UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK
BINGHAMTON DIVISION

William A. Jacobson, on behalf of himself and others similarly situated,

Plaintiff,

v.

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

Defendant.

Case No. 3:22-CV-33 (MAD/ML)

CLASS-ACTION COMPLAINT

The New York Department of Health recently established guidelines for medical providers to give automatic priority to "non-whites" and individuals with "Hispanic/Latino ethnicity" in distributing life-saving COVID-19 treatments. *See* Memorandum of December 27, 2021 (attached as Exhibit 1). Under these guidelines, non-Hispanic white individuals who test positive for COVID-19 are ineligible for oral antiviral treatments unless they also demonstrate "a medical condition or other factors that increase their risk for severe illness." *Id.* at 2. But similarly situated "non-white" or "Hispanic/Latino" individuals are *automatically* eligible for these life-saving antiviral treatments—regardless of the individual's medical situation—because New York has proclaimed that one's status as a racial or ethnic minority is itself a "risk factor" for severe illness from COVID-19, even if the individual has no pre-existing condition that would make him more susceptible to harm from COVID-19. In the words of the Department of Health:

> 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.

Id. at 2. The result is that a "non-white" or "Hispanic/Latino" individual who tests positive for COVID-19 automatically qualifies for these life-saving oral antiviral treatments, while an identically situated non-Hispanic/Latino white individual is ineligible for these treatments unless he demonstrates a "medical condition" or "risk factor" that increases his risk for severe illness from COVID-19. New York's use of racial preferences in the distribution of COVID-19 treatments is patently unconstitutional and should be immediately enjoined.

Using a patient's skin color or ethnicity as a basis for deciding who should receive lifesaving medical treatment is appalling. And directing medical professionals to award or deny medical care based on immutable characteristics such as skin color, without regard to the actual health condition of the individual who is seeking these antiviral treatments, is nothing more than an attempt to establish a racial hierarchy in the provision of life-saving medicine. Worse still, New York's racial preferences ignore the obvious race-neutral alternative policy of making antiviral treatments available to patients of *any* race who can demonstrate risk factors, such as advanced age, obesity, a compromised immune system, or other medical conditions.

JURISDICTION AND VENUE

1. The Court has subject-matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1343.

2. Venue is proper because a substantial part of the events giving rise to the claims occurred in this district and division. *See* 28 U.S.C. § 1391(b).

PARTIES

3. Plaintiff William A. Jacobson is a citizen and resident of Tompkins County, New York, where he teaches law at Cornell University.

4. Defendant Mary T. Bassett is the Acting Commissioner of the New York Department of Health. She can be served at the New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York, 12237. Plaintiff sues her in her official capacity.

STATEMENT OF FACTS

5. On December 27, 2021, the New York Department of Health issued a memorandum to health-care providers and health-care facilities entitled "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products." Its stated purpose is to make health-care providers and facilities in New York "aware of information about available COVID-19 outpatient therapeutics, including newly authorized oral antiviral treatments." A copy of this memorandum is attached as Exhibit 1.

6. The memorandum defines a patient's "eligibility" for these oral antiviral treatments, and it states as follows:

> 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

Exhibit 1 at p. 2 (emphasis added).

7. The memorandum directs health care providers and health care facilities within New York to "adhere" to the Department's "prioritization" instructions because of the "severe shortage of oral antiviral and monoclonal antibody treatment products."

8. Relatedly, on December 29, 2021, the New York Department of Health issued further guidance on the matter 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." A copy of this guidance is attached as Exhibit 2. The guidance has a chart that advises medical providers on how to make decisions about patients within certain groups—including based on the number of risk factors present for an individual within each group—and notes 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." Exhibit 2 at p. 3.

9. New York's policy creates a racial hierarchy in the distribution of life-saving COVID-19 medication. Non-white and Hispanic/Latino individuals who test positive for COVID-19 automatically qualify for oral antiviral treatments, while an identically situated non-Hispanic/Latino white individual is ineligible unless he demonstrates a "medical condition" or "risk factor" that increases his risk for severe illness from COVID-19.

10. New York's use of racial preferences to distribute COVID-19 treatments violates the Constitution and numerous federal statutes.

11. Due to the highly contagious Omicron variant, the number of Americans contracting COVID-19 is skyrocketing. "As of January 12, 2022, the current 7-day moving average of daily new cases (782,766) increased 33.2% compared with the previous 7-day moving average (587,723)." Centers for Disease Control and Prevention,

COVID Data Tracker Weekly Review, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html (last accessed January 16, 2022). As the FDA Commissioner recently testified, "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), https://wapo.st/3fqyxVt.

