



BARDA INDUSTRY DAY

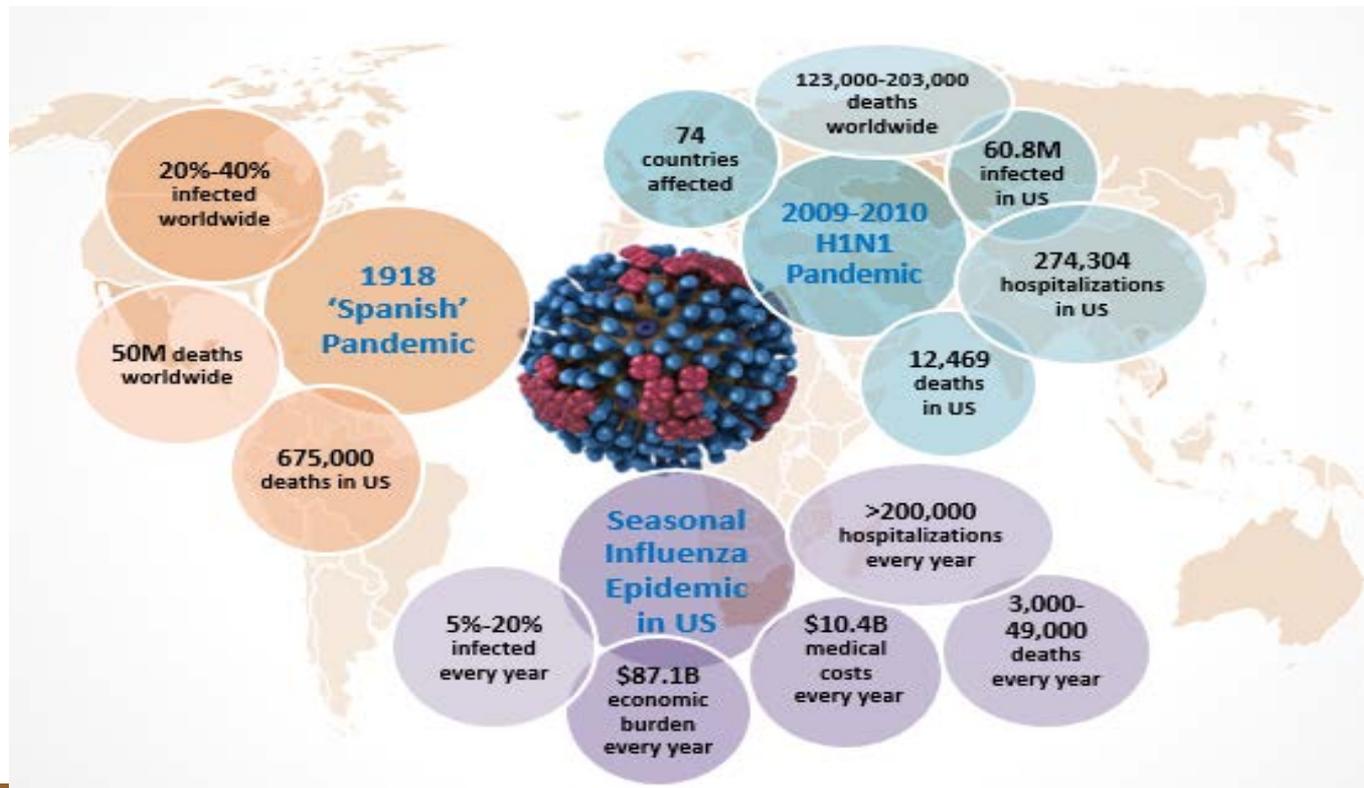
Influenza and Emerging Infectious Diseases (IEID) Vaccine Development

