



**National Vaccine Advisory Committee (NVAC)
June 14–15, 2011, Meeting
Participants**

Committee Members in Attendance

Guthrie S. Birkhead, M.D., M.P.H., Chair
Tawny Buck
Richard D. Clover, M.D.
Seth Hetherington, M.D.
Philip S. LaRussa, M.D.
Clem Lewin, Ph.D., M.B.A.
James O. Mason, M.D., Dr.P.H.
Marie McCormick, M.D., Sc.D.
Julie Morita, M.D.
Christine Nevin-Woods, D.O., M.P.H.
Walter A. Orenstein, M.D., M.P.H.
Amy Pisani, M.S.
Laura E. Riley, M.D.
Thomas E. Stenvig, R.N.
Litjen Tan, Ph.D., M.S.

NVAC Ex Officio Members

Limone Collins, M.D. (for COL Renata Engler)
Department of Defense (DoD)
Geoffrey Evans, M.D., Health Resources and
Services Administration (HRSA), Vaccine
Injury Compensation Program (VICP)
Rick Hill, D.V.M., M.S., Department of
Agriculture (USDA)
Jeffrey Kelman, M.M.Sc., M.D., Centers for
Medicare and Medicaid Services (CMS)
Barbara Mulach, Ph.D., National Institutes of
Health (NIH)

Melinda Neuhauser, Pharm.D., M.P.H. (for
Richard Martinello, M.D.), Department of
Veterans Affairs (VA)
RADM Anne Schuchat, M.D., U.S. Public
Health Service (USPHS), Centers for
Disease Control and Prevention (CDC)

NVAC Liaison Representatives

Carol Baker, M.D., Advisory Committee on
Immunization Practices (ACIP)
Charlene Douglas, Advisory Commission on
Childhood Vaccines (ACCV)
Claire Hannan, M.P.H., Executive Director,
Association of Immunization Managers
(AIM)
Paul Jarris, M.D., M.B.A., Association of State
and Territorial Health Officials (ASTHO)
Wayne Rawlins, M.D., M.B.A., America's
Health Insurance Plans (AHIP)
Jose Romero, M.D., Vaccines and Related
Biological Products Advisory Committee
(VRBPAC)
Kathy Talkington, M.P.A., ASTHO

Executive Secretary

Bruce G. Gellin, M.D., M.P.H., Deputy
Assistant Secretary for Health (DASH) and
Director, National Vaccine Program Office
(NVPO)

**National Vaccine Advisory Committee
June 14–15, 2011, Meeting Minutes**

Day 1—June 14, 2011

Opening Remarks and Chair’s Report—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead welcomed the participants. His assistant, Robert A. Bednarczyk, Ph.D., has provided invaluable support to the chair and to the National Vaccine Advisory Committee (NVAC), particularly the working groups, for three years and is now leaving to pursue an academic research career. Dr. Birkhead presented Dr. Bednarczyk with a plaque from NVAC, Bruce G. Gellin, M.D., M.P.H., DASH and Director of the National Vaccine Program Office (NVPO), and Howard Koh, M.D., M.P.H., Assistant Secretary for Health (ASH), in recognition of his dedication, expertise, and hard work in support of NVAC’s goal of saving lives through vaccination.

Dr. Birkhead reviewed the minutes of the previous meeting, noting that most of the items on the matrix of NVAC actions and recommendations requiring follow-up have been completed. He summarized the [agenda](#) and reiterated the charge of the Committee. The next NVAC meeting is scheduled for September 13–14, 2011.

Action Item

NVAC approved the February 2011 minutes.

Welcome—Bruce G. Gellin, M.D., M.P.H., DASH, Director, NVPO

Dr. Gellin thanked the Committee on behalf of Dr. Koh. He said NVAC helped shape the National Vaccine Plan, which was released in February. Dr. Gellin suggested that recommendations of the Adult Immunization Working Group (AIWG), the Vaccine Safety Working Group (VSWG), and others be considered in the context of the Plan. Given current budget constraints, Dr. Gellin also asked NVAC to consider prioritizing those activities that are not already underway and that would have the most significant impact, although it is always a challenge to balance competing priorities. In addition, he asked that NVAC provide input on improving the overall vaccine system.

Dr. Gellin and Dr. Koh look forward to NVAC’s thoughts on implementation of the universal recommendation for influenza vaccination. Dr. Gellin said the Department of Health and Human Services (HHS) was criticized—and rightly so—for starting some of its demonstration projects late in the 2010–2011 influenza season, such as the retail pharmacy vouchers. Because there will likely be more influenza vaccine available sooner for 2011–2012, he anticipated an earlier start and hoped NVAC would provide planning advice.

The Vaccines for Children (VFC) program is a good mechanism for addressing vaccine disparities among kids, but more work is needed for adults, said Dr. Gellin. The AIWG is addressing disparities among adults, but more attention may be needed. The Office of Minority Health (OMH) is overseeing implementation of the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*.

Dr. Gellin announced that HHS released *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for Prevention, Care, & Treatment of Viral Hepatitis*. On Thursday, June 16, HHS will roll out the National Prevention Strategy, said Dr. Gellin. Further assignments for NVAC may arise from the new strategy.

Action Item

NVAC will evaluate the immunization portions of the HHS documents the *HHS Action Plan to Reduce Racial and Ethnic Health Disparities* and *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for Prevention, Care, & Treatment of Viral Hepatitis*.

Discussion

It was noted that the HHS Partnership for Patients and the National Health Care Quality Strategy offer additional opportunities for NVAC to weigh in on quality issues and community health services around vaccines.

Action Item

The NVAC September 2011 meeting agenda will include an overview of the HHS Partnership for Patients and the National Health Care Quality Strategy.

Adult Immunization Working Group (AIWG) Recommendations—Julie Morita, M.D.

