Fluzone Vaccine and Influenza Market Update

Phil Hosbach, Vice President Immunization Policy

Agenda

- 2012-2013 Fluzone Vaccine Campaign
- Influenza Immunization: Progress report
- Sanofi Pasteur’s Commitment to Influenza Education and Immunization
Sanofi Pasteur: A Unique Partner in the Fight Against Influenza

● Commitment
  ● Decades of experience producing Fluzone vaccine
  ● Longstanding investment in vaccine development and influenza education
  ● Customer and Consumer focused

● Capacity
  ● Two US based influenza vaccine manufacturing facilities
  ● Capacity increased to meet increased demand
  ● Continuous Improvement – Greater Efficiency
  ● Pandemic Preparedness

Sanofi Pasteur: A Unique Partner in the Fight Against Influenza

● Comprehensive Influenza Portfolio
  ● Fluzone Vaccine indication starting at 6 months of age
  ● Fluzone High-Dose Vaccine – 65 years of age and older
  ● Fluzone Intradermal Vaccine – 18-64 years of age

● Coming Soon
  ● Fluzone Quadrivalent vaccine file submitted for 6 months of age and older; anticipated FDA action in June
  ● Fluzone Intradermal and Fluzone High-Dose to follow over next few years

● What’s next?
  ● Universal Vaccine development Program
  ● H7N9 .....???
2012-2013 Fluzone Vaccine Season

- Over 60M doses delivered
  - No delay in licensing or production of Fluzone vaccine despite 2 strain changes compared to the prior season
  - ~72% of customer reserved doses shipped by end of August

- Increased number of presentations and brands in the marketplace make it more complex and more difficult to predict HCP demand by presentation

- Improved packaging to meet customer demands
  - All Fluzone presentations are not made with natural rubber latex
  - Reduced all prefilled syringe package sizes
    - 38% reduction in syringe presentation package size
    - 26% reduction in Fluzone Intradermal vaccine package size

Fluzone High-Dose Vaccine: Influenza Vaccine For Older Adults

- People 65 years of age and older suffer disproportionately from influenza-related complications
  - 90% of deaths

- Aging, weakened immune systems do not respond as well as younger immune systems

- Fluzone High-Dose vaccine was designed to generate a more robust immune response in people 65 years of age and older – met superiority criteria relative to Fluzone vaccine
  - Up to 80% greater response compared to Fluzone vaccine
  - Post-licensure studies consistently demonstrate significantly higher antibody responses to Fluzone High-Dose vaccine

- Fluzone High-Dose usage increased substantially over 2011
  - 1 in 5 of immunized persons 65 years of age and older received Fluzone High-Dose vaccine during the 2012-2013 season
Fluzone Intradermal Vaccine – An Alternative for Persons 18 through 64 Years of Age

- 2012-2013 first full year Fluzone ID was on the market
- Device makes vaccination more efficient for immunizers
  - Ready-to-use formulation minimizes prep time
  - Integrated needle shield activated post-vaccination
  - 1.5mm microneedle accurately delivers antigen into dermis
- Survey data suggest provider and patient experiences were positive
  - 90% of providers were satisfied, 89% will use it again next year, and 30% will use it for all of their 18-64 year old patients (n=600)
  - 91% of patients said that they would get it again

Prior to the Surge in Disease, Immunization Rates Were Tracking to be Flat Once Again

Claims Data Shows an Increase in Late Season Immunization in Response to Disease

Source: IMS Health’s electronic healthcare claims database. Note: Reflects projected number of patients receiving flu vaccine in physician offices. Excludes immunizations given through other channels (employers, pharmacies, senior centers, etc.) and those not submitted for reimbursement (Vaccines for Children program, vaccines paid 100% out-of-pocket).

Media Highlighted the Impact of Disease as the Season Progressed

“Death rates from flu have soared well above those of the last few years, confirming that this will be a severe flu season. The Centers for Disease Control and Prevention issued guidelines to doctors, suggesting giving high-dose flu shots to the elderly.”

“The nation’s nasty flu season has created a sudden surge in demand for vaccine, leaving some sites across the country short on the shots that can prevent illness.”

“An early and fierce start to this year’s flu season, which has already drawn the “epidemic” label from the Centers of Disease Control, has driven New Yorkers to snap up the vaccine.”

“Most of the US is nearing peak levels seen during moderately severe flu seasons, according to the CDC. People who haven’t gotten vaccinated and want to get the vaccine may have to look several places for it.”