Armen Donabedian, PhD
Branch Chief, Vaccine Development
October 29, 2018

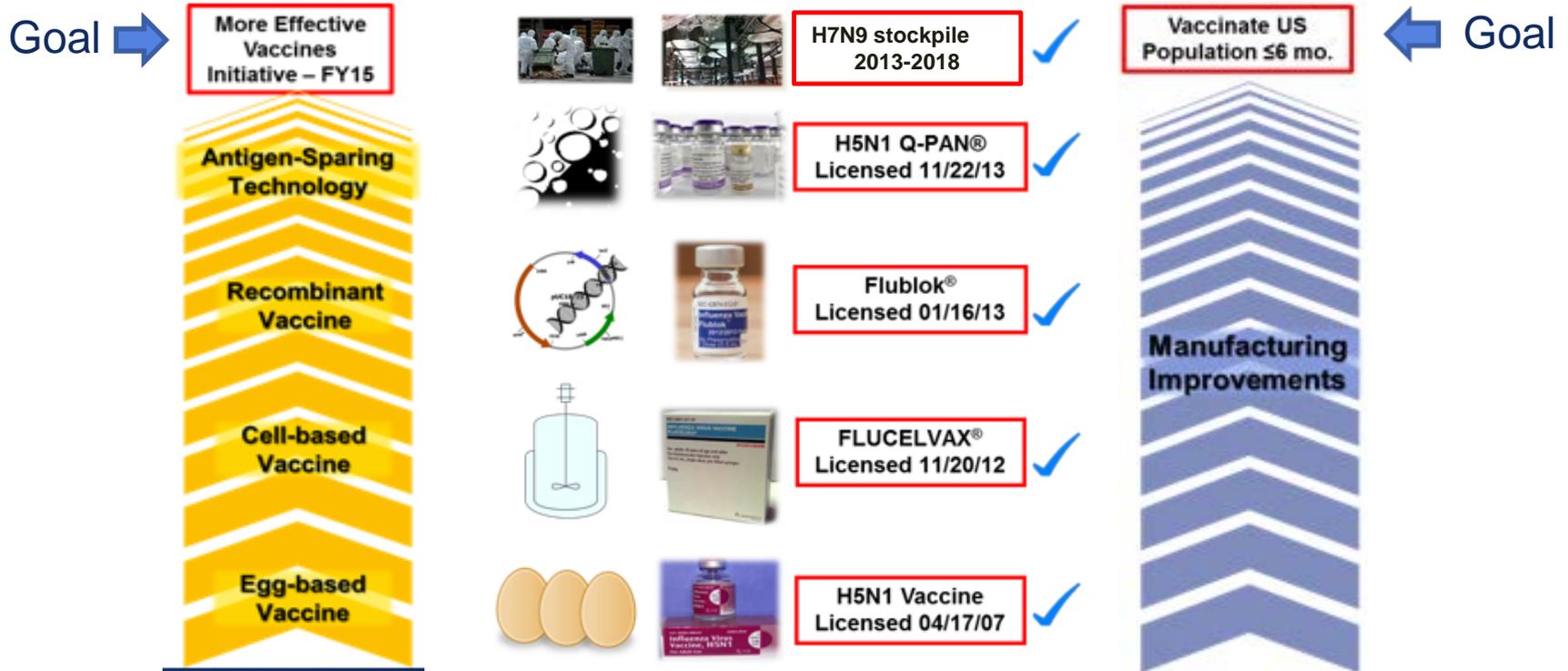
October 29-30, 2018 | Grand Hyatt • Washington, D.C.