Dr. Morita described the AIWG's process for developing the report *Adult Immunization: Complex Challenges and Recommendations for Improvement* and summarized the recommendations. The report reflects input received at stakeholder engagement meetings held in Denver and Chicago in April 2011. The primary recommendations cover the need for national leadership, resources, and a strategic action plan to develop an Interagency Adult Immunization Working Group to engage stakeholders, establish a National Adult Immunization Program, and meet the goals of Healthy People 2020 and the National Vaccine Plan. The report also describes focused activities that address the key elements of a comprehensive program and gaps in the existing knowledge base:

- Bolster the general infrastructure for adult immunization** by aligning goals across agencies, including information about adult immunization in CDC grant guidance, and supporting the development of infrastructure and quality measures for adult immunization.
- Expand vaccine access** by ensuring a consistently adequate supply of vaccines for adults, opening the CDC Immunization Grant Program (Section 317) to include more adults, fostering partnerships with public health and other organizations, and updating the maximum allowable reimbursement under Medicaid.
- Implement provider/system-based interventions** that include quality assurance efforts, enhance provider education, expand the adult provider network, expand immunization information registries to include adults, and increase awareness about Affordable Care Act (ACA) benefits and immunization business practices.
- Increase community demand** through an ongoing, comprehensive education and outreach campaign that uses multiple media outlets and provides culturally and linguistically appropriate information for patients and providers.
- Support research** on costs, coverage, economic impact, provider education and certification, relationship of office practices to disparities, effect of Medicaid reimbursement policies, standardized evaluation practices, impact of health literacy, impact of social networking, State policies and practices, and new and improved vaccines and delivery systems.

For each recommendation, the AIWG identified responsible government entities and other stakeholders that should be involved in implementation as well as suggested timeframes. An appendix to the report includes suggestions for prioritization of the research recommendations compiled from a brief survey of stakeholders.

Discussion

Dr. Morita noted that the AIWG sought to address health disparities throughout the report. She added that retail pharmacies are identified as responsible partners and can play a big role in adult immunization. Committee members anticipated financial challenges to implementing the recommendations, including a cut to Section 317 funding. In light of budget constraints, said Dr. Morita, the report targeted some activities that don't require new resources, such as enhancing guidance to existing Section 317 programs on leveraging funds to support adult immunization and encouraging health departments to employ health information technology (HIT). The AIWG acknowledged concerns that recommendations for adult immunization would draw resources away from childhood vaccination efforts.

Committee members emphasized the substantial cost savings of prevention and the need to measure the value of adult immunization, especially in comparison with other preventive interventions. It was noted that recent updated data on the cost-benefits of pediatric vaccination are powerful, and similar data for adults would be influential. Cost analyses should specify where savings are realized (e.g., in which programs), when possible. Members also noted the need to model how ACA provisions would affect the flow of Section 317 funds. Further, providers of all types would benefit from better understanding of ACA provisions for vaccination coverage; the American Medical Association is piloting a continuing medical education course on business practices for adult immunization.

It was noted that the increased supply of vaccines, introduction of new vaccines, and increased demand will increase the load on vaccine safety and surveillance systems. Surveillance systems are addressed in the report in the context of provider education.

Phil Hosbach of Sanofi-Pasteur supported assessing whether ACA provisions alleviate pressure on Section 317 funding and also educating public health departments on billing private providers when appropriate. He advocated maintaining the current level of Section 317 funding. RADM Anne Schuchat, M.D., described CDC efforts, including a planned economic model of adult immunization, funding for HIT to improve tracking and safety monitoring, and funding to promote partnerships between public health and private organizations. RADM Schuchat said CDC will work closely with NVAC and NVPO to implement the AIWG recommendations.

In response to Shannon Dzubin of GlaxoSmithKline, Dr. Morita said the report acknowledges the differences between public and private insurance in provider reimbursement and coverage of adult vaccines and the complexities faced by health departments in billing private insurers. Eddy Bresnitz, M.D., of Merck & Company, suggested adding manufacturers to the list of responsible parties who can assist with implementation of the recommendations. A member of the public who commented by phone asked that vaccine information statements better reflect the cautions indicated on vaccine labels. The caller suggested that vaccine protocols provide more instruction for providers on following up on suspected vaccine-related injuries and that reporting adverse events related to vaccination be mandatory.

NVAC unanimously approved the report *Adult Immunization: Complex Challenges and Recommendations for Improvement* with minor changes.

Recommendation

NVAC endorses the report *Adult Immunization: Complex Challenges and Recommendations for Improvement* with the following changes:

- In Recommendation 3A, include a statement about measuring and assuring quality among providers in all settings.

- Note that the existing infrastructure for vaccinating children can be leveraged to promote community demand for adult vaccination.
- In Recommendation 3, add manufacturers to the list of entities that should play a role in provider education and networks.
- Revise Recommendation 5M to include improved vaccination policies to support immunization.
- Include the Agency for Healthcare Research and Quality as appropriate among the responsible government partners.
- In Recommendation 5C, bolster the case for adult immunization by emphasizing the return on investment and cost-savings of vaccination.
- Add a recommendation to better measure the value of vaccination in comparison with other medical preventive services.
- In describing cost-savings, identify specific program savings where possible.
- Model how Section 317 funding will be affected by implementation of ACA provisions to determine whether those funds can be shifted to meet other needs.

Andrew Pavia, M.D., suggested considering the interface between adult immunization and the emerging accountable care organizations (ACOs). CDC is planning a stakeholder meeting around ACOs.

Action Item

As ACOs gain a foothold, NVAC will consider their relationship to adult immunization issues.

2010–2011 Influenza Season—Cindy Weinbaum, M.D., M.P.H., CDC

Dr. Weinbaum summarized recent data, noting that more vaccine doses were available earlier than in previous seasons. Safety concerns were raised about a vaccine used in Australia that was associated with febrile seizures, and Vaccine Safety Datalink identified an increase in febrile seizures among toddlers when vaccine was given concurrently with pneumococcal conjugate vaccine. The attributable risk of febrile seizure was 60 cases per 100,000 concurrent doses, and none of the children affected had lasting adverse sequelae, said Dr. Weinbaum. Survey results confirm that most children and adults over 65 years receive vaccinations at a doctor's office or a clinic, while those 18–64 years are more evenly split among doctors' offices, clinics, the workplace, and retail settings.

State-level data were available earlier than ever and posted online in an interactive format. They demonstrated less of a delay in vaccine uptake compared with previous seasons. In 2010–2011, about the same number of adults and elderly but more children under 17 were vaccinated as in 2008–2009. The number of those at high risk who were vaccinated did not increase in the past season. Coverage for Blacks, Whites, and Hispanics increased across the board. Dr. Weinbaum described impressive advances in vaccinating pregnant women and health care workers (HCWs), noting that HCW vaccination rates vary by the type of workplace. Despite “flu fatigue,” coverage gains made in 2009–2010 were sustained. Dr. Weinbaum said the Centers for Medicare and Medicaid Services (CMS) has proposed adding HCW influenza vaccination as a quality measure for 2015.

