Medical Xpress

Virus drugmaker fights pediatricians' new advice

July 28 2014, by Lindsey Tanner

Respiratory Syncytial Virus (RSV) is a common, seasonal virus contracted by nearly 100% of babies by the age of 2, and is the leading cause of hospitalization for babies during their first year of life in the U.S. And, while every baby is at risk for developing RSV disease, premature babies are twice as likely as full-term infants to be hospitalized for RSV-related symptoms.

Since 1998, an FDA-approved therapy has been available to significantly reduce the risk of hospitalizations due to severe RSV disease among high-risk infants.

But every few years, a committee within the American Academy of Pediatrics (AAP) issues recommendations that progressively narrow the population of babies they believe should qualify for this medicine. And on July 28, they are about to do it again – this time endorsing drastic reductions that will leave approximately 140,000 babies unprotected (as compared to the FDA-approved label).

Why put these babies at risk?

Take action to help protect our most vulnerable babies.
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This photo shows a full-page ad by MedImmune that was published Tuesday, July 22, 2014, in the New York Times. MedImmune, a division of AstraZeneca, ran full-page ads in the New York Times and other newspapers in recent weeks

protesting pediatricians' new recommended limits on Synagis, a drug for preventing serious lung problems in premature infants caused by a common but usually mild virus. A new policy from the American Academy of Pediatrics says the costly drug has limited benefits and recommends scaling back its use. The policy was published online Monday, July 21, 2014, in Pediatrics. (AP Photo)

(AP)—A costly drug given mostly to premature babies is at the center of a clash between the manufacturer and the leading U.S. pediatrician's group, which recommends scaling back use of the medicine.

The dispute involves new guidelines from the American Academy of Pediatrics, which say medical evidence shows the drug benefits few children other than very young preemies. The medicine guards against a common but usually mild virus that can cause serious lung problems.

It's the second time in two years that the influential group has recommended narrowing use of the drug, sold by MedImmune under the brand name Synagis. MedImmune is fighting back with full-page newspaper ads that say the updated policy threatens "our most vulnerable babies."

Synagis protects against RSV, or respiratory syncytial virus, which infects nearly all U.S. children by the age of 2. For most, it causes only mild, cold-like symptoms. But it is also the most common cause of pneumonia in U.S. infants, and as many as 125,000 young children are hospitalized with RSV each year, according to the federal Centers for Disease Control and Prevention.

It was approved in 1998 for use in certain "high-risk" children, based on research showing benefits for certain children including premature infants born at 35 weeks or earlier. The pediatricians' group says it has

sought to provide more specific guidance because the government's definition of high risk is vague.

The medicine is given in a series of seasonal injections costing thousands of dollars, and a recent lag in Synagis sales may explain MedImmune's tactics, which include recruiting parents to help tout the drug.

Sales for the first quarter of 2014 totaled $328 million, down 19 percent from $414 million in the same period last year, according to an earnings report from parent company AstraZeneca.

Company spokeswoman Alisha Martin said it placed full-page ads in The New York Times and several other newspapers because "we felt it important to inform parents—including the half-a-million women who give birth prematurely each year—of the decisions being made that could impact the lives of their children."

Studies show the drug can slightly reduce risks for being hospitalized but doesn't shorten hospital stays or lessen chances for long-term complications or death, said Dr. H. Cody Meissner, a member of an academy committee involved in drafting the new guidance and an infectious disease expert at Tufts Medical Center.

Advances in treatment for preemies in recent years make Synagis, also known as palivizumab, unnecessary for many, the academy says. Its new guidance recommends it only for: infants born before 29 weeks; older preemies with chronic lung disease and those with certain heart problems; and certain other at-risk children younger than age 2.

Healthy older preemies should not get the drug, the academy says in guidelines published online Monday. Its 2012 advice included use in some older, healthy preemies.

Melony Sorbero, a senior Rand Corp. researcher, has studied RSV and said the academy's narrowed recommendations make sense based on scientific evidence of limited benefits.

MedImmune's newspaper ads say the new guidelines will leave about 140,000 infants born between 29 and 35 weeks "unprotected." The ads say: "Why put these babies at risk?" They include a photo of a tiny preemie hooked up to medical machinery.

A Washington, DC-area mother, Deb Discenza, has helped the drugmaker locate parents to participate in a MedImmune RSV awareness program and says she was paid for sharing information about her daughter's experience. Her daughter was born at 30 weeks, or about two months early, in 2003. The baby may not have qualified for the medicine under the academy's new guidance but her mother believes Synagis treatment that first year "is what saved us."

The little girl's doctor declined to offer the drug after she turned 1, and she developed asthma. Discenza believes Synagis might have prevented it.

She said her health insurance covered the shots, but she's among parents who worry coverage will be denied based on the new recommendations.

Susan Pisano, spokeswoman for the industry group America's Health Insurance Plans, says insurers consider medical groups' recommendations but that it's too soon to determine if the pediatricians' new advice will affect coverage decisions.