Comments received by the National Vaccine Program Office from Health Professional Organizations on the draft strategic National Vaccine Plan through January 30, 2009.

General Comments

American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

The AAP agrees that the five broad goals of the 2008 draft of the National Vaccine Strategic Plan are appropriate. Building on the goals of the 1994 Plan, they provide the framework on which to address relevant issues related to: eliminating barriers to universal access to currently licensed vaccines in the US; improving distribution and delivery of currently available vaccines; eliminating disparities in vaccine delivery; assuring a constant, dependable vaccine supply; eliminating shortages; promoting new vaccine development and improvement of existing vaccines; vaccine safety and identification of host factors and biological mechanisms for adverse events following immunization; education of the public, providers and policy makers; enhancing communication with parents, including risk benefit communication; and developing measures to improve the public's understanding of the risks of natural infection vs. the benefits of immunization and to increase public confidence in the immunization program. The plan also appropriately includes domestic and global components. Making current vaccines available globally with the establishment of infrastructure for distribution and delivery, as well as supporting research for the development of vaccines to prevent those infectious diseases with a significant impact on global health are important components of the Plan.

- Setting goals requires quality improvement cycles of data collection and change. Data collection, processing, and evaluation are just as essential to the immunization system as vaccine administration. The totality of this strategic plan would require enormous commitment of new resources. It is important to insure that as many people as possible are appropriately immunized and that the system has the necessary resources for quality improvement

- How the National Vaccine Program Office (NVPO) should/would/could prioritize these goals in tight economic times with limited resources is unclear.

- The use of technology to enhance achievement of these goals could be better articulated.

- Does this plan adequately address how various credibility and Conflict of Interests issues will be managed?

- Many of the indicators listed in Table 1 are likely difficult or impossible to achieve and appear to be unrealistic or artificial (just so something can be measured).

- The AAP supports the strategies as noted under each defined objective. We suggest that the strategies and objectives more appropriately address the indicators in Table 1.

- The Academy encourages further review with all relevant stakeholders to reach consensus to successfully fill in the percentages in Table 1.

American Association of Colleges of Pharmacy (William Lang IV, MPH)

In general, AACP commends the National Vaccine Program Office (NVPO) for updating the 1994 strategic plan and support the draft goals and indicators established in the 2008 draft strategic National Vaccine Plan.

In particular, we are pleased that the plan recognizes the role that community-based vaccinators (including pharmacist), in addition to physicians, can play in increasing immunization rates of all patient populations. Increasing immunization rates was included as a goal of Healthy People 2010 and anticipated to remain an important goal in the development of Healthy People 2020. Colleges and schools of pharmacy provide immunization education and training to students through the professional curriculum and to practicing pharmacists through continuing education. Many of our institutions use the Centers for Disease Control and Prevention (CDC) - approved immunization training program or use the CDC approved program as a template for creating their own program. Educating a healthcare professional with strong communication skills is an important aspect of the professional curriculum in recognition that patients and consumers need assistance in translating information aimed at providing them a greater opportunity to participate in their care.

AACP and its members also appreciate that the plan includes “academia” as a non-federal stakeholder member responsible and capable of assisting the NPVO in achieving the five goals and nearly all the associated objectives. We encourage you to consider including academia as a non-federal stakeholder in meeting all the goal objectives especially those that include evaluation and research elements. Faculty at our nation’s colleges and schools of pharmacy regularly work with a broad range of federal agencies to help them develop, implement, and evaluate patient and consumer communications such as those recommended in this strategic plan. Academic pharmacy is involved with the translation of new knowledge into clinical practice supported by the Agency for Healthcare Research and Quality (AHRQ) DeCIDE network and the National Institutes of Health (NIH) Clinical and Translational Science Awards programs. Our members have worked with the Food and Drug Administration (FDA) to determine the impact of prescription drug labeling on adherence. We recommend that the research agenda that can be constructed from this strategic plan be discussed with appropriate individuals and harmonized with ongoing efforts within AHRQ, FDA, CDC and NIH.

Comments on input requests listed in the Dear Colleague letter:

- Should the plan be fully achievable, aspirational, or a combination of the two?

While the plan is substantial in its scope, given appropriate resources to support the infrastructure necessary to generate the appropriate responses to the goals, through participation of federal and non-federal stakeholders, this plan could be fully achievable. HHS leadership should be engaged and fully committed to the need for appropriate resources to fully accomplish the plan. The five goals are well stated and the associated objectives could be met through current research and infrastructure available to academia. We again recommend the NVPO working with other federal agencies to harmonize research components of the draft plan.

- What recommendations can you offer for the numeric targets for the indicators?

At this time we are not able to assist with addressing the numeric targets. We would recommend that Healthy People 2010 and the National Health and Nutrition Examination Survey, among other federal data resources, be mined to create proxy measures for stakeholder consideration as a starting point.

- Please comment on the overall vaccine and immunization enterprise.

AACP members of the Section of Teachers of Pharmacy Practice indicate that "we have many excellent old and new vaccines, that are generally very safe compared to other products in the pharmaceutical arsenal. It is lack of access to these vaccines, even for those who desire to be vaccinated, that is currently the largest barrier hindering optimal immunization rates. Access problems do include potential lack of an adequate and stable supply of virtually all vaccines (especially if demand reflected the size of the true target populations). However, for most vaccines, the supply is generally sufficient for the current demand."

AACP recommends that the NVPO consider creating federal support for collaborative research initiatives that build upon the knowledge and skills of faculty researchers across professions as one approach for development of new vaccines. This is an approach utilized by the FDA through its support of the National Institute of Pharmaceutical Technology and Education (NIPTE). The development of new vaccines can be a low priority for private industry due to start up costs and low return on investment, especially for vaccines with targeted at a small population. Public private partnerships like NIPTE offer the opportunity for new product and manufacturing approaches to be developed as well as improvements to existing product manufacturing.

How should accountability of non-federal stakeholders that are part of the plan be described?

Accountability would be described after non-federal stakeholders are asked to participate within specific activities related to goal, objective, or strategy attainment. Without agreed to frameworks of participation accountability can neither be described nor evaluated.

