



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



Influenza Priorities Update

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Office of the Assistant Secretary for Preparedness & Response



BARDA INDUSTRY DAY

Ronald Reagan Building &
International Trade Center
Washington, DC

Oct. 15-17, 2014



The banner features a background image of a scientist in a lab coat, mask, and safety glasses, holding a pipette. The text is in white and gold. The ASPR logo is on the left, and the BARDA logo is on the right.



The Problem: Influenza Causes Widespread Morbidity and Mortality



5%-20% infected every year

\$87.1B economic burden every year

3,000-49,000 deaths every year

>200,000 hospitalizations every year

\$10.4B medical costs every year

Seasonal Influenza Epidemic in US

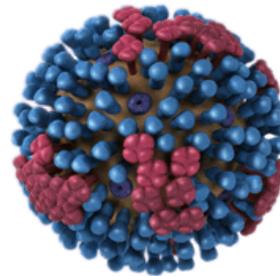
2009-2010 H1N1 Pandemic

74 countries affected

123,000-203,000 deaths worldwide

60.8M infected in US

274,304 hospitalizations in US



12,469 deaths in US

1918 'Spanish' Pandemic

20%-40% infected worldwide

50M deaths worldwide

675,000 deaths in US



The Problem: Response Capabilities Insufficient to Address the Threat

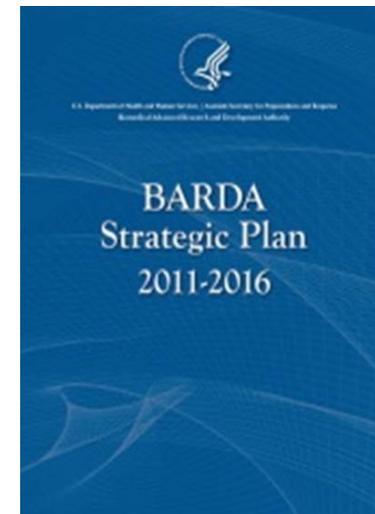
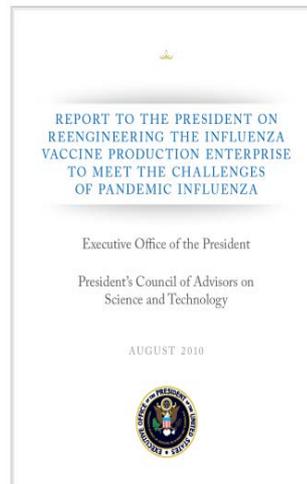
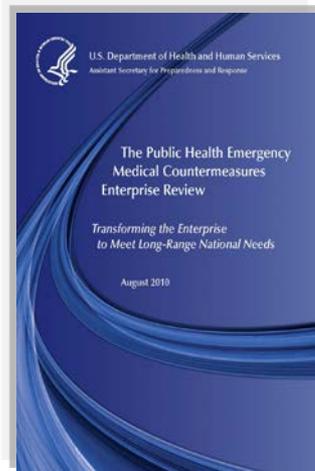
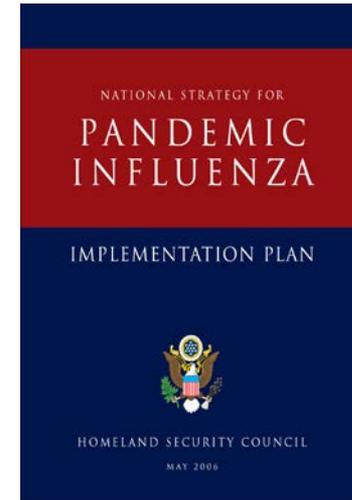
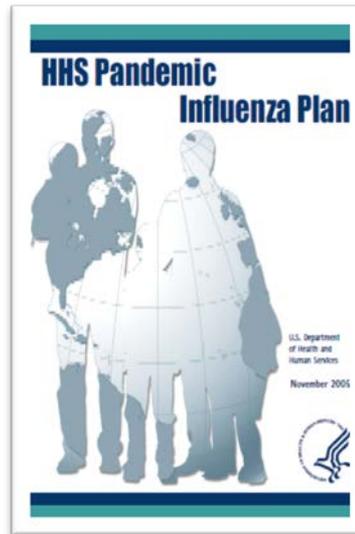
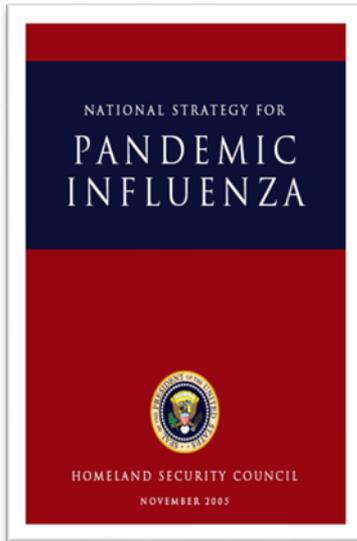


