



# National Influenza Vaccine Summit

CSL Biotherapies Influenza Vaccine

2008-2009 Season

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**CSL Biotherapies**

# CSL's Flu Vaccine Business

- Global headquarters: Parkville, Australia
  - US headquarters: King of Prussia, PA
- Flu vaccines sold in 17 countries worldwide
  - Afluria approved by FDA in September 2007
- Annual capacity: 40 million doses
- Primarily prefilled syringes, preservative free
- Thimerosal withdrawn from bulk manufacturing process
- Latex free



**CSL Biotherapies**

# We manufacture for Southern and Northern hemispheres, year round



- Committed to consistently developing flu vaccines based on strains changes decided by WHO and FDA
  - Expertise in early prediction of strains changes - ahead of official regulatory decisions e.g., 2008/09
    - H1N1 'Brisbane 59-like' strain was anticipated by CSL and can be produced
    - H3 N2 'Brisbane 10-like' strain
    - B 'Florida – like' strain
  - Early planning and improvement of our yields to allow early delivery to market
- } previously used in Southern Hemisphere '08 vaccine

# Afluria<sup>®</sup>: Thimerosal-free, latex-free



CSL Biotherapies



A NEW FLU VACCINE FROM A RELIABLE SOURCE.

## The Word Is Out. Pass It On.

Now there's a new vaccine to help protect your patients and your community from flu...all season long.

- **Thimerosal-free** and **latex-free\*** (CPT<sup>®</sup> code 90656)
- **Convenient**, single-use, prefilled syringe delivery
- **Reliable availability** throughout the flu season
- **From a trusted influenza vaccine manufacturer** with 40 years' experience

### Important Safety Information

Afluria<sup>®</sup> is indicated for active immunization of persons 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. The indication is based on the immune response elicited by Afluria<sup>®</sup>; no controlled clinical studies have demonstrated a decrease in influenza disease after vaccination with Afluria<sup>®</sup>.

Afluria<sup>®</sup> should not be administered to individuals with hypersensitivity to eggs or chicken protein or other components of Afluria<sup>®</sup>, or to anyone who has had a life-threatening reaction to previous influenza vaccination.

The most common injection-site adverse reactions were tenderness, pain, redness, and swelling. The most common systemic adverse reactions were headache, malaise, and muscle aches.

Vaccination with Afluria<sup>®</sup> may not protect all individuals. Immunocompromised persons may have a diminished immune response. If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give Afluria<sup>®</sup> should be based on careful consideration of the potential benefits and risks.

Please see brief summary of full prescribing information on adjacent page.

\*Afluria<sup>®</sup> is also available in a latex-free, multidose vial formulation containing thimerosal as a preservative (CPT<sup>®</sup> code 90658).

<sup>†</sup>CPT is a registered trademark of the American Medical Association.



For a list of authorized distributors, call **1-888-4FLU-OFF** (1-888-435-8633).

To learn more about new Afluria<sup>®</sup>, visit [www.afluria.com](http://www.afluria.com).

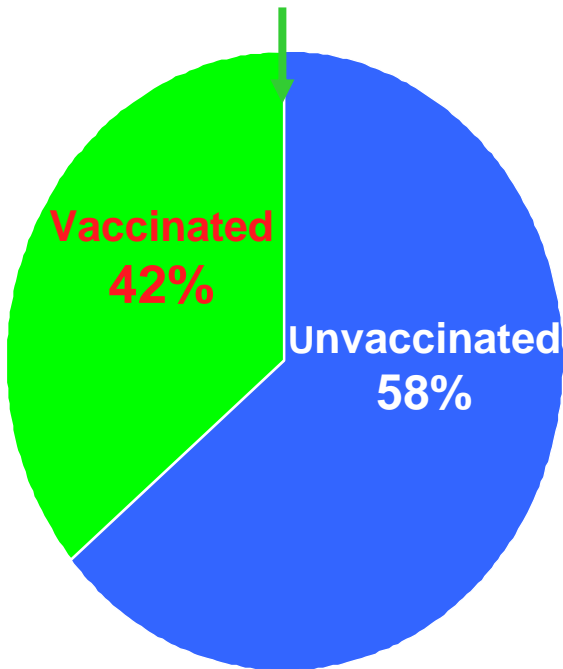
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Introducing  
**afluria.**  
influenza virus vaccine

# CSL's Commitment to Public Health



Health care worker  
vaccination 2006



**You take care of everyone else.  
Now take care of yourself.**

Get immunized against influenza.