American Association of Occupational Health Nurses, Inc. (Richard J. Kowalski, RN, MSA, COHN-S)

The American Association of Occupational Health Nurses, Inc. (AAOHN) is the national association representing the specialty practice of occupational and environmental health nursing, committed to create a positive economic impact through worker health and well being leading to optimal performance. As an organization supportive of population-based health care within a prevention and health promotion framework, AAOHN appreciates the invitation and opportunity to provide input into the draft strategic National Vaccine plan.

Vaccines are not just to protect the individual receiving the vaccination, but society (direct protection of the majority provides indirect protection of others-*herd immunity*). Vaccine-preventable disease levels are at or near record lows and the number of vaccines for preventable diseases have increased. On the flip side, the number of individuals receiving vaccines have declined, possibly related to fear of adverse effects, cost, access to provider, number of vaccines required per site (arm, thigh) or visit, age, etc., and the number of emerging infectious disease exposures and vaccine-preventable disease outbreaks have increased, e.g., measles, mumps, etc. As a global society, exposure to infectious diseases must be considered a significant U.S. as well as a world health issue, e.g., international travel and increase potential for exposure, importation of food, in appropriate use of antibiotics, access to health resources and environmental changes, e.g., hurricanes.

The last Vaccine Plan was developed fifteen years ago (1994). Many of the challenges for disease prevention and vaccine enhancements in 1994 are still relevant today. Success will be influenced by financial factors and non-financial factors, i.e., attitude toward vaccination, vaccine safety and vaccination effectiveness as well as key immunization stakeholders. These key stakeholders should not be limited to federal (CDC, USAID) or international (WHO), but professional organizations and agencies (administrators of vaccines), consumers (recipients of vaccines) and global immunization trends must be considered.

Given the length of the current document and complexity of the objectives, success of the plan will be challenging, but achievable. AAOHN supports the document with the following recommendations**:**

- The plan should be fluid because emerging diseases are constantly changing and/or mutating.
- Confidentiality needs to be maintained due to the perceived implications of genomic and biomarkers personal information misuse.

The goal of the plan is to eradicate, eliminate or control infectious, vaccine preventable diseases. As the primary health care provider for workers, worker populations, employers and community groups, occupational and environmental health nurses (OHNs) are in the unique position to influence the development and implementation of a workplace vaccine plan and workforce vaccine rates. As a member of the health and safety team or as the

workplace licensed health care professional, the OHN facilitates the operation of the annual flu program, administration of required vaccines and meds for travel and other work related requirements, administration of the disaster preparedness plan, health education to influence best health options for workers and their families and prevention of worker exposure, which impacts worker absenteeism and productivity, and community health and economy.

American Association of Respiratory Care (Timothy R. Myers, BS, RRT-NPS)

Respiratory therapists (RTs) serve in a variety of venues and this gives our professional members access to patients and health care professionals in many different types of settings. Some examples include acute care hospitals, hospital outpatient settings, sleep disorder centers and diagnostic laboratories, rehabilitation facilities, skilled nursing facilities, patients' homes, physicians' offices, wellness centers and convalescent and retirement centers.

Given the growing number of individuals with chronic illnesses, the RTs' education, training and expertise in clinical conditions such as asthma, chronic obstructive pulmonary disease (COPD), and lung disease, also makes them uniquely positioned to expand their role into the disease management arena where coordinated care among various health delivery systems and communications about prevention and self-managed care are important aspects of the program.

American Dental Association (John S. Findley, D.D.S.)

Purpose, Perspective, and Scope. Mention is made of emergency preparedness in this plan and other plans. It might be wise to address this subject in more detail, since not all agencies may have easy access to "other HHS strategic plans" or would think of consulting other plans beyond this plan.

American Immunization Registration Association (Cindy Sutliff)

1. The draft plan should include the fact that IIS [Immunization Information Systems] provide the capability to develop and
maintain an accurate and complete consolidated record of an individual's immunizations, and also provide the ability to securely access and exchange those records.
2. Public health must be able to conduct surveillance and assess immunization coverage for at-risk populations. The draft plan should mention that this is a critical capability for public health and that IIS provide this capability.
3. The draft plan often uses the terms IIS and EMR [Electronic Medical Records] in the same sentence in a way that does not distinguish between the roles of these two tools (for example, in section 4.3.2). IIS store and provide population information, aggregating data

about groups, while EMRs are clinical tools used in a provider practice to collect and provide individual patient information. The plan should distinguish between the roles of each when mentioning them together.

The Association for Professionals in Infection Control and Epidemiology (APIC – Christine Nutty, RN, MSN, CIC)

APIC agrees with the purpose of the National Vaccine Plan (NVP) to promote achievement of the National Vaccine Program mission to prevent infectious diseases and reduce adverse reactions to vaccines by providing strategic direction and promoting coordinated implementation by vaccine and immunization enterprise stakeholders. We agree with the value of incorporating a ten-year horizon in order to balance a strategic vision while also allowing for adjustments that will be needed to integrate changing circumstances and new opportunities. We also support promoting accountability and flexibility through an annual monitoring process.

National Association of State Directors of Developmental Disabilities Services (Linda Rolfe, Director, Washington state Division of Developmental Disabilities)

1. While the 5 goals outlined in the strategic plan are broad with a 10 year horizon in mind, we have certain concerns about with administration and buy in from the consumer as new vaccines are developed. We would hope that there would also be an added focus on developing combination vaccines, studying their efficacy and possible synergistic effects and development of herd immunity as we move forward with the strategic plan. There is growing resistance from families to the administration of multiple vaccines especially in infants and children, despite efforts by providers to educate them on its benefits. Mostly the resistance does not appear to be to the vaccine itself but to the number of pokes the child has to endure to receive the multiple vaccines.

Society for Adolescent Medicine (Richard E. Kreipe, MD)

1. GENERAL COMMENTS

This is a clear and comprehensive document that reflects both the priorities and the policy statements of the Society for Adolescent Medicine. We were pleased that adolescent vaccination issues were addressed throughout the document.