- No National Strategy for influenza pandemic preparedness
- No pre-pandemic vaccine or antiviral stockpile – federal or state
- Less diverse landscape for MCM development
- Limited domestic manufacturing capability for pandemic response
- Limited partnerships between USG & industry for MCM development
- Global lack of vaccine supply for a pandemic response
- Candidate pandemic influenza vaccines were poorly immunogenic
- All US licensed seasonal vaccines were egg-based (1940s-1950s technology)
 - No cell-based and no recombinant-based influenza vaccine licensed
 - No adjuvanted pandemic vaccines licensed

Need for **More Vaccine** and **Faster Response**

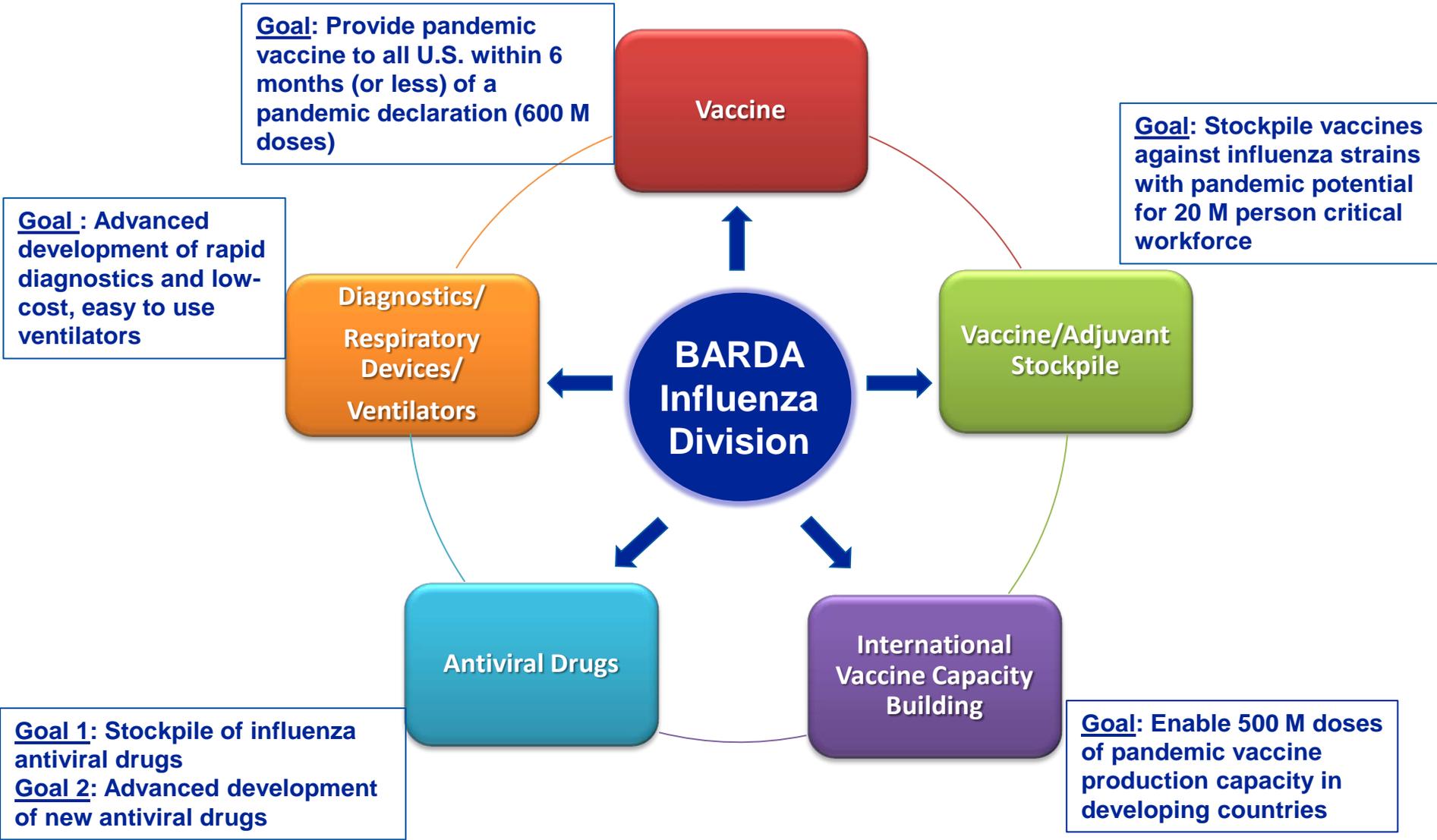


Strategic Guidance





BARDA Influenza Division: Goals & Approaches to 2014



Accomplishments: More Vaccines

Egg-based Vaccines



H5N1 Vaccine
Licensed 04/17/2007

sanofi pasteur – Swiftwater, PA

1st US FDA approved pandemic-ready site for cell-based Vaccines

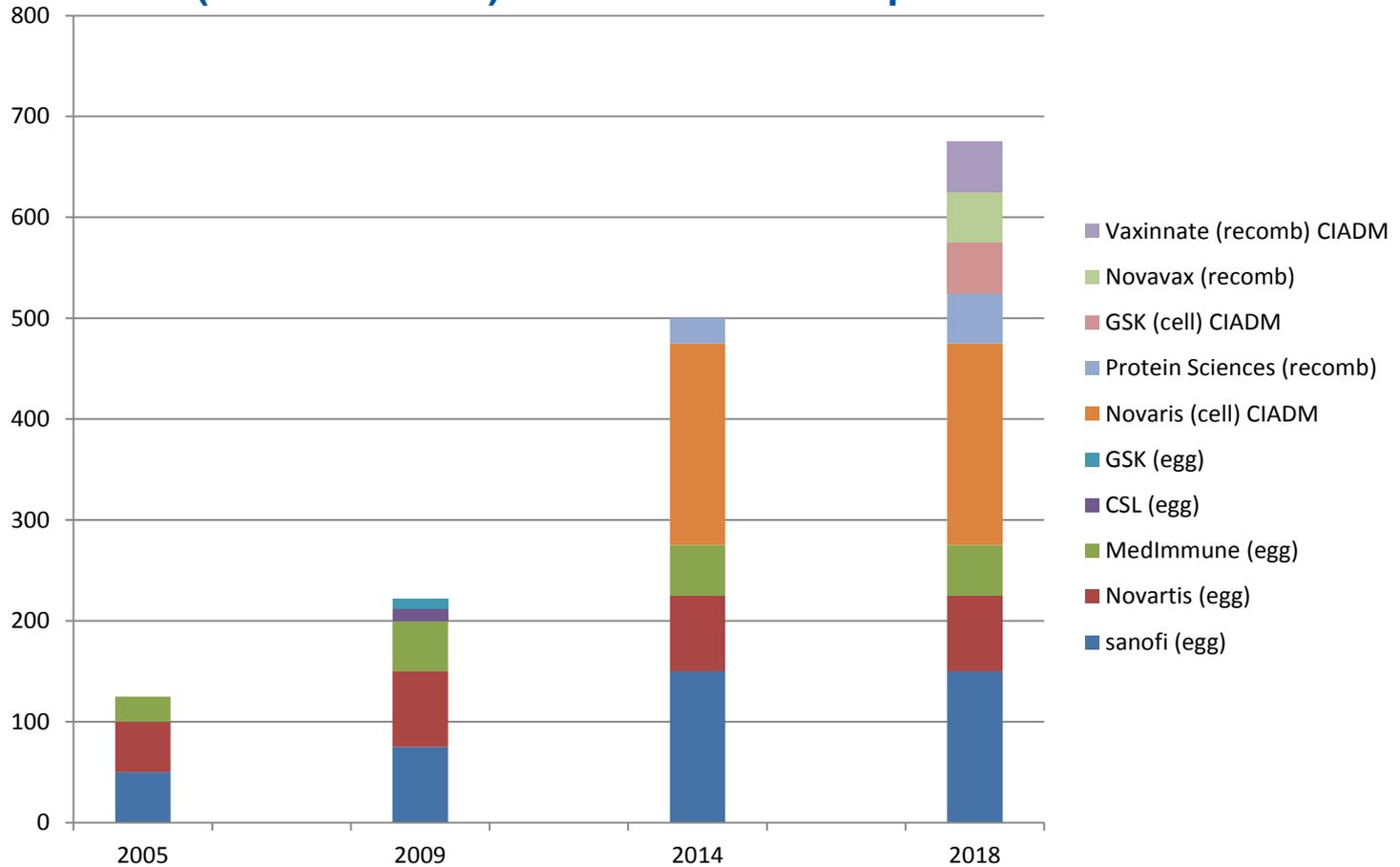


Centers for Innovation in Advanced Development and Manufacturing (CIADMs)

