Decision 1 - June 1st

Decision 2 - est. Sept 15th

Decision 2: $1.6B
- Initiate vaccine formulation, start fill and finish ($259M)
- Acquisition of additional adjuvants ($1.3B) (reallocated)

1. Develop a H1N1 vaccine Virus Reference Strain/Clinical Studies
   Task orders to be issued ASAP. Completion - (? Oct 15th)

2. Potency Assay Reagents are in preparation - tentative completion Aug 1st

3. Procurement of bulk adjuvant for stockpile started and decision to purchase for mass immunization by June 15th

4a. Procurement of bulk antigen for stockpile started (5/09) and decision to purchase bulk antigen for mass immunization by June 1st

4b. Seasonal flu vaccine bulk manufacturing will finish ~Aug 1st

5. Decision to procure mass quantities of syringes/needles decision by June 1st

6. Decision to start the vaccine formulation, upon completion of clinical studies and potency reagents/calibration. Epidemiology complete Oct 15th
   Clinical study results on safety, immunogenicity, dosage, adjuvant safety and effect (? Oct 15th)

7a. Decision to move forward with vaccine formulation/fill-finish manufacturing (? Oct 15th)

7b. Seasonal flu vaccine fill-finish manufacturing campaign will finish ~ Oct 31st

8. Decision to Immunize the nation (? Sept 15th)

Decision 1: $6.9 B- Procurement of bulk adjuvant, bulk antigen, and syringes/needles ($6.4 B)- Letters of intent to manufacturers - Phase one of vaccine immunization planning preparatory funds for State immunization planning ($453.4M)

Prior Decisions: $800M- Vaccine Development ($150M) Production of clinical investigational vaccine lots, clinical studies, and potency assay reagent production- Commercial Scale Up ($650M)

Decision 3 - est. Oct 15th

Decision 3: $3.9 - $4.3B
- Fund immunization program ($3.9B - $4.3B)
- Initiate immunization program

H1N1 2nd Wave

U.S. 2009-H1N1 Vaccine Strategy

Epidemiology of the Virus
Determination of virus severity and transmissibility in populations

Vaccine Manufacturing

Potency Assay Reagents Prep. and Calibration

Commercial Scale Bulk Antigen Manufacturing Without Adjuvant

Commercial Scale Bulk Antigen Manufacturing With Adjuvant

Bulk Adjuvant Manufacturing

Commercial Scale Syringe/Needles

Immunization Planning

Vaccine Formulation Fill-Finish

Vaccine Distribution & Administration

Monitoring Effectiveness & Safety

Seasonal Flu Vaccine Manufacturing – SH

Seasonal Flu Vaccine Formulation/Fill Finish Manufacturing – NH

Seasonal Flu Vaccine Formulation/Fill Finish Manufacturing – NH

Seasonal Flu Southern Hemisphere 2009

Seasonal Flu Northern Hemisphere 2009-10 Season