12. New York State has been averaging more than 60,000 new COVID cases per day since January 1. Tompkins County, with a population of just over 100,000, has recently been averaging more than 200 cases per day.

13. Plaintiff does not qualify under the New York guidelines as "[n]on-white race or Hispanic/Latino ethnicity," and he sues on behalf of a plaintiff class consisting of individuals in New York State who do not qualify under the New York guidelines as "[n]on-white race or Hispanic/Latino ethnicity."

14. Plaintiff is especially at risk for contracting COVID-19 because he teaches at Cornell University, which recently had a severe outbreak despite its extensive COVID protocols. Madeline Rosenberg and Anil Oza, *COVID-19 Update: Cornell Reports Record--High 469 Active Student Cases*, Cornell Sun (Dec. 13, 2021), https://bit.ly/3GBXrx5.

15. Plaintiff is suffering injury in fact from New York's racially discriminatory policy because he and other non-Hispanic/Latino white individuals cannot obtain oral antiviral treatments in New York when they contract COVID-19 unless they demonstrate a "medical condition or other factors that increase their risk for severe illness" from the virus, while non-white and Hispanic/Latino residents of New York are not required to make such a showing. This discriminatory treatment inflicts injury in fact, regardless of whether Plaintiff and his fellow class members would ultimately obtain the antiviral treatments in the absence of New York's racially discriminatory policy. *See Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 666 (1993) ("When the government erects a barrier that makes it

more difficult for members of one group to obtain a benefit than it is for members of another group, a member of the former group seeking to challenge the barrier need not allege that he would have obtained the benefit but for the barrier in order to establish standing. The 'injury in fact' in an equal protection case of this variety is the denial of equal treatment resulting from the imposition of the barrier, not the ultimate inability to obtain the benefit.").

16. New York's policy also injures Plaintiff and his fellow class members by subjecting them to an increased risk of serious illness or death when they acquire COVID-19. *See Massachusetts v. EPA*, 549 U.S. 497, 525 n.23 (2007) ("[E]ven a small probability of injury is sufficient to create a case or controversy—to take a suit out of the category of the hypothetical—provided of course that the relief sought would, if granted, reduce the probability") (quoting *Village of Elk Grove Village v. Evans*, 997 F.2d 328, 329 (7th Cir. 1993)); *Baur v. Veneman*, 352 F.3d 625, 633 (2d Cir. 2003) ("[C]ourts of appeals have generally recognized that threatened harm in the form of an increased risk of future injury may serve as injury-in-fact for Article III standing purposes.").

17. Finally, New York's policy injures Plaintiff by inflicting emotional and psychological harm on Plaintiff (and others) who are facing increased risk of harm from the pandemic on account of New York's racially discriminatory policies. *See TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2211 (2021) ("[A] plaintiff's knowledge that he or she is exposed to a risk of future physical, monetary, or reputational harm could cause its own current emotional or psychological harm.").

18. All of these injuries are fairly traceable to the racial preferences enforced by Acting Commissioner Bassett, and they will be redressed by declaratory and injunctive relief that prohibits the Commissioner from using racial criteria in determining eligibility for COVID-19 oral antiviral treatments.

Claim 1: The Department's Racial Preferences Violate The Fourteenth Amendment

19. The Fourteenth Amendment prohibits state officials from discriminating on account of race or ethnicity. *See Shaw v. Hunt*, 517 U.S. 899, 907 (1996) ("Racial classifications are antithetical to the Fourteenth Amendment, whose central purpose was to eliminate racial discrimination emanating from official sources in the States.").

20. The New York Department of Health is violating the Fourteenth Amendment by discriminating on account of race in determining eligibility for COVID-19 oral antiviral treatments.

21. The Department's policy fails any level of constitutional scrutiny. Even if the Department has an interest in ensuring that only the most at-risk patients will receive scarce antiviral treatments, the policy's racial preferences are not closely or narrowly tailored to achieving that interest. The Department could have effectively pursued the same goals through the obvious race-neutral alternative of requiring *all* patients to have enumerated medical conditions or risk factors in order to receive antiviral treatments.

22. The Court should declare the Department's racial preferences unconstitutional and permanently enjoin the Acting Commissioner from enforcing them.

23. Plaintiff brings this claim under the causes of action established in 42 U.S.C. § 1983 and the Declaratory Judgment Act.