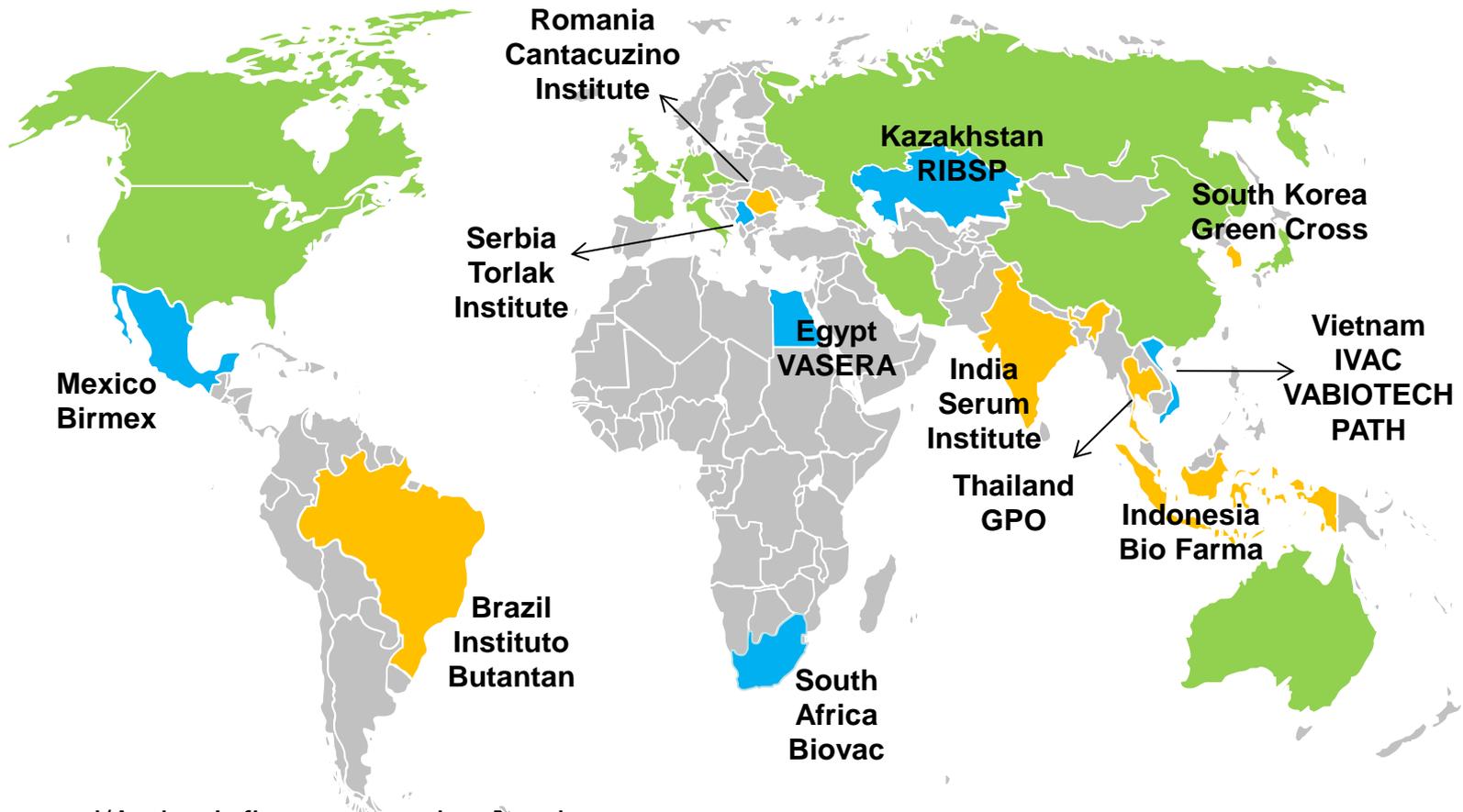


Accomplishment: Expanded Domestic Vaccine Manufacturing Surge Capacity

Pandemic influenza vaccine target is two doses for everyone (~ 600 M doses) within 4 months of pandemic onset



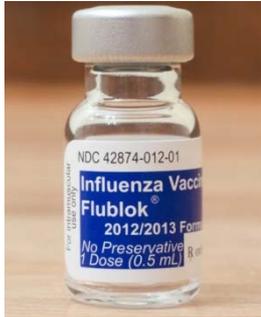
Accomplishment: **More** International Vaccine Manufacturing Capacity



- Licensed/Active Influenza vaccine Producers
- BARDA/WHO Cooperative Agreement Grantees
- BARDA/WHO Licensed Vaccine for Human Use (as of 2/2014)