Public Health Impact of Influenza

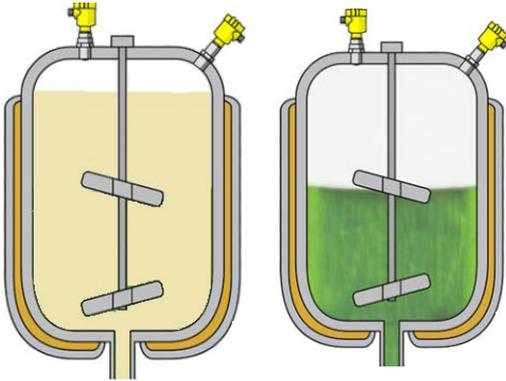


Influenza Pandemic Preparedness Accomplishments



Ongoing Influenza Countermeasure Initiatives

Domestic Capacity Gaps



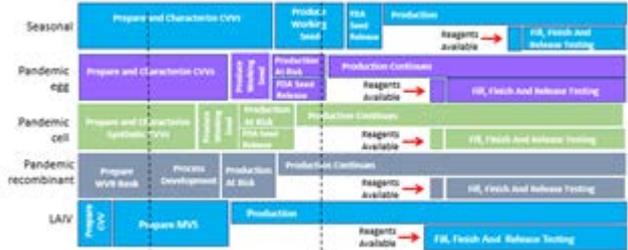
Antigen supply

Adjuvant supply

*Better, Faster,
Flu Vaccines*



Speed/Flexibility

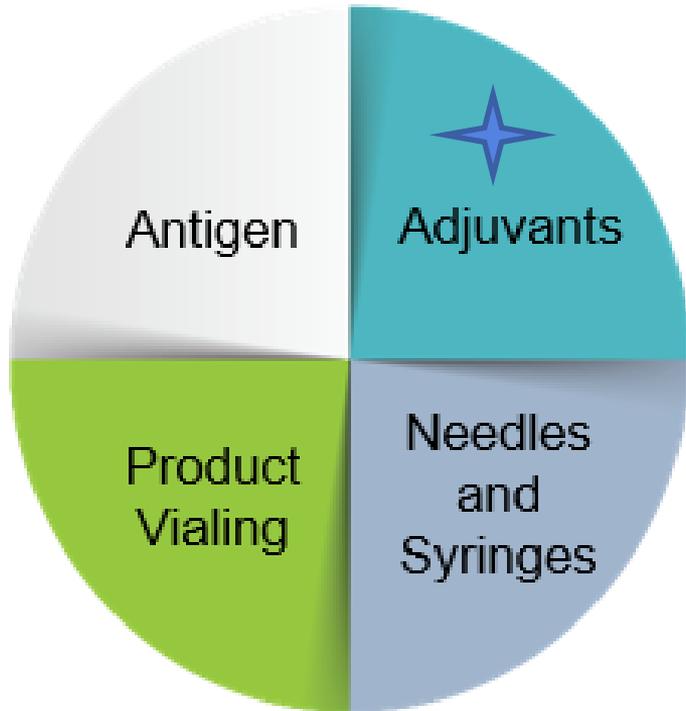


Efficacy



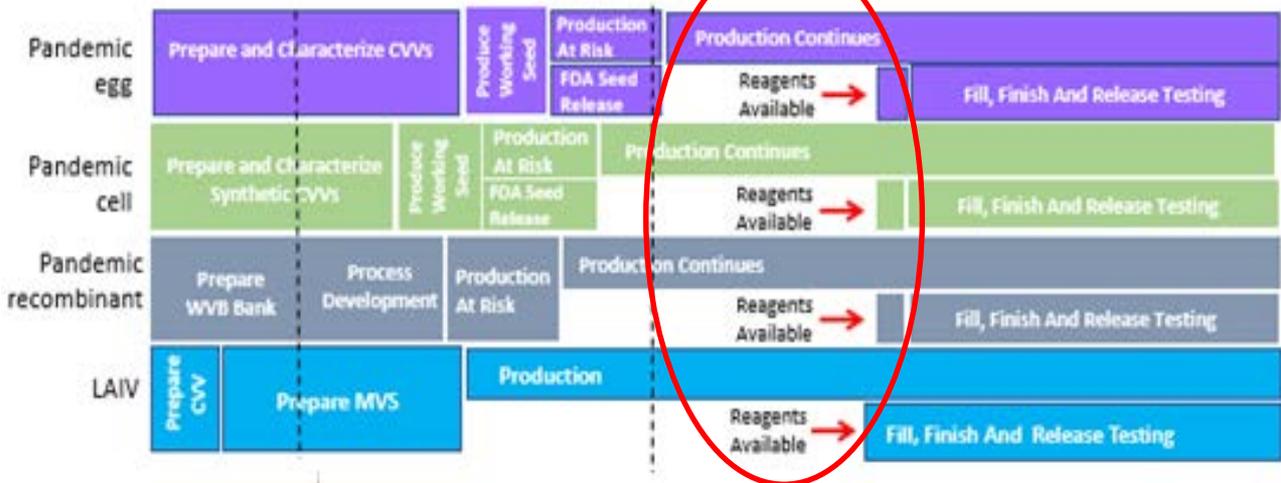
One develops disease

Domestic Capacity Gaps



Speed

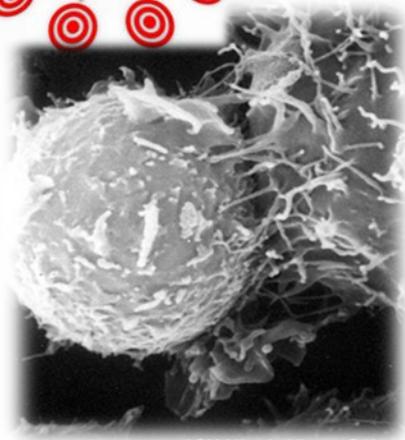
Modernized release testing



Break Through Vaccine!