Discussion

RADM Schuchat said CDC has demonstrated vaccine effectiveness across the board by age and serotype. CDC's long-term goal is to assess the impact of vaccine each influenza season, but that goal is complicated because the disease, the vaccine, and the susceptible population(s) vary each season. According to the National Flu Survey, people don't get vaccinated because they don't perceive an individual risk of serious illness from influenza; communication efforts attempted to address that

perception this year, but the data are not yet available to determine their success. Carol Baker, M.D., said nearly half of influenza-related pediatric deaths occur in otherwise healthy children, so future messaging should reinforce the need to vaccinate healthy children. It is not clear why the number of Black and Hispanic children vaccinated has increased dramatically, but RADM Schuchat noted that 70 percent of Black and Hispanic children are eligible for the VFC program, and there may be higher acceptance of influenza vaccine among Hispanic families for various reasons. Better media outreach to minorities may also have contributed.

Katherine Harris, Ph.D., M.A., of RAND Corporation noted that rates of vaccination of HCWs correlated with programs, policies, and requirements supporting vaccination. With or without penalties, vaccine requirements are effective, as is simply offering vaccination in the workplace. Dr. Birkhead suggested evaluating the potential correlation between vaccination status of HCWs and the patients they treat. Dr. Weinbaum added that vaccination in retail pharmacies increased.

Update from the National Influenza Vaccine Summit

Overview—Litjen Tan, Ph.D., M.S.

Dr. Tan said the breadth of stakeholders who take part in the annual Summit enhances communication and provides a comprehensive perspective of the vaccine enterprise. A summary of the meeting and other materials are available on the Summit's [website](#). Dr. Tan highlighted the following key messages from the Summit:

- Complementary providers and partners have an increasing role in influenza immunization. The “anytime, anywhere” concept may be reducing some of the market share for traditional, appointment-based vaccination clinics. Large marketing campaigns by retail pharmacies appear to have driven increased vaccination in physician offices.
- Involving more partners can increase communications among diverse provider types and help iron out differences of opinion.
- HHS will continue its seasonal influenza task force and work with partners to improve influenza vaccination uptake, reduce coverage disparities, collaborate with pharmacy and other community immunizers, and promote vaccination for pregnant women and HCWs.
- Vaccine manufacturers estimate producing 166–173 million doses of vaccine for 2011–2012, beginning shipping in July, and delivering most doses by the end of October.
- Experts vary in their interpretation of vaccine effectiveness and the strength of the data, but all agree there is a large burden of disease and the vaccine is safe. A clear message about influenza vaccine effectiveness is needed to reduce confusion and improve protection against influenza.
- Key communication messages from last season will continue with minimal changes; tailored messages will target specific populations. Messages will stress the need for annual vaccination even when the strain does not change.

Discussion

Christine Nevin-Woods, D.O., M.P.H., noted the Summit provided a great atmosphere and plenty of time for discussion. She pointed out that the U.S. Air Force topped all Armed Forces by achieving a 99-percent influenza vaccination rate—adding to the evidence that the true rate of medical contraindications to influenza vaccination is low. Participants discussed the findings presented at the Summit by Michael Osterholm, Ph.D., questioning the effectiveness of the influenza vaccine. Carolyn Bridges, M.D., of CDC noted that Dr. Osterholm and colleagues limited their assessment to a very narrow segment of the literature; she said the influenza vaccine is not highly effective every year, but even a moderately effective vaccine can reduce the burden of severe disease.

AIWG Subgroup on Influenza Vaccination of Health Care Providers—Christine Nevin-Woods, D.O., M.P.H.

Dr. Nevin-Woods described the subgroup's charge to develop recommendations to achieve the Healthy People 2020 annual goal of 90-percent influenza vaccine coverage for HCWs, defined as all paid and unpaid persons working in health care settings who have the potential for exposure to infectious materials. The subgroup is reviewing materials and presentations on methods used to increase HCW vaccine coverage. Dr. Nevin-Woods noted that more organizations are implementing mandatory programs, and less coercive approaches have inconsistent results. The subgroup is grappling with how to require vaccination of HCWs who are not employees of the institution they serve (e.g., medical students, hospital volunteers, contract information technology [IT] staff). The subgroup anticipates a presentation on the development of a quality measure for reporting HCW vaccination. A draft report will be presented to NVAC for review in September 2011, followed by stakeholder engagement efforts. Dr. Nevin-Woods projected the final report would be presented to NVAC for approval at the February 2012 meeting.

Vaccine Safety Working Group (VSWG) Update—Andrew Pavia, M.D.

Over the past several months, the VSWG gathered input from NVAC, Federal agency representatives, stakeholders, and the public on its draft white paper recommending improvements to the Federal vaccine safety system. The VSWG concluded that the existing system is good but must be capable of growing with the increasing number of vaccine antigens, eligible populations, and recommendations. In response to comments received, the current version includes a recommendation to evaluate costs of the proposed recommendations and to prioritize the recommendations. Many of the public and stakeholder comments focused on transparency and accountability. The current version recommends establishing a formal institutional relationship between NVAC and the existing Immunization Safety Task Force (ISTF). It also proposes several options for assurance and accountability of progress in enhancing the Federal vaccine safety system, ranging from NVAC to an independent group within the Executive branch (comparable to the National Transportation Safety Board [NTSB]). Recommendations related to research, communication, and independent oversight were the highest priorities among the public and stakeholders who commented on the report.

Discussion

Members offered numerous suggestions on the structure and tone of the report. They agreed that the report should emphasize that the current system is effective and should be maintained with adequate financial resources. Much discussion centered on whether existing mechanisms for coordination and oversight are event-driven or system-oriented. Questions arose about the roles of various existing entities in conducting research, gathering information, and presenting data to NVAC, NVPO, providers, and the public. Members weighed the value of expanding access to data against the dangers of violating privacy and confidentiality. Some were concerned about misuse or misinterpretation of data, while others noted that opening large data sets to the public can spur new research that advances the field.

