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# U.S. FDA Votes Against Pfizer/BioNTech's COVID-19 Boosters for Those Under 65

*(Source: An article by the Associated Press)*

A Food and Drug Administration advisory panel overwhelmingly voted September 17th against giving Pfizer/BioNTech's COVID-19 booster shots to most people, agreeing only to recommend them for people ages 65 and up as well as those at high risk of severe illness.

The unanimous recommendation of boosters for a limited group of Americans was the second vote called by the Vaccine and Related Biological Products Advisory Committee, or VRBPAC, during its meeting Friday. The committee of outside experts was first asked whether a third shot of Pfizer's vaccine would be safe and effective for everyone ages 16 and older. Members overwhelmingly voted against that recommendation, citing concerns about the level of evidence showing whether the boosters are safe for younger people. "We're being asked to approve this as a three-dose vaccine for people 16 years of age and older, without any clear evidence if the third dose for a younger person when compared to an elderly person is of value," said committee member Dr. Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia.

Such feedback led to further debate among the committee members about specific age groups or populations that may be most appropriate for a third dose of vaccine. The panel subsequently narrowed the recommendation to those over age 65 and anyone at higher risk for severe illness. People at high-risk of exposure at work, such as health care workers and teachers, will likely also be eligible for a booster dose. The panel's recommendation will now go to the FDA, which is not required to follow VRBPAC's vote, but usually does. The FDA will decide whether to issue an emergency use authorization for the booster doses. Though three Covid vaccines are in use, Friday's vote focused on the Pfizer vaccine only, and would only apply to those who originally received the Pfizer shots. It does not apply to people who have received the Moderna or Johnson & Johnson vaccines. The panel's ultimate recommendation was a measured response and "appropriate based on the data that was provided," said Dr. Richard Besser, president of the Robert Wood Johnson Foundation and former acting Centers for Disease Control and Prevention director.

Still, the decision could put the FDA at odds with Biden administration officials who have been pushing to begin giving out booster shots to the general population starting the week of Sept. 20th, essentially starting the countdown for the FDA and the CDC to act. The booster question will now go to a group of advisers to the CDC, which will take up the issue in a two-day meeting next week. Members of the FDA advisory committee struck a skeptical

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## In Brief...

- **Viatris Pharmaceutical Japan** announced that it has taken over the marketing authorizations and marketing rights of 14 off-patent drugs from **Pfizer Japan**. Included in the list are: I*antanoprost; Iatanoprost + timolol*; *eplerenone*; *sildenafil*; *amlodipine*; *sertraline*; *eletriptan*; *amlodipine + atorvastin*; *doxazosin*; *sildenafil*; *alprazolam*; and, *tolterodine*. Regarding two remaining drugs, *pregabalin* and *venlafaxine*, the existing marketing alliance with **Eisai** and **Sumitomo Dainippon Pharma**, respectively, will continue.
- **AstraZeneca (AZ)** and the **European Commission** have settled their dispute over AZ's planned shipments of millions of COVID-19 doses to EU countries, the company announced. Under the agreement, AZ will supply the EU with 200 milliondoses of its vaccine *Vaxzevrie* by March of 2022. This will complete their 300 million-dose supply deal inked last year. Sixty million doses will be sent by the end of September, 75 million by the end of 2021 and the remaining 65 million by the end of the first quarter of 2022.
- Leading global analytics and solutions provider, **IQVIA** announced a transformative collaboration with **NRx Pharmaceuticals (NRx)**, a company dedicated to creating innovative, life-saving treatments and bringing hope to those with life-altering conditions with no approved disease-modifying therapies or cures. The collaboration will provide pharmacovigilance services and medical information in preparation for potential regulatory actions. This collaboration will allow NRx to access IQVIA's domain experience with COVID-19, its unparalleled data assets, and analytics to support potential emergency use authorization (EUA) of *ZYESAMI*. IQVIA will work closely with NRx to support key activities required for EUA activation, including the pharmacovigilance and medical information programs.
- **McKesson Corporation** unveiled its McKesson's *Rapid Returns Solution for Health Systems*, a systems solution designed to help hospitals and health systems increase the amount of credit received for returned pharmaceuticals and over-the-counter products, expedite credit processing, and simplify the returns process to enable staff more time for

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## U.S. FDA (cont.)...

tone during the meeting Friday, questioning Pfizer's conclusions that immunity is waning to the point that vaccinated people of all ages need an additional dose to protect against hospitalization and death six months after they've received their second dose. Representatives from Pfizer said the need for a booster is based on data from Israel, which showed that severe cases increased tenfold from July to August, despite the fact that 60 percent of the population there was fully vaccinated.

