**National Vaccine Advisory Committee (NVAC)**
**September 16–17, 2008, Meeting Minutes**

## Meeting Overview

The Committee discussed the need for an NVAC annual report and decided to develop a transition guidance document focusing on the status of the National Vaccine Program, vaccine safety, and financing. It unanimously approved the recommendations of the Vaccine Finance Working Group (VFWG) and agreed to evaluate the fiscal implications of the recommendations at a future meeting. The Committee also reviewed the Adolescent Immunization Working Group's recommendations, approved by NVAC in June, and the Centers for Disease Control and Prevention's (CDC's) Adolescent Vaccination Implementation Plan, which addresses many of those recommendations. It also approved the recommendations to improve use of immunization information systems (IIS).

The Committee heard presentations on vaccine hesitancy from a number of perspectives and agreed that the Department of Health and Human Services (HHS) should provide more support to CDC's efforts to evaluate public perceptions of vaccines and inform the public about vaccine safety. It also received updates from its recently established Vaccine Safety and Adult Immunization Working Groups as well as updates from liaisons and ex officio members on their organizations' efforts. Presentations also included overviews on HHS' hospital-acquired infections (HAIs) initiative, CDC's efforts to address vaccine supply issues, to include the limited availability of rabies vaccine, and new modeling software for identifying targets in the Vaccines for Children (VFC) stockpile. Additionally, there was a presentation on the status of influenza vaccine doses and recommendations as well as related CDC public information campaigns. Finally, the Committee heard a summary of newly published research demonstrating the benefits to infants of maternal influenza vaccination during pregnancy.

## Committee Members in Attendance

Guthrie S. Birkhead, M.D., M.P.H., Chair
Jon R. Almquist, M.D.
Richard D. Clover, M.D.
Cornelia L. Dekker, M.D.
Mark Feinberg, M.D.
Jaime Fergie, M.D., F.A.A.P.
Lance K. Gordon, Ph.D.
Sharon G. Humiston, M.D., M.P.H.
Lisa Jackson, M.D., M.P.H.
Charles Lovell Jr., M.D., F.A.C.P.
James O. Mason, M.D., Dr.P.H.
Marie McCormick, M.D., Sc.D.
Christine Nevin-Woods, D.O., M.P.H.
Trish Parnell
Andrew T. Pavia, M.D.

## Executive Secretary

Bruce G. Gellin, M.D., M.P.H., Director, National Vaccine Program Office

**Assistant Secretary for Health**

ADM Joxel Garcia, M.D., M.B.A.

**NVAC Ex Officio Members**

Norman Baylor, Ph.D., Food and Drug Administration
Neal Brandes, U.S. Agency for International Development
George Curlin, M.D., National Institutes of Health
COL Renata J. M. Engler, Department of Defense
Geoffrey Evans, M.D., Health Resources and Services Administration
Jeffrey A. Kelman, M.D., M.M.Sc., Centers for Medicare & Medicaid Services
Anne Schuchat, M.D., Rear Admiral, U.S. Public Health Service, CDC
Ronald O. Valdiserri, M.D., M.P.H., Department of Veterans Affairs

**NVAC Liaison Representatives**

Lisa Belzak, M.D. Public Health Agency of Canada
John Modlin, M.D., Vaccines and Related Biological Products Advisory Committee
Dale Morse, M.D., Advisory Committee on Immunization Practice
Wayne Rawlins, M.D., M.B.A., America's Health Insurance Plans
Tamara Tempfer, M.S.N., P.N.P., Advisory Commission on Childhood Vaccines

**Committee Members Absent**

Calvin Johnson, M.D., M.P.H.
Laura E. Riley, M.D.

**Invited Speakers**

Alan Hinman, M.D., M.P.H., CDC
Ed Moreno, Keystone Center
Barbara Mulach, Ph.D., National Institute of Allergy and Infectious Diseases
Walter A. Orenstein, M.D., Emory University
Christy Phillips, Pediatric Infectious Diseases Society
Lance Rodewald, M.D., CDC
Charles E. Rupprecht, V.M.D., M.S., Ph.D., CDC
Dan Salmon, Ph.D., M.P.H., National Vaccine Program Office
Jeanne M. Santoli, M.D., M.P.H., CDC
Kristine Sheedy, Ph.D., CDC
Phillip J. Smith, Ph.D., CDC
Mark C. Steinhoff, M.D., Johns Hopkins Bloomberg School of Public Health, School of Medicine
Shannon Stokley, M.P.H., CDC
Raymond A. Strikas, M.D., CAPT, U.S. Public Health Service, National Vaccine Program Office
L.J. Tan, Ph.D., American Medical Association
Gregory Wallace, M.D., M.S., M.P.H., CDC
Don Wright, M.D., M.P.H., Principal Deputy Assistant Secretary for Health

## Day 1—September 16, 2008

**Opening Remarks, Introduction, and Report of the Chair—Dr. Guthrie Birkhead**

Dr. Birkhead welcomed the participants and invited the Committee members to introduce themselves. The minutes of the June 2008 meeting were approved by the Committee. The next meeting is scheduled for February 5–6, 2009.

Dr. Birkhead summarized NVAC's recent accomplishments, noting that the VFWG will present its recommendations at this meeting. The Vaccine Safety Working Group and the Adult Immunization Working Group are newer entities whose members have been meeting via teleconference since the June NVAC meeting. NVAC will contribute its expertise to the revised National Vaccine Plan, which was originally written in 1994.

Dr. Birkhead said NVAC's charge includes reporting annually on the most important areas of government and nongovernmental cooperation in implementing the National Vaccine Program. While the Committee is not required to provide an annual report to Congress, Dr. Birkhead asked the members to consider what kind of annual reporting would be appropriate and useful.

In addition to ensuring a strong, continued commitment to the national immunization effort, Dr. Birkhead emphasized that NVAC should advise the National Vaccine Program Office (NVPO) during the transition to the next administration. A contractor hired by NVPO is conducting a study assessing NVAC's effectiveness. Improving processes for gathering stakeholder input and public engagement are NVAC priorities that will inform National Vaccine Plan development.

Dr. Birkhead offered a number of suggestions for addressing the legislative charge and strengthening NVAC's advisory role:

- Produce a year-end "state of the program" report on the National Vaccine Program that could serve as a guide for the transition to the next administration
- Develop an up-to-date list of NVAC recommendations and the status of each and post it on the Committee's website
- Coordinate with NVPO on the transition to a new administration
- Review the makeup of NVAC to ensure stakeholders are sufficiently represented and stagger members' terms
- Consider the findings of the study of NVAC's effectiveness
- Provide input on the National Vaccine Plan

Dr. Birkhead sent comments on behalf of NVAC to the Assistant Secretary for Health, ADM Joxel Garcia, on a Centers for Medicare and Medicaid Services (CMS) proposed rule. The comments support the inclusion of clinical staff times for quality related activities into payment mechanisms to increase vaccine administration reimbursement for providers.

***Discussion***

Several members expressed interest in learning the results of the study of NVAC's effectiveness, as the Committee currently has no way of gauging whether its recommendations are useful. Andrew Pavia, M.D., said other Federal advisory groups have prominent public profiles and clear influence on policy decisions. Dr. Birkhead concurred, saying that updating the list of NVAC recommendations and their status via the website would be a good start.

Members discussed what an NVAC annual report should address. Dr. Birkhead hoped a summary document could be produced before December 2008 that could serve as guidance for transition. Some felt it should assess progress in fighting vaccine-preventable disease and identify mechanisms for improvement, while others did not want to get bogged down in assessing each of the components. Some felt NVAC should use the report to identify pressing issues to the Secretary. Marie McCormick, M.D., Sc.D., commented that a transition guidance report should be separate from an NVAC annual report. Dr. Birkhead proposed a matrix that encompasses the nine areas that the statute directs NVAC to address and the activities of NVAC in response to each. Jaime Fergie, M.D., pointed out the difficulty of identifying measurable outcomes for broad advisory recommendations and advocated for a short (one-page) report identifying prominent threats.

***Action Item***

By December 31, 2008, NVAC should develop a report that serves as guidance for the transition to a new administration. The document will focus on three key issues: the status of the National Vaccine Program, vaccine safety (including hesitancy to use vaccines), and finance considerations. Further discussion is needed to identify who will write the report and how member input will be gathered.

**Welcome of the Assistant Secretary for Health—ADM Joxel Garcia**

ADM Garcia welcomed the members and congratulated NVAC on its work. He thanked the Committee for addressing vaccine financing, an issue of particular importance at the State level and one that persists in HHS' discussions with pediatric care providers and in CMS' efforts to work more effectively with State departments of health.

ADM Garcia said HHS is also focused on vaccine safety and stressed the need to strengthen the integrity of the system in place. Improving technology and communication among providers, patients, and systems will improve outcomes and lay the groundwork for a more proactive safety system. Because public health is one component of protecting and strengthening the nation, HHS has partnered with the Department of Defense (DoD) and Veterans Administration (VA) to enhance research on safety.

ADM Garcia charged NVAC with playing a key role in the process to update the National Vaccine Plan. He pointed out that vaccination programs in the United States have succeeded in significantly reducing the spread of many diseases, so many people, including health care providers, are unaware of the impact those diseases could have if their rates increased dramatically. He emphasized that if vaccine safety systems in the United States were to fail, developing countries could be devastated economically.

Finally, ADM Garcia has recommended that the position of Director of NVPO be given a more prominent leadership role in HHS by becoming a Deputy Assistant Secretary for Health. Such a move would allow NVPO to have more impact and to draw on the resources of other public health efforts.

**Implementation Plan for Adolescent Immunization Working Group Recommendations—Dr. Lance Gordon, Ms. Shannon Stokley**

Dr. Gordon summarized the makeup and activities of the Working Group. The Committee approved the recommendations of the Working Group at its June 2008 meeting, with the exception of those related to financing, which were passed on to the VFWG for consideration. The Working Group has published two papers in the American Journal of Preventive Medicine, one outlining key issues and challenges and one summarizing the Working Group's recommendations on mandatory vaccination for school entry. A paper summarizing the full set of recommendations approved by NVAC has been submitted to the same journal for publication. Those recommendations address venue and health care utilization, consent,

communication and public engagement, surveillance, and school mandates. The full report of the Working Group will be published as an appendix to the article and will be available free online.

Ms. Stokley compared CDC's Adolescent Vaccination Implementation Working Group with NVAC's Working Group, noting that CDC defines adolescents as those 11–21 years old. She outlined six key areas of the CDC's Adolescent Vaccination Implementation Plan; for each area, she noted the CDC's goals, current and planned activities, and program gaps.