Comments on Executive Summary and Introduction:

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

PIDS has some concerns about the Overview of the vaccine and immunization enterprise as shown in Figure 1.

a.) Should the "Develop vaccine recommendations" box have some relationship, either a direct relationship with an indicator arrow to High Vaccination Rates, or indirectly through an arrow from "Develop vaccine recommendations" to Vaccination (adult, adolescent, and childhood) then an arrow to High Vaccinations Rates? As shown, the Figure implies that those making vaccine recommendations have no expected impact on Vaccination rates (or vaccination for that matter).

b.) Similarly, the "Develop vaccine recommendations" box, should have both a forward and backward arrow with the Communication and Education Strategies box. The Communication and Education Strategies box should also have bidirectional arrows to/from Attitudes about Vaccinations, given all the emphasis recently on bidirectional communication between patients/parents and providers (and other stakeholders).

c.) As shown in the Figure, "Development of vaccine recommendations" is a completely separate portion of the vaccine and immunization enterprise. Perhaps this issue, as drawn, is correct and may be part of the continuing issue patients, parents and providers are experiencing (or perceived to be experiencing) with vaccine acceptance and usage in the U.S. If there is meant to be meaningful "feedback" it needs to be shown in the Figure.

Goal 1 Comments: Develop new and improved vaccines

American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

Many of the indicators listed in Table 1 are likely difficult or impossible to achieve and appear to be unrealistic or artificial (just so something can be measured). Specific examples include:

- Getting clinical trials started within 6 months of identifying a need for a vaccine is an unrealistic expectation.
- Developing a certain number of vaccines in a certain number of years. This sounds nice, but is not necessarily scientifically or logistically possible to do.

- The AAP recommends a focus on the development of new technologies for production of influenza vaccine and delivery of influenza vaccine annually to a large segment of the population in a short timeframe. This influenza vaccine delivery prototype could serve as a model for mass immunization campaigns (i.e., pandemic flu; avian flu).

American Association of Colleges of Pharmacy (William Lang IV, MPH)

Academic pharmacy can assist the NVPO with prioritizing the needs for new vaccines since our faculty are involved with this type of analysis for other biomedical entities.

Academic pharmacy and the students they educate form a significant network of community-based healthcare professionals able to conduct surveillance activities that can inform prioritization.

Pharmacy faculty, supported by federal grant funding, already are providing insight into new biomedical interventions. Federal grant funding for vaccine development would garner interest from the academy and may be an approach toward creation of new vaccines that may initially have a low return on investment, thus making the endeavor less favorable to private industry. Federal extra-mural grant funding could also be focused on specific patient populations such as pediatrics and older adults.

Pharmacy faculty are capable and currently engaged in comparative effectiveness research providing a ready research infrastructure for comparing/determining effectiveness and safety of vaccines.

Pharmacy faculty, collaborating across institutions, are currently at work to improve the manufacturing process of pharmaceuticals. This approach of collaborative, interprofessional research should be encouraged and recommended throughout Goal 1 Objective 1.3 and throughout the entirety of the plan.

American Association of Occupational Health Nurses, Inc. (Richard J. Kowalski, RN, MSA, COHN-S)

AAOHN supports public and private, national and global collaboration to leverage communication, education and research on vaccine use, indication, adverse effects, etc. as well as to leverage legislation and financial support. However, vaccine research should investigate other routes of vaccine administration as well as the continued efforts to combine vaccines and decrease the number of associated adverse events. Although genetic testing is a possible alternative to decreasing adverse effects, there are legal and ethical implications.

Research is imperative and should not be limited to just U.S. public and private stakeholders but have a global collaboration and exchange.

With current vaccine fears and biases, continued research is needed to explore host factors related to adverse effects and failures at different stages in life, e.g., infancy, adolescence, pregnancy, elderly, etc. as well as those associated with workplace exposures, genomic characteristics and/or biomarkers immune responses/indicators.

American Nurses Association (Linda J. Stierle, MSN, RN, NEA-BC and Rebecca M. Patton, MSN, RN, CNOR)

Strategy 1.5.1 (Page 30) – HHS should consider broadening this expansion of research to study genetic variances in immunological response based on ethnicity and race.

National Association of State Directors of Developmental Disabilities Services (Linda Rolfe, Director, Washington state Division of Developmental Disabilities)

As we move forward with developing new vaccines – the burden of disease has to be factored in to the equation. Some diseases although debilitating affect only a very small segment of society

In our enthusiasm to develop new vaccines , the existing vaccines should not be forgotten. These vaccines have to be studied for new ways of delivery, effects on recall of immune memory and efforts should be made continuously to retain immunogenicity in the vaccinated population and they nor we should be lulled into a false sense of life time immunity.

Although vaccines have made major contributions on the world stage in terms of reducing disease burden and mortality, resistant organisms are a constantly evolving threat and development of more synthetic vaccines has to be explored aggressively.

This process may reduce manufacturing time as well decrease the costs of vaccines, thereby ensuring affordability.

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

[Priorities:]

Continue development of new vaccines, including *S. aureus*, HIV, hepatitis C, CMV, RSV, parainfluenza, and improved vaccines for influenza (including avian strains)

Development of an effective malaria vaccine

Development of an effective tuberculosis vaccine

Development of an HIV vaccine

Goal 2 Comments: Enhance the safety of vaccines and vaccination practices

American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

Another example of a way to reduce errors in vaccine administration can include the depth of injection (2.6.3)

American Association of Colleges of Pharmacy (William Lang IV, MPH)

As mentioned above [in Goal 1 comments], pharmacy faculty, collaborating across institutions, are currently at work to improve the manufacturing process of pharmaceuticals. This approach would help meet Goal 2 Objective 2.1.

Academic pharmacy and the students they educate form a significant network of community-based healthcare professionals able to conduct surveillance activities that can inform prioritization. This network includes nearly 12,000 students dispersed throughout the healthcare system from one end of its continuum to the other. This network, supported and reinforced by licensed healthcare providers offers a practice-based research network that can detect trends in real time and help create active surveillance systems and enhance timely detection and evaluation of vaccine safety signals outlined in Goal 2 Objective 2.2

This same opportunity for the creation of a practice-based research network utilizing students and educators would readily address the concerns, new and emerging, regarding vaccine safety and surveillance identified in Goal 2 Objectives 2.3, 2.4, and 2.5.

