindicated for patients with history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; are on drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or are on drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.
- Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.
- Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

- Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.

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- Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
- For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

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

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

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

Referring Patients for Oral Antivirals

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

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and support in numerous other languages through language line. Prescriptions confirmed by 5 p.m. on weekdays or 1 p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

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

Changes to Monoclonal Antibody Use

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

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HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD, MSc
Commissioner

are extremely limited and providers should adhere to NYS DOH prioritization guidance, and refer to the NYC Health Department's Letter to Providers: Omicron and Monoclonal Antibodies.

As of December 23, 2021, there is a pause on further allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. Bamlanivimab with etesevimab and REGEN-COV do not retain activity against omicron and should not be used. Monoclonal antibody treatment can no longer be used as post-exposure prophylaxis.

Outpatient Use of Remdesivir

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

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

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

Sincerely,

Celia Quinn MD, MPH
Deputy Commissioner
Division of Disease Control

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jonathan Roberts and Charles Vavruska,

Plaintiffs,

-against-

Mary T. Bassett, in her official capacity as Commissioner for New York State Department of Health; New York City Department of Health and Mental Hygiene,

Defendants.

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

Declaration of Jonathan Roberts in Support of Plaintiffs' Motion for Preliminary Injunction

I, Jonathan Roberts, declare as follows:

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

2. I was born in Manhattan and raised in the Flushing area of Queens in New York City. My mother immigrated to the United States from Hungary as a child, where her family faced anti-Semitism that prevailed in Europe at that time. For high school, I tested into Bronx High School of Science. After high school I attended Harvard where I earned a math degree. My time at Harvard was the only time of my life in which I lived outside of New York. I currently reside in Manhattan.

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

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

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

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

Executed on February 17, 2022.

Jonathan Roberts

JONATHAN ROBERTS

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jonathan Roberts and Charles Vavruska,

Plaintiffs,

-against-

Mary T. Bassett, in her official capacity as Commissioner for New York State Department of Health; New York City Department of Health and Mental Hygiene,

Defendants.

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

Declaration of Charles Vavruska in Support of Plaintiffs' Motion for Preliminary Injunction

I, Charles Vavruska, declare as follows:

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

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

3. I am white and not Hispanic, 55 years old, and fully vaccinated against COVID-19. In March 2020, I contracted COVID-19 and was hospitalized for 10 days.

4. I reviewed the list of risk factors on a CDC website entitled "Persons with Certain Medical Conditions," that I have one of the risk factors (overweight and obesity) listed on the website. The link to the website appears on footnote 8 to the complaint in this case. I have reviewed the New York guidelines attached as Exhibit B to the complaint in this case. According to the guidelines, I qualify for inclusion in the last tier (1E) of the risk groups established by the New York State Department of Health and New York City's Department of Health and Mental Hygiene

for prioritization of certain COVID-19 treatments. But an otherwise identical situated person who is either non-white or Hispanic would be prioritized for COVID-19 treatment over me.

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

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

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

Executed on _____.

_____
CHARLES VAVRUSKA

or Hispanic would be prioritized for COVID-19 treatment over me.

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

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

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

Executed on February 18, 2022

Charles Vavruska

CHARLES VAVRUSKA

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

JONATHAN ROBERTS and CHARLES VAVRUSKA,

Plaintiffs,

-against-

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

Defendants.

DECLARATION OF MICHELLE E. MORSE, M.D., MPH

22-CV-00710 (NGG)(RML)

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

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

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

3. Prior to working at the Health Department, I served as a Health Policy Fellow at the National Academy of Medicine; Assistant Professor at Harvard Medical School; Assistant Program Director of the Internal Medicine Residency Program at Brigham and Women's Hospital; and Deputy Chief Medical Officer at Partners In Health.

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

5. For the reasons discussed herein, DOHMH's Health Advisory # 39, which was created to inform hospitals and medical care providers of newly authorized COVID-19 treatments,

furthers the public health goals of minimizing the hospitalization and morbidity rates due to COVID-19 in New York City.

COVID-19 Background

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

7. In indoor settings, the virus can also travel through the air and infect people who are much further than 6 feet away. It is also possible for people to become infected by touching a surface that has the virus on it, and then touching their eyes, nose or mouth with unwashed hands, though this is thought to be less common than other forms of transmission. There is significant evidence that people can transmit the virus whether or not they have symptoms; while people with symptoms are likely more contagious than people without symptoms, the number of people infected, on average, by people without symptoms may be greater, because they continue to conduct activities with others and do not know to isolate themselves. Based on current knowledge, the time between virus exposure and the onset of illness (the incubation period) can range from 2–14 days with most people developing symptoms 4–6 days after exposure. There is some evidence that the Omicron variant incubation is shorter than prior strains, with one study estimating the average incubation period as 3 days.[1]

8. COVID-19 has affected the lives of hundreds of millions of people worldwide and

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

remains a serious threat all over the world, including New York City residents. As of February 17, 2022, there have been over 418 million reported cases of COVID-19 worldwide,[2] including over 77 million in the United States,[3] of which over 1.9 million have been in New York City.[4] There have been over 5.85 million reported deaths from COVID-19 worldwide,[5] with more than 923,000 reported deaths in the United States[6] and 39,503 confirmed and probable deaths in New York City alone.[7]

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

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

COVID-19 in NYC Today

11. While New York City is no longer experiencing the widespread crisis that marked

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[2] See COVID-19 Dashboard, Johns Hopkins, https://www.arcgis.com/apps/dashboards/bda7594740fd40299423467b48e9ecf6, (last accessed Feb. 17, 2022).

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

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

[5] See COVID-19 Dashboard, supra note 2.

[6] See COVID-19 Data Tracker, supra note 3.

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

the winter/spring of 2020, there have been new variants and surges, meaning that community transmission remains an ongoing public health concern. The Centers for Disease Control and Prevention (CDC) reports that New York City is experiencing a substantial level[8] of community transmission.[9] From the end of November, 2021 through the end of January, 2022, New York City experienced the largest wave of reported cases yet during the pandemic. As of February 17, 2022, over the last 28 days in New York City, there was an average of 3,296 reported new cases per day, with a peak 7-day average of 43,636 reported new cases on January 4, 2022.[10] This surge was driven by the highly transmissible Omicron variant, which more easily infected persons who had existing immunity from previous infection or vaccination than previous variants of the virus.

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

13. As of the date of this declaration, New York City still is battling COVID-19 but the surge in positive cases has fallen dramatically. For the week ending February 19, 2022, there were an average of 790 new cases reported in New York City daily, compared with 2,000 cases reported daily over the previous 28 days.[12]

The State's December 27, 2021 Guidance

14. As the Omicron variant began to surge throughout the country, the Food and Drug

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

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

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

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

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

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

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

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

17. The "Eligibility" section of the State's Guidance sets forth health-based risk factors to consider when determining courses of treatment in times of supply shortages. One of the risk factors to consider is race and ethnicity. Indeed, evidence-based studies and data have shown that there has been longstanding inequality in impact of COVID-19, including treatment, in non-white and Hispanic/Latino communities.[13]

18. Specifically, the State Guidance provides "Oral antiviral treatment is authorized for patients who meet all of the following criteria: . . . Have a medical condition or other factors that increase their risk for severe illness . . . Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequalities have contributed to an increase risk of severe illness and death from COVID-19."

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

DOHMH's December 27, 2021 Guidance

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

20. The City Guidance closely mirrors the State Guidance and similarly informs hospitals and medical providers of the newly available treatments (along with their scarcity at the time) and to address certain factors to be considered when administering these therapies among infected individuals.

21. Specifically, the City Guidance provides that hospitals and medical providers "[c]onsider race and ethnicity when assessing an individual's risk. Impacts of longstanding systemic health and social inequities put Black, Indigenous and People of Color at increased risk of severe COVID-19 outcomes and death."

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

23. The City Guidance is not a mandate, law, or order restricting COVID-19 treatment by race or any other single factor. The City Guidance is not meant to replace a medical provider's sound clinical judgment of what course of treatment is best for patients. Rather, the City Guidance

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

is intended to address evidence-based data that Black, Indigenous, Latinx, and other people of color communities have been disproportionally impacted by COVID-19, and to remind providers to consider all factors that have been shown to contribute to poor outcomes from COVID-19, including social determinants of health like race and ethnicity.

24. As noted by the CDC, five key areas of social determinants of health contribute to marginalized racial and ethnic groups being disproportionately affected by COVID-19: neighborhood and physical environment, health and healthcare, occupation and job conditions, income and wealth, and education. Discrimination, which includes racism and associated chronic stress, influences each of these key topic areas.[15] Exposure to racism has biological consequences.[16] Specific to COVID-19, one large-scale study found that, compared with non-Hispanic White patients of similar ages with similar comorbidities, non-Hispanic Black patients had significantly higher length of hospital stay and odds of ventilator dependence and death.[17] A study of 219.1 million adults aged 25 years or older, found that racial disparities persisted in age-adjusted COVID mortality rates in 2020 when comparing within levels of education, stating "If all racial and ethnic populations had experienced the same mortality rates as college-educated non-Hispanic White populations, 71% fewer deaths among racial and ethnic minority populations would have occurred."[18] Other studies have found that, after adjusting for various socioeconomic

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[15] See COVID-19 Racial and Ethnic Health Disparities, CDC.gov (Dec. 10, 2022) https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html.

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

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

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

measures, significant racial disparities remained in COVID disease severity[19] and hospitalization.[20]

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

26. The City's Guidance does not prevent any individual from receiving treatments should they contract COVID-19. Individuals who are qualified based on risk factors will not be turned away from necessary treatment based on race.

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

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

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

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

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

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

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

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

New York City" to alert providers of this fact.

Dated: New York, New York
February 25, 2022

Michelle E. Morse, M.D., MPH

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

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

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Date: December 27, 2021
To: Health Care Providers and Health Care Facilities
From: New York State Department of Health

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

Summary:

- Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).
  - Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 when started early after symptom onset.
  - Paxlovid is the preferred product and is available for patients age 12 years and older.
  - Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA- authorized COVID-19 treatment options are not accessible or clinically appropriate.
- At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.
  - There will be a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV beginning 1/3/2022.
- Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.

The announcement is to make you aware of information about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatments.

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

COVID-19 Oral Antiviral Treatment

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

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

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

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

Eligibility

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

- Age 12 years and older weighing at least 40 kg (88 pounds) for Paxlovid, or 18 years and older for molnupiravir
- Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
- Have mild to moderate COVID-19 symptoms
    - Patient cannot be hospitalized due to severe or critical COVID-19
- Able to start treatment within 5 days of symptom onset
- Have a medical condition or other factors that increase their risk for severe illness.
    - Non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19

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

- Therapy is contraindicated for patients (1) with a history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; (2) treating with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or (3) treating with drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.
- Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.
- Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

- Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.
- Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
- For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

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

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

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

Referring Patients for Oral Antivirals Outside of NYC

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

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

Referring Patients for Oral Antivirals in NYC

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

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and through a language line in Russian, Mandarin, Vietnamese, Arabic, and Korean. Prescriptions confirmed by 5 p.m. on weekdays or 1p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

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

Changes to Monoclonal Antibody Use

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

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

Please continue to monitor our website regularly for updated guidance, including on treatment supply and prioritization: COVID-19 Monoclonal Antibody (mAb) Therapeutics: Information for Providers | Department of Health (ny.gov).

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

County Name	Store #	Store Name	City	Zip
Albany	417	CVS	ALBANY	12205
Albany	2702	CVS	COLONIE	12205
Albany		CENTRAL AVE PHARMACY	ALBANY	12206
Broome	1835	Walmart	VESTAL	13850
Cayuga	62	Kinney Drugs	AUBURN	13021
Cayuga	73	Kinney Drugs	MORAVIA	13118
Chautauqua	10870	Rite Aid	JAMESTOWN	14701
Chautauqua	10811	Rite Aid	DUNKIRK	14048
Chemung	10880	Rite Aid	HORSEHEADS	14845
Chemung	260	Rite Aid	ELMIRA	14901
Chenango	2120	Walmart	NORWICH	13815
Clinton		Condo Pharmacy	PLATTSBURGH	12901
Clinton		Cornerstone Drug & Gift	ROUSES POINT	12979
Columbia	242	CVS	HUDSON	12534
Cortland	7	Kinney Drugs	CORTLAND	13045
Delaware	19432	Walgreens	STAMFORD	12167
Dutchess	418	CVS	POUGHKEEPSIE	12601
Dutchess		Beekman pharmacy	POUGHQUAG	12570
Erie		Tile Pharmacy	CHEEKTOWAGA	14225
Erie		Kenmore Rx Center	KENMORE	14217
Erie		Wanakah Pharmacy	HAMBURG	14075
Erie		Larwood Pharmacy, Inc.	EAST AURORA	14052
Erie		Cy's Elma Pharmacy	ELMA	14059
Erie	3288	Walgreens	BUFFALO	14215
Essex	95	Kinney Drugs	LAKE PLACID	12946
Essex		Moriah Pharmacy	PORT HENRY	12974
Essex		Willsboro Pharmacy	WILLSBORO	12996
Franklin	10591	Walgreens	MALONE	12953
Fulton	18296	Walgreens	JOHNSTOWN	12095
Genesee	10807	Rite Aid	BATAVIA	14020
Hamilton		NATHAN LITTAUER HOSPITAL	SPECULATOR	12164
Herkimer	27	Kinney Drugs	ILION	13357
Jefferson		BOLTONS PHARMACY	WATERTOWN	13601
Jefferson	42	Kinney Drugs	ALEXANDRIA BAY	13607
Lewis	20	Kinney Drugs	LOWVILLE	13367
Livingston	5072	CVS	DANSVILLE	14437
Madison		Dougherty Pharmacy	MORRISVILLE	13408
Madison	46	Kinney Drugs	CHITTENANGO	13037

County Name	Store #	Store Name	City	Zip
Monroe	5123	CVS	BROCKPORT	14420
Monroe	831	CVS	WEBSTER	14580
Monroe	10512	Walgreens	ROCHESTER	14621
Montgomery	25	Kinney Drugs	ST. JOHNSVILLE	13452
Nassau	997	CVS	GLEN COVE	11542
Nassau	2028	CVS	HEMPSTEAD	11550
Nassau	1084	CVS	FREEPORT	11520
Niagara	10817	Rite Aid	LOCKPORT	14094
Niagara	3600	Rite Aid	NIAGARA FALLS	14301
Oneida	639	Rite Aid	UTICA	13502
Oneida	610	Rite Aid	ROME	13440
Oneida		Bassett Medical Center OP Pharmacy	COOPERSTOWN	13326
Onondaga	43	Kinney Drugs	BALDWINSVILLE	13027
Onondaga	79	Kinney Drugs	LIVERPOOL	13088
Onondaga	108	Kinney Drugs	SYRACUSE	13206
Onondaga	64	Kinney Drugs	EAST SYRACUSE	13057
Ontario	10846	Rite Aid	GENEVA	14456
Ontario	10842	Rite Aid	CANANDAIGUA	14564
Orange	10688	CVS	NEWBURGH	12550
Orange	2908	CVS	MONROE	10950
Oswego		Wayne Drug- Oswego	OSWEGO	13126
Otsego	2262	Walmart	ONEONTA	13820
Putnam		COMMUNITY PHARMACY INC	BREWSTER	10509
Putnam	5054	CVS	CARMEL	15012
Rensselaer	906	CVS	TROY	12182
Rensselaer	2137	CVS	WYNANTSKILL	12198
Rockland	2205	CVS	SPRING VALLEY	10977
Saratoga	10384	Walgreens	WILTON	12866
Saratoga	5046	CVS	CLIFTON PARK	12065
Schenectady	2340	CVS	SCHENECTADY	12304
Schenectady	5385	CVS	SCOTIA	12302
Schoharie	7326	CVS	COBLESKILL	12043
Schuyler	3221	Walmart	WATKINS GLEN	14891
Seneca	65	Kinney Drugs	SENECA FALLS	13148
St. Lawrence	1	Kinney Drugs	GOUVERNEUR	13642
St. Lawrence		The Medicine Place-KimRos Inc.	OGDENSBURG	13669
St. Lawrence		Adk Pharmacy COVID-19	STAR LAKE	13690
Steuben	2326	Walmart	HORNELL	14830
Steuben	2992	Walmart	PAINTED POST	14810

County Name	Store #	Store Name	City	Zip
Suffolk	3099	CVS	BAY SHORE	11706
Suffolk	6026	CVS	RIVERHEAD	11901
Suffolk	1271	CVS	ROCKY POINT	11778
Suffolk	2961	CVS	HUNTINGTON STATION	11746
Sullivan		Rock Hill Healthmart Pharmacy	ROCK HILL	12775
Sullivan		K & K Pharmacy	LIBERTY	12754
Tompkins	80	Kinney Drugs	ITHACA	14850
Ulster	8945	CVS	KINGSTON	12401
Ulster	323	CVS	SAUGERTIES	12477
Warren	419	CVS	QUEENSBURY	12804
Washington	2685	CVS	HUDSON FALLS	12839
Wayne	66	Kinney Drugs	LYONS	14489
Westchester	5048	CVS	PEEKSKILL	10566
Westchester	5350	CVS	PORT CHESTER	10573
Westchester	4539	CVS	YONKERS	10701
Wyoming		Sinclair Pharmacy	WARSAW	14569
Yates	442	Rite Aid	PENN YAN	14527

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HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD, MSc
Commissioner

2021 HEALTH ADVISORY #39

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

- **Two COVID-19 oral antiviral therapies have received Emergency Use Authorization from the U.S. Food and drug Administration (FDA), Paxlovid (Pfizer) and molnupiravir (Merck).**
  - **Paxlovid and molnupiravir reduce the risk of hospitalization and death by 88% and 30% respectively, in patients at high-risk for severe COVID-19 disease when started early after symptom onset.**
  - **Prescriptions in New York City (NYC) will be filled by Alto Pharmacy to provide free, same day home delivery regardless of insurance or immigration status.**
  - **Paxlovid is the preferred product and is available for patients age 12 years and older.**
  - **Molnupiravir should be considered for patients age 18 years and older for whom alternative FDA- authorized COVID-19 treatment options are not accessible or clinically appropriate.**
- **At this time, Sotrovimab (Xevudy) is the only authorized monoclonal antibody product expected to be effective against the omicron variant of SARS-CoV-2.**
  - **There is a pause on allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. These products do not retain activity against omicron and should not be used.**
- **Adhere to New York State Department of Health (NYS DOH) guidance on prioritization of high-risk patients for anti-SARS-CoV-2 therapies during this time of severe resource limitations.**
- **While therapeutic shortages continue, off-label use of remdesivir on an outpatient basis may be an option.**
- **Check nyc.gov/health/covidprovidertreatments regularly for updates.**

December 27, 2021

Dear Colleagues,

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

While the availability of oral antivirals for treatment of COVID-19 is an important milestone, it comes at a time of a significant surge in cases and reduced effectiveness of existing

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

COVID-19 Oral Antiviral Treatment

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

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

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

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

Eligibility

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

- Age 12 years and older for Paxlovid, or 18 years and older for Molnupiravir
- Weigh at least 40 kg (88 pounds)

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- Test positive for SARS-CoV-2 on a nucleic acid amplification test or antigen test; results from an FDA-authorized home-test kit should be validated through video or photo but, if not possible, patient attestation is adequate
- Have mild to moderate COVID-19 symptoms
    - Patient cannot be hospitalized or receiving oxygen therapy due to COVID-19
- Are able to start treatment within 5 days of symptom onset
- Have a medical condition or other factors that increase their risk for severe COVID-19 illness.
    - Consider race and ethnicity when assessing an individual's risk. Impacts of longstanding systemic health and social inequities put Black, Indigenous, and People of Color at increased risk of severe COVID-19 outcomes and death.

For Paxlovid only:

- Therapy is contraindicated for patients with history of clinically significant hypersensitivity reactions to its active ingredients or any other components of the product; are on drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions; or are on drugs that are potent CYP3A inducers where significantly reduced Paxlovid plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. See list of medications in the Paxlovid Fact Sheet for Providers, Section 7.
- Therapy is not recommended for patients with severe kidney (eGFR <30 mL/min) or liver (Child-Pugh Class C) impairment. Dosage adjustments are needed for patients with moderate renal impairment. Providers should discuss with their patients with kidney or liver problems whether Paxlovid is right for them.
- Paxlovid may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in patients with uncontrolled or undiagnosed HIV-1 infection. Patients on ritonavir- or cobicistat-containing HIV or HCV regimens should continue their treatment as indicated.

For molnupiravir only:

- Molnupiravir should be prescribed for patients age 18 years and older for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.
- Molnupiravir is not recommended during pregnancy. Prescribing providers should assess whether a female of childbearing potential is pregnant or not. Advise individuals of childbearing potential to use effective contraception correctly and consistently for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and pumping and discarding breast milk during this time.

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- Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
- For more details, please refer to molnupiravir Fact Sheet for Providers.

Clinical Considerations

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

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

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

Referring Patients for Oral Antivirals

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

Prescriptions placed with Alto Pharmacy will be delivered to the patient's preferred address at no cost. Once the prescription is placed, patients can schedule their delivery on the Alto mobile app, by text, or by phone with Alto pharmacists. Alto Pharmacy can offer direct support in English and Spanish and support in numerous other languages through language line. Prescriptions confirmed by 5 p.m. on weekdays or 1 p.m. on weekends will be delivered the same night. For instructions on how to prescribe oral antivirals in NYC, visit nyc.gov/health/covidprovidertreatments and look for "Referring or Offering Oral Antiviral Therapy" in the "Oral Antiviral Treatment" section.

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

Changes to Monoclonal Antibody Use

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

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are extremely limited and providers should adhere to NYS DOH prioritization guidance, and refer to the NYC Health Department's Letter to Providers: Omicron and Monoclonal Antibodies.

As of December 23, 2021, there is a pause on further allocations of bamlanivimab and etesevimab together, etesevimab alone, and REGEN-COV until further notice. Bamlanivimab with etesevimab and REGEN-COV do not retain activity against omicron and should not be used. Monoclonal antibody treatment can no longer be used as post-exposure prophylaxis.

Outpatient Use of Remdesivir

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

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

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

Sincerely,

Celia Quinn MD, MPH
Deputy Commissioner
Division of Disease Control

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

JONATHAN ROBERTS and
CHARLES VAVRUSKA,

Plaintiffs,

-against-

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

Defendants.

DECLARATION OF EUGENE HESLIN, M.D., FAAFP

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

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

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

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

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

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

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

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

BACKGROUND ON COVID-19

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

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

extended.

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

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

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

including those with risk factors for severe illness.

THE GUIDANCE AND ITS SCIENTIFIC BASIS

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

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

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

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

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

See Exhibit A (emphasis added).

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

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

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

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

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

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

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

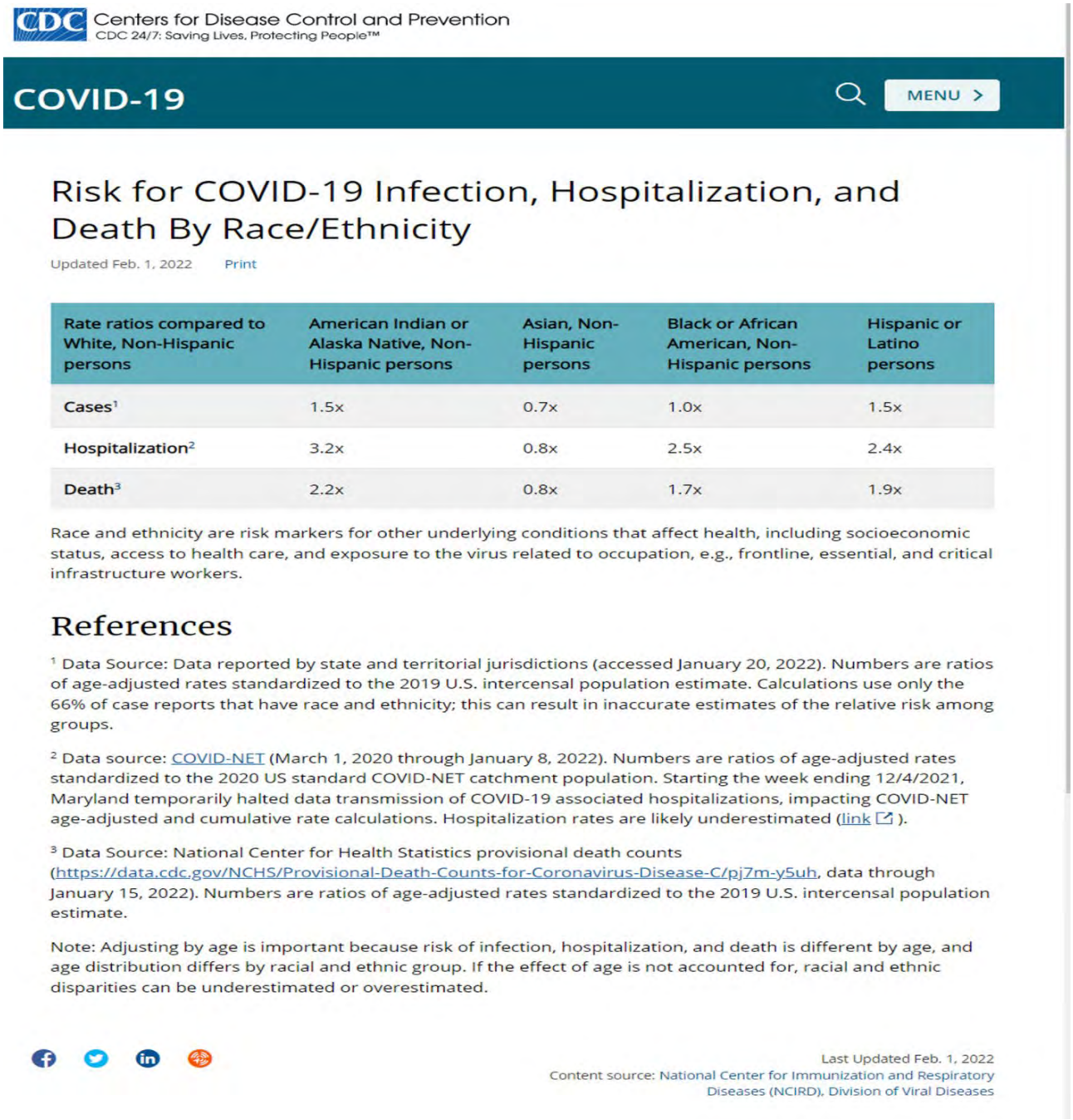
18. A study published on December 10, 2020, found that people from racial and ethnic minority groups were more likely to have increased COVID-19 disease severity upon admission to the hospital when compared with non-Hispanic white people. A copy of the December 10, 2020 study is attached here to as **Exhibit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

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

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

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

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



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

COVID-19 MENU >

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

Updated Feb. 1, 2022 Print

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

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

References

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

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

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

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

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

CDC. [4]

22. All of this data supports that non-white race or Hispanic/Latino ethnicity should be considered a risk factor, as longstanding systemic health and social inequities have contributed to an increased risk of severe illness and death from COVID-19.

HOW THE GUIDANCE OPERATES

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

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

[4] CDC, Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity (updated Feb. 1, 2022), *available at* https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html.
[5] *See* DOH & NYCDOHMH Healthcare Provider Webinar on COVID-19, *available at* https://www.youtube.com/watch?v=jm7-BQ0RvHQ.

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

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

discussion.

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

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

NO CURRENT SHORTAGE OF MEDICATIONS

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

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

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

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

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

CONCLUSION

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

31. The Guidance is based on data that shows COVID-19 mortality rates are higher among certain demographic groups, including non-white/Hispanic communities. No one in New York, who is otherwise qualified based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier.

Dated: February 25, 2022

EUGENE HESLIN, M.D., FAAFP

Daily Community Clusters

Report Data as of 2/16/2022

- Note on multi-county clusters: Clusters that appear across multiple counties are now reported together as the same cluster if they originated at the same source. Each county where that cluster appears, as well as its associated case/contact counts, are listed as separate rows within the cluster on the detailed cluster report. These multi-county clusters are only counted once in the overall cluster counts on the summary report page.
- A cluster is defined as 2 or more non-household laboratory-confirmed cases of SARS-CoV-2 infection among individuals with an epidemiological link (i.e., event, extended family, workplace, childcare, school, university, sports team/event, etc.).
- This dashboard is not comprehensive of all clusters, as reporting clusters into CommCare varies by county and region.

Total Clusters (Cumulative)
4,829

Total Clusters (2/16/22)
1

Total Associated Cases (Cumulative)
47,603

Total Associated Cases (2/16/22)
4

Industries with New Clusters (2/16/22)
1

Regions with New Clusters (2/16/22)
1

Daily Community Cluster Summary by Industry

Cluster Setting	Clusters	1 Day	1 Week	4 Weeks	Associated Cases	(vs. prior day)
Total	**4,829**	**+1**	**+6**	**+14**	**47,603**	**+4**
School (Pre-K-12)	781			+1	6,567	
Social Gathering/Community Gathering/..	424				3,073	
Daycare	413		+1	+2	2,860	
Other manufacturing	360			+1	3,253	
Group home for adults or children	312		+1	+3	2,865	
Retail	291				1,546	
Restaurant/Bar	280				1,769	
Unspecified Workplace	244				1,317	
College/University/Other Higher Ed	240	+1	+2	+2	7,708	+4
Government/Public Service	154				905	
Jail/Prison/Juvenile Detention Center	149			+2	5,921	
Other	145			+1	847	
Healthcare Faciliity	128		+1	+1	1,027	
Religious gathering	107				1,097	
Food Manufacturing	105				970	
Sporting Event	94				664	
Industrial/Warehouse	94				821	
Summer Camp	89				639	
Other care provider setting	81				736	
Geographic (i.e. locality, zip code)	45				537	
Transportation	40				209	
Arts & Entertainment	37				396	
Construction	36				183	
Gym/Fitness Class	35				222	
Mass Gathering Event	34				640	
Hair Salon/Barber and Personal Care	34				136	
Power/Utilities	31				172	
Accommodations	29				176	
Agri., Forestry, Fishing & Hunting	22				204	
Work-setting with immunocompromised..	16		+1	+1	82	
Shelter	12				61	

Daily Community Cluster Summary by Region

Region	Clusters	1 Day	1 Week	4 Weeks	Associated Cases	(vs. prior day)
Grand Total	**4,829**	**+1**	**+6**	**+14**	**47,603**	**+4**
Mid-Hudson	916	+1	+5	+9	6,722	+4
Long Island	896				8,978	
Central New York	814		+1	+1	8,501	
Southern Tier	516				5,055	
Finger Lakes	479			+1	4,915	
Capital Region	454			+2	2,980	
Mohawk Valley	345				4,016	
Western New York	284				3,225	
North Country	197			+1	3,211	

Active Cluster Spread by Cluster

Report Data as of 2/16/2022

- Note on multi-county clusters: Clusters that appear across multiple counties are now reported together as the same cluster if they originated at the same source. Each county where that cluster appears, as well as its associated case/contact counts, are listed as separate rows within the cluster on the detailed cluster report. These multi-county clusters are only counted once in the overall cluster counts on the summary report page.

- A cluster is defined as 2 or more non-household laboratory-confirmed cases of SARS-CoV-2 infection among individuals with an epidemiological link (i.e., event, extended family, workplace, childcare, school, university, sports team/event, etc.).

- This dashboard is not comprehensive of all clusters, as reporting clusters into CommCare varies by county and region.

Cluster Name	Cluster Type	Region of Cluster Site	County of Cluster Site	County of Residence	Case Type	Start Date	Last Updated Date	Total Cases	Total Contacts
SUNY New Paltz friends Feb.2022	College/University/Other Higher Ed	-	-	Ulster	Customer(s) (patron, student, or resident)	2/16/2022	2/16/2022	4	0
			Grand Total					**4**	**0**

Federal Response to COVID-19: Therapeutics Clinical Implementation Guide

Outpatient administration guide for healthcare providers

12/29/2021

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1. **Introduction to COVID-19 Outpatient Therapeutics & Product Selection**
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   - Site and patient logistics
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   - Team Roles and Responsibilities
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   - Introduction to COVID-19 Oral Antiviral Therapies
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1. Introduction to COVID-19 Outpatient Therapeutics & Product Selection

Summary of COVID-19 Preventative Agents & Therapeutics

No Illness	Exposed Per CDC Close Contact Criteria	Mild to Moderate Symptoms			Hospital Admission		ICU Admission	
Baseline health status, no infection	Not hospitalized, no limitations	Not hospitalized, with limitations	Hosp. no act. medical problems	Hospitalized, not on oxygen	Hospitalized, on oxygen		Hospitalized, high flow oxygen/ non-invasive ventilation	Hospitalized, mechanical ventilation/ ECMO

Remdesivir

COVID-19 VACCINES

Monoclonal Antibodies for PrEP
- Tixagevimab + cilgavimab (AZ)

Monoclonal Antibodies for PEP
- Casirivimab + Imdevimab (RGN)**
- Bamlanivimab + Etesevimab (Lilly)**

Oral Antivirals
- Paxlovid (Pfizer)
- Molnupiravir (Merck)

Monoclonal Antibodies for treatment
- Sotrovimab (GSK/Vir)
- Bamlanivimab + Etesevimab[1] (Lilly)**
- Casirivimab + Imdevimab (RGN)**

Tocilizumab

Dexamethasone

Baricitinib

**Not expected to be active against omicron variant

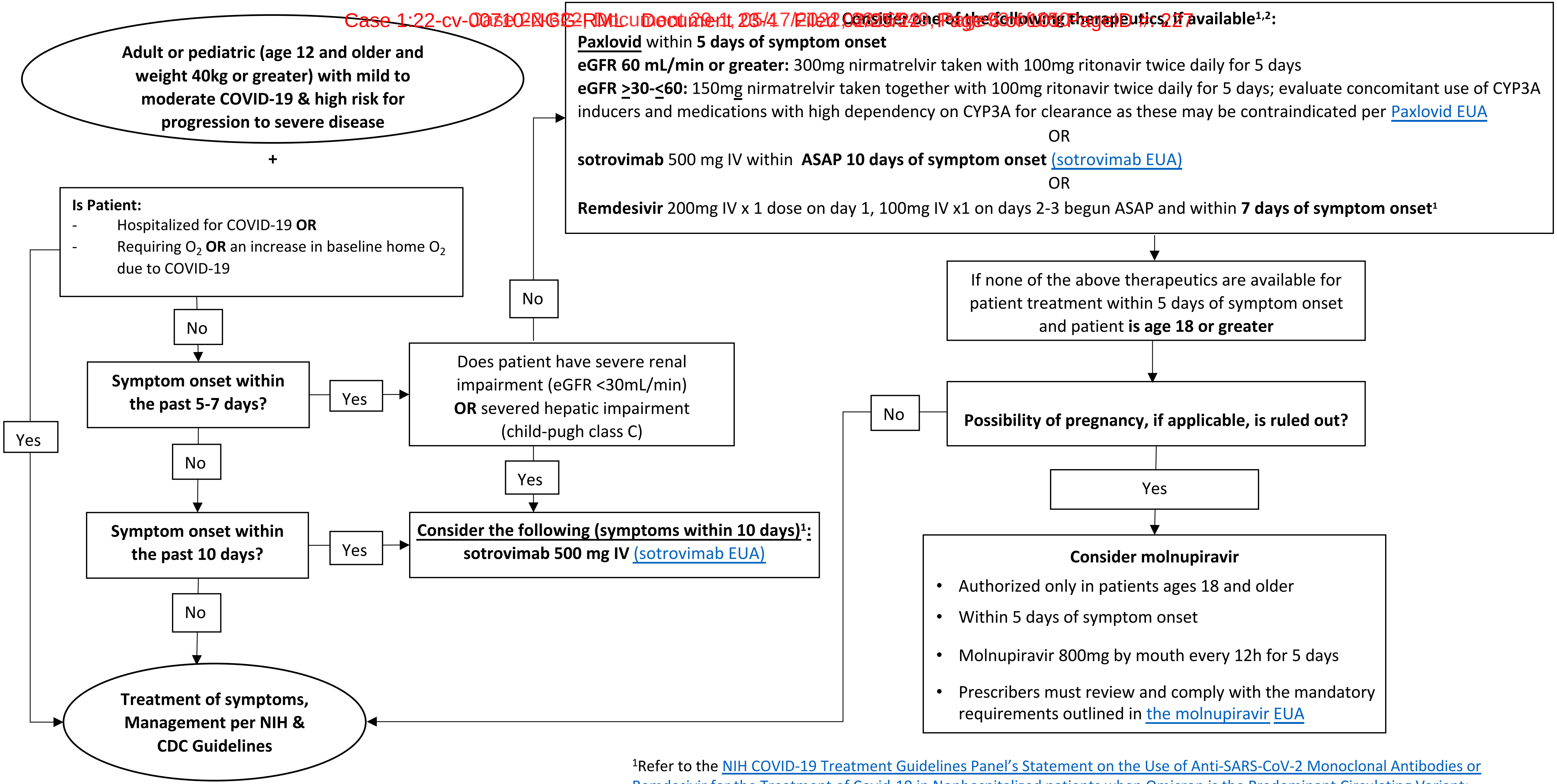
NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

Tools to Assist in COVID-19 Outpatient Therapeutic Selection

As variant prevalence changes and new therapeutics become available, there are tools and resources available to assist in clinical decision-making for prescribers.

- Clinical Decision Aid: A pathway for decision-making including outpatient parenteral and oral therapeutics
- Side-by-Side Overview of Outpatient Therapeutics (https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overview-of-mAbs-Treatment.aspx)
- NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant (https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron)
- The COVID-19 Treatment Guidelines Panel's Interim Statement on Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints (https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/)
- The COVID-19 Treatment Guidelines Panel's Statement on Potential Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir (Paxlovid) and Concomitant Medications (https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-paxlovid-drug-drug-interactions/)



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2] COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)

mAb Susceptibility to CDC Variants of Concern

- Information on variants of concern updated in **Section 15 of FDA fact sheets** for monoclonal antibodies
- bamlanivimab/etesevimab and REGEN-COV are not expected to be active against the Omicron variant[1]; sotrovimab is expected to retain activity against omicron
- The CDC monitors and publishes variant information on the CDC Covid Data Tracker https://covid.cdc.gov/covid-data-tracker/#variant-proportions

- Recommendations for Providers:
  - If Delta still represents a significant proportion of infections locally and other options are not available, eligible patients offered bamlanivimab/ etesevimab or REGEN-COV must be informed these therapeutics are likely ineffective if infected with Omicron.

Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (https://www.fda.gov/media/145802/download)
Fact Sheet for Health Care Providers Emergency Use Authorization for EVUSHELD (https://www.fda.gov/media/154701/download)
Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COVTM (casirivimab and imdevimab) (https://www.fda.gov/media/145611/download)
Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab (https://www.fda.gov/media/149534/download)

[1] NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant (https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron)

NIH COVID-19 monoclonal antibody guidelines when there are logistical constraints

- The NIH COVID-19 Treatment Guidelines Panel recommends using anti-SARS-CoV-2 monoclonal antibodies for the treatment of mild to moderate COVID-19 and for post-exposure prophylaxis (PEP) of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19, as outlined in the FDA Emergency Use Authorizations (EUAs). See the individual EUAs for details.
- Logistical constraints (e.g., limited space, not enough staff who can administer therapy) can make it difficult to administer these agents to all eligible patients. In situations where it is necessary to triage eligible patients, the Panel suggests:
  - **Prioritizing the treatment of COVID-19 over PEP of SARS-CoV-2 infection.**
  - **Prioritizing the following groups over vaccinated individuals who are expected to have mounted an adequate immune response**:
    - Unvaccinated or incompletely vaccinated individuals who are at high risk of progressing to severe COVID-19
    - Vaccinated individuals who are not expected to mount an adequate immune response (e.g., immunocompromised individuals).
- **Providers should use their clinical judgment** when prioritizing treatments in a specific situation. When there are no logistical constraints for administering therapy, these considerations **should not** limit the provision of anti-SARS-CoV-2 monoclonal antibodies.