- Identifying, evaluating, and supporting implementation of **effective strategies** includes two studies supported by NVPO (reminder/recall efforts and vaccination via retail-based clinics). Gaps include reaching groups over 18 years old.
- **Monitoring coverage** of adolescents includes assessing a number of national surveys that involve adolescents. The quality of IIS and lack of mechanisms to assess college students are gaps.
- Addressing **communication, education, training, and partnerships** involves, for example, updating Advisory Committee on Immunization Practices (ACIP) recommendations to include adolescent vaccination, conducting a national preteen campaign, and supporting State and local health department vaccination efforts. Gaps include limited resources and staff.
- Monitoring the **epidemiology** of vaccine-preventable diseases among adolescents includes evaluating a wide range of efforts around a number of diseases. Gaps include limited resources and ability to collect and evaluate data.
- **Ensuring vaccine safety** includes establishing safety as a priority in the research agenda and evaluating existing databases. Gaps include limited resources and ability to collect and evaluate data.
- **Supporting adolescent immunization providers and programs** includes gathering and disseminating comparative assessments of State laws, programs, and requirements. Gaps include the lack of information to support State-level funding requests.

***Discussion***

Dr. Gordon suggested more coordination between the NVAC and CDC Working Groups, which operate in parallel. Ronald Valdiserri, M.D., M.P.H., felt CDC should get more input directly from adolescents using social networking and other approaches. Christine Nevin-Woods, D.O., M.P.H., suggested getting more information about older adolescents, noting that State and local health departments and college campus health facilities may have mechanisms in place to establish adolescent focus groups. Mark Feinberg, M.D., suggested CDC interact with vaccine manufacturers who target adolescents to learn more about specific challenges.

RADM Anne Schuchat, M.D., said high-level staff at CDC discuss the issues identified by this and other working groups and use it to inform their efforts. She confirmed that NVAC's recommendations assist CDC in prioritizing research and in securing NVPO funding for evaluation projects.

Dr. Pavia felt the communication between the two working groups would help ensure that NVAC's recommendations are implemented. He praised the table provided by Ms. Stokley comparing NVAC and CDC activities; he suggested adding a column for future opportunities and maintaining the table with periodic updates.

Phil Hosbach, of Sanofi Pasteur suggested NVAC assess current government spending on vaccine initiatives and identify gaps.

***Action Items***

NVAC will seek budget information from HHS agencies to determine current spending on vaccine initiatives.

The table "Implementation of NVAC Adolescent Recommendations" will be maintained and updated annually. It may also serve as a model for tracking other NVAC recommendations.

The status and impact of the NVAC recommendations on adolescent immunization will be discussed at future NVAC meetings. Discussion will be informed by CDC reports tracking adolescent vaccination coverage, safety issues, and disparities.

**Proposed Recommendations of the Vaccine Finance Working Group—Dr. Walter Orenstein, Dr. Guthrie Birkhead**

Dr. Birkhead asked whether NVAC should vote on the proposed recommendations and then request cost analyses of the recommendations from NVPO or postpone voting until cost analyses are available. Some argued that the recommendations were incomplete without cost analyses to assess their benefits and establish priorities; others said cost-benefit analyses would be more useful but far too complicated to conduct quickly. Still others felt the substance of the recommendations would not be affected by cost. Dr. Gordon suggested that all future NVAC recommendations include consideration of associated costs; Dr. Valdiserri cautioned that not all recommendations require a cost analysis. Margaret Coleman of CDC added that costs vary dramatically depending on how costs are defined and who pays for them.

Dr. Orenstein summarized VFWG's 24 recommendations, which he grouped into eight blocks (or topic areas). For each block, Dr. Orenstein described the key conclusions supporting the recommendations and the pros and cons of the recommendations. All of the recommendations refer to vaccinating children and adolescents; finance issues for adults are being considered separately.

**PROPOSED RECOMMENDATIONS**

Recommendation #1. NVAC recommends the VFC program be extended to include access to VFC eligible underinsured children and adolescents receiving immunizations in public health clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.

Recommendation #2. NVAC recommends expansion of VFC to cover vaccine administration reimbursement for all VFC-eligible children and adolescents. (Currently the vaccine administration fee is not covered by VFC.) This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee. The vaccine administration reimbursement should be sufficient to cover the costs of vaccine administration (as referenced elsewhere in these recommendations).

Recommendation #3. NVAC recommends CDC and CMS annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.

Recommendation #4. NVAC recommends CMS update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by current studies. These efforts should be coordinated with AMA's review of RVU coding (Rec. #6).

Recommendation #5. NVAC recommends increasing the federal match (i.e. a larger federal proportion) for vaccine administration reimbursement in Medicaid to levels for other services of public health importance (e.g. family planning services).

Recommendation #6. NVAC recommends the American Medical Association's (AMA) RVS Update Committee (RUC) should review its Relative Value Unit (RVU) coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.

Recommendation #7. NVAC recommends vaccine manufacturers and third-party vaccine distributors work on an individual basis with providers to reduce the financial burden for initial and ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

Recommendation #8. NVAC recommends professional medical organizations provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical societies should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive federal assistance from CMS or other relevant agencies.

Recommendation #9. NVAC recommends medical providers, particularly in smaller practices, should participate in pools of vaccine purchasers to obtain volume ordering discounts. This may be done by individual providers joining or forming purchasing collaboratives, or through a regional vaccine purchasing contract held by professional medical organizations on behalf of providers.

Recommendation #10. NVAC recommends CDC, professional medical organizations, and other relevant stakeholders develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Recommendation #11. NVAC recommends health insurers and all private healthcare purchasers adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period.

Recommendation #12. NVAC recommends that all public and private health insurance plans voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

Recommendation #13. NVAC recommends that insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Recommendation #14. NVAC recommends Congress request an annual report on the CDC's professional judgment of the size and scope of the Section 317 program appropriation needed for vaccine purchase, vaccination infrastructure, and vaccine administration. Congress should ensure that Section 317 funding is provided at levels specified in CDC's annual report to Congress.

Recommendation #15. NVAC recommends CDC and CMS continue to collect and publish data on the costs and reimbursements associated with public and private vaccine administration. Costs include costs associated with the delivery of vaccines including activities such as inputting data into immunization registries and maintenance of appropriate storage requirements for vaccines. NVAC recommends that these published data be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. States and local health departments should use this information in determining vaccine administration reimbursements rates in Medicaid.

Recommendation #16. NVAC recommends NVPO calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Recommendation #17. NVAC recommends that NVAC convene one or more expert panels representing all impacted stakeholders to determine if policy options could be developed that would be acceptable to stakeholders to address the burden of financing for private sector child and adolescent vaccinations on the topic of tax credits as incentives for insurers, employers, and/or employees (consumers) to reduce or eliminate underinsurance, and whether these credits would provide added value to vaccination of children and adolescents.

Recommendation #18: NVAC recommends that the CDC substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

Recommendation #19: NVAC recommends that Congress expand Section 317 funding to support the additional national, state and local public health infrastructure (e.g., widespread and effective education and promotion for healthcare providers, adolescents, and their parents; coordination of supplementary and alternative venues for adolescent vaccinations; record keeping and registries; vaccine safety surveillance; disease surveillance) needed for adolescent vaccination programs as well as childhood vaccination programs for new recommendations such as universal influenza vaccination.

Recommendation #20: NVAC recommends continuation of federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

Recommendation #21. NVAC recommends that state, local and federal governments along with professional organizations outreach to medical providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician gynecologists) is a particular priority.

Recommendation #22. NVAC recommends states and localities develop mechanisms for billing insured children and adolescents served in the public sector. NVAC recommends CDC provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. This may require additional resources not currently in CDC's immunization program budget. Further, NVAC urges states and localities to reinvest reimbursements from public and private payers back into immunization programs.

Recommendation #23: NVAC recommends ensuring adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization mandates for school attendance.

Recommendation #24: NVAC recommends promotion of shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts.

***Block I: Public Sector Vaccine Purchase for the Underinsured in Public Health Clinics (Recommendation 1)***

Vaccinating uninsured children and adolescents poses financial stress on the public health system. The stress could be alleviated by expanding eligibility for the existing VFC program. The approach would alleviate financing problems in all 50 States but would also expose the legislation authorizing VFC to modification that could weaken the program. The recommendation does not address underinsured patients seeing private providers and could result in patients leaving their medical home for vaccination. The proposal does not affect market share, (i.e., balance of public vs. private markets) which is important to manufacturers.

***Discussion***

John Modlin, M.D., pointed out that in States that use universal purchasing, limiting the financing to the public health system could mean that underinsured children who see private providers may not be covered. Dr. Birkhead said the recommendation seeks to strike a balance by enabling all underinsured children to receive vaccinations at a Federally funded clinic or at a local public health department, not in any clinical setting. Dr. Orenstein said the VFWG had concerns that covering all underinsured children would create an incentive for families to drop private insurance coverage and affect the market share

***Block II: Funding Vaccine Administration Reimbursement for All VFC-Eligible Children and Adolescents (Recommendation 2)***

The recommendation supports vaccination for children and adolescents who are eligible for VFC but not enrolled in Medicaid. Administration costs for providers are substantial, but providers cannot refuse to vaccinate children who are not covered and cannot pay an administration fee. The proposal would establish a uniform reimbursement process, save State Medicaid funds, and give providers incentive to serve all VFC-eligible children. However, it would expose the VFC legislation to modification, increase Federal spending, and require States to develop mechanisms to reimburse providers for vaccine administration.

***Discussion***

Bruce Gellin, M.D., M.P.H., noted that this recommendation would have the highest associated costs. He clarified that a "uniform" system does not mean a flat rate for all providers across the country.

***Block III: Improving Vaccine Administration for VFC-Eligible People Enrolled in Medicaid (Recommendations 3–5)***

These recommendations would be unnecessary if Recommendation 2, above, was fully implemented. However, if Recommendation 2 is not enacted, these recommendations will address the concerns about inadequate public sector administration fees. In 1994, CMS set the current state-specific maximum reimbursement rates for vaccine administration and has not updated them since. They are insufficient to cover administrative costs in most States. The proposal could spur States to reevaluate their reimbursement rates, but State budgets are limited. The effects of the proposal would be limited to Medicaid administration fees.