Assessment of health professions education curriculum for contemporary competencies is a regular endeavor of academic pharmacy. The NVPO should consider convening or creating an advisory group of health professions educators with the aim of ensuring that health professions education curricula continually are updated to reflect current scientific evidence. This would assist the NVPO in addressing Goal 2 Objective 2.6

This same advisory group approach should be considered for Goal 2 Objective 2.7 and 2.8

American Immunization Registration Association (Cindy Sutliff)

Section 2.2.1
Current: Improve the effectiveness and timeliness of AEFI signal identification and assessment through coordinated use of national passive and active surveillance systems.
Recommended Wording: Improve the effectiveness and timeliness of AEFI signal identification and assessment through coordinated use of national passive and active

surveillance systems, including IIS.
Section 2.3.3
Current: Enhance capacity to monitor immunization safety in the event of a mass vaccination campaign.
Recommended Wording: Enhance capacity to monitor immunization safety in the event of a mass vaccination campaign by quickly aggregating the data in a state, local or regional IIS.

American Nurses Association (Linda J. Stierle, MSN, RN, NEA-BC and Rebecca M. Patton, MSN, RN, CNOR)

Strategy 2.6.3 (Page 37) - Reducing errors in vaccine assessment and administration will require a closer look at the increasingly complex and confusing immunization schedule as recommended by the Centers for Disease Control and Prevention. In the past 10 years, a host of vaccines have been added to the schedule, with varying indications for age and number of doses. It is quite difficult for many health care providers to stay current on the immunization schedule, and to decipher patient vaccine records and make vaccine recommendations in accordance with that schedule. Simplification of the schedule is one way to reduce errors from incorrect assessments of vaccine records. This may require HHS to work with vaccine developers to encourage vaccine products that require less boosting to achieve effective immunological response. Another is federal financial support for states to develop and implement immunization registries that provide vaccine assessments and recommendations.

The Association for Professionals in Infection Control and Epidemiology (APIC – Christine Nutty, RN, MSN, CIC)

APIC encourages efforts to improve public perceptions about vaccine safety, and efforts to improve reporting of adverse events from immunization (AEFI) and reduce errors in administration of vaccines via training, education and engineering controls. We also advocate improved methods of monitoring vaccine safety, especially in the event of a mass vaccination campaign, which would involve using an improved process for reporting adverse events. In addition, APIC supports ongoing research and surveillance to monitor changing trends resulting from current vaccine use.

APIC supports Objective 2.2 to enhance timely detection and evaluation of vaccine safety signals; however, we have some concerns about possible under usage of the Vaccine Adverse Event Reporting System (VAERS). Since hospitalized patients often receive the pneumococcal/influenza vaccine shortly before discharge, the vaccine provider may not be aware of AEFIs that may occur post-discharge and events may go unreported. We recommend more specific suggestions on how active surveillance would be implemented. Some options might include follow-up phone calls, return visits to offices or vaccine providers, or surveys mailed to patients. We also recommend adding to Strategy 2.2.2 that information gleaned through active surveillance be reported back to healthcare professionals in a timely manner. This could facilitate Strategy 2.2.3, to assess lay public

and professional questions and concerns about vaccine safety. In addition, we suggest expanding the term “lay public” to include community vaccine groups, particularly those who oppose vaccination.

To implement Strategy 2.3.3, we believe that involving healthcare systems in the reporting process could help enhance capacity to monitor immunization safety in the event of an influenza pandemic or other mass vaccination campaign.
Objective 2.6, to improve clinical practice to prevent, identify and manage AEFIs, is especially important. APIC welcomes the opportunity to assist in improving training and communications on vaccine safety and administration, as identified in Strategy 2.6.1, and we believe this will help in implementing Strategy 2.6.3 to reduce errors. We agree with the need, identified in Strategy 2.6.2, to develop additional evidence-based guidelines for vaccination or revaccination for persons at increased risk of AEFI. We are especially concerned about dated and conflicting evidence regarding revaccination of children with reactions to diphtheria, pertussis, and tetanus vaccines. We also agree with Strategy 2.7.3 to improve laboratory, epidemiological and statistical methods used in vaccine safety research. However, we believe that identifying the gaps in current methods and research is an essential first step, and we recommend adding language identifying this to Strategy 2.7.3.

National Association of State Directors of Developmental Disabilities Services (Linda Rolfe, Director, Washington state Division of Developmental Disabilities)

> Ongoing assessment of risk and adverse events while being closely monitored, this information should be disseminated proactively to the providers who administer these vaccines for early detection of potential problems and education of the consumer.

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

The agenda should include the development of strategies to better capture post marketing vaccine adverse effects. This would assure that recipients, regardless of location, race, and socioeconomic status, would be adequate represented.

Goal 3 Comments: Support informed vaccine decision-making by the public, providers, and policy-makers

American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

Health care providers report having accurate and complete information. How will the practitioner know if she/he has complete and accurate information? Why not just say "have access to information?"

The AAP recommends expanding the language in the strategic plan to include the education of the public about the benefits of vaccines and the risks associated with vaccine refusal. The AAP recommends providing further detail in outlined initiatives and strategies to counter negative media, publications, internet, etc. which strive to negate the scientific evidence supporting the benefit of vaccines.

The responsibility to communicate to caregivers and the public about new vaccines and safety data after substantial experience is good – the timeline for this process would be difficult to predict

Vaccine curriculum in medical schools and primary care residencies is a good idea, and examination of knowledge in this content area is appropriate.

Other outcome consideration:

- Development of curriculum content to be utilized by professional schools and training programs

Health literacy at all levels is not sufficiently explained. The AAP recommends more specific details because health literacy is such an important issue to ensure the proper delivery of vaccines to all populations.

American Association of Colleges of Pharmacy (William Lang IV, MPH)

AACP is concerned that academia is not included as a non-federal stakeholder within Goal 3 Objectives 3.1, 3.2, 3.3 and 3.4.
Academia can assist the NVPO with meeting the stated objectives through research and evaluation of communication approaches and other activities developed to address these objectives. As mentioned earlier, faculty at colleges and schools of pharmacy work with other federal agencies to evaluate communications developed within the agency for dissemination to the public.

