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

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

Plaintiff,

-against-

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

Defendant.

DECLARATION OF EUGENE HESLIN, M.D., FAAFP

Case No. 3:22-cv-00033(MAD)(ML)

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

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

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

3. During the COVID-19 pandemic I have supported the response, initially working with a testing site in New Rochelle, subsequently working with hospitals and alternative care sites most recently working with the vaccination site opening at the Javits Center, providing support for the Commissioner and for the Office of Primary Care Health Systems Management ("OPCHSM"), projects and working with supporting the Covid therapeutics.

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

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

BACKGROUND ON COVID

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

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

8. As Commissioner Bassett stated in her testimony on February 8, 2022, at the Joint Legislative Public Hearing on the State Fiscal Year 2022-2023 Executive Budget Proposal ("Joint Public Hearing")[1], DOH efforts have been successful in leading to a 90 percent drop in

[1] Joint Legislative Public Hearing on 2022 Executive Budget Proposal: Topic Health/Medicaid | NY State Senate (nysenate.gov)

the state's positivity rate in the last month. The February 17, 2022 state-wide cluster dashboard attached hereto as **Exhibit AA** identified one new cluster in state with 4 associated cases.

9. It is my understanding that Plaintiff brought this litigation challenging specific portions of the guidance issued by DOH entitled "COVID-19 Oral Antiviral Treatments Authorized and Severe Shortage of Oral Antiviral and Monoclonal Antibody Treatment Products" ("Guidance"). A copy of the Guidance is attached hereto as **Exhibit A**. This publication is guidance and is not a "treatment policy". There is no "scoring system" and you do not have to "get enough points" in order to receive the medication as Plaintiff asserts. It was issued by the DOH, to health care providers and health care facilities on December 27, 2021, concerning, among other things, the treatment and prevention of severe COVID-19 with oral antivirals within certain categories, including those with risk factors for severe illness.

THE GUIDANCE AND ITS SCIENTIFIC BASIS

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

11. As a result, the DOH released the December 27, 2021, Guidance to make providers and hospitals aware of the newly authorized treatments. A copy of the Guidance is attached hereto **Exhibit A.** Additionally, the Guidance was meant to address factors to be

considered when administering therapies amongst tranches of patients considering supply shortages.

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

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

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

***See* Exhibit A (emphasis added).**

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

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

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

17. Additional evidence supports these findings. A National Center for Health Statistics 2020 Report: showed a disproportionate impact on life expectancy due to the COVID-19 pandemic. From 2019 to 2020, Hispanic people experienced the greatest drop in life

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[2] *See* https://www1.nyc.gov/assets/doh/downloads/pdf/han/advisory/2021/covid-19-oral-treatments-authorized-shortage.pdf

[3] *See* https://www.cdc.gov/mmwr/volumes/71/wr/mm7103e1.htm?s_cid=mm7103e1_w

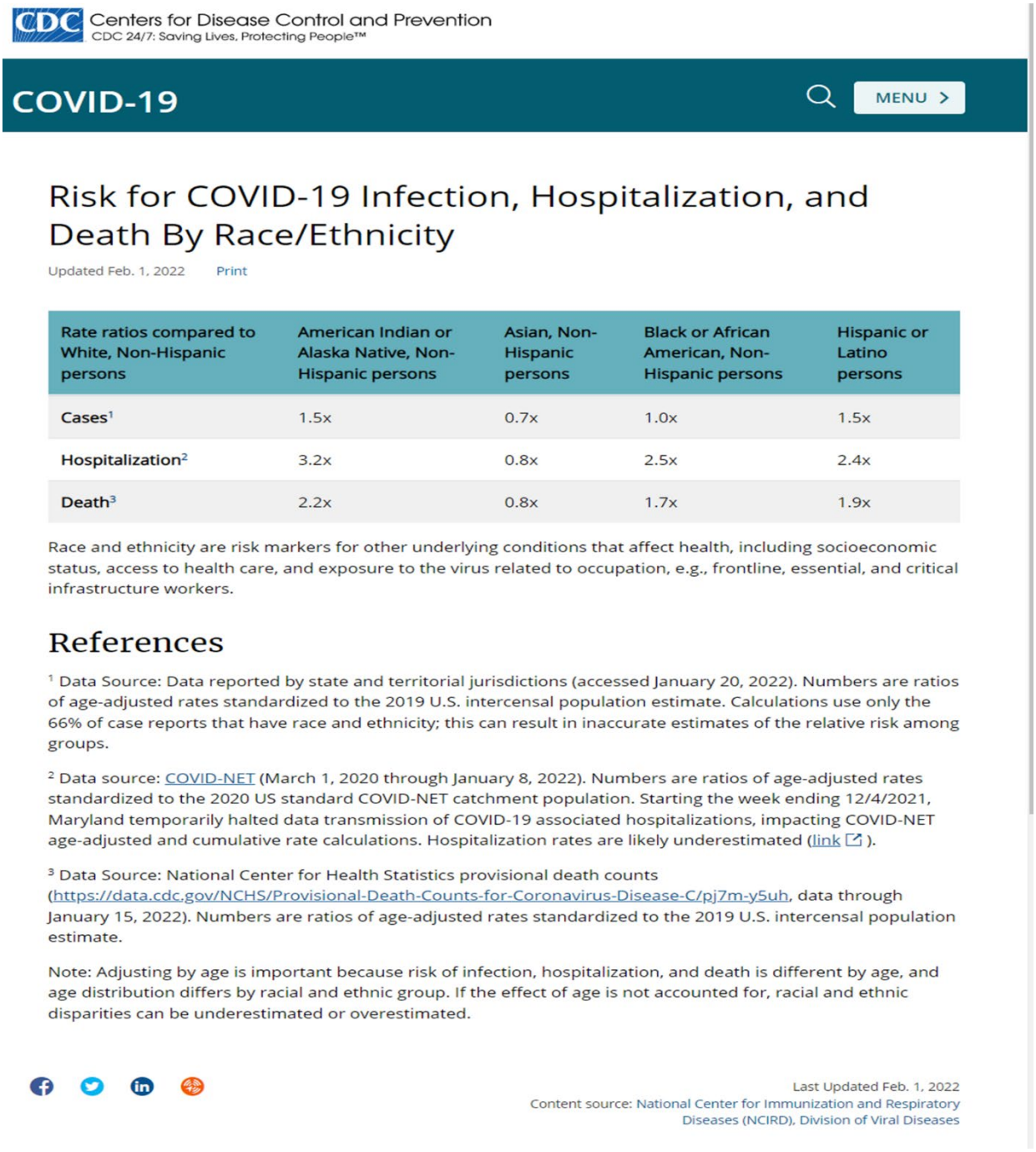
expectancy — three years — and Black Americans saw a decrease of 2.9 years. White people experienced the smallest decline, of 1.2 years. A copy of the National Center for Health Statistics 2020 Report is attached hereto as **Exhibit C**.

