

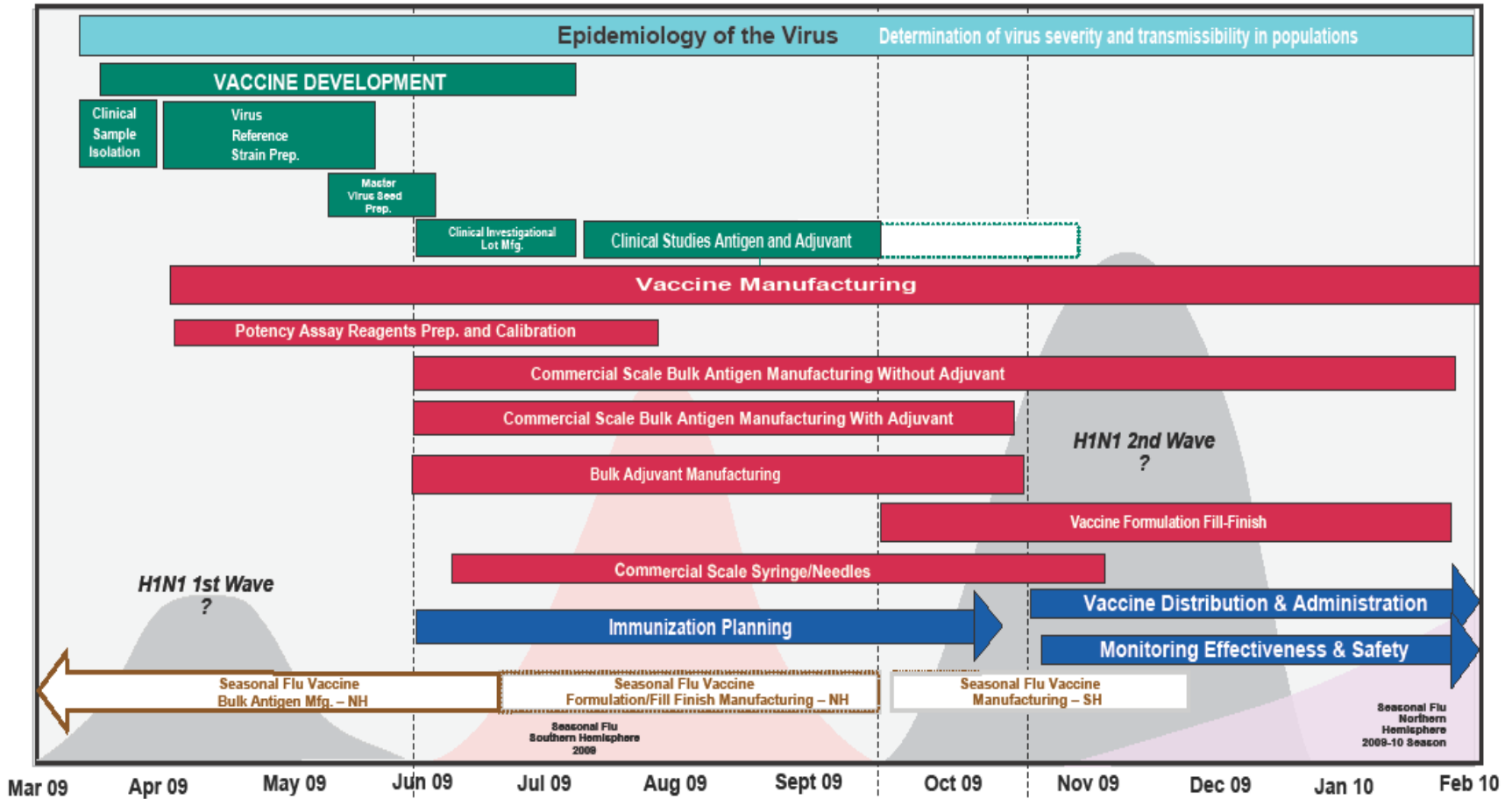


H1N1 Vaccine & Antivirals

GHSI Meeting

**Robin Robinson, Ph.D.
HHS/ASPR/BARDA Director
November, 2009**

U.S. 2009-H1N1 Vaccine Strategy





ASPR H1N1 Vaccine Timelines & Issues

- **Clinical lots formulated using surrogate HPLC assays & clinical studies began (Jul/Aug 09) to inform vaccine formulation and safety profile**
- **Licensure of seasonal monovalent antigen-alone vaccine formulations recommended by VRBPAC (7/23) as strain changes**
- **H1N1 vaccine formulated with adjuvant may be considered under EUA**
- **H1N1 vaccine availability by September 2009 recommended by NBSB (7/17)**
- **Inactivated, subunit vaccine production factors (Summer 09)**
 - low production yields
 - seasonal vaccine campaign completion
 - potency assay reagents availability
 - syringe fill finish manufacturing capacity
- **Determination of targeted population for H1N1 vaccination by ACIP (7/29) affect amount, timing, and type of H1N1 vaccines**