***Discussion***

Jeffrey Kelman, M.D., M.M.Sc., pointed out that changing the Federal match formula for vaccine administration would require legislative efforts and significant costs. Dr. Orenstein noted that changing that legislation would not expose the VFC legislation to modifications.

***Block IV: Improving Business Practices in Private Providers' Offices (Recommendations 6–9)***

The current coding system for reimbursement must be updated to better reflect the high costs to private providers of offering vaccines. These proposals could increase providers' return on investment and provide incentives for office practices to provide vaccines, especially small practices. They also rely on collaboration with professional medical organizations and manufacturers. However, they could reduce revenue for manufacturers and create situations leading to violations of antitrust laws (e.g., sharing information on contracts and purchasing prices).

***Discussion***

Other than shifting the opportunity costs from the provider to the manufacturer, Dr. Birkhead said these proposals carried no significant cost implications.

***Block V: Reducing Financial Barriers to Vaccinating the Privately Insured (Recommendations 10–13)***

These recommendations address the lack of uniformity of vaccination coverage in benefit programs and concerns about the adequacy of reimbursement; they also support voluntary efforts over State mandates. The proposal emphasizes the cost-effectiveness of vaccines to employers and could ensure that more children are vaccinated and that providers are adequately reimbursed. However, the proposal leaves room for a patchwork approach to implementation. Most importantly, first-dollar coverage could increase premiums.

***Discussion***

Dr. Birkhead said VFWG debated the cost implications of these recommendations at length and determined that those bearing the brunt of the costs currently (providers and patients) are less able to continue bearing the costs than insurers and health care purchasers. Dr. Orenstein said a high proportion of providers said they delayed offering a vaccine for financial reasons (e.g., the ACIP recommendation was not yet reflected in an insurer's coverage).

***Block VI: Activities of Federal Agencies and Offices Related to Vaccine Financing (Recommendations 14–20)***

These recommendations address the timing of incorporating ACIP recommendations into coverage policies, the lack of information on the costs of covering all recommended vaccines, and the lack of data on cost-effectiveness of vaccination. The proposals would provide more realistic assessments of need and improve understanding of the costs and benefits of vaccines. However, the 317 funding mechanism is impermanent, and cost calculations may not be applicable to all types of insurance plans.

***Discussion***

Dr. Birkhead noted that NVAC has recommended increasing 317 funding for many years.

***Block VII, Activities of State Agencies and Offices Related to Vaccine Financing (Recommendations 21–22)***

The VFC program has been successful in providing vaccines to eligible children. Mechanisms are needed to ensure that, when appropriate, private insurers pay for vaccines provided at the expense of the public health system. The proposal would add providers to the VFC program and conserve funds. However, it may require State legislation, and States may prefer that private insurance reimbursement go into local general funds.

***Block VIII, Supporting Child And Adolescent Vaccination In Complementary Venues (Recommendations 23–24)***

Adolescents are more likely than children to be underinsured and less likely to get routine preventive care. The public health system may not be capable of supporting the large number of new vaccines recommended without private-sector assistance. The approach proposed would reach more children and adolescents outside the traditional health care system and support the notion of societal benefit of vaccines. Specific sources of funding are not identified, however, and limited State and school funding would be problematic.

***Discussion of All Recommendations***

Charles Lovell Jr., M.D., moved to adopt all of the recommendations, and Dr. Gordon seconded the motion.

Jon Abramson, M.D., of the American Academy of Pediatrics (AAP) said his organization supports most of NVAC's recommendations but believes the goal of ensuring that all children and adolescents receive all ACIP-recommended vaccines will not be met if each State dictates its own approach. Also, AAP is concerned about exposing VFC legislation to modifications. Dr. Abramson said that vaccine administration rates at the State level are at least equal to those of Medicare and are paid according to a clear, consistent methodology. Finally, he noted that AAP supports vaccination in complementary settings but hopes recommendations don't minimize the importance of the medical home as the ideal site for vaccination. Dr. Birkhead called the question; the motion was passed unanimously with no abstentions.

***Recommendation***

NVAC endorses the recommendations put forth by VFWG.

***Action Items***

NVAC will transmit the 24 recommendations on vaccine finance and the accompanying document, "Assuring Vaccination without Financial Barriers," to the Assistant Secretary for Health.

NVPO staff will determine the fiscal implications of each vaccine finance recommendation and provide the findings to NVAC at the February 2009 meeting.

The recommendations and the accompanying document, "Assuring Vaccination without Financial Barriers," will be finalized and posted on the NVAC website. Previous versions will be removed.

The CDC will be asked to publish a notice in MMWR directing readers to the NVAC website to obtain the recommendations and the accompanying document, "Assuring Vaccination without Financial Barriers."

## Adolescent Immunization Working Group's Recommendation on Vaccine Finance—Dr. Lance Gordon

Dr. Gordon pointed out that in 1999, NVAC recommended that all insurance plans be required to provide first-dollar coverage for vaccines for infants. He noted that vaccines recommended for adolescents are expensive. Adolescents are less likely than children to be covered by insurance and, if they are covered, more likely than children to be underinsured. Also, fewer adolescents than children are eligible for VFC. Therefore, the Adolescent Immunization Working Group recommends national legislation to mandate first-dollar insurance coverage of ACIP-recommended adolescent vaccines (and associated vaccination costs) in all health plans covered by the Employee Retirement Income Security Act (ERISA) and in all health plans serving Federal employees.

### *Discussion*

Trish Parnell suggested broadening the recommendation to all insurers; Jon Almquist, M.D., said limiting the scope of the recommendation was intended to avoid a battle with insurers and the business community. Dr. Gordon cited CDC data showing that the proportion of adolescents underinsured in terms of vaccine coverage is nearly twice that of infants. Emily Levine of HHS' Office of General Counsel advised that the proposed recommendation must clarify that it is intended to cover ACIP-recommended vaccines administered to adolescents (and not vaccines recommended for adolescents when they are given to other populations). Dr. Pavia supported the notion of mandating coverage but suggested the Committee hold off to see how the health system evolves in the very near future.

Wayne Rawlins, M.D., M.B.A., of America's Health Insurance Plans (AHIP) said that mandating a revision of ERISA would be impractical. Dr. Birkhead noted that a 2004 NVAC finance recommendation encouraged "promotion," but did not mandate first-dollar coverage of immunizations, and that recommendation, being more recent, would appear to supersede the 1999 recommendation. James Mason, M.D., Dr.P.H., stated that the Committee had just approved the VFWG recommendations and moved that the Committee go no further; the motion was seconded, and a majority voted in favor. The recommendation will not go forward.

#### *Action Item*

The concerns raised by the Adolescent Immunization Working Group on insurance coverage of vaccines for adolescents will be reflected in the document accompanying the NVAC recommendations on vaccine finance, "Assuring Vaccination without Financial Barriers."

## Vaccine Hesitancy

### *National Immunization Survey (NIS) Data and Attitudinal Module—Dr. Phil Smith*

Dr. Smith described the annual NIS, which assesses vaccination rates, for infants 19–35 months of age. In 2003, over 2,200 parents completed the NIS parental concerns module: 17 percent of them reported delaying vaccination of their infants, and 37 percent of those parents said they object to vaccination on the basis of political or religious reasons. The most commonly delayed vaccine was for varicella. Most often, parents delayed vaccinating their infant because the child was ill (37 percent), although concerns about safety (29 percent) and efficacy (12 percent) of vaccines were also cited. Of those parents who delayed vaccination, 92 percent of those who had an ill child sought information about the decision from a doctor, as did 72 percent who had safety or efficacy concerns. Of the same group, 1 percent who had an ill child sought information on the Internet, while 17 percent of those with safety or efficacy concerns did so. Dr. Smith concluded that parents concerned about safety and efficacy have different patterns of seeking information.

From 2003 NIS data, CDC concluded that although mild illness is not a contraindication to vaccination, many parents delay vaccination when their children are ill. When parents delay vaccination, their children may fall out of step with the vaccination schedule and also with their providers' recall/reminder system, so their vaccine coverage may be incomplete. Finally, parents who delay vaccination because of concerns about safety and efficacy are less likely to seek information from a doctor, but when their children are vaccinated, doctors have an opportunity to address parents concerns and administer missed doses.

Dr. Smith also described the National Teen Immunization Survey, which will collect data annually from adolescents 13–17 years old using a template similar to that of the NIS. In 2007, NVAC contributed to the development of the parental concerns module to explore reasons for delay and refusal of vaccines and sources of information that parents seek out. In July 2008, CDC began administering the module in six metropolitan areas and selected counties. In addition, CDC is evaluating trends among parents whose children have received no vaccinations and a systematic review of the literature on parental vaccine concerns.

***Vaccine Hesitancy and School Immunization Exemptions—Dr. Dan Salmon***

Dr. Salmon presented an assessment of the most extreme example of vaccine hesitancy: parents who seek exemption from school immunization requirements. Requirements vary widely by State. Children who are not vaccinated are at greater risk of disease and pose a risk to others, including those who cannot be vaccinated for medical reasons. Dr. Salmon showed that counties with the highest rates of children exempted from school vaccination requirements also had higher rates of pertussis outbreaks.

In States that allow exemptions for philosophical or religious reasons, more difficult administrative processes—such as requiring notarization of the request—resulted in fewer exemptions being granted. In States that allow exemptions only for religious reasons, the number of exemptions granted has been relatively stable for many years and does not correlate with the difficulty of the administrative process.

Dr. Salmon presented patterns of school exemption rates in Washington State from 1999 to 2007 showing a steady increase of exemptions, with rates as high as 25 percent in some counties.

Dr. Salmon presented a study that surveyed 800 parents who had sought exemptions and 1600 parents whose children were vaccinated. Respondents represented four States whose children attended both private and public elementary schools. Notably, 69 percent of parents of exempt children said they did not vaccinate their children because the vaccine might cause harm, and 49 percent thought the vaccine might overload the child's immune system. Of the same group, 37 percent felt their children were not at risk for the disease, and 21 percent felt the disease was not dangerous. (The survey allowed parents to provide more than one reason.) Only 13 percent did not vaccinate because they thought the vaccine might not work; 9 percent did not do so because of ethical or moral issues, and 9 percent because vaccination was contrary to their religious beliefs.

The survey identified a constellation of parental perceptions about vaccination; those who sought exemptions had low perceptions of disease susceptibility and severity and vaccine safety and efficacy; they also had low levels of trust in health care providers and government recommendations. Among parents of exempt children, eighty-one percent reported that children get more immunizations than is good for them. In this same group, over 50 percent believed it is better to develop disease immunity by contracting the disease than by vaccination. Additionally, 26 percent of parents with exempt children believed healthy children don't need vaccinations.