“Some parts of the country are experiencing spot shortages of the flu vaccine because of increased demand in a flu season that is more severe than previous years.”
Incidence of Influenza Highest Since 2007-2008 Season

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Illness Surveillance Network (ILInet), Weekly National Summary, 2012-13 and Selected Previous Seasons

http://www.cdc.gov/flu/weekly/ accessed 4-3-13

Pediatric Deaths Occurred Mostly in Unvaccinated Patients

90% of deaths in children (<18 years of age) were in those who were not vaccinated
- Estimated immunization rate for children was <40% (as of November CDC survey)
- 40% of the children who died had no recognized chronic health problems (percentage in line with previous years estimates)

http://www.cdc.gov/flu/spotlights/children-flu-deaths.htm accessed 5-7-2013
Market Research Continues to Report the Same Reasons Why Patients Get Immunized

<table>
<thead>
<tr>
<th>Reasons for receiving a Seasonal flu immunization</th>
<th>PEDS</th>
<th>ADULTS</th>
<th>CHRONICALLY ILL</th>
</tr>
</thead>
<tbody>
<tr>
<td>I [have my child] get the flu vaccine every year</td>
<td>65%</td>
<td>68%</td>
<td>81%</td>
</tr>
<tr>
<td>Doctor’s recommendation</td>
<td>44%</td>
<td>33%</td>
<td>45%</td>
</tr>
<tr>
<td>News exposure</td>
<td>18%</td>
<td>20%</td>
<td>16%</td>
</tr>
</tbody>
</table>

The main reason for not immunizing is perceived lack of need

<table>
<thead>
<tr>
<th>Reasons for Not Immunizing</th>
<th>PEDS</th>
<th>ADULTS</th>
<th>CHRONICALLY ILL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Don’t believe [my child] needs a flu vaccination</td>
<td>39%</td>
<td>45%</td>
<td>35%</td>
</tr>
<tr>
<td>Concerned with getting the flu from the vaccine</td>
<td>13%</td>
<td>18%</td>
<td>19%</td>
</tr>
<tr>
<td>Don’t like to receive shots</td>
<td>9%</td>
<td>18%</td>
<td>19%</td>
</tr>
</tbody>
</table>

Recommendations Wane After October Despite Patients Continuing to be in the Office

Doctor Visits and Immunizations Offered for Adults (Average number of visits for Sept-Apr among those going = 2.6)

<table>
<thead>
<tr>
<th></th>
<th>September (n=337)</th>
<th>October (n=307)</th>
<th>November (n=254)</th>
<th>December (n=257)</th>
<th>January (n=316)</th>
<th>February (n=260)</th>
<th>March (n=294)</th>
<th>April (n=353)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was offered a Seasonal Vaccine</td>
<td>49%</td>
<td>44%</td>
<td>30%</td>
<td>26%</td>
<td>23%</td>
<td>16%</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Was not offered a Seasonal Vaccine</td>
<td>41%</td>
<td>45%</td>
<td>55%</td>
<td>61%</td>
<td>63%</td>
<td>68%</td>
<td>73%</td>
<td>72%</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9%</td>
<td>11%</td>
<td>14%</td>
<td>13%</td>
<td>13%</td>
<td>12%</td>
<td>11%</td>
<td>12%</td>
</tr>
</tbody>
</table>

See “Notes” section for question text. BASE: Those who visited their doctor’s office during <month>.
The National Influenza Vaccine Summit
Mission is More Important Than Ever

- Education will be critical to increasing influenza immunization rates
  - Incidence of disease has direct impact on vaccination rates – motivating public to get immunized during mild years will continue to be a challenge
  - Year after year, market research indicates that consumers are more likely to get immunized if offered vaccination from their provider

- To ensure that we achieve growth in immunization rates, we must make sure our messages are clear
  - Vaccination is a safe and effective way to help prevent influenza
  - Influenza is a serious disease and everyone is at risk
  - Vaccination must continue throughout the full season

IMPORTANT SAFETY INFORMATION
Important Safety Information

Indication
Fluzone, Fluzone High-Dose, and Fluzone Intradermal vaccines are indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccines.

Fluzone vaccine is approved for use in persons 6 months of age and older. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older. Fluzone Intradermal vaccine is approved for use in persons 18 through 64 years of age.

Approval of Fluzone High-Dose vaccine is based on superior immune response relative to Fluzone vaccine. Data demonstrating a decrease in influenza disease after vaccination with Fluzone High-Dose vaccine relative to Fluzone vaccine are not available.

Safety Information
The most common local and systemic adverse reactions to Fluzone and Fluzone High-Dose vaccines include pain, erythema, and swelling at the vaccination site; fever, headache, malaise, and myalgia. Erythema, induration, swelling, and pruritus at the vaccination site occur more frequently with Fluzone Intradermal vaccine than with Fluzone vaccine. Other adverse reactions to Fluzone Intradermal vaccine include pain at the vaccination site; headache, myalgia, and malaise. Adverse reactions other than those listed above may occur.

Fluzone, Fluzone Intradermal, and Fluzone High-Dose vaccines should not be administered to anyone with a severe allergic reaction (eg, anaphylaxis) to any vaccine component, including egg protein, egg products, or thimerosal (the multi-dose vial of Fluzone vaccine is the only presentation that contains thimerosal), or to a previous dose of any influenza vaccine. The decision to give Fluzone, Fluzone Intradermal, or Fluzone High-Dose vaccine should be based on the potential benefits and risks, especially if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine. Vaccination with Fluzone, Fluzone Intradermal, or Fluzone High-Dose vaccines may not protect all individuals.

Before administering Fluzone, Fluzone Intradermal, or Fluzone High-Dose vaccines, please see accompanying full Prescribing Information.

Thank you.