

**The National Vaccine Program  
2008 State of the Program Report  
February 2009**

**The National Vaccine Advisory Committee**

***Executive Summary:***

This report by the National Vaccine Advisory Committee (NVAC) describes the state of the National Vaccine Program (NVP) and recommends key steps for the NVP to address, on the 22<sup>nd</sup> anniversary of its establishment, to better achieve the promise of its broad statutory charge (see Appendix I).

The NVP was created as part of the National Childhood Vaccine Injury Act of 1986 (P.L. 99-660), which directs it to “coordinate and provide direction” to all federal activities related to vaccines and immunization programs. The NVP is housed within the U.S. Department of Health and Human Services (HHS), and is directed by the Assistant Secretary for Health (ASH). The National Vaccine Program Office (NVPO) manages the NVP on behalf of the ASH. The NVAC advises and makes recommendations to the ASH regarding the work of the NVP and assures input from a broad range of stakeholders including, but not limited to, federal, state and local health agencies, vaccine manufacturers and distributors, health care providers, employers and insurers, and consumers. The federal agencies with liaison members on the NVAC include the Public Health Service agencies in HHS, as well as the Department of Defense (DoD), the US Agency for International Development (USAID) and the Veterans Administration (VA).

In many ways, the state of the national vaccine enterprise in 2008 is strong. The recent period has seen an unprecedented number of new vaccines licensed and recommended for routine use in children, adolescents and adults. Immunization coverage levels in children for the vaccines recommended for routine use before 2000 are at historic high levels and morbidity and mortality from the diseases they prevent are low. New vaccines are under development for the future.

However, vaccination efforts face a number of significant challenges that threaten both future progress and current accomplishments. Three of the most pressing challenges include difficulties in financing the delivery of new vaccines, the failure to realize the promise of immunization of adults, and parental concerns about vaccine safety which may limit access to the newer vaccines and may threaten coverage levels of older vaccines. Federal efforts have suffered from a lack of coordination and oversight of vaccine-related activities, highlighted most recently by the need for the Secretary of HHS to empanel a special interagency vaccine safety working group to better address this growing concern. In addition to specifically addressing each of these challenges and others outlined in this report, NVPO is undertaking the critical step of developing the first update of the National Vaccine Plan in over a decade. This Plan will provide the blueprint to achieve five key goals: developing new and improved vaccines; enhancing the safety of vaccines and vaccination practices; supporting informed vaccine decision-making by the public, providers, and policy-makers; ensuring a stable supply of recommended vaccines, and achieving better use of existing vaccines to prevent disease,

disability and death in the United States; and increasing global prevention of death and disease through safe and effective vaccination.

To assure that the National Vaccine Program (NVP) can fully and effectively meet its statutory charge to coordinate and direct the US vaccine enterprise, the NVAC recommends that:

1. The NVP should be given the resources and effective organizational authority within HHS necessary to carry out its mission to coordinate and direct the vaccine-related efforts of the federal PHS agencies. Having the NVP report directly to the Secretary of HHS would achieve the needed organizational authority.
2. The National Vaccine Plan should specifically address how the NVP will improve its effectiveness.
3. The NVP should be evaluated regularly and its effectiveness reviewed as part of each revision of the National Vaccine Plan.
4. The NVPO should improve the effectiveness of the NVAC based on the recommendations of the pending NVAC evaluation report.

## ***Immunizations: A public health success story***

Immunizations are among the most successful public health interventions ever employed and are a major tool to prevent communicable diseases. The use of vaccines to prevent disease has expanded greatly, from seven routinely recommended vaccines for children and adolescents when the NVP was formed in 1986 to 16 in 2008 (Table 1). As shown in Table 2, vaccines targeting 10 communicable diseases (smallpox, diphtheria, measles, mumps, pertussis, paralytic polio, rubella and congenital rubella syndrome, tetanus, and *Haemophilus influenzae* type b invasive disease) have resulted in significant declines in disease morbidity from the pre-vaccine era. For vaccine-preventable diseases with more recently recommended vaccines, such as varicella (1), invasive pneumococcal disease (2) and hepatitis A (3), morbidity decreases though not as dramatic, have been seen. Preliminary data indicate similar decreases for rotavirus and meningococcal disease.

