

# Fluzone® Vaccine and Influenza Market Update

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## Agenda

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- 2013-2014 Fluzone Vaccine Campaign
- Influenza Immunization: Progress Report
- Sanofi Pasteur's Commitment to Influenza Education and Immunization

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## Sanofi Pasteur: A Unique Business Partner in the Fight Against Influenza

- Reliability
  - Proven track record
    - Over 40 years of experience producing Fluzone vaccine in Swiftwater, PA
  - Manufacturing capacity
    - Two US manufacturing facilities dedicated to influenza vaccine for every customer commitment
    - Distributed over 60M doses during the 2013-2014 season
- Breadth of products
  - Fluzone High-Dose vaccine
  - Fluzone Intradermal vaccine
  - Fluzone Quadrivalent vaccine
  - Fluzone vaccine
- Service
  - Full suite of materials and solutions to help grow immunization rates
  - Consistent investment in educating health care providers and patients about the need for influenza immunization

## Fluzone Family of Vaccines Aligns With the Diversity of the Population

|                              |   |                            |  |
|------------------------------|---|----------------------------|--|
| Fluzone High-Dose Vaccine    |  | 65 years of age and older  | <ul style="list-style-type: none"> <li>● Fluzone High Dose Vaccine               <ul style="list-style-type: none"> <li>● Generates a more robust immune response in adults 65 years of age and older</li> </ul> </li> </ul>   |
| Fluzone Intradermal Vaccine  |  | 18 through 64 years of age | <ul style="list-style-type: none"> <li>● Fluzone Intradermal Vaccine               <ul style="list-style-type: none"> <li>● Eliminates steps in the immunization process helping to increase overall efficiency during influenza vaccination season</li> </ul> </li> </ul> |
| Fluzone Quadrivalent Vaccine |  | 6 months of age and older  | <ul style="list-style-type: none"> <li>● Fluzone Quadrivalent Vaccine               <ul style="list-style-type: none"> <li>● Broadens protection for those patients whom the B strain can be devastating</li> </ul> </li> </ul>  |
| Fluzone Vaccine              |  | 6 months of age or older   | <ul style="list-style-type: none"> <li>● Fluzone Vaccine               <ul style="list-style-type: none"> <li>● Helps provide trivalent protection for patients 6 months and above</li> </ul> </li> </ul>  |

## Older Adults Continue to be Impacted Despite Higher Rates of Immunization

- People 65 years of age and older suffer disproportionately from influenza-related complications
  - 90% of influenza-related deaths typically occur in people 65 years of age and older<sup>1</sup>
  - 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
- Anticipate 1 out of every 3 patients 65 years of age and older receiving Fluzone High-Dose Vaccine this upcoming season
  - 2013-2014 season – 1 in 4 patients received Fluzone High-Dose Vaccine

References 1. Centers for Disease Control and Prevention (CDC). *MMWR*. 2009;58(RR-8):1-52.

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## Children – Focus on Second Dose Compliance Needed

- Among 105 pediatric influenza-associated deaths that were reported during the 2012-2013 season (through Mar 22, 2013)<sup>1</sup>
  - ~90% of deaths occurred in unvaccinated children
  - In 40% of deaths, the child had no recognized chronic health problem
- During 2012-2013 season, pediatric 2nd dose immunization rates remained low regardless of age<sup>2</sup>
  - 45.5% of 6-35 months old (vs. 65.9% receiving at least one dose)
  - 31.4% of 24-59 months old (vs. 45.9% receiving at least one dose)
- Routine reporting of second dose immunization rates as part of the National Influenza Survey can help track compliance

Reference: 1. CDC. CDC reports about 90 percent of children who died from flu this season not vaccinated. <http://www.cdc.gov/flu/spotlights/children-flu-deaths.htm>. Accessed May 13, 2013. 2. Singleton JA. Influenza vaccination distribution and coverage, United States, 2012-13 season. ACIP presentation, October 24, 2013. <http://www.cdc.gov/vaccines/acip/meetings/slides-oct-2013.html> accessed May 5, 2014.

