



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



Filling & Finishing Manufacturing Network (FFMN)

BARDA Industry Day 2014

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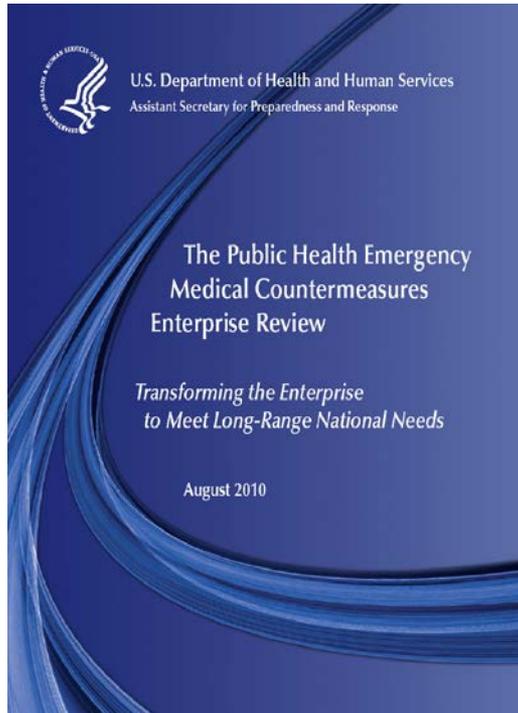
Manufacturing Facilities and Engineering Division (MFE)

Biomedical Advanced Research and Development Authority



“The Public Health Emergency Medical Countermeasures Enterprise Review”, August 2010.

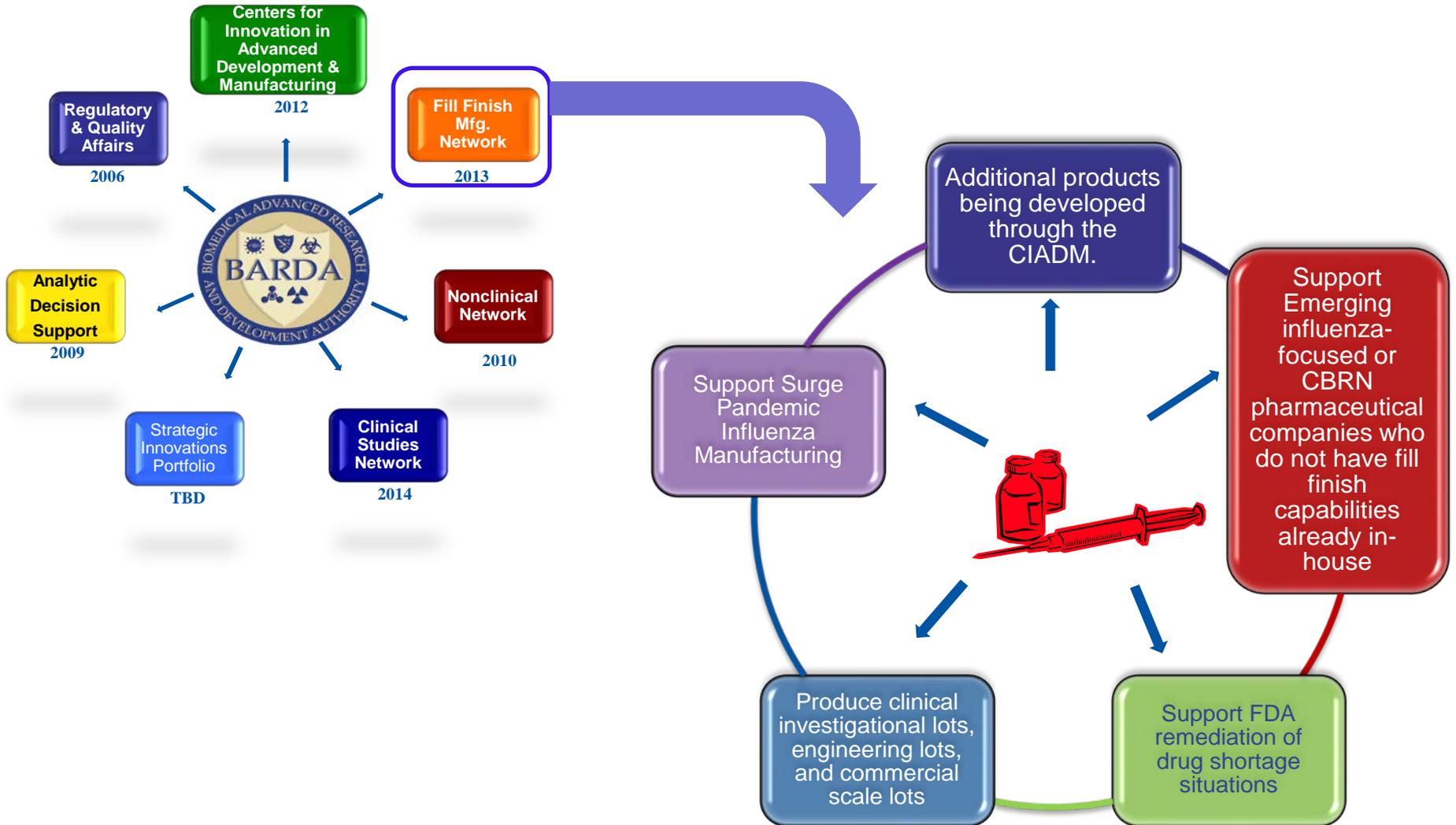
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Manufacturing capacity