For each US birth cohort vaccinated with the 7 vaccines (diphtheria, tetanus and acellular pertussis (DTaP), tetanus and diphtheria (Td), *Haemophilus influenzae* type b (Hib), polio, measles, mumps and rubella (MMR), hepatitis B, and varicella) in the recommended childhood immunization schedule prior to 2000, it is estimated that 14 million cases of disease are prevented and 33,000 lives are saved over the lifespan of the birth cohort. These reductions in morbidity and mortality result in \$9.9 billion savings in direct health care costs and \$33.4 billion saving to society in indirect costs for each birth cohort. For every dollar spent to vaccinate children, there are savings of more than \$5 in medical costs and more than \$16 in societal costs (4).

Immunizations are unique among public health prevention methods in having the potential for a health benefit beyond the individual persons receiving them. This is due to the impact of “community immunity”, the phenomenon where high levels of vaccination coverage in a population interrupt disease transmission and protect those who are unimmunized, who cannot be immunized because of immunosuppression, or those in whom immunization did not result in protective immunity. This principle makes it critical to maintain high vaccine coverage levels to achieve population-wide protection from disease. Immunizations may also protect populations other than those immunized if the vaccinated population serves as a primary reservoir or transmission source of infection. This has been seen with routine pneumococcal conjugate vaccination of young children resulting in decreased pneumococcal disease in older age groups specifically due to the pneumococcal serotypes contained in the vaccine (Figure 1)(5).

Vaccine coverage in the U.S. for routinely recommended childhood vaccines is currently at a record high level (Table 3), reflecting the combined efforts of physicians and allied health care providers, insurers and other payors, government, pharmaceutical manufacturers, and parents. State immunization requirements for school entrance are a very important tool for assuring high coverage levels of childhood vaccinations (6). Vaccine coverage levels for routinely recommended adolescent and adult vaccines are much lower. A comparison of these rates is shown in the Table 3.

There are currently 17 diseases against which very safe and effective vaccines are recommended for routine use in selected populations in the U.S. Since 2000, six new vaccines

have been licensed and eight new national recommendations have been established for routine use of vaccines in children and adolescents. Two new vaccines have been routinely recommended for adults. This speaks to the vitality of new vaccine development and of the system of incorporating vaccines into the routine immunization schedule. In addition, vaccines are now being introduced that prevent not only acute diseases (e.g., rotavirus, meningococcal disease), but also chronic diseases (e.g., liver cirrhosis and cancer, cervical cancer), opening up new possibilities for disease prevention.

### ***Immunizations: New and continuing challenges***

While there is much promising news regarding vaccinations in the United States, these successes require constant attention and vigilance to be maintained and to form the basis for future expansion.

Recent outbreaks of measles, mumps and pertussis have highlighted the need to maintain high vaccination coverage levels. In particular, localized groups who reject vaccination pose a challenge to achieving population-wide immunity needed to prevent disease through community immunity, also known as herd immunity. Outbreaks of measles in 2008 occurred in children whose parents had declined vaccination (7). Similarly, Minnesota recently reported a resurgence of invasive Hib disease with five cases, three of which were in children who had been purposefully not vaccinated; one child died. A shortage of Hib vaccine also may have contributed to lower coverage levels and decreased community immunity (8). Although vaccination coverage is high in the wider community, improvement is needed to assure community protection in the event of disease introduction.

The system of vaccine financing and delivery is threatened by the growing complexity and high cost of the vaccine schedule, as well as by the increasing number of uninsured and underinsured Americans.

While vaccines are a safe and effective way to prevent disease, their use is not totally risk-free. Vaccine safety has become a major concern among some parents. The occurrence of adverse events, even though the most severe are quite rare, draws attention in part because of the lack of awareness of the severity of the diseases the vaccines prevent. In addition, some parents may attribute adverse events to vaccines where there are little or no data to support those concerns.

Historically, the focus of immunization programs was childhood vaccination. However, the use of vaccines across the lifespan should be a key component of maintaining health in all phases of life. Recently, a number of vaccines have been approved and recommended for use in adolescent and adult populations. The uptake of these vaccines has not approached levels for childhood vaccines.

The NVAC has addressed these issues in some cases by forming working groups and in others by extended discussion at NVAC meetings. Status reports for these activities as well as the NVAC's 2008 annual assessment, called for in section 2105 of PHSA Title XXI, of the most

important areas of government and non-government cooperation that should be considered in implementing sections 2102 and 2103 of the Act are summarized in Appendix 2.

