



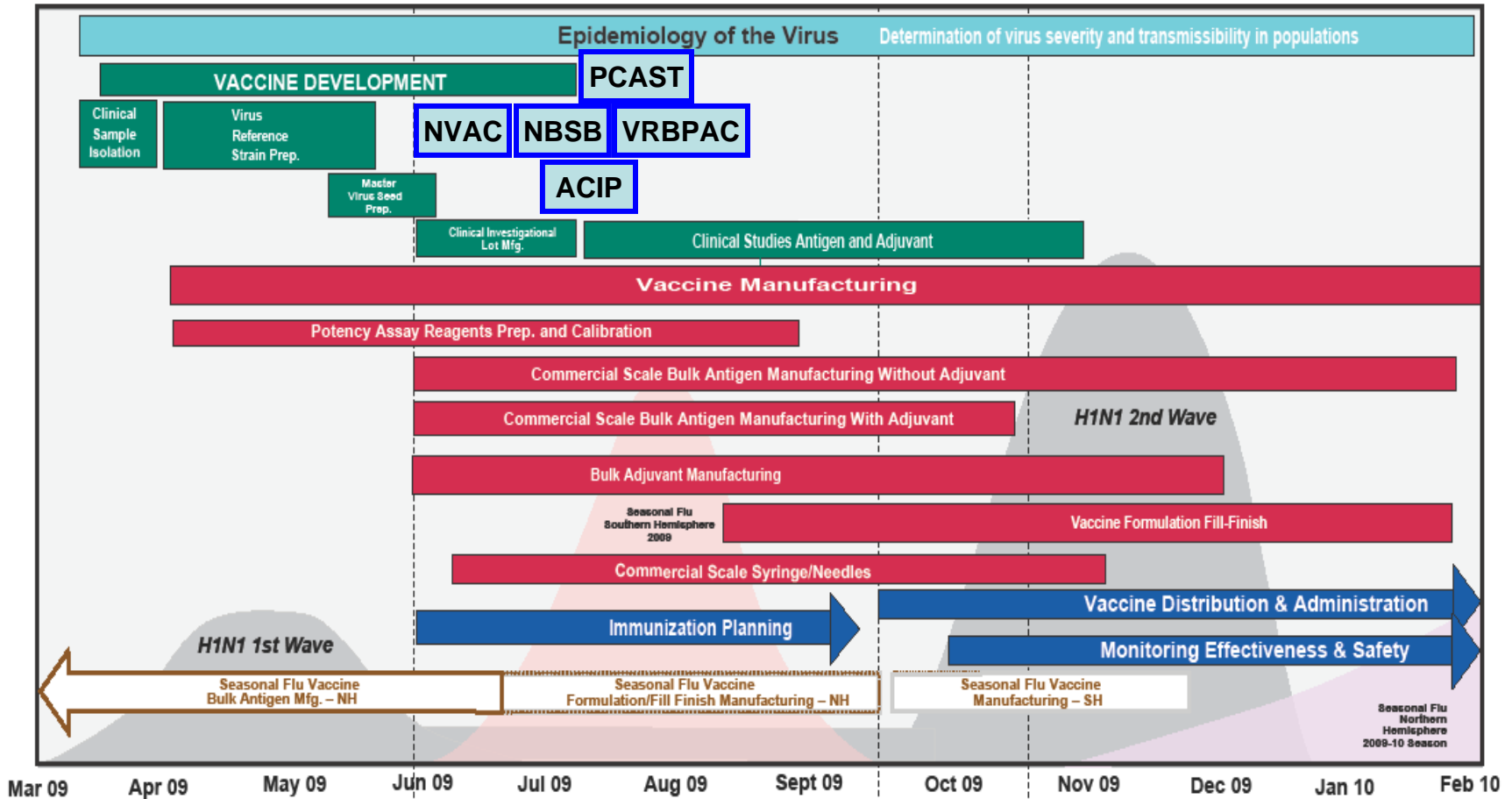
H1N1 Pandemic: HHS Perspective - Vaccines

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HHS/ASPR/BARDA



U.S. 2009-H1N1 Vaccine Strategy





United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)



