United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR)

The Pandemic Influenza Countermeasures Portfolio

Biomedical Advanced Research and Development Authority (BARDA)

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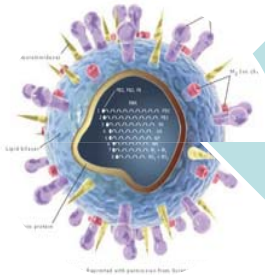
HHS/ASPR/BARDA

Today:

- Influenza: Virus(es) and disease(s)
- Consequences of Pandemic Influenza
- US response(s) and evolution of the Pandemic Influenza Portfolio
- BARDA's Influenza Division

Influenza



Virus(es)

Hemagglutinin

Neuraminidase

Subtypes

H5N1

H1N1

Antigenic ¨shift¨

Antigenic ¨drift¨

Sero-conversion

Zoonoses

Transmission

Re-assortants

Mild URT infections

Severe URT infections

Viral pneumonia

Bacterial pneumonia

Severe Acute Respiratory disease.

Systemic infections

Epidemics, pandemics, sporadic infections

High risk groups

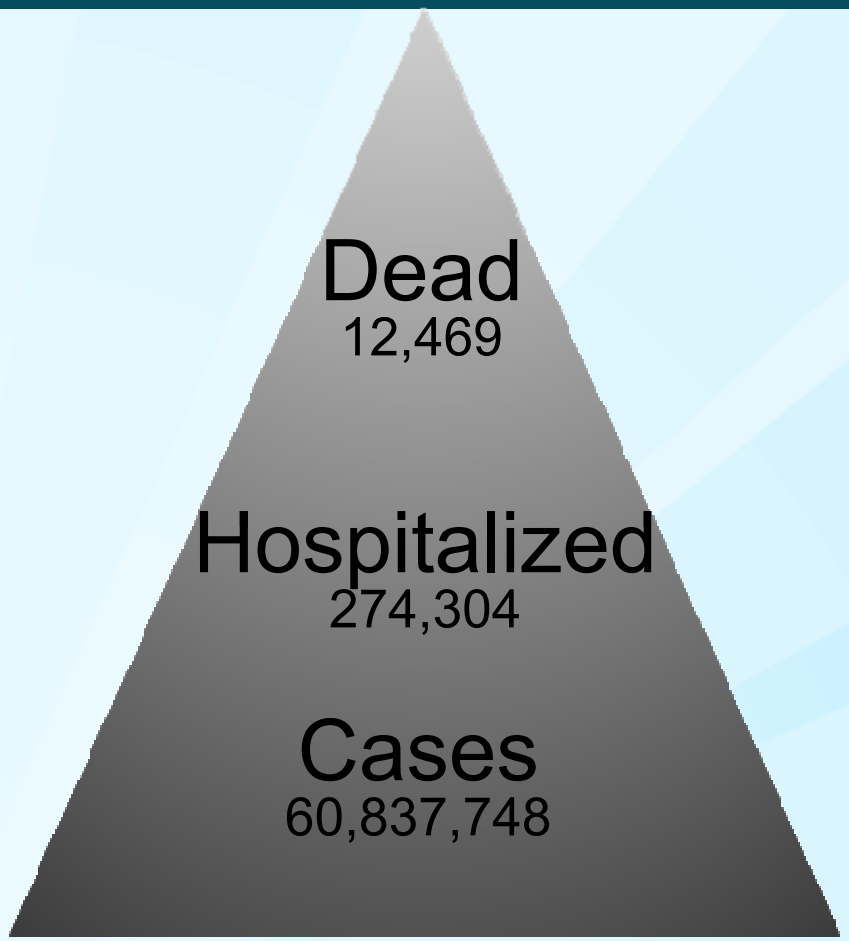
Disease(s)