The Nation currently lacks the domestic manufacturing capacity to rapidly produce and package a vaccine for the American public in the face of a pandemic... **This difficulty in producing, filling, and finishing enough vaccine** that could be broadly available before the virus had spread widely **is an important reminder of the unmet need for this capacity**, as well as of the technical challenges related to virus growth and the ability to produce adequate dose yields and the reliance on old technologies that need to be enhanced or replaced

A BARDA Core Service



FFMN Objective and Capabilities

Objective:

Establishes a network of existing facilities that are pre-qualified and under contract to fill and finish vaccine/drugs for U.S. Government-contracted manufacturers.

Fill and Finish expertise in the following:

- Formulation, Fill & Finish Vials and Syringes
- Technology Transfers
- Regulatory Support
- Analytical Development
- Clinical Trial and Commercial Scale lots
- Labeling & Packaging
- Storage and Distribution
- Lyophilization



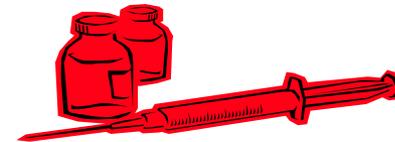
Pandemic Surge inventory



Analytical development;
Lab Services

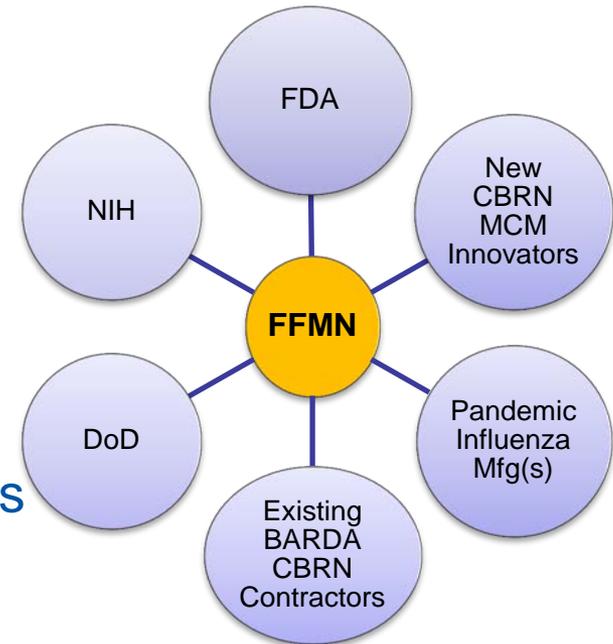


Technology Transfer



Clinical and Commercial Lot Manufacturing

- FFMN will provide filling and finishing capabilities by coordinating with:
 - Pandemic influenza vaccine manufacturers
 - Contract Manufacturing Organizations (Bulk CBRN MCMs)
- FFMN supports:
 - Pandemic influenza vaccine manufacturers
 - FDA (drug shortage)
 - Existing BARDA CBRN contractors
 - New CBRN MCM innovators
 - DoD
 - NIH



Who is Our Network?

Let's Redefine Possible
a whole new world of possibilities for pharmaceutical companies

