



Health Watch USAsm

Member of the National Quality Forum and a designated "Community Leader" for Value-Driven Healthcare by the U.S. Dept. of Health and Human Services

RE: Written Comment January 26, 2023 FDA VRBAC Meeting

January 24, 2023

Another important reason for updating the COVID-19 vaccine's formulation is the mounting evidence of significant immunological imprinting which occurs with SARS-CoV-2 or vaccine exposure. In other words, your first exposure to the virus shapes your immunological response to all future exposures.

This was evident from the data presented at the Sept. 1, 2022, ACIP meeting where all animals were vaccinated with the original SARS-CoV-2 strain, and then had a robust response to the original viral strain with the Monovalent BA4/5 booster. In addition, booster efficacy data from a number of other studies showed, what some would describe, as a less than expected advantage of the bivalent booster over the original booster.

Thus, it would appear advantageous to administer to SARS-CoV-2 immunologically naive individuals, such as young children, the most immunologically diverse and up-to-date vaccine possible.

I would like to encourage the committee to approve the administration of the current SARS-CoV-2 bivalent formulation to young children and to update this formulation on a regular basis.

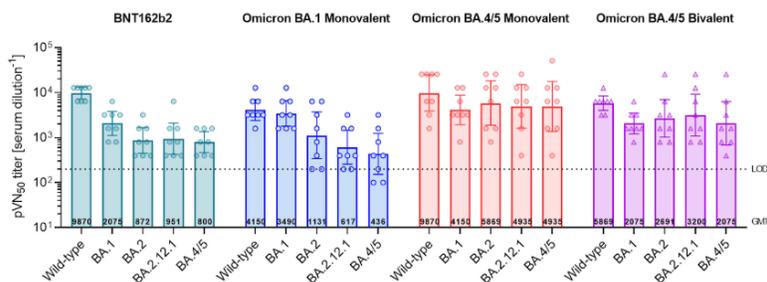
Thank you,

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Omicron BA.4/BA.5 Monovalent and Bivalent Boosters in Mice Substantially Increase Omicron Neutralization Responses to all Omicron Variants Including BA.4/5

Compared to BNT162b2 Neutralizing BA.4/5 titers increase by ~6.2 fold [mono BA.4/5] or ~2.6 fold (bivalent BA.4/5)

Day 7 PD3

References:

Mice preimmunized with 2 doses of BNT162b2; boosters given at day 104 post Dose 2. Vaccines administered at 1 mcg dose level; Wild type, Wuhan-Hu-1; LOD, Limit of Detection

CC-16

Kavanagh KT. Immune Imprinting and the Prevention of Spread. Infection Control Today. Dec. 27, 2022. <https://www.infectioncontrolday.com/view/immune-imprinting-prevention-spread>

Kavanagh KT. The Autumn COVID-19 Booster Is Here: Is it Safe and Effective? Infection Control Today. Sept. 2, 2022. <https://www.infectioncontrolday.com/view/the-autumn-covid-19-booster-is-here-is-it-safe-and-effective->