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November 7, 2022

VIA EMAIL

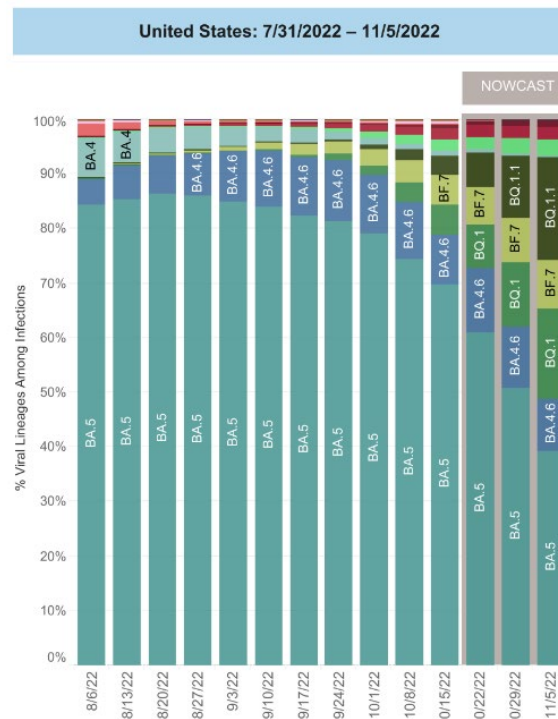
Robert Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
commissioner@fda.hhs.gov

Rochelle Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329
Aux7@cdc.gov

Re: *Omicron Dominance and Emergency Use Authorization for the Omicron-Booster*

Dear Doctor Califf and Doctor Walensky:

We write on behalf of Informed Consent Action Network. Because Omicron is no longer the dominant circulating variant of SARS-CoV-2,¹ we write to ask whether the FDA plans to revoke the Emergency Use Authorization (“EUA”) for, and whether CDC will rescind its recommendation for, the Bivalent COVID-19 booster since it is targeted towards the BA.4 and BA.5 lineages of the Omicron variant.



¹ See <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>.

We note that the FDA has previously revoked the EUA status of monoclonal antibody treatments in instances where they were targeted towards variants that were no longer dominant.²

Very truly yours,

A handwritten signature in blue ink, appearing to read 'ASiri', is positioned above the typed names.

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Catherine Cline, Esq.

² See, e.g., <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization>.