The plan does recognize academia as a non-federal stakeholder in Goal 3 Objective 3.6, but should be included in Objective 3.7

American Association of Occupational Health Nurses, Inc. (Richard J. Kowalski, RN, MSA, COHN-S)

Change consumer/client attitudes about vaccinations through education and re-education, information sharing, consumer stakeholders input, etc.

American Association of Respiratory Care (Timothy R. Myers, BS, RRT-NPS)

We concur with the list of stakeholders that have been identified in the plan for Goal 3. However, while it may be assumed that patient advocacy groups, or patient information organizations (PIOs), are included among the term "the public", we believe it is important to make a distinction that recognizes the important roles these groups play in reaching a vast audience who can benefit from the goals and objectives outlined in the National Vaccine Plan. We recommend adding these types of organizations to the list of non-Federal stakeholders.

Overall, RTs are professional providers of quality health care to all age groups in hospitals, alternate sites and in the home. As a professional organization, the AARC has numerous resources and tools that our members can use to assist in carrying out some of the objectives and strategies outlined in Goal 3 of the National Vaccine Plan. We see the AARC's role as a stakeholder taking on a variety of initiatives:

- Improving our grassroots efforts at the local level. Our state societies have websites and newsletters and state conferences where the AARC can request state societies to assume the task of generating interest in the value of vaccines and the need for immunizations. RTs and their state societies are already working together on pandemic flu/mass casualty/disaster planning.

- Using our section chiefs and "list servs" to enhance the delivery of timely, accurate and transparent information about the risks and benefits of vaccines and the vaccine program. The AARC has numerous specialty sections that provide an e-mail message list, monthly e-newsletters, quarterly bulletins and a specialty section website for those RTs who practice in a particular area of respiratory care. Some examples of these specialties include adult acute care, continuing care/rehabilitation, home care, long-term care, neonatal-pediatrics, sleep, and diagnostics.

- Partnering with organizations like the COPD and Alpha 1 Foundations, the Asthma & Allergy Foundation of America, the Pulmonary Education and Research Foundation (PERF) and others to promote the vaccine program. The AARC works closely with a number of patient organizations on a regular basis in an effort to coordinate our activities that share a common interest.

- Using the AARC.org web site and YourLungHealth.com to frequently remind health care professionals and patients about the value of the vaccine program. The AARC

website is designed to provide valuable information not only to our RTs but a vast majority of the public and health care community who are interested in gaining a better understanding of respiratory illnesses, accessing evidence-based literature and clinical practice guidelines, or keeping up to date on the latest developments and regulatory activities that impact those who treat or suffer from respiratory illnesses. The YourLungHealth web site is aimed at providing similar information to the patient population. This year, in collaboration with the CDC and the National Vaccine Program Office, we used these websites to stress the value getting a flu shot.

- Publishing articles in our magazine, AARC Times, to increase awareness of vaccine preventable diseases and the benefits and risks of flu and pneumococcal vaccines. The AARC Times is a monthly magazine that is available to our members and the professional health care community. We can offer a valuable service to our readers through continuing education on the importance of the goals and objectives identified in the National Vaccine Plan.

- Enhancing our public relations guide book to reach targeted audiences with timely and accurate information about the risks and benefits of the flu and pneumococcal vaccines so they can make informed decisions. As members of AARC, our RTs have access to multiple resources to assist them in developing local public relations campaigns. For example, we provide guidance and categories to assist them in writing press releases, replying to press inquiries, developing fact sheets on a number of relevant topics, and triggering other publicity ideas. Our audiences include the AARC Leadership, patients and lay caregivers, the general public, the health care community, employers, payers, government, educators, industry and competitors.

- Developing information on the benefits and risks of getting vaccinated from the perspective of the respiratory therapists. The benefits and risks of vaccinations is a perennial topic for health care providers and patients. Our RTs can play an important role in educating a broad sector of the health care community about the flu and pneumococcal vaccine from the vantage point of treating patients with respiratory illnesses.

- Updating our human resources survey to include questions around the vaccine program. Every five years, the AARC conducts a survey of its members to gather important statistics on a number of topics. The survey will be conducted this year and for the first time we have included questions that will enable us to track immunization rates among RTs in order to measure success in improving the rate of flu vaccines among health care workers as part of the Healthy People 2010 initiative. In the future, we can use this tool to incorporate questions that will provide pertinent information about expanding the knowledge base of those who are served by our RTs as to the benefits and risks of being vaccinated or immunized against the flu and/or pneumonia.

American Dental Association (John S. Findley, D.D.S.)

Objective 3.2. The American Dental Association and its local dental societies could be valuable collaborators in enhancing communications with the general public on vaccination issues. People generally see their dentist regularly rather than episodically, as they do with other health care providers. This concept of the importance of preventing disease is a basic tenet of dental practice, so dental personnel could be enthusiastic proponents.

Objective 3.6. Special educational programs concerning vaccines and vaccination programs should be made available to dentists (like the smallpox materials sent out to all dentists by the Centers for Disease Control and Prevention) for their use.

American Immunization Registration Association (Cindy Sutliff)

Section 3.6.1
Current: Expand and implement training and education of immunization providers at all levels of their education on the proper use of vaccines, the proper storage and handling of vaccines, the basis of immunization recommendations, vaccine safety, and on the standards of immunization practice.
Recommended Wording: Expand and implement training and education of immunization providers at all levels of their education on the proper use of vaccines, the proper storage and handling of vaccines, the basis of immunization recommendations, vaccine safety, on the standards of immunization practice, and the use of IIS as a decision-support tool.

Section 3.6.2
Current: Develop and implement educational strategies for providers on vaccine preventable diseases, including diagnosis, modes of transmission, prevention and control, and reporting requirements.
Recommended Wording: Develop and implement educational strategies for providers on vaccine-preventable diseases, including diagnosis, modes of transmission, prevention and control, reporting requirements, and the use of IIS as a decision-support tool.