2. Overview of Emergency Use Authorizations

The Role of Emergency Use Authorization (EUA) in COVID-19 Therapeutics

Q: What is an emergency use authorization and how is it being used to respond to COVID-19

A: In certain types of emergencies, the FDA can issue an emergency use authorization, or EUA, to provide more timely access to critical medical products (including medicines and tests) that may help during the emergency when there are no adequate, approved, and available alternative options.

The EUA process is different than FDA approval, clearance, or licensing because the EUA standard may permit authorization based on significantly less data than would be required for approval, clearance, or licensing by the FDA. This enables the FDA to authorize the emergency use of medical products that meet the criterial within weeks rather than months to years.

EUAs are in effect until the emergency declaration ends but can be revised or revoked as we evaluate the needs during the emergency and new data on the product's safety and effectiveness, or as products meet the criteria to become approved, cleared, or licensed by the FDA.

About Emergency Use Autorizations (EUAs)

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#abouteuas

Monoclonal Antibody Indications and Routes of Administration

Monoclonal Antibody	PRE-EXPOSURE PROPHYLAXIS (PREP) for eligible individuals	POST-EXPOSURE PROPHYLAXIS (PEP) for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease	TREATMENT of Mild to Moderate COVID-19 Infection within 10 days of symptom onset in patient with high risk of progression to severe disease
bamlanivimab and etesevimab[1] (Eli Lilly) **	N/A	**Dose:** bamlanivimab 700mg and etesevimab 1400mg **Route:** Intravenous **Post-administration observation:** 60 minutes ***Weight-based pediatric (< 40kg) dosing[1]*** **	**Dose:** bamlanivimab 700mg and etesevimab 1400mg **Route:** Intravenous **Post-administration observation**: 60 minutes ***Weight-based pediatric (< 40kg) dosing[1]*** **
casirivimab and imdevimab[2] (REGEN-COV) **	N/A	**Dose:** casirivimab 600mg and imdevimab 600mg **Route:** Intravenous is preferred route, however subcutaneous injection may be utilized in situations where there would be a delay in intravenous administration **Post-administration monitoring:** 60 minutes **	**Dose:** casirivimab 600mg and imdevimab 600mg **Route:** Intravenous or subcutaneous **Post-administration monitoring:** 60 minutes **
sotrovimab[3] (Glaxo Smith Kline)	N/A	N/A	**Dose:** sotrovimab 500mg **Route:** Intravenous **Post-administration monitoring:** 60 minutes
tixagevimab and cilgavimab[4] (AstraZeneca)	**Dose:** tixagevimab 150mg and cilgavimab 150mg **Route:** Intramuscular **Post-administration monitoring:** 60 min	N/A	N/A

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

Refer to product Emergency Use Authorizations for detail on indications and administration

[1] Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (https://www.fda.gov/media/145802/download)
[2] Fact Sheet for Health Care Providers Emergency Use Authorization of REGEN-COVTM (casirivimab and imdevimab) (https://www.fda.gov/media/145611/download)
[3] Fact Sheet for Health Care Providers Emergency Use Authorization of Sotrovimab (https://www.fda.gov/media/149534/download)
[4] Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab (https://www.fda.gov/media/154701/download)

Oral Antiviral Indications and Dosing

Antiviral Agent	PRE-EXPOSURE PROPHYLAXIS (PREP) for eligible individuals	POST-EXPOSURE PROPHYLAXIS (PEP) for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease	TREATMENT of Mild to Moderate within 5 days of symptom onset in patients with high risk or progression to severe disease
Paxlovid (Pfizer)	N/A	N/A	**Dose:** **eGFR ≥60 ml/min:** 300mg nirmatrelvir (#2 150mg tablets) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days **eGFR ≥30 to <60 mL:** 150mg nirmatrelvir (#1 150mg tablet) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days **Severe renal impairment (eGFR <30 mL/min):** NOT Recommended **Severe hepatic impairment (Child-Pugh Class C):** NOT recommended
Molnupiravir (Merck)	N/A	N/A	**Dose:** 800mg molnupiravir (#4 200mg tablets) ORALLY twice daily for 5 days (No renal or hepatic dosing restrictions)

Outpatient Therapeutics
Provider and Patient EUA Fact Sheets

- Each product under EUA also has an FDA fact sheet for providers and one for patients and caregivers
  - bamlanivimab and etesevimab
    - Bamlanivimab and etesevimab provider fact sheet: https://www.fda.gov/media/145802/download
    - Bamlanivimab and etesevimab Patient fact sheet: https://www.fda.gov/media/145803/download
    - Bamlanivimab and etesevimab Patient fact sheet (Spanish): http://pi.lilly.com/eua/span/bam-and-ete-eua-factsheet-patient-span.pdf
  - casirivimab and imdevimab (REGEN-COV)
    - Casirivimab and imdevimab Provider fact sheet: https://www.fda.gov/media/145611/download
    - Casirivimab and imdevimab Patient fact sheet: https://www.fda.gov/media/145612/download
    - Casirivimab and imdevimab Patient fact sheet (Spanish): https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-patient-spanish.pdf
  - sotrovimab
    - Sotrovimab Provider fact sheet: https://www.fda.gov/media/149534/download
    - Sotrovimab Patient fact sheet: https://www.fda.gov/media/149533/download
    - Sotrovimab Patient fact sheet (Spanish): https://www.sotrovimab.com/content/dam/cf-pharma/hcp-sotrovimab-phase2/en_US/sotrovimab-eua-fact-sheet-for-patients-in-spanish.pdf
  - tixagevimab and cilgavimab (Evusheld)
    - Tixagevimab and cilgavimab Provider fact sheet: https://www.fda.gov/media/154701/download
    - Tixagevimab and cilgavimab Patient fact sheet: https://www.fda.gov/media/154702/download

Outpatient Therapeutics
Provider and Patient EUA Fact Sheets

- Each product under EUA also has an FDA fact sheet for providers and one for patients and caregivers
  - Paxlovid
    - Paxlovid provider fact sheet: https://www.fda.gov/media/155050/download
    - Paxlovid patient fact sheet: https://www.fda.gov/media/155051/download
    - Paxlovid patient fact sheet (Spanish): https://www.fda.gov/media/155075/download
  - Molnupiravir
    - Molnupiravir provider fact sheet: https://www.fda.gov/media/155054/download
    - Molnupiravir patient fact sheet: https://www.fda.gov/media/155055/download
    - Molnupiravir patient fact sheet (Spanish): https://www.fda.gov/media/155115/download

3. Overview of Outpatient Therapeutic Distribution Process

Principles for USG allocation and distribution

1. Maximize use of existing infrastructure within USG, as well as manufacturer and distributor channels
2. Allocations must ensure both ***temporal*** and ***geographic*** equity
3. USG to allocate to state and territorial health departments based on:
   - Confirmed Hospitalizations (7- Day Incident)
   - Confirmed Cases (7- Day Incident)
4. States/Territories responsible for distribution to administration sites
5. Sites required to report product utilization
6. Manufacturer tracks pharmacovigilance and follows mandatory reporting guidance

Reporting Requirements

For bam/ete, sotrovimab, REGEN-COV

Long Term Care / Skilled Nursing Facilities

NHSN

Hospitals / Hospital Pharmacies

HHSProtect/TeleTracking/
Health Departments

Non-hospital Facilities

HHS TeleTracking

Reporting required by 11:59 pm each Wednesday

For Evusheld, Paxlovid, molnupiravir

HPOP

Reporting required by 11:59 pm daily

Sites administering/dispensing USG-purchased COVID-19 therapeutics must provide information on product utilization and stock on hand

4. Monoclonal Antibody Administration

4. Monoclonal Antibody Administration: *Site and Patient Logistics*

Monoclonal Antibody Administration Can Occur Across a Wide Variety of Models

Hospital

- Hospital-based infusion centers
- Emergency departments
- Urgent care/Obs units/Fast track areas
- Converted space within hospital for COVID infusion
- Alternate care sites

Ambulatory center

- Infusion centers
- Urgent care clinics
- Dialysis centers
- Alternate care sites

Nursing homes

- Skilled nursing facilities
- Long-term care facilities

Mobile sites

- Bus/trailer
- Other mobile sites

Home

- At patient's home

Sample Staffing Models for Monoclonal Antibody Administration

Examples of staff plans *(recommended positions may vary depending on the State's scope of practice for Paramedics as it related to Subcutaneous and or Intravenous administration of medications or mAbs)*

- 8-10 bed mAb infusion/observation site
  - 1 physician / advanced practitioner (present or available via telemedicine)
  - 2 Nurses
  - 1 Nurse or Paramedic
  - 2 Paramedics
  - 1 flex position – administrative/ logistics/ runner
- Single station or mobile visit Subcutaneous administration site
  - 1 physician / advanced practitioner (present or available via telemedicine)
  - 1 Nurse / Paramedic per single mobile visit or single station

Average patient (door to door) visit can range from 80-120 minutes

Site Preparation

- Collect administration site location(s), address, and points of contact
  - For mobile or deployed teams, identify the point of contact at the administration site and make contact
  - Site will need dedicated space for isolation of COVID-19 patients[1]
  - Rededication of existing clinical space is permitted under the CMS Hospital Without Walls Initiative
- Ensure a patient scheduling and referral process is in place
- Identify and understand which therapeutics will be administered
- Determine who is responsible for ordering the monoclonal antibody administration
  - Referring provider
  - On-site or telemedicine provider
  - Standing order
- Brief administration team with site objectives
- Team training
  - Site workflow
  - Monoclonal administration
  - Managing adverse reactions with rescue medications on site as applicable

[1] *Select recommendations for outpatient setting, for more information reference CDC guidelines*
https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

4. Monoclonal Antibody Administration: *Patient Pathways to Monoclonal Administration*

Pathway to Monoclonals: Patient with Confirmed COVID-19 Infection

- Treatment likely most beneficial to patients if given **early in symptom progression**
- EUA requires administration of **treatment as soon as possible after** confirmed positive test result and within **10 days of symptom onset**
- Strong **partnership and communication** between patients and HCP to get right treatment to right patients at right time
- Fast testing turnaround needed, to efficiently **identify positive tests** and **schedule for treatment**

Example of timeline which would fulfill EUA requirements

Onset of symptoms	Clinical visit and diagnostic test	Confirmed positive test	Treatment
	≤ 3 days *post symptom onset*	***≤ 24 hours*** *post diagnostic test*	***ASAP*** *post positive test result*

Treatment required within 10 days of symptom onset

Testing sites should recommend COVID+ patients that are high risk confer with their HCP on potential suitability for Tx

Please reference EUA factsheet for specific treatment guidelines including recommended treatment window

Early administration of treatment needs fast testing turn-around and patient scheduling

Planning required for "Test and treat" or "Test and refer" models

Patient Flow for Outpatient mAbs Product

Scenario 1: Confirmed positive patient referred for treatment

Pre-treatment

Confirm documentation of COVID-19 infection via either

- Participant-provided lab report
- Medical record lab report
- Direct communication from a provider or laboratory

Discuss treatment with patient

- Ensure patient meets treatment requirements and understands risks

Schedule the patient to come in for treatment ASAP

- Provide guidance on site visit protocols to patients
- Provide patient education on what to expect with administration

Pre-treatment steps should be completed via telemedicine as possible (~30 mins)

Treatment

Pre-book time for administration space and follow clear protocol for coming onsite

- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

Provide treatment to patient

- Infusion duration up to ~1 hr[1] with an additional 1 hr of observation post infusion (checks during infusion and observation)
- Infusion pumps or gravity-based infusion acceptable
- Subcutaneous administration if appropriate per EUA[2]

Ensure preparation for administration reactions as unlikely but possible side effect

- Infusion rate may be reduced based on patient circumstances
- Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

Post-treatment

Discharge patient immediately following monitoring completion

- Follow clear protocol to minimize risk of exposure to others

Post-treatment care encouraged to be via telemedicine as possible

- Normal follow-up care, no special data tracking requirements

1. Contingent on product dilution, reference EUA fact sheet for dilution and infusion timing
2. Reference EUA for route of administration

Patient Flow for Outpatient mAbs Product

Scenario 2 and 3: Patient arrives for testing at site with unknown diagnosis

Same process as Scenario 1

Pre-treatment

Direct patient to typical testing process for site (onsite or offsite)

- Quick response testing needed for early diagnosis to enable early treatment

Assuming patient discharged to await test results, once patient confirmed positive outreach on treatment *(~30 mins)* :

- Discuss treatment with patient
  - Ensure patient meets treatment requirements and understands risks
  - Provide guidance on administration and site visit protocols to patients
- Schedule the patient to come in for treatment ASAP
- Pre-treatment discussion and scheduling should be via telemedicine as possible

In case of point-of-care rapid testing, consider same-day administration. Needs

- Isolated location for patient to wait
- Availability of treatment space and staff

Treatment

Pre-book time for administration space and follow clear protocol for coming onsite

- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

Provide treatment to patient

- Infusion duration up to ~1 hr[1] with an additional 1 hr of observation post infusion (checks during infusion and observation)
- Infusion pumps or gravity-based infusion acceptable
- Subcutaneous administration if appropriate per EUA[2]

Ensure preparation for administration reactions as unlikely but possible side effect

- Infusion rate may be reduced based on patient circumstances
- Ensure emergency action plan in place; ability to activate EMS if necessary, a requirement for administration under EUA

Post-treatment

Discharge patient immediately following monitoring completion

- Follow clear protocol to minimize risk of exposure to others

Post-treatment care encouraged to be via telemedicine as possible

- Normal follow-up care, no special data tracking requirements

1. Contingent on product dilution, reference EUA fact sheet for dilution and infusion timing
2. Reference EUA for route of administration

Patient Flow for Post-Exposure Prophylaxis

Pre-treatment

Confirm eligibility for PEP

- Patient meets CDC high risk exposure criteria[1]
- Patient is not fully vaccinated or immunocompromised[2]

Discuss treatment with patient

- Ensure patient meets treatment requirements and understands risks

Schedule the patient to come in for treatment ASAP

- Provide guidance on site visit protocols to patients
- Provide patient education on what to expect with administration

Treatment

Pre-book time for administration space and follow clear protocol for coming onsite

- Ensure operationally ready to receive and treat the patient
- Use CDC recommended practices to minimize exposure to others

Provide treatment to patient

- Infusion duration up to ~1 hr[1] with an additional 1 hr of observation post infusion (checks during infusion and observation)
- Infusion pumps or gravity-based infusion acceptable
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Post-treatment

Discharge patient immediately following monitoring completion

- Follow clear protocol to minimize risk of exposure to others

Post-treatment care encouraged to be via telemedicine as possible

- Normal follow-up care, no special data tracking requirements

1. CDC Quarantine and Isolation (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html)
2. CDC Have You Been Fully Vaccinated https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated
3. CDC Science Brief: COVID-19 Vaccines and Vaccination (https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html)

4. Monoclonal Antibody Administration: *Team Roles and Responsibilities*

Monoclonal Administration Site Team Members

- Administration Site Leadership
- Administrative personnel
- Clinical Team
  - Composition dependent on state and local regulations and route of mAb administration (intravenous or subcutaneous)
  - Medical Provider (MD/NP/PA) on-site or available via telemedicine
  - Consider staff competence and comfort with IV insertion and management of pediatric patients if pediatric patients <40kg will be treated at the site
  - Under an amendment to the PREP Act, Pharmacists and qualified Pharmacy Technicians may prescribe and administer COVID-19 therapeutics (subcutaneously, orally, or intramuscularly) unless otherwise stated in the product EUA[1]

[1] HHS PREP Act Amendment 9 Fact Sheet (https://www.ashp.org/-/media/assets/advocacy-issues/docs/GRD-HHS-PREP-Act-Declaration-Amendment-9-Fact-Sheet.pdf)

Monoclonal Antibody Administration Site Leadership

- Ensure ordering process is implemented
- Ensure required elements for administration are available
  - Personnel
  - Supplies
  - Administrative support
  - Identified site for administration
- Determination of scheduling process/logistics if treatment and PEP provided at the same site (as not all patients are COVID-positive)
- Determine mechanism for reimbursement of administration fees (product provided by the US Government is provided at no cost)
- Consider mechanism for interpreter services if patients are non-English speaking
- Delegate or perform administrative responsibilities
  - Direct ordering
  - Reporting of adverse events
  - Utilization reporting

Record-Keeping Requirements and Adverse Event Reporting

Sites receiving monoclonal antibody will follow established mechanisms for tracking and reporting **serious adverse events**

- Events that are potentially attributable to monoclonal antibody use must be reported to the FDA
  - Refer to the Fact Sheet for Healthcare Providers as part of EUA for guidance
  - Complete and submit a MedWatch form or complete and fax FDA Form 3500 to report

Site must **maintain records** regarding use of the monoclonal antibody by patients

- **Inventory information:** e.g., lot numbers, quantity, receiving site, receipt date, product storage
- **Patient information:** e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered

Ensure that any records associated with this EUA are **maintained for inspection** upon request

Sites will report utilization weekly through the mechanism indicated by their local, state, or territorial health department

CMS: Coverage of Monoclonal Antibody Products to Treat COVID-19

Medicare

Site of Care[1]	Payable by Medicare	Expected Patient Cost-Sharing
Inpatient Hospital	✓	No patient cost-sharing
Outpatient Hospital or "Hospital without Walls[2]"	✓	No patient cost-sharing
Outpatient Physician Office/Infusion Center	✓	No patient cost-sharing[3]
Nursing Home (See third bullet in Key Facts on CMS enforcement discretion)	✓	No patient cost-sharing
Home	✓	No patient cost-sharing

[1] Services must be furnished within the scope of the product's FDA authorization or approval and within the provider's scope of practice.

[2] Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.

[3] Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn't participate in Medicare.

Expected Payment to Providers: Key Facts

- Medicare payment for monoclonal antibody products to treat COVID-19 is similar across sites of care, with some small differences.
- Medicare pays for the administration of monoclonal antibody products to treat COVID-19. For example, Medicare will pay a national average of approximately $450 for the administration of certain monoclonal antibody products . Home infusion is reimbursed at a higher rate.
- CMS will exercise enforcement discretion to allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law to bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments to Medicare Part A Skilled Nursing Facility residents
- Medicare will pay the provider for these monoclonal antibody products when they are purchased by the provider. Medicare won't pay if the product is given to the provider for free by, for example, a government entity.
- When purchased by the provider, Medicare payment is typically at reasonable cost or at 95% of the Average Wholesale Price (an amount determined by the manufacturer). These payment amounts vary depending on which type of provider is supplying the product. Original Medicare will pay for these products for beneficiaries enrolled in Medicare Advantage.
- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these Frequently Asked Questions.

Additional information can be found on Coverage of Monoclonal Antibody Products to Treat COVID-19 at https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf

CMS Billing Codes for mAb Administration

Regen-COV Product Codes

M0243:

- Long Descriptor: intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion and post administration monitoring

M0244:

- Long Descriptor: intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring in the home or residence

Bamlanivimab and Etesevimab Product Codes

M0245:

- Long Descriptor: intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring

M0246:

- Long Descriptor: intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring in the home or residence

Sotrovimab Product Codes

M0247:

- Long descriptor: intravenous infusion, sotrovimab, includes infusion and post-infusion monitoring

M0248:

- Long descriptor: intravenous infusion, sotrovimab, includes infusion and post-infusion monitoring in the home or residence

CMS.gov: Monoclonal Antibody COVID-19 Infusion – Monoclonal Antibody Products to Treat COVID-19

https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion

Clinical Team Responsibilities

Important to manage patient flow in a healthcare setting

Ensure appropriate infection control practices in place based on latest CDC guidelines, e.g.:

- Have patient **wait to enter the site** until scheduled time for treatment
- Ensure patient **wearing a mask or face covering** before entering the building
- Escort patient **directly to room, limit transport and movement of the patient outside of the room**
- As all patients treated are confirmed positive for COVID-19, **multiple patients may be treated simultaneously in one area**.
- Medical and support personnel entering room need to **wear sufficient PPE** based on CDC guidelines
- Room should undergo **appropriate cleaning and surface disinfection** before it is returned to routine use

Select recommendations for outpatient setting, for more information reference CDC guidelines
https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

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Clinical Team Responsibilities: Patient Intake

- *If MD/NP/PA is on site, they can provide order for mAb after patient intake/screening completed*
- Patient intake (healthcare provider type determined by state regulations/ scope of practice)
  - Ensure patient is **masked** for duration of encounter
  - Patient registration completed
  - Vital signs obtained (ensure patient does not require oxygen unless on home 02, therefore making them ineligible for mAb therapy and requiring escalation of care)
  - Eligibility criteria reviewed
    - Treatment eligibility criteria
    - Post exposure Prophylaxis Criteria
  - Patient Fact Sheet provided to patient prior to administration of mAb

Clinical Team Responsibilities Monoclonal Administration

- mAb preparation for subcutaneous or intravenous administration
- Ensure patient privacy is maintained in accordance with HIPPA
- mAb administration
- Post-administration monitoring (60 minutes for all patients)
- Response to administration reaction
- Patient discharge and follow-up instructions

4. Monoclonal Antibody Administration: *Indications and Administration*

Indications for Monoclonal Therapy & Appropriate mAbs for Treatment

- Pre-Exposure Prophylaxis in eligible persons
  - EVUSHELD (tixagevimab and cilgavimab)
- Active COVID-19 Infection in high risk individuals with mild to moderate symptoms
  - Bamlanivimab and Etesevimab
  - REGEN-COV (casirivimab and imdevimab)
  - Sotrovimab
- Post-Exposure Prophylaxis in vulnerable persons (i.e. not fully vaccinated or immunocompromised) who are at high risk for progression to severe COVID-19
  - REGEN-COV (casirivimab and imdevimab)
  - Bamlanivimab and Etesevimab

Indications for Pre-Exposure Prophylaxis (PrEP)

- EVUSHELD (tixagevimab and cilgavimab)

EVUSHELD (tixagevimab and cilgavimab) Eligibility for Pre-Exposure Prophylaxis*

EVUSHELD (tixagevimab and cilgavimab) is indicated for pre-exposure prophylaxis of COVID-19 in adults and pediatric (12 years of age and older and weighing at least 40kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **AND**
- who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination **OR**
- for whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and /or COVID-19 vaccine component(s)

See Limitations of Authorized Use

Fact Sheet for Health Care Providers Emergency Use Authorization for Evusheld (tixagevimab co-packaged with cilgavimab (https://www.fda.gov/media/154701/download)

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to[1]:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

[1] CDC Clinical Considerations for COVID-19 Vaccines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

EVUSHELD (tixagevimab and cilgavimab) Pre-Exposure Prophylaxis: Limitations of Authorized Use

- Evusheld is not authorized for use in individuals:
    - For treatment of COVID-19, or
    - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination
- EVUSHELD may only be prescribed by a healthcare provider licensed under State law to prescribe drugs for an individually identified patient and who has the education and training to make the clinical assessment necessary for appropriate use of EVUSHELD

EVUSHELD (tixagevimab and cilgavimab)
Preparation, Dose, & Administration

- Dose: tixagevimab 150mg and cilgavimab 150mg
- Administration
  - Administer the two components sequentially
  - Withdraw 1.5mL of tixagevimab and 1.5mL of cilgavimab solution into TWO separate syringes
  - Administer the intramuscular (IM) injections at different injection sites, preferably one in each of the gluteal muscles, one after the other. The vastus lateralis is acceptable if gluteal injection is contraindicated
  - The solutions for injection do not contain a preservative. Discard unused portion in accordance with local requirements
  - As with any other IM injection, administer with caution to patients with thrombocytopenia or any coagulation disorder
- Observation: 60 minutes post-administration
- Storage: Refrigerate unopened vials at 2-8°C/36-46°F

Indications for Post-Exposure Prophylaxis (PEP)

- bamlanivimab and etesevimab**
- REGEN-COV (casirivimab and imdevimab)**

** Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

bamlanivimab/etesevimab** and REGEN-COV**
Eligibility for POST-EXPOSURE PROPHYLAXIS**

Bamlanivimab/etesevimab or casirivimab/imdevimab indicated for post-exposure prophylaxis of COVID-19 in individuals who are:

- Adult or pediatric (≥ 12 years of age and weighing at least 40kg) patient **at high risk for progressing to severe disease or death (*see high risk criteria*) *OR***
- Pediatric Patient <40kg (including neonates)*** **at high risk for progressing to severe disease or death (*see high risk criteria*) ****bamlanivimab/etesevimab only* AND**
- Not fully vaccinated[1] **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications[2]) **AND**
  - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC[3] **OR**
  - **who are at high risk of exposure to an individual infected with SARS-CoV-2** because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons) [*see limitations of authorized use*]

******Limitations of Authorized Use:***

- *Post-exposure prophylaxis with monoclonal antibody therapy is not a substitute for vaccination against COVID-19*
- *Bamlanivimab/etesevimab or casirivimab/imdevimab antibody therapy is not authorized for pre-exposure prophylaxis for prevention of COVID-19*

1. CDC's Have You Been Fully Vaccinated? (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated)
2. CDC's Science Brief: COVID-19 Vaccines and Vaccination (https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html)
3. CDC's Quarantine and Isolation (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html)

**Not expected to retain activity against omicron variant

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Resources: Monoclonal Eligibility for POST-EXPOSURE PROPHYLAXIS

1 Individuals are considered to be **fully vaccinated** 2 weeks after their second vaccine dose in a 2-dose series (such as the Pfizer or Moderna vaccines), or 2 weeks after a single-dose vaccine (such as Johnson & Johnson's Janssen vaccine). See this CDC website for more details on Have You Been Fully Vaccinated? (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated)

2 CDC's Science Brief: COVID-19 Vaccines and Vaccination (https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html)

3 Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). See this website for additional details on Quarantine and Isolation (https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html)

Indications for Treatment of Patients with Confirmed COVID-19 Infection

- bamlanivimab and etesevimab**
- REGEN-COV (casirivimab and imdevimab)**
- sotrovimab

** Not expected to retain activity against omicron variant

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mAb Eligibility Criteria for TREATMENT of Mild-Moderate Covid-19 Infection in High Risk Adult and Pediatric (≥ 40kg) Patients

Mild to moderate COVID-19 cases early in infection, who are at **high risk for progressing to severe COVID-19 and/or hospitalization**; with following criteria:

- Adult or pediatric (≥ 12 years of age and weighing at least 40kg) patient
- Confirmation via **positive PCR or antigen test**
- Treatment **as soon as possible** following positive viral test and **within 10 days of symptom onset**
- Patient symptomatic but **not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy)**

Monoclonal antibodies given EUA for mild to moderate symptoms of COVID-19 are *not authorized* for use in patients:

- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

Benefit of treatment with mAbs has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

mAb Eligibility Criteria for TREATMENT of Mild-Moderate Covid-19 Infection in High Risk Pediatric Patients <40kg**

Mild to moderate COVID-19 cases early in infection, who are at **high risk for progressing to severe COVID-19 and/or hospitalization**; with following criteria:

- Neonate through pediatric and less than 40 kg
- Confirmation via **positive PCR or antigen test**
- Treatment **as soon as possible** following positive viral test and **within 10 days of symptom onset**
- Patient symptomatic but **not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy)**

Monoclonal antibodies given EUA for mild to moderate symptoms of COVID-19 are *not authorized* for use in patients:

- 2 years and older who are hospitalized due to COVID-19, OR

Regardless of age:

- who require oxygen therapy support due to COVID-19, OR
- who require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 in those on chronic oxygen therapy or respiratory support due to underlying non-COVID-19 related comorbidity

Benefit of treatment with mAbs has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation

**Indicated therapeutic not expected to retain activity against omicron variant

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

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

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

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

Product Storage

Product Storage	bamlanivimab/etesevimab	casirivimab/imdevimab	sotrovimab
Storage of UNOPENED VIALS in original carton	Refrigerated (2-8°C/36-46°F): until expired	Refrigerated (2-8°C/36-46°F): until expired Room temperature (up to 25°C/ 77°F): 30 days	Refrigerated (2-8°C/36-46°F): until expired
Storage of PREPARED IV SOLUTION	Refrigerated (2-8°C/36-46°F): 24 hours Room temperature (20-25°C/68-77°F): 7 hours	Refrigerated (2-8°C/36-46°F): 36 hours Room temperature (up to 25°C/ 77°F): 4 hours	Refrigerated (2-8°C/36-46°F): 24 hours Room temperature (up to 25°C/ 77°F): 6 hours
Storage of PREPARED SYRINGES**	n/a	Refrigerated (2-8°C/36-46°F): 24 hours Room temperature (up to 25°C/ 77°F): 8 hours	n/a
Time to Equilibrate to Room Temperature before Administration (Per EUA language)	Approximately 20 minutes	30 minutes	Approximately 15 minutes

For most up to date information, refer to product EUA Fact Sheets:

- EUA of bamlanivimab and etesevimab - http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf
- EUA of REGEN-COV (casirivimab and imdevimab) - https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf
- EUA of sotrovimab - https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS

NOTE: Temperature ranges and specifications are per each product EUA

mAb Preparation

Note: product can be prepared for infusion and subcutaneous administration bedside by any qualified medical professional

Administration preparation process:

- Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies
- Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter

Needs for space to prepare mAb drug:

- Dedicated preparation area with sufficient capacity onsite or nearby

Acceptable equipment for mAb drug storage:

- Refrigerated storage (2-8° C)
- Temperature control mechanism including temperature monitoring process
- Storage area for REGEN-COV if stored at room temperature

Please see EUA manufacturer fact sheet for drug-specific requirements

General Guidelines for bamlanivimab/etesevimab Dosing, Dilution, & Administration: Adult and Pediatric (40+kg) Patients**

Table 1: Recommended Dilution and Administration Instructions for Bamlanivimab and Etesevimab for IV Infusion[3] in Adults (≥18 years regardless of weight) and Pediatric Patients (<18 years and weighing at least 40 kg)

Drug[a]: Add 20 mL of bamlanivimab (1 vial) and 40 mL of etesevimab (2 vials) for a total of 60 mL to a prefilled infusion bag and administer as instructed below		
Size of Prefilled 0.9% Sodium Chloride Infusion Bag	**Maximum Infusion Rate**	**Minimum Infusion Time**
50 mL	310 mL/hr	21 minutes
100 mL	310 mL/hr	31 minutes
150 mL	310 mL/hr	41 minutes
250 mL For patients weighing at least 50 kg	310 mL/hr	60 minutes
250 mL[b] For patients weighing ≥40 kg and <50 kg	266 mL/hr	70 minutes

[a] 700 mg of bamlanivimab and 1,400 mg of etesevimab are added to the same infusion bag and administered together as a single intravenous infusion.

[b] The minimum infusion time for patients weighing at least 40 kg and less than 50 kg who are administered bamlanivimab and etesevimab diluted in a 250-mL prefilled 0.9% Sodium Chloride infusion bag must be extended at least 70 minutes to reduce endotoxin load.

**Not expected to retain activity against omicron variant

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Fact Sheet for Health Care Providers Emergency Use Authorization of Bamlanivimab and Etesevimab (http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf)

General Guidelines for bamlanivimab/etesevimab Dosing & Administration: Pediatric Patients <40kg (including neonates)

Table 2: Recommended Dosing, Preparation and Administration Instructions for Undiluted Bamlanivimab (BAM) and Etesevimab (ETE) for IV Infusion in Pediatric Patients (<18 years and weighing less than 40 kg)**

Body Weight	BAM/ETE dose (mg)	Amount of BAM (as mL)[a]	Amount of ETE (as mL)[a]	Maximum Infusion Rate
>20 kg to <40 kg	350 mg / 700 mg	10 mL	20 mL	1.88 mL/min
>12 kg to 20 kg	175 mg / 350 mg	5 mL	10 mL	0.94 mL/min
>11 kg to 12 kg	138 mg / 276 mg	3.9 mL	7.9 mL	0.74 mL/min
>10 kg to 11 kg	126 mg / 252 mg	3.6 mL	7.2 mL	0.68 mL/min
>9 kg to 10 kg	114 mg / 228 mg	3.3 mL	6.5 mL	0.61 mL/min
>8 kg to 9 kg	102 mg / 204 mg	2.9 mL	5.8 mL	0.54 mL/min
>7 kg to 8 kg	90 mg / 180 mg	2.6 mL	5.1 mL	0.48 mL/min
>6 kg to 7 kg	78 mg / 156 mg	2.2 mL	4.5 mL	0.42 mL/min
>5 kg to 6 kg	66 mg / 132 mg	1.9 mL	3.8 mL	0.36 mL/min
>4 kg to 5 kg	54 mg / 108 mg	1.5 mL	3.1 mL	0.29 mL/min
>3 kg to 4 kg	42 mg / 84 mg	1.2 mL	2.4 mL	0.23 mL/min
>2 kg to 3 kg	30 mg / 60 mg	0.9 mL	1.7 mL	0.16 mL/min
>1.5 kg to 2 kg	21 mg / 42 mg	0.6 mL	1.2 mL	0.11 mL/min

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casirivimab/imdevimab Formulations and Dose Preparation
Dose: REGEN-COV (casirivimab 600mg and imdevimab 600mg)**

Administration Route	Single Product Vials	REGEN-COV
Intravenous **(Mixed and administered per EUA instructions)** Intravenous infusion is strongly recommended for treatment of active infection. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment. *For Post-Exposure prophylaxis either subcutaneous injection or intravenous route can be used.* [Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COVTM (casirivimab and imdevimab)](https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf) [https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf]	casirivimab (REGN10933) **5ml total** (from 2.5 or 11.1 mL vials)   imdevimab (REGN10987) **5ml total** (from 2.5 or 11.1 mL vials)  	**10 mL total** 
Subcutaneous	Two syringes with 2.5 mL each of casirivimab (REGN10933) (**total of 5 ml casirivimab**) Two syringes with 2.5 mL each of imdevimab (REGN10987) (**total of 5 ml imdevimab**)	Four syringes each containing 2.5mL REGEN-COV for a **total of 10mL**

**Not expected to retain activity against omicron variant

[NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant](https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/)

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

casirivimab and imdevimab Co-Packaged Cartons (from Roche Pharmaceuticals)**

11.1 ML VIALS COPACK

1 VIAL OF CASIRIVIMAB
11.1 mL
NDC 61755-024-00

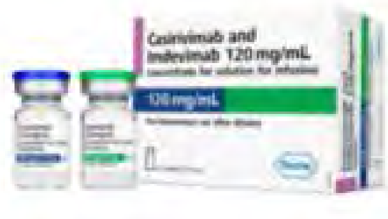
AND

1 VIAL OF IMDEVIMAB
11.1 Ml
NDC 61755-025-00

Although the carton is labeled "2 vials of 20 mL, "this is referring to the vial size and not the content of the vial.
This presentation contains 2 vials of 11.1 mL (one of casirivimab and one of imdevimab)

This co-pack contains product for two patient courses

2.5 ML VIALS CO-PACK



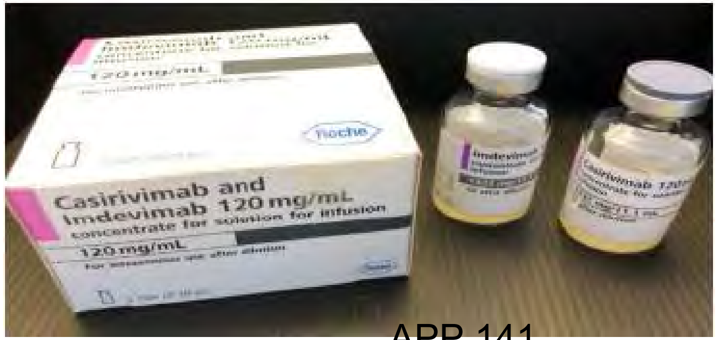
1 VIAL OF CASIRIVIMAB
2.5 mL
NDC 61755-026-00

AND

1 VIAL OF IMDEVIMAB
2.5 mL
NDC 61755-027-00

Although the carton is labeled "2 vials of 6 mL, "this is referring to the vial size and not the content of the vial.
This presentation contains 2 vials of 2.5 mL (one of casirivimab and one of imdevimab)

Two cartons of this combination are required for one patient course



**Not expected to retain activity against omicron variant

[NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant]

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

Utilizing REGEN-COV (casirivimab and imdevimab) Dose Pack**

NDC 61755-**035**-02
Combination of 2 vials

1 vial of Casirivimab 11.1 mL

AND

1 vial of imdevimab 11.1 mL

NDC 61755-**036**-08
Combination of 8 vials

4 vials of Casirivimab 2.5 mL

AND

4 vials of imdevimab 2.5 mL

Previously created REGEN-COV Dose Pack contains **2 patient courses** as of the June 2021 EUA[1] (enclosed information sheet has dosing from prior EUA). **1 patient course is 5ml casirivimab/ 5ml imdevimab**

The dose pack may be utilized for two doses. **Once punctured, the vials should be discarded after 4 hours.**

Refer to the "Regeneron Important Prescribing Letter" for more information

Please contact Regeneron Medical Affairs with any questions about using **existing** inventory to treat patients at 1-844-734-6643

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Guidelines for REGEN-COV Repeat Dosing for Post-Exposure Prophylaxis**

- For individuals whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination

- The initial dose is 600 mg of casirivimab and 600 mg of imdevimab by subcutaneous injection or intravenous infusion

- Followed by subsequent repeat dosing of 300 mg of casirivimab and 300 mg of imdevimab by subcutaneous injection or intravenous infusion once every 4 weeks for the duration of ongoing exposure.

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NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

General Guidelines for REGEN-COV Intravenous Dosing, Dilution, and Administration**

Dilution Instructions for REGEN-COV (600 mg Casirivimab and 600mg Imdevimab) for intravenous infusion

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Preparing Using Co-Formulated Casirivimab and Imdevimab Vial	Preparing Casirivimab and Imdevimab Using Individual Vials[a]
50 mL	Add 10 mL of co-formulated Casirivimab and Imdevimab (1 vial) into a prefilled 0.9% sodium chloride infusion bag and administer as instructed below	Add: • 5 mL of Casirivimab (may use 2 vials of 2.5 ml OR 5 mL from 1 vial of 11.1 mL) • 5 mL of Imdevimab (may use 2 vials of 2.5 ml OR 5 mL from 1 vial of 11.1 mL And inject into a prefilled 0.9% sodium chloride infusion bag and administer as instructed below.
250 mL		

[a] 600 mg of Casirivimab and 600 mg of Imdevimab are added to the same infusion bag and administered together as a single intravenous infusion.

Table 2: Recommended Administration Rate for Casirivimab and Imdevimab for Intravenous Infusion

Size of Prefilled 0.9% Sodium Chloride Infusion Bag used	Maximum Infusion Rate	Minimum Infusion Time
50 mL[b]	180 mL/hr	20 minutes
100 mL	310 mL/hr	21 minutes
150 mL	310 mL/hr	31 minutes
250 mL	310 mL/hr	50 minutes

[b] The minimum infusion time for patients administered casirivimab and imdevimab together using the 50 mL prefilled 0.9% Sodium Chloride infusion bag must be at least 20 minutes to ensure safe use.

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) or REGEN-COVTNM (casirivimab and imdevimab)

https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

General Guidelines for REGEN-COV Subcutaneous Dosing and Administration**

Administration Instructions for REGEN-COV (600 mg Casirivimab and 600mg Imdevimab) for subcutaneous injection[1]

Prepare 600 mg of Casirivimab and 600 mg of Imdevimab	Preparation of 4 Syringes
Using Casirivimab and Imdevimab Co-formulated Vial	Withdraw 2.5 mL solution per syringe into FOUR separate syringes.
Using Casirivimab and Imdevimab Individual Vials	• Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes. • Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes. For total of 4 syringes.

