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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Counsel for Plaintiffs

**Pro Hac Vice Pending*

JS 44 (Rev. 4-29-21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Jonathan Roberts, Charles Vavruska

(b) County of Residence of First Listed Plaintiff New York
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Jonathan M. Houghton, Pacific Legal Foundation, 3100 Clarendon Blvd, Suite 610, Arlington VA 22201, 916-419-7111

DEFENDANTS

Mary T. Bassett, in official capacity as Comm'r, NY St. Dep't of Health; Dep't of Health and Mental Hygiene of the City of New York

County of Residence of First Listed Defendant Albany
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

Does this action include a motion for temporary restraining order or order to show cause? Yes☐ No☑"

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☒ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
42 USC 1983, U.S. Const. amend. XIV

Brief description of cause:
Defendants' use of racial classifications in prioritizing Covid-19 treatment allocation violates Equal Protection.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER [see attachment]

DATE 2/8/2022

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.7 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of $150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

Case is Eligible for Arbitration ☐

I, Jonathan M. Houghton, counsel for Plaintiffs, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

☐ monetary damages sought are in excess of $150,000, exclusive of interest and costs,

☑ the complaint seeks injunctive relief,

☐ the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks:

No plaintiff is a corporation.

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County? ☐ Yes ☑ No

2.) If you answered "no" above:

a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? ☐ Yes ☑ No

b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? ☑ Yes ☐ No

c) If this is a Fair Debt Collection Practice Act case, specify the County in which the offending communication was received:

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? ☐ Yes ☐ No

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

☑ Yes ☐ No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

☐ Yes (If yes, please explain ☑ No

I certify the accuracy of all information provided above.

Signature: _____

Attachment

The following cases are arguably related pursuant to Division of Business Rule 50.3.1:

(1) *Jacobson v. Bassett*, 3:22-cv-00033-MAD-ML (N.D.N.Y. Filed Jan. 16, 2022) (assigned to Judge D'Agostino); and

(2) *Foundation Against Intolerance and Racism, Inc. v. City of New York et al.*, 1:22-cv-00528-KPF (S.D.N.Y. Filed Jan. 20, 2022) (assigned to Judge Failla).

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

Jonathan Roberts and Charles Vavruska

Plaintiff(s)

v.

Mary T. Bassett, in her official capacity as Comm'r for NYS Dep't of Health; and the Dep't of Health and Mental Hygiene for the City of New York

Defendant(s)

Civil Action No. 1:22-cv-00710

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Mary T. Bassett, Commissioner
New York State Department of Health
Corning Tower
Empire State Plaza,
Albany, NY 12237

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Jonathan M. Houghton
Pacific Legal Foundation
3100 Clarendon Blvd. Suite 610
Arlington VA 22201

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

BRENNA B. MAHONEY
CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:22-cv-00710

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

Jonathan Roberts and Charles Vavruska

Plaintiff(s)

v.

Mary T. Bassett, in her official capacity as Comm'r for NYS Dep't of Health; and the Dep't of Health and Mental Hygiene for the City of New York

Defendant(s)

Civil Action No. 1:22-cv-00710

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

NYC Department of Health and Mental Hygiene
125 Worth Street
New York, NY 10013
OGC@health.nyc.gov

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jonathan M. Houghton
Pacific Legal Foundation
3100 Clarendon Blvd. Suite 610
Arlington VA 22201

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BRENNA B. MAHONEY
CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:22-cv-00710

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Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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

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

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

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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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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