

## New US influenza vaccine recommendations: continued focus on children

**LONDON, UK----12 August 2008----ExpertREACT.** In the same week that the US Advisory Committee on Immunization practices (ACIP) updated their recommendations for influenza vaccination for the 2008/2009 season, two of largest flu vaccines manufacturers, Novartis and Sanofi Pasteur continued to jostle for the position of number 1 supplier. Although both will gain from increasing demand in the 5-18 yrs group, capturing new vaccinees will not be easy. The focus on young children (6 months – 4 years) will benefit Sanofi more.

Influenza is a RNA-based virus (*Orthomyxoviridae*) which is highly transmissible between humans that are in close contact. Each year the virus causes epidemics, which in the Northern hemisphere occur during the autumn or winter months, but sometimes as late as April or May. In most individuals influenza illness or “flu” is uncomplicated where the characteristic symptoms of fever, myalgia and malaise resolve within a week after onset. However, in very young children, the elderly or those with severe underlying comorbidities e.g. lung or heart disease influenza can result in hospitalization and/or death. Latest figures suggest that between 1990 and 1999, influenza caused a yearly average of 36,000 deaths and 226,000 hospitalizations in the US (1). On a global scale, influenza is estimated to cause 250-500,000 deaths making it a significant healthcare priority (WHO Figures).

Annual vaccination is considered the most effective strategy for minimizing the impact of influenza illness. Over recent years, especially within the United States, enormous emphasis has been placed by healthcare policy makers to ensure more influenza vaccine is produced and more people are vaccinated. Each year the US Advisory Committee on Immunization Practices (ACIP) updates its recommendations for those who should receive influenza vaccine. For the coming 2008-09 season the new recommendations continue to place primary focus on children (6 months – 4 years) but in addition the recommendations now include all children aged 5-18 years.

Vaccinating young children against influenza is important for a number of reasons. Firstly, during two consecutive recent US influenza seasons (2002 to 2004) as high as a third of emergency department visits of children <5yrs were due to laboratory confirmed influenza illness (1). Although US deaths due to influenza among children (average ~80 per year) are much lower than adults (>65yrs), significantly some deaths occurred in children with no underlying conditions and in others that had not previously been vaccinated.

Young children are also an important reservoir of influenza virus, and while vaccination coverage levels remain low (~30-40%) in this group, children can pose a transmission risk to persons in close proximity especially with underlying comorbidities. Indeed, the latest ACIP recommendations suggest that in times of limited flu vaccine supply, priority for vaccination should be given to contacts of children aged <6 months (1). Lastly, another important consideration might be one of accessibility. It is well known that logistically children are easier to vaccinate than adults because of the many other vaccines they receive as part of recommended pediatric schedules. If the importance of reducing the impact of influenza on the community as a whole increasingly rests with children, then it seems that a strategy of “get them young” is now emerging for influenza vaccination.

With the advent of the new ACIP recommendations and the seemingly fierce competition between US flu vaccine suppliers it is tempting to speculate with regard to who might benefit most from a predicted increase in demand. According to the CDC, the six companies which supplied the US flu vaccine market in the 2007-2008 season distributed 113 million doses. Total production for the 2008-09 season is estimated to exceed 130 million doses (1). Both leading rivals Novartis Vaccines and Sanofi Pasteur have already released statements in early August (2, 3) suggesting they are keen to be the number one company in terms of supply volume and earliest delivery time. However, in light of the ACIP statement stating that children 6 months through 4 years should “continue to be a primary focus of vaccination efforts” – could this more benefit Sanofi whose product has a lower age range than Novartis Vaccines? Conversely, any loss to Novartis Vaccines in the youngest groups could be made-up in the 5-18 years expansion which involves 10 of millions of additional vaccinees.

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AstraZeneca/Medimmune is also likely to benefit from the continued focus on the younger age group with its live-attenuated influenza vaccine (LAIV) known as "Flumist". Flumist, which is administered intranasally, is licensed for vaccination of children aged above 2 yrs and adults aged less than 49 yrs. Although, the vaccine is a small component of the overall US market registering a mere \$57 million in 2007 (estimated 4 million distributed doses), AZ/Medimmune have announced intentions to triple production in the coming years due to increasing demand (4). In previous recommendations, the manufacturer was able to gain a lower age range than the initial 4 yrs for its vaccine.

Looking forward to the coming season, **VacZine Analytics** believes that with the new recommendations, flu manufacturers will embark on active promotion programs to ensure capture of the 5-18 yrs expansion. This will especially be the case in the 6 months – 8 years group where they have the opportunity to sell two doses to a child that has not been vaccinated at any time previously or received one dose in their first year of vaccination. However, with coverage presently at rates of ~17% (5-17 yrs) and a higher focus on HPV vaccination, it won't be easy convincing otherwise robust teenagers that they need a vaccine for flu.

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- (2) Novartis Vaccines. Corporate Press Release, August 7, 2008. Available at: [http://www.novartisvaccines.com/us/news/07aug08\\_fluvirin\\_ships.pdf](http://www.novartisvaccines.com/us/news/07aug08_fluvirin_ships.pdf). Accessed: August 2008
- (3) Sanofi Pasteur: Corporate Press Release, August 1, 2008. Available at: Accessed: [http://www.sanofipasteur.com/sanofi-pasteur2/front/index.jsp?siteCode=SP\\_CORP](http://www.sanofipasteur.com/sanofi-pasteur2/front/index.jsp?siteCode=SP_CORP). August 2008
- (4) Medimmune to triple Flumist Production. Washington Business Journal. February 2008. Available at: <http://washington.bizjournals.com/washington/stories/2008/02/25/daily43.html>. Accessed August 2008

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**About VacZine Analytics:**

VacZine Analytics is a new strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines.

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