It was noted that a previous public engagement effort focused on the CDC's immunization research agenda revealed concerns about conflicts of interest, transparency, reporting mechanisms, and other issues related to the vaccine safety system and its oversight; similar concerns were raised in the public and stakeholder comments on the current report. To improve quality assurance and accountability, some participants argued in favor of creating an independent body modeled on the NTSB, because it is well-respected, recognized, and trusted by the public to address concerns. Others countered that the NTSB only engages after a crisis occurs and does not identify potential problems or facilitate communication among stakeholders in advance. Much discussion ensued on the ability of NVAC to act objectively; some noted that any independent body would likely mirror the composition of NVAC. Most NVAC members who

spoke felt that NVAC has the representation, authority, expertise, and mechanisms in place to provide objective external assurance of the vaccine safety system, but it was agreed that communication, public engagement, and accountability can be enhanced to improve public perception of NVAC's role. A member suggested an external review, for example by the Institute of Medicine (IOM), of the implementation of the NVAC safety recommendations after five years.

Action Item

The VSWG will incorporate the following suggestions from NVAC and circulate a revised draft to NVAC members for review in advance of the September 2011 meeting. The VSWG will also survey NVAC members to inform prioritization of the recommendations.

General Comments

- In addition to adding an executive summary to the report, consider writing a summary for the general public that captures the main ideas in plain language.
- Expand the discussion on the benefits of vaccination.
- Clarify the purpose and goals of the document early in the text. Consider explaining how the report contributes to the goals of the National Vaccine Plan. Consider defining the role of NVAC in improving the vaccine safety system.
- State more clearly that the current system is effective and should be maintained.
- Add a recommendation that the integrity of the current system be maintained with adequate funding to ensure its strong, continued function.

Recommendation 2

- Clarify the intent to create a formal structure to coordinate vaccine safety efforts and highlight the functions that structure should cover without dictating how that happens (e.g., remove references to establishing specific ISTF subcommittees). Also emphasize the need to define NVAC's role in coordination. Coordination should focus on establishing regular communication in the absence of a crisis.

Recommendation 3

- Emphasize that data security, privacy, and confidentiality must be addressed in any effort to expand access to data.

Recommendation 8

- Include Option 1 only (empower NVAC to be responsible for vaccine safety assurance) and note that NVAC can seek external input, including public and stakeholder input, as needed to ensure that NVAC takes into account various perceptions and competing interests. Consider adding a recommendation that NVAC or another entity, such as the Institute of Medicine (IOM), be charged to undertake a five-year review to assess its progress toward vaccine safety assurance.

Public Comment

Jim Moody of the National Autism Association supported creation of an independent agency for oversight. As evidence of public perception that no appropriate objective body exists currently, Mr. Moody said an increasing number of people are requesting exemptions from school vaccination requirements and half of all people think vaccines cause autism. He said that getting data on unvaccinated children would help identify vaccine-related adverse events. The government is not being honest about the relationship between autism and vaccines when it says that vaccines do not cause autism, said Mr. Moody. He pointed out that in the 1990s, several cases of vaccine-caused autism were reported, and in

response, the VICP revised its Vaccine Injury Table to negate those claims. Mr. Moody said many issues have resulted in public distrust of vaccines. He concluded that the common ground among all stakeholders is the desire for healthy children, which should be reflected in an equal commitment to eliminating adverse events and treating them when they do occur.

Another public commenter also said an independent oversight committee is needed, noting that ACIP recommends the human papillomavirus (HPV) vaccine despite the fact that no study shows the HPV vaccine prevents cervical cancer. The required follow-up studies of the HPV vaccine have not been performed, she said, and she is not the only one concerned about the lack of follow up.

Jake Crosby commented that NVAC members lack independence or objectivity and said an NVAC member had stated that NVAC will never determine that autism is caused by a vaccine, and he questioned how such a member could be considered objective.

Report on the 2010–2011 Influenza Season and Universal Recommendations—Robert Bednarczyk, Ph.D.

Dr. Bednarczyk described key findings that influenced the draft report *Evaluation of the First Year of the Universal Influenza Vaccine Recommendation* and summarized the recommendations. For example, purchasing vaccine through CDC contracts for the VFC and Section 317 programs may require additional steps that affect the timing of distribution and administration, but studies vary on whether privately insured patients receive vaccine sooner than publicly insured patients. Supply and distribution disruptions are not always communicated clearly to Section 317 grantees. The findings take into account a vast range of data presented to NVAC regarding overall vaccine uptake, racial and ethnic disparities, types of providers and settings, and sources of messaging, among other information. Many of the draft recommendations call for continuing current efforts (e.g., surveillance) and maintaining or enhancing communication. The report recommends ensuring an adequate supply of vaccine, streamlining and improving CDC's vaccine ordering system, increasing coordination and collaboration among nontraditional vaccine providers, adopting the CMS proposal to offer vaccine to all Medicare beneficiaries, addressing barriers to use of immunization information systems, continuing research, and periodically reviewing the universal recommendation. The report also recommends continued funding for infrastructure, communication, and research.

Discussion

Members discussed the need to continue raising awareness about the potential serious outcomes of influenza. It was noted that CDC tracks the total amount of vaccine distributed but does not know how much of that is returned or otherwise goes unused. A member suggested pediatricians consider offering influenza vaccine to parents of patients to enhance convenience. Mr. Hosbach pointed out that vaccine supply is driven by demand, which varies each year. As noted earlier, better data are needed on the impact of annual influenza vaccination. Discussion ensued about the variety of providers now involved in influenza vaccination and the range of delivery approaches and mechanisms. CDC already provides guidance and training to providers, but some called for a body to make recommendations on, for example, new formulations as they become available. However, others said the simplicity of the universal recommendation could be muddied by efforts to tailor recommendations.

NVAC unanimously approved the report *Evaluation of the First Year of the Universal Influenza Vaccine Recommendation* with changes.

Recommendation

NVAC endorses the report *Evaluation of the First Year of the Universal Influenza Vaccine Recommendation* with the following changes:

- Note the need to better understand current practices among private health care providers who purchase vaccine through CDC and to streamline the CDC ordering and distribution process.
- Consider using the term “complementary” instead of “nontraditional” to describe providers outside of medical settings.
- Recommend that resources should be made available to monitor the impact of influenza vaccination annually.
- Strengthen the recommendation to continue communication and outreach efforts.
- Replace the recommendation regarding manufacturers with the following: Manufacturers should plan to meet the increased demand as we move toward universal vaccine coverage.