Intravenous infusion is strongly recommended for treatment of active infection. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment.

For Post-Exposure Prophylaxis either subcutaneous or intravenous route can be used.

Preparation and Administration:

- Obtain four 3mL or 5mL luer lock syringes and four 21 gauge 1½ inch transfer needles
- Withdraw 2.5 mL into each syringe per preparation instructions. **Prepare all four syringes at the same time.**
- Replace the 21 gauge transfer needle on each syringe with a 25-gauge or 27-gauge needle for subcutaneous injection
- Administer the subcutaneous injections consecutively, **each at a different injection site**, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.
- **It is recommended that providers use different quadrants of the abdomen, upper thighs, or back of the upper arms to space apart each injection**
- DO NOT inject into skin that is tender, damaged, bruised, or scarred

Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab)

https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

REGEN-COV Subcutaneous Injection Sites**

- The prescribing healthcare provider and/or the provider's designee are responsible for mandatory reporting of all medication errors and **ALL SERIOUS ADVERSE EVENTS** potentially related to REGEN-COV. These adverse events must be reported within seven calendar days from the onset of the event.
- Healthcare facilities and providers must report therapeutics information and demonstrate adequate utilization via data reported through HHS Protect, TeleTracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services.
- **MedWatch adverse event reports can be submitted to the FDA, by submitting a postage-paid Form FDA 3500 and returning by mail/fax, or by calling 1-800-FDA-1088 to request a reporting form**. In addition, please provide a copy of all FDA MedWatch forms to Regeneron Pharmaceuticals, Inc via fax (1-888-876-2736) or email (medical.information@regeneron.com).

Back of the upper arm

Abdomen[a]

[a]Except for within two inches of the navel

Upper thigh

**Not expected to retain activity against omicron variant

NIH COVID-19 Treatment Guidelines Panel's Statement on SARS-CoV2 Monoclonal Antibodies or Remdesidivir for the Treatment of COVID-19 in Nonhospitalized Patients When Omicron is the Predominant Circulating Variant

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/

General Guidelines for Sotrovimab Dosing, Dilution, and Administration

Preparation

Sotrovimab is supplied in a single-dose vial and must be diluted prior to administration.
Sotromivab injection should be prepared by a qualified healthcare professional using aseptic technique.

- Gather the materials for preparation
  - Polyvinyl chloride (PVC) or polyolefin (PO), sterile prefilled infusion bag. Choose one of the following sizes: prefilled 50-mL or 100 – mL infusion bag containing 0.9% Sodium Chloride Injection, and
  - One vial of sotrovimab (500 mg/8 mL).

- Remove one vial of sotrovimab from refrigerated storage and allow to equilibrate to room temperature, protected from light, for approximately 15 minutes.
- Inspect the vial of sotrovimab visually for particulate matter and discoloration prior to administration. Should either be observed, the solution must be discarded, and a fresh solution prepared.
  - Sotrovimab is a clear, colorless or yellow to brown solution

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- Gently swirl the vial several times before use without creating air bubbles. **Do not shake the vial.**

- Withdraw 8 mL sotrovimab from one vial and insect into a prefilled infusion bag containing 0.9% Sodium Chloride Injection.

- Discard any product remaining in the vial.

- Prior to the infusion, gently rock the infusion bag back and forth by hand 3 to 5 times. **Do not invert the infusion bag.** Avoid forming air bubbles.

- This product is preservative-free; therefore, the diluted infusion solution should be administered immediately.
  - If immediately administration is not possible, store the diluted solution of sotrovimab up to 4 hours at room temperature (20°C to 25°C [68°F to 77°F]) or refrigerated up to 24 hours (2°C to 8°C [36°F to 46°F])

Administration

- Infuse over 30 minutes
- Do NOT deliver via IV push or IV bolus
- Monitor patient for 60 minutes after infusion

[Fact Sheet for Healthcare Providers Emergency Use Authorization (EUA) of Sotrovimab](https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS)
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Sotrovimab/pdf/SOTROVIMAB-EUA.PDF#nameddest=HCPFS

mAb Post-Administration Monitoring

- Per EUA, “Clinically monitor patients during dose administration and observe patients for at least 1 hour after intravenous infusion or subcutaneous dosing is complete”
- Provide education on follow-up, required isolation per CDC guidelines after COVID-19 exposure or diagnosis, red flags for seeking emergency care
- Respond to severe adverse events/ anaphylaxis
- “Discharge” patient after one hour post-administration monitoring if stable and without symptoms of severe adverse reaction
- Report any severe adverse events as required by the FDA through the process outlined in the EUA

4. Monoclonal Antibody Administration: *Response to Adverse Events*

Managing Adverse Reactions to mAbs

- **Monoclonal antibodies may only be administered** in settings in which health care providers have immediate access to medications to treat a severe infusion or hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

- Early identification of anaphylaxis. Symptoms may include:
  - Respiratory: throat tightness, stridor, hoarseness, wheezing, respiratory distress, coughing, trouble swallowing/drooling, nasal congestion/drainage, sneezing
  - Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain, cramps
  - Cardiovascular: dizziness, fainting, tachycardia, hypotension, cyanosis, pallor, flushing
  - Skin/mucosal: hives, erythema, itching, swelling of eyes, lips, tongue, mouth, face, or extremities
  - Neurologic: agitation, convulsions, altered mental status, sense of impending doom
  - Other: sudden increase in secretions, urinary incontinence

Managing Adverse Reactions to mAbs: Medications and Equipment

- **Should be available** at all sites:
  - Epinephrine (e.g., prefilled syringe or autoinjector)
  - H1 antihistamine (e.g., diphenhydramine, cetirizine)
  - Blood pressure monitor
- **If feasible,** include at sites (not required)
  - Oxygen
  - Bronchodilator (e.g., albuterol)
  - H2 antihistamine (e.g., famotidine, cimetidine)
  - Intravenous fluids
  - Intubation kit
  - Adult-sized pocket mask with one- way valve (CPR mask)

Adapted from CDC Interim Considerations: Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites

https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf

Please note… EUA guidelines continue to evolve

Please reference EUA fact-sheets for latest treatment guidelines and information, including:

- Therapeutic dosing
- Administration routes
- Dilution requirements and infusion time for intravenous or parenteral administration

COVID-19 Vaccination after mAb Administration

The current recommendation based on CDC guidance:

- **Delay COVID-19 vaccine for 90 days after mAb for treatment of COVID-19 infection**
- **Delay COVID-19 vaccine for 30 days after mAb for post exposure prophylaxis**

CDC Advisory Committee on Immunization Practices:

(*Updated August 21, 2021*)

People who previously received passive antibody therapy

Currently, there are limited data available on the safety and effectiveness of COVID-19 vaccines in people who received passive antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment or post-exposure prophylaxis. Based on the estimated half-life of such products and the anticipated period of protection against infection (when receiving anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis) or reinfection (when receiving passive antibody therapy for treatment), COVID-19 vaccination should be temporarily deferred as a precautionary measure during the time period specified below after receiving passive antibody products to avoid potential interference of the product with vaccine-induced immune responses:

Passive antibody product used for post-exposure prophylaxis: defer COVID-19 vaccination for 30 days
Passive antibody product used for COVID-19 treatment: defer COVID-19 vaccination for 90 days
However, if passive antibody products and a COVID-19 vaccine dose are administered within these recommended deferral periods (30 or 90 days), the vaccine dose does not need to be repeated.

CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States
(https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

4. Monoclonal Antibody Administration: *Supplies and Resources*

Site Supplies Needed

Infrastructure

- Seating area with appropriate spacing for patients to receive mAb
- Steel table for product preparation
- Privacy screens if needed
- Protocol/outline for patient flow (written protocol not required however patient flow and infection control should be addressed at each administration site)
- Emergency response plan (written plan not required, however all staff should be aware of the plan for emergency response)

General supplies

- Infusion Reaction Kit
- Refrigerator
  - *Optional to store prepared solution onsite*
- Sharps container
- Biohazard disposal bag
- Trash bins and liners
- Disposable disinfecting wipes
- Hand sanitizer
- Thermometer probe covers *(if required)*
- 70% alcohol wipes
- Paper towels

PPE

- NIOSH-certified, disposable N95 filter facepiece respirators or better
- Gloves in appropriate sizes
- Gowns
- Surgical face masks for patients
- Eye and face protection (e.g. goggles, safety glasses, face shields)

Patient Intake

- Vital signs machine
- Pulse oximeter
- Thermometer
- Copies of eligibility checklist for treatment/ PEP

Administrative

- Site-specific documentation
- Patient fact sheets to provide each patient (copies in English, Spanish and other appropriate languages)

Administration Supplies- Subcutaneous

- Alcohol wipes
- 3 or 5mL luer lock syringes (4 required for each patient for subcutaneous administration)
- Appropriate needles for product preparation and subcutaneous administration
  - 21 gauge 1.5 inch needles for product transfer
  - 25 or 27 gauge needles for subcutaneous administration (4 per each patient course)

Administration Supplies- Intravenous

- IV poles
- Alcohol wipes
- 2x2 gauze pads
- Adhesive bandages
- Medical tape
- Tegaderm bio-occlusive dressing
- Absorbent underpads (blue pads)
- Normal saline bags for mixing/administration- 50-250 mL
- IV administration sets: *PVC infusion set with/without DEHP containing 0.2 or 0.22 micron polyethersulfone (PES) in-line filter*
- IV catheters
- IV extension set tubing
- 3mL saline syringes
- Needles – stainless steel 18ga
- *Optional: Transilluminator (vein finder)*

5. Oral Antiviral Administration

5. Oral Antiviral Administration: *Introduction to COVID-19 Oral Antiviral Therapies*

Paxlovid (Pfizer)

- FDA has issued an EUA for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults (12 years of age and older weighing more than 40kg) who are at high risk for progression to severe COVID-19, including hospitalization and death.

- Paxlovid includes: nirmatrelvir (a SARS-CoV-2 main proteases inhibitor) and ritonavir (a CYP34A inhibitor)

- Limitations of authorized use:
  - Not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19
  - Not authorized for use longer than 5 consecutive days

- PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).

Fact Sheet for Health Care Providers Emergency Use Authorization of Paxlovid (https://www.fda.gov/media/155050/download)

Molnupiravir (Merck)

- Molnupiravir has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults who are at high-risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate

- Not authorized for:
  - Patients less than 18 years of age
  - Initiation of treatment in patients requiring hospitalization due to COVID-19
  - Use longer than 5 consecutive days

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

Fact Sheet for Health Care Providers Emergency Use Authorization of Molnupiravir (https://www.fda.gov/media/155054/download)

Oral Antiviral Indications and Dosing

Antiviral Agent	PRE-EXPOSURE PROPHYLAXIS (PREP) for eligible individuals	POST-EXPOSURE PROPHYLAXIS (PEP) for individuals who are not fully vaccinated or immunocompromised, with high risk of progression to severe disease	TREATMENT of Mild to Moderate within 5 days of symptom onset in patients with high risk or progression to severe disease
Paxlovid (Pfizer)	N/A	N/A	**Dose:** **eGFR ≥60 ml/min:** 300mg nirmatrelvir (#2 150mg tablets) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days **eGFR ≥30 to <60 mL:** 150mg nirmatrelvir (#1 150mg tablet) with 100mg ritonavir (#1 100mg tablet) ORALLY twice daily for 5 days **Severe renal impairment (eGFR <30 mL/min):** NOT Recommended **Severe hepatic impairment (Child-Pugh Class C):** NOT recommended
Molnupiravir (Merck)	N/A	N/A	**Dose:** 800mg molnupiravir (#4 200mg tablets) ORALLY twice daily for 5 days (No renal or hepatic dosing restrictions)

Fact Sheet for Health Care Providers Emergency Use Authorization of Paxlovid (https://www.fda.gov/media/155050/download)
Fact Sheet for Health Care Providers Emergency Use Authorization of Molnupiravir (https://www.fda.gov/media/155054/download)

5. Oral Antiviral Administration: *Prescriber Journey for Prescribing*

Paxlovid Provider Checklist

- ❑ Positive SARS-CoV-2 test
- ❑ Age ≥12 years
- ❑ Weight ≥40 kg
- ❑ High-risk criteria met
- ❑ Symptoms consistent with mild-moderate COVID-19
- ❑ Symptom onset with **5 days***
- ❑ Not hospitalized due to COVID-19
- ❑ If clinically indicated, assess patient renal function
  - eGFR ≥60 mL/min, standard dosing
  - eGFR 30-60 mL/min, dose modification
  - eGFR <30 mL/min, contraindicated
- ❑ If clinically indicated, assess patient hepatic function
  - Child-Pugh Class C, contraindicated
- ❑ Assess patient's home medication list for drug-drug interactions
  - See next slide for more detail

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by _____[insert date]_____. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.

Paxlovid Contraindications

Hypersensitivity Reactions	• History of clinically significant hypersensitivity reactions (e.g., TEN, SJS) to its active ingredients (nirmatrelvir or ritonavir) or any other components of the product
Drugs highly dependent on CYP3A4 for clearance and for which elevated concentrations are associated with severe/life-threatening reactions*	• Alpha1-adrenoreceptor antagonists: alfuzosin • Analgesics: pethidone, piroxicam, propoxyphene • Antianginal: ranolazine • Antiarrhythmic: amiodarone, dronedarone, flecainide, propafenone, quinidine • Anti-gout: colchicine • Antipsychotics: lurasidone, pimozide, clozapine • Ergot derivatives: dihydroergotamine, ergotamine, methylergonovine • HMG-CoA reductase inhibitors: lovastatin, simvastatin • PDE5 inhibitor: sildenafil (Revatio) when used for PAH • Sedative/hypnotics: triazolam, oral midazolam
Drugs that are potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir concentrations are associated with loss of virologic response or resistance*	• Anticancer drugs: apalutamide • Anticonvulsant:: carbamazepaine, phenobarbital., phenytoin • Antimycobacterials: rifampin • Herbal product: St John's Wort (*hypericum perforatum)*

***NOT COMPLETE LIST OF ALL DDI's. ALWAYS USE CLINICAL TOOLS/DDI CHECKER AND USE CLINICAL JUDGMENT**

Molnupiravir Provider Checklist

- ❑ Positive SARS-CoV-2 test
- ❑ Age ≥18 years
- ❑ Alternate COVID-19 treatment options authorized by FDA are not accessible
- ❑ High-risk criteria met
- ❑ Symptoms consistent with mild-moderate COVID-19
- ❑ Symptom onset with **5 days***
- ❑ Not hospitalized due to COVID-19
- ❑ Assessment pregnancy and breastfeeding status (if applicable)
- ❑ Provide appropriate counseling
  - Females of childbearing potential treated: should use a reliable method of contraception correctly and consistently, as applicable, for the *duration of treatment and for **4 days** after the last dose of molnupiravir*
  - Breastfeeding is not recommended for the *duration of treatment and for **4 days** after the last dose of molnupiravir*
  - Males of reproductive potential treated: if sexually active with females of childbearing potential, should use a reliable method of contraception correctly and consistently *during treatment and for at least **3 months** after the last dose*

*Prescriber is encouraged to include a note to the pharmacist in the prescription stating: Please fill prescription by _____[insert date]_____. This prescription fill by date is within 5 days from symptom onset and complies with the patient eligibility criteria under the EUA.

Molnupiravir Prescriber Requirements

All Patients

1. Provide electronic or hard copy of patient fact sheet
2. Document that patient has received an electronic or hard copy of the patient fact sheet
3. Review the information contained within the patient factsheet with the patient and counsel patient on the known and potential benefits and risks of MOV
4. Advise patients on need for contraception use as appropriate
   - Females of childbearing potential treated: should use a reliable method of contraception correctly and consistently, as applicable, for the *duration of treatment and for **4 days** after the last dose of molnupiravir*
   - Breastfeeding is not recommended for the *duration of treatment and for **4 days** after the last dose of molnupiravir*
   - Males of reproductive potential treated: if sexually active with females of childbearing potential, should use a reliable method of contraception correctly and consistently *during treatment and for at least **3 months** after the last dose*
5. The prescribing healthcare provider and/or the provider's designee must report all medication errors and serious adverse events potentially related to molnupiravir within 7 calendar days from the healthcare provider's awareness of the event

Molnupiravir Prescriber Requirements

Individuals of Childbearing Potential

1. Assess whether pregnant or not
   - Report of LMP in an individual who has regular menstrual cycles, uses a reliable method of contraception correctly and consistently or has had a negative pregnancy test
   - Negative pregnancy test (recommended but not required if other criteria are not met)
2. If pregnant:
   - Counsel the patient regarding the known and potential benefits and potential risks of molnupiravir use during pregnancy
   - Document that the patient is aware of the known and potential benefits and potential risks of molnupiravir use during pregnancy
   - Make the individual aware of the pregnancy surveillance program
   - If the pregnant individual agrees to participate in the pregnancy surveillance program and allows the prescribing healthcare provider to disclose patient specific information to Merck, the prescribing healthcare provider must provide the patient's name and contact information to Merck (at 1-877-888-4231 or pregnancyreporting.msd.com)
3. If not pregnant:
   - Make the individual aware of the pregnancy surveillance program and encourage them to participate should they become pregnant
   - Review contraception requirements
4. How and where documentation occurs is at the discretion of the prescribing health care provider and their clinical site.

Patient Flow for Antiviral Oral Therapies

Scenario 1: Patient arrives at provider visit and medication available onsite

Visit with Provider

Confirm documentation of COVID-19 infection via either

- Participant-provided lab report
- Medical record lab report
- Direct communication from a provider or laboratory

Discuss treatment with patient

- Ensure patient meets treatment requirements and understands risks

Prescribe therapy for patient & provide the medication fact sheet

- Document required patient assessment in medical record
- Provide patient education on medication therapy being prescribed.

Pre-treatment steps should be completed via telemedicine as possible (~30 mins)

Visit Discharge

Medication and Fact Sheet provided to the patient

- Ensure patient is understands medication therapy being provided
- Ensure medication therapy being dispensed complies with federal/state dispensing laws.

Post-visit

Patient to begin prescribed therapy immediately and continue x 5 days

Patient to report any adverse effect to FDA Medwatch

- Patients that present for hospital visit may continue their prescribed antiviral during hospitalization (at discretion of provider).

Patient Flow for Antiviral Oral Therapies

Scenario 2: Patient arrives at provider visit and medication NOT available onsite

Visit with Provider

Confirm documentation of COVID-19 infection via either
- Participant-provided lab report
- Medical record lab report
- Direct communication from a provider or laboratory

Discuss treatment with patient
- Ensure patient meets treatment requirements and understands risks

Prescribe therapy for patient & provide the medication fact sheet
- Document required patient assessment in medical record
- Provide patient education on medication therapy being prescribed.

Determine locations medication is available in local area.

Visit Discharge

Prescription and Fact Sheet provided to the patient
- Ensure patient is understands medication therapy being prescribed
- Ensure patient is advised where to go pick up the medication therapy

Post-visit

Pharmacy receives patient prescription
- Pharmacy should prioritize the prescription fill and ensure timely turnaround to support same day start for therapy.
- Pharmacist verifies prescription is appropriate for patient. Any concerns are clarified with prescribing provider.

Pharmacy staff dispenses product to the patient
- Patient is counseled on medication therapy and reminded to start immediately.

Patient to begin prescribed therapy immediately and continue x 5 days

Patient to report any adverse effect to FDA Medwatch
- Patients that present for hospital visit may continue their prescribed antiviral during hospitalization (at discretion of provider).

5. Oral Antiviral Administration: *Pharmacy Journey for Dispensing*

Pharmacy Journey

Pharmacy receives antiviral Rx (either product) for patient

Pharmacist reviews fill-by date to ensure Rx still valid

STOP:
No fill if outside 5-day therapeutic window & contact prescriber

Molnupiravir

Dispense prescribed product & Molnupiravir EUA Fact Sheet
(if not provided by prescriber)

Responsibility of Prescriber to provide EUA Fact Sheet

If pharmacist has question regarding dosing/possible DDI/known contraindication, will need to contact prescriber same day in order to have minimal dispensing delay to patient (time-sensitive nature of drug)

Paxlovid

Review patient chart for major drug interactions
(if information available)

Dispense prescribed product & Paxlovid EUA Fact Sheet
(if not provided by prescriber)

Review prescribed dosing for any required renal adjustment requirements prior to dispensing

Dispense prescribed product per EUA required renal dosing packaging requirements & Paxlovid EUA Fact Sheet
(if not provided by prescriber)

Paxlovid Renal Adjustment Instructions for Pharmacists

STEP 1:
remove one 150mg nirmatrelvir tablet from each dose of blister card (closet to middle)

STEP 2:
affix blister card with one sticker from the provided tear pad to cover the blister cavities

STEP 3:
repeat steps 1 and 2 for every blister card in the carton (total of 5)

STEP 4:
affix one sticker from provided tear pad to cover the pre-printed dosing regimen (new dosing regimen for renal adjustment)

Paxlovid EUA Renal Adjustment Instructions for Pharmacists

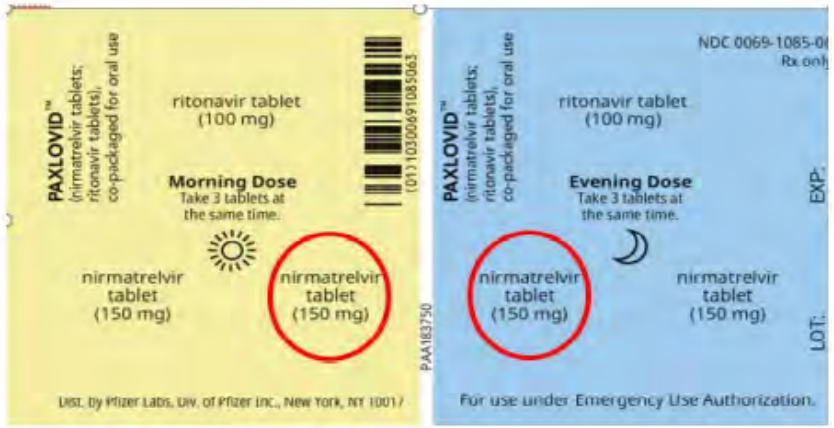


Figure 1: Remove the nirmatrelvir tablets circled in red from the blister card

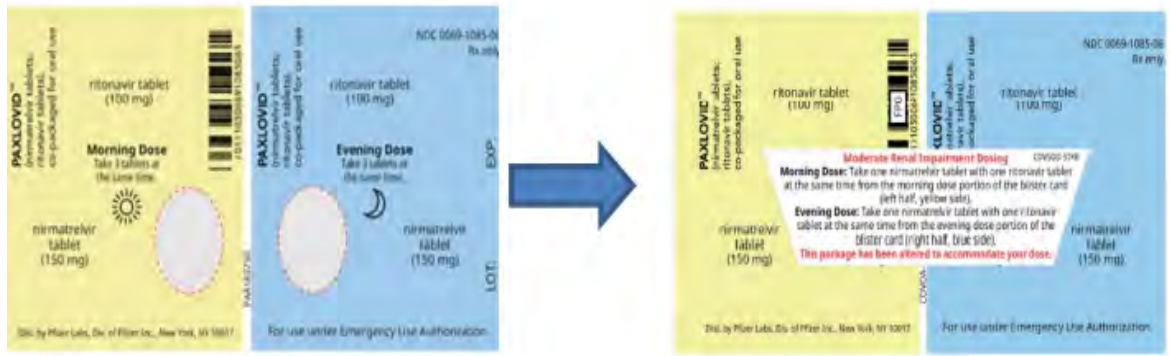


Figure 2: Placement of sticker over empty blister cavities and pre-printed dosing instruction after removal of nirmatrelvir tablets

Figure 3: Placement of sticker over pre-printed dosing regimen on carton

CMS: Coverage of Oral Antiviral Therapies to Treat COVID-19

Medicare

Site of Care[1]	Payable by Medicare	Expected Patient Cost-Sharing
Inpatient Hospital	✓	No patient cost-sharing
Outpatient Hospital or "Hospital without Walls[2]"	✓	No patient cost-sharing
Outpatient Physician Office	✓	No patient cost-sharing[3]
Nursing Home	✓	No patient cost-sharing
Pharmacy	✓	No patient cost-sharing

[1] Services must be furnished within the scope of the product's FDA authorization or approval and within the provider's scope of practice.

[2] Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.

[3] Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn't participate in Medicare.

Expected Payment to Providers: Key Facts

- CMS will provide a list of pharmacies that have provider agreements with the USG to dispense the drug in compliance with the terms and conditions of authorization. CMS will provide a list of these pharmacies, including National Provider Identifier (NPI), on the Health Plan Management Site as soon as it is available.
- Pay dispensing fees: While certain USG-procured oral antiviral drug(s) will be made available at no cost to pharmacies, the procurement does not include payment of a dispensing fee to pharmacies. CMS encourages Part D sponsors to pay a dispensing fee to pharmacies that submit claims for these drugs. No ingredient cost can be paid on these claims.
- Part D sponsors should not charge enrollee cost sharing on dispensing fees paid to the pharmacies.
- Sponsors should consult NCPDP Emergency Preparedness Guidance for "Billing for Reimbursement of a Free Product (No associated cost) with No Administration Fee" as they prepare to implement these changes.
- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these Frequently Asked Questions.

Additional information can be found on Permissible Flexibilities Related to Oral Antiviral Drugs for Treatment of COVID-19 that May Receive U.S. Food and Drug Administration Emergency Use Authorization and are Procured by the U.S. Government https://www.cms.gov/files/document/hpms-memo-oral-antiviral-guidance.pdf

CMS Billing Codes and HRSA Coverage for Uninsured

CMS Codes

- Molnupiravir Product Codes

  NDC numbers: 0006-5055-06, NDC-0006-5055-07

- Paxlovid Product Codes

  NDC number: 0069-1085-06

Continue to check CMS website for most up to date information: **www.CMS.gov**

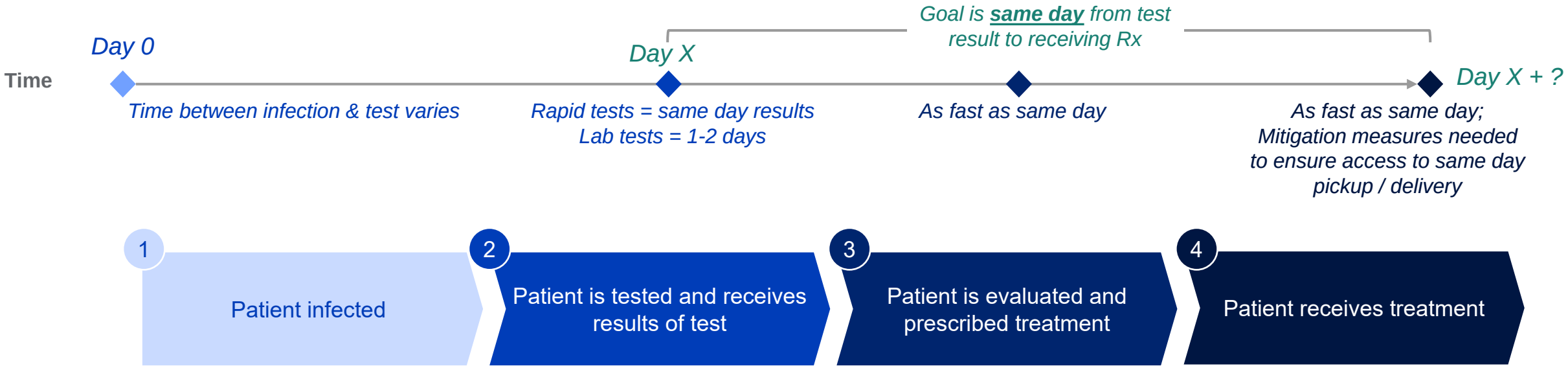
HRSA Coverage for Uninsured

HRSA uninsured fund (https://www.hrsa.gov/CovidUninsuredClaim)

Emergency Use Authorization of Molnupiravir (https://www.fda.gov/media/155053/download)
Emergency Use Authorization of Paxlovid (https://www.fda.gov/media/155049/download)

5. Oral Antiviral Administration: *Patient Journey*

Patient journey | Given need for treatment within 5 days of symptom onset, patient journey timeline should aim for rapid Rx access



Note: If patient unvaccinated (or no booster) at time of oral antiviral treatment, patient may receive a COVID-19 vaccination once isolation/quarantine period completed.[1]

[1] CDC clinical considerations. (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination)

Patient journey | Overview of patient journey for oral antivirals based on testing channel

	1 Patient infected	2 Patient is tested and receives results of test	3 Patient is evaluated and prescribed treatment	4 Patient receives treatment
Common steps across most patient journeys	• Patient infected (with/without symptoms) • Patient decides to get tested (symptoms/exposure)	• Patient tested with either rapid or lab test • Patient receives results	• Patient seeks treatment, makes appt, and is evaluated by provider • Provider issues Rx if patient eligible • Patient educated on Tx options	• Pharmacy/ clinic dispenses Rx to patient
Different channels where test occurs:				
Retail Rx site	• Patient may also test due to regular screening	• Patient locates, makes appt, travels to retail pharmacy	• If clinic/prescriber is available at Retail site, potential for patient to seek care on-site	• Patient locates Pharmacy if using one different than retail site • Patient arranges for fulfillment of Rx (delivery or pick up)
Outpatient clinic	• *No variation to common steps*	• Patient locates, may make appt, travels to ER/urgent care/other HCP office	• Patient may see same or different provider for evaluation as they did for testing	• Patient locates Pharmacy or dispensed at point of care • Patient arranges for fulfillment of Rx (delivery or pick up)
Patient's Home	• *No variation to common steps*	• Patient locates then orders/picks up at home test • "At home collection" tests require patient to send sample; "At home self tests" patient conducts test	• *No variation to common steps*	• Patient locates Pharmacy • Patient arranges for fulfillment of Rx (delivery or pick up)
Temp. testing site (e.g., mass testing)	• *No variation to common steps*	• Patient locates, travels to site	• *No variation to common steps*	• Patient locates Pharmacy • Patient arranges for fulfillment of Rx (delivery or pick up)

Non-exhaustive list – many other patient journeys exist

6. Additional Resources

Oral Antiviral Therapies

[Paxlovid Product Information]
https://www.pfizer.com/products/product-detail/paxlovidtm

[Molnupiravir Product Information]
https://www.molnupiravir-us.com/

Other Oral Antiviral Resources

Paxlovid

- Paxlovid Provider fact sheet https://www.fda.gov/media/155050/download
- Paxlovid Patient fact sheet https://www.fda.gov/media/155051/download
- Paxlovid Patient fact sheet (Spanish) https://www.fda.gov/media/155075/download

Molnupiravir

- Molnupiravir Provider fact sheet https://www.fda.gov/media/155054/download
- Molnupiravir Patient fact sheet https://www.fda.gov/media/155055/download
- Molnupiravir Patient fact sheet (Spanish) https://www.fda.gov/media/155115/download

Submit adverse event and medication error reports to FDA MedWatch using one of the following methods:

- **Online:** https://www.fda.gov/medwatch/report.htm
- **Complete and submit a postage-paid** FDA Form 3500 **and returning by mail/fax**
- Call 1-800-FDA-1088 to request a reporting form

Centers for Disease Control and Prevention: Healthcare Workers Information on COVID-19
https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html

Product-Specific Sites for Monoclonal Antibody Administration

Provides additional detail on administration of etesevimab and bamlanivimab

https://www.covid19.lilly.com/bam-ete/hcp

Provides additional detail on administration of REGEN-COV (casirivimab and imdevimab)

https://www.regencov.com/hcp

Provides additional detail on administration of sotrovimab

https://www.sotrovimab.com

Provides additional detail on administration of Evusheld (tixagevimab co-packaged with cilgavimab)

https://www.evusheld.com

Helpful Links

- **Federal Monoclonal Antibody Site**
  - https://www.phe.gov/mAbs
- **PHE COVID-19 Toolkit**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/toolkit.aspx
- **CMS Hospital Without Walls**
  - https://www.cms.gov/newsroom/press-releases/cms-announces-comprehensive-strategy-enhance-hospital-capacity-amid-covid-19- surge
- **CMS Monoclonal Antibody Reimbursement**
  - Coverage of Monoclonal Antibody Products to Treat COVID-19
    - https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf
  - Monoclonal Antibody COVID-19 Infusion: Monoclonal Antibody Products to Treat COVID-19
    - https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion
- **CDC COVID Data Tracker**
  - https://covid.cdc.gov/covid-data-tracker/#datatracker-home
- **Clinical Trial Information for Patients not Eligible for EUA**
  - Lilly Clinical Trials
    - https://trials.lillytrialguide.com/en-US/
  - Regeneron Clinical Trials
    - https://www.regeneron.com/covid19

Helpful Resources for Clinicians

- **COVID-19 Outpatient Therapies Side-by-Side Overview**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/Side-by-Side-Overview-of-mAbs-Treatment.aspx
- **Patient Prioritization for Outpatient Anti-SARS-CoV-2 Therapies or Preventive Strategies When There Are Logistical or Supply Constraints**
  - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/
- **Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19**
  - https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/
- **COVID-19 Monoclonal Antibody Eligibility Checklist: Treatment and PEP**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/mAb-eligibility-treatment-and-post-exposure-prophylaxis.aspx
- **COVID-19 Monoclonal Antibody Checklist for Subcutaneous and Intravenous Administration**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/covid19-mAb-checklist-subcutaneous-intravenous-administration.aspx

Helpful Resources for Clinicians continued

- **Subcutaneous Injection Instructions**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/REGEN-COV-SubQ-FactSheet-July2021-508.pdf
- **EMS Template Protocol**
  - https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/EMS-Template-Protocol-for-COVID19-mAbs-Administration.aspx
- **Guidelines on Vaccination after mAb administration**
  - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Educational Opportunities: Project Echo Sessions on Monoclonal Antibodies

HHS Collaboration with the University of New Mexico Project Echo Program

Recordings of past programs presented by panels of clinical experts

Project Echo Presentation Title	Date	Link
Monoclonal Antibodies - Bamlanivimab	2/9/2020	https://www.youtube.com/watch?v=YKjRgQGl-Nw
Equitable Access- Outpatient Infusion Site	2/16/2020	https://www.youtube.com/watch?v=0ZZixudBeog
Monoclonal Antibodies: OSU experience	12/3/2020	https://www.youtube.com/watch?v=p3Jsr9wasEU
Where are we now? mAb Therapy in Michigan	1/6/2021	https://www.youtube.com/watch?v=CnniyMayiXc
Monoclonal antibodies: A Healthcare system's approach (mAb Treatment at Mass General) • Presentation by Rajesh T. Gandhi, MD • Presentation by Inga T. Lennes MD, MPH.MBA	1/13/2021	https://hsc.unm.edu/echo/_docs/hhs-covid/rajgandhi1.13.21-monoclonalntibodies-.pdf https://hsc.unm.edu/echo/_docs/hhs-covid/1.13.21-hhs-mab-lennes.pdf
Managing infusion reactions Northwell Health Experience	1/27/2021	https://www.youtube.com/watch?v=zaem2mDUvKE
EMS involvement in mAb infusion programs	2/1/2021	https://www.youtube.com/watch?v=CZnCv4ktnmw
Achieving Speed and Scale in FQHCs and Health Systems • Presentation by Corinna Manini, MD • Presentation by Brandon Webb, MD	2/10/2021	https://hsc.unm.edu/echo/_docs/hhs-covid/2.10.21-manini.pdf https://hsc.unm.edu/echo/_docs/hhs-covid/2.10.21-webb.pdf
Regional Approaches to mAb Administration- Operationalizing Partnerships	2/17/2021	https://www.youtube.com/watch?v=h-ewtgAO1gI
Equity and Underserved Populations	2/24/2021	https://www.youtube.com/watch?v=IGeh2h5SlmQ
Clinical trials update and Patient/Provider Outreach	3/3/2021	https://www.youtube.com/watch?v=7AHSUqC5tWc
Partnering with Urgent Care Centers to Increase Access and Utilization of COVID mAbs: NYC Health	3/10/2021	https://www.youtube.com/watch?v=tDTVZy7FDe4
Where We're Headed: Variants and COVID-19 Therapy	3/24/2021	https://www.youtube.com/watch?v=edPa0zLmerM
Real world effectiveness and implementation of COVID-19 monoclonal antibodies	4/22/2021	https://www.youtube.com/watch?v=s2ktRGL4uJ4

For information on upcoming sessions visit: HHS ASPR Clinical Rounds

Questions?

https://phe.gov/mAbs

Email: covid19therapeutics@hhs.gov

Thank you!

Case 1:22-cv-00712-NGG-RML Document 23-5 Filed 02/15/22 Page 1 of 125

NVSS Vital Statistics Rapid Release

Report No. 015 ■ July 2021

Provisional Life Expectancy Estimates for 2020

Elizabeth Arias, Ph.D., Betzaida Tejada-Vera, M.S., Farida Ahmad, M.P.H., and Kenneth D. Kochanek, M.A.

Introduction

The National Center for Health Statistics (NCHS) collects and disseminates the nation's official vital statistics through the National Vital Statistics System (NVSS). NCHS uses provisional vital statistics data for conducting public health surveillance and final data for producing annual national natality and mortality statistics. NCHS publishes annual and decennial national life tables based on final vital statistics. To assess the effects on life expectancy of excess mortality observed during 2020, NCHS published provisional life expectancy estimates for the months January through June, 2020 in February 2021 (1). This report presents updated estimates of life expectancy based on provisional mortality data for the full year, January through December, 2020. Provisional data are early estimates based on death certificates received, processed, and coded, but not finalized, by NCHS. These estimates are considered provisional because death certificate information may later be revised, and additional death certificates may be received until approximately 6 months after the end of the year.

This report presents life expectancy estimates calculated using abridged period life tables based on provisional death counts for 2020, by sex, for the total, Hispanic, non-Hispanic white, and non-Hispanic black populations. Estimates for the American Indian and Alaska Native (AIAN), Asian, and Native Hawaiian and Other Pacific Islander (NHOPI) populations were not produced due to the impact of race and ethnicity misclassification on death certificates for these populations on the precision of life expectancy estimates (2). There are two types of life tables: the cohort (or generation) and the period (or current) life table. The cohort life table presents the mortality experience of a particular birth cohort from the moment of birth through consecutive ages in successive calendar years. The period life table does not represent the mortality experience of an actual birth cohort but rather presents what would happen to a hypothetical cohort if it experienced throughout its entire life the mortality conditions of a particular period. Period life expectancy estimates based on final data for 2019 by sex, Hispanic origin, and race are also provided in this report for purposes of comparison (see Technical Notes and reference 3 for description of methodology). Unlike the previous estimates based on 6 months of data, this full-year report presents contributions of causes of death to the changes in life expectancy using a life table partitioning technique (see Technical Notes).

Keywords: life expectancy • Hispanic origin • race • cause of death • National Vital Statistics System

Data and Methods

Provisional life expectancy estimates were calculated using abridged period life tables based on provisional death counts for 2020 from death records received and processed by NCHS as of May 13, 2021; provisional numbers of births for the same period based on birth records received and processed by NCHS as of April 7, 2021; and, July 1, 2020, monthly postcensal population estimates based on the 2010 decennial census. Provisional mortality rates are typically computed using death data after a 3-month lag following date of death, as completeness and timeliness of provisional death data can vary by many factors, including cause of death, month of the year, and age of the decedent (4,5). Mortality data used in this report include over 99% of the deaths that occurred in 2020, but certain jurisdictions and age groups may be underrepresented for later months (5). Deaths requiring investigation, including infant deaths, deaths from external injuries, and drug overdose deaths may be underestimated (6,7). See Technical Notes for more information about the calculation of the abridged period life tables, 2019 life expectancy estimates by race and Hispanic origin, and life table partitioning by cause of death.