Patheon

Performance the World Over®

nanotherapeutics



COOK

PHARMICA

BioPharma Solutions

The Promise of Science
Realized



PAR

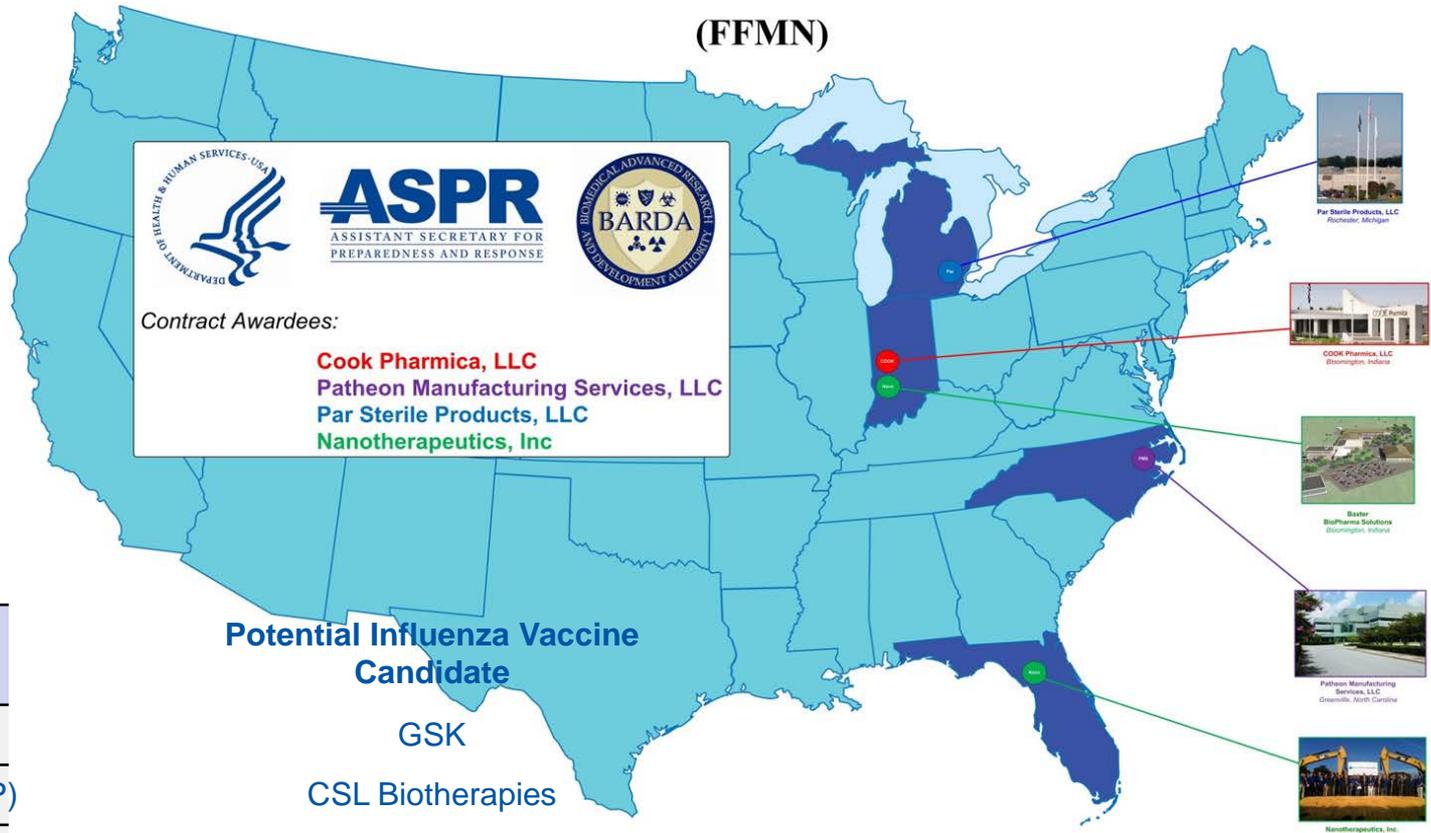
PHARMACEUTICAL

JHP

PHARMACEUTICALS
Partners For Healthcare Excellence



Fill and Finish Manufacturing Network Members







Contract Awardees:

- Cook Pharmica, LLC**
- Patheon Manufacturing Services, LLC**
- Par Sterile Products, LLC**
- Nanotherapeutics, Inc**

Potential Influenza Vaccine Candidate

Contractor	
Cook Pharmica	GSK
Par (formerly JHP)	CSL Biotherapies
Patheon (formerly DSM)	Novartis
Nanotherapeutics partnered with Baxter Pharmaceutical Solutions (BPS)	TBD



What happened in 2014?



- Name Changes/Acquisitions:
 - JHP → Par
 - DSM → Patheon
- Task Orders Initiated:
 - Pandemic Influenza Candidate Agreement and Tech transfer (within 3 years of award)
 - Pilot Production of CDER approved products/drug shortage list examples
- Actively involved in BARDA Ebola response activities
 - Possible task orders for therapeutics and vaccines

- Confirm Pandemic Influenza Partner
- Tech Transfer Pandemic Candidate
- Establish Pandemic Surge Capacity
- Support CBRN Projects