Agency, Department, Advisory Committee, and Liaison Reports

Vaccines and Related Biological Products Advisory Committee (VRBPAC)—Jose Romero, M.D.

Dr. Romero said VRBPAC met in April to discuss meningococcal vaccine and W-135 conjugate vaccines.

Department of Defense (DoD)—Limone Collins, M.D.

Dr. Collins said DoD achieved 90-percent compliance for influenza vaccination across all the services by December 2010, and the rate increased by March 2011. Beginning in 2010, beneficiaries were allowed to receive vaccination at pharmacies through TRICARE, and over 200,000 did so, as did 13,000 active-duty members. Not all of those pharmacies provide pediatric vaccinations, but that may change in the coming year, said Dr. Collins. DoD hopes to see its universal immunization tracking system reach fruition soon. It is also awaiting implementation of a new adenovirus vaccine.

National Institutes of Health (NIH)—Barbara Mulach, Ph.D.

Dr. Mulach said NIH is holding consultative conferences about enrollment and safety of pregnant women in trials of vaccines and antimicrobials, allowing representatives of various agencies to talk with researchers about such issues as trial design and inclusion/exclusion criteria. Also, the National Institute of Allergy and Infectious Diseases [Showcase](#) website describes how biomedical research impacts health and provides a nice overview of childhood vaccines.

Centers for Disease Control and Prevention (CDC)—RADM Anne Schuchat, M.D.

The Immunization Safety Office (ISO) updated its website to incorporate the five-year scientific research agenda, new resources on implementation, and progress reporting on the agenda. CDC updated its pediatric economic model to assess the return on investment in vaccination. For each year of babies born in one year in the United States and vaccinated according to the ACIP schedule through age 6 years (not including influenza vaccination), 20 million illnesses are prevented, 42,000 premature deaths are averted, \$13.6 billion in medical costs are saved, and \$69 billion in direct medical and indirect societal costs are saved.

The United States is experiencing a record year of measles outbreaks, with 152 cases so far in 2011, more than any year since 1996. Relentless outbreaks have occurred in Europe, especially France, that have been exported to the United States (although some cases have come via Asia). Some of the U.S. outbreaks have been difficult to control, said RADM Schuchat.

CDC added materials to its [vaccine acceptance communication toolkit](#) in April and updated its [teen vaccination website](#). RADM Schuchat said donors pledged \$4.3 billion to the GAVI Alliance to save an additional four million lives by vaccination through 2015. The pledges exceeded the goal of \$3.7 billion and include commitments from manufacturers to reduce vaccine costs. Global polio eradication efforts are doing well in India and Nigeria. RADM Schuchat said several regions aim to eliminate polio and measles, and the global goal is to reduce deaths by 95 percent, but more focus is needed on measles and polio as part of the Decade of Vaccines. Finally, RADM Schuchat provided a snapshot of vaccines in the Strategic National Stockpile and offered to provide annual updates.

Vaccine Injury Compensation Program (VICP)—Geoffrey Evans, M.D.

Dr. Evans said the VICP is adjudicating a lot of non-autism-related claims. It is on track to address about the same number of claims as last year. About half of claims are related to the influenza vaccine. The duration of the adjudication process is decreasing, from about three to four years from filing a claim to compensation to the current average of about 1.5 years. Many claims are resolved in less than a year. The trust fund is stable and includes about \$3.3 billion, said Dr. Evans, although the fund used to have more money.

The Omnibus Autism Proceeding from 2002 has ended, but some claims will be pursued, said Dr. Evans. In October 2010, the court asked counsel whether clients wanted to pursue claims based on causes not already adjudicated; as of January 2011, the Petitioner's Steering Committee disbanded. The court is now aiming its efforts at awarding attorneys' fees and costs that are permitted for unsuccessful claims. The court is working with five firms representing 2,500 clients. Thus, the amount of awards by VICP will go up in the next year or two, said Dr. Evans. The U.S. Supreme Court issued a ruling in a case that addressed whether the National Childhood Vaccine Injury Act limits design defect claims against a manufacturer after an individual has gone through the VICP process and in light of State law barring claims against manufacturers.

Addressing the public confusion about autism claims awarded by VICP, Dr. Evans clarified that VICP has reviewed 1,300 cases of alleged encephalopathy caused by vaccination in children who have various degrees of neurological deficits. These cases were compensated on the basis of encephalopathy, not autism, said Dr. Evans, noting that the related nomenclature has changed since the 1970s and 1980s. VICP expects that developmental problems, including autism, are part of the cases compensated. Dr. Evans emphasized that VICP has not compensated for autism alone in the absence of the sudden onset of neurological conditions at the time of vaccination. Most of the cases heard have not fit that definition, said Dr. Evans, and it's important to make distinctions, because various media have provided mixed messages. Asked whether HHS would support amending the Vaccine Injury Table to reflect the standards used by the VA, Dr. Evans said the standard of proof for, for example, Agent Orange exposure, is more relaxed. He believes that using the VA standards for the Vaccine Injury Table would be a less scientific process. About 60–70 percent of VICP claims are compensated, which he said indicates the program is fulfilling its goals.

Advisory Commission on Childhood Vaccines (ACCV)—Charlene Douglas

Ms. Douglas said the ACCV met in June and heard reports from various Federal agencies; reviewed information statements on hepatitis B, influenza, and meningococcal vaccine; and received a clinical update on cases of complex regional pain syndrome. In September, the group will hear a briefing from the IOM on vaccines and adverse events related to varicella, influenza, hepatitis A and B, HPV, diphtheria/tetanus/pertussis, and measles/mumps/rubella. The IOM's final report will be completed in July 2012.

Department of Agriculture (USDA)—Rick Hill, D.V.M., M.S.

Dr. Hill said the World Organization for Animal Health declared that cattle plague has been eradicated, with vaccines playing a huge role. Later in June, it is expected that the United Nations' Food and Agriculture Organization will make a similar declaration. In response to a question, Dr. Hill said an equine herpes outbreak seems to be under control. The equine herpes vaccine is licensed for respiratory and reproductive forms of the disease but not for neurological forms, he noted, and the data do not support that the vaccine is effective for the neurological form.

Public Comment

No comments were made.