H1N1 Vaccine Products

Standard vaccine – U.S.-licensed



Multi-dose vial

**Single-dose
Syringe**

**Intranasal
Sprayer**

CSL Novartis sanofi pastuer GSK

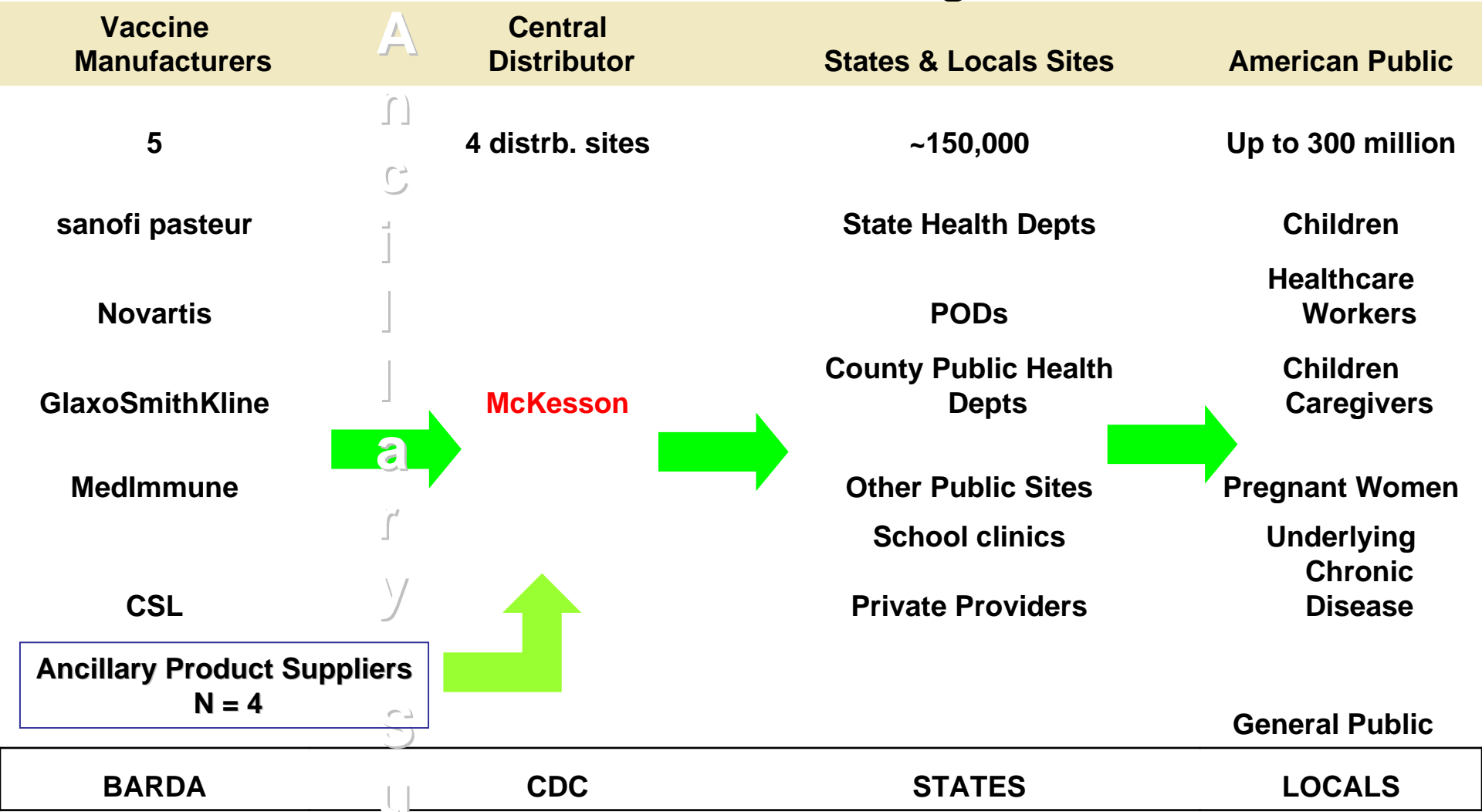
MedImmune

Inactivated, subunit vaccine

Live, attenuated vaccine



U.S. H1N1 Vaccine Manufacturing – Distribution





H1N1 Vaccine Lessons Learned

- **Vaccine Development**
 - HHS experience with manufacturers & VTEUs paid off well
- **Vaccine Manufacturing**
 - Better methods needed to select & archive high growth virus strains
 - Better production methods needed for manufacturing seasonal & pandemic vaccine
 - More domestic bulk vaccine manufacturing capacity needed
 - Clear communication of vaccine capacity vs. actual vaccine production when potency assay data needed to set more reasonable expectations on vaccine availability
 - More rapid and better vaccine potency assay needed
 - Fill finish manufacturing into multidose vials for inactivated vaccine
 - Sharing of working virus seed stocks and manufacturing information among manufacturers
 - Sooner rehearsals of new production lines
 - Utilization of veterinary flu vaccine manufacturing expertise on swine flu strains



More Lessons Learned from H1N1 Pandemic

- **Having a commercial market changes the game**
- **Dual usage principle exemplified by influenza vaccines**
- **Vaccine development, manufacturing, & distribution, & administration are vital links in the pandemic vaccine program**
- **HHS interagency collaboration was key to success**
- **Collaboration/transparency with industry is just as important**
- **Find ways to reduce undue influence in science and decision-making**
- **Crises can bring out the best in everyone involved**
- **Expect the unexpected**
- **Don't forget the role of the public**



Future Directions

- **Short term**
 - Countermeasure Enterprise Review ordered by Sec. Sebelius
 - Complete, expand, & expedite pandemic influenza countermeasure development & manufacturing infrastructure building following after action reviews
 - Potency assays: SRID assay → new methods (e.g., mass spec) reduce from 8-12 weeks → days
 - Sterility assays: std. 14 day → 5 day assay
 - Virus seed selection for high growth & library of possible pandemic strains
 - Expanded domestic fill finish manufacturing network
- **Mid-term**
 - Cell-based vaccines with clinical virus isolates passaged in cells to make virus reference strains (1-2 weeks savings)
- **Long term**
 - Recombinant- and molecular-based vaccines that are non-dependent on virus growth (up to 8 weeks savings)