Results

Life expectancy in the United States

The Table summarizes life expectancy by age, Hispanic origin, race, and sex. Life expectancy at birth represents the average number of years a group of infants would live if they were to experience throughout life the age-specific death rates prevailing during a specified period. In 2020, life expectancy at birth for the total U.S. population

Table. Provisional expectation of life, by age, Hispanic origin, race for the non-Hispanic population, and sex: United States, 2020

Age (years)	All races and origins			Hispanic			Non-Hispanic white			Non-Hispanic black		
	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
0	77.3	74.5	80.2	78.8	75.3	82.4	77.6	75.0	80.2	71.8	68.0	75.7
1	76.7	73.9	79.6	78.2	74.7	81.8	76.9	74.3	79.5	71.6	67.8	75.4
5	72.8	70.0	75.6	74.2	70.8	77.8	73.0	70.4	75.6	67.7	63.9	71.5
10	67.8	65.0	70.7	69.3	65.8	72.8	68.0	65.5	70.6	62.8	59.0	66.6
15	62.9	60.1	65.7	64.3	60.9	67.9	63.0	60.5	65.6	57.9	54.1	61.7
20	58.0	55.3	60.8	59.5	56.1	63.0	58.2	55.7	60.7	53.2	49.6	56.8
25	53.3	50.8	56.0	54.7	51.5	58.1	53.4	51.1	55.9	48.8	45.3	52.1
30	48.7	46.2	51.2	50.1	46.9	53.3	48.8	46.5	51.1	44.3	41.0	47.4
35	44.1	41.8	46.5	45.4	42.4	48.5	44.2	42.1	46.4	39.9	36.8	42.8
40	39.6	37.4	41.8	40.8	37.9	43.7	39.7	37.6	41.7	35.6	32.6	38.3
45	35.1	33.0	37.2	36.2	33.5	39.0	35.2	33.3	37.1	31.3	28.6	33.9
50	30.7	28.7	32.7	31.8	29.2	34.4	30.8	29.0	32.6	27.3	24.6	29.6
55	26.5	24.7	28.3	27.6	25.1	29.9	26.6	24.9	28.2	23.4	21.0	25.6
60	22.6	20.9	24.1	23.6	21.3	25.7	22.6	21.1	24.0	19.8	17.6	21.7
65	18.8	17.4	20.1	19.8	17.8	21.6	18.8	17.5	20.0	16.6	14.7	18.2
70	15.3	14.1	16.3	16.4	14.7	17.8	15.2	14.1	16.1	13.7	12.1	15.0
75	12.0	11.1	12.8	13.2	11.8	14.2	11.8	10.9	12.5	11.1	9.8	11.9
80	9.1	8.4	9.6	10.4	9.3	11.1	8.8	8.2	9.3	8.7	7.8	9.3
85	6.7	6.2	7.0	8.1	7.3	8.6	6.4	5.9	6.6	6.7	6.1	7.0

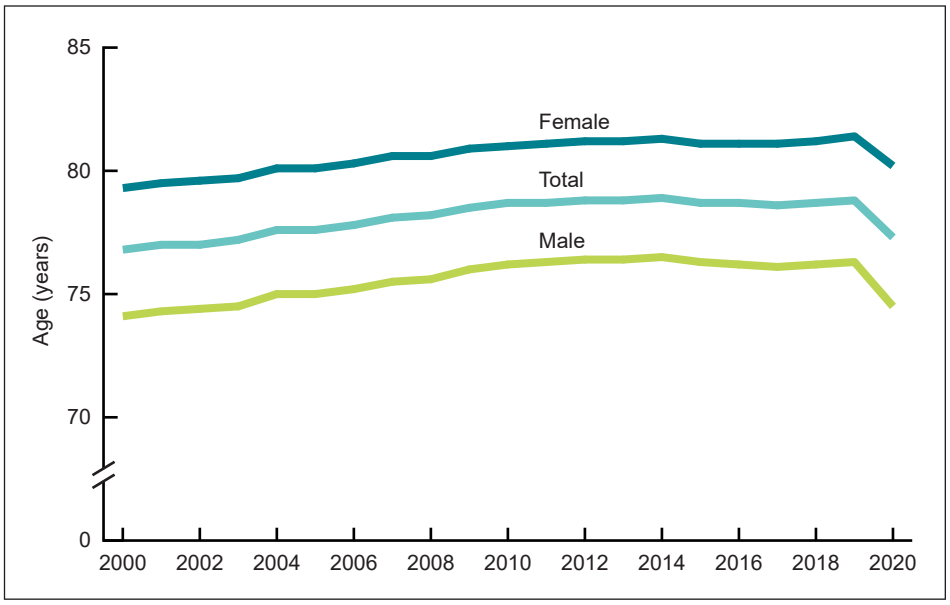
NOTES: Life tables by Hispanic origin are based on death rates that have been adjusted for race and ethnicity misclassification on death certificates. Updated classification ratios were applied; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.

SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality, 2020.

was 77.3 years, declining by 1.5 years from 78.8 in 2019 (8). Life expectancy at birth for males was 74.5 years in 2020, representing a decline of 1.8 years from 76.3 years in 2019. For females, life expectancy declined to 80.2 years, decreasing 1.2 years from 81.4 years in 2019 (Figure 1).

The difference in life expectancy between the sexes was 5.7 years in 2020, increasing from 5.1 in 2019. Between 2000 and 2010, the difference in life expectancy between the sexes narrowed from 5.2 years to a low of 4.8 years and then gradually increased to 5.1 in 2019 (Figure 1).

Figure 1. Life expectancy at birth, by sex: United States, 2000–2020



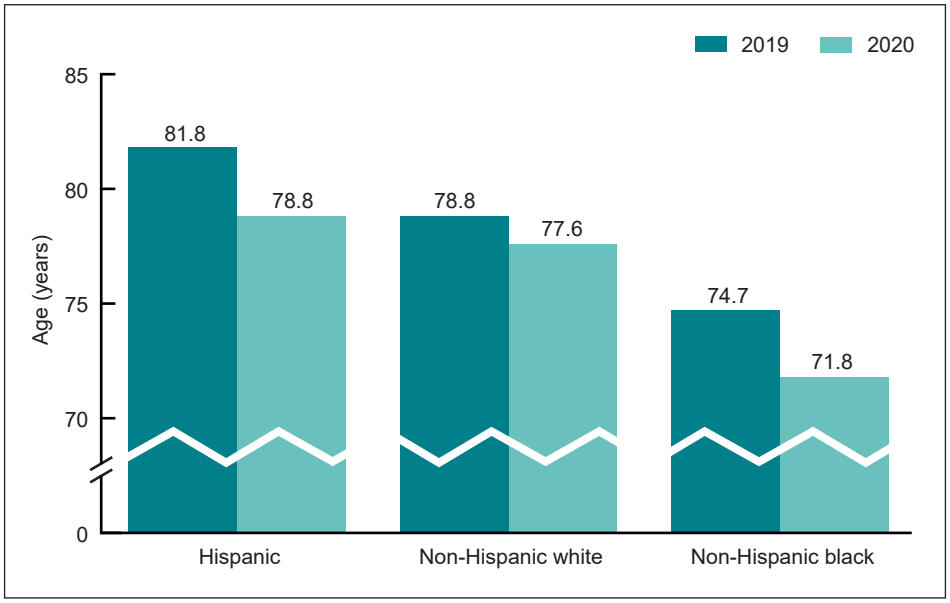
NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

Life expectancy by Hispanic origin and race

Between 2019 and 2020, life expectancy decreased by 3.0 years for the Hispanic population (81.8 to 78.8) (Figure 2). It decreased by 2.9 years for the non-Hispanic black population (74.7 to 71.8) and by 1.2 years for the non-Hispanic white population (78.8 to 77.6). In 2020, the Hispanic population had a life expectancy advantage of 1.2 years over the non-Hispanic white population, declining from an advantage of 3.0 years in 2019 (Figure 3). The Hispanic advantage relative to the non-Hispanic black population decreased from 7.1 to 7.0 years between 2019 and 2020. The non-Hispanic white life expectancy advantage relative to the non-Hispanic black population increased from 4.1 to 5.8 years between 2019 and 2020.

Among the six Hispanic origin -race-sex groups (Figure 4), the decrease in life expectancy between 2019 and 2020 was greatest for Hispanic males, whose life expectancy declined by 3.7 years (79.0 to 75.3), followed by non-Hispanic black males with a decline of 3.3 years (71.3 to 68.0), non-Hispanic black females with a decline of 2.4 years (78.1 to 75.7),

Figure 2. Life expectancy at birth, by Hispanic origin and race: United States, 2019 and 2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

Hispanic females with a decline of 2.0 years (84.4 to 82.4), non-Hispanic white males with a decline of 1.3 years (76.3 to 75.0), and non-Hispanic white females with a decline of 1.1 years (81.3 to 80.2).

Effect on life expectancy of changes in cause-specific mortality

Increases or decreases in life expectancy represent the sum of positive and negative contributions of cause-specific death rates. Declines in cause-specific mortality contribute to increases in life expectancy while increases in cause-specific mortality contribute to decreases in life expectancy. If the negative contributions (i.e., increases in cause-specific death rates) are greater than the positive contributions (i.e., decreases in cause-specific deaths rates) then the result is a decline in life expectancy. If negative and positive contributions offset each other, then the result would be no change in life expectancy (see Technical Notes for a description of the partitioning method).

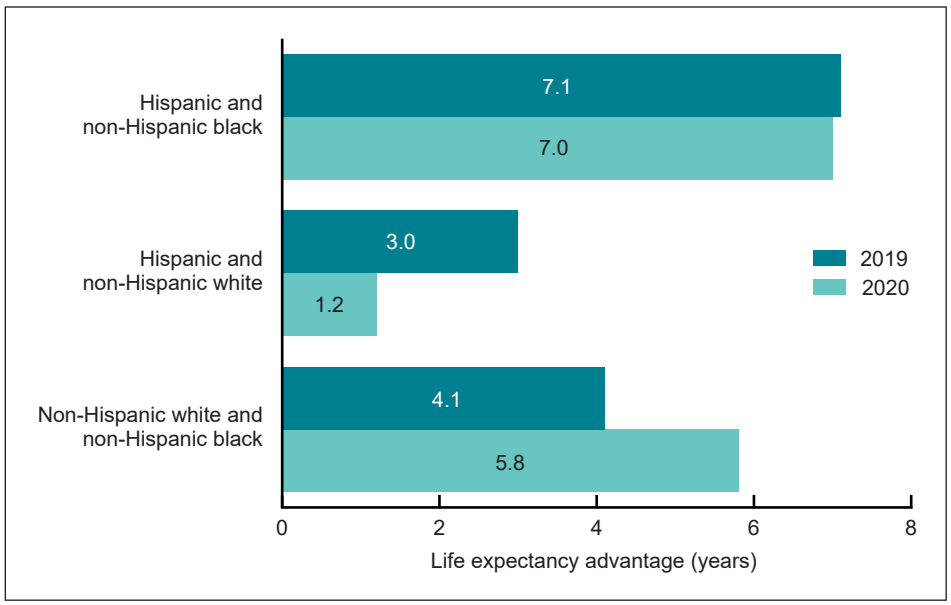
The decline of 1.5 years in life expectancy between 2019 and 2020 was primarily due to increases in mortality due to COVID-19 (73.8% of the negative contribution), unintentional injuries (11.2%), homicide (3.1%), diabetes (2.5%), and Chronic liver disease and cirrhosis (2.3%) (Figure 5). The decline in life expectancy would have been even greater were it not for the offsetting effects of decreases in mortality due to cancer (45.2%), Chronic lower respiratory diseases (CLRD) (20.8%), heart disease (5.0%), suicide (4.6%), and Certain conditions originating in the perinatal period (4.0%).

For the male population, the 1.8 year decline in life expectancy was mostly due to increases in mortality due to COVID-19 (68.7%), unintentional injuries (14.0%), homicide (4.4%), diabetes (2.4%), and Chronic liver disease and cirrhosis (2.3%). The decline in life expectancy was offset by decreases in mortality due to cancer (51.7%), CLRD (17.5%), Influenza and pneumonia (5.3%), Alzheimer disease (4.7%), and suicide (4.6%).

For females, the decline in life expectancy of 1.2 years was primarily due to increases in mortality due to COVID-19 (79.8%), unintentional injuries (6.8%), diabetes (2.7%), Chronic liver disease and cirrhosis (2.3%), and homicide (1.0%). These effects were offset by decreases in mortality due to cancer (34.7%), CLRD (21.2%), heart disease (16.3%), suicide (4.1%), and stroke (3.7%).

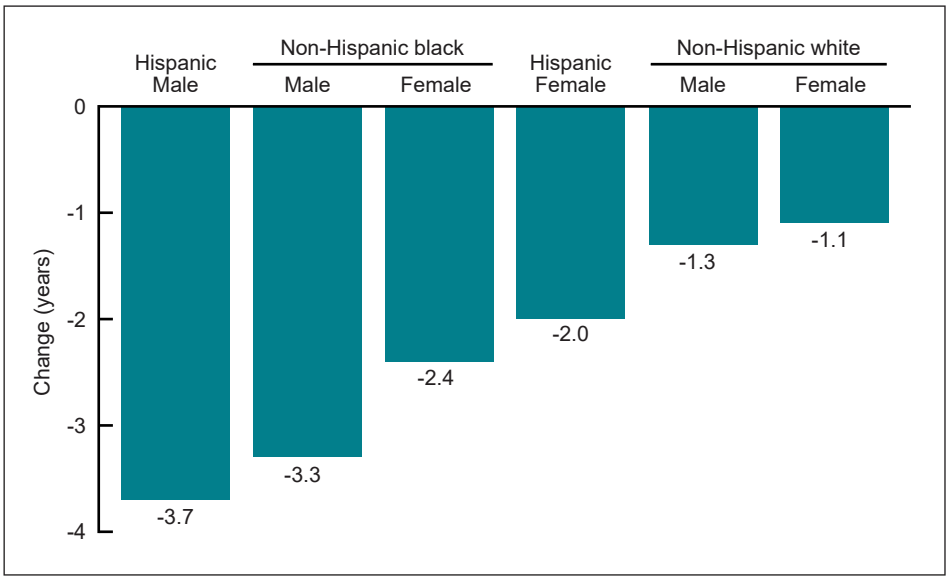
The Hispanic population experienced the largest decline in life expectancy between 2019 and 2020 (3.0 years). This decrease was primarily due to increases in mortality due to COVID-19 (90.0%), unintentional injuries (4.2%), diabetes

Figure 3. Differences between groups in life expectancy at birth: United States, 2019 and 2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

Figure 4. Change in life expectancy at birth, by Hispanic origin and race and sex: United States, 2019–2020



NOTES: Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

(1.8%), homicide (1.0%), and Chronic liver disease and cirrhosis (0.9%) (Figure 6). The decline in life expectancy would have been greater were it not for the offsetting effects of decreases in mortality due to cancer (38.2%), heart disease (14.1%), stroke (9.7%), CLRD (9.1%), and Alzheimer disease (8.4%).

The second greatest decline in life expectancy was experienced by the non-Hispanic black population (2.9 years). The decline was due primarily to increases in mortality due to COVID-19 (59.3%), unintentional injuries (11.9%), homicide (7.7%), heart disease (5.9%), and diabetes (3.6%). The decrease in life expectancy was offset by decreases in mortality due to cancer (68.0%); Certain conditions originating in the perinatal period (11.3%); Congenital malformations, deformations and chromosomal abnormalities (4.4%); Aortic aneurysm and dissection (2.5%); and Pneumonitis due to solids and liquids (2.2%).

The non-Hispanic white population experienced the smallest decline in life expectancy (1.2 years), primarily due to increases in mortality due to COVID-19 (67.9%), unintentional injuries (14.2%), Chronic liver disease and cirrhosis (3.3%), diabetes (2.2%), and homicide (1.2%). The negative effects of these causes were offset by decreases in mortality due to cancer (40.1%), CLRD (28.2%), suicide (11.8%), kidney disease (4.4%), and Pneumonitis due to solids and liquids (2.8%).

Discussion and Conclusions

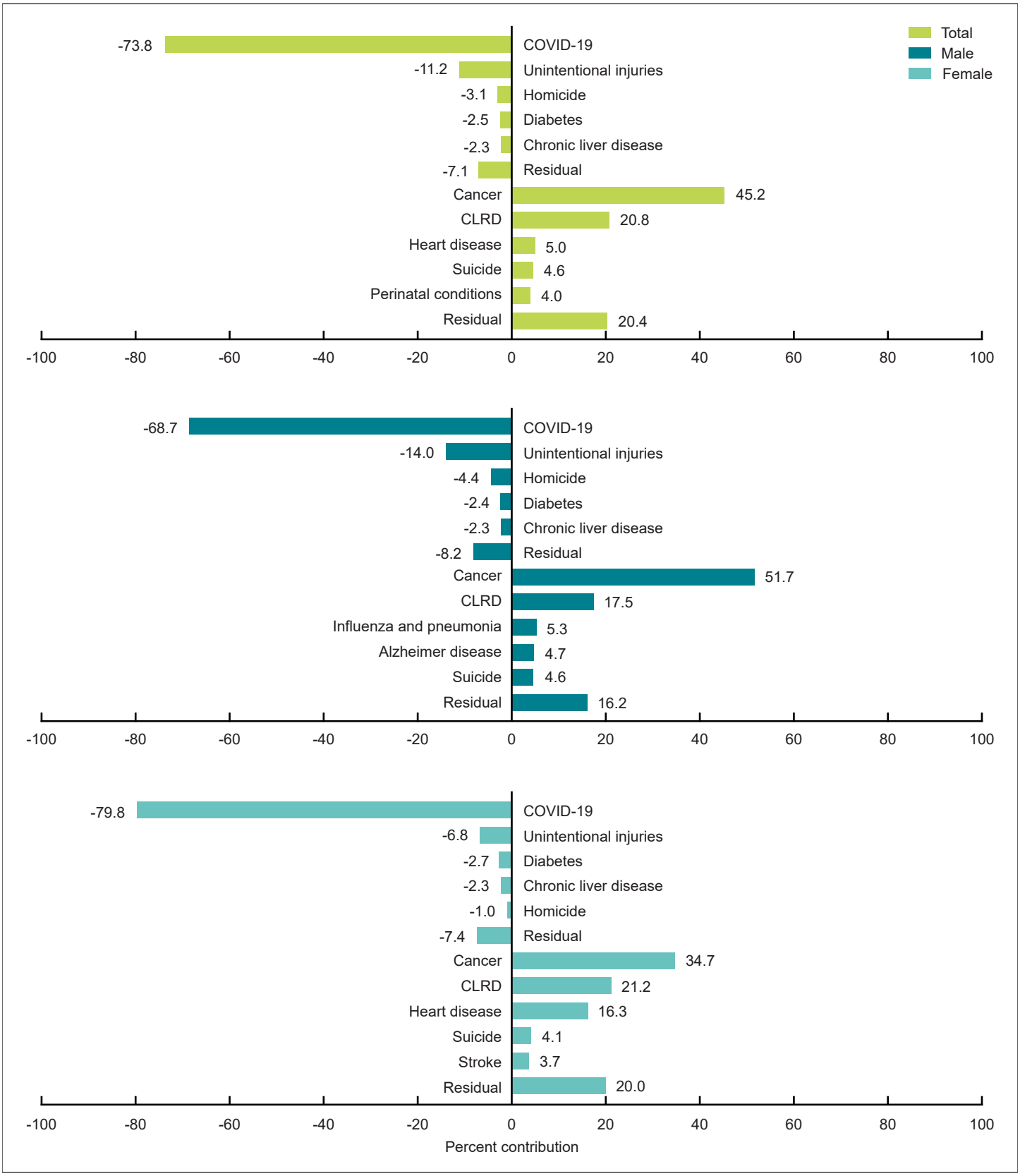
U.S. life expectancy at birth for 2020, based on nearly final data, was 77.3 years, the lowest it has been since 2003. Male life expectancy (74.5) also declined to a level not seen since 2003, while female life expectancy (80.2) returned to the lowest level since 2005. The Hispanic population experienced the largest decline in life expectancy between 2019 and 2020, from 81.8 to 78.8 years, reaching a level lower than what it was in 2006 (80.3 years), the first year for which life expectancy estimates by Hispanic origin were produced (9). The non-Hispanic black population experienced the second largest decline in life expectancy (from 74.7 to 71.8) and was the lowest estimate seen since 2000 for the black population (regardless of Hispanic origin). Life expectancy for the non-Hispanic white population declined from 78.8 to 77.6 years, a level last observed in 2002 for the white population (regardless of Hispanic origin).

Racial and ethnic mortality disparities in life expectancy increased in 2020. For example, the non-Hispanic white life expectancy advantage over the non-Hispanic black population increased by 41.5% between 2019 (4.1) and 2020 (5.8). Life expectancy for the black population has consistently been lower than that of the white population, but the gap had been narrowing during the past three decades, from 7.1 years in 1993 to 4.1 years in 2019 (10). The last time the gap in life expectancy between the white and black populations was this large was in 1999 (10).

Conversely, the gap between the Hispanic and non-Hispanic white populations decreased by 60% between 2019 (3.0) and 2020 (1.2). The Hispanic population lost more than one-half of the mortality advantage it had experienced relative to the non-Hispanic white population. Rather than a positive outcome, the narrowing of the life expectancy gap between the two populations is a stark indicator of worsening health and mortality outcomes for a population that paradoxically has been, prior to the COVID-19 pandemic, able to defy expectations consistent with its disadvantaged socioeconomic profile (2,9,11).

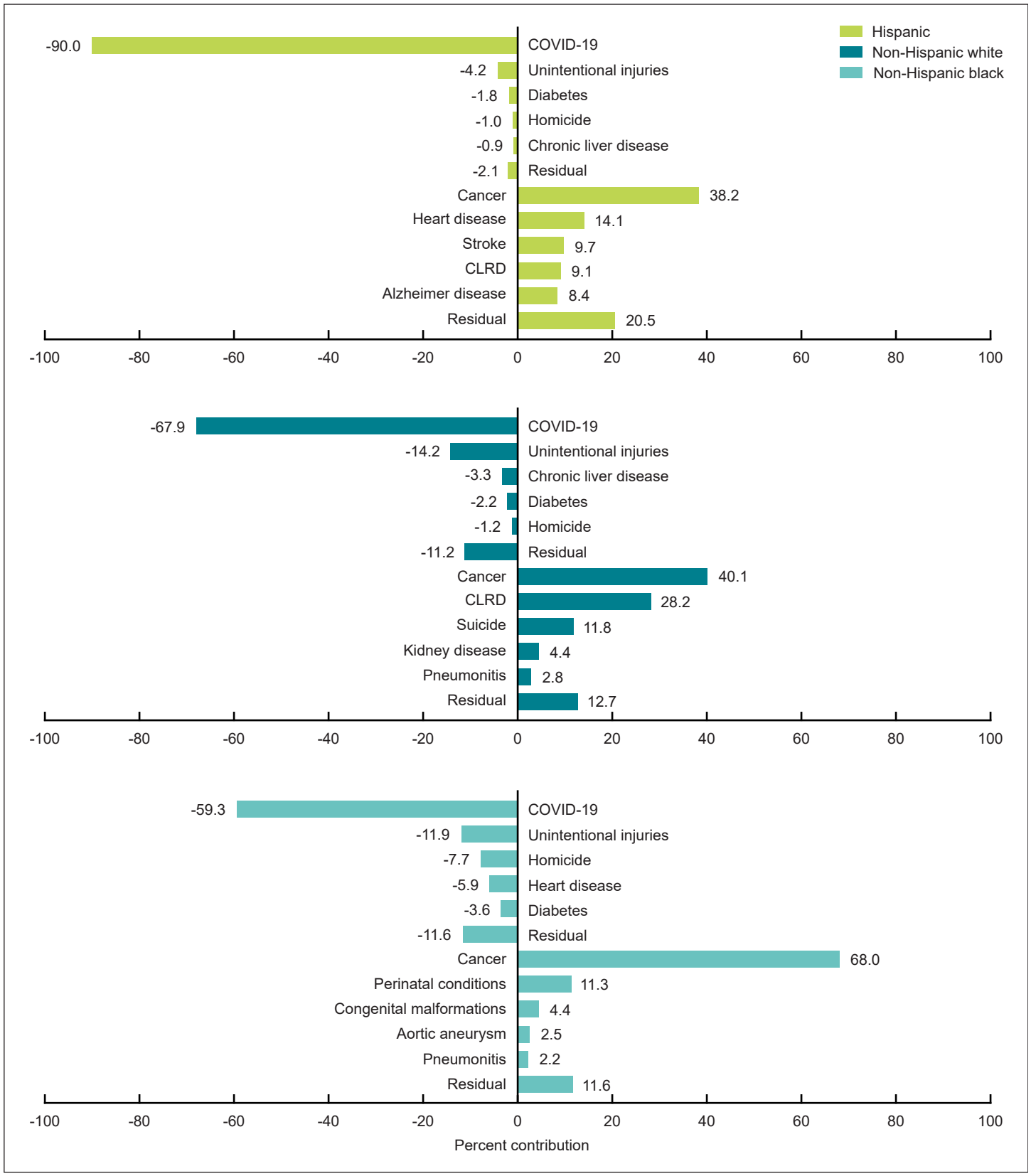
Mortality due to COVID-19 had, by far, the single greatest effect on the decline in life expectancy at birth between 2019 and 2020, overall, among men and women, and for the three race and Hispanic-origin groups shown in this report. Among the causes contributing negatively to the change in life expectancy, COVID-19 contributed 90% for the Hispanic population, 67.9% for the non-Hispanic white population, and 59.3% for the non-Hispanic black population. Among the other causes of death that negatively contributed to the change in life expectancy, unintentional injuries, homicide, and diabetes affected all three Hispanic origin and race groups. For all three populations, unintentional injuries had the greatest

Figure 5. Contribution of leading causes of death to the change in life expectancy, by sex and total population: United States, 2019–2020



NOTES: CLRD is Chronic lower respiratory diseases. Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

Figure 6. Contribution of leading causes of death to the change in life expectancy, by Hispanic origin and race: United States, 2019–2020



NOTES: CLRD is Chronic lower respiratory diseases. Life expectancies for 2019 by Hispanic origin and race are not final estimates; see Technical Notes. Estimates are based on provisional data for 2020. Provisional data are subject to change as additional data are received.
SOURCE: National Center for Health Statistics, National Vital Statistics System, Mortality data.

effect out of these three causes (14.2%, 11.9%, and 4.2% for the non-Hispanic white, non-Hispanic black, and Hispanic populations, respectively). Increases in unintentional injury deaths in 2020 were largely driven by drug overdose deaths (12).

The life expectancy estimates presented in this report differ in important ways from those based on data for the first half of 2020 (January through June) (1). Life expectancy for the Hispanic population declined an additional 1.1 years from 79.9 years for the first half of 2020 to 78.8 years for the full-year 2020. Life expectancy declined a further 0.4 year for the non-Hispanic white population (78.0 to 77.6) and 0.2 year for the non-Hispanic black population (72.0 to 71.8). As a result, the Hispanic and non-Hispanic black populations switched places. Between 2019 and the first half of 2020, the non-Hispanic black population experienced a decline in life expectancy of 2.7 years, followed by the Hispanic population (1.9 years), and the non-Hispanic white population (0.8 year). Between 2019 and 2020 (full year), the Hispanic population experienced a decline in life expectancy of 3.0 years, followed by the non-Hispanic black (2.9 years), and non-Hispanic white (1.2 years) populations. A likely explanation for these changes may be group differences in the monthly distributions of COVID-19 deaths throughout the year. Indeed, a review of the monthly distribution of COVID-19 deaths revealed notable differences between the three populations. For the non-Hispanic black population, the percentages of COVID-19 deaths were similar across the two halves of the year (49.5% and 50.3%). In contrast, for the Hispanic population, 67.6% of all COVID-19 deaths occurred during the second half of the year. Similarly, for the non-Hispanic white population 70.5% of COVID-19 deaths occurred during the second half of the year.

The provisional mortality data on which the life tables are based have several limitations. First, the timeliness of death certificate data varies by jurisdiction and time. Some jurisdictions have historically taken longer to submit death certificates because paper records were submitted rather than electronic records, staffing shortages, or other localized issues. More recently, jurisdictions were differently affected by the pandemic. Many jurisdictions increased their frequency of death certificate submissions, while some faced staffing challenges, data processing disruptions, or other issues. Some jurisdictions expanded their use of electronic death registration systems in 2020, which may have affected the timeliness of data submission. The effect of recent changes in timeliness will not be apparent until data are finalized. Another limitation is the variation in timeliness due to age and cause of death. Certain age groups, particularly under 5 years, may be underrepresented (5). Deaths requiring investigation, including infant deaths, deaths due to external injuries, and drug overdose deaths take longer to complete and may be underreported in the 3 to 6 months after the death occurred. Lastly, the timeliness of death certificate data by race or ethnicity has not been studied. Differences in timeliness by these factors may result in underestimation of deaths for specific groups. The underestimation of infant deaths, for example, will have a disproportionate effect on life expectancy at birth given the latter's sensitivity to infant mortality, which is generally higher than mortality at all other ages up to the mid-50s or so.

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Technical Notes

The methodology used to estimate the provisional 2020 life tables (Internet tables I–1 through I–12), on which the life expectancy estimates presented in this report are based, differs from what is used to estimate the annual U.S. national life tables in several ways (3). First, the life tables presented in this report are based on provisional death counts rather than on final death counts. Second, they are based on monthly population estimates rather than on annual mid-year population estimates. Third, they are abridged period life tables closed at ages 85 and over rather than complete period life tables closed at ages 100 and over. The main reason for the differences in methodology is data availability. Final death counts for the year 2020 will be not be available until late in 2021. Similarly, census mid-year population estimates for 2020 are not yet available. The tables are closed at ages 85 and over because Medicare data, used to supplement vital statistics data at older ages, are not yet available. Another difference is the use of provisional birth counts rather than final birth counts and linked birth and infant death data used for life tables by Hispanic origin and race as these data are not yet available. Finally, abridged rather than complete life tables are used to address the effects of small death counts for some Hispanic origin-race-sex-age groups (Internet tables I–1 through I–12).

Standard errors of the two most important functions, the probability of dying and life expectancy (Internet tables I–3 through I–4), are estimated under the assumption that the data are only affected by random error because over 99% of deaths that occurred during the first half of 2020 are included. However, the possibility that certain jurisdictions and age groups may be underrepresented for later months could potentially lead to biases not accounted for by the estimated standard errors. Other possible errors, including age, and Hispanic origin and race misreporting on death certificates are also not considered in the calculation of the variances or standard errors of the life table functions.

The methodology used to estimate the 2019 complete period life tables, from which the 2019 life expectancy estimates in this report are generated, is the same as that used every year to estimate the annual U.S. life tables, with a minor modification (3). The standard 2019 birth and mortality data files were used rather than the 2019 linked birth/infant death data file for the life tables by Hispanic origin and race, because the linked data for 2019 are not yet available. The final 2019 life tables by Hispanic origin and race will be updated once the linked birth and infant death data become available (Internet table I–15).

Data for calculating life table functions

Vital statistics data

Mortality data used to estimate the life tables presented in this report include over 99% of the deaths that occurred in 2020, although certain jurisdictions and age groups may be underrepresented for later months. Death data are typically over 99% complete 3 months after the date of death, but this can vary by jurisdiction, age of the decedent, and the cause of death. Most jurisdictions submit over 90% of death data by 3 months after the date of death, but some jurisdictions may take longer to submit death records. Death data for decedents aged under 5 years are 90% complete 3 months after the date of death, and 95% complete 6 months after the death occurred. Provisional estimates of infant mortality are typically presented with a 9-month lag as infant deaths require additional investigation and take longer to complete. Timeliness also varies by cause of death; with deaths due to external causes taking additional time to investigate and complete death certificates. Provisional estimates for most external causes of death (e.g., falls, suicides, unintentional injuries) are presented with a 6-month lag, while drug overdose deaths are presented with a 9-month lag.

Beginning with the 2018 data year, all 50 states and D.C. reported deaths based on the 2003 revision of the U.S. Standard Certificate of Death for the entire year (3). The revision is based on the 1997 Office of Management and Budget (OMB) standards (3). The 1997 standards allow individuals to report more than one race and increased the race choices from four to five by separating the Asian and Pacific Islander groups. The Hispanic category did not change, remaining consistent with previous reports.

The Hispanic origin and race groups in this report follow the 1997 standards and differ from the race categories used in reports for data years prior to 2018. From 2003 through 2017, not all deaths were reported using the 2003 certificate revision that allowed the reporting of more than one race based on the 1997 OMB race standards (3). During those years, multiple-race data were bridged to the 1977 standard single-race categories. Use of the bridged-race process was discontinued for the reporting of mortality statistics in 2018 when all states collected data on race according to 1997 OMB guidelines for the full data year.

Census population data

The population data used to estimate the life tables shown in this report are July 1, 2020, monthly postcensal population estimates based on the 2010 decennial census and are available from the U.S. Census website at https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html.

Preliminary adjustment of the data

Adjustments for unknown age

An adjustment is made to account for the small proportion of deaths for which age is not reported on the death certificate. The number of deaths in each age category is adjusted proportionally to account for those with not-stated age. The following factor (F) is used to make the adjustment. F is calculated for the total and for each sex group within a racial and ethnic population for which life tables are constructed:

$$F = D / D^a$$

where D is the total number of deaths and D^a is the total number of deaths for which age is stated. F is then applied by multiplying it by the number of deaths in each age group.

Adjustment for misclassification of Hispanic origin and race on death certificates

The latest research to evaluate Hispanic origin and race reporting on U.S. death certificates found that the misclassification of Hispanic origin and race on death certificates in the United States accounts for a net underestimate of 3% for total Hispanic deaths, a net underestimate of less than one-half percent for total non-Hispanic black deaths, and no under or overestimate for total non-Hispanic white deaths or for the population racially classified as white or black, irrespective of Hispanic origin (10). These results are based on a comparison of self-reported Hispanic origin and race on Current Population Surveys (CPS) with Hispanic origin and race reported on the death certificates of a sample of decedents in the National Longitudinal Mortality Study (NLMS) who died during the period 1999–2011 (10).

NLMS-linked records are used to estimate sex-age-specific ratios of CPS Hispanic origin and race counts to death certificate counts (2). The CPS to death certificate ratio, or "classification ratio," is the ratio of the weighted count of self-reported race and ethnicity on the CPS to the weighted count of the same racial or ethnic category on the death certificates of the sample of NLMS decedents described above. It can be interpreted as the net difference in assignment of a specific Hispanic origin and race category between the two classification systems and can be used as a correction factor for Hispanic origin and race misclassification (10). The assumption is made that the race and ethnicity reported by a CPS respondent is more reliable than proxy reporting of race and ethnicity by a funeral director who has little personal knowledge of the decedent. Further, public policy embodied in the 1997 OMB standard mandates that self-identification should be the standard used for the collection and recording of race and ethnicity information (10).

The NLMS-based classification ratios discussed above are used to adjust the age-specific number of deaths for ages 1–85 years and over for the total, Hispanic, non-Hispanic white, and non-Hispanic black populations, and by sex for each group, as follows:

$$_nD_x = {}_nD_x^F \bullet {}_nCR_x$$

where ${}_nD_x^F$ is the age-specific number of deaths adjusted for unknown age as described above, ${}_nCR_x$ are the sex- and age-specific classification ratios used to correct for the misclassification of Hispanic origin and race on death certificates, and ${}_nD_x$ are the final age-specific counts of death adjusted for age and Hispanic origin and race misclassification.

Because NLMS classification ratios for infant deaths are unreliable due to small sample sizes, corrections for racial and ethnic misclassification of infant deaths are addressed by using infant death counts and live birth counts from the linked birth and infant death data files rather than the traditional birth and death data files (3). In the linked file, each infant death record is linked to its corresponding birth record so that the race and ethnicity of the mother reported on the birth record can be ascribed to the infant death record. Due to the unavailability of birth and infant death data at this time, the traditional birth and death data files are used instead for both the 2019 and 2020 life tables. Typically, infant mortality rates based on these data are overestimated by approximately 4% for the Hispanic population and 3% for the non-Hispanic black population and underestimated by 2% for the non-Hispanic white population (1).

Calculation of abridged life tables

The abridged life tables were constructed using the methodology developed by Chiang with minor modifications described below (13). The life table columns include:

Age

The age interval between two exact ages, x and $x + n$. The abridged life tables contain 19 age groups (in years): 0–1, 1–5, 5–10, 10–15, …, 80–85, and 85 and over.

Probability of dying, ${}_nq_x$

The first step in the calculation of an abridged period life table is the estimation of the age-specific probability of dying, ${}_nq_x$. The probability of dying between two exact ages, x and $x + n$, is defined as:

$$_nq_x = \frac{n_x \bullet {}_nM_x}{1+(1-a_x)\bullet n_x \bullet {}_nM_x}$$

where ${}_nM_x$ is the age-specific period death rate, $\frac{{}_nD_x}{{}_nP_x}$, and ${}_nD_x$ is the age-specific provisional death count, ${}_nP_x$ is the July 1, 2020, age-specific monthly population estimates based on the 2010 decennial population census population count; n_x is the size in years of the age interval; and a_x is the fraction of life lived by those who died in the age interval.

Number surviving, l_x

The number of persons surviving to the beginning of the age interval from the original 100,000 hypothetical live births is defined as:

$$l_{x+n} = l_x - {}_nd_x$$

where the radix of the table $l_0 = 100{,}000$.

Number dying, ${}_nd_x$

The number of persons dying in the hypothetical life table cohort in the age interval x and $x + n$ is defined as:

$$_nd_x = l_x \bullet {}_nq_x$$

Person-years lived, ${}_nL_x$

The number of person-years lived by the hypothetical life table cohort within an age interval x and $x + n$ is defined as:

$$ {}_nL_x = n_x \bullet (l_x - {}_nd_x) + a_x \bullet n_x \bullet {}_nd_x $$

where ${}_\infty L_x$, the person-years lived in the final open-ended age interval, is defined as:

$$ {}_\infty L_x \circ \frac{l_x}{{}_\infty M_x} $$

Total number of person-years lived, T_x

The number of person-years that would be lived by the hypothetical life table cohort after the beginning of the age interval x and $x + n$ is defined as:

$$ T_x = \sum_{x=0}^{x=x+\infty} {}_nL_x $$

Expectation of life, e_x

The average number of years to be lived by those in the hypothetical life table cohort surviving to age x is defined as:

$$ e_x = \frac{T_x}{l_x} $$

Variances and standard errors of the probability of dying and life expectancy

Variances are estimated under the assumption that the mortality data on which the life tables are based are not affected by sampling error and are subject only to random variation. However, although over 99% of deaths that occurred from January through December, 2020 are included, the data may be biased by the possibility that certain jurisdictions and age groups may be underrepresented for later months. These errors as well as those resulting from age and Hispanic origin and race misreporting on death certificates are not considered in the calculation of the variances or standard errors of the life table functions.