In Ashland, OR, where 28 percent of kindergarten students have exemptions, 58 percent of the people surveyed believe the public should be more concerned about the safety of vaccines, and 18 percent are

uncertain about the efficacy of vaccines. Dr. Salmon concluded that while safety is a primary issue related to vaccine hesitancy, clearly it is not the only issue of concern.

***Parental and Provider Views on Immunization—Dr. Kris Sheedy***

Dr. Sheedy presented findings from focus groups of first-time mothers with young children. Overall, mothers described similar efforts to ensure their children's health (nutrition, hygiene, regular health care) and said vaccinations were a routine part of regular health care appointments. They vaccinated their children to prevent disease, meet daycare requirements, and comply with social norms. However, nearly all had concerns about safety and efficacy, including the frequency of vaccines, side effects, safety of multiple vaccines given at once, vaccine ingredients, effectiveness, and necessity. African-American mothers were more likely to raise concerns about short-term side effects (e.g., fever), while Caucasian mothers were more likely to raise concerns about long-term side effects (e.g., autism or unknown complications). More Caucasian mothers than African-American mothers were aware of the option of alternative vaccination schedules.

Most mothers said they turned to their child's doctor for vaccine information, although many also cited the Internet and friends and family. Dr. Sheedy said mothers hoped to find consistent information from all three sources. They also wanted their health care providers to talk with them about what's known and unknown and to give recommendations. Caucasian mothers were more likely to request information from a physician, while African-American mothers were more likely to feel that nurses provided better information. Mothers often made their decisions about vaccination during pregnancy. Personal experiences of friends, family, or others had a significant impact on mothers' decisions. Dr. Sheedy said the focus group findings suggest that African-American and Caucasian mothers have different concerns and seek information in different ways.

In testing some potential new educational messages, including some that acknowledged the unknowns surrounding vaccination, CDC found that mothers reacted negatively to messages they felt were condescending and also to those they felt were too directive. At the same time, messages that were ambiguous or acknowledged uncertainty were alarming. All the mothers said the source of the information should be identified, because it affects the credibility.

CDC also interviewed family physicians and pediatricians in three cities. Few physicians were aware of the Hannah Poling decision and most felt the decision did not establish a link between vaccine and autism. They said the case had not been a significant factor in their discussions with parents, beliefs in vaccination, or changes in practice. Physicians said addressing vaccine safety issues is now a regular and growing part of their daily practice. They are frustrated by the persistence of the belief that the measles-mumps-rubella (MMR) vaccine is linked to autism and by the perception that CDC and AAP are not doing enough to address the issue. All the providers were strongly opposed to CDC publishing an alternative vaccine schedule because it would cause confusion and because they felt the current schedule allows for sufficient flexibility.

While children are still receiving vaccinations in physicians' office, vaccination is taking more time and becoming burdensome to some providers. Some family physicians are losing interest in providing vaccines. On the basis of these and other studies, Dr. Sheedy said, CDC is developing a provider toolkit with information for providers and parents as well as a media toolkit and updating its website.

***Organizational Perspective—Ms. Christy Phillips***

Ms. Phillips read a statement from the Pediatric Infectious Diseases Society, which established a Vaccine Advocacy Task Force in June 2008. The Task Force's efforts to improve communication strategies for

promoting immunization targets two audiences: misinformers (intentional and unintentional) and concerned parents.

For misinformers, communication must convey the value of well-designed, rigorous scientific research as the arbiter of truth and the only sound basis for progress in public health. Communicators must stand firm against the use of anecdotal evidence to inform policy; implausible hypotheses that do not warrant the expense of research funding; and misguided political, religious, or other agendas. Educators must reinforce the value of science over celebrity opinion and tabloid testimonials.

At the same time, communication must convey that science does not have all the answers, nor can it eliminate all threats, but that the health care community joins with parents in seeking the best care for children. Messages must position health care providers as aiding parents in getting information on which to base decision-making and sharing the goal of protecting children against serious diseases that can cause death or lifelong disability. Health care providers can provide parents with science-based sources of information that are not related to the government or vaccine manufacturers.

Ms. Phillips said her organization has responded to media coverage of vaccines, alerting editors and journalists about inaccuracies or commending them for balanced, informative coverage. It also refers media representatives to the National Network for Immunization Information's website for credible information about immunization. Also, the Society has joined AAP's Immunization Alliance, provided opinion on State and Federal legislation, and established a vaccine information clearinghouse on its website.

***Perceptions of a Practicing Pediatrician—Dr. Jon Almquist***

Dr. Almquist said he spends up to 25 percent of his time addressing parents' questions about the value of vaccines. The discussion generally takes about 5 minutes per visit, and for those who persistently refuse, the discussion may recur at every visit. Parents' concerns vary depending on media coverage, the type of vaccine, and the number of antigens in a given product—the latter being "bad news" for combination vaccines, said Dr. Almquist.

The ethical issues surrounding decision-making are a persistent concern for physician practices. Some practices prefer not to treat children of parents who refuse vaccines, while others feel they have an obligation to treat such children. Patients with disease pose a threat to other patients in the office who have immune deficiencies. Dr. Almquist described the extraordinary measures and expense required to mitigate concerns when his practice learned that a child with measles had been in the building.

Vaccine refusal poses administrative and logistic burdens as well. Billing forms now include 10 codes to document reasons for a parent's refusal of vaccine, and parents must be repeatedly counseled about alerting providers to the fact that their child is not vaccinated and therefore at risk. Office staff must be alert to symptoms of disease. While Healthcare Effectiveness Data and Information Set (HEDIS) measures include the number of children vaccinated as a quality measure, Dr. Almquist said it's not clear than any insurer is taking into account the new modifiers of that measure that document parent refusal when the insurers assess a provider's performance on immunization rates. Finally, Dr. Almquist was concerned that parents who did not trust their physicians on the need for vaccination also may not trust their physicians to help them make other decisions.

***Perspectives of a State Health Department Administrator—Dr. Guthrie Birkhead***

Dr. Birkhead said the two biggest complaints that the New York State Department of Health receives about vaccines are the time spent counseling parents and the cost of storing vaccine in the office. State legislators hear concerns about vaccine safety from their constituents. The State is developing a public

information campaign on the safety of vaccines. Dr. Birkhead felt that communication needs to be addressed at the State level.

***Discussion***

Committee members wondered what was driving the dramatic increases in exemptions in Washington State; Dr. Salmon said no specific external events or program changes could be linked to the increases. Dr. Almquist said that well-educated parents are inundated by media reports of possible risks related to vaccines. RADM Schuchat said CDC is using focus groups to better understand the different perspectives and motivations of parents who seek exemptions. Dr. Sheedy said the most common reason for concern reported was that a child suffered from side effects following a visit that involved multiple vaccinations. She said CDC is exploring new communications mechanisms that rely on social networking and peer-to-peer influence. For example, CDC sent information about influenza vaccines directly to highly visible bloggers who write about parenting issues.

Asked what messages work, Dr. Sheedy said the one consistently effective approach has been to educate parents that they have the power to protect their children against 14 vaccine-preventable diseases. Parents want to hear more about the benefits of vaccines, and they respond to narrative formats that convey personal experience in story form. Dr. Feinberg suggested NVAC focus more on how to communicate science-based information to parents without being condescending or inaccurate. Ms. Parnell said her organization is seeking funding to develop an audiovisual library of first-person vignettes about vaccine and disease that would be available for anyone to use.

COL Renata Engler called for more attention to side effects and adverse reactions and suggested the United States emulate the more positive European model of immunization. Dr. McCormick asked for more research on how vaccine safety concerns originate and spread. Dr. Salmon responded that CDC has refined the NIS parental concerns module in response to findings of its Risk Communication and Public Engagement Working Group.

Dr. Birkhead said parental confidence and hesitancy are big concerns for NVAC. Ms. Parnell said the public health community must listen to parents and acknowledge their opinions. RADM Schuchat said it is also important to address parents' concerns that vaccination programs are motivated more by profit-oriented manufacturers than by children's health. NVAC members reviewed a letter submitted by AAP on behalf of the Immunization Alliance that calls for more action by HHS in response to media coverage about vaccine safety.

***Action Items***

NVAC will communicate to the Assistant Secretary for Health that HHS should increase support for the CDC's efforts to evaluate public perceptions and to inform the public about the safety of vaccines. NVAC will suggest that the Federal Immunization Safety Task Force address the issue of public perception and communication.

NVAC will seek more information about what government and professional organizations are already doing to address public concerns about vaccine safety through the work of the Vaccine Safety Working Group.

## Vaccine Safety

### *Federal Immunization Safety Task Force—Dr. Bruce Gellin*

Dr. Gellin said the Task Force, which transcends HHS, is looking at scientific and programmatic components of the National Vaccine Plan, communication among governments, and public engagement. A draft of the plan may be available for NVAC to review by late October.

### *Discussion*

Ellyn Ogden of U.S. Agency for International Development (USAID) said her organization would like to engage with the Task Force to facilitate communication with developing countries about dispelling myths and rumors that pose barriers to vaccination. Dr. Gellin said that ADM Garcia believes a decay in trust in vaccination could have global effects.

### *Vaccine Safety Working Group Update—Dr. Andrew Pavia*

Dr. Pavia reiterated the charge of the Working Group and recognized the members and staff of the group. The group categorized the research agenda of the CDC's Immunization Safety Office (ISO) into four research topics (specific questions, vaccines and vaccination practices, special populations, and clinical outcomes) and seven areas of clinical guidance capacity (e.g., infrastructure of existing surveillance systems, laboratory methods, and clinical practice guidance). The Working Group has created four subgroups, each of which will address one research topic and two capacity areas.

Themes emerging from Working Group discussions so far include resources, funding, and capacity; the involvement of other Federal partners; the need for research on risk perception and communication; and the disconnect between scientific findings and persistent public concerns. Dr. Pavia said the group raised the following questions, among others:

- What's the perceived significance of singling out a particular product or vaccine component on the research agenda?
- What's the value of further study of the effects of thimerosal?
- What outcomes should be considered in genomic studies?
- Are there shared risk factors between common acute reactions and severe adverse effects?
- Would a retrospective assessment of previous vaccine safety controversies uncover signals and provide insight into effective approaches that could be applied to the research agenda?

Members of the Working Group's subgroup on public engagement are participating in HHS efforts to maximize the public engagement process.