H1N1 Vaccine Products

Standard vaccine – U.S.-licensed



Multi-dose vial

CSL Novartis

Inactivated, subunit vaccine



**Single-dose
Syringe**

sanofi pastuer GSK



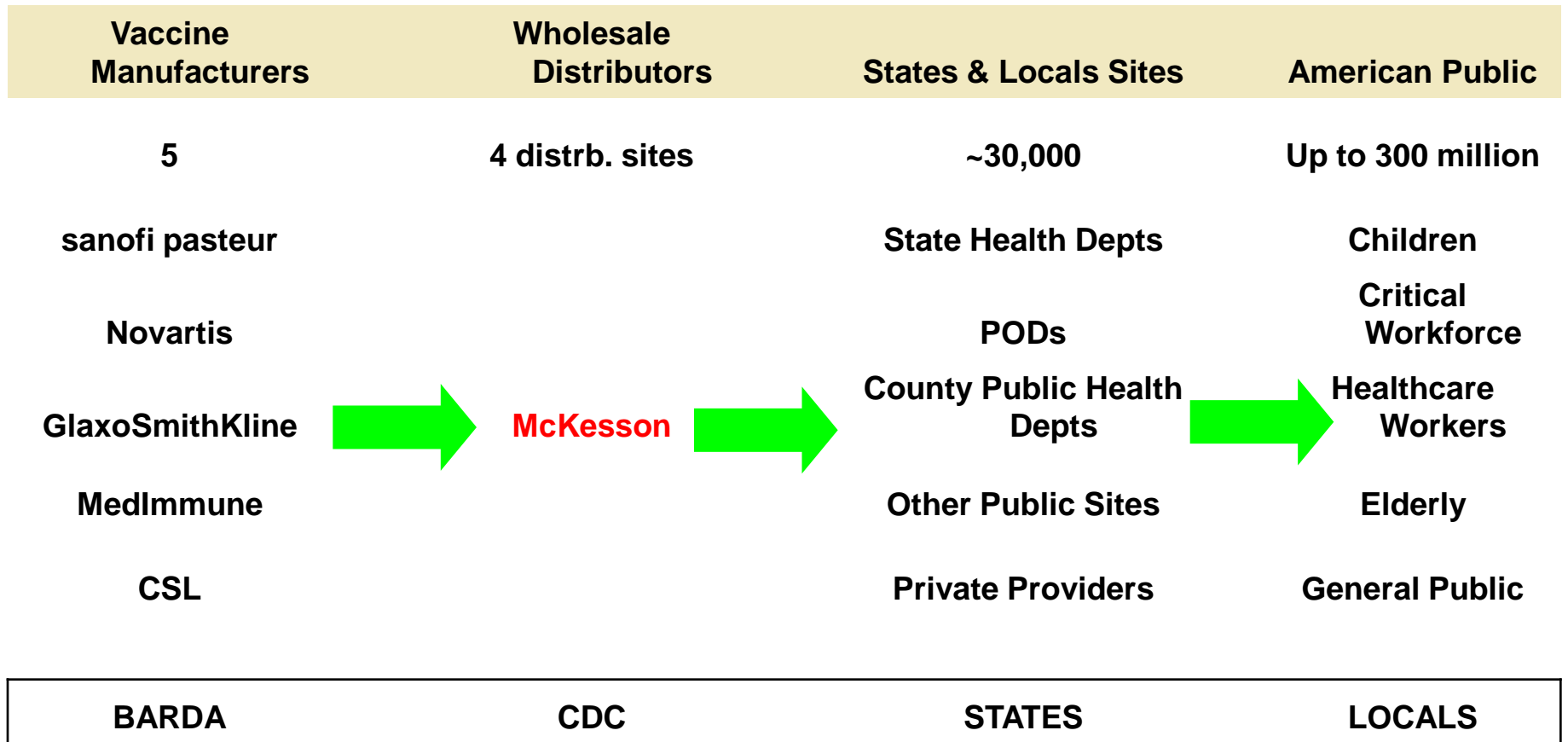
**Intranasal
Sprayer**

MedImmune

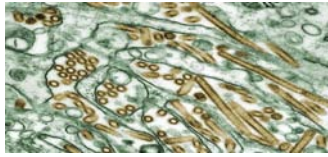
Live, attenuated vaccine



H1N1 Vaccine Distribution Options



H1N1 Vaccine Manufacturing Process



Virus

H5N1 Stockpile Contracts (2004)



Incubation



Eggs

Egg Supply Contract (2004)



Inoculate Eggs



Production

Sanofi Retrofit (2007)



Filling

MedImmune Retrofit (2007)



Packaging



Syringes



Distribution Centers



CDC Distribution to States

- Poor Virus Growth
- Production Challenges
- Delayed Seasonal Vaccine Completion
- Start up Issues with New Lines
- Formulation
- Filling Capacity Limits may Constrict Vaccine Supply



National Pandemic Influenza Antiviral Drug Stockpiles

Antiviral Drug Stockpiles Totals	Treatment Courses In-Stock	Treatment Courses Awaiting Delivery	Treatment Courses Awaiting Ordering	Est'd. Total Treatment Courses By Fall 09
Federal Totals	43,146,220	14,000,000	0	57,146,220
State Totals	35,323,779			35,323,779
Total (80:20 Tamiflu: Relenza)	78,469,999	14,000,000	0	92,469,999

IV antivirals procured and used for critically ill influenza patients under Emergency Usage Authorization

As of 11/04/09