



United States Department of
Health & Human Services

Office of the Secretary
Office of the Assistant Secretary for
Preparedness and Response (ASPR)

BARDA Vaccine Programs

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(BARDA)**

IOM Committee on National Vaccine Plan

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Mission

Office of the Assistant Secretary for Preparedness and Response

Lead the Nation

*in preventing, preparing for, and
responding to the adverse health effects
of public health emergencies and disasters,
natural or manmade,
for the civilian population.*



National Vaccine Plan 1994

- Objective 1.1

Strategy 1.1.4 : “...research on vaccines to prevent endemic infectious diseases ...and to protect against biological weapons.”

Strategy 1.1.5: “Conduct periodic reevaluation of priorities for new and improved vaccines including those against emerging diseases.”

- Objective 1.2

Strategy 1.2.4: “Develop contingency plans to deal effectively with new epidemics”



Biodefense Vaccines

- **Acambis ACAM2000 smallpox vaccine**
- **Bavarian-Nordic MVA smallpox vaccine**
- **Emergent Biosolutions AVA anthrax vaccine**
- **BAA-NIH-BARDA-2007-007: Sept 21, 2007
Vaccine Enhancement**
- **RFP for rPA anthrax vaccine: Feb 29, 2008**



Projected Acquisitions for Top-Priority MCMs

Near-Term (FY 2007-08) Funding Source and Level	Mid-Term (FY 2009-13) Funding Source and Level
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Medical Countermeasures (MCMs) for Biological Threats

Diagnostics		SRF ≤ \$100 M
Broad spectrum antibiotic(s)	DSNS ≤ \$100 M	DSNS ≤ \$100 M SRF > \$100 M
Anthrax antitoxin(s)		SRF > \$100 M
Anthrax vaccine(s)	SRF > \$100 M	
Filovirus MCMs		SRF > \$100 M
Smallpox antiviral(s)		SRF ≤ \$100 M
Smallpox vaccine	SRF > \$100 M	

Medical Countermeasures for Radiological and Nuclear Threats

ARS/DEARE	SRF > \$100 M	SRF > \$100 M
Biodosimetry, Bioassay		SRF ≤ \$100 M
Radionuclide-specific agent(s)		SRF ≤ \$100 M

Medical Countermeasures for Chemical Threats

Enterprise CHEMPACKs		DSNS > \$100 M
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CBRN Vaccine Acquisition (2004- present)

Material Threat	Product	Courses	Company	Award Date
Smallpox	ACAM2000* (CDC)	192.5M	Acambis (UK)	9/00, 11/01
	MVA	20.0M	Bavarian Nordic (Denmark)	6/07
Anthrax	rPA vaccine	75.0M	VaxGen (USA)	Cancelled 12/06
	rPA vaccine	25.0M	To be determined	2008
	AVA vaccine*	5.0M (2x), 18.75M	Emergent Biosolutions (USA)	5/05, 5/06, 9/07

*Delivered to SNS

- **Pre-pandemic vaccine**
 - Vaccine against viruses with “pandemic potential”
 - Produced during gaps in annual vaccine production
 - Match with pandemic strain and efficacy unknown
- **Pandemic vaccine**
 - Vaccine against the specific pandemic virus
 - Can only be produced once the pandemic occurs
 - Limited U.S. based vaccine production capacity



Pre-Pandemic Vaccine: Stockpile Challenges

- Virus antigenic drift
- Vaccine product stability
- Optimal vaccine product formulation
- Multiple vaccine products & manufacturers
- Vaccination strategy



Pandemic Vaccine: Stockpile Challenges

- Pandemic strain characterization
- Optimal vaccine product formulation
- Rapid production and scale up
- Regulatory strategy



Influenza Vaccines: BARDA Integrated Program

<p>27 contracts</p> <p>2 grants</p> <p>\$3.5 B</p>	<p>Vaccines</p>	<p>Antivirals</p>	<p>Diagnostics/ Respiratory Devices</p>
<p>Advanced Development</p>	<p>Cell-based Antigen-sparing Next Generation Recombinant</p>	<p>Peramivir</p>	<p><u>Diagnostics</u> Point of Care Clinical Lab <u>Ventilators</u> Next Generation</p>
<p>Stockpile Acquisitions</p>	<p>H5N1 Pre-Pandemic Vaccine Stockpiles</p>	<p><u>Tamiflu & Relenza</u> Federal Stockpiles State Stockpiles</p>	<p>Masks & Respirators</p>
<p>Infrastructure Building</p>	<p>Retrofit Existing Mfg Facilities Build New Cell- based Mfg Facilities Egg-based Supply</p>		