The methods used to estimate the variances of ${}_nq_x$ and e_x are based on Chiang (13) with a minor modification in the estimate of the variance of e_x in the closing age of the life table (14). Based on the assumption that deaths are binomially distributed, Chiang proposed the following equation for the variance of ${}_nq_x$:

$$ Var({}_nq_x) = \frac{{}_nq_x^2(1 \circ {}_nq_x)}{{}_nD_x} $$

where ${}_nD_x$ is the age-specific number of deaths.

$$ Var(e_x) = \frac{\sum_{x=0}^{x=75-84} l_x^2 \bullet [(1-a_x) \bullet n_x + e_{(x+n)}]^2 \circ Var({}_nq_x)}{l_x^2} $$

and for ages 85 and over:

$$ Var(e_{85+}) = \frac{l_{85+}^2}{M_{85+}^4} \bullet Var(M_{85+}) $$

Causes of death contributing to changes in life expectancy

To measure changes in mortality, a discrete method, developed by Arriaga (15–17), was used to estimate the contribution of mortality change by causes of death based on changes in life expectancy, which is described as a procedure that "estimates the number of years added to or removed from life expectation because of the decrease or increase (respectively) of the central mortality rates of life tables" (16). With this method one can partition the change in life expectancy over time or between two separate groups of populations. In this report, Arriaga's technique is used to partition by cause-of-death changes in life expectancy at birth in the United States from 2019 to 2020.

The method partitions changes into component additive parts and identifies the causes of death having the greatest influence, positive or negative, on changes in life expectancy based on rankable causes of death (15–17). This is the same method as that used by NCHS annually to analyze changes in life expectancy (18).

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COVID-19

Risk of Severe Illness or Death from COVID-19

Racial and Ethnic Health Disparities

Updated Dec. 10, 2020

Why are some racial and ethnic minority groups disproportionately affected by COVID-19? The following links provide specific information about underlying health and social inequities that put many racial and ethnic minority groups at increased risk of getting sick, having more severe illness, and dying from COVID-19.

1. Introduction
2. Risk of Exposure to COVID-19
3. **Risk of Severe Illness or Death from COVID-19**
4. Disparities in COVID-19 Illness
5. Disparities in COVID-19-Associated Hospitalizations
6. Disparities in COVID-19 Deaths
7. Unintended Consequences of COVID-19 Mitigation Strategies
8. What We Can Do to Move Towards Health Equity

Some of the many inequities in social determinants of health that may increase risk of severe illness (such as hospitalization, intubation, and death) from COVID-19 include access to quality healthcare, general health status, education, economic stability, and many other factors that affect health risks and outcomes. Because of these and other inequities, people from some racial and ethnic minority groups are less likely to be vaccinated against COVID-19 than non-Hispanic White people. COVID-19 vaccination reduces the risk of COVID-19 and its potentially severe complications. Discrimination, which includes racism, shapes social and economic factors that put people at increased risk of severe COVID-19 illness.[1,2,3,4,5] Unfortunately, discrimination exists in systems meant to protect well-being and health. For example, discrimination within the healthcare system may deter people from seeking or receiving timely testing, vaccination, and treatment for health concerns, including COVID-19.[6]

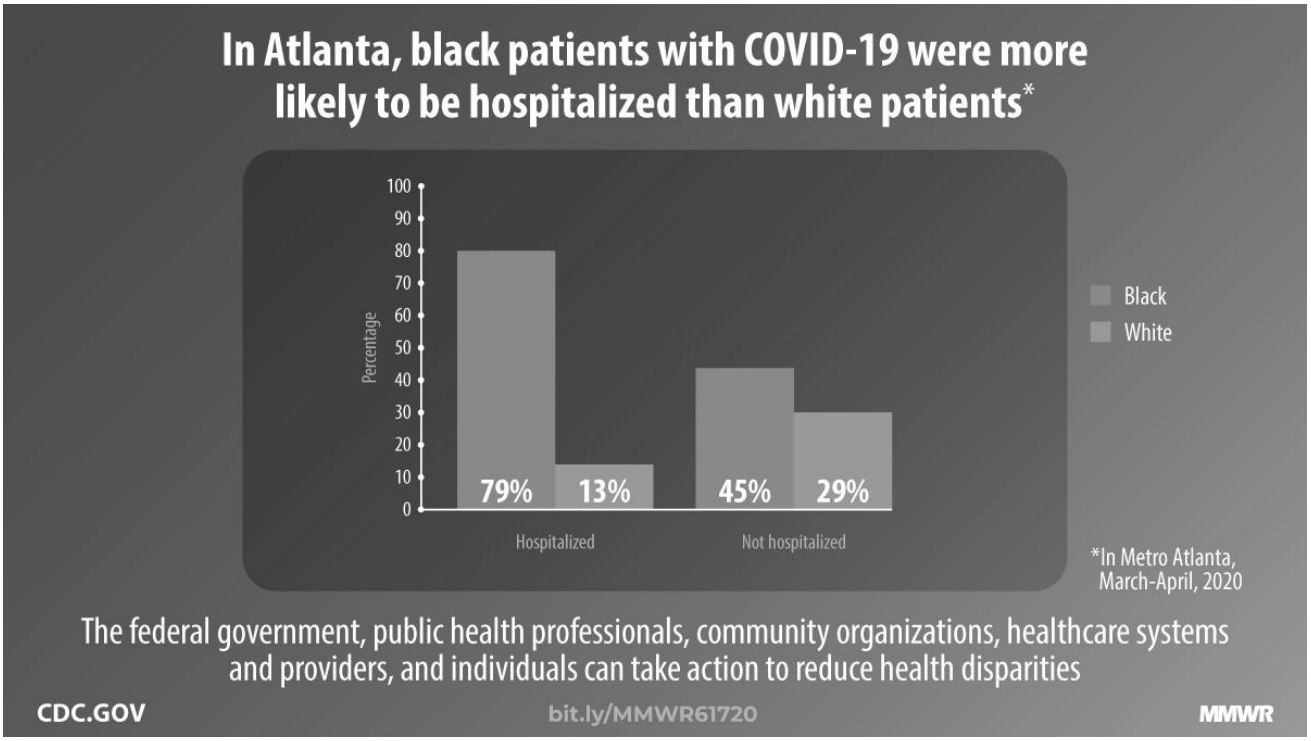
To explore additional information and data related to COVID-19 health and vaccination disparities, please visit the Health Equity and Vaccine Equity landing pages within the CDC COVID Data Tracker.

Evidence for factors that contribute to risk for severe illness from COVID-19

Severe illness means that the person with COVID-19 requires hospitalization, intensive care, or a ventilator to help them breathe. Severe illness can lead to death. Among adults, the risk of severe illness from COVID-19 increases with age, with older adults at highest risk. Additionally, people of any age, race, ethnicity, and sex with certain underlying medical conditions are at increased risk of severe illness from COVID-19. CDC continues to review the evidence and provide updates about the underlying medical conditions that might increase risk of severe illness from COVID-19. More detailed evidence summaries are also available.

COVID-19 is a new disease. Currently, few studies have examined the social factors that increase risk of severe illness from COVID-19. However, these limited studies have found differences between racial and ethnic groups in the health and social factors that may increase risk of severe illness or death from COVID-19.[7–21] Some of the studies are from the entire United

States; others are from specific cities and communities. These studies consistently identify underlying factors that are associated with increased risk of severe illness from COVID-19. CDC will continue to monitor the latest evidence and provide updated information.



View Larger

Text Description

Title:
In Atlanta, black patients with COVID-19 were more likely to be hospitalized than white patients*

Body of Graphic:
Y axis shows Percentage
X axis shows Hospitalized and Not hospitalized
Each racial/ethnic group has two vertical bars, different color—first color is blue for black persons, second color is green for white persons
Hospitalized: 79% black, 13% white
Not hospitalized: 45% black, 29% white

Bottom of graphic:
The federal government, public health professionals, community organizations, healthcare systems and providers, and individuals can take action to reduce health disparities

Footnote:
*In Metro Atlanta, March-April, 2020

Current evidence shows that the following factors are associated with increased risk of severe illness from COVID-19 for racial and ethnic minority groups:

- **Healthcare:** A recent study found that people from racial and ethnic minority groups were more likely to have increased COVID-19 disease severity upon admission at the hospital compared with non-Hispanic White people.[7,8,9,10] Healthcare access can also be limited for these groups by other factors, such as lack of transportation or child care, inability to take

time off work, communication and language barriers, cultural differences between patients and providers, not having a usual source of care, and historical and current discrimination in healthcare systems.[11] Some people from racial and ethnic minority groups may hesitate to seek care because they distrust the government and healthcare systems. This distrust may be due to the roles of the government and healthcare systems in current inequities in treatment [12] and their responsibility for discriminatory, unethical, and abusive historical events. These historical events include the Tuskegee Study, which studied intentionally untreated syphilis in non-Hispanic Black men without their knowledge, and the sterilization of racial and ethnic minority people without their knowledge or permission. [13,14,15,16]

A recent study found that people from racial and ethnic minority groups were more likely to have increased COVID-19 disease severity upon admission at the hospital compared with non-Hispanic White people. More severe disease increased the likelihood that these patients would need intubation, be admitted to the Intensive Care Unit, or die. [17] A separate study found that compared with non-Hispanic White people, non-Hispanic Black people were more likely to be hospitalized and were more likely to be tested for COVID-19 at a hospital than in the ambulatory (outpatient) setting. The researchers noted that the findings suggest non-Hispanic Black people may have delayed seeking care. [18]

- **General health status:** Underlying medical conditions that increase risk for severe illness from COVID-19 may be more common among people from racial and ethnic minority groups.[19] Common underlying conditions among those who require mechanical ventilation or died included diabetes, high blood pressure, obesity, chronic kidney disease on dialysis, and congestive heart failure. [20] It is important to note that many of the same social determinants of health that increase risk of COVID-19 illness also increase the risk of health conditions such as obesity, high blood pressure, and diabetes. These specific social determinants of health include education, economic stability, and physical environment, and healthcare system factors (e.g., insurance coverage, access to care and treatment).

  A study in New York City found that non-Hispanic Black and Hispanic or Latino people had higher obesity rates and higher COVID-19 mortality rates compared with non-Hispanic Asian and non-Hispanic White people. [21] A study in Boston found that among patients hospitalized with COVID-19 at an urban medical center, non-Hispanic Black patients were more likely to have one or more underlying medical conditions than people from other racial or ethnic groups. In another study of patients hospitalized with COVID-19, non-Hispanic Black patients were more likely to have high blood pressure and diabetes compared with all other racial and ethnic groups combined. [22] Another study found that among Black patients hospitalized with COVID-19, those with higher body mass index at arrival to the hospital were more likely to die.[23] Additionally, pregnant people may have an increased risk of severe illness from COVID-19. [24, 25] Given long-standing disparities in maternal health and birth outcomes, [26] it is important to consider how COVID-19 may affect these outcomes for people from racial and ethnic minority groups.

- **Education, income, and wealth gaps**: Inequities in access to high-quality education for people from racial and ethnic minority groups can lead to lower high school completion rates and barriers to college entrance.[27] This may limit future job options and lead to lower paying or less stable jobs. People with lower paying jobs often do not have paid sick leave and cannot afford to miss work, even if they're sick, because they would not be able to pay for essential items like food or other important living needs if their income decreased. Lower income is strongly associated with morbidity and mortality. Compared with non-Hispanic White people, American Indian, non-Hispanic Black, and Hispanic or Latino people have lower household incomes and shorter life expectancies, as well as higher rates of underlying medical conditions that increase risk of severe illness from COVID-19.[28,29]

  As of August 2020, more Hispanic or Latino people (53%) and non-Hispanic Black people (43%) reported that they had lost a job or taken a pay cut because of COVID-19 compared with non-Hispanic White people (38%). More non-Hispanic Black and Hispanic or Latino people, 40% and 43%, respectively, reported that they had to use money from savings or retirement to pay bills since the outbreak began, compared with 29% of non-Hispanic White people. Additionally, 43% of non-Hispanic Black people and 37% of Hispanic or Latino people reported having trouble paying their bills in full compared with non-Hispanic White people (18%). [30]

To reduce the substantial toll COVID-19 has had on individuals and communities, we need to work together to address inequities in the social determinants of health that increase risk of severe illness from COVID-19 for racial and ethnic minority groups. We must also ensure that everyone has fair and just access to COVID-19 vaccination. Learn more about what we can do to move towards health equity and about what CDC is doing to address COVID-19 Vaccine Equity for Racial and Ethnic Minority Groups (cdc.gov).

Related Pages

- COVID-19 Health Equity – Promoting Fair Access to Health
- CDC Social Determinants of Health: Know What Affects Health

- Environmental Public Health Tracking Network – Select “COVID-19” content area for options to view data on several factors related to increased risk of COVID-19

More Information

Robert Wood Johnson Foundation’s 2020 County Health Ranking State Reports

National Association of County and City Health Officials’ COVID-19 Resources for Local Health Departments

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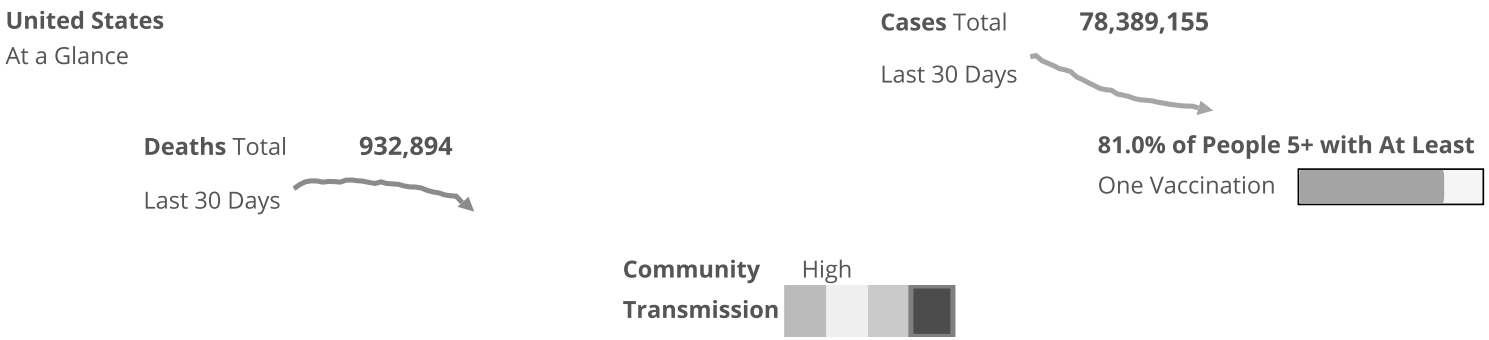
United States at a Glance Collapse



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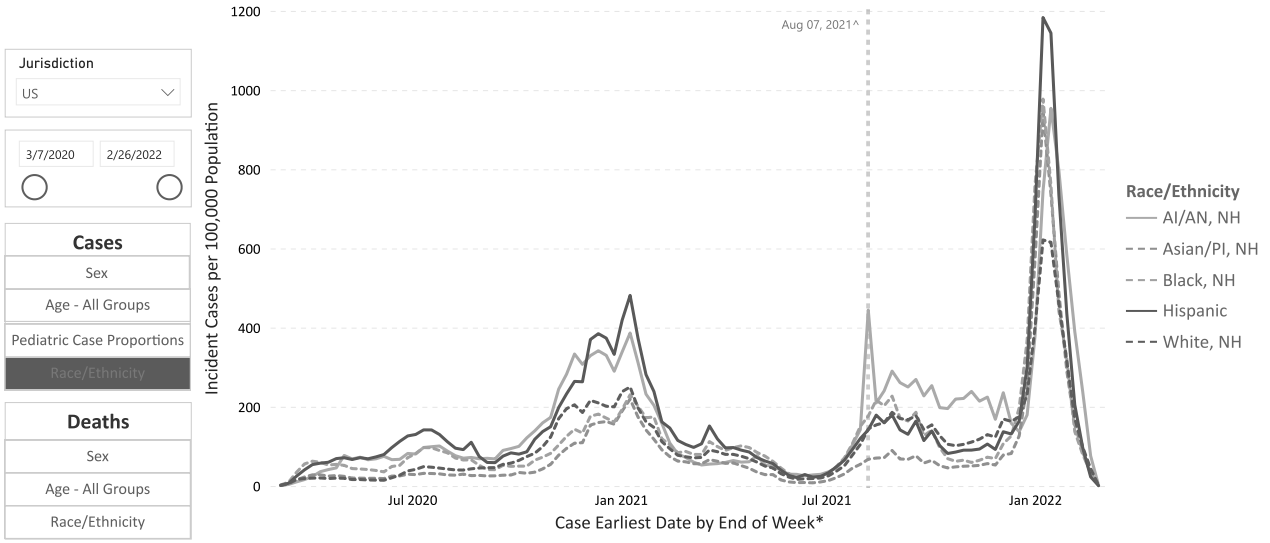
Cases and Deaths by Urban/Rural Status and Social Factors

Health Care Settings +

Variants and Genomic Surveillance +

COVID-19 Weekly Cases per 100,000 Population by Race/Ethnicity, United States

March 01, 2020 - February 26, 2022*



US: The most recent line level case record was reported during the week ending on Feb 26, 2022. Percentage of cases reporting race by date - 62.88%.

US territories are included in case and death counts but not in population counts. Potential six-week delay in case reporting to CDC denoted by gray bars. AI = American Indian, AN = Alaska Native, NH = Non-Hispanic, PI = Pacific Islander. Excludes cases with unknown or multiple races. *Case Earliest Date is the earliest of the clinical date (related to illness or specimen collection and chosen by a defined hierarchy) and the Date Received by CDC. The date for the current week extends through Saturday.

^Case rates during the week ending Aug 07, 2021 are reflective of a data reporting artifact from South Dakota. Surveillance data are provisional, and as additional clinical date data becomes available, the case rates over time are subject to change.

Last Updated: Feb 23, 2022

Source: CDC COVID-19 Case Line-Level Data, 2019 US Census, HHS Protect; Visualization: Data, Analytics & Visualization Task Force and CDC CPR DEO Situational Awareness Public Health Science Team

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Footnotes and Additional Information

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Racial disparities in COVID-19 outcomes exist despite comparable Elixhauser comorbidity indices between Blacks, Hispanics, Native Americans, and Whites

Fares Qeadan[1]✉, Elizabeth VanSant-Webb[2], Benjamin Tingey[1], Tiana N. Rogers[2], Ellen Brooks[1], Nana A. Mensah[1], Karen M. Winkfield[3,4], Ali I. Saeed[5], Kevin English[6] & Charles R. Rogers[1]

Factors contributing to racial inequities in outcomes from coronavirus disease 2019 (COVID-19) remain poorly understood. We compared by race the risk of 4 COVID-19 health outcomes—maximum length of hospital stay (LOS), invasive ventilation, hospitalization exceeding 24 h, and death—stratified by Elixhauser comorbidity index (ECI) ranking. Outcomes and ECI scores were constructed from retrospective data obtained from the Cerner COVID-19 De-Identified Data cohort. We hypothesized that racial disparities in COVID-19 outcomes would exist despite comparable ECI scores among non-Hispanic (NH) Blacks, Hispanics, American Indians/Alaska Natives (AI/ANs), and NH Whites. Compared with NH Whites, NH Blacks had longer hospital LOS, higher rates of ventilator dependence, and a higher mortality rate; AI/ANs, higher odds of hospitalization for ECI = 0 but lower for ECI ≥ 5, longer LOS for ECI = 0, a higher risk of death across all ECI categories except ECI ≥ 5, and higher odds of ventilator dependence; Hispanics, a lower risk of death across all ECI categories except ECI = 0, lower odds of hospitalization, shorter LOS for ECI ≥ 5, and higher odds of ventilator dependence for ECI = 0 but lower for ECI = 1–4. Our findings contest arguments that higher comorbidity levels explain elevated COVID-19 death rates among NH Blacks and AI/ANs compared with Hispanics and NH Whites.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, has disproportionately affected counties across the United States (US) that have substantially more racially and ethnically diverse populations[1,2]. Total deaths from COVID-19 in the US have eclipsed 540,000 (as of March 24, 2021)[3], with the highest mortality occurring among non-Hispanic (NH) Blacks and American Indians/Alaska Natives (AI/ANs), whose mortality rates are 1.9 and 2.4 times higher, respectively, than those of NH Whites (as of March 12, 2021)[4].

A confluence of social, economic, and biologic factors, together with a higher prevalence of comorbidities in AI/AN, Hispanic/Latino, and NH Black communities, has resulted in a greater COVID-19 burden and worse outcomes among medically underserved and minority populations[2]. According to the Centers for Disease Control and Prevention (CDC), comorbidities such as cardiovascular diseases, cancer, and obesity present some of the strongest and most consistent evidence for risk of hospitalization, intensive care unit admission, need for ventilation, and death due to COVID-19[5]. The higher prevalence of comorbidities experienced by Hispanics/Latinos, NH Blacks, and AI/ANs may account for why these populations are, respectively, 3.1, 2.9, and 3.7 times more likely than NH Whites to be hospitalized for COVID-19[4]. NH Blacks are more likely to require mechanical ventilation[6]. Despite similar median lengths of hospital stay across racial/ethnic groups[7,8], and despite race

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not being associated with an increased risk of in-hospital death from COVID-19[9], minority populations often experience twice the mortality rate of NH Whites[6,10]. While studies of other respiratory infectious diseases such as influenza, specifically H1N1 influenza, have suggested links between race and worse outcomes[11,12], the widespread nature of the COVID-19 pandemic also suggests that factors independent of underlying health conditions may be contributing to COVID-19 severity in the US.

The increased burden of comorbidity among NH Blacks[13,14] is hypothesized to be a major contributing factor to adverse COVID-19 outcomes[15,16], including an increased risk of death[17,18]. However, both single-site and multisite studies report that disparities in COVID-19 hospitalizations and deaths among NH Blacks persist after adjustment for comorbid conditions[7,19,20]. We hypothesize that racial disparities in COVID-19 outcomes exist despite comparable Elixhauser comorbidity index (ECI) scores among AI/ANs, NH Blacks, Hispanics/Latinos, and NH Whites.

We used the ECI[21] to further interrogate COVID-19 disparities and objectively ascertain the burden of comorbid conditions on COVID-19 health outcomes. The ECI encompasses 31 diagnoses, including cardiovascular disease, diabetes, liver disease, and pulmonary disease, each weighted by mortality risk. A total ECI score is generated from the sum of individual weights; a higher score indicates a higher burden of comorbidity[21,22]. Studies with sample sizes ranging from 574 to more than 14,000,000 have established the ECI's validity as a prognostic indicator[23,24].

Prior studies using the Charlson[25] and Elixhauser comorbidity indices to account for comorbid conditions in the context of COVID-19 have (1) failed to account for racial disparities[26], (2) used data from single sites or single hospital systems[19,27–29] or (3) failed to capture other relevant COVID-19 health outcomes beyond death and hospitalization (e.g., length of hospital stay[30] [LOS], need for ventilation[31,32]). Our study therefore aimed to evaluate 4 COVID-19 health outcomes stratified by ECI ranking: hospitalizations exceeding 24 h, maximum LOS, ventilation, and death.

Methods

Settings. We used data from the Cerner COVID-19 De-Identified Data cohort, a subset of the Cerner Real-World Data cohort. Data in Cerner Real-World Data is extracted from the electronic health records (EHRs) of hospitals with which Cerner has a data use agreement and may include pharmacy, clinical and microbiology laboratory, and admission data, as well as billing information from affiliated patient-care locations. All admissions, medication and dispensing orders, laboratory orders and specimens are date and time stamped, providing a temporal relationship between treatment patterns and clinical information. Cerner Corporation has established Health Insurance Portability and Accountability Act (HIPAA)–compliant operating policies to establish de-identification for Cerner Real-World Data[33,34]. EHR data are cleaned, standardized, and person-matched before being completely de-identified per HIPAA standards. Records of patients identified as having an encounter associated with a diagnosis of or a recent (up to 2 weeks prior) positive lab test for COVID-19 between January and June 2020 were included in the COVID-19 data set. To assess possible disease histories, all encounters and additional medical information for this patient cohort are collected, extending as far back as January 1, 2015, where available. A total of 62 health systems across the US contributed records to this data set.

The University of Utah Institutional Review Board (IRB #136696) determined that this study did not meet the definition of human subjects research according to federal regulations because (1) the investigators used secondary data and did not collect data through intervention or interaction with an individual, and (2) no personally identifiable information was captured in the data. The IRB also determined that the study did not meet the US Food and Drug Administration's (FDA's) definition of human subjects research because it did not involve a drug, device, or any other FDA-regulated product. Thus, the IRB waived the requirements for ethical approval and informed consent for this study.

Measurements. The outcomes of interest involved 4 indications of clinical complications in patients with COVID-19: hospitalization, maximum hospital LOS, invasive ventilator dependence, and death. These indications were constructed from EHR data to reflect a unique risk profile per patient. Additionally, every outcome had to involve a COVID-19 diagnosis or laboratory indication.

We measured maximum LOS by calculating the difference in days between the start and end dates of each patient encounter and taking the maximum difference per patient. Hospitalization was a binary indicator of whether a patient ever had an LOS of 1 day or more. Invasive ventilator dependence was a binary indicator of whether a patient ever had a diagnosis, procedure, encounter, result, or indication signifying reliance on an invasive ventilator. The full list of code types (Current Procedural Terminology [CPT], International Classification of Diseases [ICD], Logical Observation Identifiers Names and Codes [LOINC], and Systematized Nomenclature of Medicine—Clinical Terms [SNOMED CT]) and the corresponding codes used to define invasive ventilator dependence are found in Supplemental Table 1. These codes were kept separate from indications of less-severe ventilator dependence. Death was a binary indicator of whether a patient died at discharge or any time thereafter until the time of data collection. For additional analyses, in-hospital death was obtained and restricted to death at discharge (excluding any later deaths occurring outside of the hospital).

The predictors of interest were race (AI/AN, Asian/Pacific Islander [API], NH Black/African American, White, other/unknown race); ethnicity (Hispanic or Latino); and a comorbidity score derived from the ECI. Like the Charlson comorbidity index (CCI)[18], the ECI measures patient comorbidity by calculating a risk-assessment score based on ICD-10 diagnosis codes. However, the ECI considers more chronic disease indications (with some more relevant to COVID-19 complications) than does the CCI (31 vs. 17)[35] The ECI is weighted using the Agency for Health Care Research and Quality (AHRQ) methodology[36] and scores are grouped into categories of less than 0, 0, 1–4, and 5 or higher[24]. A full list of the diseases involved in the score calculation and the corresponding

ICD-10 codes is found in Supplemental Table 2[37]. Other demographic characteristics included for analysis were sex, insurance status, and 1-digit zip-code region (categorical variables) and age in years (a continuous variable).

Statistical analysis. Overall demographic characteristics were presented for patients in the COVID-19 cohort. Categorical variables were expressed by frequencies and percentages. Because continuous variables were not normally distributed, they were expressed as medians and interquartile ranges (IQRs). These characteristics were also stratified by ECI group to assess significant demographic differences across comorbidity groups. Categorical variables were compared using a chi-square test and nonparametric continuous variables by a Kruskal–Wallis rank sum test. Each outcome was presented across the demographic and clinical characteristics of interest: gender, race/ethnicity, insurance status, and ECI group. Medians (IQRs) were presented for maximum LOS and frequencies (percentages) for hospitalization, invasive ventilator dependence, and death.

To determine the adjusted associations of race/ethnicity and comorbidity with outcomes, multi-level regression models were fit using logistic regression models for hospitalization, invasive ventilator dependence, and death. Because LOS followed a continuous, exponential distribution, an exponential regression model was fit for maximum LOS. Adjusted odds ratios with 95% confidence intervals (CIs) were reported for the logistic model predictors. Adjusted exponentiated coefficients relating to the percentage change in expected maximum LOS with 95% CIs were reported for the exponential model predictors. All models were fit with race/ethnicity and ECI score and adjusted for age, sex, and insurance status. Additionally, models involved a random effect of 1-digit zip-code to account for clustering of results in similar regions. The predictive ability of the models was assessed for both logistic and exponential models. For logistic regression models, an area under the receiver operating characteristic curve (AUC) was calculated to assess the models' ability to correctly classify outcome categories. For the exponential model, the coefficient of determination (R^2) was calculated to estimate the percentage of variation in LOS as explained by the model predictors.

To assess the adjusted impact of race/ethnicity and comorbidity on the hazard of death, a Cox proportional hazards regression model was fit and adjusted for all variables included in the previous models. The outcome involved both time (from hospital admission to hospital discharge) and indication of in-hospital death (dead or alive at discharge).Adjusted hazard ratios (aHRs) and 95% CIs were reported. For all models, diagnostics were performed to ensure optimal model fit.

To further assess differences across comorbidities, sub-analyses were performed by stratifying the cohort by ECI groups (less than 0, 0, 1–4, 5 or higher) and running the same models within each group. Additionally, scatterplot figures were constructed to show the impact of race/ethnicity and comorbidity on the predicted outcomes of clinical complications. Each figure showed the predicted outcome against the ECI score. Smoothed lines were fit amongst the data by generalized additive regression models with shrinkage cubic-regression splines. This was done by fitting different lines for the different racial/ethnic groups. All hypothesis tests were 2-sided with a significance level of 5%. R version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria) was used for all analyses. In addition, R package "comorbidity" (version 0.5.3) was used to calculate comorbidity scores.

Sample size calculation. Using 80% power, the stratified race/ethnicity distribution by Elixhauser AHRQ-weighted comorbidity group (Table 1), and the risk of COVID-19 complications by race/ethnicity (Table 2), we needed a sample size of at least 3,591 subjects for each ECI category, assuming the most stringent comparison between AI/AN and NH Whites, to achieve a small effect size[38] of OR = 1.68 in a 2-sided examination. This sample size was attainable in our study given that we had a total of 52,411 subjects (8976; 16,177; 4220; and 23,038 for ECI groups less than 0, 0, 1–4, and 5 or higher, respectively), as shown in the data flow chart (Fig. 1).

Results

A total of 52,411 unique patients with a COVID-19 diagnosis or recent positive laboratory result were included in the analysis cohort. The median (IQR) patient age was 53 years (35–68); 50.6% (26,512) were female. Most patients were Hispanic/Latino (18,425; 35.2%), followed by NH White (15,048; 28.7%), NH Black/African American (10,667; 20.4%), NH other or unknown race (5754; 11.0%), API (1447; 2.8%), and AI/AN (1070; 2.0%). Most had private insurance (18,015; 34.4%), followed by Medicare (11,791; 22.5%) or Medicaid (8597; 16.4%) coverage. Most lived in the southeastern US (9867; 18.8%). Forty-four percent of patients (23,038) had an ECI score of 5 or higher; 30.9% (16,177) had an ECI score of 0 (Table 1).

Table 1 also shows patient demographic characteristics stratified by ECI group. Those with higher comorbidity were older and more likely to be male, NH White, and covered by Medicare. Significant differences were observed between all demographic groups when stratified by ECI group (all $p < 0.001$).

Table 2 shows crude risk results for COVID-19-related clinical complications across patient characteristics. Compared with women, men had higher percentages of hospitalization (55.8% vs. 50.2%), a higher median LOS (2.0 vs. 1.0), higher percentages of invasive ventilator dependence (14.2% vs. 9.3%), and higher percentages of death (10.6% vs. 7.4%). NH Whites had the highest outcomes for all clinical complications except invasive ventilator dependence (hospitalization, 65.2%; median LOS, 3.0 days; death, 13.3%). AI/ANs had the highest odds of invasive ventilator dependence (22.1%). Hispanics consistently had the lowest risk of complications across all outcomes. Patients covered by Medicare and those with ECI scores of 5 or higher had the highest risk of complications across all outcomes.

Table 3 shows the association of the adjusted predictors with the 4 clinical complications of hospitalization, maximum LOS, invasive ventilator dependence, and death. (Survival modeling for time to death is presented here; logistic modeling for death is reported in Supplemental Table 3). Older patients and men (compared with women) consistently showed a higher risk of complications for all outcomes. AI/ANs had consistently higher risk of complications for all outcomes than NH Whites, all of which were significant (hospitalization aOR 1.21;

		Elixhauser AHRQ-weighted comorbidity group				
		< 0	0	1–4	≥ 5	
	Total n (%[a])	n (%[a])	n (%[a])	n (%[a])	n (%[a])	*p* value[f]
Comparison	52,411 (100.00)	8976 (17.1)	16,177 (30.9)	4220 (8.1)	23,038 (44.0)	
Age (Years)[b]	53 (35–68)	51 (37–62)	32 (20–47)	46 (28–61)	64 (48–77)	**< 0.001[g]**
Gender						**< 0.001**
Female	26,512 (50.6)	4902 (54.6)	8206 (50.7)	2354 (55.8)	11,050 (48.0)	
Male	25,800 (49.2)	4053 (45.2)	7950 (49.1)	1857 (44.0)	11,940 (51.8)	
Other[c]	99 (0.2)	21 (0.2)	21 (0.1)	9 (0.2)	48 (0.2)	
Race and ethnicity						**< 0.001**
Non-Hispanic American Indian or Alaska Native	1070 (2.0)	179 (2.0)	503 (3.1)	72 (1.7)	316 (1.4)	
Non-Hispanic Asian or Pacific Islander	1447 (2.8)	208 (2.3)	401 (2.5)	98 (2.3)	740 (3.2)	
Non-Hispanic Black or African American	10,667 (20.4)	2200 (24.5)	2429 (15.0)	954 (22.6)	5084 (22.1)	
Non-Hispanic White	15,048 (28.7)	2141 (23.9)	3197 (19.8)	1156 (27.4)	8554 (37.1)	
Non-Hispanic Other[d]	5754 (11.0)	877 (9.8)	2236 (13.8)	381 (9.0)	2260 (9.8)	
Hispanic or Latino	18,425 (35.2)	3371 (37.6)	7411 (45.8)	1559 (36.9)	6084 (26.4)	
Insurance						**< 0.001**
Private	18,015 (34.4)	3678 (41.0)	7129 (44.1)	1687 (40.0)	5521 (24.0)	
Government/misc	1853 (3.5)	312 (3.5)	676 (4.2)	138 (3.3)	727 (3.2)	
Medicaid	8597 (16.4)	1837 (20.5)	2936 (18.1)	782 (18.5)	3042 (13.2)	
Medicare	11,791 (22.5)	1262 (14.1)	929 (5.7)	743 (17.6)	8857 (38.4)	
Self-pay	4906 (9.4)	804 (9.0)	2842 (17.6)	371 (8.8)	889 (3.9)	
Missing	7249 (13.8)	1083 (12.1)	1665 (10.3)	499 (11.8)	4002 (17.4)	
Zip-code region[e]						**< 0.001**
0	6210 (11.8)	958 (10.7)	1451 (9.0)	388 (9.2)	3413 (14.8)	
1	5593 (10.7)	1050 (11.7)	1754 (10.8)	437 (10.4)	2352 (10.2)	
2	8139 (15.5)	1468 (16.4)	1893 (11.7)	667 (15.8)	4111 (17.8)	
3	9867 (18.8)	1725 (19.2)	4552 (28.1)	978 (23.2)	2612 (11.3)	
4	2701 (5.2)	546 (6.1)	753 (4.7)	218 (5.2)	1184 (5.1)	
5	337 (0.6)	65 (0.7)	122 (0.8)	33 (0.8)	117 (0.5)	
6	1551 (3.0)	241 (2.7)	491 (3.0)	120 (2.8)	699 (3.0)	
7	3116 (5.9)	522 (5.8)	834 (5.2)	232 (5.5)	1528 (6.6)	
8	3321 (6.3)	477 (5.3)	1156 (7.1)	257 (6.1)	1431 (6.2)	
9	9012 (17.2)	1589 (17.7)	2803 (17.3)	698 (16.5)	3922 (17.0)	
Missing	2564 (4.9)	335 (3.7)	368 (2.3)	192 (4.5)	1669 (7.2)	

Table 1. Demographic and clinical characteristics of COVID-19 infected patients by Elixhauser AHRQ-weighted comorbidity Index and overall. [a]% = column percentage. [b]Median (Q1–Q3). [c]Other or unknown. [d]Other, unknown, or mixed race. [e]0 (Connecticut, Massachusetts, Maine, New Hampshire, New Jersey, Rhode Island, Vermont), 1 (Delaware, New York, Pennsylvania), 2 (DC, Maryland, North Carolina, South Carolina, Virginia, West Virginia), 3 (Alabama, Florida, Georgia, Mississippi, Tennessee), 4(Indiana, Kentucky, Michigan, Ohio), 5 (Iowa, Minnesota, Montana, North Dakota, South Dakota, Wisconsin), 6 (Illinois, Kansas, Missouri, Nebraska), 7 (Arkansas, Louisiana, Oklahoma, Texas), 8 (Arizona, Colorado, Idaho, New Mexico, Nevada, Utah, Wyoming), 9 (Alaska, California, Hawaii, Oregon, Washington). [f]Chi-squared test (unless otherwise noted). [g]Kruskall–Wallis rank-sum test. Bold indicates statistical significance at the 5% level (i.e., *p* value < 0.05).

maximum LOS $e^{\hat{\beta}}$ 1.32; ventilator aOR 3.49; death aHR 2.06). Compared with NH Whites, APIs stayed significantly longer in the hospital (maximum LOS $e^{\hat{\beta}}$ 1.15; 95% CI [1.05, 1.27]) and were significantly more likely to be ventilator dependent (aOR 1.44; 95% CI [1.22, 1.69]).

Compared with NH Whites, NH Blacks/African Americans had significantly longer hospital LOS ($e^{\hat{\beta}}$ 1.13; 95% CI [1.08, 1.19]), and were significantly more likely to be ventilator dependent (aOR 1.31; 95% CI [1.21, 1.43]) or die (aHR 1.22; 95% CI [1.13, 1.32]). Other race groups showed significantly higher associations with ventilator dependence and death compared with NH Whites (ventilator dependence aOR 1.72; death aHR 1.58). Hispanics/Latinos had lower odds of hospitalization (aOR 0.81; 95% CI [0.77, 0.86]), lower LOS (maximum LOS e^{β}: 0.88; 95% CI [0.85, 0.92]), and a lower hazard of death (aHR 0.89; 95% CI [0.82, 0.97]) compared with NH Whites. There was no evidence that Hispanics/Latinos had significantly higher odds of ventilator dependence (aOR: 1.09; 95% CI [1.00, 1.19]). All logistic models were classified with an AUC of 0.86. The exponential model explained 33% of the variation in maximum LOS.

Comparison	Hospitalization n (%[a])	Maximum length of stay (days) Median (IQR: Q1–Q3)	Invasive ventilator dependence n (%[a])	Deceased n (%[a])
Total	27,774 (53.0)	1.6 (0.1–6.5)	6150 (11.7)	4695 (9.0)
Gender				
Female	13,307 (50.2)	1.0 (0.1–5.8)	2472 (9.3)	1962 (7.4)
Male	14,406 (55.8)	2.0 (0.1–7.2)	3664 (14.2)	2723 (10.6)
Other	61 (61.6)	2.4 (0.2–6.7)	14 (14.1)	10 (10.1)
Race and ethnicity				
Non-Hispanic American Indian or Alaska Native	574 (53.6)	1.9 (0.1–7.8)	236 (22.1)	113 (10.6)
Non-Hispanic Asian or Pacific Islander	876 (60.5)	2.7 (0.2–8.3)	220 (15.2)	150 (10.4)
Non-Hispanic Black or African American	6131 (57.5)	2.1 (0.2–7.5)	1383 (13.0)	1072 (10.0)
Non-Hispanic White	9811 (65.2)	3.0 (0.2–7.8)	2020 (13.4)	1998 (13.3)
Non-Hispanic other	2944 (51.2)	1.2 (0.1–6.9)	822 (14.3)	533 (9.3)
Hispanic or Latino	7438 (40.4)	0.2 (0.1–4.1)	1469 (8.0)	829 (4.5)
Insurance				
Private	7067 (39.2)	0.2 (0.1–3.8)	1538 (8.5)	677 (3.8)
Government/miscellaneous	957 (51.6)	1.2 (0.11–6.1)	221 (11.9)	173 (9.3)
Medicaid	4209 (49.0)	0.9 (0.1–5.1)	850 (9.9)	367 (4.3)
Medicare	9442 (80.1)	5.5 (1.9–10.9)	2213 (18.8)	2606 (22.1)
Self-pay	97 (2.0)	0.1 (0.1–0.7)	173 (3.5)	97 (2.0)
Missing	775 (10.7)	3.4 (0.2–8.8)	1155 (15.9)	775 (10.7)
Elixhauser AHRQ-weighted comorbidity group				
< 0	3874 (43.2)	0.3 (0.1–4.0)	440 (4.9)	195 (2.2)
0	3041 (18.8)	0.1 (0.1–0.3)	496 (3.1)	252 (1.6)
1–4	1867 (44.2)	0.3 (0.1–4.3)	313 (7.4)	190 (4.5)
≥ 5	18,992 (82.4)	5.4 (2.0–11.2)	4901 (21.3)	4058 (17.6)

Table 2. Risk of complications from COVID-19 by patient characteristics. [a]Row percentage.

