

18 August 2022

Dear Dr Vasani and Dr Bassett:

We are a group of queer health advocates and experts, and we write to you with serious concerns about the federal Monkeypox virus (MPV) vaccine dose-sparing strategy. As you know, the Jynneos monkeypox vaccine is FDA-approved for subcutaneous injection with one vial of vaccine product [“For subcutaneous injection only. Administer two doses (0.5 mL each) 4 weeks apart.”]¹

Recently, to increase vaccine supply, the federal government, without community input, released an EUA to approve the vaccine for intradermal (ID) injection using 1/5 of the dose needed for subcutaneous injection.

This decision is based on scant research, including one published paper from 2015 using immunobridging² and another from the **1970s that has yet to be translated from German**³. The 2015 study excluded people living with HIV.

Cities, including New York and Philadelphia, are already receiving dose allocations of Jynneos based estimates of 100% intradermal use. Intradermal injection requires training to be done properly. While most cities have not yet released vaccine equity data, North Carolina recently reported that, while **70% of the MPV cases in their state were in Black people, 67% of those who received vaccine were white people**.⁴ Moving to a dose-sparing intradermal strategy will disproportionately affect those Black and Brown people who have yet to be vaccinated. This morning, the White House told reporters that cities that don't switch immediately to ID dosing will not receive additional shipments of vaccine. **This decision was made without community consent and puts our communities at risk. It forces city and state health care officials to move to ID dosing whether or not they believe it to be in the best interests of the health of their citizens.**

To promote vaccine equity while also ensuring an increased total number of doses, we propose a mixed-dosing strategy wherein all vaccine recipients receive one full dose of Jynneos subcutaneously. All second doses will then be given intradermally. While this doesn't increase supply five-fold, as the all ID strategy might, **the US would be able to vaccinate hundreds of thousands of additional people with two doses using only the current supply**, depending

¹ FDA Jynneos package insert, August 2019. <https://www.fda.gov/media/131078/download>

² Frey SE, et al. Comparison of lyophilized versus liquid modified vaccinia Ankara (MVA) formulations and subcutaneous versus intradermal routes of administration in healthy vaccinia-naïve subjects. *Vaccine*. 2015 Sep 22;33(39):5225-34. doi: 10.1016/j.vaccine.2015.06.075. <https://pubmed.ncbi.nlm.nih.gov/26143613/>.

³ Mayr A, et al. [The smallpox vaccination strain MVA: marker, genetic structure, experience gained with the parenteral vaccination and behavior in organisms with a debilitated defense mechanism (author's transl)]. *Zentralbl Bakteriell B* 1978 Dec;167(5-6):375-90. <https://pubmed.ncbi.nlm.nih.gov/219640/>.

⁴ North Carolina Department of Health & Human Services. Monkeypox Response Update: Equity Data Report on Cases, Vaccines and Testing. 10 August 2022. <https://www.ncdhhs.gov/media/17508/open>.

on the strategy. We also insist on filling and finishing the 15 million doses currently in bulk storage to increase supply by Fall of 2022 instead of Winter of 2023.

This strategy has benefits beyond ensuring equity and transparency for those receiving vaccine early, who are predominantly white and likely economically advantaged:

- If New York City were to use uniform mixed-dosing, rapid immunological studies could be performed by New York City and/or New York State to determine the response to this dosing regime.
- Immediately moving to all-ID dosing will lead to mixed dosing; some may receive two doses subcutaneously, others may receive two doses intradermally, and everyone who has been vaccinated already will receive mixed dosing. It is unclear whether these dosing regimes will be studied thoroughly. **Individuals may be unclear on how their dosing regime will protect them, which may influence their behavior.**
- Intradermal dosing requires training, which will take time. This strategy will allow first vaccine doses to continue using the subcutaneous route.
- If first doses are given intradermally and the vaccine is misplaced, an individual may think they're protected without receiving any immunity at all. This strategy ensures everyone receives one dose via the easiest route of administration.
- Intradermal dosing has a higher risk profile than subcutaneous dosing, including common scars and contraindications for those with a history of keloid scarring, which is more common in Black and Brown people with darker skin. **The CEO of Bavarian Nordic, a co-author of the 2015 study used to promote intradermal dosing, has told reporters from *The Washington Post* that he opposes this strategy due to its safety risks.**^{5,6}
- Scarring or a mark at the vaccination site may cause individuals to resist vaccination altogether as a visible mark of a stigmatized community.
- Intradermal dosing can be painful and may cause individuals not to return for a second dose.
- Community-based health organizations report that they do not have the infrastructure necessary to perform ID vaccination, limiting the community outreach program at the center of vaccine equity in New York City.
- **At a minimum we demand that the federal government stop sending doses only counted as intradermal** and allow for flexible ordering of doses to be given as either intradermal or subcutaneous, as approved or authorized by the FDA.

While we understand the emergency situation we find ourselves in, we remain frustrated by the restricted and incompletely validated options the federal response has given cities and states and our communities. We must work together to insist that the federal government provide the

⁵ Diamond D. Monkeypox vaccine maker voices concerns on U.S. dose-splitting plan. *The Washington Post*, 10 August 2022.

<https://www.washingtonpost.com/health/2022/08/10/monkeypox-vaccine-bavarian-nordic-opposition/>

⁶ Diamond D, et al. Inside America's monkeypox crisis — and the mistakes that made it worse. *The Washington Post*, 17 August 2022.

<https://www.washingtonpost.com/health/2022/08/17/monkeypox-biden-vaccine-testing-mistakes/>
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flexibility we need to increase vaccine equity. We request a meeting with city and state partners to discuss this, and other, vaccine strategies prior to their roll-out.

Signed:

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[– *list in formation* –]

cc: Robert Fenton, Dr Demetre Daskalakis, Alondra Nelson , Xavier Becerra,
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