Influenza Vaccines: Advanced Development

- **Five Projects** (9 contracts - \$1.5 B; 2 grants - \$11 M)

Projects	Contract Awards	Industry Partners	Expected Results
Cell-based	\$1.3 B	sanofi pasteur Novartis GlaxoSmithKline MedImmune Solvay DynPort/Baxter	Expand domestic flu vaccine mfg. Provide 475 M doses pandemic vaccine by 2011
Antigen-sparing	\$133 M	Novartis GlaxoSmithKline IOMAI	Reduce amount of vaccine antigen needed BARDA Mix-N-Match Studies
Next Generation: Recombinant	RFP Oct. 07	Contract awards expected in FY08	Diversify flu vaccine mfg. Reduce mfg. time
Intl. Vaccine Develop.	\$11 M	VABIOTECH WHO	Facilitate flu vaccine development & mfg. cap. In developing countries



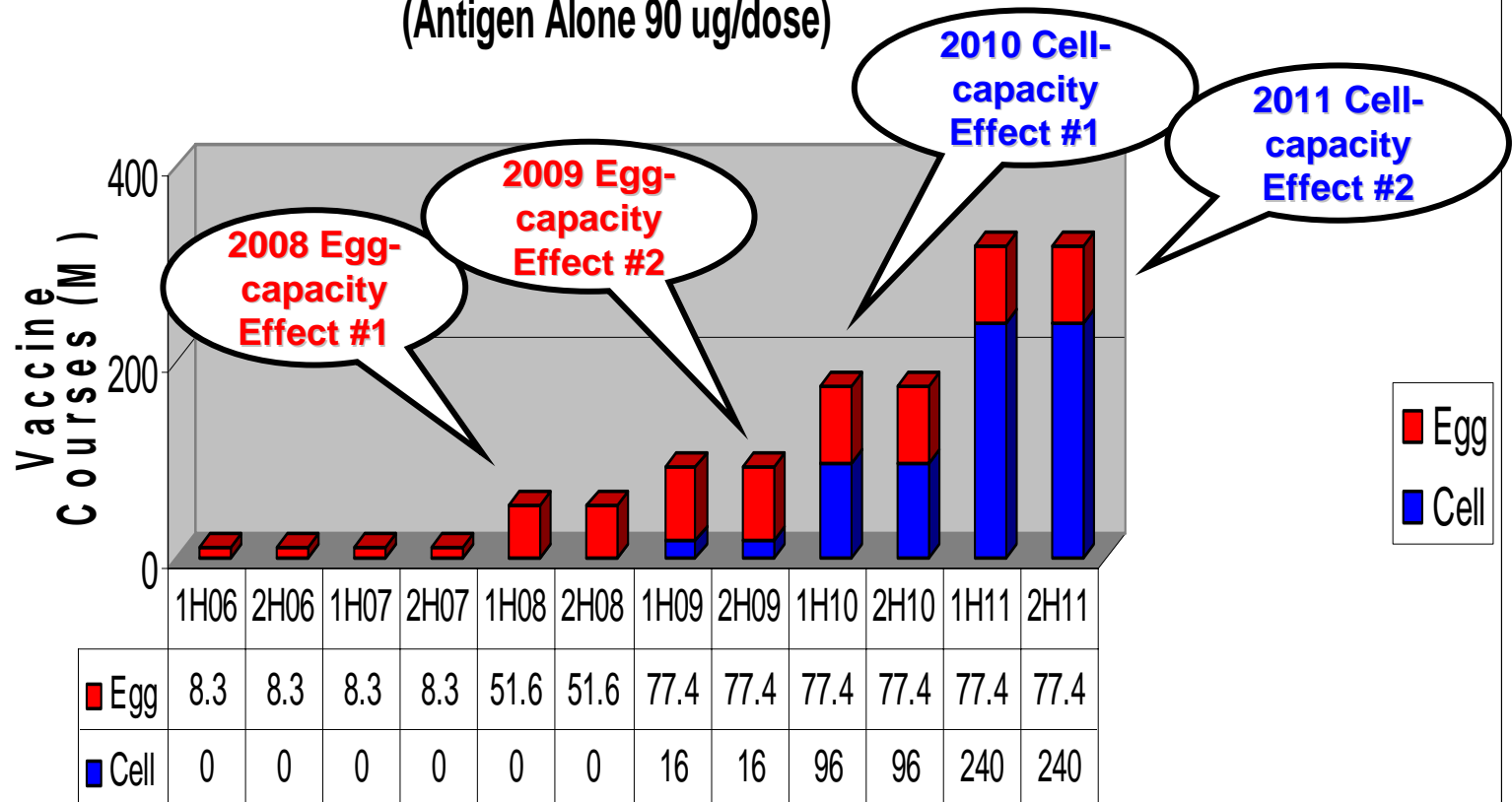
Influenza Vaccines: Stockpile Acquisitions