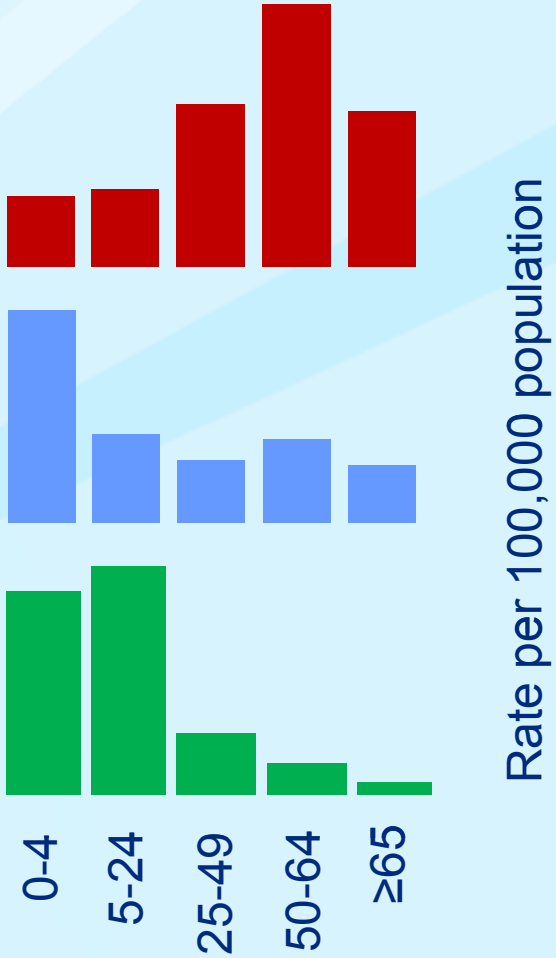
1918-19 Influenza

Measures of Disease Burden

Estimates of morbidity and mortality 2009 pH1N1 Influenza

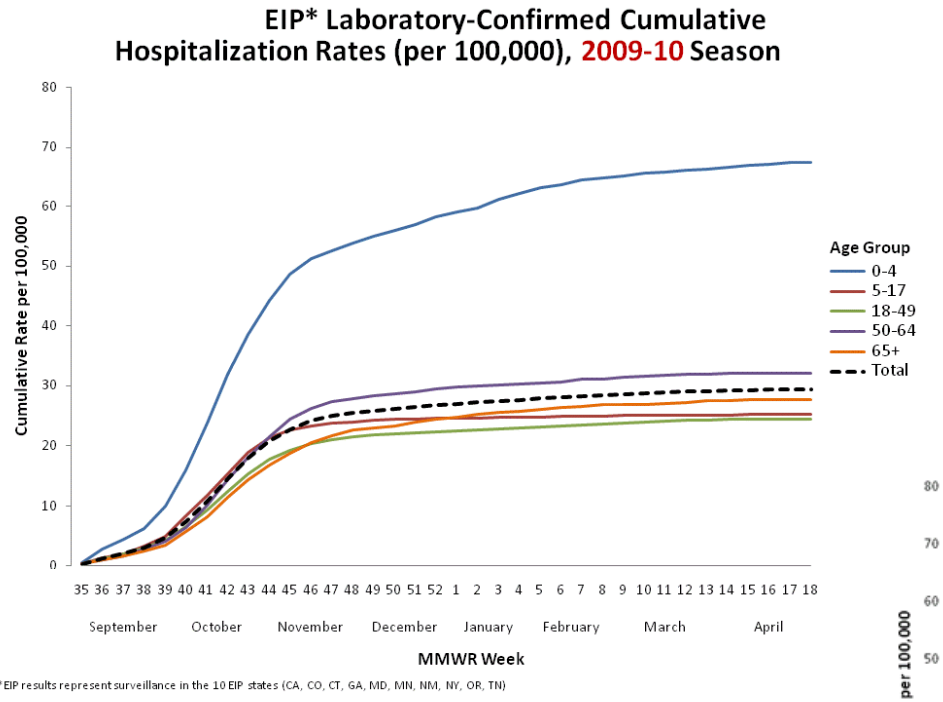
April 2009 - April 2010



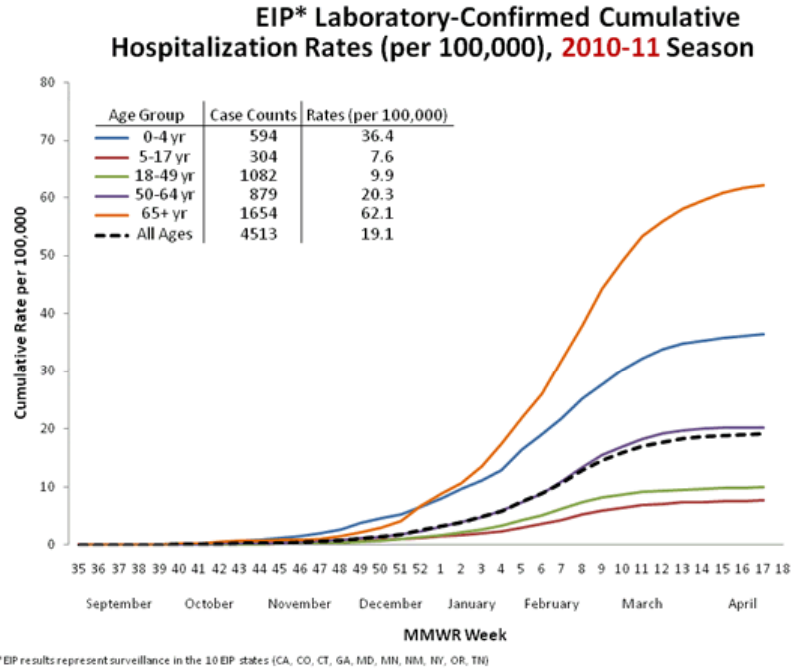


Slide courtesy of Lyn Finelli- CDC

H1N1 hospitalization rates



*EIP results represent surveillance in the 10 EIP states (CA, CO, CT, GA, MD, MN, NM, NY, OR, TN)



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OUR MISSION: Using the influenza virus against itself

