



# Enhancing the work of the HHS National Vaccine Program in Global Immunizations



## *Presentation of Draft Report and Draft Recommendations*



## *National Vaccine Advisory Committee Global Immunizations Working Group*

*11 September 2013*

*Phil LaRussa, MD  
Amy Pisani, MS*



# Global Immunizations – the Ground Truth

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- Global immunizations are one of the ***most cost-effective, evidence-based*** public health measure there is to reduce morbidity and mortality from infectious diseases
- Yet, a child still dies from a vaccine-preventable disease ***every 20 seconds***
- Better access to routine and new, and underutilized vaccines have ***the potential to save 23 million lives between 2011-2020***
- The U.S. ***directly benefits from strong, effective global immunization systems***
  - Reduce the risk of disease importations,
  - Strengthen global surveillance for infectious diseases
  - Contribute to overall global economic growth and stability
- ***HHS contributions of technical assistance and scientific expertise*** should be leveraged to enhance global efforts such as the Decade of Vaccines



# Charge to NVAC – Feb 2012

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- To review **the role of HHS** in global immunizations
- To review the effects of global immunizations on global populations and the effects of global immunizations on US populations
- To recommend how **HHS** can best continue to contribute to these efforts, **consistent with its newly established Global Health Strategy and Goal 5 of the National Vaccine Plan**
- To recommend how to best communicate this information to decision makers and the general public to ensure continued sufficient resources for global vaccination efforts

# Membership

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## **NVAC Members**

*Walt Orenstein- NVAC chair*

*Phil LaRussa – GIWG co-chair*

*Amy Pisani – GIWG co-chair*

*Seth Hetherington*

*Clem Lewin*

*Bonnie Maldonado*

*Jim Mason*

*Charles Mouton*

*Thomas Stenvig*

## **Federal Ex Officio Members**

*Steve Cochi – CDC*

*Theresa Finn – FDA*

*Cyril Gay – USDA/ARS*

*Marion Gruber - FDA*

*Rick Hill – USDA/APHIS*

*Jeff Kelman- CMS*

*Philip Krause - FDA*

*Iris Mabry-Hernandez- AHRQ*

*Richard Martinello- VA*

*Justin Mills- HRSA*

*Barbara Mulach- NIH*

*Jane Seward- CDC*

*Angela Shen - USAID*

*Diana Parzik- DoD*

*Holly Wong - OGA*

## **Liaison Representatives**

*Maritel Costales – UNICEF, Immunization Team*

*Mahima Datla – Developing Countries Vaccine  
Manufacturers Network*

*Armin Fidler – World Bank, Health, Policy, and Strategy*

*Andrea Gay – United Nations Foundation*

*Alan Hinman – Task Force for Global Health*

*Akira Homma – Developing Countries Vaccine  
Manufacturers Network*

*John Klein– American Academy of Pediatrics*

*Steve Landry – Bill and Melinda Gates Foundation*

*Nina Schwalbe- GAVI Alliance*

*Peter Strebel – WHO, Dept. of Immunization, Vaccines,  
and Biologicals*

## **NVPO**

*Bruce Gellin – Designated Federal Official*

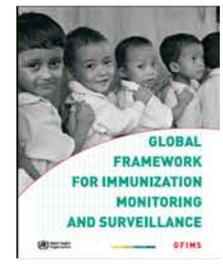
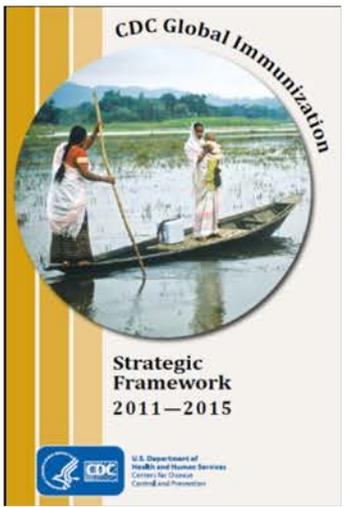
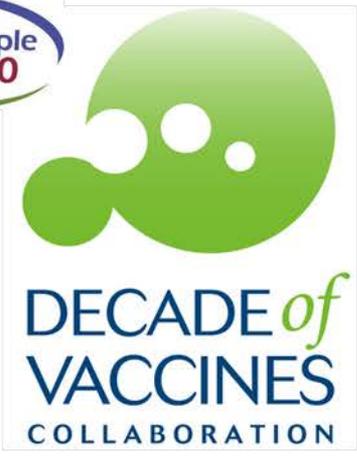
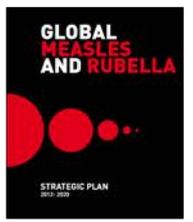
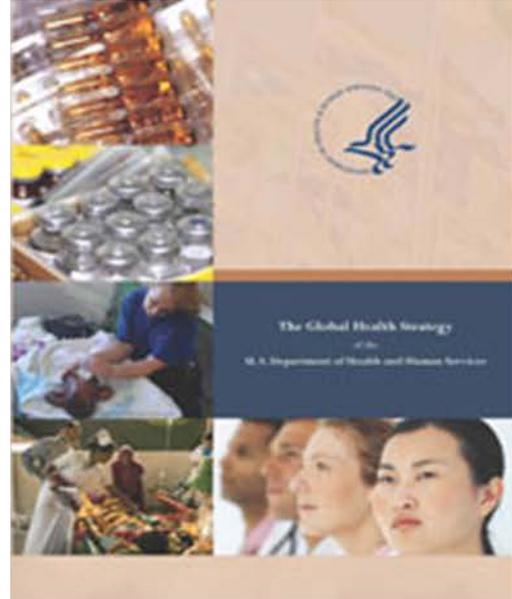
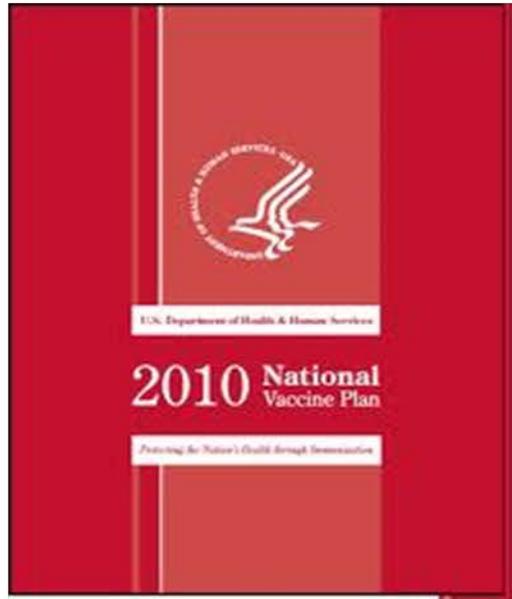
*Jennifer Gordon*