Section 3.7.3
Current: Develop evidence-based tools to assist individuals, parents, and providers synthesize relevant vaccine-related information to make informed decisions regarding vaccination.
Recommended Wording: Develop evidence-based tools and use IIS to assist individuals, parents, and providers in synthesizing relevant vaccine-related information to make informed decisions regarding vaccination.

American Nurses Association (Linda J. Stierle, MSN, RN, NEA-BC and Rebecca M. Patton, MSN, RN, CNOR)

HHS should prioritize the strengthening of public confidence in vaccine safety. Anti-vaccine sentiments have become more prominent in the media, as outspoken celebrities

and other vaccine opponent groups have gained attention and support from some in the public, prompting fears and suspicions of vaccines and vaccine safety. Unfortunately, the government's efforts to reassure the public of vaccine safety have been met with skepticism for various reasons. A priority for HHS should be to seek out more champions for vaccination from the private sector. In addition, greater transparency in the processes of vaccine licensure and practices approval could be beneficial in increasing the public's confidence in and understanding of the decision making, and decrease suspicion that political or economic factors enter into these processes (pertinent to Objective 3.7).

Strategy 3.6.4 (Page 45) - Health care providers should allow and encourage the public to report to VAERS on their own, and this information should be clear on federally produced vaccine information statements.

The Association for Professionals in Infection Control and Epidemiology (APIC – Christine Nutty, RN, MSN, CIC)

APIC agrees that timely and accurate information is essential to improving vaccine delivery and safety. We support enhanced communications with healthcare professionals concerning the perceived benefits and risks of vaccines and improved dissemination of research findings to facilitate implementation of evidence-based strategies. APIC stands ready to partner with the Centers for Disease Control and Prevention (CDC) in distribution of vaccine information to our members and is willing to collaborate in educational initiatives.

National Association of State Directors of Developmental Disabilities Services (Linda Rolfe, Director, Washington state Division of Developmental Disabilities)

While the 5 goals outlined in the strategic plan are broad with a 10 year horizon in mind, we have certain concerns about with administration and buy in from the consumer as new vaccines are developed. We would hope that there would also be an added focus on developing combination vaccines, studying their efficacy and possible synergistic effects and development of herd immunity as we move forward with the strategic plan. There is growing resistance from families to the administration of multiple vaccines especially in infants and children, despite efforts by providers to educate them on its benefits. Mostly the resistance does not appear to be to the vaccine itself but to the number of pokes the child has to endure to receive the multiple vaccines.

Bring more transparency to the decision making process by involving both the providers and consumers on a large scale, utilizing newer technology to solicit input in a timely and effective manner. This promotes empowerment and buy in which is crucial for the success of the program.

Minimize the efforts of lobbyists and private interest groups to influence the decision making process. While their input may be valuable from a funding stand point, a credible independent body free of such biases should be the prime analyst and decision maker.

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

[Priority:]

Improved public education on safety and efficacy of vaccines to counter disinformation and myths

Society for Adolescent Medicine (Richard E. Kreipe, MD)

Indicators – first bullet: By Y (year), enhance communication with stakeholders and the public to more rapidly inform them (within _X_ days) about urgent and high-priority vaccine and vaccine-preventable disease issues (e.g., outbreaks, supply shortages, vaccine safety concerns).
While it is critical for the public to be able to access information about vaccine safety concerns, it is just as critical for them to have information about the high quality and safety of existing vaccines. Communicating only information about safety concerns may be misleading and be picked up by the media, only reinforcing the media bias toward concerns about vaccine safety. Thus, in the first bulleted indicator, we would suggest including communication about vaccine quality and safety as well as vaccine safety concerns. This will help ensure the plan is proactive as well as reactive. This is consistent with objective 3.3.1.

Indicators – second bullet: _X___ % of the public will report that they are satisfied with how their health care provider answers their questions about the benefits and risks of vaccines by Y (year).
This is a passive indicator that essentially depends upon the "consumer" knowing about product availability. It seems that a more critical component is making sure providers are discussing the availability of the vaccine, noting the fact that there is a national recommendation for vaccination, and answering questions about vaccination. There are providers who are not routinely discussing immunizations with patients, especially if they do not feel the vaccines are appropriate. We would suggest a measure that ensures that patients are being made aware of the availability of nationally recommended vaccines as well as the important information associated with those vaccines.

Indicators – general comment. Finally, all indicators seem to assume that immunizations will be delivered by traditional health care providers. The use of alternative sites is growing; it would be helpful to consider rewording indicators or creating new indicators that take this trend into account (what type of certification will be required, is there a minimum standard for those who immunize). This is addressed in part

in a later objective, but these indicators could also incorporate the reality that not only office-based physicians are providing vaccination.

Objective 3.3.: Enhance delivery of timely, accurate, and transparent information to public audiences and key intermediaries (such as media) about what is known and unknown about the benefits and risks of vaccines and the vaccination program.
Consider including an additional strategy: proactively encouraging responsible journalism and providing guidance to journalists regarding reliable and unreliable sources of vaccine information.

Objective 3.4.: Increase public awareness of vaccine preventable diseases, and benefits and risks of vaccines and immunization, especially among populations at risk of under immunization.
Despite the phrase "especially among populations at risk of under immunization," there are no specific strategies that address these populations. Consider including a strategy to enhance access to information and education among minority, low-income populations at risk for under-immunization. Culturally appropriate educational efforts will be important. Thus, objective 3.2.3 (Collaborate with partners and stakeholders to communicate vaccine benefits and risks in appropriate languages, methods, and literacy levels) may be more appropriate here than where it is currently.

In addition, within the enumerated strategies listed, it is important to expand the role of public service announcements on television. These are trusted methods of communication via a very accessible medium. They do not require the ability to read – which is critical – and, when done well, are extremely effective.

It will also be important to include in this objective taking a more active role in addressing misinformation about vaccine public safety. The new cases of Hib deaths reinforce the need for a more aggressive approach to the misunderstandings that have led to personal belief exemptions. This is the explicit role of those who know and understand the data.