Advancing science and technology into countermeasures

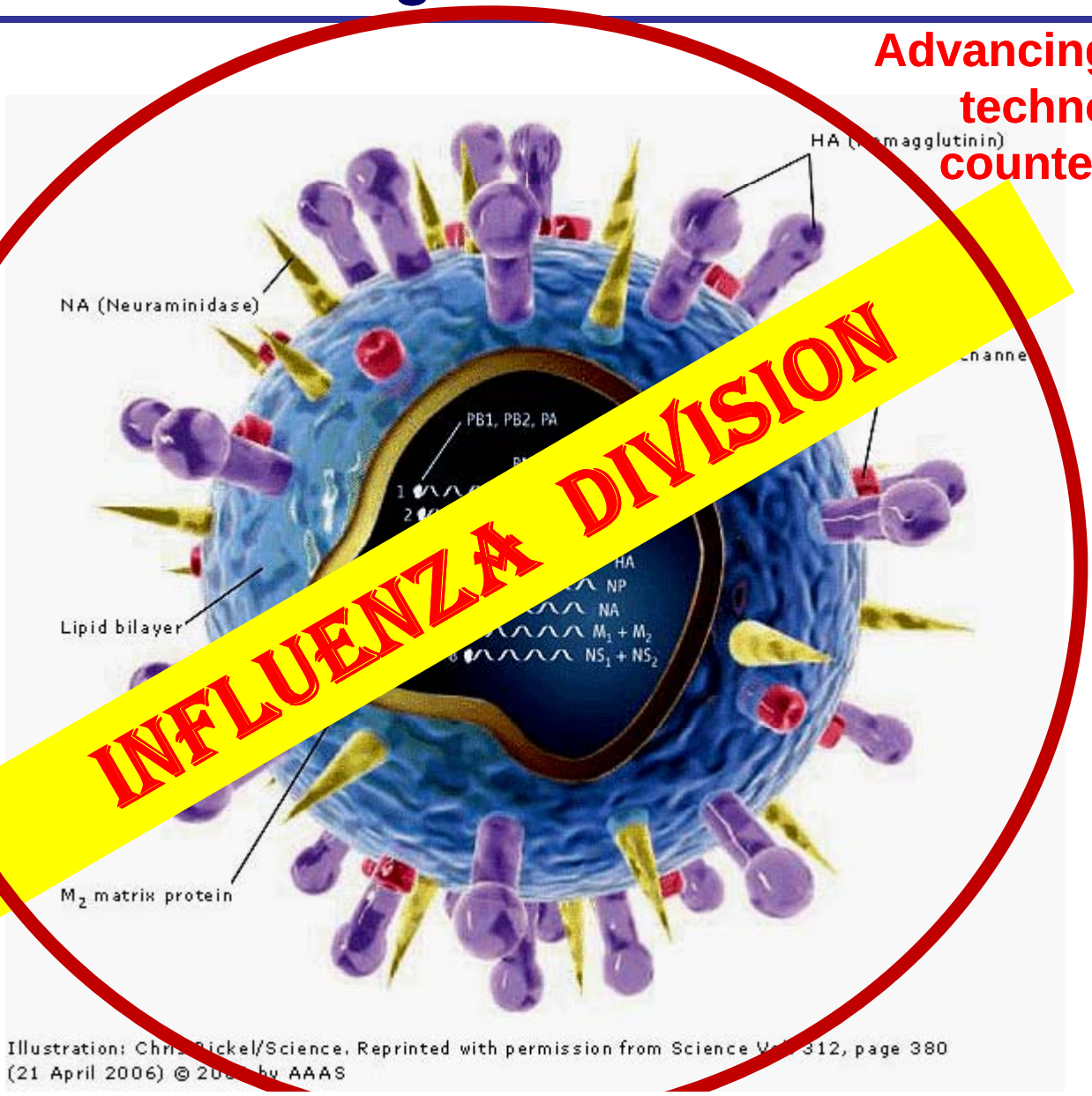
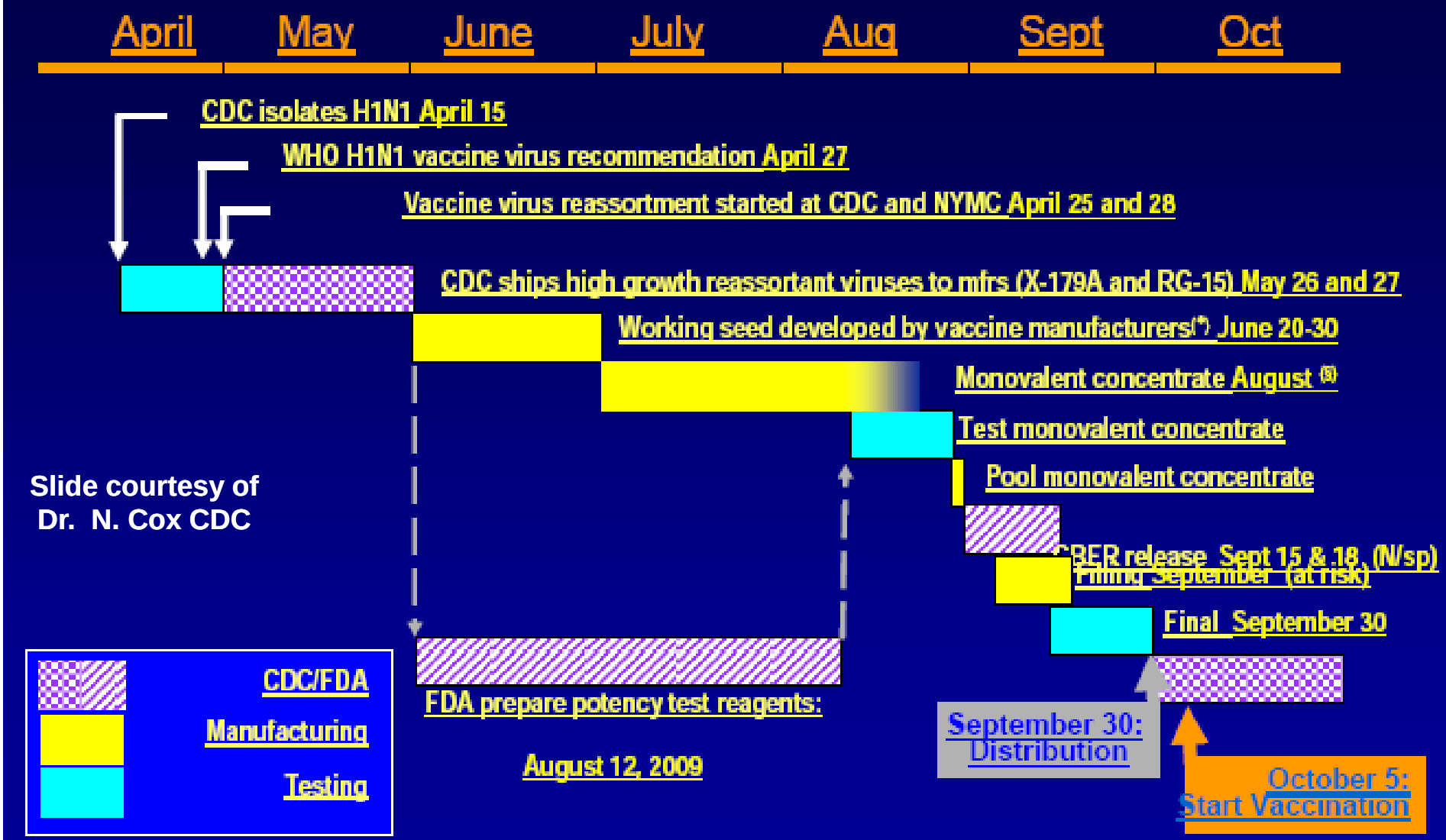