*S. Claire Slesinski*

## **Special Assistants**

*Katy Seib – Special Assistant to the NVAC chair*

# GIWG recommendations highlight where **HHS** support/ efforts can help enhance international immunization goals and objectives



# Putting the Report into Context

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## **The report does not**

- Intend to describe or represent all of USG efforts in global immunizations efforts
- Imply that HHS is the sole USG contributor to any of these efforts.

## **Instead, the intent of the report is to:**

- Raise awareness of ongoing HHS contributions that fulfill HHS global objectives
- Show how these efforts fit into broader global immunization efforts
- Better communicate HHS's activities and accomplishments to decision-makers, other USG agencies, and the public

# GIWIG Findings and Recommendations Focus on 6 Key Areas

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- 1) Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals
- 2) Strengthening global immunization systems
- 3) Enhancing Global Capacity for Vaccine Safety Monitoring and Post-Marketing Surveillance
- 4) Building global immunization R&D capacity
- 5) Strengthening capacity for vaccine decision-making
- 6) Coordination of HHS Global Immunization Efforts

# Report Structure

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- **Each section under the 6 key areas includes:**
  - NVAC's recommendation to strengthen HHS activities within the topic area
  - Background and supporting rationale for the recommendation
    - Description of challenges/barriers/ areas of opportunity
    - Key global initiatives/ on-going efforts
  - Overview of ongoing HHS activities in each area
- **Appendix to show how NVAC recommendations align with objectives in the NVP (goal 5), the HHS Global Health Strategy, the CDC Global Immunization Strategic Framework, and the Decade of Vaccines Global Vaccine Action Plan**

# Finalizing the Report for NVAC Consideration

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- June NVAC discussion of draft report and draft recommendations
- July Revisions and new information added based on NVAC and WG member input
- August Report released for public comment through the Federal Register
- Public comment received from 5 organizations and 2 members of the public
  - Public comment was very supportive with additional suggestions for examples and additional recommendations to consider
  - Public and additional comments by NVAC members were deliberated by GIWG 08/20 and adjudicated
  - Revisions are reflected in the final draft report and draft recommendations presented here
- Today Present to NVAC for deliberation and Final Vote

# Tackling Time-Limited Opportunities to Complete Polio Eradication and to Advance Measles Mortality Reduction and Regional Measles/Rubella Elimination Goals

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## Summary of Rationale for Recs. 1.1 – 1.4 (pages 7-8 of Draft Report)

### Polio

- 25 April 2013 Release of 2013-2018 Polio Endgame Strategy
- Importations to neighboring countries, violence, poor management of programs and weak health systems threaten the completion of these goals

### Measles

- Global Objective to eliminate measles/rubella in 5 WHO regions by 2020, reduce measles mortality by  $\geq 95\%$  of 2000 levels by 2015
- 2010-2011 – Measles incidence increased and large outbreaks now reported in a number of countries including importations and outbreaks to the US
  - 2010: 220 measles cases in US, 72 cases directly traced to importations
- Efforts include significant CDC resources and programmatic activities (e.g., STOP program) that should be show-cased and, if possible, enhanced
- Opportunity for HHS to deliver targeted communications that garner political and public support and to raise awareness of funding gaps that jeopardize completion of these goals
- Opportunity to incorporate the HHS “lessons learned” from these efforts to inform and shape future activities in immunization systems strengthening and disease prevention and control

# Strengthening Global Immunization Systems

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## Summary of Rationale for Recs. 2.1 – 2.7 (pages 8-9 of Draft Report)