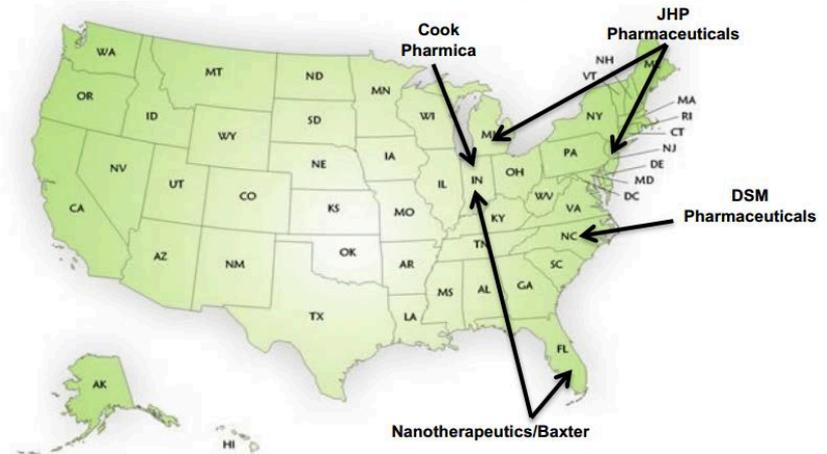
Accomplishment: Faster Response Capability

Recombinant-based Influenza Vaccine: Flublok®

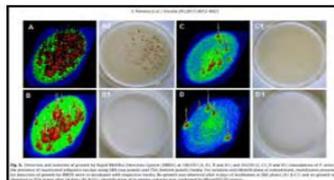
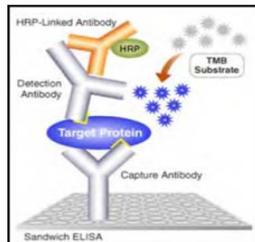
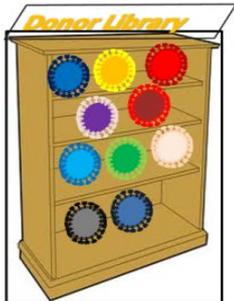


**Protein Sciences
Licensed 01/16/2013**

Fill Finish Manufacturing Network



Influenza Vaccine Manufacturing Improvement Initiative



Centers for Innovation in Advanced Development and Manufacturing (CIADM)