### *Public Engagement—Mr. Ed Moreno*

Mr. Moreno outlined the experience of the Keystone Center, which has contracted with the Association of State and Territorial Health Officials (ASTHO) to increase understanding of the ISO's scientific agenda and to solicit public input for consideration in the research agenda. Meetings with stakeholders and the public are tentatively set to begin in early November. A final report of findings will be presented to NVAC in February 2009.

Among the challenges the Keystone Center hopes to address is whether the timing of public engagement efforts is sufficient to affect the research agenda and how to organize and present public input in a relevant, helpful way. NVAC members will be asked to assist in identifying stakeholders.

***Discussion***

Dr. Pavia said the Working Group felt it was important to get a better understanding of the public's values, priorities, and concerns related to vaccine research. The group also hopes to assess the capacity of surveillance tools such as the Vaccine Adverse Event Reporting System and Vaccine Safety Datalink.

**Adult Immunization Working Group Update—Dr. Richard Clover**

Dr. Clover presented the mission statement of the new 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 improved vaccination uptake in adults in these programs. In its first three meetings, the Working Group reviewed four HHS adult immunization programs and identified the following issues:

- CDC: More information is needed about vaccine coverage assessment and use of IIS.
- Indian Health Service: The program provides some success stories of adult immunization in a decentralized model but does not offer human papillomavirus (HPV) or zoster vaccines.
- Health Resources and Services Administration (HRSA): The program has limited ability to assess coverage or improvements among Federally qualified health centers, but its sentinel survey might be modified to improve assessment.
- Medicaid: CMS is in the process of reviewing vaccines covered by State programs.

The group plans to review programs offered by Medicare and the Agency for Healthcare Research and Quality (AHRQ), follow-up on CDC programs and their use of IIS, and partner with VFWG.

***Discussion***

Dr. Birkhead agreed with NVAC members that DoD and VA should be represented on the Working Group [Note: COL Engler had already agreed to be the DoD representative for this Working Group].

> ***Action Item***
>
> Dr. Valdiserri offered to identify a VA representative to participate in the Working Group.

**American Medical Association's (AMA's) Adult Vaccine Financing Report—Dr. L. J. Tan, Dr. Sandra Fryhofer**

Dr. Tan described the makeup and functions of AMA's Council of Science and Public Health, which identified four basic barriers to adult immunization:

- Undervaluation of immunization
- Inadequate infrastructure
- Limited public-private collaboration
- Unsatisfactory payment for vaccine procurement and administration

Dr. Tan asked for NVAC input on the Council's proposed recommendations, which include exploring mechanisms for financial relief for providers (e.g., deferred payment plans, buyback of unused inventory, and patient assistance programs), encouraging vaccination at novel points of contact (e.g., visitors to long-term care facilities), and developing Current Procedural Terminology (CPT) codes for counseling so providers can be paid for their time when they refer patients to other sites for vaccination. The Council calls for increased Federal resources to support adult immunization, optimization of existing resources, and stronger State support, in particular, increasing the Medicaid payment rate and maximum rates for vaccine administration.

The Council suggests that insurers assist purchasers in improving the efficiency of vaccine management, provide first-dollar coverage for vaccines, and improve accountability through performance measures. Insurers should also offer incentives to providers to offer vaccines. Manufacturers should work to ensure market stability and improve outreach to providers. The Council's final recommendations will be sent to the AMA's House of Delegates in November.

Dr. Fryhofer, an internist and member of the AMA Council, said AMA is developing communications materials for providers to encourage adult and adolescent vaccination as well as tools to assist providers with coding questions.

***Discussion***

Dr. Birkhead said NVAC could not offer formal recommendations in the timeframe requested but suggested AMA refer to the VFWG recommendations approved by NVAC. NVAC members are free to offer their opinions as private citizens but their comments will not represent the consensus opinion of NVAC.

Dr. Lovell said vaccine buyback and payment for counseling are crucial components of adult immunization from the provider's perspective. Dr. Valdiserri raised concerns about disparities in health care for minorities and suggested the HHS Office of Minority Health be included in discussions of vaccine availability and financing. Dr. Tan said AMA is also seeking input from specialty medical societies.

**IIS—Dr. Alan Hinman**

Dr. Hinman presented for NVAC approval the finalized recommendations from the February 2008 meeting Enhancing Participation in Immunization Information Systems (see below). He reiterated the summary of the recommendations that he provided at the June 2008 NVAC meeting.

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*Policy/Regulatory Approaches*

- IIS participation is a public health imperative. All people and all providers should participate.
- Immunizations should be reportable events across the lifespan. Records in IIS should be stored in perpetuity.
- Access to IIS information should be available to community partners (e.g., schools, Women Infant Children [WIC] programs, daycare settings) and health plans. To support IIS interstate data sharing:
    - Explore the feasibility of using the National Association for Public Health Statistics and Information Systems (NAPHSIS) interstate transfer standard agreement model for IIS interstate data exchange for both IIS and individual providers.
    - Explore the feasibility of federal legislation similar to that covering cancer registry reporting to allow state-to-state data exchange for IIS and providers
    - Until national solutions can be developed, states should consider passing legislation which ensures the timely, secure interstate exchange of immunization information. One example of a model statute exists at http://www.ecbt.org/registries/modelinterstate.cfm.

- Assure IIS are interoperable with electronic health record (EHR) systems
- Reinterpret the Family Educational Rights and Privacy Act to remove barriers to sharing information between schools and IIS.

*Provider Incentives*

Four broad categories of provider incentives were identified to increase participation in IIS:

- Monetary - possible approaches are:
  - Provide periodic rewards for achievement (e.g., for each fully immunized child documented in IIS).
  - Include the cost of entering the data into the registry in the reimbursement for administering vaccine.
  - Work with the Centers for Medicare and Medicaid Services (CMS) and state Medicaid directors to increase state Medicaid reimbursement for vaccine administration to the maximum allowable level.

- Workflow Efficiency/Medical Decision Making
  - Provide technical support to medical offices to integrate IIS use into office work patterns
  - Use IIS forecasting ability to replace having to look up complicated immunization schedules.
  - Include vaccine inventory management in IIS
  - IIS should be integrated with other preventive health services information systems
  - Remove legal and policy barriers to allow bi-directional sharing of data between schools and other appropriate stakeholders.

- Education
  - Quality Improvement:
    - Feed data being collected currently back to physicians to show them the value of participating in the registry.
    - Develop continuing education materials on the use of IIS (working with manufacturers/vendors/specialty professional organizations).
  - Incorporate IIS topics in certification and re-certification processes.

- Technology
  - Provide real-time exchange of information with medical providers.
  - Assure IIS allow bulk data import and return data to medical providers (bi-directional) using HL7 format by 2010
  - Promote common standards usage with HL7 format.

*Financial Support*

- A dedicated sustainable permanent federal funding source for Immunization Information Systems is essential. At the present time, there are two vehicles for doing that, VFC operational funding and the 317 program. VFC and 317 programmatic funds should be increased to provide more support.
- Assure other federal funding programs that support activities that relate to IIS (e.g., WIC, pandemic influenza, bio-preparedness) are more than just permissive. These programs should encourage the use of their funding to support the IIS infrastructure.
- Explore other potential sources, such as
  - federal funding for health information technology initiatives in which registries are an important component
  - a new per-dose excise tax on vaccines

***Discussion***

Dr. Hinman said 43 States have some kind of registry of vaccinations; about half of all States have vaccination registries that providers consider useful. Most State registries include adults but the level of detail varies greatly. State registries tend to underestimate coverage. The recommendations do not address death/termination of adult records. Dr. Lovell moved to accept the recommendations, and the motion passed unanimously with no abstentions.

> ***Recommendation***
>
> NVAC endorses the recommendations described in the document, "Enhancing Participation in Immunization Information Systems."

**National Vaccine Plan and the Institute of Medicine (IOM)—CAPT Ray Strikas**

CAPT Strikas said the goals of the updated National Vaccine Plan would include the need to achieve better global use of existing vaccines to prevent disease, disability, and death around the world. The IOM Committee on Review of Priorities in the National Vaccine Plan is soliciting input on its proposed recommendations. The final IOM report with recommendations for the National Vaccine Plan is expected in late 2009. Proposed recommendations address the following:

- Who should partner with NVPO in implementing the plan
- How stakeholders can be motivated to implement the plan's objectives
- Rationale for inclusion and exclusion of plan components
- Mechanisms to address and incorporate emerging issues
- Framework for communicating risks and benefits of vaccination
- Research on vaccine supply problems

An HHS Steering Committee that includes NVPO, CDC, Food and Drug Administration (FDA), National Institutes of Health (NIH), and HRSA representatives is working with the DoD, VA, and USAID to outline priorities and goals, which it will provide to IOM by December 2008. Public engagement meetings are planned for early 2009.

NVPO conducted phone interviews with NVAC members and identified a number of issues that are not explicitly addressed in the draft National Vaccine Plan. They include concerns about vaccine safety communication, global vaccine supply, plan accountability/milestones, rapid vaccine coverage assessment and use of IIS, and infrastructure for adult vaccination.

HHS has contracted with the Rand Corporation to develop a framework that maps existing policies, identifies gaps, and incorporates priorities into planning. The Rand study will identify the policy areas most in need of further analysis and development. Current analyses by NVPO underscore the complexity of the national vaccine system and the number of stakeholders involved, all of whom interface with the system at multiple points. CAPT Strikas asked for NVAC's advice on how to involve all the stakeholders and gather their input on the IOM's process.

***Discussion***

Dr. Gellin emphasized that Federal agencies have identified their priorities but stakeholder input is needed to develop a truly national plan. Lengthy discussion ensued about the ideal meeting format in which NVAC could gather stakeholder input. No consensus was reached.

## Day 2—September 17, 2008

### Agency, Department, Advisory Committee, and Liaison Reports

***NVPO—Dr. Bruce Gellin***

The office is focusing its efforts on vaccine safety this year, directing funds allocated to address unmet needs toward safety initiatives.

***National Center for Immunization and Respiratory Diseases—RADM Anne Schuchat***

The incidence of measles is rising, but rotavirus is decreasing. Recently released NIS data on toddlers show that the coverage gap for vaccination among those in poverty is narrowing. CDC is preparing to release data on influenza vaccination coverage for young children and teenagers. RADM Schuchat said CDC surveys now include modules on vaccine acceptance and socioeconomic factors that she hopes will be included annually.