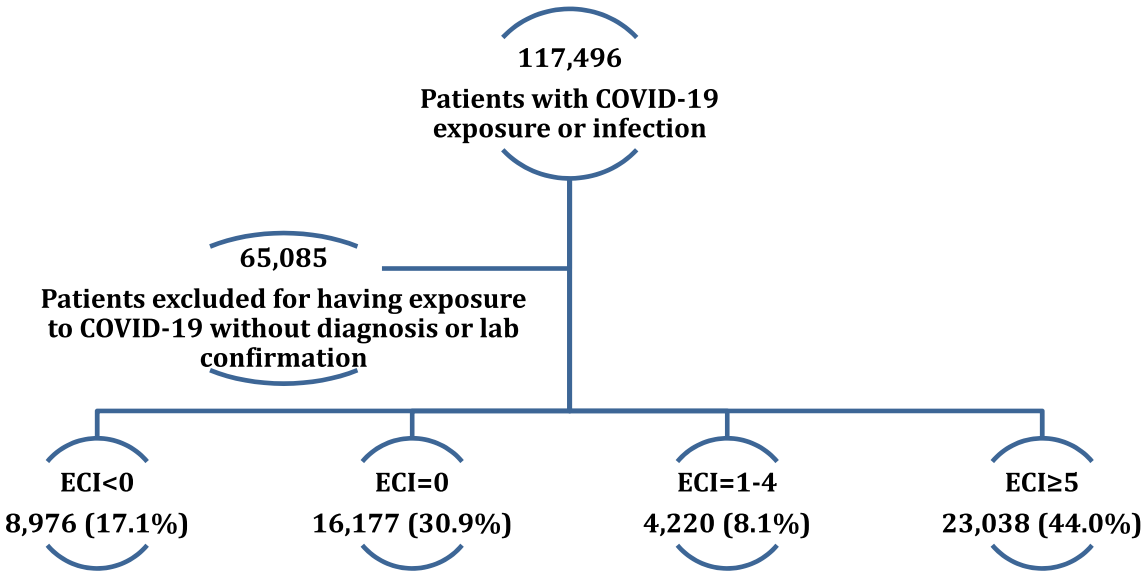

Figure 1. Data flow chart for the study. The final cohort size of 52,411 COVID-19 patients is stratified by ECI group.

Racial disparities with comparable ECI scores. Stratified analyses (in Supplemental Tables 4, 5, 6, and 7, Figs. 2 and 3, and Supplemental Figs. 1 and 2) showed differences among the outcomes. Although weighted ECI scores were comparable among races, we observed significant disparities in outcomes of COVID-19 complications. Compared with NH Whites, NH Blacks had longer hospital LOS (e^{β}: 1.20; 95% CI [1.01, 1.43] for ECI = 1–4; 1.11; 95% CI [1.04, 1.17 for ECI of 5 or higher); were more likely to be ventilator dependent (aOR:

Variables	Hospitalization aOR[a] (95% CI)	Maximum length of stay $e^{\hat{\beta}b}$ (95% CI)	Invasive ventilator dependence aOR[a] (95% CI)	Deceased aHR[c] (95% CI)
Age (years)[d]	**1.30 (1.28, 1.32)**	**1.30 (1.29, 1.31)**	**1.16 (1.14, 1.18)**	**1.58 (1.55, 1.63)**
Gender				
Female	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Male	**1.23 (1.18, 1.28)**	**1.22 (1.18, 1.26)**	**1.55 (1.46, 1.64)**	**1.40 (1.32, 1.49)**
Other	*1.60 (1.00, 2.57)*[f]	*1.37 (0.96, 1.95)*[f]	1.50 (0.82, 2.75)	1.35 (0.70, 2.60)
Race and ethnicity				
Non-Hispanic White	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Non-Hispanic American Indian or Alaska Native	**1.21 (1.03, 1.43)**	**1.32 (1.16, 1.51)**	**3.49 (2.87, 4.25)**	**2.06 (1.70, 2.50)**
Non-Hispanic Asian or Pacific Islander	1.08 (0.95, 1.23)	**1.15 (1.05, 1.27)**	**1.44 (1.22, 1.69)**	1.12 (0.95, 1.33)
Non-Hispanic Black or African American	1.02 (0.95, 1.08)	**1.13 (1.08, 1.19)**	**1.31 (1.21, 1.43)**	**1.22 (1.13, 1.32)**
Non-Hispanic other	0.99 (0.91, 1.06)	1.06 (1.00, 1.12)	**1.72 (1.56, 1.90)**	**1.58 (1.43, 1.74)**
Hispanic or Latino	**0.81 (0.77, 0.86)**	**0.88 (0.85, 0.92)**	1.09 (1.00, 1.19)	**0.89 (0.82, 0.97)**
Insurance				
Private	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
Government/misc	1.09 (0.98, 1.22)	**1.11 (1.02, 1.21)**	0.93 (0.79, 1.09)	**1.51 (1.27, 1.79)**
Medicaid	**1.64 (1.54, 1.74)**	**1.65 (1.58, 1.74)**	**1.11 (1.01, 1.22)**	**1.45 (1.27, 1.65)**
Medicare	**1.51 (1.41, 1.62)**	**1.50 (1.42, 1.58)**	**0.90 (0.82, 0.98)**	**1.34 (1.22, 1.48)**
Self-pay	**0.60 (0.55, 0.65)**	**0.66 (0.62, 0.70)**	**0.47 (0.40, 0.56)**	**1.44 (1.16, 1.80)**
Missing	**1.87 (1.74, 2.01)**	**1.69 (1.60, 1.78)**	**1.32 (1.20, 1.45)**	**1.23 (1.10, 1.37)**
Elixhauser AHRQ weighted comorbidity score[e]	**2.34 (2.28, 2.41)**	**1.78 (1.75, 1.80)**	**1.60 (1.56, 1.63)**	**1.17 (1.15, 1.20)**
AUC	0.86	–	0.86	–
R^2	–	0.33	–	–

Table 3. Adjusted associations with hospitalization, maximum length of hospital stay, dependence on invasive ventilator, and death from COVID-19. [a]Adjusted odds ratio from mixed-effect logistic regression model (clustering on one-digit zip-code). [b]Adjusted exponentiated coefficients (mixed-effect exponential regression model clustering on one-digit zip-code) relating to change in the ratio of expected maximum length of hospital stay (i.e., "male" coefficient is the ratio of the expected max LOS for males over expected max LOS for females, so max LOS is 16% greater for males than for females). [c]Adjusted hazard ratios from Cox-Proportional Hazard regression model. [d]Adjusted change in outcome for every 10 year increase in age. [e]Adjusted change in outcome for every 10 point increase in ECI. [f]*p* values on the boundary of significance: Hospitalization gender other: 0.0503, max LOS gender other: 0.08. Bold indicates statistical significance at the 5% level (i.e., *p* value < 0.05). Italic indicates *p* values are on the boundary of statistical significance (i.e.,0.05)

1.85; 95% CI [1.30, 2.64] for ECI = 0; 1.23; 95% CI [1.12, 1.35] for ECI of 5 or higher); and were more likely to die (aOR: 1.47; 95% CI [0.95, 2.27] for ECI = 0; 1.13; 95% CI [1.02, 1.25] for ECI of 5 or higher). Compared with NH Whites, AI/ANs had higher odds of hospitalization for ECI = 0 (aOR: 2.30; 95% CI [1.75, 3.02]) but lower odds of hospitalization for ECI of 5 or higher (aOR: 0.76; 95% CI [0.57, 1.02]); longer hospital LOS for ECI = 0 ($e^{\hat{\beta}}$: 2.75; 95% CI [2.28, 3.32]); a higher risk of death (aOR: 3.34; 95% CI [1.17, 9.56]) for ECI of less than 0; aOR: 5.77; 95% CI [3.07, 10.83] for ECI = 0; aOR: 2.69; 95% CI [0.87, 8.31] for ECI = 1–4); and higher odds of ventilator dependence across all ECI categories. Hispanics had a lower risk of death across all ECI categories except for ECI = 0, lower odds of hospitalization across all ECI categories, shorter hospital LOS for ECI of 5 or higher, and higher odds of ventilator dependence for ECI = 0 but lower odds of ventilator dependence for ECI = 1–4. Compared with NH Whites, patients of NH other or unknown race had longer LOS for all ECI categories except for ECI = 0 (aOR: 0.91; 95% CI [0.83, 0.99]), higher odds of invasive ventilator dependence across all ECI categories, and higher odds of death for ECI = 0 (aOR: 1.81; 95% CI [1.12, 2.91]) and ECI of 5 or higher (aOR: 1.27; 95% CI [1.11, 1.44]).

Discussion

This study answers the question of whether racial disparities in COVID-19 outcomes exist despite comparable ECIs among NH Black, Hispanic, AI/AN, and White patients. To our knowledge, it is one of the largest systematic evaluations in the US of racial and ethnic differences in survival outcomes stratified by ECI score for patients with COVID-19. Our analyses revealed significant racial disparities in health outcomes among COVID-19 patients with comparable ECI scores. In particular, compared with NH Whites, most race groups had higher risk for all outcomes (hospitalization, LOS, ventilation, and death), with greater clinical and statistical significance for AI/ANs and NH Blacks. For example, using adjusted estimates, NH Blacks had longer LOS and higher odds of both

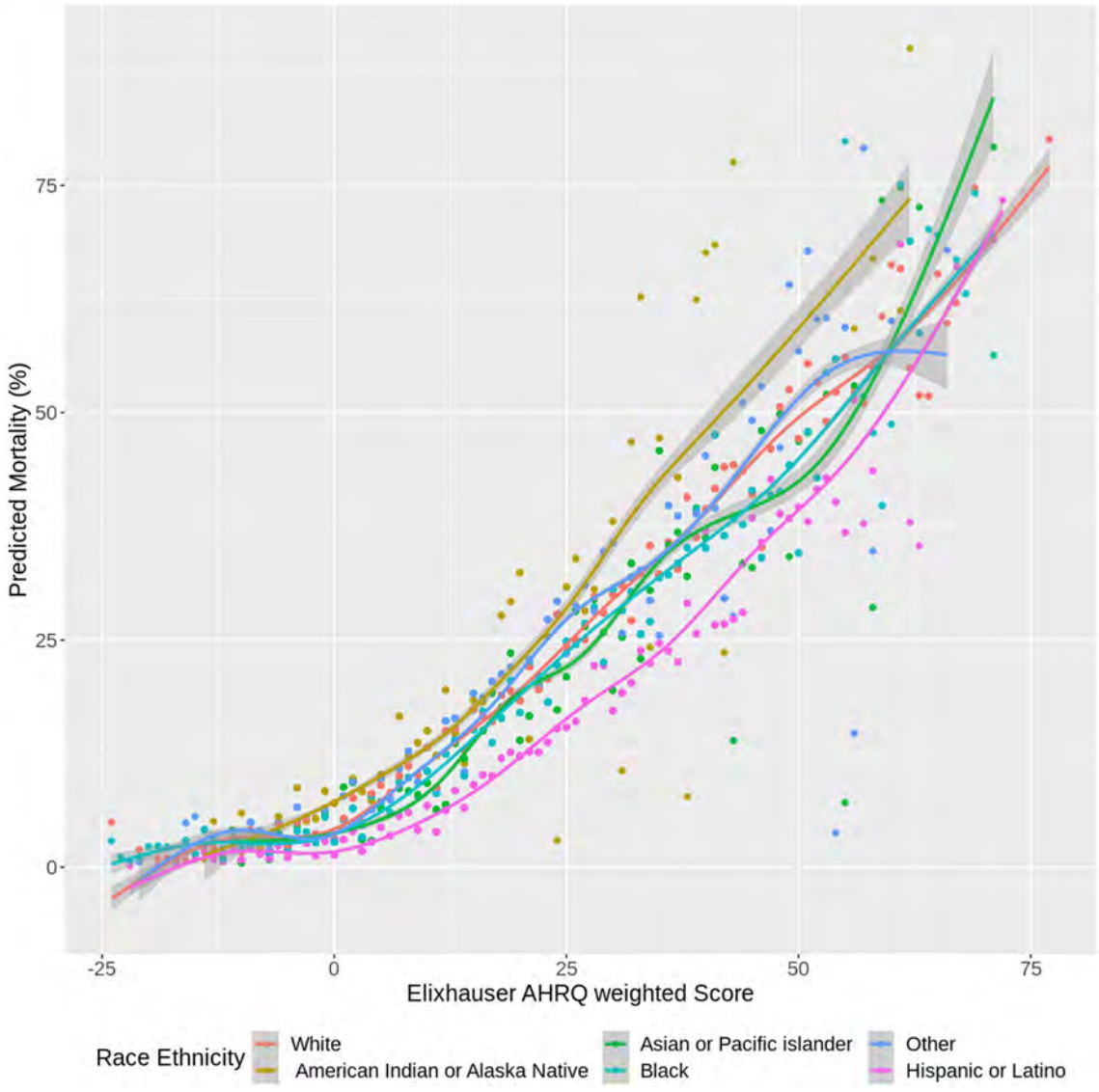

Figure 2. Predicted mortality versus Elixhauser AHRQ weighted score, among COVID-19 infected patients (by race).

ventilator dependence and death compared with NH Whites. NH Blacks and Native Americans were at increased risk for complications and death from COVID-19 compared with NH Whites.

Previous studies suggest that racial disparities in COVID-19 incidence and mortality can be explained by the complex interaction of inequities in social determinants of health, including access to health care[2,39,40], poverty[40,41], systemic racism[2,40], socioeconomic status[2], lack of testing for SARS-CoV-2 infection[39,42], discrimination[2], and virus exposure due to employment in essential-worker occupations[43,44], all of which may be best viewed through a biopsychosocial framework akin to the weathering hypothesis, which posits that cumulative exposure to chronic stress can lead to accelerated aging by inducing physiologic changes that diminish the body's ability to respond appropriately to acute stressors[45]. Preliminary investigations suggest that a higher prevalence of medical comorbidities explains the clinical differences in outcomes among patients with COVID-19[7,17,46–48]. Yet in our analysis of the 4 above-mentioned outcomes stratified by ECI AHRQ-weighted group, we still observed significant racial disparities in COVID-19 complications. Contrary to previous studies[7,17,46,49], our analysis showed that for all races, the probability of hospitalization due to COVID-19 increased in unison with an increasing ECI. Accordingly, our findings contest arguments that NH Black and AI/AN patients are dying from COVID-19 at higher rates than their NH White counterparts because they have more comorbidities.

After adjustment for predictive association with our chief outcomes, our analysis revealed a higher risk for all 4 outcomes (hospitalization, LOS, ventilation, and death) among older patients, men (compared with women), patients with higher ECI scores, and patients covered by Medicare or Medicaid (compared with those covered by private insurance). These findings align with patterns identified in previous studies of cohorts ranging in size from 191 to 11,210[7,46].

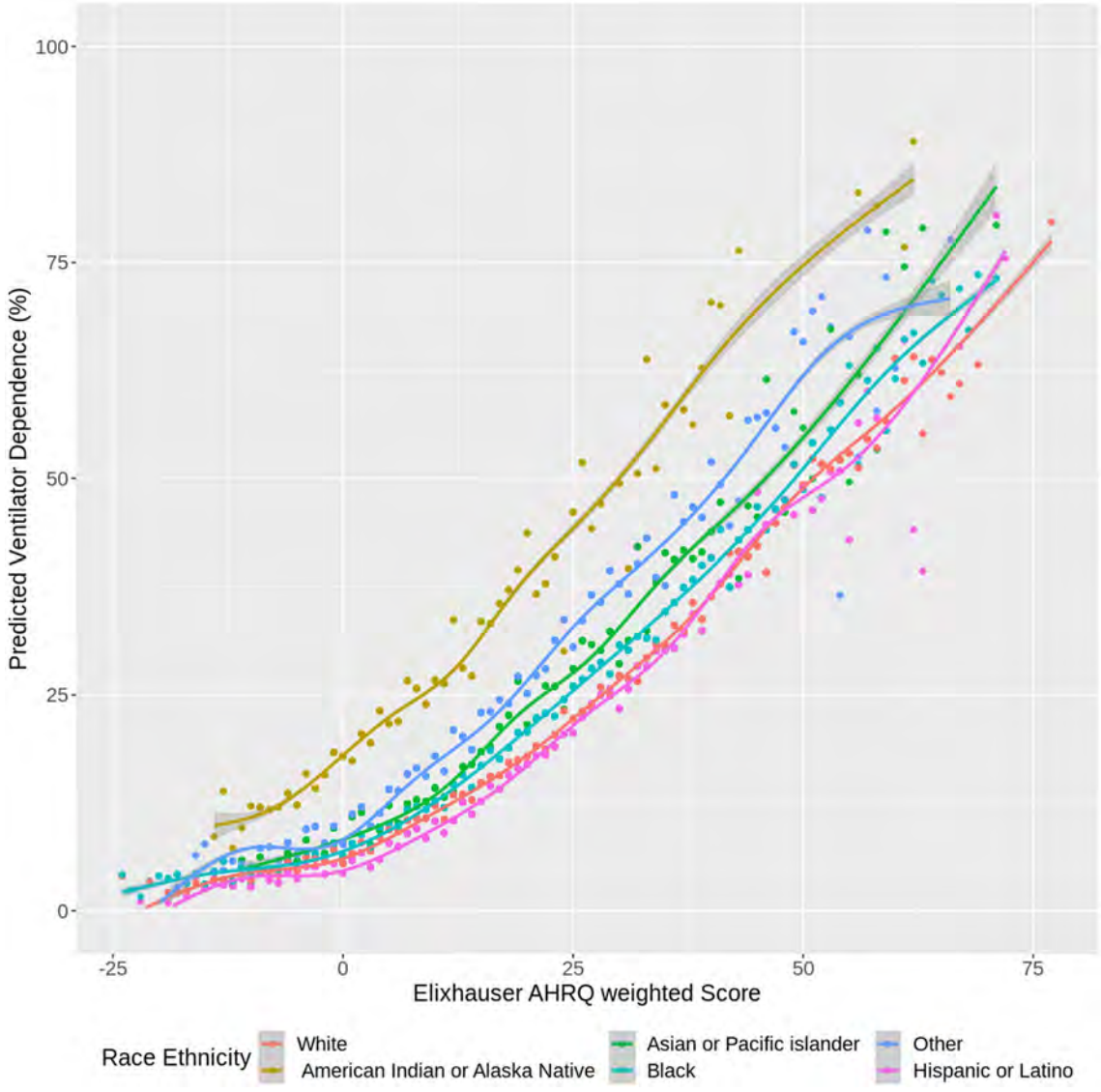

Figure 3. Predicted ventilator dependence versus Elixhauser AHRQ weighted score, among COVID-19 infected patients (by race).

Disaggregation by race and ethnicity of the analysis of all 4 primary outcomes uncovered 3 overarching disparities while controlling for comorbidity. First, we found that APIs, NH Blacks, and patients of NH other or unknown race had a higher risk for all outcomes. This aligns with previous findings on racial disparities for NH Blacks for hospitalization[50], mortality[19], and ventilation[7], and raises questions about the intersection of anti-Asian discrimination and xenophobia with health outcomes for API patients[51]. Secondly, our findings showed that, compared with NH Whites, AI/AN patients had a higher risk of death and higher odds of ventilator dependence but lower odds of hospitalization and a trend toward lower LOS for ECI of 5 or higher. These disproportionalities may be understood by the transfer of patients from Indian Health Service (IHS) facilities to non-IHS facilities, as IHS facilities are commonly ill-equipped to care for AI/AN patients with COVID-19 (e.g., they may lack invasive ventilation equipment)[52]. Third, our analysis showed that, compared with NH Whites, Hispanics/Latinos had a lower risk for death, hospitalization, and LOS, but higher odds of ventilator dependence for ECI = 0. Although these findings contradict epidemiological studies that have found a higher risk of COVID-19–related deaths within Hispanic/Latino communities[53,54], they align with the "Hispanic epidemiological paradox," which suggests that, although the socioeconomic characteristics of Hispanics/Latinos are similar to those of NH Blacks, comorbidity, mortality, and longevity outcomes in this subpopulation mirror or exceed those of NH Whites[55].

Our data clearly show that a higher percentage of older patients were NH White and a higher percentage of younger patients were Hispanic/Latino (Supplemental Fig. 3). Other studies have found that, compared with NH Whites, Hispanic/Latino patients with COVID-19 tend to be younger[56] and that older Hispanic/Latino patients with COVID-19 may have a higher risk for death[57,58]. Recent reports of higher COVID-19 death rates among older Hispanic/Latino populations[57] and higher COVID-19 hospitalization rates among Hispanic/Latino

children[59] may challenge the "Hispanic paradox." To better address the needs of the Hispanic/Latino population, future researchers should employ additional data disaggregation to address this question.

Lastly, our results indicate that older patients and individuals with higher ECI scores had an increased risk of death from COVID-19. Likewise, men compared with women, all races (except Hispanics/Latinos) compared with NH Whites, and patients with all other health insurance types compared with those with private insurance had an increased likelihood of death. These results are supported by recent findings of higher COVID-19 fatality rates among men, older persons, and patients with a disproportionate burden of comorbidities[60,61]. Emerging literature also points to an association of minority status and insurance type with poor COVID-19 outcomes[7]. Our logistic regression findings reveal similar associations with minority status and insurance type for hospitalizations, death, ventilator dependence, and hospital LOS.

This study has potential limitations. Some of the outcomes and predictors were identified by medical record codes (i.e., ICD and LOINC) that are known to limit the specificity of a study. However, we additionally applied a variety of alternative methods, such as text matching, to provide an additional net with which to capture all possible indications in the data. Medical histories were only available going back 5 years on qualifying patients included in the cohort. Our study included only patients who sought treatment for COVID-19. It is important to note that medically underserved and minority populations without insurance may not seek testing and treatment for COVID-19[62], which has implications for both Hispanics/Latinos and NH Blacks, who are 2–3 times more likely to be uninsured compared with their NH White counterparts[63]. In addition, because (1) the data we analyzed included only individuals who had accessed health care services, and (2) post-mortem COVID testing is not routinely done, we may have underestimated the death rate among Hispanics/Latinos. Lastly, social variables that could play a potential confounding role in our study were not captured in the EHR data that we analyzed and thus were not included in the multilevel analyses.

Conclusion

Compared with NH White patients with similar ECI scores, NH Black patients had significantly higher LOS and odds of ventilator dependence and death, while AI/AN patients were more likely to have worse indications across all 4 outcomes analyzed: hospitalization, LOS, ventilation, and death. COVID-19 has laid bare an imperative to investigate its negative health outcomes that may be exacerbated by a complex interplay of social, environmental, and behavioral factors faced by indigenous, Hispanic/Latino, and NH Black communities[31], indicating a need for upstream intervention at patient, community, and policy levels to close the health equity gap.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to restrictions by Cerner, the owner of the data. Data may be accessed by signing a data-sharing agreement with Cerner and covering any costs that may be involved.

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The authors declare no competing interests.

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Variation in COVID-19 Mortality in the US by Race and Ethnicity and Educational Attainment

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Abstract

IMPORTANCE Racial and ethnic inequities in COVID-19 mortality have been well documented, but little prior research has assessed the combined roles of race and ethnicity and educational attainment.

OBJECTIVE To measure inequality in COVID-19 mortality jointly by race and ethnicity and educational attainment.

DESIGN, SETTING, AND PARTICIPANTS This cross-sectional study analyzed data on COVID-19 mortality from the 50 US states and the District of Columbia for the full calendar year 2020. It included all persons in the United States aged 25 years or older and analyzed them in subgroups jointly stratified by age, sex, race and ethnicity, and educational attainment.

MAIN OUTCOMES AND MEASURES Population-based cumulative mortality rates attributed to COVID-19.F

RESULTS Among 219.1 million adults aged 25 years or older (113.3 million women [51.7%]; mean [SD] age, 51.3 [16.8] years), 376 125 COVID-19 deaths were reported. Age-adjusted cumulative mortality rates per 100 000 ranged from 54.4 (95% CI, 49.8-59.0 per 100 000 population) among Asian women with some college to 699.0 (95% CI, 612.9-785.0 per 100 000 population) among Native Hawaiian and Other Pacific Islander men with a high school degree or less. Racial and ethnic inequalities in COVID-19 mortality rates remained when comparing within educational attainment categories (median rate ratio reduction, 17% [IQR, 0%-25%] for education-stratified estimates vs unstratified, with non-Hispanic White individuals as the reference). If all groups had experienced the same mortality rates as college-educated non-Hispanic White individuals, there would have been 48% fewer COVID-19 deaths among adults aged 25 years or older overall, including 71% fewer deaths among racial and ethnic minority populations and 89% fewer deaths among racial and ethnic minority populations aged 25 to 64 years.

CONCLUSIONS AND RELEVANCE Public health research and practice should attend to the ways in which populations that share socioeconomic characteristics may still experience racial and ethnic inequity in the distribution of risk factors for SARS-CoV-2 exposure and infection fatality rates (eg, housing, occupation, and prior health status). This study suggests that a majority of deaths among racial and ethnic minority populations could have been averted had all groups experienced the same mortality rate as college-educated non-Hispanic White individuals, thus highlighting the importance of eliminating joint racial-socioeconomic health inequities.

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Key Points

Question How did COVID-19 mortality rates during 2020 in the United States vary by race and ethnicity in combination with educational attainment?

Findings In this cross-sectional study of 219.1 million adults aged 25 years or older, most racial and ethnic minority populations had higher age-adjusted mortality rates than non-Hispanic White populations, including when comparing within levels of educational attainment. If all racial and ethnic populations had experienced the same mortality rates as college-educated non-Hispanic White populations, 71% fewer deaths among racial and ethnic minority populations would have occurred.

Meaning This study suggests that public health research and practice should attend to the ways in which populations that share socioeconomic characteristics may still experience racial and ethnic inequity in COVID-19 mortality rates.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Introduction

Numerous studies have documented racial and ethnic inequities in COVID-19 mortality rates in the United States.[1-3] Racial and ethnic inequalities are large, with cumulative mortality rate ratios (MRRs) exceeding those of other major causes of death.[3] However, to our knowledge, few studies have assessed COVID-19 mortality inequities by race and ethnicity in combination with socioeconomic position, and the data to conduct such analyses on the national level have been unavailable until recently. One US-wide study found roughly equal cumulative mortality rates by race and ethnicity within educational attainment categories, but the data source did not allow for age standardization and, as the authors noted, the results were likely to underestimate racial and ethnic inequities because US White populations have distributions that skew older.[2] That study, along with another analysis of California's Latinx population,[4] found that persons in the lowest socioeconomic position experienced the highest COVID-19 mortality rates within racial and ethnic groups.

Our study uses a recently available public data set on COVID-19 mortality, which permits subgroup analysis by race and ethnicity, educational attainment, age, and sex, and therefore allows for a more complete examination of racialized socioeconomic inequities than previous studies. Our research is informed by prior literature that has illustrated how racialized differences in health are not reducible to inequalities in educational attainment, and involve multiple other pathways (eg, medical discrimination, inequitable treatment by the criminal justice system, and environmental injustice).[5] We assessed 3 hypotheses with our study: (1) racial and ethnic minority populations would experience higher age-adjusted COVID-19 mortality rates than the non-Hispanic White population; (2) within racial and ethnic groups, age-adjusted COVID-19 mortality rates would be highest among those with the lowest educational attainment; and (3) racial and ethnic inequalities in COVID-19 mortality rates would remain when comparing within levels of educational attainment.

Methods

We conducted cross-sectional analyses of cumulative COVID-19 mortality rates for US population aged 25 years or older. Although data on younger individuals were available, we excluded them for 2 reasons. First, there were a small number of deaths among those aged 24 years or younger (n = 714; <0.3% of all deaths). Second, educational attainment may not be a valid indicator of socioeconomic position for this group, as many are too young to have been able to complete schooling. Reflecting this concern, the US Census Bureau's own analyses of education data typically exclude those younger than 25 years of age.[6] This study analyzed solely deidentified, public-use data and was therefore exempt from institutional review board approval. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines for cross-sectional studies.[7]

We quantified racial and ethnic inequity as MRRs, both overall and within educational attainment categories. The analyses were conducted separately for each age-sex subgroup. Finally, we calculated the number of COVID-19 deaths that would have occurred if everyone had experienced the same mortality rate as college-educated non-Hispanic White individuals (the group that theoretically has the most racialized socioeconomic privilege) of the same age and sex. All analyses were based on publicly available US Census and US mortality data.

Data Sources

We analyzed open access COVID-19 mortality data provided by the US Centers for Disease Control and Prevention (CDC).[8] The data set is based on reporting by the 50 states and the District of Columbia for the full calendar year 2020 and reported to CDC by February 24, 2021. This data set represents the most recent available data. The file includes counts of deaths due to COVID-19 stratified by race and ethnicity, age group, sex, and educational attainment (reported as 3 categories: high school or General Educational Development (GED) certification or less; some college, which

includes an associate's degree; or a bachelor's degree or more). We treated educational attainment as a measure of socioeconomic position; other measures such as income, wealth, and occupation were not provided in the data set and are not as readily available on death certificate–based mortality reporting systems.[9] The CDC notes that the data set is provisional because there may be undercounts in later weeks due to reporting lags—however, the data were current as of 8 weeks past December 31, 2020, so the effect of lags should be minimal.

Sociodemographic data are reported on death certificates, typically by the funeral director. Sex was reported as "male" and "female," with no data on whether decedents were nonbinary or transgender. Race and ethnicity were reported as "Hispanic" (Latinx; in combination with any race), as well as non-Hispanic racial groups: non-Hispanic Black, non-Hispanic White, non-Hispanic Asian, non-Hispanic American Indian or Alaska Native, and non-Hispanic Native Hawaiian and Other Pacific Islander. We treated the small proportion of decedents (<0.3%) whose race and ethnicity was categorized as "non-Hispanic more than one race" as missing and excluded them from subsequent analyses. We additionally obtained census microdata from the US Census American Community Survey for the period from 2017 to 2019.[10] We tabulated these data for use as population denominators for all cumulative mortality rate calculations.

Statistical Analysis

We calculated cumulative mortality rates for COVID-19 by race and ethnicity, sex, and educational attainment for the population aged 25 years or older. We conducted analyses for the entire population aged 25 years or older, as well as for the younger (25-64 years) and older (≥65 years) populations. When calculating rates for the overall, younger, and older populations, we applied direct standardization using the *dstdize* command in Stata, version 16 (StataCorp LLC) based on the CDC year 2000 standard population.[11] To compare racial and ethnic inequality within educational attainment categories, we calculated age-adjusted cumulative MRRs comparing COVID-19 death rates for each racial and ethnic group with non-Hispanic White individuals of the same age group, sex, and education group.

In addition, we simulated a counterfactual scenario to estimate the number of deaths that would have occurred had each population group experienced the same cumulative mortality rate as the group that, theoretically, has the most racialized socioeconomic privilege: college-educated non-Hispanic White individuals. We did this by multiplying each stratum's populations size by the mortality rate observed among college-educated non-Hispanic White individuals of the same age and sex.

All 95% CIs for cumulative mortality rates and MRRs reported below assume that mortality rates follow a Poisson distribution and are calculated using standard formulas for directly standardized rates and rate ratios.[12,13] However, the 95% CIs represent uncertainty owing to sampling, but the mortality data represent a finite population (ie, all deaths attributed to COVID-19 in the United States), which are not subject to sampling error. Confidence intervals for MRRs that include the null value of 1.0 should therefore not be interpreted as "no statistically significant difference." We include uncertainty estimates by convention, but focus our interpretations on the point estimates of rates and MRRs.

Results

Among 219.1 million adults aged 25 years or older (113.3 million women [51.7%]; mean [SD] age, 51.3 [16.8] years), 376 125 individuals ages 25 years or older died of COVID-19 during the year 2020 (**Table**). Among these decedents, missingness was less than 2% for educational attainment and less than 1% for race and ethnicity. Age-adjusted cumulative mortality rates for the overall population were highest among persons with the lowest educational attainment (208.1 per 100 000 population [95% CI, 207.3-208.9 per 100 000 population]). Within racial and ethnic groups, mortality rates were highest among American Indian or Alaska Native individuals (334.5 per 100 000 population

[95% CI, 324.2-344.7 per 100 000 population]) and Native Hawaiian and Other Pacific Islander individuals (356.9 per 100 000 population [95% CI, 327.6-386.2 per 100 000 population]) and lowest among non-Hispanic White individuals (116.4 per 100 000 population [95% CI, 115.9-116.8 per 100 000 population]) and non-Hispanic Asian individuals (110.9 per 100 000 population [95% CI, 108.9-112.8 per 100 000 population]) (**Figure 1**). Racial and ethnic minority women of died at higher rates than non-Hispanic White men of the same age group, with the exception of non-Hispanic Asian women.

Age-adjusted cumulative mortality rates per 100 000 population ranged from 54.4 (95% CI, 49.8-59.0 per 100 000 population) among Asian women with some college to 699.0 (95% CI, 612.9-785.0 per 100 000 population) among Native Hawaiian and Other Pacific Islander men with a high school degree or less. Within race-gender groups, the highest age-adjusted cumulative mortality rates were consistently experienced by those with the lowest educational attainment (**Figure 2**). For the population aged 25 years or older, non-Hispanic White men with the least education died at a rate of 199.7 per 100 000 population (95% CI, 198.2-201.3 per 100 000 population), similar to the rates of college-educated non-Hispanic Black men (199.4 per 100 000 population [95% CI, 192.0-206.8 per 100 000 population]), college-educated American Indian or Alaska Native men (196.3 per 100 000 population [95% CI, 166.3-226.3 per 100 000 population]), and college-educated Latino men (198.6 per 100 000 population [95% CI, 190.7-206.5 per 100 000 population]) and lower than that of college-educated Native Hawaiian and Other Pacific Islander men (259.6 per 100 000 population [95% CI, 175.5-343.6 per 100 000 population]).

Nearly all racial and ethnic minority subgroups (54 of 60 age-sex-race-education subgroups, with age strata defined as 25-64 years or ≥65 years) experienced higher mortality (MRR >1.0) than

Table. COVID-19 Cumulative Deaths and Mortality Rates by Select Characteristics (2020)

Characteristic	Deaths, No.	Population, millions	Cumulative mortality rate per 100 000 population (95% CI)	
			Crude	Adjusted for age[a]
Total	376 125	219.1	116.2 (115.7-116.7)	145.9 (145.5-146.4)
Age group, y[b]				
25-39	5023	65.0	7.7 (7.5-7.9)	NA
40-54	21 896	60.5	36.2 (35.7-36.7)	NA
55-64	44 565	41.7	106.9 (105.9. 107.9)	NA
65-74	80 413	30.3	265.4 (263.6-267.2)	NA
≥75	224 228	21.6	1038.1 (1033.8-1042.4)	NA
Missing	0	NA	NA	NA
Sex				
Women	172 124	113.3	151.9 (151.2-152.6)	119.3 (118.7-119.8)
Men	204 715	105.9	193.3 (192.5-194.1)	178.6 (177.8-179.4)
Missing	0	NA	NA	NA
Race and ethnicity[c]				
American Indian or Alaska Native	4474	1.4	322.0 (312.6-331.4)	334.5 (324.2-344.7)
Asian	13 346	13.1	101.8 (100.1-103.5)	110.9 (108.9-112.8)
Black	59 528	26.2	226.9 (225.0-228.7)	237.9 (235.9-239.9)
Hawaiian and Other Pacific Islander	679	0.2	297.1 (274.8-319.5)	356.9 (327.6-386.2)
Latinx or Hispanic	68 577	34.2	200.3 (198.8-201.8)	265.2 (263.1-267.2)
White	227 532	143.9	158.1 (157.4-158.7)	116.4 (115.9-116.8)
Missing[d]	2703	NA	NA	NA
Educational attainment				
≤High school or GED	247 745	85.0	289.8 (290.3-292.6)	208.1 (207.3-208.9)
Some college	61 116	62.9	96.5 (96.4-97.9)	97.1 (96.3-97.9)
≥Bachelor's degree	57 711	71.3	80.5 (80.3-81.6)	89.3 (88.6-90.0)
Missing	10 267	NA	NA	NA

Abbreviations: GED, General Educational Development certification; NA, not applicable.

[a] Age-adjusted rates based on the 2000 standard US population, and numerators include complete cases only.

[b] Age group–specific rates are not further adjusted for age.

[c] Groups other than Latinx or Hispanic are non-Hispanic.

[d] Includes 1124 decedents identified as having more than 1 non-Hispanic race and ethnicity.

their non-Hispanic White counterparts (**Figure 3**). The only groups with lower mortality than non-Hispanic White individuals were: older non-Hispanic Asian women of all 3 education levels, younger non-Hispanic Asian women in the lowest education category, older non-Hispanic Asian men in the highest education category, and older Native Hawaiian and Other Pacific Islander men in the highest education category. Although death was relatively rare among younger adults, the MRRs measuring racial and ethnic inequity were highest among this age group, ranging from 0.8 (95% CI, 0.6-0.1) for non-Hispanic Asian women with the least education to 11.1 (95% CI, 6.5-18.9) for Native Hawaiian and Other Pacific Islander men with some college.

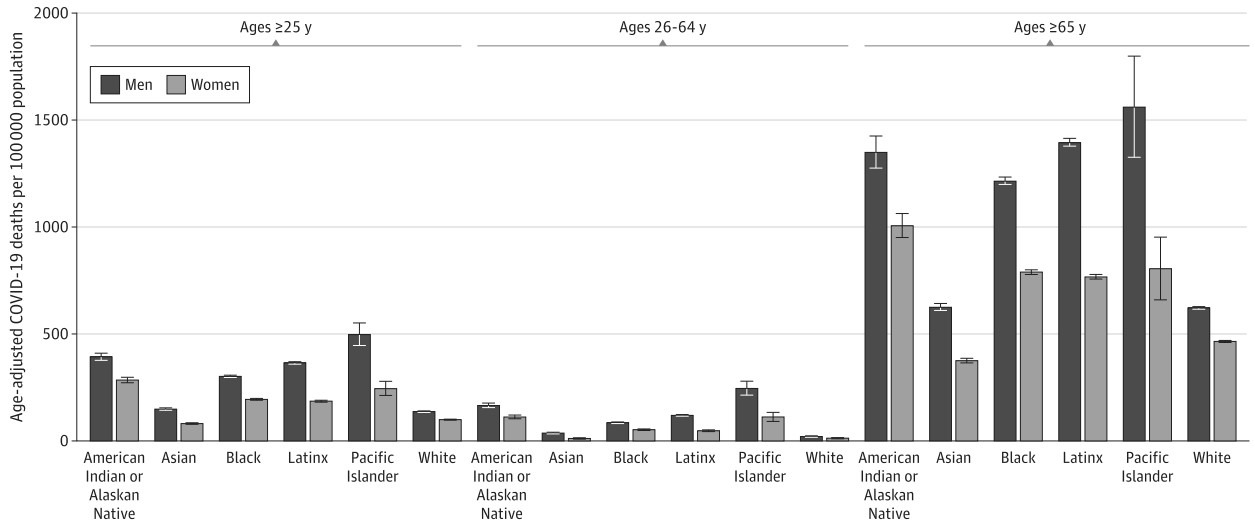
Racial and ethnic inequality in mortality for the overall population remained and was slightly attenuated, on average, when comparing within education categories. For the results presented in Figure 3, the median within-education MRR was 17% lower (IQR, 0%-25%) than the MRR for all education categories combined. In some cases, the within-education MRR was larger than the overall MRR. For example, younger non-Hispanic Black women died at 4.2 (95% CI, 3.9-4.5) times the rate of younger non-Hispanic White women. Within education categories, the MRR for younger non-Hispanic Black women (vs younger non-Hispanic White women of the same education level), ranged from 3.2 (95% CI, 2.9-3.5) for those with the lowest education level to 5.4 (95% CI, 4.6-6.4) for those with the highest education level.