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## Adults - Immunization Rates for Adults Remains Low – 33.1%<sup>1</sup>

- Adult immunization rates remain the lowest among all populations
  - 18-49 year old population had 31.1% coverage during 2012-2013 season<sup>1</sup>
- 2013-2014 season resurgence of H1N1 showed overall increase in rate of hospitalization for adult population - people 18-64 years accounted for approximately 60% of reported hospitalized cases<sup>2</sup>
- Recommendation from provider remains number one reason adults get immunized
  - “Lack of need” main reason why adults not vaccinated

**References:** 1. National Immunization Survey (NIS) and Behavioral Risk Factor Surveillance System (BRFSS). Flu Vaccination Coverage, United States, 2011-12 Influenza Season [http://www.cdc.gov/flu/fluview/coverage\\_1112estimates.htm](http://www.cdc.gov/flu/fluview/coverage_1112estimates.htm). Accessed 4-16-14 2. FluView: Influenza Hospitalization Surveillance Network, Centers for Disease Control and Prevention. <http://www.cdc.gov/flu/weekly/> accessed 5-2-2014.

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## Fluzone Intradermal Vaccine – To be Quadrivalent for 2015-2016 Season

- 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



- 2013 Time and Motion study compared the efficiency of Fluzone Intradermal vaccine to both a Fluzone vaccine syringe and multi-dose vial
  - Showed a time savings of between 31-46 seconds per dose over using a prefilled syringe presentation
    - Allows for up to 23 additional doses in an hour (in a clinic setting)
    - Potentially 2.2 fewer immunizers to vaccinate 1000 people in 4 hour clinic

## Sanofi Pasteur Continues to Invest in the Future of Influenza Prevention

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- Broadening protection through converting presentations to quadrivalent formulation
  - Pediatric syringes are only available in Quadrivalent formulation
  - Fluzone Intradermal Vaccine
  - Fluzone High Dose Vaccine
- Facilitating tracking immunizations
  - 2D barcoding for unit of use
- Researching options for every age group
  - Robust universal vaccine development programs, egg alternatives, adjuvants

## The National Influenza Vaccine Summit Mission is More Important Than Ever

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- Educate that the risk is real - perceived lack of need is biggest barrier to immunization
  - Incidence of disease has direct impact on vaccination rates – motivating public to get immunized during “mild” seasons will continue to be a challenge
- Despite best efforts, provider recommendations for immunization decline in November and December
- To ensure immunization rates continue to grow, messages must be 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 entire season

# IMPORTANT SAFETY INFORMATION

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## Important Safety Information

### Indication

Fluzone Quadrivalent, Fluzone Intradermal, and Fluzone High-Dose vaccines are inactivated influenza virus vaccines indicated for active immunization for the prevention of influenza disease caused by influenza subtype A and type B viruses contained in each vaccine.

Fluzone Quadrivalent vaccine is approved for use in persons 6 months of age and older.

Fluzone Intradermal vaccine is approved for use in persons 18 through 64 years of age. Fluzone High-Dose vaccine is approved for use in persons 65 years of age and older. 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 Quadrivalent and Fluzone High-Dose vaccines include soreness, pain (tenderness in young children receiving Fluzone Quadrivalent vaccine), and swelling at the injection site; myalgia, malaise, headache, and fever (also irritability, abnormal crying, drowsiness, appetite loss, and vomiting in young children receiving Fluzone Quadrivalent vaccine). The most common local and systemic adverse reactions to Fluzone Intradermal vaccine include erythema, induration, swelling, pain, and pruritus at the injection site; headache, myalgia, and malaise. Other adverse reactions may occur.

Fluzone Quadrivalent, Fluzone Intradermal, and Fluzone High-Dose vaccines should not be administered to anyone with a known hypersensitivity (eg, anaphylaxis) to any vaccine component, including egg protein or thimerosal (the multi-dose vial is the only presentation containing thimerosal), or to a previous dose of any influenza vaccine. If Guillain-Barré syndrome has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone Quadrivalent, Fluzone Intradermal, or Fluzone High-Dose vaccine should be based on careful consideration of the potential benefits and risks. Vaccination with Fluzone Quadrivalent, Fluzone Intradermal, or Fluzone High-Dose vaccine may not protect all individuals.

Before administering Fluzone Quadrivalent, Fluzone Intradermal, or Fluzone High-Dose vaccine, please see full Prescribing Information.

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Thank you.