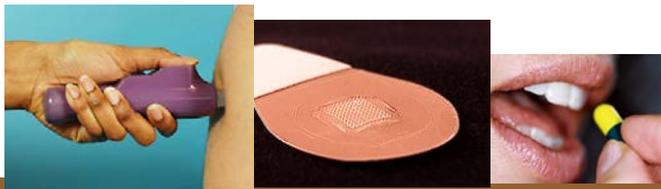


Multi-target



e.g. CMI

Administration technologies

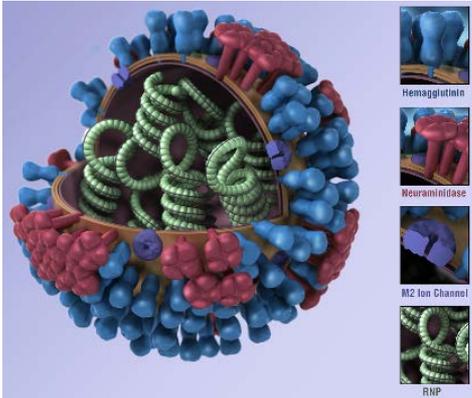


Saving Lives. Protecting Americans.

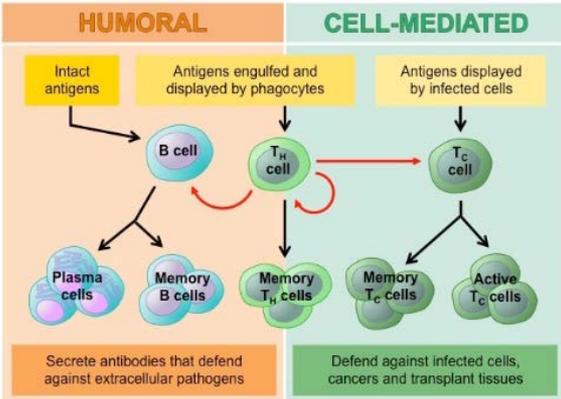
Effectiveness

Vaccine Targets

HA stem



Multiple immune pathways



Mucosal Immunity



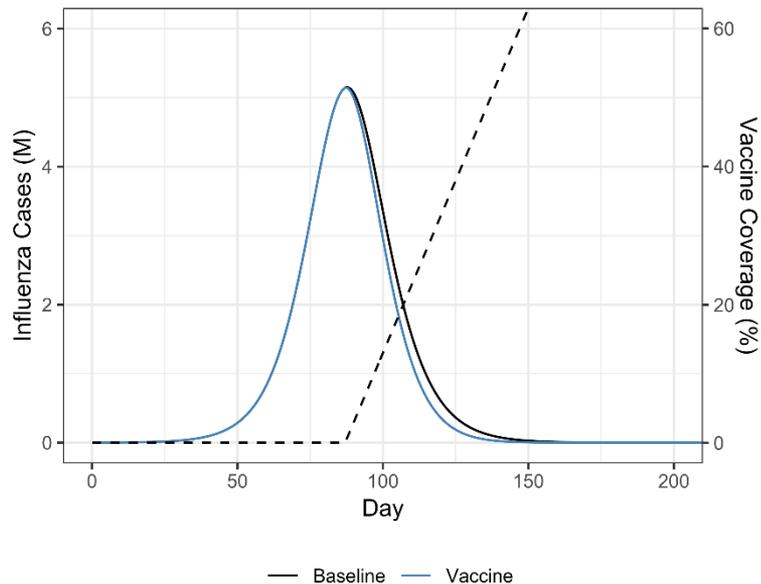
Improved vaccine formulations



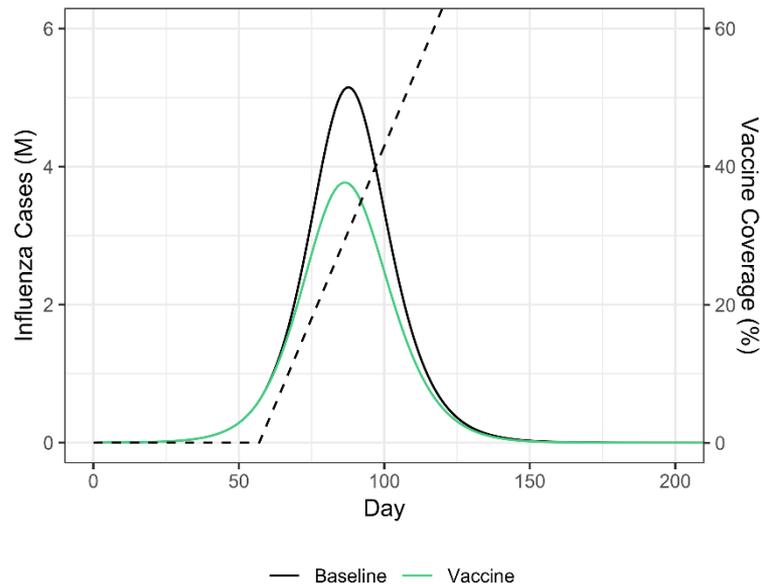
Adjuvants
Single Dose

Speed >> Efficacy

Later Vaccine with Higher Efficacy



Earlier Vaccine with Lower Efficacy



Partnership Requirements

The vaccine candidate must offer a substantial improvement in pandemic response

HIGH CAPACITY
TONS!