### ***Roles and Status of the National Vaccine Program and National Vaccine Advisory Committee***

The immunization enterprise is complex and involves the interaction of many governmental and non-governmental partners. For example, agencies such as the National Institutes of Health (NIH), Department of Defense (DoD), and the Department of Homeland Security (DHS) are involved in basic biomedical research and contribute to vaccine development in conjunction with private pharmaceutical manufacturers. The Food and Drug Administration (FDA) licenses vaccines and monitors vaccine production as well as safety and efficacy post licensure. Pharmaceutical companies manufacture vaccines and retain accountability for the supply of safe and effective vaccines. The Centers for Disease Control and Prevention (CDC) monitors vaccine-preventable disease morbidity, promulgates vaccination recommendations, funds the purchase of vaccines through the Vaccines for Children program (VFC) and supports state and local health departments to carry out immunization programs. CDC also is responsible, along with FDA, in monitoring and researching vaccine safety. Non-governmental partners such as professional medical associations (e.g., AAP, AAFP, AMA) participate in the formulation of vaccine policy and educate their members and members of the public. Employers and health insurers determine insurance coverage for vaccinations. Parents ultimately decide if their children receive vaccines.

The NVP and its advisory committee, NVAC, are charged with the coordination and oversight of this complex system of developing, producing, delivering and monitoring the nation's vaccines, vaccination programs and vaccine-preventable diseases. This involves not only the coordination of the activities of federal agencies, but also facilitating the interaction of governmental and non-governmental organizations and the obtaining of stakeholder input. In addition, the NVP has the authority to make available supplemental funds as appropriated for the other federal agencies. In short, the NVP is the central coordinating body for vaccination programs and policy in the United States.

The broad statutory authority described for the NVP gives the Program a unique position to ensure that Americans have access to widely available, safe, and effective vaccines to reduce the burden of infectious diseases. However, these broad responsibilities require the authority and resources to ensure they are appropriately accomplished. There are several indications that the current authority and resources of the NVP are not sufficient and that it is not carrying out its full functions as envisioned in Title XXI. For example, the National Vaccine Plan called for in statute has not been updated in more than a decade; the effectiveness of the NVAC, and by extension the NVP, has never been evaluated; concerns of some parents about vaccine safety have progressed to a near-crisis level in some groups without a fully coordinated response from the medical and public health communities to date; public and private sector financing for vaccines and vaccine delivery have been the subject of multiple sets or recommendations over the past decade with little evidence of a response and mounting concerns that these issues will become a barrier to access to new vaccines; the ASH currently does not have authority over the PHS Agencies programs and budgets as was the case in the past. While an update of the National Vaccine Plan and an evaluation of the NVAC are now underway, it can be argued that

these steps are long overdue and the effectiveness of the vaccine enterprise has been threatened by delay. Recently, the Secretary of HHS found it necessary to convene a separate interagency taskforce on vaccine safety to develop a coordinated federal response plan, not relying on the existing framework for coordination provided by the NVPO and the NVAC. A new set of vaccine finance recommendations have been issued by NVAC, but given past history, it is not clear that these recommendations, or others by the NVP, will be effectively implemented.

### ***Conclusions and Recommendations***

Over the course of its regular meetings in 2008, the NVAC revisited its charge and that of the NVP to assess the degree to which they have been met. Although a number of reports have been issued and a number of forward looking activities are underway, such as those detailed in Appendix 2, NVAC believes that optimal coordination of federal vaccine efforts has not been achieved. This is due to the complexity of the task, the lack of resources for the NVP, and to NVP's organizational placement within HHS which separates it from the line of authority to the primary Public Health Service agencies (e.g. CDC, FDA, NIH, CMS, HRSA) that are responsible for the main elements of the federal vaccine enterprise. NVAC concludes that effective coordination of federal vaccine efforts will not be fully realized until adequate resources are made available for coordination and organizational changes are made to assure the authority of the NVP can be fully exercised. This NVAC review of its and the NVP's charges and the arrival of a new federal administration, make this an opportune time to make needed changes.

