

FDA panel backs RSV vaccine for infants, some toddlers

June 9 2023, by Cara Murez



A U.S. Food and Drug Administration advisory panel on Thursday

recommended that the agency approve an RSV vaccine for infants and some toddlers.

The monoclonal antibody shot would protect against [respiratory syncytial virus](#) (RSV) in infants born during or entering their first RSV season, the *New York Times* reported. It could also be used for toddlers up to 24 months old who are particularly vulnerable to the virus.

The panel voted 21-0 in favor of using the vaccine, called Beyfortus, for infants and 19-2 in favor of use in toddlers, the *Times* said.

While RSV can be as minor as a cold for many people, it is a leading killer around the world for infants and toddlers, the *Times* reported.

As many as 80,000 kids younger than age 5 are hospitalized with RSV annually. Up to 300 die, according to the [U.S. Centers for Disease Control and Prevention](#). It also can be serious in [older adults](#), leading to about 160,000 hospitalizations and 10,000 deaths in people 65 and older.

Now, it's up to the FDA to decide whether to approve the shot, though it typically follows the recommendations of its panels. The agency has said it would continue to monitor the treatment for safety even after approval.

Drugmakers Sanofi and AstraZeneca gave more than 3,200 infants the antibody shot during studies of the vaccine. [One of those studies](#) found that the vaccine's effectiveness against very severe RSV was 79% after six months.

A vaccine has recently been FDA-approved for older adults. Another—which would be delivered to women in pregnancy to help shield newborns—has been recommended by a different FDA panel, although there are concerns about a small increase in preterm births, the

Times reported.

The shot for [infants](#), if approved, could be available in the fall.

More information: The U.S. Centers for Disease Control and Prevention has more on [RSV](#).

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