Update of
The National Vaccine Plan

Raymond A. Strikas, MD
National Vaccine Program Office
Department of Health and Human Services
Presentation Outline

• Statutory basis for the National Vaccine Program Office and National Vaccine Plan

• Review of the 1994 National Vaccine Plan and areas for revision
  – Goals and objectives
  – Priorities

• Vision for a revised National Vaccine Plan

• Evolution of Vaccination Issues since 1994

• Scope of the revision

• Process for revision
  – HHS role
  – IOM role
  – Draft process flowchart
Statutory Basis for the National Vaccine Program*

• Title XXI Public Health Service Act (P.L. 99-660, Section 2101):
  – The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal protection against human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.

*The National Vaccine Program Office monitors, coordinates, and provides leadership for the overall collaborative effort that is the Program.
Statutory Basis for the National Vaccine Program - 2

• Title XXI Public Health Service Act (P.L. 99-660, Section 2102): National Vaccine Program Director [the Assistant Secretary for Health] shall coordinate and provide direction for

- Vaccine research
- Vaccine development
- Safety and efficacy testing of vaccines
- Licensing of vaccine manufacturers and vaccines
- Production and procurement of vaccines
- Distribution and use of vaccines
- Evaluating the need for and the effectiveness and adverse effects of vaccines
- Governmental and non-governmental activities
- Funding of federal activities

*The National Vaccine Program Office monitors, coordinates, and provides leadership for the overall collaborative effort that is the Program.*
Statutory Basis for the National Vaccine Program Office - 3

• Title XXI Public Health Service Act (P.L. 99-660, Section 2103):

  – NVP Director shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 2102.

  – The plan shall establish priorities in [list in sec. 2102] and describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their functions in consultation and coordination with the Program and in conformity with such priorities.
1994 National Vaccine Plan Goals

1. Develop new and improved vaccines

2. Ensure the optimal safety and effectiveness of vaccines and immunization

3. Better educate the public and members of the health professions on the benefits and risks of immunization

4. Achieve better use of existing vaccines to prevent disease, disability, and death
1994 National Vaccine Plan Priorities

• Specific priorities within the broad goals and objectives of the overall plan
  – Childhood Immunization Initiative:
    • Improving quality, quantity of vaccination delivery services
    • Increasing community participation, education, partnerships
    • Reducing vaccine cost
    • Improving monitoring of disease and vaccination coverage
    • Improving vaccines and vaccine use
1994 National Vaccine Plan Priorities - 2

• Vaccine Development
  – HIV vaccines
  – CDC Emerging Infections Plan
  – NIAID Blue Ribbon Panel
    • Improve pertussis, measles vaccines
    • Combined vaccines
    • STD vaccines
    • Respiratory, enteric vaccines
    • New approaches for vaccine delivery
    • Vaccine safety

• Policy and Program Development
  – Pandemic Plan update
  – Address unmet needs
National Vaccine Plan Status

• Completed in 1994

• Reviewed at NVPO retreat – 1997
  – NVPO, agencies’ activities related to each Goal, Objective and Strategy catalogued, reviewed

• No other formal evaluation performed
  – Evaluation may be difficult, given broad sweep of the Plan’s Goals and Objectives.
  – Virtually all vaccine-related activities fit in it

• No revisions since publication
Vision for National Vaccine Plan Update

- 1/19/07: Charge from the Assistant Secretary for Health that the plan be updated “to reflect current priorities and potential future directions … will provide valuable input to me and to HHS in our consideration of forthcoming budget initiatives.”

- “The updated Plan should summarize current priorities for vaccine- and immunization-related research, development and use; contribute to efforts to prioritize the use of existing resources; and identify needs for new resources.”
Evolution of Vaccination Issues since 1994

- Disease incidence changes
- New vaccines
- New schedules for children and adults
- Changes in vaccine coverage
- Implementation of immunization information systems (registries)
- Adolescent immunization focus
- Impact of bio-defense and pandemic preparedness activities
Other Continuing Challenges

- Vaccine safety
- Vaccine financing
- International vaccine issues
- Vaccine Supply
- Achieving Adult Immunization Goals
- Influenza
Scope of National Vaccine Plan Revision

• National plan (led by the federal government)
• Address priorities for 2010-2015
• Include timelines and metrics, where feasible
• Begin with current priorities to develop goals and objectives (to be presented today)
• Link to Healthy People 2020 (to be discussed today)
HHS Process

- Develop targeted objectives and strategies for each priority
  - Steering Committee: NVPO, CDC, FDA, NIH

- Use 2010-15 milestones

- National Vaccine Advisory Committee (NVAC) review of materials as interim stakeholder input, or “reality check”
Charge to IOM: 1. Evaluation of 1994 Plan

- Institute of Medicine (IOM) to complete evaluation of 1994 Plan
  - The committee will review the 1994 plan and determine to what extent the four goals and 26 objectives (and/or other outcomes) have been met.
  - The committee will develop a letter report of its evaluation of the 1994. The report will undergo the typical process of external review before being finalized.
  - The letter report will be delivered to NVPO.
2. IOM Stakeholder Involvement Approach

• The IOM committee will hold workshops with national expert stakeholders in medicine, public health, industry, and vaccinology to review publicly available, draft planning documents from the Department of Health and Human Services.

• Commissioned papers will be presented on less well explored areas of the plan.

• IOM stakeholders’ five meetings for new Plan priorities’ discussions will begin mid-2008, to conclude in 2009.

• The committee will prepare a report with conclusions and recommendations about priority actions within the major components of the draft planning documents.
Public Engagement

“When big things are at stake, the danger of error is great. Therefore, many should discuss and clarify the matter together so the correct way may be found.”

Shotoku Taishi, first Buddhist emperor of Japan, 604 AD
Definition of Public Engagement

• Collaborative problem solving

• Shared decision making

• Co-development or co-creation of a solution or decision

• Participation, not just consultation
Draft Process Flow

Process Flow: National Vaccine Plan Development, 2007-2009 [numbers tie to sequence in narrative; deliverable documents are underlined]