To assure that the National Vaccine Program (NVP) can fully and effectively meet its statutory charge to coordinate and direct the US vaccine enterprise, the NVAC recommends that:

1. The NVP should be given the resources and effective organizational authority within HHS necessary to carry out its mission to coordinate and direct the vaccine-related efforts of the federal PHS agencies. Having the NVP report to the Secretary of HHS would achieve the needed organizational authority.
2. The National Vaccine Plan should specifically address how the NVP will improve its effectiveness.
3. The NVP should be evaluated regularly and its effectiveness reviewed as part of each revision of the National Vaccine Plan.
4. The NVPO should improve the effectiveness of the NVAC based on the recommendations of the pending NVAC evaluation report.

Specific operational recommendations to help achieve better coordination of federal vaccine efforts should include, but not be limited to, the following:

1. On an ongoing and routine basis, vaccination-related initiatives, regulatory amendments, etc., under consideration by other Federal agencies or advisory committees, should be brought to the

attention of the NVPO to ensure that appropriate oversight by the NVP and input by the NVAC can be given.

2. Acknowledging the broad reach of NVAC recommendations, many of which require legislative action to enact, the NVAC should work more closely with the NVP, to ensure that its recommendations are appropriately considered and addressed.
3. The fundamental role of the NVAC to assure inclusive, meaningful and ongoing input from a broad array of stakeholders, including the public, into the development of vaccine policy should be reinforced and more effective ways to achieve this input should be undertaken.

## REFERENCES

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## TABLES AND FIGURES

Table 1. Vaccines recommended for routine use in children and adolescents in the United States, 1986, 1998 and 2008.

<b>Infections preventable by recommended vaccines</b>		
<b>1986</b>	<b>1998</b>	<b>2008</b>
Diphtheria	Diphtheria	Diphtheria
Tetanus	Tetanus	Tetanus
Pertussis	Pertussis	Pertussis
Measles	Measles	Measles
Mumps	Mumps	Mumps
Rubella	Rubella	Rubella
Polio	Polio	Polio
Hepatitis B	Hepatitis B	Hepatitis B
	<i>Haemophilus influenzae</i> type b	<i>Haemophilus influenzae</i> type b
	Varicella	Varicella
		<i>Streptococcus pneumoniae</i>
		Rotavirus
		Hepatitis A
		<i>Neisseria meningitidis</i>
		Human papillomavirus
		Influenza

Source: Advisory Committee on Immunization Practices. Recommended Immunization Schedule for Persons 0-6 Years—United States, 2008 and Recommended Immunization Schedule for Persons Aged 7-18 Years—United States 2008. Available at <http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable>.

Table 2. Annual morbidity in the 20<sup>th</sup> century pre-vaccine era and morbidity in 2007 due to selected vaccine-preventable diseases, United States.

Disease	Annual morbidity, pre-vaccine era	2007 reported cases	Percent decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Polio (paralytic)	16,316	0	100%
Congenital Rubella Syndrome	152	0	100%
Measles	530,217	43	>99%
Mumps	162,344	800	>99%
Rubella	47,745	12	>99%
<i>H. influenzae</i> type b	20,000	202	99%
Pertussis	200,752	10,454	95%
Tetanus	580	28	95%

Source: Adapted from Schuchat A. Current status of immunization in the United States. Presentation given at the 2008 annual meeting of the American Public Health Association, San Diego, CA, October 2008.

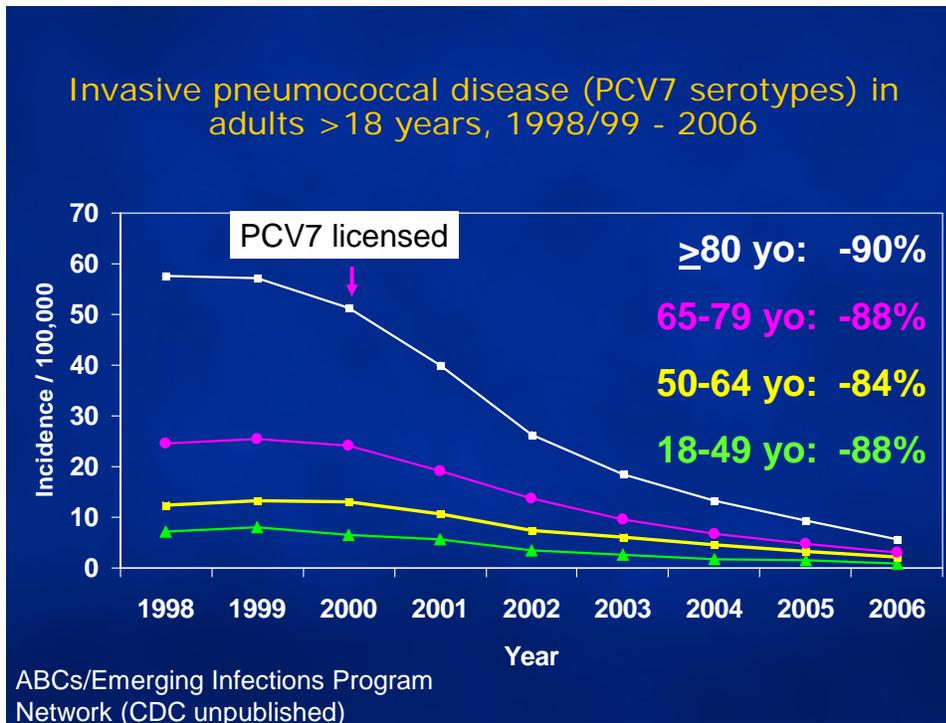
Table 3. Immunization coverage levels for routinely recommended childhood, adolescent and adult vaccines.