Pandemic Vaccine Stockpile: Better Prepared



- Program established in 2005
 - With adjuvant, the stockpiled H5N1 vaccines can potentially provide 200-400M doses
- Modified in 2012 to be more flexible to allow staged response
 - Incorporation of additional risk assessment tools to inform stockpiling decisions/actions
- **New RFP planned for FY2015**



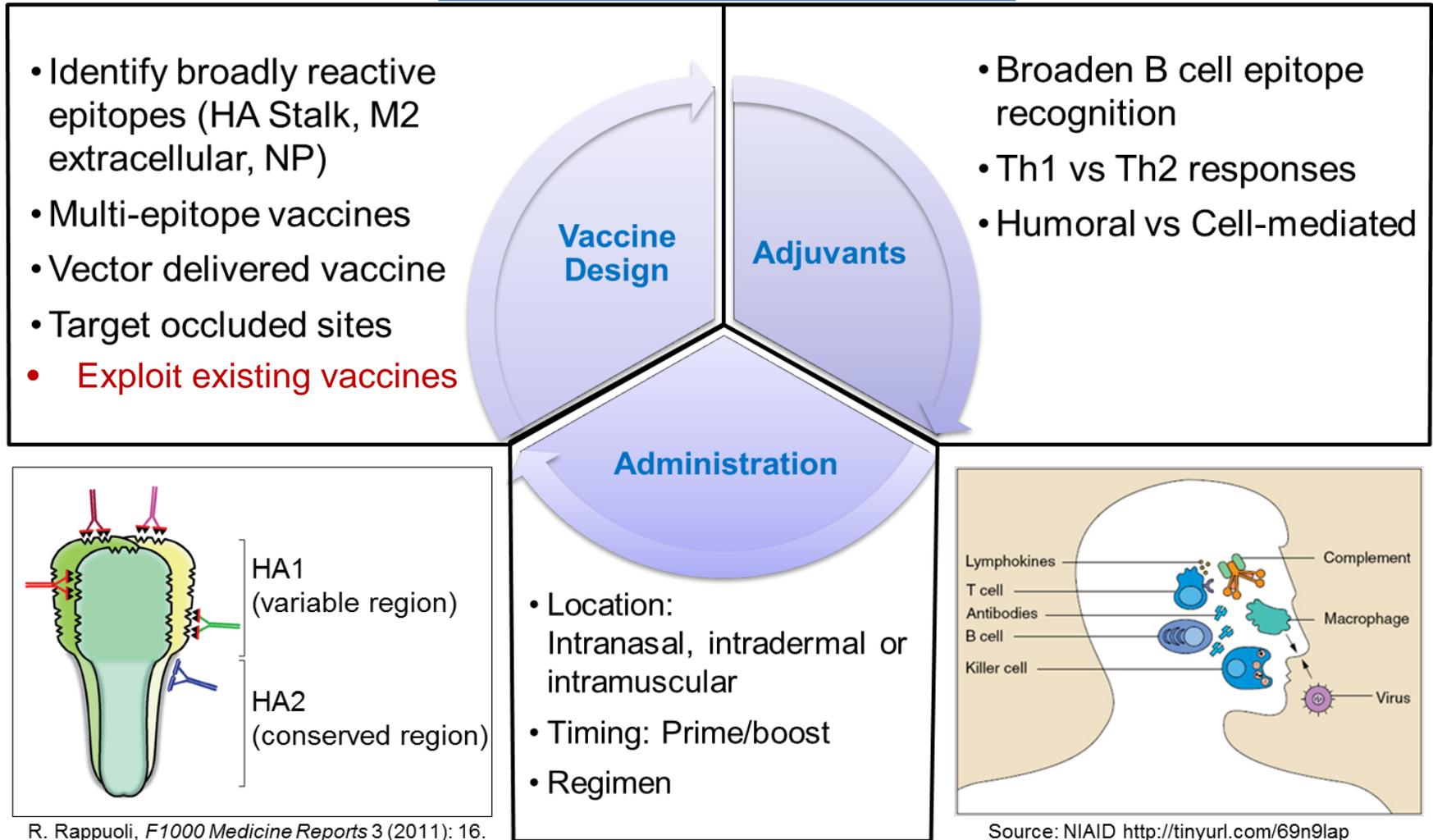


Pandemic Vaccine Stockpile: Faster Response



- **2005 H5N1 outbreak in SE Asia**
 - Established stockpile and met stockpile goals
 - Implemented innovative Mix and Match program
- **2009 H1N1 Pandemic**
 - 186 M doses of H1N1 vaccine were filled by the manufacturers
 - 120 M doses of bulk adjuvants (AS03 & MF59) purchased as a contingency
- **2012 H3N2v outbreak in the US**
 - Clinical lots were made and clinical trials conducted
- **2013 H7N9 outbreak in China**
 - Clinical lots were made and clinical trials conducted
 - Stockpiled bulk antigen

Universal Influenza Vaccine



R. Rappuoli, *F1000 Medicine Reports* 3 (2011): 16.

Source: NIAID <http://tinyurl.com/69n9lap>



Accomplishment: **More** Antiviral Drugs



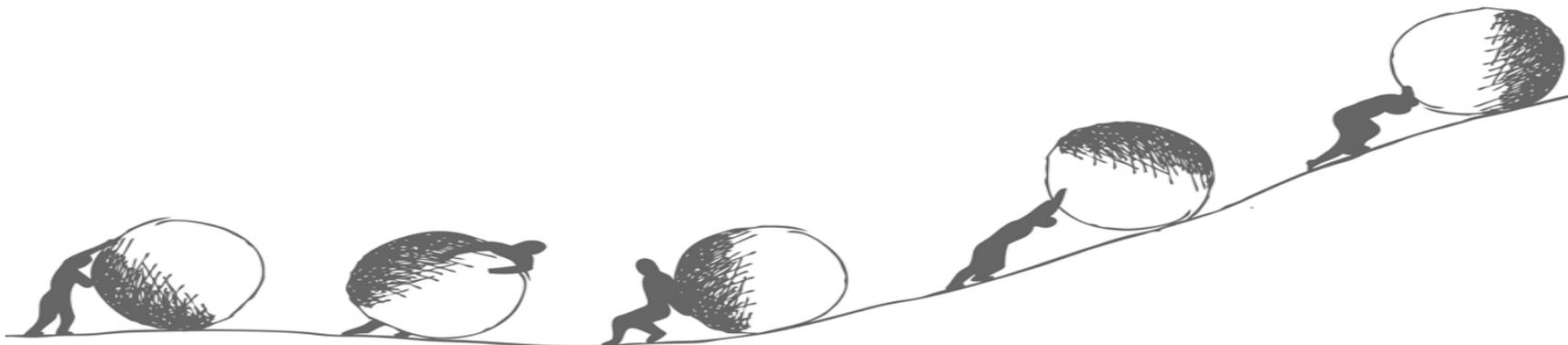
- Collaborated with CDC and State and local partners to establish antiviral stockpiles
