National Vaccine Advisory Committee

Gus Birkhead, MD MPH

Chair
Deputy Commissioner, Office of Public Health
New York State Department of Health
June 26, 2008

Title XXI Public Health Service Act

Sec. 2102: National Vaccine Program

- Section 2102: NVP Responsibilities
 - 1) Vaccine Research
 - 2) Vaccine Development
 - 3) Safety and efficacy testing of vaccines
 - 4) Licensing of vaccine manufacturers and vaccines
 - 5) Production and procurement of vaccines
 - 6) Distribution and use of vaccines
 - 7) Evaluating the need for, the effectiveness, and adverse effects of vaccines and immunization activities
 - 8) Coordinating governmental and non-governmental activities
 - 9) Funding of federal agencies

Title XXI: National Vaccine Program

- S.2103 National Vaccine Plan:
 - establish the priorities in research,
 - development of new vaccines,
 - optimal use of resources, etc...
- S.2104 Annual report to Congress
- S.2105 National Vaccine Advisory Committee

Section 2105 – NVAC

NVAC shall recommend:

- ways to encourage the adequate supply of safe and effective vaccines,
- research priorities and other measures to enhance the safety and efficacy of vaccines,
- on the implementation of secs 2102, 2103
- And, identify annually for NVP the most important areas of government and nongovernment cooperation in implementing sections 2102, 2103 and 2104.

NVAC: Current Members

- Jon Almquist
- Gus Birkhead
- Richard Clover
- Cornelia Dekker
- Jaime Ferge
- Sharon Humiston
- Lisa Jackson
- Calvin Johnson
- Charles Lovell

- James Mason
- Marie McCormick
- Trish Parnell
- Andrew Pavia
- Laura Riley
- Christine Nevin-Woods

Pharmaceutical reps

- Mark Feinberg
- Lance Gordon

NVAC: Recent Accomplishments

- Report on Immunization Information Systems development
- Report on Adolescent Immunization
- New Working Group structure:
 - Vaccine Finance
 - Vaccine Safety
 - Adult Vaccination
- NVAC participation in the National Vaccination Plan

NVAC: Vaccine Finance Working Group

- Chair: Gus Birkhead
- Process with broad stakeholder input
- Stakeholder meeting April 29-30, 2008
- Draft presented to NVAC at June meeting
- Planned vote on final recommendations to the Assistant Secretary at September 2008 meeting

Vaccine Finance Stakeholder Meeting, April 2008

- AIM
- CMS
- US Chamber of Commerce
- AHIP
- NBGH
- NASMD
- NCSL
- PKIDs
- IAC
- March of Dimes
- APhA
- McKesson
- ACOG
- AAFP
- Acambis

- ASTHO
- NACCHO
- CDC
- Merck
- GSK
- Wyeth
- Chiron
- sanofi pasteur
- MedImmune
- Henry Schein
- Novartis
- Aetna
- AAP
- IDSA
- 317 Coalition
- CSL Biother.

- BIO/PhRMA
- HIDA
- Maxim
- PIDS
- State of CT
- State of NH
- VA DMAS
- Cook County DPH
- Baxter
- AMA
- AAPA
- ECBT
- Becton Dickinson
- HHS/ASRT
- World Vacc. Org.
- Akorn

Structure of NVAC Vaccine Finance Recommendations

Public Sector

- I. Providing vaccines for the underinsured
 - A. VFC
 - B. 317
 - C. State and local funds
- II. Covering the cost of vaccine administration
 - A. Covering for all VFC-eligible children
 - B. Setting reimbursement levels
 - C. Improving current Medicaid reimbursement
- III. Administrative and other steps

Private Sector

- I. Insurance coverage for vaccination
- II. Administrative and other steps

NVAC: Vaccine Safety Working Group

- Chair: Andrew Pavia
- Goal 1. Review CDC Immunization Safety Office (ISO) Scientific Agenda:
 - http://www.cdc.gov/vaccinesafety/agenda.htm
- Goal 2. Review and recommendation on overall federal government vaccine safety agenda.
- Wide scale public engagement process to receive input from the general public.

NVAC Vaccine Safety Working Group Sub-groups

Sub Group	Research Topic	Capacity Topic(s)
1	Specific Vaccine Questions	1. VAERS Infrastructure 2. VSD Infrastructure
2	Clinical Outcomes	 Epi/Statistical Methods Case Definitions
3	Special Populations	1. Lab Methods 2. Genomics
4	Vaccines and Vaccinations	1. Clinical Guidance 2. CISA

NVAC: Adult Vaccination Working Group

- Chair: Richard Clover
- Charge to Working Group:

"To assess public health adult immunization activities in HHS programs, identify gaps, and recommend improvements, particularly in program implementation, coordination, evaluation and collaboration across agencies, that will lead to improve vaccination uptake in adults in these programs."

National Vaccine Plan

- NVPO is developing a draft National Vaccine Plan, updating the previous 1994 plan, with input from all applicable federal agencies.
- NVAC will provide input into the process.
- The Institute of Medicine is reviewing Plan priorities: http://www.iom.edu/vaccineplan
 - IOM has scheduled a series of public stakeholder workshops, the first scheduled July 24, 2008 in Chicago. ACIP members are invited.
- ACIP members and others are invited to familiarize themselves with the plan, and provide comments and ideas to NVPO.

National Vaccine Plan Draft Priorities

- Enhance Vaccine Research and Development
- Develop Specific Vaccines
- Adult Immunization
- Adolescent Immunization
- Childhood Vaccination
- Financial Barriers

- Vaccine Supply
- Vaccine Safety
- Vaccine Injury/ Compensation
- Communication and Education
- Surveillance
- Preparedness
- Global Health

NVAC: Future Priorities

- Assure a strong, continued commitment to the national immunization effort
- Advise during Federal administration transition
- Carry out the mandates of Title XXI
- Participate in the development of the National Vaccine Plan
- Study of NVAC's effectiveness
- Improve processes for stakeholder input and public engagement

Acknowledgements

- Bruce Gellin
- Megan Lindley
- Julie Moreno
- Walt Orenstein
- Lance Rodewald
- Dan Salmon

- Jenny Salesa
- Ben Schwartz
- Angela Shen
- Ray Strikas
- Kristen Vannice