***ACIP—Dr. Dale Morse***

A record number of new vaccines were approved in the past two years, and ACIP is focusing its efforts this year on fine-tuning existing recommendations. The group updated its existing guidelines on anthrax and pneumococcal vaccines. Pending FDA approval, it will consider extending HPV vaccine guidelines to women over 26 years old; also pending FDA approval of a new inactivated Japanese Encepthalitis (JE) vaccine, ACIP will consider revised recommendations for the use of JE vaccines for US travelers [last updated in 1993].

ACIP is addressing safety concerns surrounding the combined MMR-varicella, HPV, and meningococcal vaccines. It is also looking at rabies vaccine supply issues, updated influenza season recommendations, and combined tetanus-diphtheria-pertussis vaccines for adults. The decline in rotavirus represents a tremendous success story, Dr. Morse said. For example, New York has seen an 80-percent reduction in cases of rotavirus in hospitals in 2008 when compared to the previous three years.

***HRSA/Vaccine Injury Compensation Program (VICP)—Dr. Geoffrey Evans***

Dr. Evans said the number of non-autism claims is split evenly between those related to vaccination in children and adults. The influenza vaccine was added to the program in 2005, leading to a surge of claims 2 years later when the filing deadline passed for claims dating back 8 years from the effective date of vaccine coverage. Many of the nearly 200 claims filed during that time have been adjudicated. Regarding the Omnibus Autism Proceeding, the program has over 5,000 autism claims pending. The results of hearings on three test cases on the combined theory (MMR vaccine and thimerosal-containing vaccines) that took place in 2007 are expected this year.

***Advisory Commission on Childhood Vaccines (ACCV)—Ms. Tamara Tempfer***

Ms. Tempfer reminded Committee members that the ACCV is comprised of physicians, attorneys, and the general public, two of whom must be parents of children injured by a vaccine. The Commission has been following progress of a petitioners' evaluation survey, the preliminary results of which are to be presented at the next ACCV meeting in November. The Commission is also interested in increasing program outreach activities so that the public is more aware of the VICP.

***FDA—Dr. Norman Baylor***

Dr. Baylor said FDA approved a number of new vaccines and expanded the indications for some others; more vaccines are in the pipeline. Implementation of the FDA Amendments Act involves fine-tuning the Pediatric Research Equity Act, which would require post-market surveillance. FDA is focusing on developing guidance documents to explain how the FDA Amendments Act affects the regulatory process.

One concept under discussion is development of a voucher for priority review of future products that would be granted to manufacturers as an incentive to produce vaccines for smaller markets or foreign markets.

Dr. Baylor said FDA has a pathway for approval of a vaccine for a pandemic disease, and one such vaccine is already included in the Strategic National Stockpile (SNS). The agency is debating the challenges of pandemic vaccines, such as the risks and benefits of testing a pandemic vaccine in pediatric populations when there is no threat of disease. It is planning a meeting in 2008 to discuss safety of adjuvants and the possibility of using adjuvants in more than one vaccine.

> ***Action Item***
>
> NVPO staff will update NVAC on FDA's voucher incentive program as more details become available.

***Vaccines and Related Biological Products Advisory Committee (VRBPAC)—Dr. John Modlin***

At its September meeting, VRBPAC will undertake the first review of intramural research sponsored by the Office of Vaccines Research and Review (OVRR). It will also review the response of the Center for Biologics Evaluation and Research to the OVRR Office Site Visit Review Report that was presented and approved by VRBPAC in 2007. The Committee will discuss the use of Madin-Darby canine kidney cells (MDCK) for manufacture of live attenuated influenza virus vaccines. Dr. Modlin said the canine cell line has not yet been used for vaccines but if it were approved, would speed up the manufacturing process by circumventing the need for chickens and eggs.

***NIH—Dr. George Curlin***

In late August, the National Institute of Allergy and Infectious Diseases (NIAID) and CDC together published two program announcements to fund research on vaccine safety, and well-established academic centers have already begun responding. The designation "program announcement" means that no money is specifically set aside for the grants but rather will come from a large pool of research funding. Grants will be reviewed by NIH experts in corresponding fields. Dr. Curlin added that NIH's budget line for funding research has been flat for the past few years, and increasing the budget could spur more vaccine research.

***CMS—Dr. Jeffrey Kelman***

CMS will emphasize the importance of pneumococcal vaccine as it promotes the influenza vaccine. Medicare Part D now includes a vaccine administration payment for providers. Also, CMS will now pay for dispensing and administering vaccines that are covered under Medicare Part B (either preventive or post-exposure administration) and Part D (for preventive administration only). Dr. Kelman said CMS gathers data on nearly everything it does but complicated regulations govern how information can be shared.

> ***Action Item***
>
> NVPO staff will explore mechanisms for tracking CMS's proposed regulatory changes related to vaccine administration and ways to work better with CMS. NVPO will also determine how to obtain data from CMS programs that can be shared with NVAC.

***DoD—COL Renata Engler***

COL Engler referred to a written report distributed to NVAC members on the status of the Immunization Vaccine Program as of August 31. She said that DoD instituted minimum quality standards for vaccination in nontraditional settings. She suggested NVAC review the military's vaccine programs,

which include several health surveillance mechanisms, pointing out that the military has the largest population from which to draw post-licensure data required by FDA. COL Engler called for more integration, suggesting that DoD, VA, and others become more engaged with efforts such as CDC's Clinical Immunization Safety Assessment Network.

***VA—Dr. Ronald Valdiserri***

In Dr. Valdiserri's absence, NVAC reviewed the written report from Dr. Valdiserri outlining the goals of increasing the number of VA employees and patients who receive influenza vaccination. Also, VA updated a directive, reiterating its policy to provide care for reservists and National Guard members who develop reactions to smallpox vaccine and are unable to access a military treatment facility in their own geographic area.

***USAID—Mr. Neal Brandes***

Mr. Brandes noted that USAID has been contributing its insight to help develop the National Vaccine Plan. He thanked NVAC for hosting a presentation by Mark Steinhoff, M.D., and asked that members reflect on the links between international and domestic efforts.

***AHIP—Dr. Wayne Rawlins***

At an AHIP meeting in July, representatives of member insurance plans and several medical societies discussed vaccine coverage. Dr. Rawlins said AHIP hopes to present NVAC with the results of its survey of members' vaccine coverage practices in 2009. Also, AHIP is identifying those plans that have scored high on HEDIS vaccine measures. It is also developing an education program for employers that promotes vaccine coverage.

***Public Health Agency of Canada—Dr. Lisa Belzak***

Dr. Belzak said the Public Health Agency is evaluating its national immunization strategy. The agency is also determining how to report annually on progress and impact. In late November, the annual Canadian Immunization Conference will be structured around core competencies on immunization that are being developed in conjunction with professional associations. Dr. Belzak also reported on the status of some specific vaccination supply issues.

> ***Action Item***
>
> Dr. Belzak will provide NVAC the results of the Public Health Agency of Canada's evaluation of its national immunization strategy when available.

**Hospital Acquired Infections (HAIs) Task Force**

***Overview—Dr. Donald Wright***

Dr. Wright noted that HHS recently launched an initiative to encourage more health care workers to get the seasonal influenza vaccine. This year, HHS is also focusing efforts on increasing influenza vaccination uptake rates at long-term care facilities and among HHS employees.

Dr. Wright described HHS' initiative to address HAIs, which affect 5–10 percent of all hospitalized people every year in the United States and add nearly $20 billion to overall health care costs annually. About 99,000 deaths in the United States every year are associated with HAIs. HHS is focusing its attention on the top four HAIs: urinary tract infections (UTIs), surgical site infections, bloodstream infections, and pneumonia.

Looking at this issue, the Government Accountability Office (GAO) called for better coordination of HHS programs to track and prevent HAIs. GAO pointed out the need to prioritize the vast number of

recommended clinical practices related to HAIs. Because a significant percentage of health care facilities are accredited through CMS bodies, HHS has an opportunity to strengthen accreditation requirements to improve infection control among those facilities. Dr. Wright added that common definitions for HAIs and consistent measurement approaches are needed to improve data collection and facilitate a national survey of HAIs that can be used to track progress.

HHS convened a Steering Committee on HAIs to identify immediate priorities for hospitals. The group involves public health entities within and outside HHS and will also set longer-term goals for addressing other HAIs in other settings. The Steering Committee will seek opportunities to collaborate with external stakeholders and gather public input as it develops an HHS plan that may eventually evolve into a national plan for reducing HAIs. The immediate priorities for hospitals include the top four HAIs related to procedure areas associated with infection and *Clostridium difficile*.

The Steering Committee established five working groups, each with its own lead agency:

- The Prevention and Implementation Working Group, led by CDC, will partner with the Healthcare Infection Control Practices Advisory Committee to prioritize the best recommended clinical practices, identify the top 10 recommended guidelines, review best practices, and suggest strategies for implementing guidelines into care.
- The Research Working Group, led by AHRQ, will identify knowledge and research gaps, prioritizing research needs accordingly and coordinating the research agenda to strengthen science around prevention of HAIs. It will also develop and test use of technology to prevent HAIs.
- The Incentive and Oversight Working Group, led by CMS, will explore adding specific infection control practices to the Medicare and Medicaid Conditions of Participation and seek opportunities to partner with the Joint Commission and other accrediting bodies to bolster compliance with infection control practices. Financial and nonfinancial incentives for improving compliance will also be considered. CMS has already established a program to deny payment for certain hospital-acquired conditions. In keeping with the Secretary's goal of increasing transparency, this Working Group may consider making individual hospitals' HAI rates public. (Presently, 26 States require hospitals to report HAIs, and two States publish those rates.)
- The Information Systems and Technology Working Group, led by CDC and the Office of the National Coordinator for Health Information Technology, will address standardizing the definitions and measurement of HAIs as well as mechanisms for sharing data across existing surveillance systems. Since the GAO report, more hospitals are using the CDC's National Healthcare Safety Network to meet their States' infection reporting requirements, Dr. Wright added.
- The Outreach and Messaging Working Group, lead by the Office of Public Health and Science, will determine how best to communicate with all stakeholders, including consumers, about reducing HAIs. It will explore how to link HAI rates to the Secretary's Value-Driven Healthcare initiative.

Dr. Wright concluded that NVAC can assist in the HAI initiative by encouraging health care workers to get vaccinations for seasonal influenza and other occupational hazards. About 42 percent of health care workers get influenza vaccines now [per 2006 CDC data; 2007 data show an increase of 3 percent, for a total of 45 percent), putting the Healthy People 2010 goal of 60 percent out of reach. Dr. Wright called for NVAC's aid in improving the science for vaccine development related to the top HAIs, particularly *Staphylococcus aureus*, methicillin-resistant *S. aureus*, and *C. difficile*. He hoped NVAC would give input on the Steering Committee's initial action plan, projected to go out in mid-October.