Illustration: Chris Bickel/Science. Reprinted with permission from Science Vol. 312, page 380 (21 April 2006) © 2006 by AAAS

Estimated Timeline of H1N1pdm Vaccine Development and Delivery in the U.S.



Slide courtesy of
Dr. N. Cox CDC

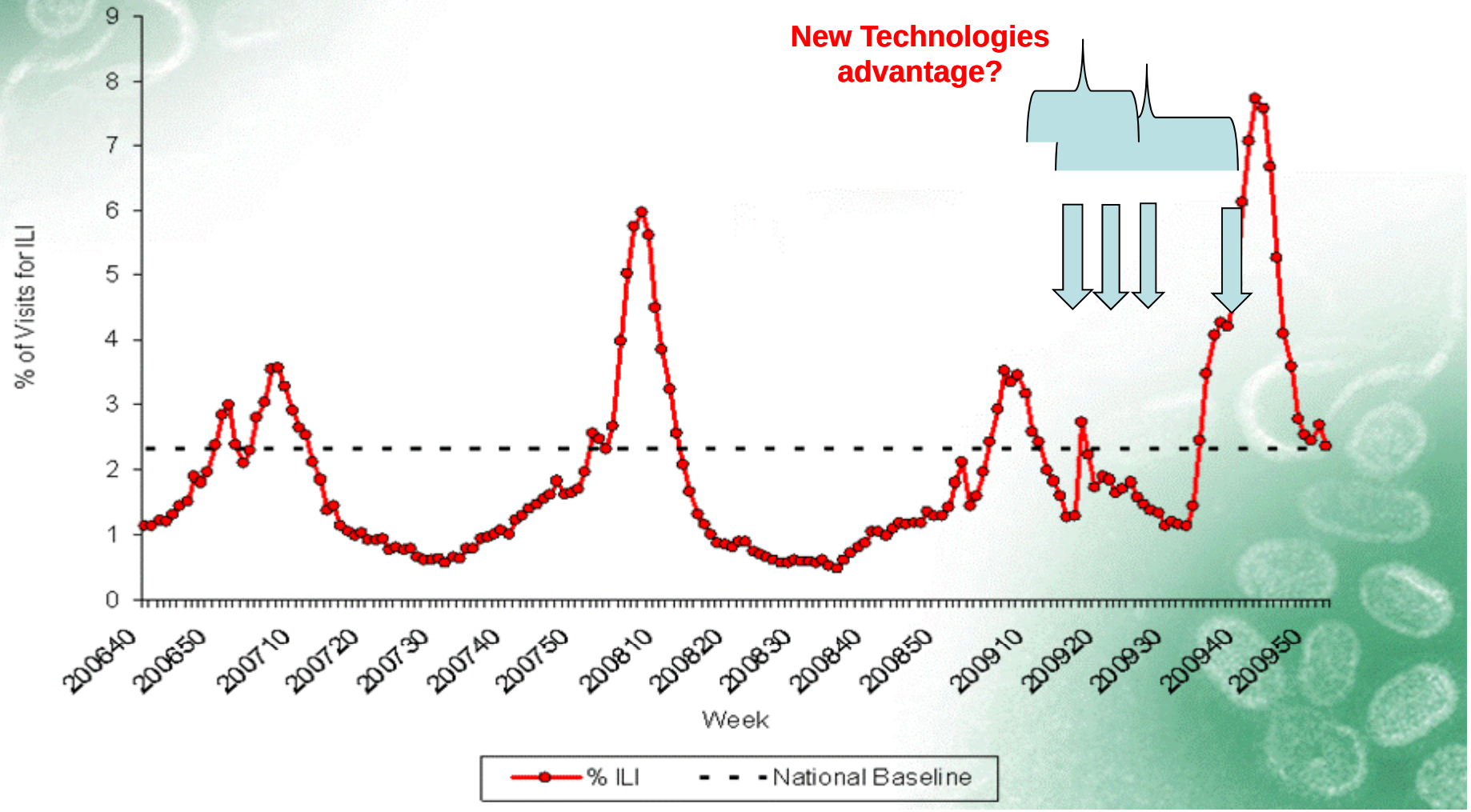
(*) Manufacturers were transiently limited in their ability to develop seed viruses due to lack of facilities to grow virus in large volume at the required BSL3 biocontainment
(§) Production of monovalent inactivated vaccine is a continuous process
www.cdc.gov/H1N1flu

FLUVIEW

A Weekly Influenza Surveillance Report Prepared by the Influenza Division

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, October 1, 2006 – January 2, 2010