Recommended group	Vaccine	Year	Vaccine Coverage
Children	Diphtheria, tetanus, pertussis (DTP)	2006	85%
Children	Polio	2006	93%
Children	Measles, mumps, rubella (MMR)	2006	92%
Children	Haemophilus influenzae type b (Hib)	2006	93%
Children	Hepatitis B	2006	93%
Children	Varicella (chickenpox)	2006	89%
Children	Combined series (4+ DTP, 3+ polio, 1+ MMR, 3+ Hib)	2006	77%
Adolescents	Quadrivalent meningococcal conjugate (MCV4)	2007	32%
Adolescents	Tetanus, diphtheria, acellular pertussis (Tdap)	2007	30%
Adolescent females	Human papillomavirus (HPV)	2007	25%
Adults	Influenza	2007	69%
Adults	23-valent pneumococcal polysaccharide (PPV23)	2007	66%
Adults	Tetanus, diphtheria (Td)	2007	44%
Adults	Herpes zoster (shingles)	2007	2%

Source for childhood vaccination rates: <http://www.cdc.gov/nchs/fastats/immunize.htm>

Source for adolescent and adult vaccination rates: Schuchat A. Current status of immunization in the United States. Presentation given at the 2008 annual meeting of the American Public Health Association, San Diego, CA, October 2008.

Figure 1. Effect of community immunity, also known as herd immunity, illustrated by decreases in pneumococcal disease in adults following vaccination of infants with pneumococcal conjugate vaccine.



## **Appendix 1. Statutory charge to the National Vaccine Program and National Vaccine Advisory Committee**

The National Vaccine Program (NVP), National Vaccine Program Office (NVPO), and National Vaccine Advisory Committee (NVAC) were created in 1986 as part of the National Childhood Vaccine Injury Act of 1986. The relevant Federal statutes governing these entities are found in 42 USC 300aa-1 – 300aa-6, which correspond to Title XXI of the Public Health Service Act (P.L. 99-660), sections 2101-2106. Section 2104 was repealed as part of the Federal Reports Elimination Act of 1998 (P.L. 105-362).

### *Roles and responsibilities of the NVP and the NVAC*

The Director of the NVP is the Assistant Secretary for Health, United States Department of Health and Human Services (DHHS). As outlined in Section 2102 of Title XXI of the Public Health Service Act, there are nine responsibilities assigned to the Director of the NVP:

- (a) Vaccine research – coordinate and provide direction for research carried out in or through the National Institutes of Health (NIH), the Centers for Disease Control (CDC), the Office of Biologics Research and Review of the Food and Drug Administration (OBRR), the Department of Defense (DoD), and the Agency for International Development (AID) on means to introduce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.
- (b) Vaccine development – coordinate and provide direction for activities carried out in or through the NIH, OBRR, DoD, and AID to develop the techniques needed to produce safe and effective vaccines.
- (c) Safety and efficacy testing of vaccines – coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the NIH, CDC, OBRR, DoD and AID.
- (d) Licensing of vaccine manufacturers and vaccines – coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.
- (e) Production and procurement of vaccines – ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, DoD, and AID meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.
- (f) Distribution and use of vaccines – coordinate and provide direction to the CDC and assistance to the States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and make health practitioners and the public aware of potential adverse reactions and contradictions to vaccines.
- (g) Evaluating the need for, and the effectiveness, adverse effects of vaccines and immunization activities – coordinate and provide direction to the NIH, CDC, OBRR, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effective and adverse effects of vaccines and immunization activities.