***Potential Vaccine Candidates—Dr. Barbara Mulach***

Dr. Mulach gave an overview of research underway or recently completed within HHS on prevention and treatment of HAIs, summarizing efforts that focused on *S. aureus*. To better understand antimicrobial resistance to treatment, NIAID is funding research on both off-patent and optimal use of antimicrobials. It is reviewing proposals for a 2009 initiative to fund research on reducing the risk of antimicrobial resistance, particularly through improved treatment of infectious diseases. For 2010, NIAID is proposing to fund research specifically on antimicrobial resistance in treatment of pneumonia, otitis media, UTI, and bacteremia. Also for 2010, NIAID is proposing an initiative of partnerships between academia and industry to develop vaccines against high-priority pathogens. Dr. Mulach asked for input on how best to structure the partnership initiative to get high-quality proposals and focused research.

***Discussion***

Dr. Modlin questioned the need to pursue vaccines for conditions for which effective prevention techniques (e.g., handwashing) already exist. If safe and effective vaccines against *S. aureus* and *C. difficile* were available, he wondered, how would they be used? He urged NIAID to consider such issues before vaccines are developed. Dr. Mulach agreed, noting that the partnership initiative requires participants to identify target populations or otherwise make the case for the vaccine and to detail how it would be used in practice. She added that multiple strategies are needed to address infectious diseases, and vaccines are just one part; better diagnostic tools are also needed. Dr. Modlin said that thanks to the Joint Commission requirements, his institution improved handwashing rates dramatically and has seen fewer nosocomial infections as a result.

> ***Action Item***
>
> At Dr. Birkhead's request, Dr. Mulach agreed to seek details on NIAID's process of assessing the feasibility and status of research to determine what appears promising for vaccine development.

Dr. Fergie emphasized the need for pediatric-specific guidelines. He supported the concept of publicly posting hospitals' infection rates but said the public needs careful, considered explanation of what the rates mean. In terms of incentives, he raised concerns about hospitals attempting to game the system by claiming patients had infections before they arrived at the hospital. He also asked that the research agenda include peripartum antibiotics.

Dr. Wright noted that he would like more consumers to monitor the care they received. RADM Schuchat said surveys offer an opportunity for consumers to point out that a health care provider did not wash his/her hands.

Mr. Hosbach, referring to his role as chair of a hospital quality improvement committee, stated that he expects to see his hospital conduct more screening and cultures to protect against losing any Medicare payments related to HAIs, which means health care costs to consumers will rise.

> ***Action Item***
>
> At the request of Dr. Nevin-Woods, Dr. Wright agreed to ask the HAI Working Groups for more guidance on how NVAC can encourage health care workers to get seasonal influenza vaccinations.

## Vaccine Supply

***Overview—Dr. Lance Rodewald***

Dr. Rodewald summarized the statutory charge to the CDC to stockpile a six-month supply of pediatric vaccines for emergencies. Funding for such stockpiling was low until it was enhanced through VFC. As a

result, VFC funds are supporting private-sector vaccine manufacturers. Currently, CDC relies on manufacturers to store and rotate stock of most vaccines, distributing them to States as needed. Most vaccines have a shelf life of about six months (after distribution to end users). Most influenza vaccine purchased for the stockpile goes unused; some is used late in the influenza season, and some is donated to South America.

Limited throughput—i.e., the number of doses that can be administered per day—affects what vaccines the Federal system can use and the size of the stockpile. Maintaining an adequate level of throughput requires more than the six-month supply of vaccine mandated by statute. Further, no funding is set aside for outbreaks. Because manufacturers store and rotate the vaccine stockpiles, CDC's ability to build up the stockpile is limited. The stockpile also can be affected by manufacturer supply disruptions. Dr. Rodewald pointed out that the stockpile played almost no role in the management of vaccine shortages in 2000 and 2001.

Following those shortages, GAO recommended revising the strategy for stockpiling pediatric vaccines, and NVAC recommended increased funding for stockpiling as well as improved planning and management. As a result, CDC received substantial funding for the stockpile. Build-up efforts face some logistic challenges. CDC can now act as a distributor for most pediatric and adolescent vaccines, with some ability to adjust supply. CDC's contract with manufacturers addresses storage and rotation, and CDC is pilot testing its ability to manage a stockpile.

Stockpiling poses some unique challenges, such as the financial risk associated with storage. CDC would like to be able to adjust stockpile amounts without affecting manufacturers' market share. No policy addresses how to deal with outmoded vaccines. No strategy has been devised for vaccines with small throughput (e.g., most adult vaccines), vanishing throughput (e.g., polio vaccine), or no CDC throughput (e.g., travel vaccines, rabies vaccine).

Dr. Rodewald suggested NVAC consider the following issues:

- Stockpiling as a preparedness asset
- Rescoping of current stockpile (non-VFC vaccines and those with small or no throughput)
- Balancing cost, financial risk, and scope (storage, disposition, assumption of risk)
- Need for polio vaccine stockpile in case of emergency
- Quantitative rescoping and sequencing of VFC stockpile in anticipation of resuming build-up

***Discussion***

Dr. Gellin clarified that the CDC's vaccine stockpile is distinct from the SNS. Dr. Rodewald added that his staff is meeting with people involved in CDC preparedness efforts to discuss including other vaccines in the CDC stockpile. It is not clear how CDC would add smallpox vaccine to its stockpile; it is included in the SNS but not VFC. Dr. Rodewald said CDC cannot sell leftover vaccine to other countries.

***Vaccine Stockpile: Computer Model—Dr. Gregory Wallace***

Dr. Wallace provided a snapshot of the contents of VFC's current pediatric vaccine stockpile, which shows some progress in building the stockpile and some gaps as well. He explained the methodology for establishing targets for the stockpile, which is based on a birth cohort of about 4 million. The methodology is imperfect, though, because it does not account for the public health impact or cost of a given disease, the real demand for vaccine, or public health priorities. Further, it does not always reflect a six-month need and only looks at the number of doses to complete a series within one year. The number of recommended doses in a series may vary by manufacturer. The model also fails to consider catch-up doses and the possibility of double-counting with combination vaccines.

For these reasons, a CDC work group is developing a model for evaluating potential financial and health impacts of stockpile targets. Ideally, the model will be transparent yet still allow investigators to change and update the inputs and assumptions of the model. The model would also accommodate policy decisions to cover the worst case scenario for any vaccine.

The work group's near-term recommendations will be presented to the Office of Management and Budget (OMB) by December. Feedback is welcome. Dr. Wallace emphasized that the new model can be updated periodically. He walked through the steps to determine stockpile targets under the proposed new model. For example, instead of using only census data on birth cohorts, the model would also account for demand. The model can be used to depict the probability of vaccine shortages in various scenarios. Inputs would include specific, real-world information, such as the incidence of disease, morbidity, and mortality among those not vaccinated, which yields information on potential health consequences (of vaccine shortages), for example.

The model would also provide more accurate information on the costs of replenishing vaccines in the stockpile that are used as well as those that expire. Dr. Wallace said the model may contribute to a better understanding of how to ramp up quickly and how to handle new vaccines and changing markets. He asked for input from NVAC members on whether the assumptions described for the model seem to be appropriate from the perspective of experts in the field.

***Discussion***

Dr. Wallace clarified that CDC uses the model to determine the annual budget required for VFC, then proposes that budget to OMB. Dr. Rodewald added that prices are locked in on the basis of CDC contracts. Dr. Wallace described some costs not included in the model.

> ***Action Item***
>
> Drs. Birkhead and Gellin will discuss how NVAC can weigh in on the current modeling by the end of September and consider a long-term strategy to enable NVAC to provide input on the VFC stockpile modeling software over time.

***Rabies Vaccine Supply Issues—Dr. Charles Rupprecht***

Dr. Rupprecht noted that cases of animal rabies increased last year and he believes rates will continue to rise, but it is very difficult to estimate the number of cases that might occur or to plan for shortages of rabies vaccine. The current supply is very limited but does not meet HHS's definition of a shortage. In March 2008, HHS established an Ad Hoc Working Group on rabies to draft interim guidelines in case of a forecasted shortage of vaccine for prophylaxis. At present, Sanofi Pasteur is the only manufacturer producing the vaccine; Novartis plans to have vaccine available in October.

No known cases of human rabies have occurred in 2008. A shortage, according to HHS, would be insufficient supply of rabies vaccine to meet demand for post-exposure prophylaxis. The current supply is inadequate to meet the pre-exposure needs of those at risk, such as first responders. HHS would undertake interim actions if evidence suggested that the amount of vaccine available for post-exposure prophylaxis in humans outstripped the estimated need.

The Ad Hoc Working Group is focusing first on communication of current messages about the use of rabies vaccine. It is also looking at mitigation efforts (specifically diagnosis and animal control), risk assessment during times of limited supply, health and economic implications, and products still in the investigation stage. For each of these areas, the group has proposed some general guidelines.

The use of passcodes has been contentious, but it ensures that local health care providers consult with knowledgeable public health officials about the risk of the disease and the need for post-exposure prophylaxis. More outreach and education is needed for key health care providers that reinforces basic rabies prevention principles. For example, it is reasonable to await the results of diagnostic tests before giving the vaccine. More attention should be given to determining whether exposure is likely to have occurred, and interim guidelines would offer a risk-stratified approach to use of the vaccine.

Dr. Rupprecht said an intradermal vaccine is under investigation. Alternative schedules and routes of administration should be considered. ACIP is reconsidering its recommendations on the number of doses needed.

Current supplies of rabies vaccine will be reserved for post-exposure prophylaxis; when more vaccine is available, first responders and those at highest risk for exposure will have priority for pre-exposure vaccination. In case of a shortage, the Ad Hoc Working Group believes that international travel would be a lower priority for pre-exposure vaccine than post-exposure prophylaxis.

The economic implications of alternative strategies for limiting the use of rabies vaccine supply are unclear because precise estimates of the risk of transmission of rabies do not exist. For cases in which the risk of transmission of rabies to a human is not certain, estimates of the cost-effectiveness of post-exposure prophylaxis vary dramatically. There do not appear to be supply limitations of rabies immune globulin at this time, but market changes in plasma collection could affect supply beyond 2009.