HHS Responses to Influenza Pandemics

Effective Vaccines and Programs-More, Better, Faster

Effective Antivirals and Delivery- Avoiding resistance

Sensitive, Specific Diagnostics- Usage and interpretation

Mitigation of Severe Respiratory Impact- Stockpiles, surge, simplicity

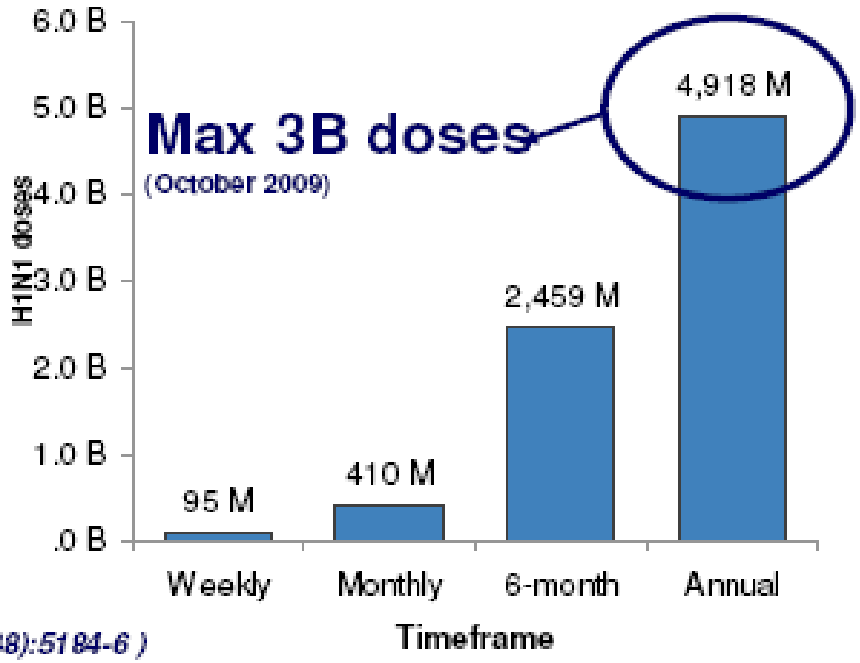
Infrastructure Development-cell based production

Global pandemic (H1N1) 2009 vaccine production capacity: June 2009 estimate

Assumptions / Methodology

- Survey sent to 36 potential influenza vaccine manufacturers
  - 100% response rate
  - All 21 current influenza vaccine producers responded
  - 26 manufacturers that intend to produce pandemic vaccines
  - Includes LAIV and one recombinant vaccine capacity
- Survey assumes
  - 1:1 H1N1 to seasonal yields
  - Most dose sparing formulation for each manufacturer
  - Use of full production capacity

Estimated H1N1 Vaccine Capacity
At 1:1 yields, most dose-sparing formulation, full capacity



Source: WHO survey (Collin N. et al, Vaccine 2009. 27(38):5184-6)

World Health Organization

ID International Program Objectives

1. **Protect America by reducing risks of influenza epidemics outside our borders-one world one health.**
2. **Help to develop and sustain influenza vaccine manufacturing capabilities and capacity and pandemic readiness: promote investment; establish partnerships**
3. **Help achieve sustainable influenza vaccine production capacity worldwide by leveraging BARDA's unique resources.**

International Capacity Building
Total Financial Commitment through 2009: $52 million

- **FY 2005** — $1 million ASPR funding to Vabiotech-Vietnam
- **FY 2006** — $10 million of emergency supplemental funding to WHO; granted to India, Indonesia, Vietnam, Thailand, Mexico & Brazil
- **FY 2007** — Funding requested in annual budget; not appropriated
- **FY 2008** — $14.4 million of annual funding to WHO; granted to six original grantees plus Egypt, Serbia and Romania.
- **FY 2009** — $3.6 million to WHO; granted to Russia's Institute for Experimental Medicine; plus $7.9 million to PATH; and $3.5 for rapid diagnostics to support clinical trials
- **FY 2010** — $11M to WHO, Universities: Lausanne, NC State, Utah State. Non-profit: IDRI (Seattle)
- **FY 2011** — $11: WHO, adjuvants, training, multiproduct manufacturing feasibility

Serum Institute of India, Pune

BARDA Influenza Division (Transitional)

Director: Michael Perdue (until July 19)
Deputy Director: Robert Huebner

Current Staff: 32 (27 FTE, 5 Contractors)

5 Divisional Teams: Antivirals; Vaccines-advanced development; Vaccines-Stockpiles; Diagnostics/Devices; "International"

BARDA Pandemic Influenza Program: > 50 staff including manufacturing, clinical, regulatory, innovation

Interfacing with BARDA

- www.phe.gov
  - Program description, information, news, announcements
- www.medicalcountermeasures.gov
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- www.fedbizopps.gov
  - Official announcements and detailed information about all government contract solicitations