In a counterfactual scenario in which all people experienced the same mortality rates as college-educated non-Hispanic White individuals of the same age and sex, the total number of deaths due to COVID-19 would have been 48% lower among adults aged 25 years or older, preventing 176 000 of the 364 000 deaths for which complete sociodemographic data were available. For all racial and ethnic minority individuals, the number of deaths due to COVID-19 would have been 71% lower, preventing 100 000 deaths out of 141 000. For racial and ethnic minority individuals aged 25 to 64 years, the number of deaths would have been 89% lower, preventing 40 000 deaths out of 45 000.

Discussion

Public-access data covering the entire United States have recently become available to examine inequities in COVID-19 mortality jointly by race and ethnicity and socioeconomic position. Our study of population-based data among adults aged 25 years or older identified inequities by educational attainment for the overall population and within racial and ethnic groups. Racial and ethnic minority

Figure 1. Cumulative Mortality Rates for COVID-19 in the US by Race and Ethnicity and Sex (2020)

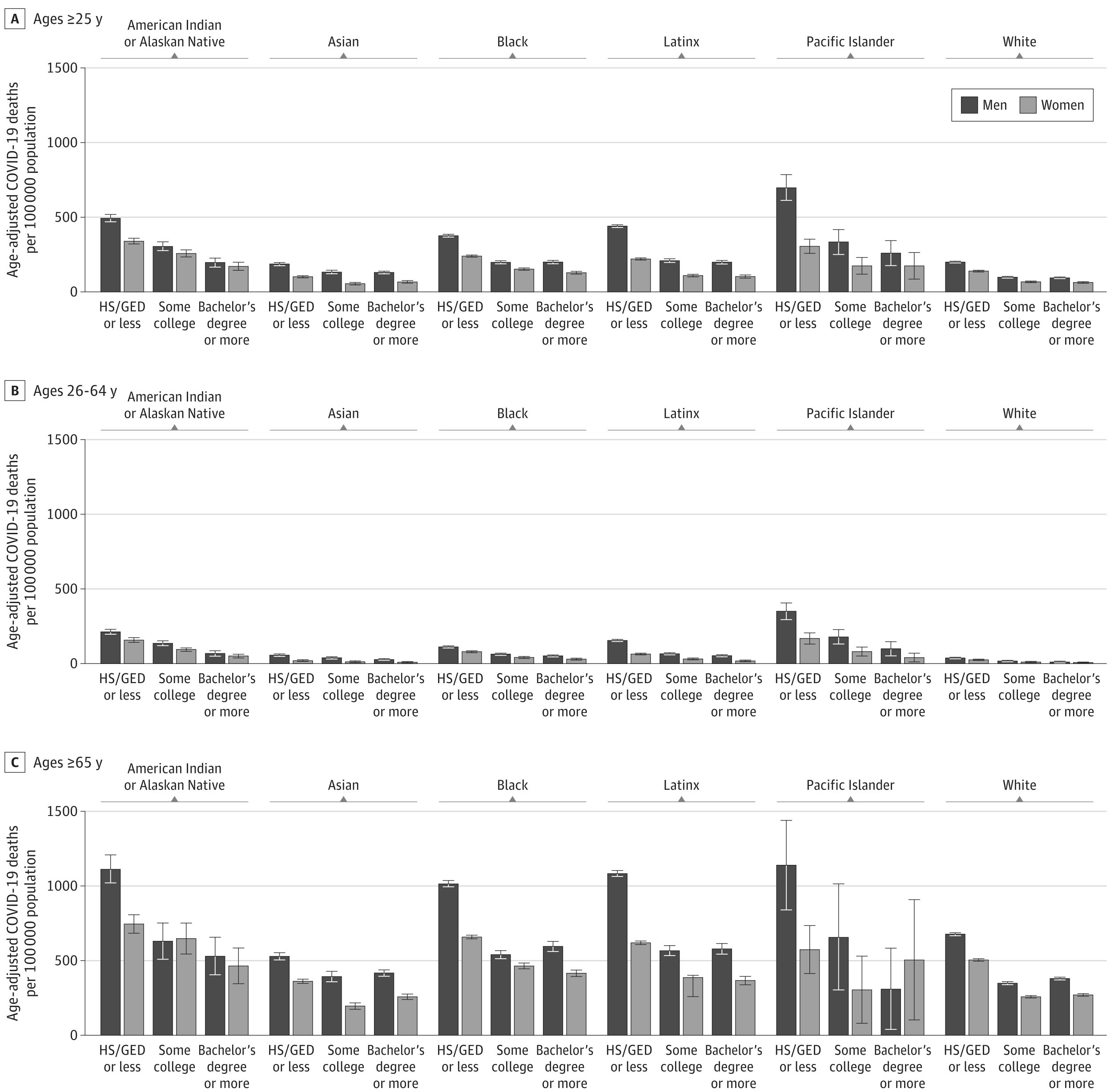


Error bars indicate 95% CIs.

populations typically experienced higher age-adjusted mortality rates than non-Hispanic White individuals and those with the lowest socioeconomic position (high school or GED completion or less) also died at the highest rates within racial and ethnic groups. The socioeconomic privilege afforded by higher educational attainment among racial and ethnic minority populations was often insufficient to overcome racial and ethnic inequality. For example, adjusting for age, college-educated non-Hispanic Black men had higher COVID-19 mortality rates than non-Hispanic White men who had completed high school or GED or less. Although a gradient in mortality rates by educational attainment was found within all population groups, the association of unequal educational attainment with racial and ethnic inequalities in COVID-19 deaths was likely modest.

Racialized socioeconomic inequities played a substantial role in the overall death toll of the pandemic. Had all population groups experienced the mortality rates observed among the group

Figure 2. Cumulative Mortality Rates for COVID-19 in the US by Race and Ethnicity, Sex, and Educational Attainment (2020)

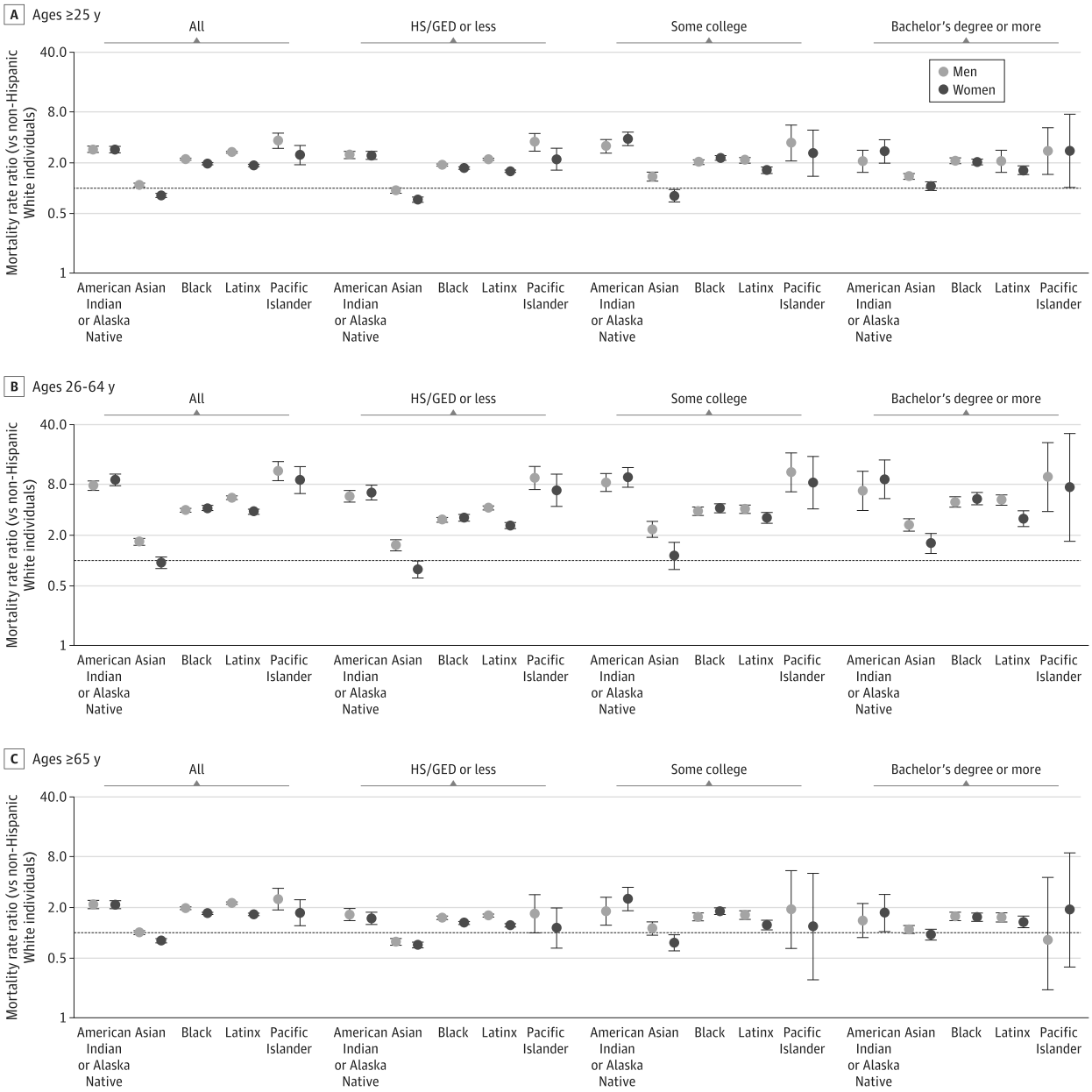


HS/GED indicates high school or General Educational Development certification. Error bars indicate 95% CIs.

assumed to be the most racially and socioeconomically privileged (college-educated non-Hispanic White individuals), the overall number of COVID-19 deaths in the US during 2020 would have been halved, and deaths among racial and ethnic minorities aged 25 to 64 years would have been reduced to about one-tenth of the observed number.

One of our key findings—that the magnitude of racial inequities was only slightly attenuated on average when stratifying by educational attainment categories—warrants further explanation and, ultimately, more exploration in future research. Racial and ethnic differences in educational attainment, and in socioeconomic position more broadly, capture only one mechanism through which structural racism is associated with health. Prior research shows that racial and ethnic

Figure 3. Cumulative Mortality Rate Ratios for COVID-19 in the US by Race and Ethnicity, Sex, and Education (2020)



HS/GED indicates high school or General Educational Development certification. The black horizontal line at 1.0 indicates the mortality rate among non-Hispanic White individuals. Error bars indicate 95% CIs.

differences in economic assets vary considerably even within education levels. For example, non-Hispanic Black college graduates in the US have less wealth and lower rates of home ownership when compared with non-Hispanic White college graduates and even when compared with non-Hispanic White indiviuals who have not graduated high school.[14,15] With regard to COVID-19 specifically, census data show all racial and ethnic groups other than non-Hispanic White individuals are more likely to have risk factors for SARS-CoV-2 exposure (household crowding, multigenerational housing, and potential occupational and paraoccupational exposure owing to employment in high-risk jobs or cohabitation with such workers) than non-Hispanic White individuals of the same educational attainment category (eFigure in the Supplement). Prior research suggests that racial and ethnic minority populations have been infected with COVID-19 at far higher rates than non-Hispanic White individuals,[16-18] and that inequities in COVID-19 mortality rates may in large part be associated with these differences in exposure to the virus.[19] Although there has been a small number of studies exploring the degree to which racial and ethnic differences in COVID-19 outcomes may be associated with differences in population genetics, the evidence for this has so far been very limited.[20] In addition, racial and ethnic groups that do not share geographic ancestry (eg, American Indian and Pacific Islander) have nevertheless experienced the highest COVID-19 mortality rates, suggesting that similarities in COVID-19 outcomes are associated more with similar social conditions than population genetics.

Different measures of socioeconomic position such as wealth or income may have yielded different patterns of racial inequality. In addition, accounting for social class, which, unlike socioeconomic position, is defined by one's position in economic relationships (eg, as a worker or owner),[9] may be particularly useful in analyses of COVID-19 outcomes, because class is closely tied to power—in this case, power to mitigate exposure to SARS-CoV-2.

Limitations

This study has some limitations. The analyses in this study relied on race and ethnicity classification of decedents from death certificates, which prior research has demonstrated to substantially underestimate mortality for American Indian or Alaska Native populations.[21] It is unclear whether similar underestimation of mortality also applies to Native Hawaiian and Other Pacific Islander individuals, as they have not been disaggregated from non-Hispanic Asian individuals in prior research on misclassification of race and ethnicity in mortality data. In addition, COVID-19 is likely misclassified in mortality data, and the CDC estimates that the true number of COVID-19 deaths was 30% higher than reported for the period from March 2020 to May 2021,[22] although whether misclassification varies by sociodemographic groups is unknown. As this was a cross-sectional study, we were also unable to assess whether the magnitude of inequalities changed over time. Finally, owing to limitations in the mortality data set, we were not able to assess potential mediators associated with racial and ethnic and socioeconomic inequalities, including geography, SARS-CoV-2 exposure, health care access, and comorbidities.

Conclusions

During the first year of the COVID-19 pandemic, which largely preceded the availability of vaccines, there were extremely high levels of racialized economic inequity in the distribution of COVID-19 mortality. Future research may investigate the specific pathways that produced these joint racial and ethnic and socioeconomic inequities, as well as whether the longstanding political disempowerment of populations among whom the virus was most lethal (ie, economically marginalized racial and ethnic minority groups) was associated with policy responses to the pandemic. What is clear is that the mortality burden of these inequities is high. Future research can help inform interventions that yield equitable responses to both the ongoing burden of COVID-19 and potential future pandemics that spread similarly to SARS-CoV-2.

ARTICLE INFORMATION

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Author Contributions: Dr Feldman had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Both authors.

Acquisition, analysis, or interpretation of data: Feldman.

Drafting of the manuscript: Feldman.

Critical revision of the manuscript for important intellectual content: Both authors.

Statistical analysis: Feldman.

Administrative, technical, or material support: Feldman.

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SUPPLEMENT.

eFigure A. Distribution of Household Crowding (>1 Person/Room)

eFigure B. Distribution of Employment in Exposure Occupations and/or Household Exposure to Such Workers

eFigure C. Multigenerational Housing Among Those Ages ≥65 Years

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jonathan Roberts and Charles Vavruska,

Plaintiffs,

-against-

Mary T. Bassett, in her official capacity as Commissioner for New York State Department of Health; New York City Department of Health and Mental Hygiene,

Defendants.

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

DECLARATION OF WENCONG FA

I, Wencong Fa, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am over eighteen years of age, have personal knowledge of the facts stated herein, and if called upon to do so, could and would testify competently thereto.

2. I am an attorney at Pacific Legal Foundation and represent Plaintiffs Jonathan Roberts and Charles Vavruska, in the above-styled action.

3. I provide this declaration in support of Plaintiffs' Motion for a Preliminary Injunction.

4. Attached hereto as Exhibit 1 is a true and correct copy of a screenshot of the COVID-19 Health Equity Dashboard, which I accessed at https://covid19.emory.edu/ on February 27, 2022.

5. Attached hereto as Exhibit 2 is a true and correct copy of a screenshot of the CDC COVID Data Tracker, which I accessed at https://covid.cdc.gov/covid-data-tracker/#demographicsovertime on February 27, 2022, by selecting "NY" for jurisdiction, the "Race/Ethnicity" tab under "Deaths," and right-clicking "show as table" on the page.

6. Attached hereto as Exhibit 3 is a true and correct copy of a screenshot of the COVID-19 Guidance Repository, which I accessed at https://coronavirus.health.ny.gov/covid-19-guidance-repository on February 27, 2022.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

DATED this 28th day of February, 2022.

/s/ Wencong Fa
WENCONG FA

AFFIRMATION OF SERVICE

I, Wencong Fa, declare under penalty of perjury that I filed the foregoing with the Clerk of the Court of the Eastern District of New York through the CM/ECF system, which will serve notice of said filing on all counsel of record.

s/ Wencong Fa
Attorney for Plaintiffs

The Latest on this Dashboard

Georgia COVID-19 Health Equity Dashboard

Georgia COVID-19 Health Equity Dashboard
The Georgia COVID-19 Health Equity dashboard is a tool to dynamically track and compare the burden of cases and deaths across counties in Georgia. Click to Access.

Digesting COVID-19 data
Ms. Ana Claudia Chacin talks about the challenges she and other journalists have faced in accessing and reporting accurate COVID-19 data in Florida.for more.

"Antibodies are driving a lot of the protection, but it's not the whole story"
Dr. David Benkeser talks about analyses of COVID-19 vaccine trials data on the immune response to those vaccines.for more.

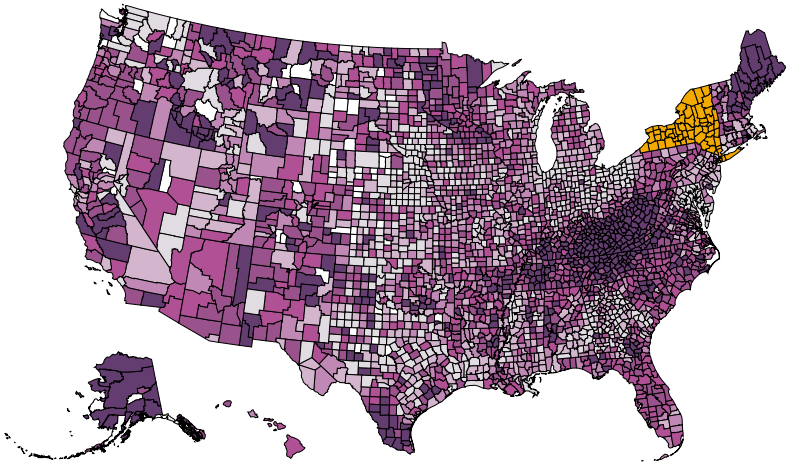
United States /

See Dashboard Guide (PDF / YouTube)

COVID-19 is affecting every community differently.
Some areas are much harder-hit than others.
What is happening where you live?

Average Daily COVID-19 Cases per 100K

1 13 18 23 30 43 2K
Low High
None Reported



Data as of: 02/23/2022, updated every weekday.

▸ About the data

Current Cases and Deaths in New York

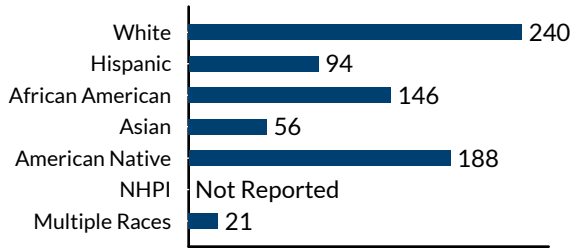
Daily Cases	Daily Deaths
2,665 ↓ 56% 14-day change	58 ↓ 56% 14-day change

*14-day change trends use 7-day averages.

Disparities in COVID-19 Mortality **New York**

COVID-19 Death Rates | COVID-19 Death and Population

COVID-19 Death Rate per 100k



The chart shows race and ethnicity groups that constitute at least 1% of the state population and have 30 or more deaths. Race and ethnicity data are known for 95% of deaths in the nation. Rates are not reported for race & ethnic groups with < 30 deaths recorded or groups that constitute at least 1% of the state populatio
NHPI: Native Hawaiians and Pacific Islanders.

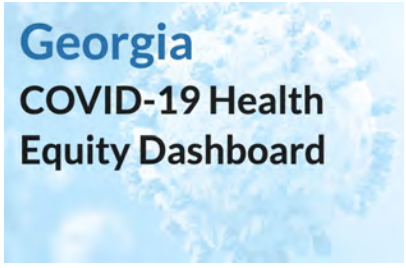
EXHIBIT 1

National Report

Click on icon for an overview of COVID-19 in the U.S.

Vaccination Tracker

Click on icon for latest information on COVID-19 vaccination.



Georgia COVID-19 Health Equity Dashboard

Other Tools

Click on icon to to explore other tools.

About This Dashboard

Click on icon to learn about the goal of the dashboard and its team.

Sources & Interpretation

Click on icon for a complete list of measures' definitions and sources.

Media Hub

Click on icon for the latest video, podcast, and blog on COVID-19.

Latest Podcast

Katie Kirkpatrick discusses the ramifications of COVID-19 in the business community...

Early data about COVID-19 suggests that communities are affected very differently due to social determinants of health like population density, poverty, residential segregation, underlying chronic health conditions, and availability of medical services. In order to predict how the epidemic will continue to unfold and prepare for the future, it is critical to understand differences in underlying risk factors. There is no one-size-fits all approach to combat the epidemic, but accurate and meaningful data is a key component of a robust public health response that is informed by contextual factors and prioritizes health equity.

The COVID-19 Health Equity Dashboard (COVID19.emory.edu) seeks to fill the gaps in county-level data about the virus and underlying social determinants of health. Our goal is to facilitate easy comparisons of counties with respect to COVID-19 outcomes and social determinants. We hope this becomes a valuable resource for and critical component of tailored public health responses to COVID-19 across the wide range of environments that Americans inhabit.

- Semantic UI React by @levithomason and an amazing community of contributors
- Create React App by Facebook

Centers for Disease Control and Prevention

COVID Data Tracker

United States at a Glance Collapse

United States
At a Glance

Deaths Total **944,517**
Last 30 Days

Cases Total **78,732,221**
Last 30 Days

81.1% of People 5+ with At Least
One Vaccination

Use CDC's COVID-19 Community Levels to determine the level of healthcare burden and disease spread in your community and take action. Check back soon for COVID Data Tracker updates incorporating COVID-19 Community Levels information.

- Data Tracker Home
- COVID Data Tracker Weekly Review
- Your Community +
- Health Equity Data
- Pediatric Data

COVID-19 Weekly Cases and Deaths per 100,000 Population by Age, Race/Ethnicity, and Sex

View Footnotes and Additional Information

EXHIBIT 2

Pregnancy Data

Vaccination Delivery and Coverage +

Vaccine Effectiveness and Breakthrough Surveillance +

Cases, Deaths, and Testing +

Demographic Trends −

Trends in Cases and Deaths by Race/Ethnicity, Age, and Sex

Total Cases and Deaths by Race/Ethnicity, Age, and Sex

Cases and Deaths by Urban/Rural Status and Social Factors

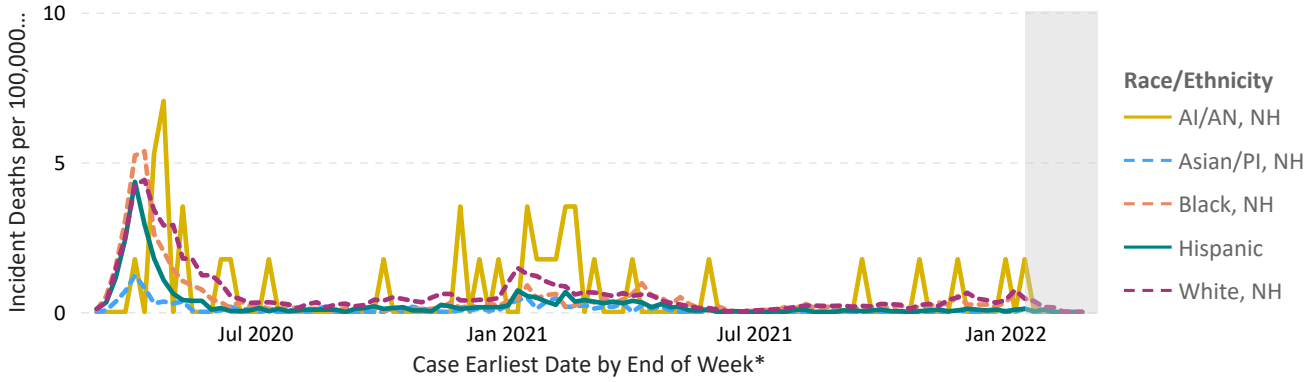
Health Care Settings +

Variants and Genomic Surveillance +

Antibody Seroprevalence +

People at Increased Risk +

Back to report



End of Week	AI/AN, NH	Asian/PI, NH	Black, NH	Hispanic	White, NH
2021-12-25	0.00	0.06	0.18	0.08	0.31
2022-01-01	1.76	0.00	0.32	0.03	0.40
2022-01-08	0.00	0.00	0.64	0.08	0.73
2022-01-15	1.76	0.12	0.46	0.11	0.45
2022-01-22	0.00	0.00	0.28	0.03	0.36
2022-01-29	0.00	0.00	0.04	0.08	0.17
2022-02-05	0.00	0.00	0.04	0.00	0.16
2022-02-12	0.00	0.00	0.00	0.00	0.02
2022-02-19	0.00	0.00	0.00	0.00	0.00
2022-02-26	0.00	0.00	0.00	0.00	0.00

Microsoft Power BI 7 of 7

Footnotes and Additional Information

Expand each accordion to view footnotes

Footnotes +

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Multisystem Inflammatory Syndrome in Children (MIS-C)

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Cite COVID Data Tracker

Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services, CDC; 2022, February 27. https://covid.cdc.gov/covid-data-tracker

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COVID-19 GUIDANCE DOCUMENTS

Though extensive, this is not an exhaustive list of current and archived COVID-19 guidance released by New York State since the start of the pandemic.

ALL

COVID-19 Documents

237 results found

Guidance, Current

COVID-19 Immunization Screening and Consent Form: Children and Ad... (/covid-19-immunization-screening-and-consent-form-children-and-adolescents-ages-5-11-years-old)

Updated January 6, 2022 - COVID-19 Immunization Screening and Consent Form: Children and Adolescents Ages 5-11 years old.

Also available in: Español (/covid-19-immunization-screening-and-consent-form-children-and-adolescents-ages-5-11-years-old-0) .

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Current

Interim Updated Isolation and Quarantine Guidance (/interim-updated-isolation-and-quarantine-guidance)

EXHIBIT 3

January 4, 2022 - This is interim guidance for local health departments, school districts, congregate care settings, healthcare providers. CDC guidance is in flux and will...

DOWNLOAD (/INTERIM-UPDATED-ISOLATION-AND-QUARANTINE-GUIDANCE)

Archived

Interim Advisory on Return-to-Work Protocols for Personnel with S... (/interim-advisory-return-work-protocols-personnel-sars-cov-2-infection-or-exposure-healthcare)

January 4, 2022 - Clarifies when to follow the NYSDOH return-to-work guidance issued on December 24, 2021 (NYSDOH Shortening Isolation) (https://coronavirus.health.ny.gov/system/files/documents/2021/12/return-to-work-isolation-guidance_12-24-21.pdf) for healthcare workers and when...

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Current

List of Hospitals Sent an Initial Allocation of Evusheld (/list-hospitals-sent-and-initial-allocation-evusheld)

Updated January 10, 2022: The following is a list of hospitals sent an initial allocation of Evusheld.

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Current

Advisory on Shortening Isolation Period for Certain Fully Vaccina... (/advisory-shortening-isolation-period-certain-fully-vaccinated-healthcare-workers-and-other-critical)

December 24, 2021: The information contained herein supersedes portions of previously issued Return to Work guidance for Healthcare Personnel and other previous guidance related to returning...

DOWNLOAD (/ADVISORY-SHORTENING-ISOLATION-PERIOD-CERTAIN-FULLY-VACCINATED-HEALTHCARE-WORKERS-AND-OTHER-CRITICAL)

Guidance, Current

Test to Stay Update (/test-stay-update)

December 23, 2021: The purpose of this document is to provide Local Health Departments (LHDs) with clarification on the new information regarding testing and quarantine, particularly...

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Guidance, Current

Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies and Oral ... (/prioritization-anti-sars-cov-2-monoclonal-antibodies-and-oral-antivirals-treatment-covid-19-during)

Updated December 29, 2021 - This document is intended to provide a framework for providers to identify patients at highest risk for severe COVID-19 that...

DOWNLOAD (/PRIORITIZATION-ANTI-SARS-COV-2-MONOCLONAL-ANTIBODIES-AND-ORAL-ANTIVIRALS-TREATMENT-COVID-19-DURING)

Current

Face Masks for COVID-19 (/face-masks-covid-19)

December 17, 2021: Guidance on how to properly wear a mask.

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Current

Experiencing COVID-19 Symptoms? Poster (/experiencing-covid-19-symptoms-poster)

December 17, 2021: If you are experiencing these COVID-19 Symptoms call your health care provider today to see if they recommend treatment.

Also available in: Español (https://health.ny.gov/publications/13305.pdf) ...

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Current

Proof of Vaccination Poster for Businesses (/proof-vaccination-poster-businesses)

December 13, 2021: This poster can be printed and displayed by businesses requiring proof of vaccination.

Also available in: Español (/proof-vaccination-poster-businesses-spanish) .

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STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

LETITIA JAMES
ATTORNEY GENERAL

DIVISION OF STATE COUNSEL
LITIGATION BUREAU

Writer's Direct Dial: (212) 416-6536

March 4, 2022

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

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

Dear Judge Garaufis:

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

DOH uses the Health Commerce System ("HCS"), an online portal and secure website, to facilitate web-based interactions and secure communications with health care facilities, providers, and practitioners in New York. The Integrated Health Alerting and Notification System ("IHANS") is a communications application within the HCS. DOH used IHANS to distribute the DOH Guidance via email to health care facilities and prescribing medical professionals in New York, including licensed physicians, nurse practitioners, and physicians' assistants. DOH did not distribute the DOH Guidance to pharmacies.

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

Respectfully submitted,

/s/
Erin Kandel
Assistant Attorney General

cc: All counsel via ECF

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

LETITIA JAMES
ATTORNEY GENERAL

DIVISION OF STATE COUNSEL
LITIGATION BUREAU

Writer's Direct Dial: (212) 416-6536

March 7, 2022

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

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

Dear Judge Garaufis:

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

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

The March 4, 2022 Guidance does not supersede the December 2021 Guidance but acts an update to it, informing practitioners that there is currently no shortage of supplies constraining their ability to prescribe the antiviral and monocloncal antibody treatment therapies at issue in this case ("the Therapies") if they determine that treatment is clinically appropriate. The purpose of the March 4, 2022 Guidance is to remind practitioners of the COVID-19 treatment options available, including the Therapies; to inform practitioners that "COVID-19 treatment options are available and there are no current shortages"; and to encourage practitioners "to evaluate all treatment options as early as possible." *See* Ex. A. The March 4, 2022 Guidance further states: "Starting the week of March 7th, we anticipate new sites will open in New York State through President Biden's Test to Treat program. These Test to Treat sites will provide increased availability of immediate testing and early treatment and will also be displayed on the COVID-19 Therapeutics Locator." *Id.*

The Therapies remain subject to the Emergency Use Authorizations issued by the United

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

Respectfully submitted,

/s/
Erin Kandel
Assistant Attorney General

cc: All counsel via ECF

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

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

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

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

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

Summary:

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

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

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

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

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

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

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

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Jonathan Roberts and Charles Vavruska,

Plaintiffs,

-against-

Mary T. Bassett, in her official capacity as Commissioner for New York State Department of Health; New York City Department of Health and Mental Hygiene,

Defendants.

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

NOTICE OF APPEAL

PLEASE TAKE NOTICE that Plaintiffs Jonathan Roberts and Charles Vavruska, by and through their undersigned counsel, hereby appeal to the U.S. Court of Appeals for the Second Circuit from the Court's Memorandum and Order dismissing the case (Dkt. 35) entered on March 15, 2022.

Respectfully submitted this 23rd day of March 2022.

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AFFIRMATION OF SERVICE

I, Wencong Fa, declare under penalty of perjury that I filed the foregoing with the Clerk of the Court of the Eastern District of New York though the CM/ECF system, which will serve notice of said filing on all counsel of record.

s/ Wencong Fa
Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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JONATHAN ROBERTS ET AL.,

Plaintiffs,

- versus -

MARY T. BASSETT ET AL.,

Defendants.

----------x

22-CV-710(NGG)

United States Courthouse
Brooklyn, New York

March 2, 2022
11:00 a.m.

TRANSCRIPT OF CIVIL CAUSE FOR MOTION
BEFORE THE HONORABLE NICHOLAS G. GARAUFIS
UNITED STATES SENIOR DISTRICT JUDGE

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Proceedings recorded by mechanical stenography. Transcript produced by computer-aided transcription.

AVERY N. ARMSTRONG, RPR
Official Court Reporter

(In open court.)

(Judge NICHOLAS G. GARAUFIS enters the courtroom.)

THE COURT: Call the case.

THE COURTROOM DEPUTY: Okay. Civil cause for a motion hearing.

Beginning with the plaintiff, please state your appearances for the record.

MR. FA: Wencong Fa for the plaintiff.

MR. TROTTER: As well as Caleb Trotter for plaintiffs.

THE COURT: All right. Please be seated. Everyone can be seated. Just let me just hear the other side.

MS. KANDEL: Erin Kandel with the New York State of the Office of the Attorney General on behalf of Mary T. Bassett, the Commissioner of New York State Department of Health.

Good morning, Your Honor.

THE COURT: Good morning.

MS. SCHONFELD: Samantha Schonfeld, Assistant Corporation Counsel for the New York City Department of Health.

Good morning.

MS. KATZEN: And Jessica Katzen, Assistant Corporation Counsel with the New York City Department of Health.

AVERY N. ARMSTRONG, RPR
Official Court Reporter

THE COURT: Thank you, everyone.

Is there anyone in the courtroom who's not vaccinated? Just raise your hand so I know who it is who is not vaccinated.

Okay. So when you're speaking, if you want to take off your mask, please feel free to do so, so I can actually understand what you're saying. If you wish to keep your masks on, speak loudly and into the microphone, because it's sometimes hard to understand people who are wearing a mask when they speak. Okay.

Now, the plaintiffs, Jonathan Roberts and Charles Savruska --

MR. FA: Vavruska, Your Honor.

THE COURT: Vavruska. Had moved for a preliminary injunction in this case.

And so let me hear from plaintiff's counsel first as to why the Court should issue a preliminary injunction.

Thank you. And welcome from California.

MR. FA: Thank you, Your Honor.

THE COURT: Okay.

MR. FA: Thank you, Your Honor. May it please the Court. Plaintiffs are life-long New Yorker who want equal access to COVID-19 treatments during these unpredictable times, but they know that they do not equal access to highly effective antivirals that must be taken within five days of

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symptom onset that is because both the City and the State of New York have issued directives to physicians that treat patients and to providers that prescribe them directing them to treat people differently on the basis of race. This is unconstitutional. Just as the Government cannot itself directly discriminate on the basis of race, it cannot ask medical professionals to discriminate on the basis of race.

So I want to start off where we left off last week at the pre-motion conference and that's by addressing Article Three standing. Plaintiffs have Article Three standing because they meet all three elements of Article Three standing as set by the Supreme Court in the Lujan decision. Reading defendant's responses, I think the main issue -- the main dispute between the parties as to Article Three standing is with respect to the injury, in fact, element. And I think plaintiffs meet that element, because as defendants concede, the injury, in fact, in an Equal Protection Clause case such as this one is the imposition of the barrier that stands between the way of plaintiffs -- that stands between the plaintiffs and the benefit, and not the ultimate denial of the plaintiff's itself.

So I think the SYNAREL® case that they cite is actually very helpful because it says, is there a barrier, are plaintiffs disadvantaged by the barrier, and can plaintiffs -- would in a favorable decision from this Court eliminate the

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barrier. So the barrier here is the specific risk tiers as specified in the directives that are at issue that are attached as exhibits to our complaint, I believe, Exhibits B and C. And defendants say a lot about, you know, physicians are not required — they're free to ignore the directives if they choose to do so. But that does not change the fact that the directives themselves set forth tiers that instruct providers to treat people differently on the basis of race. And I think it would be surprising if defendants set forth these directives in a time of very limited supply, sent them as the City's declaring note to 75,000 e-mail addresses, including medical professionals and other interested parties, if they didn't expect people to enforce them and for people to follow them.

And as we noted in our reply brief, defendants can't have it both ways. They can't say that to maintain a race-neutral system would be akin to maintaining a discriminatory system, and say on the other hand, that providers are free to ignore the directives. The directives call for the prioritization of COVID-19 treatments and they call for the use of race as an independent risk factor in both prioritizing people among the same risk group and also moving people from a lower risk group to a higher risk group.

THE COURT: What if there were an African American patient, goes to see a doctor, and this risk factor, if you

will, raised in the mind of the doctor, gee, I really should look carefully at the person's sugar level, this person hasn't been to see a doctor in 20 years because he doesn't have insurance, he's poor, he works two jobs, and we just — let me -- I'll do some tests. And it turns out that the individual has onset diabetes.

Would that risk factor be an appropriate signal to the doctor that there might be some additional concern about the individual's susceptibility to COVID?

MS. KANDEL: So I think that's a much tougher call, because in that scenario, if I understand the hypothetical correctly, the doctor would not necessarily be distributing benefits and burdens on the benefit of race. The doctor would considering race as a factor in determining potentially what kind of —

THE COURT: -- treatment or what kind of -- what kinds of tests to undertake to determine whether this person met other risk factors which are not identified, by the way, in the State and City guidelines, what they call their guidelines.

So what I'm saying to you is, should the Court be looking at this more holistically than just if someone -- you know, you look at the individual and say this person is a Hispanic or this person is African American, but looking at it and say, what is it about this person, because of this

person's race that we should be looking at more closely to determine what the risk factors really are.

MR. FA: Yeah. I think if New York did something like that or adopted a policy like that, our clients would probably not be challenging this policy. But what the actually policy actually does is that it sets forth five different risk groups, it instructs providers to prioritize based on the risk group, and also to prioritize within each risk group, based on risk factors, and race is used not in a holistic manner, according to the directives themselves, but race is used, instead, in a very crude mechanical way. It's considered a risk factor for every non-white or every Hispanic individual in the State of New York.

THE COURT: So if the State guidelines simply said, we're following the CDC guidelines on risk factors -- it's the CDC, right?

MS. KANDEL: Yes, the CDC.

THE COURT: That would not be a problem?

MR. FA: So as I understand -- I want to be clear about that -- as I understand the CDC's guidance, it instructs providers and physicians to look at patients in a holistic way to see what their needs are, to talk to the patients, and that's, I think, what the defendants tried to paint their directives as. You know, I certainly don't think -- if that were the case and the physicians are not granting any sort of

special preferences on the basis of race, I don't think our clients would be here challenging these directives, I don't think any other person would be challenging this directive.

I feel like every patient, what they want from their physicians is a holistic evaluation based on that person's, you know, age, vaccination status, anything that the doctor might seem relevant. So if it's true it's just a conversation-starter and not a system that gives racial preferences, you know, I think our clients would not be here challenging that. But what the directives do is it considers race as an independent risk factor. It says, During times of limited supply, physicians and providers should prefer certain patients over others, and here are the risk groups by which physicians and providers should make that analysis. That's what sets forth the barrier that is unconstitutional. It's a barrier based on race, and it's a barrier that, according to cases like the Jacksonville case cited in all of the parties briefing, imposes an injury for purposes of Article Three.