- (h) Coordinating governmental and non-governmental activities – provide for the exchange of information between Federal agencies involved in the implementation of the Program and the non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental funding activities under the Program.
- (i) Funding of Federal agencies – shall make available to Federal agencies funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the Plan.

The NVAC provides recommendations to the Director of the NVP within four defined responsibility areas. As outlined in Section 2105 of Title XXI of the Public Health Service Act, NVAC shall:

- (a) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States
- (b) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines
- (c) advise the Director of the Program in the implementation of sections 2102 and 2103 of Title XXI of the Public Health Service Act
- (d) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102 and 2103 of Title XXI of the Public Health Service Act.

## **Appendix 2. Recent NVPO/NVAC Activities**

### ***I. NVAC 2008 assessment pursuant to Section 2105 of PHS Act Title XXI, of the most important areas of government and non-government cooperation that should be considered in implementing sections 2102 and 2103 of the Act***

Government and non-government cooperation is critical to the US vaccine enterprise. Maintaining robust and ongoing, multi-way communication is key to assuring that issues are identified and dealt with in a timely and comprehensive fashion. NVAC has traditionally served the role of assuring stakeholder input by the makeup of its membership and the content of its agenda. In 2008, the NVAC and the NVP undertook a number of steps to improve stakeholder input and communication.

In September 2008, the NVAC approved a series of vaccine finance recommendations that had been developed over the course of two years. During this period, wide-reaching stakeholder input was solicited, including representation by stakeholder groups on the Vaccine Finance Working Group. This effort was unprecedented. The Working Group included not only NVAC members from traditional stakeholder groups such as health care providers, vaccine manufacturers and health insurers, but also by consumers, state and local public health departments, employers, and state legislatures and Medicaid agencies. Through these efforts, consensus was reached by all parties on the content of the vaccine finance recommendations, which may ultimately aid in their implementation, as the key players have already come to an agreement. It is hoped that this model of governmental and non-governmental cooperation will serve as an example for future NVP endeavors.

A second major effort to improve stakeholder input as part of assuring governmental and non-governmental cooperation will take place in the upcoming year with regard to vaccine safety. A Vaccine Safety Working Group (VSWG) has been formed by NVP to review the CDC Immunization Safety Office Scientific Agenda, while engaging citizens and stakeholder groups to review the agenda. As part of this review process, three public engagement meetings are being held around the US as well as a two-day stakeholder engagement meeting. Additionally, a meeting of the VSWG to discuss the Scientific Agenda was open to the public.

In a similar way, the update of the National Vaccine Plan is being led by efforts from the NVPO and NVAC, with a series of public and stakeholder engagement sessions being hosted by the Institute of Medicine. The input gained from these meetings will be incorporated into the developing National Vaccine Plan, helping it to become a truly national plan, rather than a Federal plan.

Finally, outreach to manufacturers has also been a recent advance in governmental/non-governmental cooperation. As part of the vaccine finance recommendation development, vaccine manufacturers were included in the discussions. Additionally, the NVPO has been holding periodic meetings with vaccine manufacturers in an effort to dialogue with industry on various issues and to get a sense of what vaccines are currently under development.

## ***II. Update to the National Vaccine Plan***

### **Overview**

The National Vaccine Plan was first published in 1994, with no subsequent updates. Given the increase in the number of vaccines newly available since 1994, and issues related to vaccination (e.g., vaccine financing, safety, and supply), a revised Plan is critical to sustaining the successes we have had in the use of vaccinations to prevent disease.

### **Current Actions**

The NVPO has submitted a first draft of the updated National Vaccine Plan to the Institute of Medicine (IOM) and has circulated it for comment. The NVAC is playing a key role in the process. Actions assigned to the NVAC for this process include providing comments on the draft HHS plan, providing comments to the IOM on their Review of Priorities in the National Vaccine Plan, coordinating and participating in public engagement sessions to identify relevant public input on the update of the National Vaccine Plan, and providing comments on the revised recommendations from the IOM.