- IV peramivir: 1st Emergency Use Authorization (EUA) issued for unapproved drug
 - Used to treat hospitalized patients during 2009 H1N1 pandemic



Peramivir
BioCryst
NDA filed in 2013



Influenza Antiviral Drugs The Unmet Need



- New influenza therapeutics are needed to address:
 - **Severely ill, hospitalized patients**
 - **Pediatric population**
 - Novel mechanism of action
 - Wider therapeutic treatment window
 - Threat of resistance
 - Broad spectrum activity for influenza and emerging diseases
 - Potential for combination therapy

ASPR: Resilient People. Healthy Communities. A Nation Prepared.



FY 2015 New Initiatives



- **Universal Influenza Vaccine**
 - Broad spectrum, long duration immunity
 - RFP planned for early FY 2015
- **New Influenza Therapeutics**
 - Novel Mechanism of Action
 - Targeted to pediatric and severely ill, hospitalized populations
 - RFP planned for early FY 2015
- **National Pre-pandemic Influenza Vaccine Stockpile**
 - RFP planned for mid FY 2015

Watch this space:

Website: <http://www.phe.gov/about/barda>

Broad Agency Announcement (BAA)

<https://www.medicalcountermeasures.gov/newsroom/2013/now-open-broad-agency-announcements.aspx>

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