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

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

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

21. Perhaps the most convincing data point can be found in this simple chart compiled by the CDC. [4]



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

COVID-19 MENU >

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

Updated Feb. 1, 2022 Print

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

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

References

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

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

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

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

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

[4] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html

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

HOW THE GUIDANCE OPERATES

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

24. The recommendation that providers and hospitals should consider race and ethnicity as a risk factor when prescribing oral antiviral treatments is in no way meant to be read as a mandate, or a restriction of COVID-19 treatments by race. The Guidance does not replace doctors' clinical judgment, and does not prevent any patient from receiving necessary treatment. Rather, the Guidance is intended to address the well documented reality that communities of color have been disproportionately impacted by the COVID-19 pandemic. This has been reiterated publicly in discussion about using these medications and I have personally, publicly spoken to this in multiple venues including: (1) a widely publicized and attended New York State New York City webinar[5]; (2) monthly calls held by the New York State Medical Society and New York State Association of County Health Officials (attended by public health directors of any county that chooses to participate) and (3) weekly regional calls with hospitals, county officials, and advocacy organizations.

25. Despite Plaintiff's provocations, the Guidance does not, nor is it intended to, operate as a barrier to care for white people or create a racial hierarchy in the delivery of care.

[5] See https://www.youtube.com/watch?v=jm7-BQ0RvHQ

To provide an example at the extremes, as contemplated by Plaintiff: a white person and person of color both present to a treating doctor; only one oral antiviral treatment is available; the white person has various comorbidities and is in a seriously medically compromised state; the person of color presents as asymptomatic with no comorbidities. In this situation the DOH would expect the physician, using her or his medical judgment, to prescribe the one antiviral treatment available to the white person. Please keep in mind I offer this simple explanation for the court's benefit. In reality conjecture at the extremes often oversimplifies matters. In a clinical setting, pursuant to my training and experience I would expect a practitioner should: (1) take a detailed history and conduct a physical examination, (2) understand the risks and benefits of treatment versus non treatment based upon the person presented in front of you, 3) have a discussion with the patient about risk, benefits, and alternatives especially since these medications are only approved for use pursuant to emergencies authorizations and thus have not received full FDA approval. Only then after using appropriate medical clinical judgment should a medication be prescribed. These decisions should always be based upon the physician-patient relationship and a shared decision-making process that is part and parcel to patient care. Guidance issued by the DOH is simply a suggestion to help focus the thoughts of practitioners and inform reasonable discussion.

26. In short, the Guidance is just that -- guidance. It is not a substitute for the use of sound clinical judgment by practitioners or hospitals[6]. It merely points to one of many factors to be considered when prescribing treatment. All things being equal among patients, the Guidance

[6] Joint Legislative Public Hearing on 2022 Executive Budget Proposal: Topic Health/Medicaid | NY State Senate (nysenate.gov) at 2 hours 13 minutes in response to a question posed by Assemblyman Colin Schmitt

is meant to allow the flexibility for health care providers to consider persons of color as being at an increased risk due to the disproportionate impact of COVID-19 on communities of color.

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

NO CURRENT SHORTAGE OF MEDICATIONS

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

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

CONCLUSION

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

31. The Guidance is based on data that shows COVID-19 mortality rates are higher among certain demographic groups, including non-white/Hispanic communities. No one in New

[7] https://www2.erie.gov/health/index.php?q=press/erie-county-department-health-highlights-availability-covid-19-oral-antiviral-medications; http://outbreaknewstoday.com/new-york-city-announces-the-availability-of-paxlovid-covid-19-oral-treatment-50398/

York, who is otherwise qualified based on their individual risk factors, will be turned away from life-saving treatment because of their race or any demographic identifier.

Dated: February 17, 2022

EUGENE HESLIN, M.D., FAAFP