THE COURT: Sometimes everyone can find something to quote in the same case on opposite sides.

MR. FA: That's right.

THE COURT: That's what's so wonderful about the practice of law, isn't it.

Now, but we do have, you know, the declarations of Judge Heslin, and is it Judge Moore?

MS. SCHONFELD: Yes, Dr. Moore.

THE COURT: I'm sorry, Dr. Heslin and Dr. Moore. And Dr. Moore, I just saw last night on television. She does advertising for the department of health with the City of New York, so I actually can put together a name with a face which is more than usually happens with these declarations.

But they're not saying that these are directives that are written in stone. That these are, in effect, considerations that are -- you know, that the physicians can or cannot or might not, even take into account. But that they should be made aware of these circumstances that affect minorities in their medical care.

Isn't that what they're saying here?

MR. FA: So, you know, I would say that I think defendants' view of what the directives do is a little bit different from that the directives say they do.

With respect to the Moore declaration, I should say, I think it says that the City of New York has sent out this guidance, not only posted the guidance on a website, but also sent out this guidance to 75,000 e-mail addresses in the City of New York and --

THE COURT: I don't know what they are. I mean, I assume they're doctors.

MR. FA: Mostly -- from what the declaration says, it's medical professionals and other interested parties.

THE COURT: Well then, do you have any knowledge of whether those interested parties, in turn, include pharmacists?

MR. FA: I think they would, because I believe the defendant's briefing referred to physicians and providers. But that's perhaps --

THE COURT: I'll ask that question of the other side.

MR. FA: Sure. And I would note, Your Honor, as you know, this is a preliminary injunction hearing. We're at a preliminary state. We're certainly happy to conduct discovery on an expedited basis.

THE COURT: I see. All right. Well, I need to have a better idea of what the injury, potential injury would be.

MR. FA: Right. Yes.

THE COURT: And one of the questions that I would have is, is this just another e-mail that you get and you look at the title of the e-mail and then you delete it, because these are very busy people, we're all very busy, and unless we're told, you know, this is the rule of law like a statute, it may be that the doctors who were known for their, you kn know, strong views, independence, and resolve, to do what's best for their patients due to the Hippocratic oath, don't -- I assume, don't always take the advice of bureaucrats.

MR. FA: So I don't think it's dispositive to the

injury whether this is a law with penalties or whether it's a guidance. Guidance documents are presumed to be followed and some of the recent guidance that the State of New York has issued, they stated that individuals must follow them.

And what's more is when you look at the injury, I think you look at what is likely at this stage. And I think when defendants -- and this is just the City, by the way. When defendants have issued these guidance documents to, at least, 75,000 individuals, you -- I think that it's fair to presume that many of them, or some of them, at least, would follow what the directives are saying. And that's especially true as in this case, where we have a antivirals that was in severely limited supply, lots of people demanding them, and there needs to be a system for the prioritization of doling out these antivirals and other COVID-19 treatments.

THE COURT: Okay.

MR. FA: So I mean, I don't think if -- the Government and plaintiffs obviously disagree on a lot of things. But I don't think, you know, the government would dispute the fact that they say that they wanted to ensure that these treatments are distributed to the people most in need. And I think it would sort of strain credulity if they just issued these guidance, they sent it out to tens of thousands of people, and then expected people not to follow what they actually said in the prioritization of COVID-19 treatment.

THE COURT: Go ahead. Do you have something else for the moment or should I go to the other side?

MR. FA: Sure. I'm happy to hear from the other side on that. I was also going to get to the merits, but it sound like --

THE COURT: Let's hold off on the merits for the moment.

MR. FA: Sure. Yes.

THE COURT: But before you do, did you have a chance to hear the president's State of the Union address last night?

MR. FA: I did not, Your Honor. I was preparing for this argument.

THE COURT: Well, I did. And you know, I'm never off duty.

So one of the statements he made was as follows, speaking about COVID, he said -- and I have the transcript here, at least the transcript that was provided to me by the -- our friends at the New York Times.

He said, we're also ready with antiviral treatments. If you get COVID-19, the Pfizer pill reduces your chances of ending up in the hospital by 90 percent. I've ordered more of these pills, more of these pills than anyone in the world has. Pfizer is working overtime to get us 1 million pills this month and more than double that next month. And we're launching the Test to Treat, in quotes, initiative, so people

can get tested at a pharmacy, and if they prove positive, receive antiviral pills on the spot at no cost. If you're immunocompromised or have some other vulnerability, we have treatments and free high-quality masks. We're leaving no one behind or ignoring anyone's needs as we move forward.

So what he is saying -- end quote.

So what he's saying is that we have enough pills for everybody. We're not going to distinguish between one group or another group. If you've got COVID, you get the pill. And you can get it -- you will get it at the pharmacy, no questions asked, you just get it.

Does that undermine your need for some sort of preliminary relief here?

MR. FA: I don't think so, Your Honor. And I'll make two points about that. I feel -- so one, with respect to the preliminary relief in particular, these are treatments that -- according to the directives themselves, the antivirals must be taken five days within symptom onset, and I think that's why preliminary relief is so important, because no plaintiff would have the ability to have symptoms, go to the doctor, test positive, you know, find a lawyer, get a TRO, and get a decision on the TRO all within that five-day period. So I think that's a basis for preliminary relief.

THE COURT: But the guy who runs the CDC, the president, in effect, is the guy who runs the executive

branch. He says that everyone's going to get this medicine and you don't need your doctor to bless, you know, your getting the medicine because you meet all these different considerations, that you're sick, you get the medicide.

And doesn't that preempt whatever the guidelines the CDC has or that the City has or that the State of New York has, you just get the medicine and -- because there's enough medicine to go around?

Now you're saying, if that should change, you know, you won't have enough time to go to court to get the medicine because your doctor would say, well, you don't meet the guidelines, somebody else is ahead of you line who has more issues, medical and other socioeconomic, racial, whatever, issues, that have been listed by the CDC and by the City or State of New York. So I understand what you're saying about, you know, what needs to happen right away. But he -- what President Biden is saying, is there's enough, and we're going to make it so easy to get this medicine without cost that no person in this country has to worry about, you know, meeting some sort of factoring process.

MR. FA: So I hope what the president says is true. I mean, if --

THE COURT: Well, if he said it. I assume it's true that this is what they intend to do.

MR. FA: So that might be what they intend to do.

But I think if the president could -- you know, if that fact, if the fact that there were -- there would be indefinitely supply -- supply would indefinitely outmatch demand for indefinitely, then I think that would be a different issue. But I think if that were the case, you would expect the guidance to be retracted or withdrawn or archived on the State's website, as is the case with other guidance.

THE COURT: So you think you'd have a case still then, even if it's retracted?

MR. FA: If it's retracted, I think we can work out -- I mean, we did ask for nominal damages.

THE COURT: That's why I'm asking the question.

MR. FA: Yeah.

THE COURT: All right. Well, I appreciate your comments. And hopefully, everything that the president has stated regarding the availability of these therapeutic medicines will come about. But we'll see.

We're dealing here right now with whether there's Article Three standing and rightness, and so I appreciate your comments.

MR. FA: Right, Your Honor. If I can make two small points --

THE COURT: Sure. Anyone who comes from California to this courtroom gets to make as many, you know, discrete comments as time will allow.

MR. FA: I appreciate that, Your Honor.

So a couple of points, because I think this goes to the mootness point, and we did have a part for nominal damages in the relief section. But beyond that if you look at what we say and what the defendants say, defendants concede, I think, two important facts that go to whether or not there's still an ongoing controversy and whether or not relief would be ineffectual whatsoever. I mean, defendants, the State, for example, says that as we've learned in the past two years, supply shortages can happen at any time, and the City adds that, you know, the City of New York is still under emergency order until, I think, at least mid March, and there's an ongoing concern with community transmission.

So you know, over the last two years, we've, I think all, have been hoping for the end of coronavirus for quite some time. But there have been surges, there have been variants such as Delta, Omicron. The declarations themselves say that the most cases, coronavirus cases that have impacted the State of New York was actually from November of last year to January this year when the variant unexpectedly was highly transmissible and impacted people who were already thought to be immunized or immune due to either vaccination or preview transmission.

And I thank the Court for its time.

THE COURT: Thank you very much, sir.

Ms. Kandel. Welcome.

MS. KANDEL: Thank you, Your Honor.

THE COURT: I have a question.

MS. KANDEL: Yes.

THE COURT: Why does the State's guidelines only delineate one factor of so many factors that should be considered by physicians when prioritizing, if you will, the availability of these therapeutic medicines for COVID-19?

MS. KANDEL: It delineates that specific factor because that -- the fact that non-white race and Latino Hispanic ethnicity causes poorer outcomes in COVID-19 is something that has come out of recent research, and well documented research in this pandemic. And this was an occasion, with the FDA's emergency approval of medications that are only approved for people who are high risk of developing severe COVID which then requires a physician to consider who is at high risk of developing severe COVID. It was the time to highlight that risk factor that is well established and that plaintiffs really can't deny that the science establishes that they are risk factors for developing severe COVID-19. So that is one of the reasons why it was highlighted.

And that — and it also tracks the CDC guidelines that also highlight that race and ethnicity can lead to poorer outcomes in the COVID pandemic, and that is being studied and

documented by the data.

THE COURT: Go ahead.

MS. KANDEL: So jump right into the standing point?

THE COURT: Sure.

MS. KANDEL: Plaintiffs do this the have Article Three standing in order to maintain these claims and succeed on their motion for preliminary injunction.

Under the established case law, they not only have to show that it creates -- that the guidance creates a barrier, but that they suffered some identifiable harm from that barrier, and that their alleged injury is not hypothetical or imminent. Not only can they not show that there are a barrier here, there isn't any injury.

As we've already — you've already discussed with plaintiff's counsel, there's no shortage of the therapies. There hasn't been a shortage in City of New York for weeks, and that's set out in the record that's put before the Court. The State is encouraging anyone who is interested in receiving the therapies to discuss that possibility with their doctor.

Now, breaking news last night after the State of the Union, the president is saying that as of next month, a new programs that we've rolled out that anyone who tests positive at a pharmacy will be automatically entitled to receive oral antiviral treatment. Again, there's no shortage here. The plaintiffs may have the ability to go and get this treatment

if they need it. They have not attempted to do so, so they really can't point to any injury that they've suffered here.

THE COURT: I asked this question before and it's really a question for you. Are Dr. Basset's guidelines -- were they distributed to physicians and pharmacists or just the physicians and hospitals, let's say?

MS. KANDEL: That, I don't actually have the answer that question, Your Honor. I know they were distributed to physicians, I don't know if they were distributed to pharmacists.

THE COURT: Do you know how many physicians there are in the State of New York?

MS. KANDEL: Many, but I --

THE COURT: No, I know.

MS. KANDEL: But I could not tell you an exact number.

THE COURT: There are many in Manhattan. But I don't know if it's 75,000 and to whom these guidelines were distributed, whether it was to certain subsets of the total number of physicians only, internists and not psychiatrists. I just don't -- it's nowhere in the papers as far as I could see.

MS. KANDEL: That's certainly information that I could get from my client and bring back to the Court if that would be helpful.

THE COURT: I appreciate it.

Who got the document that is the centerpiece of this litigation?

And it's the same question for the City.

MS. KANDEL: Sure. I can absolutely provide that information at a later date.

I do think it's important to remember, you know, plaintiff's indicated that they would not be troubled by a more holistic approach to laying out the prioritization scheme in terms of who should receive the therapies, which again, are only authorized by the FDA to treat patients at high risk of developing severe COVID-19. That's exactly what these guidelines are intended to do. Their audience is busy practitioners who have received guidance from public health entities before these guidance were issued, both in COVID times and before, who understand what their purpose is, to convey timely, relevant, and clinically appropriate information for them to digest in a quick and easy manner, so that they can then incorporate that into their practice of medicine in which their clinical judgment and their evaluation of the individual circumstances before them based on the patients they're treating is really what is tantamount here. So --

THE COURT: Well, Dr. Heslin's declaration indicates that whatever decision a doctor makes that may not comport

with the technical aspects of this -- of these guidelines would not be the subject of any kind of proceeding against the doctor for malpractice or abuse of his or her authority as a practicing physician.

Is that your position?

MS. KANDEL: That is my position. There's no enforcement mechanism whatsoever connected with these guidance documents.

THE COURT: So is there any other way of telegraphing these considerations to physicians without placing them in a matrix of a kind, that is set forth, you know, in the guidance from the State.

In other words, this makes it look like, you know, if you've got two people who have four different medical -- medically demonstrated comorbidities, but one in the certain category, but one is white and the other one is black, that -- and there's only one pill left, then the black gets the pill. I mean, that's the kind of -- I hate to put it this way, bean counting that these guidelines could be accused of promoting, don't you think?

MS. KANDEL: I don't think, Your Honor. And a couple of points to that. One -- and I mean that is not the way the practice of medicine generally works. Doctors aren't lining up their patients and deciding who gets one last pill. They're looking at the situations before them, the

individualized circumstances to determine whether treatment is appropriate.

Another point is, it is cited right on the face of the part of the guidance that lays out the prioritization tiers. It cites the National Institute of Health's own prioritizations of tiers and says that, again, this is -- this system of prioritization is tied to a time of severe supply limitation which is not the case right now. So it lays out a tier system that expands and mirrors the National Institute of Health's own tier system and applies only in specific circumstance which is not present, when there's a supply limitation of these drugs.

Another point is to get back, again, to the FDA's emergency authorization. It is limited to patients who are at a high risk of developing severe COVID-19, and to the extent that that means in times of severe supply limitation when the National Institute of Health, and in turn, DOH has advised doctors should consider where a patient falls in terms of their level of risk in developing severe COVID-19. To the extent that that system may mean that a vaccinated person under the age of 65 who is white and has no other risk factors isn't an appropriate patient for this treatment, that's something that goes back to the FDA's emergency authorization.

THE COURT: So let's talk about what the president said last night. Let's go back to that.

So assuming I were under 65 with -- in generally good health -- and I can remember those days -- and I go to the CVS and I have a positive COVID test, under what the president is I saying, I could get these, you know, get the medicine right away. I wouldn't have to go to a doctor.

So are we taking the doctor out of this process in a way? I don't have to be subject, because of my -- to the possibility -- the likelihood of being severely impacted by COVID-19 in order to get the medicine now.

MS. KANDEL: That's what it sounds like based on what the president said during the State of the Union. I can't comment on behalf of my clients because this develop had not happened, I had not discussed it with them. But it does sound like that, the doctor is being taken out of the equation, you're going right from testing positive at a pharmacy, to being prescribed those drugs on the spot there at the pharmacy.

THE COURT: So let's go back to the doctor. The doctor now knows that according to the federal government, there's plenty of medicine around. So if I test positive at CVS, I call my doctor and I say, I just tested positive with a PCR test, a test that tends to be more accurate than the rapid tests, and what do I do.

Now, the doctor will say, I'll write you a prescription and you just go right down to -- you just go

right down to the pharmacy and they'll be filling the prescription and you can have it in an hour. So that would be -- it would mean that anyone could get the prescription who tested positive, you wouldn't have to wait five days, you could get it right away?

MS. KANDEL: I will note --

THE COURT: Are you going to be sending out a revision of these guidelines, assuming that the White House is correct, in order to reestablish -- to establish a new protocol?

Are we talking about the protocol that is about to be withdrawn and a new protocol put into place because the medicines are available to everybody?

MS. KANDEL: At this point, I am not aware that they're going to withdraw the policy. I understand, as a general matter, DOH does not rescind guidance, it updates it. So however, I would imagine it does seem to be a fast-moving landscape based on the availability of these drugs, there's no longer a shortage. In fact, there's so many drugs that can be made available to more people. I would imagine particularly if there's a change in the FDA's emergency use authorization for these drugs, there would be updated guidance from DOH, but I can't say that with certainty at this point.

THE COURT: So might that make it a more clearer question on standing if this medicine were available to

everyone?

One of the arguments that's being made by the plaintiff is that even those two plaintiffs do not currently have COVID-19, that they could get it tonight, or be tested positive tonight, and then they'd have to come back -- if this case were dismissed, they would have to find a lawyer -- they have a lawyer -- but they'd have to get a lawyer to bring another case in order to protect their rights to get the medicine because the priorities -- they don't meet the priorities that are set forth in this guidance.

MS. KANDEL: I mean, I believe the increased availability of this drugs makes it more of a clear cut case that they have no standing, because there's no injury. They can go and get the drugs. They haven't tried to do to be able to say that they couldn't.

THE COURT: Well, they're not sick yet. Hopefully, they'll never be sick.

MS. KANDEL: Yes. But they can get the drugs. So I believe it makes an even stronger case for the fact that there's no injury here. Even putting aside, there's no barrier created by the guidance which -- they can keep saying it, but it doesn't direct doctors to treat patients differently based on race.

THE COURT: All I'm being asked here in this moment is -- you're objecting to imposition of a preliminary

injunction?

MS. KANDEL: Absolutely.

THE COURT: And there could still be litigation going forward off that, discovery and so forth.

The question is whether the plaintiffs meet the standards to receive a preliminary relief at this time.

MS. KANDEL: Yes.

THE COURT: And the other point is, let's say they tested positive tomorrow, if I denied preliminary relief today, they could still come back tomorrow, having tested positive, because they are still subject to whatever these guidelines are, their physicians would still be subject to these quote, guidelines, that we're not sure how doctors look at these guidelines.

How do doctors -- how are doctors required to assess their obligations under these guidelines? That's the question that isn't really dealt with here.

MS. KANDEL: I mean, again, the guidelines are not currently -- the guidelines say on their face, are for times of severe shortage of the drugs, and that's not the case at the moment. But how the doctors are supposed to interpret the guidelines, again, I think it's -- they take them for what they are, guidance. It is not dispositive that it doesn't spell out for them that this is guidance that you're supposed to -- you know, don't worry you can keep using your clinical

judgment, you're the person on the grounds who knows best about the individual needs of your patients. They understand that. It's meant to be taken as a public health entity providing accurate and updated information that's relevant to their practice that they can then incorporate into their practice.

I mean, this concern, two brand new oral antiviral treatments that received emergency use authorization. So in addition to discussing risk factors, the guidance also described what the drugs were, what the FDA, you know, use authorization says about which patients should be considered, remind the doctors about considering contra-therapies and any anything that would prevent a patient from not being appropriate for the treatment.

THE COURT: Now, right now, I believe, according to what we're told, that the medicine is in wide availability.

But when there was a shortage, were these guidelines imperatives that one, a doctor would have to utilize the guidelines before making a decision as to whether to prescribe the drug to anyone under their care?

MS. KANDEL: They were not. Again, they were guidance conveying information that the DOH received from the National Institute of Health in terms of how to prioritize patients based on risk in times of the supply shortage and information from gathering information from the CDC about

relevant risk factors to consider in that process.

THE COURT: There was an article that was pointed out by, I think, the plaintiffs here, in the New York Post which -- in which a -- it was pointed out that when a doctor prescribed the -- one of these medicines for his patient, he called in the prescription, the pharmacist asked the race of the patient.

Do you have any rules about pharmacists questioning doctors' prescriptions before providing prescription -- medicines that were prescribed by the doctors?

MS. KANDEL: That's another piece of information I don't have, Your Honor. But I could certainly ask my client if there are rules in that realm. I don't think the fact that this situation described in the New York Post, if it did, in fact, occur --

THE COURT: You can say it. It may not be an accurate description, and if -- you know, you can't always believe everything you read in the newspapers.

MS. KANDEL: And it's certainly not dispositive here. It doesn't show that the guidance created any kind of barrier based on race or that it was intended to be read and used by pharmacists in that way or that it was even connected to that incident at all.

THE COURT: Go ahead.

MS. KANDEL: Just to touch briefly, I think we've

covered standing. Though I will note that it's not just about the lack of a barrier and the lack of an actual injury. Standing isn't met here because any injury isn't traceable to DOH. The guidance doesn't create qualifications based on race and ethnicity. If a doctor -- if a patients, unfortunately, contract COVID-19 and go to their doctor to receive the therapies and they don't receive it tomorrow or some time in the future, that's not because the DOH guidance instructed that that should be the outcome. That would be based on their doctor's assessment of whether they're appropriate for the treatment which as of this moment is only authorized by the FDA for patients who are at a high risk of developing severe COVID-19. And whether that will change in the future, given the president's announcement last night, remains to be seen. But that's the present facts on the ground right now.

They also don't have standing because their injuries aren't redressable by the preliminary relief that they seek. Even if the DOH was ordered to strike any reference to race and ethnicity in the guidelines, doctors still have to make clinical decisions based on available information, and they likely won't ignore the widely publicized objective data showing that race and ethnicity is a risk factor for hospitalization and death in people of non-white race and Latino and Hispanic ethnicity.

And again, the CDC guidance that DOH guidance

tracks, it remains in effect and it advises that race and ethnicity are risk factors for severe COVID. So that is still out there. So even if they were to receive the preliminary relief that they seek which we don't believe that they should, it wouldn't redress their injuries.

THE COURT: Now, there was one other area -- and I'll have the same question for both sides. This Emory University web page that's cited by the plaintiffs regarding COVID-19 deaths by race, do you have up-to-date data on COVID-19 deaths and other relevant data such as ventilator use that's suggested for percentages of the population that are of different races?

MS. KANDEL: Yes.

THE COURT: Is there more definitive documentation as to the percentage of those individuals who have tested positive for COVID-19, of different races, who have different types of remediation, whether hospitalization or within hospitalization, having individuals placed on ventilators, the percentage of those who died of different races, as a percentage of the total population, for instance, of individuals of that race in New York?

MS. KANDEL: Yes. I believe that data exists. It's spread across several sources and the CDC collects data to that effect, as does the National Institute of Health.

THE COURT: Well, if we go forward, beyond this

preliminary relief, that would be an area for investigation.

MS. KANDEL: I would just note with regard to the Emory website as there appears to be disparity between the data that plaintiff cite and the data from Emory that State defendants in the amicus cite. The data that the defendants -- and perhaps the City as well, I honestly can't recall if they cite the Emory data, as well -- but the DOH and the amicus pull the data from the Emory page where you click on New York and you bring up the New York specific information on the Emory dashboard. And that's where we pulled the numbers that are reflected in our papers.

I believe, according to the screenshot, that plaintiff's counsel attached to their reply declaration that they were referring to data that comes up when are on the main Emory page with the United States map, and you hover your mouse over New York, some different numbers come up, apparently. But as the amicus point out in their brief, the numbers that are actually reflected when you actually click on New York, go to the New York specific page of the Emory website, that the data reflected there is supported by other research that's amply cited in the amicus curiae brief.

THE COURT: I would -- just before you sit down, let me just point out that on the -- in reviewing the amici submission, I noticed that one of the amici, Dr. Robert L. Cohen, who was a city health department official at some

point, he and I went to high school together. But I just wanted to mention that. It's nice to see that he's had a career beyond Bayside High School.

MS. KANDEL: I'm sure he feels the same about you.

THE COURT: Thank you. But you never know when these things are going to come up, small world that it is.

Okay. Anything else?

MS. KANDEL: All would just add -- since we addressed mootness to some degree, I think, again, the lack of the shortage of the therapies goes to mootness here. There is no live case or controversy here.

THE COURT: I think there's a Supreme Court case on nominal damages that may defeat mootness.

MS. KANDEL: Nominal damages, money damages are barred under the Eleventh Amendment to be collected against state officials sued in their official capacity. So we would submit that seeking nominal damages is not enough to get over the mootness --

THE COURT: The 11th Amendment comes roaring into this consideration.

MS. KANDEL: As it does.

THE COURT: That's your job to tell me that, I know.

MS. KANDEL: I would also note that in terms of this case moving forward, defendants, certainly based on the Article Three issues, standing and mootness, do intend to move

to dismiss. So I know we are only discussing a motion for preliminary injunction at this point, but we believe it's abar to the case proceeding, in general.

THE COURT: Thank you very much. I appreciate it.

MS. KANDEL: Thank you.

THE COURT: Would the City like to say a few words about this too?

MS. SCHONFELD: Yes, Your Honor.

THE COURT: Please. Be my guest.

MS. SCHONFELD: Good morning. Samantha Schonfeld for the City Department of Health.

THE COURT: Ms. Schonfeld, welcome.

MS. SCHONFELD: I'm not going to reiterate the State's arguments regarding standing. The City adopts those and that's also in our paper. We echo the state on that.

What I really would like to bring to the Court's attention is that last night we got clarification from the City Department of Health that the December 27th guidance at issue herein has been superseded and is no longer in effect. It was superseded by a health advisory note dated February 2nd, 2022, which advised everyone involved in the health network that there's now a surplus or now available medicines. The December 27th guidance is no longer on the therapeutics page on the Department of Health website, and we took that off. The department -- the City Department of

Health took that off because they felt that if they left it on, it would discourage prescribers from prescribing medicines that are now in surplus.

THE COURT: I see. Okay. All right. Well, we'll get back to that again. I'll hear from plaintiff's counsel about that.

So what you're saying is that the City's prior recommendations, set of recommendations to -- or whatever, to physicians is no longer at stand. In other words, it's been superseded by this latest notification?

MS. SCHONFELD: That's correct, Judge.

THE COURT: Okay. As of the second of February?

MS. SCHONFELD: As of February 2nd, yes, Your Honor.

THE COURT: Do you have a copy of it? Do you want to provide a copy of it?

MS. SCHONFELD: I could provide a copy of it.

THE COURT: I think you should provide it to plaintiff, to the State, and to the Court.

MS. SCHONFELD: I can provide it at a later time, Judge.

THE COURT: You can just fax it over.

MS. SCHONFELD: Okay. I'll fax it and e-mail it over to counsel.

THE COURT: That's great. Go ahead.

MS. SCHONFELD: Yes. It still remains on the

Department of Health website in terms of archives, because we archive all of the preview guidance, but it's no longer on the therapeutics page. So for that reason, we'd argue that any arguments against the City are moot as the challenge guidance has been superseded, no longer in effect. That's the point that I'd really like to highlight.

And then in terms of meeting the prongs of a preliminary injunction relief, there's no irreparable harm here. As the Stated noted in their argument, there's no injury right now. There's no emergency. There's no reason for emergency relief right now. There's plenty of medicine in the city. There's a surplus right now, as Dr. Moore stated in her declaration, and as you noted in the commercials on T.V., everyone's urging people to get treated. There's tons of treatment available.

And that's the basis of our argument right here, Judge. If you have any questions.

THE COURT: Not for you.

MS. SCHONFELD: Thank you.

THE COURT: Is the State considering filing suit with the City's determination? Are you aware one way or another?

MS. KANDEL: I'm not. At this point, I've been told there were not plans to rescind the guidance. I can certainly -- there have been develops since I last discussed

with them. I can certainly circle back.

THE COURT: If you circle back to the commissioner and there's any revision of thinking, do advise everybody.

MS. KANDEL: Thank you, Your Honor. I will.

THE COURT: Thank you. All right. Sir.

MR. FA: Thank you, Your Honor. So a few points on rebuttal. Ms. Kandel, I believe, mentioned that nominal damages barred against the State. But here we have the State and the City as defendants. Nominal damages not barred against the City. And there are cases -- I'm not sure about the Second Circuit, but there are cases in the Fifth Circuit which say that --

THE COURT: The Fifth Circuit?

MR. FA: Which if you have two -- if you have State and City defendants, all in one case, then nominal damages is appropriate to be requested in the complaint.

THE COURT: Well, see if you can find something in the Second Circuit.

MR. FA: Yes, I will. And I also wanted to note that the February 2nd health advisory notice that I think Ms. Schonfeld just mentioned was actually -- it was cited in their declaration and we mention it in our reply. As I recall, that particular piece of -- that particular document does not say anything about superseding the preview health advisory notice. And although the title of it is that

PAXLOVID™ is now available, I believe the end of that document as we mentioned in our reply, says that -- said that supplies are limited, at least, at the time it was issued which was early February. So I would say that, in addition, as Ms. Kandel noted, the State has not withdrawn the guidance, they have not updated the guidance, the guidance -- New York does note, as I believe I mentioned in Exhibit 3 to my declaration, there are guidance documents that say it's archived, but the guidance document for the COVID-19 prioritization was still listed as current, at least, as of Sunday.

You know, and we don't know when -- you mentioned President Biden's State of the Union address. We don't know when and we haven't heard anything about when the supplies are going to be made readily available. I think I heard Ms. Kandel say something like next month. But that still leaves at least a month where plaintiffs could get infected with COVID and they would only have five days, not just to seek a retraining order, but to get a restraining order from this Court. So I think the practical effect of denying preliminary relief which is to say that no plaintiff would be able in practical -- in all practicality to get preliminary relief.

THE COURT: This isn't a class action though.

MR. FA: No, it's not a class action. I think even

in a class action, the named plaintiff has to have standing. So even if it were a class action, I don't think that would make a difference for purposes of whether --

THE COURT: Well, I mean, if you were arguing that members of the class who don't even know that they're members the class, you know, might be adversely impacted by the inability to get the medicine based upon the arguable fact that somebody else got it because they were a person of color or Hispanic. You know, I mean -- but these two plaintiffs would definitely know that they would have access to you to request injunctive relief if I didn't provide it now.

MR. FA: Sure. And we could request injunctive relief. But as the directives themselves say, it's five days within symptom onset. We would not just have to request it, we would have to get it, and that's a very very short timeline.

With respect to -- you know, I think it is important here that we're seeking prospective relief and coronavirus has gone through many surges. It's endemic. It is something that the FDA commissioner has recently said that most people are going to get it. So I think we're looking at on-the-ground effects and what is likely in the context of a preliminary injunction motion. I think what is likely is that you will have New Yorkers wanting this medication, and you know, the State and the City themselves mention that there are -- as the

last two years have taught us, there are likely supply shortages.

With respect to the 75,000 number, that's not something that we just kind of created. That's in the Moore's declaration from the City, paragraph 22. They sent this out to 75,000 e-mail addresses including medical providers, professionals, and other interested parties.

I would also note that --

THE COURT: I don't know what other interested parties means, that's why I asked the question.

MR. FA: Understood, Your Honor. And with respect to your question about the pharmacies, it's certainly the case in New York City and I believe it may be the case in the State as well, where these -- the State is the supplier of these antivirals, and they say that to ensure equitable access, they've only partnered with, usually, one to two pharmacies in each jurisdiction. So New York City only has Alto Pharmacy, A-L-T-O Pharmacy, as its provider.

THE COURT: I don't even know who that is.

MR. FA: I think the list of pharmacies in the state is listed either Exhibit A or Exhibit B to our initial preliminary injunction motion.

THE COURT: Yeah. But if the medicine is more widely available, it's clear, is it not, or at least arguably expected that many many pharmacies will have availability to

fill the prescriptions. They're not going to give it to one pharmacy if it's widely available like other widely available medicines for other illnesses.

MR. FA: I think the limited -- the availability point goes to sort of, you know, what is the State doing to enforce its guidelines that it believes is ensuring equitable access. It's true that, you know, if supplies indefinitely overwhelmed is in excess of demand, then pharmacies may not have to make the same decision. But I think as we say and as defendant's declaration show, there's just no certainty that it will be abundant.

With respect to the enforcement part, you know, I think this is a situation where the State is prompting third parties to do a lot of enforcement in how to allocate certain guidance. So I don't think the fact that the state has disavowed any sort of penalties on physicians or providers for not following the guidance really matters here. I mean, as a hypothetical, I'm certain the State would not do this and I hope for the sake no state would do this today. But if a state issued a guidance document telling restaurant owners to discriminate on the basis of race by not serving African Americans, I think some restaurant owners might follow that, other restaurant owner, I would hope would just ignore it. But regardless, I think if we had an African American who wanted to go to restaurants, that person would be able to

assert Article Three standing because his options are limited and that's fairly traceable to the guidance issued by the State. And I would note that --

THE COURT: But in this case, your clients have not been -- have not shown that they are COVID positive. And so they would not be even considered for a prescription drug to deal with their COVID positivity. I mean, they've been good citizens, they went and they got the vaccine, and they're not COVID positive, and they are simply projecting what will happen if I become COVID positive and I go to the doctor and I get told, you know, there's someone in line who's ahead of you because -- and that's a person of color with the same comorbidities as I have.

MR. FA: So I think the question in a case for prospective relief is whether there is a State-created barrier. So the hypothetical I was talking about earlier, I don't think an African American person needs to go to different restaurants and wait to get denied at a restaurant first. I think in a case for prospective relief, you would be able to just say that your opportunities are limited in times of limited supply as the directive's plain texts shows. And I think the practicalities here add even to that in that you only have five days within symptom onset to be able to take these antivirals. And I think the defendants, the State defendants -- the City doesn't really make this point -- but

the State defendant's arguments as to traceability and redressability really conflate the doctrine on this issue which says that if there's one barrier along with other barriers, then it's still traceable and it's still redressable about a favorable court decision. As we cite in the reply in the Hempstead case there are many cases saying that you don't have to prove that a Court will be able to afford full and complete relief in every single case.

THE COURT: Would it be a malpractice for a doctor facing someone with comorbidities who's white who has likelihood of being severely impacted by COVID, to deny writing a prescription because there were other people out there, not his patients or who might be his patients, who also who are African American or Hispanic, and they might also need medication for COVID? Wouldn't that be a violation of their obligation to this white patient, notwithstanding anything that the guidelines show. Do they have a higher duty? Is this basically a hypothetical that is unlikely to occur and there's no real damage here because doctors act like doctors and not like politicians or government bureaucrats? Is this what this is about? Are we -- are you making a mountain of out of a molehill here?

MR. FA: No, your Honor. It's not a hypothetical. And defendants have stressed in their responses that the use of race in the directives is necessary to ensure that

antivirals go to the patients that most need it in times of limited supply. So regardless of any enforcement mechanisms that might be in the guidance itself, you know, they want doctors and physicians and providers to enforce what the directives actually say. And they couldn't have it both ways. They can't say on the one hand this is so important to ensure equitable treatment, this is important to dismantling what they consider racially discriminatory system, and also at the same time say that in the real world, doctors are going to do whatever they want.

THE COURT: Do you think if a doctor says my patient -- my white patient should go into the hospital because he has the likelihood of having a severe reaction to COVID, that that person would be denied admission to the hospital because there's also an African American patient with the same comorbidities and the same likelihood of serious reaction to COVID?

Is this something -- is this something -- does this lack a certain realism on your part?

MR. FA: I don't think so, Your Honor. And I think a part of that --

THE COURT: Maybe that's what happens in California. I'm serious about that. I mean, you come here with two people who are healthy, and what the State is attempting to do -- and I'm not saying they're right -- but what they're attempting to

do is address a social and historical imbalance that has existed for many many years because of circumstances that were not of our making, and there's a sensitivity there on the part of the State, but I'm wondering whether when looking at individual cases of positivity, that there would be a reluctance on the part of the medical community to treat everybody's condition as effectively as possible based on the circumstances of that particular patient.

MR. FA: So I hope doctors do treat patients on the basis of their individualized circumstances. At the time that the directives were adopted, we were facing the largest surge of coronavirus cases ever, and with a very very limited supply of PAXLOVID™ oral antivirals. So this is an emergency situation and a situation in which the State has decided to prioritize individuals on the basis of many factors, and the only one that we object to is the use of race as independent factor that prioritizes in the time of scarcity, an individual who is non-white over an individual -- identically situated individual who is white.

And I would say that this coronavirus pandemic, as we all know in the past couple of years, is not just limited to the State of New York. It effects people all over the country and all over the world. Many other states have adopted similar guidelines for the distribution and allocation of rare COVID-19 treatments. Some states like the State of

Washington do not use race. Other states did use race such as Utah and Montana, and they have withdrawn the use of race, and there's no reason that the State cannot do the same thing. They talk about race as being correlated with certain poor outcomes and we don't necessarily dispute that, but that's something that's quite different from saying that race leads to poor outcomes. In fact, there are CDC documents that say that race is not likely genetically or biologically lead by itself to poor COVID-19 outcomes.

THE COURT: Well, genetically and biologically are just one area. But there are also conditions that people of color experience such as the lack of appropriate medical care, poor housing conditions, poor -- the inability to have diets that are healthy, and other circumstances that are sociological or economic that lead to poorer health. So I think it may be -- someone's health large has potential to be a -- to result in a poorer outcome if someone gets sick, right?

MR. FA: So I think the purpose of the Equal Protection Clause is to ward off racial stereotyping by the Government. So it's certainly true, Your Honor, that race could be correlated with things, as defendants say, lack of insurance, you know, communities' socioeconomic status in some cases --

THE COURT: Lack of access to medical care.

MR. FA: Sure. And I think the purpose of the Equal Protection Clause is to focus the Government's efforts on addressing those race-neutral factors to get doctors to see whether any particular patient really lacks health insurance, lacks access to medical care, takes public transportation, for example. Instead of using a crude racial proxy, for example, defendants talk about individuals that live in minority communities, but that's not what the risk factor is assigned to. The risk factor is assigned to race. So you could have a white individual living in a minority community that suffers -- faces all the barriers that defendants mention, and that person would not get an additional risk factor solely on the basis of race. And they talk about --

THE COURT: Well, the thing is, I have a -- an internist. The internist knows me because I've got insurance, this is my internist, I have a record with my internist. In fact, these days, the records are in some cloud somewhere, all right. But this other individual who doesn't have insurance, doesn't go to the doctor because it's too expensive, has had all these different circumstances that are not, quote, racial, but are affected by race, goes to the doctor, has COVID, and -- doesn't the doctor need to consider race, at least, initially to find out is this person someone who's been -- who has had medical care, who's, you know, had good nutrition, and isn't it a -- isn't it a -- doesn't it provide a -- the

doctor, a doctor, with an alarm belt, in effect, as to whether this is a person who is more likely to get sick, sicker, because this person hasn't had the benefits of being a middle class white guy with health insurance?

MR. FA: So I don't think a doctor must consider race, but if a doctor, you know, uses race in a way that does not instill a racial prefetence, I think that would be a different case.

I think the Government's lawyer talked about holistic consideration. I think holistic consideration, you know, there can be holistic consideration in which race is used but not as a racial preference and that might be a different case. But there's also a holistic situation where there might be a racial preference and I think we may object to that. But in any case, holistic consideration is not simply what the guidelines say. The guidelines do not provider for -- on its face, do not provide for individualized consideration. It is, as Your Honor, sort of tallying up of different risk factors, including race as an independent risk factor, and I think that sort of bean counting, the Supreme Court has said over and over again in cases like *Gratz versus Bollinger*, that it fails strict scrutiny.

And I would mention one additional fact about race neutral factors whether -- for example, whether if race was correlated with socioeconomic status or lack of insurance.

That may be the case and if that were the case, we would encourage the Government use racial-neutral alternatives to focus on socioeconomic status, to focus on lack of insurance. Such programs might well disproportionately benefit minorities and people of certain communities, but they would not mechanically treat people on the basis of race. And I think that's why that hypothetical program would be on much sounder constitutional footing than this program.

THE COURT: Okay. Anything else from the State or the City?

MS. KANDEL: No, your Honor, unless have you any additional questions.

THE COURT: Okay. All right. Okay. That's fine.

I'll reserve on the motion for a preliminary injunction. I'd like to thank everyone for being here today, and the materials that I had requested, please provide them to the Court as soon as possible.

Thank you. Have a nice day.

(Whereupon, the matter was concluded.)

* * * * *

I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

s/ Avery N. Armstrong
AVERY N. ARMSTRONG

April 18, 2022
DATE

AVERY N. ARMSTRONG, RPR
Official Court Reporter

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system on May 12, 2022.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

s/ Wencong Fa
Wencong Fa