Day 2—June 15, 2011

Health and Human Services (HHS) Health Disparities Action Plan—Regan Crump, Dr.P.H., M.S.N., OMH

Dr. Crump said the [*HHS Action Plan to Reduce Racial and Ethnic Disparities*](#) complements the efforts of the National Partnership for Action (NPA), responds to ACA requirements, and aligns with HHS strategic goals to improve health and health care. OMH coordinates the NPA, which seeks to achieve health equity. Dr. Crump outlined the major goals of the Action Plan, noting in particular a strategy aimed at reducing disparities in influenza vaccination by building on HHS 2011 demonstration efforts to increase availability of vaccine and raising awareness about the seriousness of influenza and the safety of the vaccine. He also highlighted the goal of advancing scientific knowledge and innovation by supporting more research; for example, the NIH plans to bring together various Federal departments to promote research collaboration, utilization, and dissemination of health disparities research findings. The HHS Health Disparities Council includes representatives from across the agency; at its first meeting, members discussed how to implement the Action Plan and evaluate results. The Council will evaluate and modify the Action Plan as needed every six months and provide an annual progress report to the public.

Discussion

The Indian Health Service will play a key role in implementing the Action Plan, but it does not reach all Native Americans. Members stressed the importance of engaging minority professional organizations, such as the National Medical Association, to enhance provider education and expand outreach to minority populations. Establishing and maintaining relationships with minority professional organizations around influenza vaccination may also pave the way for addressing other adult immunization goals. Health plans are also interested in addressing health disparities. State coalitions should also be engaged in the effort.

Dr. Crump clarified that the Action Plan focuses only on racial and ethnic disparities because the best data exist for those disparities. Various HHS offices are gathering data on disparities based on disability status, gender, and geographic location. Members discussed whether immigration/citizenship status factors into immunization disparity rates. Dr. Crump asked that participants send additional considerations to him via e-mail at regan.crump@hhs.gov.

Action Items

NVPO staff will provide NVAC with more information on the effort by NIH to bring together various Federal departments around health disparities research.

NVAC will provide OMH with recommendations made over the past several years relating to health disparities. If requested, NVAC will present to the Health Disparities Council about efforts to address vaccination disparities.

OMH will evaluate immunization disparities among undocumented immigrants and report its findings to NVPO.

2010 National Vaccine Plan—Bruce G. Gellin, M.D., M.P.H., DASH, Director, NVPO

Dr. Gellin drew attention to the 10 priority areas listed in the 2010 National Vaccine Plan, developed with input from NVAC, IOM, and stakeholders. NVPO is crafting an implementation plan that incorporates stakeholder input and focuses on the identified priorities. As NVPO identifies specific indicators to measure progress, it will seek input from stakeholders through regional meetings. Some implementation is already underway, such as IOM's Committee for Vaccine Prioritization and the Decade of Vaccines project. Vaccines.gov launched March 31, 2011, and serves as a portal to all Federal vaccine information. NVPO is looking to the Consumer Confidence Index as a model for measuring public confidence in vaccines. It is also taking a broad multidisciplinary approach to better understanding vaccine hesitancy that includes, for example, input from behavioral economists.

For the implementation plan, the next steps are to define actions and measures of progress and determine how national partners (not just Federal offices) will participate. Progress will be measured periodically (short, medium, and long term). Dr. Gellin asked that NVAC consider its recommendations in the context of the Plan and give input into the annual progress reports and the mid-course review set for 2015. The Plan includes a grid identifying partners (Federal and non-Federal) who should be involved in implementing the objectives of each goal; having the right people working on the right tasks is critical to successful implementation, said Dr. Gellin.

Discussion

Members discussed the importance of metrics to understand what's being done, what's working, and what gaps remain. Many efforts to measure and track vaccine goals are underway. For example, CDC's five-year global immunization framework and Healthy People 2020 both include indicators. Dr. Gellin emphasized that NVAC is the primary external advisory body that will evaluate and track progress reported on the Plan goals. NVPO will report to NVAC the results of regional stakeholder meetings in 2011 coordinated in conjunction with ASTHO, the National Association of County and City Public Health Officials, and others. The meetings are aimed at understanding barriers and gaining cooperation from non-Federal partners; NVAC members are encouraged to attend.

Action Item

A future NVAC meeting agenda will include the Decade of Vaccines initiative.

Vaccine Financing

Overview—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead explained that NVAC's comprehensive vaccine finance recommendations did not anticipate the ACA. Presenters were invited to address new vaccine finance considerations.

Affordable Care Act (ACA)—Christen Linke Young, Office of Health Reform, Office of the Secretary, HHS

Ms. Young described the goals of the ACA, progress to date, and reforms that will be implemented in 2014 and beyond. Notably, ACA ensures more coverage for preventive services and improves access to health care coverage through State-based health insurance exchanges. The public-private Partnership for Patients focuses on improving quality by decreasing preventable complications of care. ACOs aim to improve overall patient health and thus reduce the costs of care for Medicare beneficiaries. The new CMS Innovation Center will give programs more flexibility to make changes. An independent payment

advisory board will recommend improvements to providing and coordinating care and reducing errors for Medicare beneficiaries; its recommendations would take effect only if Medicare costs rise and Congress does nothing, said Ms. Young.

To support preventive health measures, Congress allotted \$15 billion over 10 years for the Prevention and Public Health Fund. The National Prevention, Health Promotion, and Public Health Council will create a National Prevention Strategy. ACA requires first-dollar coverage for many vaccines, increases Medicaid reimbursement levels for vaccination, and allows States more authority to purchase vaccines for adults. Some health plans are exempt from the coverage requirements (i.e., grandfathered). Ms. Young noted that those who purchase insurance on an individual basis have the spottiest preventive care coverage, but they also change health insurers relatively frequently. As they do so, the insurance plans will lose their grandfather status.

Centers for Medicare and Medicaid Services (CMS) Vaccine Financing—Jeffrey Kelman, M.M.Sc., M.D., CMS

Dr. Kelman said Medicare will cover hepatitis B vaccine for those at moderate-to-severe risk with no co-pay, which should improve uptake and save money. In 2013 and 2014, certain Medicaid services—including vaccine administration—will be paid at Medicare rates. CMS is proposing that Medicare providers in all settings offer influenza vaccination to all beneficiaries who do not have contraindications. The HHS Center for Consumer Information & Insurance Oversight will ensure that health plans include ACA-required essential health benefits, including recommended vaccines, which should normalize the availability of vaccines throughout the country, said Dr. Kelman. CMS is proposing to require reporting of HCW influenza vaccination rates as a quality measure. Dr. Kelman pointed out that CMS has never before collected data on HCWs because they are not beneficiaries. Dr. Kelman encouraged practitioners to let their patients know about the Pre-Existing Condition Insurance Plan, which provides insurance to those who have not had insurance coverage for six months or more because of a preexisting condition.