- Improving mechanisms to monitor and evaluate immunization coverage and data collection in order to strengthen immunization program performance and resource allocation
- Enhanced coordination of laboratory-supported VPD surveillance at the subnational and national levels
  - Need to integrate (when possible) existing surveillance systems
  - Need for additional support to establish surveillance for introduction of new and underutilized vaccines
  - Strengthening existing programs like the CDC's Field Epidemiology (Laboratory) Training Programs to build trained public health workforce
- Evaluating strategies to improve vaccine delivery systems
  - Need to evaluate strategies to reach underserved populations
  - Pre- departure vaccination of US-bound refugees
  - Support of USAID efforts to strengthen vaccine and supply-chain logistics
  - Need to evaluate the integration/bundling of health services with immunizations to maximize impact/ cost-effectiveness of limited healthcare resources
  - Advocacy

# Enhancing Global Capacity for Vaccine Safety Monitoring and Post-Marketing Surveillance

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## Summary of Rationale for Recs. 3.1 (page 10 of Draft Report)

- Vaccine safety activities are enhanced through global coordination
- 65% of WHO member states do not have post-marketing vaccine safety monitoring systems
- Need to improve data collection and information-sharing systems
- Need to standardize case definitions and tools
- Linking data systems across countries and regions for better information sharing and collaboration can help identify rare or unexpected vaccine safety signals across populations
- Support for the WHO's Global Vaccine Safety Initiative
  - Portfolio vaccine safety capacity building activities to carry out the objectives in the Global Vaccine Safety Blueprint

# Building Global Immunization R&D Capacity

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## Summary of Rationale for Recs. 4.1 – 4.5 (pages 10-11 of Draft Report)

- Supporting basic research and discovery for vaccines and immunization technologies
  - New vaccine platforms
  - Innovations in vaccine delivery, including supply chain and logistics
  - Addressing unmet public health needs with new or improved vaccines
- Building scientific capacity in developing countries
- Enhancing vaccine R&D capacity to bring new or improved vaccines and immunization technologies to market
  - Need to establish and communicate vaccine R&D priorities (target product profiles)
  - Utilizing Product Development Partnerships
  - Harmonizing regulatory standards and building national regulatory capacity
- Supporting the role of developing country vaccine manufacturers in building global vaccine manufacturing capacity
  - Need to ensure adequate global supplies of safe and effective vaccines
  - Critical to pandemic influenza preparedness efforts

# Strengthening Capacity for Vaccine Decision-Making

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## Summary of Rationale for Recs. 5.1 – 5.2 (pages 11-12 of Draft Report)

- Introducing new and underutilized vaccines into national vaccine programs, combined with traditional vaccines, has the potential to save 23 million lives by 2020
- Evidence on disease burden, economic analysis and cost-effectiveness data, vaccine safety data, and logistical feasibility can strengthen support for the introduction of vaccines in countries and help build public demand
- Countries can benefit from the analysis of National Immunization Technical Advisory Groups (such as the US ACIP), who can provide independent recommendations to help guide assistance programs, donor funding, and programmatic efforts

# Coordination of HHS Global Immunization Efforts

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## Summary of Rationale for Recs. 6.1 – 6.2 (pages 12-13 of Draft Report)

- Coordination of HHS efforts and resources are increasingly needed to support the HHS global health strategy and overall HHS global health priorities
- Current HHS human resources policy is oriented towards HHS domestic health work
  - Efforts are underway to revise policies to support the an HHS global health career track
- Better tracking and coordination of HHS's global immunization work will multiply impact and facilitate collaborations with other USG agencies and non-federal partners
- Opportunity to convene an HHS cross-departmental working group to coordinate and provide better transparency of HHS global immunization activities
- Opportunities to better coordinate with other USG agencies, non-USG agencies, and partners and to communicate HHS efforts

# Requested Additions to the GIWG Report Based on Public Comment

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## **Addition of 3 new recommendations based on public comment and WG discussions:**

- New 2.6:** The ASH should support the work of other USG agencies and partners to strengthen global efforts pertaining to immunization program logistics management, including building and sustaining the necessary capacity for vaccine supply chain, logistics, and forecasting. (Page 9 of Draft Report)
  
- New 6.2.3:** The HHS cross-developmental working group should develop an annual report to Congress on HHS investments and HHS impacts on global immunization efforts. This report could be presented as an expanded section of an existing report to Congress or as a standalone product. (Page 13 of Draft Report)
  
- New 6.2.4:** When communicating the value of vaccines to the public and decision makers, the ASH should emphasize all of the comprehensive efforts required to optimize disease prevention through vaccination. The ASH should communicate to decision makers that investments in USG efforts in all areas of immunization are required to ensure optimal disease and death prevention and that global vaccination efforts not only save lives in other countries but enhance our own domestic health security because the potential for importation of vaccine preventable infectious organisms into this country is reduced. (Page 13 of Draft Report)

# NVAC DISCUSSION



Ali Maow Maalin in  
1977  
WHO /John F. Wickett

Ali Maow Maalin, the last person to be infected with naturally occurring  
smallpox  
(1954-2013)