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CHILDREN'S HEALTH DEFENSE NEWS & VIEWS

In a unanimous 16-0 vote, the U.S. Food and Drug Administration's vaccine advisory committee today recommended a monovalent JN.1-lineage for the 2024-2025 COVID-19 vaccine formula. Critics countered that the vaccines' risks outweigh the benefits.

by **Suzanne Burdick, Ph.D.**

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In a unanimous 16-0 vote, the U.S. Food and Drug Administration's (FDA) vaccine advisory committee today recommended a monovalent JN.1-lineage vaccine composition for 2024-2025 Formula for **COVID-19** vaccines.

The **JN.1 variant** has been most dominant this year, Reuters reported.

Last year, the agency's committee recommended COVID-19 vaccines targeting **XBB.1.5**, a subvariant of Omicron that dominated the U.S. from November 2021 to 2022.

The committee today also discussed which specific strains within the JN.1-lineage group — such as subvariants KP.2 and KP.3 — the vaccines should target. The FDA said it will later issue an official recommendation to manufacturers about what subvariants it wants to target within the JN.1-lineage group.

David Wiseman, Ph.D., a bioscience researcher, **told the committee** that in recommending continued COVID-19 vaccination, the FDA may be putting the U.S. public's **health** at risk. "Based on the totality of evidence, it is reasonable to believe that the product [COVID-19 vaccines] may be unsafe," he said.

The Vaccine Safety Project

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Wiseman, who spoke during the meeting's public comment time, recently **testified before the Texas Senate** about the recent uptick in cancers in the U.S.

Cancer trends during the COVID-19 vaccination era are "widely recognized," Wiseman said, yet Pfizer failed to test its COVID-19 vaccines for cancer effects.

Wiseman also cited **evidence obtained by Health Canada** showing Pfizer chose not to disclose to regulatory authorities **SV40 sequences** that may be **linked to cancer.**

"As guardians of public trust, where is FDA's censure of Pfizer?" he asked.

Wiseman also pointed out that the FDA in February testified before a U.S. House of Representatives committee that its officials "have not detected any increase in cancers with the COVID-19 vaccines" — yet the CDC had already generated numerous possible safety signals.

"FDA must investigate cancer signals," he said.

He referenced the comment by Pfizer's former head of vaccine R&D, Kathrin Jansen, when describing Pfizer's development of the COVID-19 vaccines. "**We flew the aeroplane** while we were still building it," she said.

"It's time to ground the plane," Wiseman said.

The FDA committee's decision to recommend an updated COVID-19 vaccine also drew criticism from **Dr. Mary Tally Bowden**, who was suspended from Houston Methodist Hospital during the COVID-19 pandemic for **treating COVID-19 patients with ivermectin**.

"The FDA needs to **pull the COVID shots off the market immediately**," she told **The Defender**. "Any other product with the types of reactions we have seen would have been pulled off the market a long time ago."

Bowden was one of three doctors who **sued the FDA** to stop the **agency** from giving **unlawful medical advice** about the off-label use of ivermectin to treat or prevent COVID-19.

The FDA in March **settled the suit**, agreeing to remove its "**You are not a horse**" posts discouraging ivermectin use from Facebook, Twitter (now X) and LinkedIn.

COVID hospitalizations at all-time low

Before today's vote, the FDA's vaccine advisory committee heard presentations from top researchers at the Centers for Disease Control and Prevention (CDC) and representatives of Pfizer/BioNTech, Moderna and Novavax.

Natalie Thornberg, Ph.D. — the CDC's lead microbiologist for its respiratory virus immunology division — presented data on current COVID-19 infection levels in the U.S.

One of her slides showed current **hospitalizations** from COVID-19 are the lowest they have ever been.

She also shared data showing that positive COVID-19 tests and deaths from COVID-19 are also at an all-time low.

No mention of COVID vaccine injury reports

Thornberg did not mention the **1,637,441** reports of injury following a COVID-19 vaccination filed in the Vaccine Adverse Event Reporting System (**VAERS**) between Dec. 14, 2020, and April 26, 2024.

VAERS is the primary government-funded system for reporting adverse vaccine reactions in the U.S. Historically, VAERS has been shown to report only **1% of actual vaccine adverse events**.

More than 61,000 of those reports involved **children ages 6-17**. More than 9,700 involved **kids 5 and under**.

Thornberg shared the results of a study that showed JN.1 elicited the same severity of symptoms as XBB.

During the public hearing part of the meeting, some commenters urged the FDA to make COVID-19 shots available in early, rather than late, fall.

Amy Harth, Ph.D., said she was concerned about getting a COVID-19 infection and asked the FDA to allow non-immunocompromised adults such as herself to get COVID-19 vaccines twice a year, rather than once a year.

Karl Jablonowski, Ph.D., who attended the meeting, noted that Harth pondered aloud why the agency would only authorize adults to receive one shot a year if they are truly safe.

"Are these shots not as safe as you claim?" she asked.

Jablonowski, a member of the **Children's Health Defense** science department, pointed out that Harth "blatantly asked" if COVID-19 vaccines have an "unstated risk."

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