United American Nurses, AFL-CIO (Sarah Markle-Elder)

UAN supports the goals of the plan, particularly *Goal 3*, supporting informed vaccine decision-making by the public, providers, and policy-makers. We note the need for "accurate, timely, transparent, complete, and audience-appropriate information" as discussed in *Goal 3* so that all populations at risk are educated about the benefits and risks of infectious disease vaccinations.

Included in this are the objectives to add vaccine education to the curricula of professional schools, training programs, and certifying examinations as described in the *Goal 3 Indicators*. Health care workers can be trained during their preparatory education and in continuing education settings. We also note that unions can assist in collaborations to educate workers as mentioned in *Objective 3.2.*

Goal 4 Comments: Ensure a stable supply of recommended vaccines, and achieve better use of existing vaccines to prevent disease, disability, and death in the United States

American Academy of Family Physicians (Belinda K. Schoof, MHA, CPHQ)

Would urge more attention to primary care physician offices and reimbursement issues they face.

It is positive that the plan includes Objective 4.2: Reduce financial and non-financial barriers to vaccination.

Strategy 4.2.8 advocates for increased "access to vaccination at sites outside of traditional medical settings," which could be troubling for immunizations other than influenza which is so time-limited.

There is not anything about vaccine management assistance to providers, which certainly would be sensible.

Changing the advance notice of when the drug pricing publishers share vaccine manufacturer price increases would be a good strategy. This would alleviate the lag in the payers' systems in increasing the payment rates for the vaccines that had a price increase.

We would also like to share the AAFP Immunizations policy:
http://www.aafp.org/online/en/home/policy/policies/i/immunizations.html

American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

Although much has been accomplished since 1994, to meet the first part of its purpose, to "achieve optimal prevention of infectious diseases through immunization," the 2008 Plan must promptly address issues with current ACIP recommended vaccines and the vaccine infrastructure in the U.S. Some current issues severely threaten the vaccine system. Significant disparities in vaccine availability and vaccination levels exist in the United States. Goal 4: Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability, and death in the US - is critical and should be a first priority for a number of reasons, some of which include:

1. The current vaccine system is under-funded. On the public side, many states are unable to provide the funding necessary to provide all ACIP recommended vaccines to uninsured or underinsured children. In addition low Medicaid vaccine administration fees and access to FQHC for underinsured children are additional barriers. Even families with health insurance experience significant out of pocket expenses when their health insurance does not provide "first dollar" coverage for childhood vaccines.

2. Pediatricians give the majority of immunizations to children in the U.S. They are becoming increasingly frustrated. Some are considering discontinuing their participation in the immunization program for a number of reasons including the inadequacy of the supply of certain vaccines as well as inadequate reimbursement; difficulty receiving payments, especially for the more expensive recently licensed vaccines; and different coverage rules from insurers. We also are aware that this sentiment is shared by our family physician colleagues. If primary care physicians do not participate, the immunization system in the U.S. will fail.
3. Certain target populations are not being effectively reached.
4. Vaccine shortages continue to be a significant problem. They are very disruptive and exasperating to both health care professionals and parents and potentially leave cohorts of target populations unprotected and at-risk to contract and spread vaccine-preventable diseases.
5. The AAP notes it will be important to ensure that objectives 4.2.7 and 4.2.8 do not negatively impact the medical home which is so important in the delivery of quality health care to all infants, children and adolescents. Immunizations are incorporated into routine comprehensive health visits for infants, children, and adolescents during which patients receive other essential preventive and therapeutic health services.

Many of the indicators listed in Table 1 are likely difficult or impossible to achieve and appear to be unrealistic or artificial (just so something can be measured). [One] specific example includes:

- A six month supply in the national stockpile is insufficient to address an interruption in the manufacture of a vaccine. For example, when one of the two manufacturers of Hib vaccine suspended production and recalled recent shipments of Hib vaccine in November, 2007, the available CDC Hib vaccine stockpile plus the available production capacity of the other supplier of Hib vaccine were unable to sustain the recommended four dose schedule of Hib vaccine. This led to the suspension of the booster dose given at 12 through 15 months of age. The shortage has lasted for over a year and the earliest estimate for return to market by the manufacturer is now the second quarter of 2009. Once the suspended product is reintroduced to the market, it is not known how long it will take for supplies to be adequate to reinstate the 4th dose. Thus, the stockpile must be adequate to support the recommended vaccine schedule for much longer than a year.

Other outcome [indicator] considerations:

- The number (%) of providers routinely using an immunization information system.
- Elimination of immunization rate discrepancies amongst target populations.

A nationwide immunization information system is needed. State systems are unable to communicate with other systems and thus information is not always available when needed. (4.3.2)

Consideration for age-specific and/or target population approaches by medical/health professional disciplines might positively influence the impact of this plan.

The AAP recommends a focus on the development of new technologies for production of influenza vaccine and delivery of influenza vaccine annually to a large segment of the population in a short timeframe. This influenza vaccine delivery prototype could serve as a model for mass immunization campaigns (i.e., pandemic flu; avian flu).

American Association of Colleges of Pharmacy (William Lang IV, MPH)

AACP recommends that the NVPO consider creating federal support for collaborative research initiatives that build upon the knowledge and skills of faculty researchers across professions and institutions. This is an approach utilized by the FDA through its support of the National Institute of Pharmaceutical Technology and Education (NIPTE). The development of new vaccines can be a low priority for private industry due to start up costs and low return on investment, especially for vaccines with targeted at a small population. Public private partnerships like NIPTE offer the opportunity for new product and manufacturing approaches to be developed as well as improvements to existing product manufacturing.

Objective 4.2 may be addressed through provision of vaccines through student-lead organizations. Student pharmacists are extremely effective and more flexible than practicing providers when you consider increasing access to vaccine provision and are not dependent on reimbursement for service provision. Student organizations at health professions institutions, including pharmacy, are a ready resource, with a proven track record of vaccine delivery across the country.

Please consider earlier comments regarding the development and support of practice-based research networks that utilize the experiential learning requirements of pharmacy education as an effective model for addressing Goal 4 Objective 4.3 and 4.4

Utilize the skills or pharmacy faculty in creating and assessing curricula for improving provider counseling and delivery in addressing Goal 4 Objective 4.5.