Claim 2: The Department's Racial Preferences Violate Title VI

24. Title VI of the Civil Rights Act of 1964 prohibits discrimination on the grounds of race, color, or national origin in any program that receives federal funds. *See* 42 U.S.C. § 2000d.

25. The New York Department of Health is violating Title VI by discriminating on account of race in programs that receive federal funds.

26. The Court should declare the Department's racial preferences violate Title VI and permanently enjoin the Acting Commissioner from enforcing them in any program that received federal funds.

27. Plaintiff brings this claim under the causes of action in 42 U.S.C. § 1983, the Declaratory Judgment Act, and Title VI.

Claim 3: The Department's Racial Preferences Violate Section 1557 Of The Affordable Care Act

28. Section 1557 of the Affordable Care Act prohibits racial discrimination in any health program or activity that receives federal financial assistance. *See* 42 U.S.C. § 18116.

29. The policy announced by the New York Department of Health violates section 1557 by inducing health-care providers that receive federal funds to discriminate on account of race when determining a patient's eligibility for life-saving medicine.

30. The Court should declare the Department's racial preferences violate section 1557 and permanently enjoin the Acting Commissioner from enforcing them against any health care provider that receives federal funds.

31. Plaintiff brings this claim under the causes of action in 42 U.S.C. § 1983 and the Declaratory Judgment Act, and 42 U.S.C. § 18116(a).

DEMAND FOR RELIEF

32. Plaintiff respectfully requests that the court:

a. certify a class of individuals in New York State who do not qualify under the New York health department guidelines for distribution of COVID-19 therapeutics as "[n]on-white race or Hispanic/Latino ethnicity";

b. award the declaratory relief described in paragraphs 22, 26, and 30;

c. enter a preliminary and permanent injunction that restrains Acting Commissioner Bassett and her successors from implementing and enforcing any discriminatory racial preferences in the Department's programs;

d. award costs and attorneys' fees under 42 U.S.C. § 1988;

e. award all other relief that the Court may deem just, proper, or equitable.

Respectfully submitted.

/s/ James P. Trainor

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Dated: January 16, 2022

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

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

JS 44 (Rev. 10/20)

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

William A. Jacobson, on behalf of himself and others similarly situated

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Gene P. Hamilton, America First Legal Foundation, 300 Independence Ave SE, Washington, DC 20003, (202) 964-3721; Jonathan F. Mitchell, Mitchell Law PLLC, 111 Congress Ave, Suite 400, Austin, Texas 78701, (512) 686-3940; Adam K. Mortara, Lawfair LLC, 125 South Wacker Dr. Suite 300, Chicago, Illinois 60606, (773) 750-7154, adam@mortaralaw.com; Jeffrey Harris, Michael Connolly, & James Hasson, Consovoy McCarthy PLLC, 1600 Wilson Blvd, Suite 700, (703) 243-9423; James P. Trainor; Trainor Law PLLC, 2452 U.S. Route 9, Malta, New York 12020 (518) 899-9200

DEFENDANTS

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

County of Residence of First Listed Defendant
(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)*

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)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 880 Defend Trade Secrets Act of 2016	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	SOCIAL SECURITY	☐ 480 Consumer Credit (15 USC 1681 or 1692)
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 861 HIA (1395ff)	☐ 485 Telephone Consumer Protection Act
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 196 Franchise				☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
				☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
					☐ 893 Environmental Matters
				FEDERAL TAX SUITS	☐ 895 Freedom of Information Act
				☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 896 Arbitration
				☐ 871 IRS—Third Party 26 USC 7609	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
					☐ 950 Constitutionality of State Statutes

REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION
☐ 210 Land Condemnation	☒ 440 Other Civil Rights	**Habeas Corpus:**	☐ 462 Naturalization Application
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence	
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General	
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty	
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	**Other:**	
	☐ 448 Education	☐ 540 Mandamus & Other	
		☐ 550 Civil Rights	
		☐ 555 Prison Condition	
		☐ 560 Civil Detainee - Conditions of Confinement	

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 U.S.C. § 1983, 28 U.S.C. 2201, 42 U.S.C. § 2000d, 42 U.S.C. § 18116(a)

Brief description of cause:
Challenge to New York's decision to ration and distribute life-saving COVID-19 treatments according to race

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 _____

DATE
January 16, 2022

SIGNATURE OF ATTORNEY OF RECORD
/s/ James P. Trainor

FOR OFFICE USE ONLY

RECEIPT # ANYNDC-5772657 AMOUNT $402.00 APPLYING IFP _____ JUDGE MAD MAG. JUDGE ML