Discussion

Currently, there is no provision to ensure that the plan to pay Medicaid providers for vaccine administration at Medicare rates will continue after 2014. Data are needed to support higher payment rates, but it may not be possible to gather reliable impact data in such a short time. Dr. Kelman pointed out that continued funding would require legislative action. Ms. Young noted there is no statutory requirement to reimburse for vaccine or administrative costs adequately, although there are “general ideas” for States and health insurance exchanges and network adequacy rules to address egregious problems. RADM Schuchat noted that reauthorization of funding for Section 317 is particularly complicated this year.

Action Item

NVAC will submit comments to CMS supporting the proposal to offer influenza vaccination to all Medicare patients (as part of the public comment process).

Immunization Financing Post-ACA—Lance Rodewald, M.D., CDC

Dr. Rodewald described how ACA incorporated many of NVAC’s vaccine finance recommendations, improving coverage of vaccines, especially for children. However, a coverage gap remains among underinsured children and adolescents; it is anticipated that ACA will close that gap when it is fully implemented. Some health department clinics recoup funds by billing private insurance plans whose beneficiaries receive services provided with VFC or Section 317 funds. With full ACA implementation, Federal funding will cover a larger proportion of the vaccine administration costs in public settings. Dr. Rodewald pointed out that to maintain operations in the face of declining budgets and growing costs,

States rely on Section 317 funds to support their VFC programs. Thus, losing Section 317 funding would damage States' ability to provide VFC programs.

The transition to full ACA implementation brings challenges, such as grandfathered plans that are not required to cover vaccines (although there are disincentives to remaining in grandfathered status) and consumers who remain underinsured. Dr. Rodewald noted that for health departments, billing private insurers is not easy and requires some investment. To assist with the transition, the Prevention and Public Health Fund offers money to Section 317 programs to develop IT solutions and billing mechanisms in health departments. To expand VFC programs to reach more underinsured children and those in grandfathered plans, HHS can "deputize" health department clinics as Federally qualified health centers (FQHCs), which relieves some of the pressure to use Section 317 funds to vaccinate underinsured children. With full ACA implementation, some Section 317 funds can be redirected to better support immunization efforts for underinsured adults and to address outbreaks, for example. Dr. Rodewald concluded that NVAC's vaccine finance recommendations made a difference and are being implemented.

Discussion

Participants emphasized the importance of maintaining Section 317 funds to support the fragile public health infrastructure. It was noted that while billing private insurers has been successful for health departments in Oregon, the State of North Carolina prevents such billing, thus requiring Section 317 funds to cover costs. RADM Schuchat clarified that a portion of Section 317 dollars goes to purchasing vaccine, and if ACA eliminates the underinsurance gaps, those funds would be freed up. However, much Section 317 funding goes to program support unrelated to delivering vaccine, such as surveillance, investigation, tracking, provider education, and quality assurance. The Prevention and Public Health Fund money recently made available to Section 317 programs targets areas to which CDC believes Section 317 funds should be redirected—including adult immunization, IT, and billing, said RADM Schuchat. A member noted that new data on cost-effectiveness of pediatric vaccines should be incorporated into any case made to support continued funding.

Members further discussed how to measure the impact of increased vaccine administration payment for Medicaid providers in 2013 and 2014; some existing evidence indicates that higher payments encourage more providers to offer vaccines, and influenza is the only vaccine for which there is a demonstrated relationship between provider fees and coverage. Demonstrating coverage increases, however, takes a long time. Members debated whether NVAC should convene stakeholders or take part in an existing stakeholder group (that includes ASTHO, the National Influenza Vaccination Summit, and others) to determine some evaluation mechanisms. Community health centers and FQHCs may be good places to measure practice changes.

In response to a public query, Ms. Young said HHS does not have the authority to collect data about the percentage of plans covering vaccination once they relinquish grandfather status. A member noted that it is unlikely health plans will want to retain grandfather status for very long because grandfathered plans are not eligible to offer coverage through the health insurance exchanges.

Action Item

NVAC will re-constitute the Vaccine Finance Working Group to evaluate the impact of ACA on vaccine financing over time, including how to measure the impact of increased vaccine administration payment for Medicaid providers in 2013 and 2014. In the short term, the group will develop recommendations that address the status of Section 317 appropriations before the next round of Congressional budget negotiations. The recommendations will make the case for maintaining Section 317 funding beyond the full implementation of ACA.

Public Comment

Theresa Wrangham, speaking on her own behalf, said she supported the comments submitted by the National Vaccine Information Center. Every member of her family has experienced an adverse reaction to a vaccine, and she wanted better monitoring of such events. Ms. Wrangham felt that consumers' views have been left out of NVAC's discussions, and although she appreciated the participation of Tawny Buck as NVAC's public member, consumers are not well represented. She said that the stakeholder engagement efforts around the H1N1 pandemic indicated overwhelming concern around choice, but there is little accountability or transparency in the current system. She believes that independent oversight is urgently needed to enhance public confidence in vaccines and postlicensure safety. She questioned the level of public confidence and trust in research, noting that researchers must be free of conflicts of interest, and research findings should be published in journals that are not supported by industry funds. The influence of industry in research has been noted by a Cochrane Collaboration review. There is a wealth of information on the erosion of public trust, Ms. Wrangham continued. Money spent on social marketing will not address the core values of safety. As consumers educate themselves about research and industry influence, they will exercise their right to refuse vaccines because of the lack of transparency and lack of meaningful involvement in decision-making. The growth of vaccine refusal is not an anti-vaccine stance, and you ignore it at the peril of the vaccine program, said Ms. Wrangham. She thanked the VSWG for offering many suggestions that could turn around the public's trust.