The current draft of the National Vaccine Plan is at:

[http://www.dhhs.gov/nvpo/vacc\\_plan/2008plan/draftvaccineplan.pdf](http://www.dhhs.gov/nvpo/vacc_plan/2008plan/draftvaccineplan.pdf)

The IOM home page for their review of the National Vaccine Plan is at:

<http://www.iom.edu/CMS/3793/51325.aspx>

### **Future Steps**

Public engagement meetings to solicit input on the National Vaccine Plan are scheduled for early 2009, with an anticipated delivery of a final report with the revised recommendations from the IOM scheduled to be delivered to the NVP by the end of 2009.

## ***III. Vaccine Finance Report: Assuring Vaccination of Children and Adolescents without Financial Barriers: Recommendations from the National Vaccine Advisory Committee (NVAC). September, 2008***

### **Overview**

Vaccines, like all other components of the health care system, are subject to issues related to access to, and payment for, health care services. Childhood vaccines are particularly impacted by these issues due to the mandates in place for up-to-date vaccination required for school entry. While there are programs in place to help provide access to vaccines, such as the Immunization Grant Program/Section 317 and the VFC Program, there are still limitations in providing all children with necessary immunizations.

### **Current Actions**

To address these limitations, the NVAC convened a Vaccine Finance Working Group (VFWG). Over the course of two years, the VFWG developed a white paper entitled “Assuring vaccination of children and adolescents without financial barriers:

Recommendations from the National Vaccine Advisory Committee” that contained a detailed overview of the issues we face when addressing the financing of vaccines, along with 24 recommendations that were voted on and approved at the September 2008 NVAC meeting. A key feature of these recommendations is the broad stakeholder input and consensus that was obtained during their creation, including input and consensus from the pharmaceutical industry, consumer advocates, health insurers and employers, health care providers, state public health agencies, state legislatures and Medicaid agencies and the National Vaccine Program.

The final report is posted at:

<http://www.hhs.gov/nvpo/nvac/CAVFRRecommendationsSept08.html>

### **Future Steps**

These recommendations have been sent to the ASH for approval and transmittal to the Secretary of HHS, with the intention that they be enacted through appropriate legislation to ensure that financial barriers to immunization are removed. An implementation plan for these recommendations will be developed by the NVAC.

## ***IV. Vaccine Safety***

### **Overview**

Vaccine safety is a topic that has received widespread attention both in the scientific community and the public at large. To address this large and complex issue, the NVAC organized a Vaccine Safety Working Group (VSWG). The first meeting of the VSWG was held in April 2008, and included presentations by the working group as well as invited speakers, and was also a forum for a wide range of public comment regarding vaccine safety issues.

### **Current Actions**

The NVAC has been charged with reviewing the proposed scientific agenda for the CDC Immunization Safety Office (ISO). This document was generated in response to a 2005 IOM report that recommended organizing a five-year immunization safety research plan at ISO. Within the VSWG there are four sub-groups, each addressing specific components of the ISO Scientific Agenda. The VSWG, and its subgroups, are in the process of developing formal recommendations to the ISO, a draft of which is expected to be presented to the full NVAC at the February 2009 NVAC meeting. In addition to reviewing the ISO Scientific Agenda, the VSWG is working to review the current federal vaccine safety system and to develop a white paper describing the infrastructure necessary for this system to assess vaccine safety in a timely manner, reduce adverse events following immunization, and improve and maintain public confidence in vaccine safety.

The NVAC VSWG web site is: <http://www.hhs.gov/nvpo/nvac/vaccinesafety.html>

### **Future Steps**

A draft of the NVAC recommendations regarding the ISO Scientific Agenda is expected to be completed and ready for review by the February 2009 NVAC meeting. Following review, it is hoped that the recommendations will be finalized and ready for voting by the full NVAC at the June 2009 NVAC meeting. An NVAC white paper describing the state of vaccine safety and efforts to address vaccine safety issues will be written.

## ***V. Report: Adolescent Immunization***

### **Overview**

Immunization of adolescents faces a unique series of challenges. New and evolving vaccines targeted for adolescents have recently been approved, and concerted efforts need to be made to encourage their uptake by adolescents. This is made more difficult because adolescents rarely have regularly scheduled medical appointments similar to “well child” visits for infants and toddlers.