- **Four Projects** (6 contracts, \$950 M)
- **First H5N1 vaccine** licensed (Apr. '07) to sanofi pasteur & #1 medical breakthrough of 2007 (Time, Dec. 14, 2007).

Projects	Contracts	Industry Partners	Current Results
H5N1 Vaccine 2004	\$21M	sanofi pasteur	Provide 0.47 M doses @ 90 ug/dose of pre-pandemic stockpile (H5N1 Clade 1)
H5N1 Vaccine 2005	\$243 M	sanofi pasteur Novartis	Provide 8.0 M doses @ 90 ug/dose of pre-pandemic stockpile (H5N1 Clade 1)
H5N1 Vaccine 2006	\$241 M	sanofi pasteur Novartis GlaxoSmithKline	Provide 4.9 M doses @ 90 ug/dose of pre-pandemic stockpile (H5N1 Subclade 2.1)
H5N1 Vaccine 2007	\$445 M	sanofi pasteur Novartis GlaxoSmithKline	Provide 11.2 M doses of pre-pandemic stockpile (H5N1 clade 2)

U.S. Pan Flu Vaccine Capacity Forecast: Antigen Alone Vaccines

U.S. Pandemic Influenza Vaccine Capacity
(Antigen Alone 90 ug/dose)





Influenza Vaccines: Infrastructure Building

- **Three Projects** (3 contracts - \$175.5 M)

Projects	Funding	Industry Partners	Expected Results
Egg-based Supply	\$43 M	sanofi pasteur Contract awarded in 2004	Provide secure year-round egg supply for flu vaccine mfg Provide clinical study vaccines
Retrofit existing mfg. facilities	\$132.5 M new RFP in FY08 for pilot & fill-finish facilities	sanofi pasteur MedImmune Contracts awarded in 2007	Increase domestic flu vaccine capacity to produce 100+ M doses of egg-based pandemic flu vaccine & warm-base operations
Build new cell-based vaccine facilities	RFP expected in FY08	Contract awards expected in FY08	Build domestic cell-based flu vaccine mfg. Capacity to support 475 M pandemic dose level



Pandemic Influenza Summary

- Robust and comprehensive **portfolio approach** to developing and acquiring a broad array of medical countermeasures (vaccines, antivirals, and diagnostics)
 - HHS awarded 27 contracts totaling \$3.5 B since Dec. 2005 for Stage 1 of the medical countermeasure program
 - HHS initiated Stage 2 programs in Sept. '07 for advanced development of next generation recombinant vaccines, expansion & management of vaccine and antiviral stockpiles, & domestic vaccine infrastructure building
- Cooperative effort leveraging resources from throughout HHS (NIH, CDC, FDA, OS & ASPR), USG, States and Industry



Future Vaccine Challenges

- **thermostable formulation**
- **long term stability**
- **adjuvants**
- **one or two doses**
- **combination vaccine (multivalent)**
- **needle free administration**
- **specific, robust immune response**
- **surge capacity production**
- **cost effective**



Website

www.hhs.gov/aspr/barda

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