A stockpile of 100,000 doses of human rabies vaccine would provide a sufficient buffer in the event of a shortage, allowing a three-month window for public health officials to assess their supply and management options. The Ad Hoc Working Group's draft guidelines for a forecast shortage will be reviewed by CDC and ACIP. Dr. Rupprecht asked for input from NVAC on the guidelines.

***Discussion***

Dr. Birkhead asked whether the current shortage was avoidable, given that one manufacturer shut down for a scheduled renovation while the other had to address a manufacturing problem. Phil Hosbach of Sanofi Pasteur said his company discussed the need to close for renovation with FDA in advance and had stockpiled what it thought was enough vaccine for over two years. However, with the production delays at Novartis, most of that supply will be gone before Sanofi Pasteur restarts production. Dr. Baylor said FDA routinely talks with manufacturers about such plans and projections. Marguerite Baxter of Novartis said an unexpected confluence of events led to both manufacturers having production problems at the same time.

Dr. Birkhead pointed out that the limited supply has resulted in "chaos" at the State level and hoped lessons could be learned to prevent future problems. Dr. Nevin-Woods favored requiring consultation with a knowledgeable public health official; she believes people at low risk are being over treated.

**Influenza: Topical Issues**

***2008–2009 Season—Dr. Jeanne Santoli***

Dr. Santoli reported that the primary changes to the ACIP recommendations for influenza vaccination for 2008–2009 are 1) all children 5–18 years old should get influenza vaccination annually and 2) for healthy people 2–49 years old, either trivalent, inactivated or live, attenuated influenza vaccine can be used, and children from 6 months old to 8 years old should receive two doses of vaccine if they have not been vaccinated previously (doses separated by four or more weeks). In 2008–2009, the influenza vaccine recommendations apply to 261,500,000 people in the United States, or 85 percent of the population—30

million more than last year and 100 million more than 2000–2001. The vaccine supply includes 11 different products and a total projected capacity of approximately 143–146 million doses.

About 20 million vaccine doses available for 2008–2009 do not contain thimerosal or preservatives. Dr. Santoli said manufacturers are responding to the public's concern about the safety of these additives in vaccines for children.

In response to the vaccine shortages of 2004–2005, CDC worked with manufacturers and distributors to create the CDC FluFinder program [access is limited to registered health department officials]. FluFinder provides information on vaccine distribution to designated State and local health officials and is updated weekly.

***Discussion***

Dr. Santoli said all the influenza vaccine manufacturers now make one product with either reduced or no thimerosal, but she could not project when a significant increase of such products would be available. Marie Mazur, Pharm.D., of CSL Biotherapies said her company has not used thimerosal in its products for the global market for six years; it is committed to serving the U.S. market and plans to bring 40 million doses of influenza vaccine to the United States. An unidentified member of the audience noted that six States have laws regarding the use of vaccines with thimerosal, but the ages targeted and the restrictions vary by State.

Charlotte Kroft of GlaxoSmithKline said her company is also producing thimerosal-free vaccine, but moving from multi-vial to single-vial products affects production timelines. Dr. Baylor noted that multi-dose vials are required to have preservatives; he added that investigators are looking into multi-dose vials without preservatives, which, if effective and safe, would make the requirement unnecessary.

> ***Action Item***
>
> Dr. Baylor will keep NVAC informed of efforts to develop multi-dose vials of influenza vaccine without preservatives.

***CDC's 2008–2009 Promotional Campaigns—Dr. Kris Sheedy***

In developing communication strategies for the upcoming influenza season, Dr. Sheedy and her colleagues at CDC applied the health belief model that has been used since the 1950s. It posits that for people to take action (in this case, get a seasonal influenza vaccination), they must perceive the threat of influenza and the benefit of vaccination, then overcome barriers to vaccination and act.

Among the key communication challenges CDC faces is that the perceived threat may be minimal. Moreover, public health officials have presented changing and seemingly conflicting messages about who is at risk and who should be vaccinated when. Most people are aware of the serious health consequences of influenza, but few feel personally concerned about illness. Some feel that profit motives—not real risk of disease—are driving the expansion of vaccine recommendations. Dr. Sheedy said the number-one reason cited for not getting an influenza vaccination was the belief, "I don't think I need it." Sheedy said communication efforts should educate the public about the costs of influenza, such as the risk of spreading influenza to those around you, some of whom may be at high risk, and the cost of missing school or work.

To address these challenges, CDC has partnered with organizations like Families Fighting Flu [www.familiesfightingflu.org] to provide media with human interest stories that convey the importance of vaccination. A DVD, "Why Flu Vaccination Matters," that features members of Families Fighting Flu

telling their own stories, will be released soon. Dr. Sheedy said the narratives may help make the need for vaccination more personally relevant.

In terms of perceived benefit, communication is hampered by the belief that the influenza vaccine is a gamble or that it doesn't work. Parents and health care workers are particularly skeptical about the benefits of influenza vaccine. Many people believe handwashing is as effective at preventing influenza as vaccination. Because vaccine effectiveness is complex and varies each season, it is difficult to craft messages that resonate.

Mothers of young children cite safety concerns about thimerosal and the number of vaccinations in early childhood as reasons for not getting vaccinations. To address these concerns, CDC will rely on health care providers to help parents understand the real risks of vaccination in the context of the risk of influenza. To address financial barriers, CDC will raise awareness that Medicare Part B and VFC cover influenza vaccine.

CDC will reach out to the media as it always does, with more efforts aimed at health care workers. It is also focusing on partnerships, e.g., working with YMCA to reach children and their parents. CDC is expanding use of the Internet and e-health communication mechanisms. National Influenza Vaccination Week (December 8–14) will help raise awareness.

***Discussion***

Dr. Sheedy said when CDC tested its "Take Three" message—which emphasized three steps to protection: getting a influenza vaccination, handwashing/preventive measures, and use of antivirals if appropriate—it learned that the message not only caused confusion but reinforced the perception that vaccination is not needed because other steps can be taken. However, the message that vaccination is a step you can take to protect your loved ones resonates very well. She said CDC has not worked directly with educators in schools and daycare settings but hopes its partnerships will help reach those audiences. The "Why Flu Vaccination Matters" DVD has been used by some parent-teacher organizations. Dr. Sheedy said CDC offers a number of communications vehicles on its website that target different audiences and carry different themes. COL Engler suggested that CDC develop educational materials for schools that focus on the science of vaccines and how they work.

***New and Improved Influenza Vaccine—Dr. Bruce Gellin***

Dr. Gellin said advisory groups and others have pointed out the need for better vaccines, and each group has its own perspective on how investment in emerging technologies (e.g., pandemic influenza vaccine, vaccine adjuvants) will affect public health. As manufacturers respond to different needs among different populations, the landscape of vaccination is becoming more complex.

***Discussion***

COL Engler anticipated the evolution of a medical specialty in immunization health care. She said the public should be reminded that vaccines are prescription drugs that require the expertise of a qualified health care provider.

Dr. Pavia wondered about the complexity of recommending specific products for specific populations if it appears that one product is more effective in certain people. He also asked whether current financial incentives are adequate to encourage manufacturers to develop more effective products. Mr. Hosbach of Sanofi Pasteur said his company has an oversupply of vaccine in response to recommendations by NVAC and others to produce more. He asked that FDA better clarify the pathway to clinical approval of new products for companies that are considering investing more in vaccine development. Dr. Gellin noted that the emphasis on preparedness for pandemic influenza has motivated companies to look at modifying

existing vaccines. Dr. Baylor said the history of influenza vaccine has always involved a unique government-manufacturer partnership. He said FDA is ready to work with manufacturers interested in going in a new direction but the rest of government must also support such efforts.

> ***Action Item***
>
> Dr. Gellin will send the Congressional Budget Office report on U.S. pandemic vaccine policies to NVAC members.

***Maternal Influenza Immunization: Protecting Mothers and Infants—Dr. Mark Steinhoff***

Dr. Steinhoff summarized his research demonstrating the benefits to infants of maternal influenza vaccination during pregnancy in Bangladesh, which was published on the *New England Journal of Medicine's* website (www.nejm.org) September 17, 2008. He said new data from CDC showed the burden of influenza on infants under 6 months old was higher than previously thought, sometimes accounting for up to 30 percent of hospital admissions. No influenza vaccine or antiviral drugs are licensed for children under 6 months old. Although influenza vaccine has been recommended for pregnant women, few get vaccinated. The Bangladesh study represented the first randomized, controlled trial to evaluate the effects of vaccination of pregnant women on their infants.

Pregnant women were randomized to receive either pneumococcal vaccine or influenza vaccine. Researchers conducted intense follow up to assess any influenza-like symptoms in the infants. Dr. Steinhoff summarized the findings, noting that for every 100 infants 0–6 months old, influenza vaccination of the mother during pregnancy was associated with 14 fewer episodes of respiratory illness with fever and 24 fewer clinic visits. For every 100 mothers of infants 0–6 months old, vaccination during pregnancy was associated with seven fewer episodes of respiratory illness with fevers and 3.8 fewer clinic visits.

Evaluating the number of vaccinations needed to prevent illness, Dr. Steinhoff said that for every five doses of influenza vaccine, one febrile illness was averted, and for every four doses, one clinic visit for illness in a mother or infant was averted. For every 18 doses, one proven influenza illness in an infant was prevented. Dr. Steinhoff concluded that trivalent, inactivated influenza vaccine was well tolerated by pregnant women, reduced proven influenza illness by 63 percent in infants 0–6 months old, and averted more than 30 percent of febrile respiratory illnesses in young infants and their mothers. He hoped the study would encourage public health officials to emphasize the message that mothers can protect their newborns as well as themselves by getting an influenza vaccination during their pregnancy.

***Discussion***

NVAC members discussed some of the details of the study, including whether timing of vaccination might impact the effectiveness. Dr. Steinhoff said the findings of his study seem plausible in light of other studies and data. Emphasizing the need for influenza vaccination among pregnant women on the basis of protecting the woman against influenza has not been persuasive. According to a recent survey, Dr. Steinhoff noted, 60 percent of obstetricians think it's good to recommend influenza vaccination to pregnant women, but 38 percent don't administer the vaccine in their offices.

**Closing Remarks**

No public comments were made. Dr. Birkhead thanked the members for their contributions to a productive meeting and adjourned the meeting.

The meeting adjourned at 2:30 pm.

I hereby certify that to the best of my knowledge, the foregoing minutes for the September 16-17, 2008 NVAC Meeting are accurate and complete.

December 17, 2008
Date

/Guthrie Birkhead/
Guthrie Birkhead, M.D., M.P.H.
Chair, National Vaccine Advisory Committee

Amended December 29, 2008