Mr. Moody of the National Autism Association said the VICP vaccine court should stay some cases and await further data. NVAC has some jurisdiction on the issue, he said, because it advises the Secretary on public acceptance of immunization. An effective safety net in the form of treatment and compensation is needed, and the lack of such is contributing to vaccine hesitancy and lack of confidence. The National Autism Association has received calls from petitioners without counsel and believes the Department of Justice wants to dismiss cases quickly before further evidence can come in. Petitioners are pressured to come up with new evidence and new claims quickly. There is not enough time to reach an informed decision about causation, and most cases lie in a netherworld of off-Table causation, said Mr. Moody. The Vaccine Injury Table creates a presumption for causation, while conditions that are not on the Table lead to a presumption against causation. Mr. Moody said he appreciated Dr. Evans' clarifying comments, but the science is still developing. The review of the ISO scientific research agenda included a call for comparing vaccinated and unvaccinated children and for evaluation of recent epidemiologic studies showing a link between vaccines and autism. Research is ongoing and takes time, said Mr. Moody, and it costs the VICP nothing to leave cases on hold if necessary to let the science mature so that cases can be resolved. Mr. Moody asked that NVAC recommend a moratorium or stay on forced dismissals of autism cases until the science matures.

Closing Remarks and Adjournment—Guthrie S. Birkhead, M.D., M.P.H.

Dr. Birkhead thanked all those who took part and adjourned the meeting at approximately noon.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Bruce Gellin, M.D., M.P.H.
Executive Secretary
National Vaccine Advisory Committee

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

These minutes will be formally considered by the Committee at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.

Summary of Action Items and Recommendations

Administrative Issues

Action Items

NVAC approved the February 2011 minutes.

NVAC will evaluate the immunization portions of the Department of Health and Human Services (HHS) document *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for Prevention, Care, & Treatment of Viral Hepatitis*.

The NVAC September 2011 meeting agenda will include an overview of the HHS Partnership for Patients and the National Health Care Quality Strategy.

A future NVAC meeting agenda will include the Decade of Vaccines initiative.

Adult Immunization

Recommendation

NVAC endorses the report *Adult Immunization: Complex Challenges and Recommendations for Improvement* with the following changes:

- In Recommendation 3A, include a statement about measuring and assuring quality among providers in all settings.
- Note that the existing infrastructure for vaccinating children can be leveraged to promote community demand for adult vaccination.
- In Recommendation 3, add manufacturers to the list of entities that should play a role in provider education and networks.
- Revise Recommendation 5M to include improved vaccination policies to support immunization.
- Include the Agency for Healthcare Research and Quality as appropriate among the responsible government partners.
- In Recommendation 5C, bolster the case for adult immunization by emphasizing the return on investment and cost-savings of vaccination.
- Add a recommendation to better measure the value of vaccination in comparison with other medical preventive services.
- In describing cost-savings, identify specific program savings where possible.
- Model how Section 317 funding will be affected by implementation of Affordable Care Act (ACA) provisions to determine whether those funds can be shifted to meet other needs.

Action Item

As accountable care organizations gain a foothold, NVAC will consider their relationship to adult immunization issues.

Vaccine Safety Working Group (VSWG)

Action Item

The VSWG will incorporate the following suggestions from NVAC and circulate a revised draft to NVAC members for review in advance of the September 2011 meeting. The VSWG will also survey NVAC members to inform prioritization of the recommendations.

- In addition to adding an executive summary to the report, consider writing a summary for the general public that captures the main ideas in plain language.
- Expand the discussion on the benefits of vaccination.
- Clarify the purpose and goals of the document early in the text. Consider explaining how the report contributes to the goals of the National Vaccine Plan. Consider defining the role of NVAC in improving the vaccine safety system.
- State more clearly that the current system is effective and should be maintained.
- Add a recommendation that the integrity of the current system be maintained with adequate funding to ensure its strong, continued function.

Recommendation 2

- Clarify the intent to create a formal structure to coordinate vaccine safety efforts and highlight the functions that structure should cover without dictating how that happens (e.g., remove references to establishing specific Immunization Safety Task Force subcommittees). Also emphasize the need to define NVAC's role in coordination. Coordination should focus on establishing regular communication in the absence of a crisis.

Recommendation 3

- Emphasize that data security, privacy, and confidentiality must be addressed in any effort to expand access to data.

Recommendation 8

- Include Option 1 only (empower NVAC to be responsible for vaccine safety assurance) and note that NVAC can seek external input, including public and stakeholder input, as needed to ensure that NVAC takes into account various perceptions and competing interests. Consider adding a recommendation that NVAC or another entity, such as the Institute of Medicine (IOM), be charged to undertake a five-year review to assess its progress toward vaccine safety assurance.

2010–2011 Influenza Season and Universal Recommendation

Recommendation

NVAC endorses the report *Evaluation of the First Year of the Universal Influenza Vaccine Recommendation* with the following changes:

- Note the need to better understand current practices among private health care providers who purchase vaccine through the Centers for Disease Control and Prevention (CDC) and to streamline the CDC ordering and distribution process.
- Consider using the term “complementary” instead of “nontraditional” to describe providers outside of medical settings.
- Recommend that resources should be made available to monitor the impact of influenza vaccination annually.
- Strengthen the recommendation to continue communication and outreach efforts.
- Replace the recommendation regarding manufacturers with the following: Manufacturers should plan to meet the increased demand as we move toward universal vaccine coverage.

HHS Health Disparities Action Plan

Action Items

National Vaccine Program Office (NVPO) staff will provide NVAC with more information on the effort by the National Institutes of Health to bring together various Federal departments around health disparities research.

NVAC will provide the Office of Minority Health (OMH) with recommendations made over the past several years relating to health disparities. If requested, NVAC will present to the Health Disparities Council about efforts to address vaccination disparities.

OMH will evaluate immunization disparities among undocumented immigrants and report its findings to NVPO.

Vaccine Financing

Action Items

NVAC will submit comments to the Centers for Medicare and Medicaid Services (CMS) supporting the proposal to offer influenza vaccination to all Medicare patients (as part of the public comment process).

NVAC will re-constitute the Vaccine Finance Working Group to evaluate the impact of ACA on vaccine financing over time, including how to measure the impact of increased vaccine administration payment for Medicaid providers in 2013 and 2014. In the short term, the group will develop recommendations that address the status of Section 317 appropriations before the next round of Congressional budget negotiations. The recommendations will make the case for maintaining Section 317 funding beyond the full implementation of ACA.