Pandemic Response Institute

Xavier Becerra, JD
Secretary of Health, U.S. Department of Health and Human Services

Robert Califf, MD,MACC
Commissioner of Food and Drug, U.S. Food and Drug Administration

Rochelle P. Walensky, MD, MPH
Director, U.S. Centers for Disease Control and Prevention Administrator, U.S. Agency for Toxic Substances and Disease Registry

July 20, 2022

Dear HHS Secretary Becerra, FDA Commissioner Califf, CDC Director Walensky,

As the leads of the newly formed New York City Pandemic Response Institute (PRI), we are writing to seek your assistance with regards to two issues: expanding access to Monkeypox vaccine and to its treatment in the U.S. as soon as possible. As you are aware, the U.S. is experiencing a rapidly growing Monkeypox outbreak, with urgent need for vaccines to protect the population at risk and for treatment to alleviate severe symptoms and prevent severe complications.

Firstly, as you are aware, currently the antiviral TPOXX (Tecovirimat) is available under the CDC's expanded access Investigational New Drug (IND) application. However, the process is onerous and time-consuming for clinicians, requiring that the CDC protocol be approved at their institution followed by, the completion of multiple case report forms, and the provision of results for a multitude of laboratory tests for the patient. We urge the Food and Drug Administration to provide emergency use authorization (EUA) for this medication in the context of this growing outbreak. This will facilitate making the medication available quickly for patients suffering from debilitating or severe symptoms and prevent the development of severe illness in immunosuppressed individuals.

The availability of a EUA will allow the clinicians to order TPOXX directly so that patients can be treated within existing systems of care. This would be a great first step in returning normalcy to our health care system, reinvigorating our clinical teams, treating promptly those who are eligible for treatment, and protecting the public. In order to promote equity and maximize access, state and local health departments should of course also ת be able to order TPOXX to provide treatment to individuals who are unable to access the regular healthcare system.

The second issue relates to access to the Jynneos Vaccine. Despite the high burden of cases, with New York State now reporting 28% of national cases, it has received significantly less than that of the limited vaccine supply. Currently, the demand for this vaccine far exceeds the supply, jeopardizing the ability to rapidly control this outbreak. With deep respect for the FDA inspection process, we urge the completion

of required inspections of the manufacturing facility and expediting shipments of the JYNNEOS vaccine from Denmark to the U.S.. This should be accompanied with an adjustment of the allocation algorithm to direct the appropriate number of doses commensurate with reported cases in specific municipalities/states.

We must break the cycle of Monkeypox transmission before another pandemic overwhelms us all. We appreciate your immediate action on this important public health issue and look forward to working together.

Sincerely,

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