RSV Vaccine to Get Priority Review by the FDA

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The Alliance for Patient Access, founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of di[1]rectors. Its physician leadership is supported by policy advocacy management and public affairs consultants.

In 2012, AfPA established the Institute for Patient Access, a related 501(c)(3) non-profit corporation. The Institute for Patient Access is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. In furtherance of its mission, IfPA produces educational materials and programming designed to promote informed discussion about patient access to approved therapies and appropriate clinical care.

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RSVpreF, which is administered to pregnant mothers, reduced infants' chances of needing to see a doctor for lower respiratory infections by 81% in Phase 3 clinical testing last year. (3,4)

This follows the FDA's December 2023 decision to expedite the review of an RSV vaccine for older adults. (5) European regulators have already approved one RSV immunization for infants and are giving multiple candidates expedited assessment. (6,7,8)

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RSV's Global Toll

And just in time. RSV is a highly contagious virus that causes cold-like symptoms in millions of patients yearly. (9) Moreover, severe cases can lead to bronchiolitis, pneumonia, or death. (9)

Almost all children contract an RSV infection by age two. (10) Globally, more than 100,000 young children die from it every year. (11) It accounts for over 2 million doctor visits and 58,000 hospitalizations annually among children under five. (12) It is also the leading cause of hospitalization among children under one.

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The physical, financial, and emotional burdens RSV imposes on children, parents and families, and the elderly are enormous. (14, 15, 16, 17) These new immunizations represent a potential breakthrough.

Relieving Burdens

"The impact would be huge," Dr. Janet Englund, a respiratory virus specialist at Seattle Children's Hospital, told the Wall Street Journal last year. (18) "It would change hospitalization rates. Young babies wouldn't have to come to the hospital so much."

RSV has been a focus of medical research and development for years. (19) The FDA's expedited review of potential immunizations

indicates that regulators know the situation's urgency. If these immunizations are approved, they could dramatically reduce RSV infections in the United States and allow international health organizations to distribute the vaccine in the developing world, where RSV patients are at even greater risk. (20)

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