But data from the United States, presented by the CDC, found the vaccines continued to provide high protection against severe disease, hospitalization, and death. Dr. Sara Oliver, an epidemic intelligence service officer at the CDC, noted that Israel and the U.S have different definitions for what's considered severe disease. In Israel, she said, it is defined as lower oxygen levels and an elevated respiratory rate. In the U.S., severe disease refers to hospitalization or death. The two countries also vary differently in population, pandemic, and acceptance of vaccines.

"You really have a very different situation in Israel than what we are facing here in the US at this point in time," said Dr. Archana Chatterjee, an expert in pediatric infectious diseases at Rosalind Franklin University in Chicago.

The FDA advisory committee also raised questions about the safety of an additional dose, particularly with regard to the risk of myocarditis, a rare side effect that's been seen primarily in males younger than 30. However, it's only been two weeks since younger adults have been given a booster in Israel and may not reflect the full scope of cases.

"I have a serious concern about myocarditis and young people," Dr. James Hildreth, CEO of Meharry Medical College in Nashville, Tennessee, and a member of the advisory committee. "The booster shots induce a very strong response that is going to amplify the risk for myocarditis in those individuals."

## PhRMA Lauds Japan's New Vision for the Pharmaceutical Industry

*(Source: A Staff article by Pharma Japan)*

The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a statement to welcome Japan's new pharmaceutical industry vision which was formally announced on September 13th.

The powerful and influental U.S. trade and lobbying group commended the Japanese government for detailing plans to guarantee the transparency and predictability of the drug pricing system, create an environment aimed to attract investments from Japanese and non-Japanese companies alike, and track and follow-up on policy progress through public-private collaborations.

In the statement issued by the chair of PhRMA's Japan-based Executive Committee, James Feliciano, he outlined Japan's need for a robust drug discovery system to protect the lives and health of its people and address some of the existing vulnerabilities that have been exposed through the COVID-19 pandemic in the area of vaccine and therapeutics development. Japan will also work to ensure a flexible and resilient healthcare system that can withstand future public health emergencies, he said.

Mr. Feliciano also emphasized that there is still a wide array of challenges that should be prioritized and addressed through public-private collaborations, adding that PhRMA is ready to participate in working-level discussions between the government and industry envisaged in the pharma vision and to help set key performance indicators (KPIs) and metrics to monitor progress.

## In Brief (cont.)...

patients. The offering is provided through **PharmaLink**, a national pharmaceutical reverse logistics and disposal provider.

- **Walgreens Boots Alliance, Inc. (WBA)** and **Shields Health Solutions** today announced that WBA, through its wholly-owned subsidiary, **Walgreen Co.**, is making a majority investment in Shields, an industry leader in integrated, health system-owned specialty pharmacy care. The approximately US$970 million investment will support the continued growth of Shields' health system-based specialty pharmacy strategy, and builds on a minority equity investment that WBA announced in July 2019. The new investment gives WBA approximately 71 percent ownership of Shields, with an option to acquire the remaining equity interests in the future. Shields' other equity holders will also have the option to require WBA to purchase the remaining equity interests, under the agreement.
- The U.S. White House is set to lay out a plan to cut prices for prescription drugs. The move is hanging over biotech and pharmaceutical stocks. The plan will allow **Medicare** to negotiate on drug pricing and would allow the **Department of Health and Human Services** to test linking payments for drugs to how the drugs benefit patients. The plan would come amid an effort from Congressional Democrats to enact drug pricing legislation. Both parties have supported efforts to cut prescription-drug prices.
- **CVS Health** (U.S) and **Novo Nordisk** are piloting a new, personalized nutrition coaching program to support people struggling with obesity, after their treatment plan has been determined by a licensed provider. More than 40% the U.S. population suffers from obesity, a chronic disease that is linked to several leading causes of premature death, including heart disease, stroke, and Type 2 diabetes. Because every individual's weight loss journey is unique, a customized plan to address his or her specific needs is critical to optimize health outcomes. The pilot will initially be offered in the Phoenix, Arizona area with plans to expand later in the year.
- U.S. and **Kaiser Permanente** researchers combing the health records of 6.2 million patients found no serious health effects that could be linked to the Pfizer and Moderna mRNA COVID-19 vaccines. The study published September 2 in *JAMA* reports the first comprehensive findings of the *Vaccine Safety Datalink (VSD)*, which studies patient records for 12 million people in five Kaiser Permanente service regions along with *HealthPartners* in Minneapolis, the Marshfield Clinic in Wisconsin, and Denver Health. The work is supported by the Centers for Disease Control and Prevention.

*(Sources: Barron's, Business Wire, Devex Newswire, Drug Store News, FiercePharma, NPR, Pharma Japan, and World Pharma News)*