### **Current Actions**

Following a 2004 meeting entitled “Strengthening the Delivery of New Vaccines to Adolescents: A National Stakeholders Meeting”, the NVAC convened an Adolescent Immunization Working Group. This working group developed a report on “The Promise and Challenge of Adolescent Immunization” and developed a series of recommendations addressing adolescent immunization that were approved by the full NVAC at the June 2008 meeting. This report and these recommendations have been published in the American Journal of Preventive Medicine.

The NVAC report on Adolescent Immunization is found at  
<http://www.hhs.gov/nvpo/nvac/documents/AdolescentVaccinationRecommend.pdf>

### **Future Steps**

An implementation plan for the Adolescent Immunization Working Group recommendations is under development, and a first draft was presented at the September 2008 NVAC meeting.

## ***VI. Immunization Information Systems***

### **Overview**

The NVAC produced and approved the report “Development of Community- and State-Based Immunization Registries” in January 1999. The original scope of these registries was to serve as “confidential, computerized information systems that contain information about immunizations and children”

(<http://www.cdc.gov/vaccines/programs/iis/pubs/nvac.htm>). In the intervening years, much progress has been made in developing, implementing and encouraging the use of Immunization Information Systems (IIS), the current preferred term for immunization registries. In addition to documenting the immunization history of children, IIS are also

being used to track immunizations delivered to adults, with the hope they will serve as a “cradle-to-grave” record of immunizations.

### **Current Actions**

Reports tracing the progress of IIS development have been developed and approved by the NVAC. Most recently, a series of recommendations to encourage participation in IIS were developed and approved by the NVAC at the September 2008 NVAC meeting.

### **Future Steps**

An implementation plan for the recently approved recommendations will be developed to ensure prompt and complete follow-up to strengthen the use of IIS.

## ***VII. Adult Immunization***

### **Overview**

Recent advances in vaccine development, licensure, and usage recommendations for adults (e.g., vaccines for herpes zoster, influenza, invasive pneumococcal disease) highlight the need for focused disease-prevention efforts in adults.

### **Current Actions**

The NVAC has formed an Adult Immunization Working Group to identify and make recommendations regarding adult immunization. This working group is currently examining all issues related to adult immunization to identify areas in which improvements need to be made. Its specific mission is "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."

### **Future Steps**

The Adult Immunization Working Group will develop a white paper outlining the challenges and problems associated with adult immunization within HHS, and will develop recommendations to be approved by the NVAC.

## ***VIII. Vaccine Development and Supply***

### **Overview**

Vaccine innovation is challenging and the issues associated with bringing a vaccine to market, encouraging uptake of the vaccine, and ensuring appropriate payment for a vaccine are complex. A single approach to innovation of new vaccines may not work as there are distinctly different markets with different factors that influence the success of any particular vaccine.

Vaccine supply has been a critical issue as of late, with shortages observed with influenza, rabies, and hepatitis B vaccines, among others. These supply problems come

about from a combination of issues, including a diminished number of vaccine manufacturers, occurrences of manufacturing-related issues (e.g., contamination), and unanticipated increases in demand for certain vaccines.

### **Current Actions**

Two reports addressing vaccine development and supply have been produced and approved by the NVAC - “Strengthening the supply of routinely administered vaccines”, (<http://www.hhs.gov/nvpo/bulletins/nvac-vsr.pdf>), which was approved in 2003, and “Dose optimization strategies for vaccines: The role of adjuvants and new technologies” (to be posted at <http://www.hhs.gov/nvpo/nvac/reports.html>) which was approved in 2008.

The drivers behind vaccine development are currently being examined to determine the best ways to encourage development of new vaccines and better versions of existing vaccines. NVPO staff sit on the CDC supply working group to inform HHS and NVAC on supply issues and steps being taken to mitigate supply disruptions. The NVAC is also receiving information from the CDC regarding vaccine stockpile plans so that comment and recommendations regarding these plans can be made.

The National Vaccine Plan will address a wide range of issues related to vaccine innovation including balancing the risks of development with the rewards for innovation. There have also been on-going discussions between the NVPO and large and small vaccine and biotechnology companies involved in vaccine development regarding vaccine innovations and identifying the drivers of vaccine development. NVAC will be discussing approaches to addressing challenges in vaccine innovation for vaccines with limited markets.

### **Future Steps**

The NVAC will continue to receive information from CDC regarding vaccine stockpile plans, and will encourage discussion and comment regarding these plans. Vaccine development is addressed in the draft National Vaccine Plan that the NVAC is reviewing, and continued comment will be provided on this topic.