Evidence of substantial improvement

Manufacturing feasibility at scale

Regulatory + Commercialization plans

Phase 1 IND clinical trial



The 'End-to-End' Solution

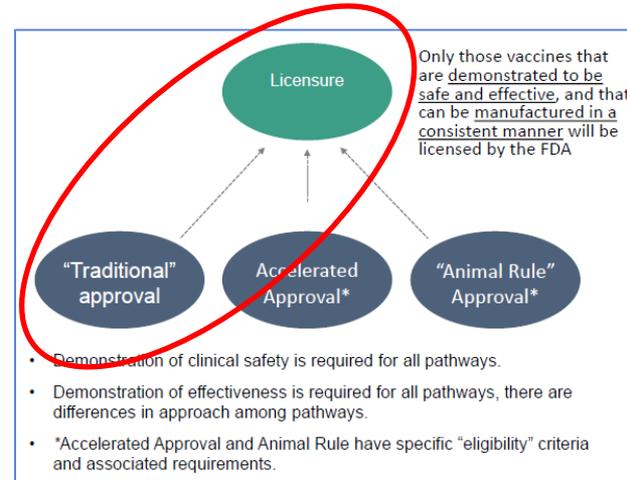
Licensure

Product Approval Information - Licensing Action

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Center for Biologics Evaluation and Research
Food and Drug Administration

Dear Development Innovator,

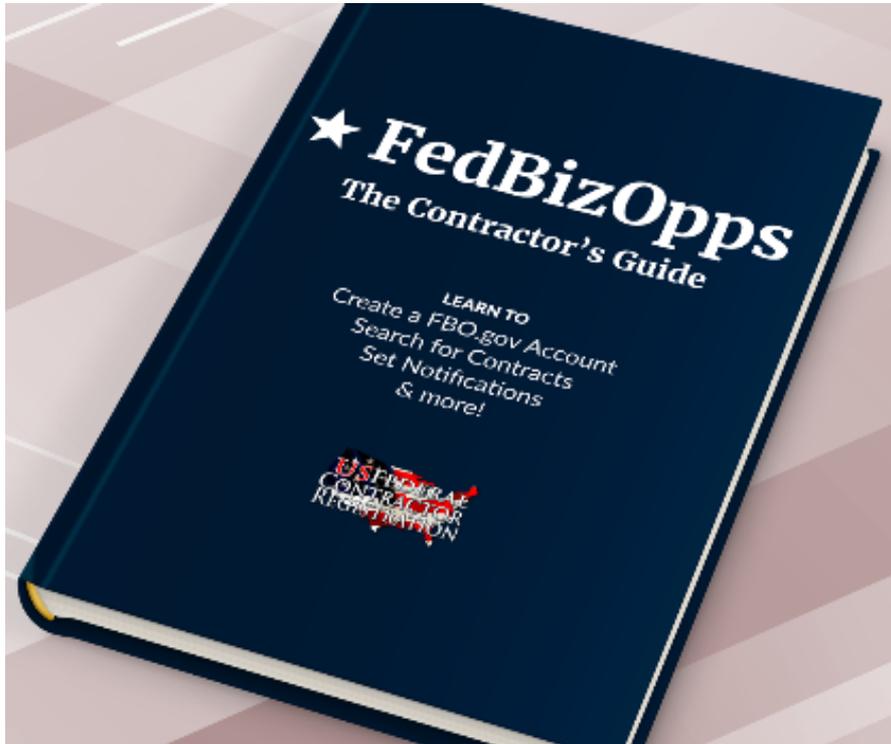
Your biologics license application
for *Awesome* is approved
effective this date...



Sustainability



Collaboration



Solicitation Number: BAA-18-100-SOL-00003

Area of Interest #8: Influenza and Emerging Infectious Diseases (IEID) Vaccines

- **8.1 Advanced development of more effective influenza vaccine candidates**
- **8.2 Innovative vaccine production enhancements.**

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How to contact BARDA



Medical
Countermeasures.gov

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.gov/home.aspx)

Portal to BARDA: **Register to request a TechWatch meeting!**



www.fbo.gov/
("FedBizOpps")

Official announcements and info for all government contract solicitations



<https://www.phe.gov/about/BARDA/Pages/default.aspx>

Program description, information, news, announcements



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