Because you work in a healthcare setting, you are at an increased risk for acquiring and transmitting the influenza virus— regardless of what your actual job is. By getting a flu vaccine, you're helping yourself and the patients around you.

For more information, go to [www.nfid.org](http://www.nfid.org).

The advertisement features a photograph of five healthcare professionals in various uniforms (scrubs, lab coats, and a nurse's cap) standing in a line. Below the photo is a blue banner with white text, followed by a white section with black text, and a footer with logos for the National Foundation for Infectious Diseases and CSL Biotherapies.

**CSL Biotherapies**

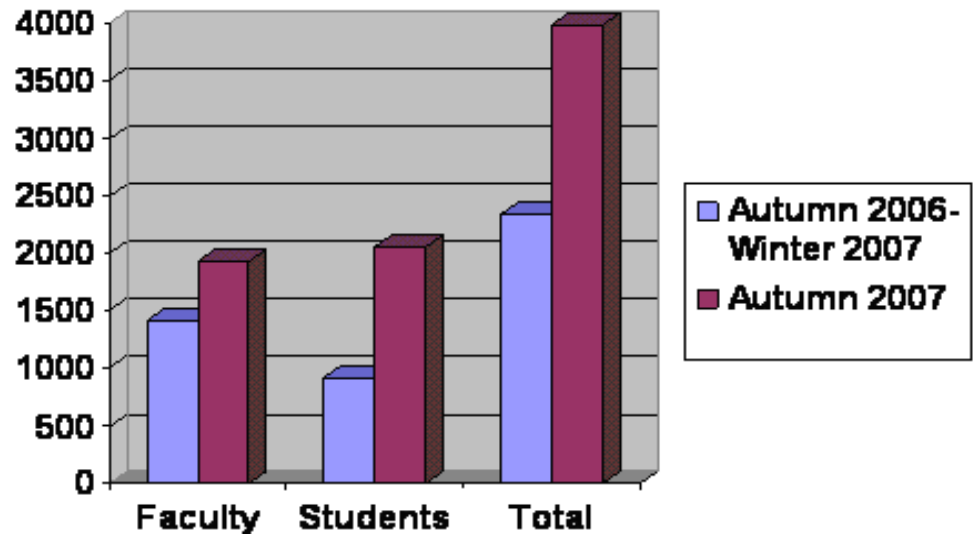
# CSL's Commitment to Public Health



- American College Health Association(2006): Flu is major impediment (26%) to academic performance
- ‘Season Pass’: Turn-key educational & motivational program to increase immunization rates on College Campuses
- **Season Pass impact: + 40% increase !**

Arizona State University

Medscape® [www.medscape.com](http://www.medscape.com)



**CSL Biotherapies**



## Afluria 2008-2009 Season

- Our goal is to distribute 6 million doses
- 90% in thimerosal-free prefilled syringes
- First market deliveries expected in late August, early September
- Continue patient advocacy, educational programs to underscore the importance of influenza prevention

# Our Short-Term Plans



- Afluria pediatric indication is a priority
  - clinical trials with thimerosal free prefilled syringe
  - pediatric indication granted by TGA in 2007
- Coming soon: fast filling syringe line - Kankakee, Ill.



# Other Vaccine Activities



## *Gardasil*

- Based on CSL technology licensed to Merck
- GARDASIL® is marketed by CSL Biotherapies in Australia and NZ

## *Iscomatrix™ adjuvant*

- Provides both antigen delivery and immunomodulatory properties
- Antigen dose reduction properties
- Manufactured in Kankakee, IL plant
- Multiple partners and applications

# In Summary...



- We have reliably produced safe flu vaccines over four decades
- CSL Biotherapies will contribute to meeting the U.S. growing demand for reliable flu vaccine each year



Thank you

**CSL Biotherapies**