FDA panel backs Pfizer's RSV vaccine for older Americans

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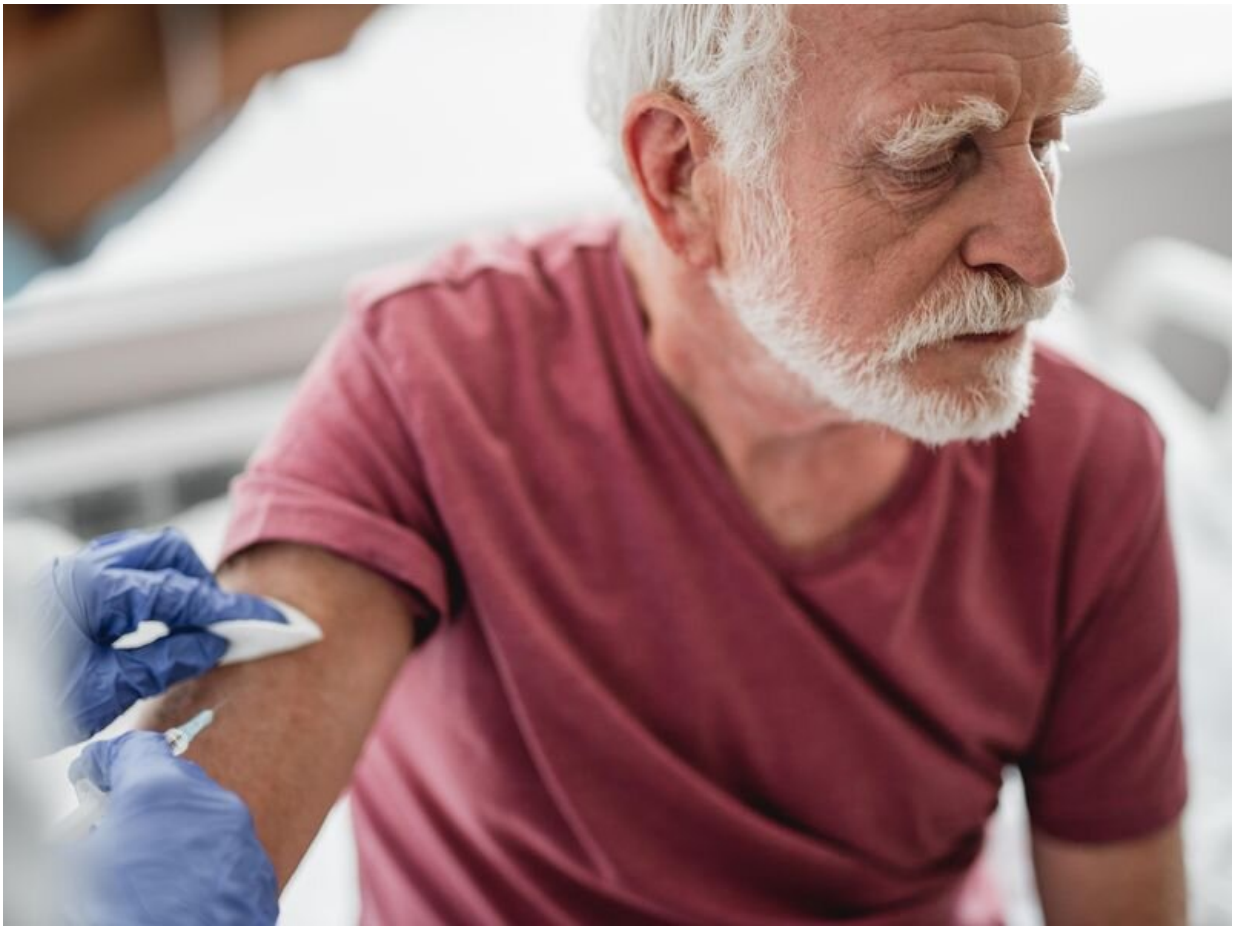

In a tight vote, U.S. Food and Drug Administration advisors on Tuesday

recommended the approval of an RSV vaccine that could be used in Americans ages 60 and up.

The vaccine, known as RENOIR, was developed by pharmaceutical giant Pfizer Inc. The same panel of advisors will weigh the potential approval of another respiratory syncytial virus (RSV) vaccine, this one from GlaxoSmithKline, on Wednesday.

"In older adults, RSV can result in serious illness, hospitalization, or even death, so there is a significant need to protect this at-risk population," Annaliesa Anderson, senior vice president and chief scientific officer for vaccine research and development at Pfizer, said in a news release announcing the panel decision. "We are encouraged by the outcome of today's... meeting, as it is a testament to the strength of our science and dedication to bringing this important vaccine candidate to the market."

If the FDA follows the recommendation of its advisors, which it typically does, Pfizer's vaccine would be the first shot to guard against RSV infection, NBC News reported. The U.S. Centers for Disease Control and Prevention would also need to recommend the single shot before it could become available to Americans.

Still, the FDA advisors were divided in their recommendation. The panel voted 7-4, with one abstention, to recommend approval of the vaccine based on its efficacy, NBC News reported. FDA advisors were also split, 7-4 with one abstention, on the safety for the Pfizer vaccine.

The vaccine's potential association with a rare neurological disorder known as Guillain-Barré syndrome (GBS) was a concern for those who voted against approval because of safety.

"It was a 1 in 9,000 risk of GBS, which is concerning," said committee chair Dr. Hana El Sahly, who voted against the shot based on its safety

profile but in favor of the shot based on its efficacy.

Common side effects of both the Pfizer and the GSK vaccines were injection site and muscle pain and fatigue. Pfizer participants reported headaches, while the GSK participants reported more frequent side effects, according to NBC News.

Pfizer has reported that its vaccine would reduce risk from RSV by as much as 86%.

GlaxoSmithKline's version would lower risk of symptomatic illness by 83% and of severe illness by 94% in adults 60 and up, according to trial data that was published in February in the New England Journal of Medicine.

These may not be the only RSV vaccines to come, as 11 are being studied in U.S. trials now, according to data from nonprofit global health organization PATH, NBC News reported. Those include vaccines from Moderna and Bavarian Nordic.

Pfizer has also tested its RSV vaccine in pregnant women. An FDA decision on that is expected in August. That vaccine reduced the risk of severe illness in infants by 82% through the first 90 days of life, NBC News reported.

A monoclonal antibody injection designed for babies is also under FDA review. That shot is from Sanofi and AstraZeneca and has already been approved in Europe, NBC News reported.

Although RSV infection is mild for for many people, the disease can be very serious for infants and older adults. It kills up to 10,000 adults ages 65 or older each year, according to the U.S. Centers for Disease Control and Prevention. Meanwhile, about 300 U.S. children under the age of 5

also die from RSV each year.

More information: The U.S. Centers for Disease Control and Prevention has more on RSV.