Similarly, pharmacy faculty should be included in any entity NVPO creates to address Goal 4 Objective 4.6

The translation of research into practice can be supported by ensuring the education of healthcare professionals includes the necessary critical thinking and communication skills to address the strategies listed in Goal 4 Objective 4.7.

American Association of Occupational Health Nurses, Inc. (Richard J. Kowalski, RN, MSA, COHN-S)

To maintain a stable supply of recommended vaccines, do not limit manufacturers to production of one vaccine but have multiple vaccine manufacturers to prevent the occurrence of vaccine shortage, e.g., influenza.

To achieve better use of existing vaccines:

- Rotate the 6 months supply of stockpile vaccines and provide to public health facilities for administration, as applicable.
- Implement or re-implement the electronic health records (increase information access to avoid missed opportunities) and the recall system, both of which were discussed 15 years ago.

American Dental Association (John S. Findley, D.D.S.)

Strategy 4.2.8. Private dental offices, dental schools and other dental facilities could easily be used as vaccination sites, especially during emergencies.

Strategies 4.5.7-10. These strategies should be emphasized for dental personnel and the families of dental personnel to be priority vaccine recipients, since they will be particularly vulnerable to infection spreading, especially in the event of a bioterrorism event.

Strategy 4.8.3. Dentistry should be included in these exercises and in planning for mass vaccination activities. This is a valuable asset that should not be overlooked. Mention in this or another section would be helpful to draw attention to the value of dental personnel in this area.

American Immunization Registration Association (Cindy Sutliff)

Section 4.3.1
Current: Identify, implement, and evaluate cost-effective and rapid methods for assessing vaccination coverage:
a. among children, adolescents, adults overall and by State, immunization grantee, and within states and grantees;
b. among persons in key population subgroups (e.g., racial/ethnic groups, pregnant women, healthcare workers); and
c. by type of vaccination financing (e.g., VFC, other public sector program, private sector).
Recommended Wording: Identify, implement, and evaluate cost-effective and rapid methods, such as the use of IIS, for assessing vaccination coverage:
a. among children, adolescents, adults overall and by State, immunization grantee, and within states and grantees;
b. among persons in key population subgroups (e.g., racial/ethnic groups, pregnant women, healthcare workers); and
c. by type of vaccination financing (e.g., VFC, other public sector program, private sector).

Section 4.3
Recommended Additional Sub-section:
4.3.3 Support and encourage electronic medical records (EMR) vendors to develop interfaces to seamlessly exchange immunization data with IIS.

Section 4.5.4
Current: Incentivize direct health care providers, health systems, and health insurers to provide vaccines by incorporating vaccination in quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).
Recommended Wording: Incentivize direct health care providers, health systems, and health insurers to provide vaccines by incorporating vaccination and use of IIS in quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).

Section 4.5
Recommended Additional Sub-section:
4.5.11 Promote using IIS as a decision-support tool to identify the appropriate timing of vaccines so providers administer them when needed. Promote use of IIS as an educational tool that provides feedback to providers about administered vaccinations being invalid due to improper timing.

Section 4.6
Recommended Additional Sub-section:
4.6.5 Leverage the data available through population-based IIS to evaluate the impact and implementation of new and existing immunization recommendations.

Section 4.9.2
Current: Implement and evaluate activities to enhance immunization coverage among travelers.
Recommended Wording: Implement and evaluate activities, such as the use of international certificate of immunization produced by IIS, to enhance immunization coverage among travelers.

American Nurses Association (Linda J. Stierle, MSN, RN, NEA-BC and Rebecca M. Patton, MSN, RN, CNOR)

ANA suggests a top priority for vaccines and immunization enterprise in the United States should be making vaccination a federal priority in decreasing disease burden, and increasing vaccination levels in children, adults and the elderly. To achieve this, the Department of Health and Human Services (HHS) should take the lead in providing funding to vaccine programs targeting adults and the elderly to decrease the financial barriers to vaccination, and to create more opportunities for adults to be vaccinated in the public sector (pertinent to Objective 4.2). Such a program might resemble the eligibility criteria of the Vaccines For Children (VFC) program, a program that has proved successful in providing vaccines for under-insured and uninsured children younger than

19 years of age.

Strategy 4.5.7 (Page 53) - ANA has developed influenza vaccination campaigns for nurses. If HHS seeks a model for communication tools as part of a comprehensive program to ensure health care professionals are appropriately immunized, we would be happy to provide these tools for your use and reference.

Strategy 4.5.9 (Page 53) - ANA discourages changing professional licensure requirements to increase vaccination rates in health care providers. A focus on licensure would actually neglect the population of unlicensed health care providers that provide routine patient care, such as patient care technicians and nursing assistants, and would not encompass the spectrum of health care providers that would benefit from vaccination.

Strategy 4.5.10 (Page 53) - ANA has a Position Statement opposing health care facility policies that mandate certain vaccines for health care workers. ANA supports health care vaccination. However, vaccination should be an informed choice of the individual and not a requirement for employment.

Strategy 4.6.1 (Page 53) – In order to ensure transparency of the decision-making processes of various federal immunization committees such as the Advisory Council on Immunization Practices, there should be increased public access to these and other pertinent proceedings. This can significantly increase broad-based support for current and future policies.

Strategy 4.6.2. (Page 53) - In order to strengthen federal vaccine decision-making and advisory committees, ANA strongly encourages diversifying membership to include representatives from the entire spectrum of health care practice beyond medical doctors. Advisory committees on vaccines often lack the voices and input of nurse representatives, even though RNs and APRNs provide the bulk of immunization services in both private practice and public health. Because of the strong role that nurses play in public education and patient advocacy, excluding nurses from participation in these important bodies is also detrimental to the patient population. HHS should take advantage of the strong link between nurses and their patients, and enlist the nursing profession in the task of encouraging the public to adhere to vaccination recommendations and policies.

Strategy 4.6.4 (Page 53) - In considering the cost-effectiveness of current immunization recommendations, HHS should include the cost of revaccination due to lost or destroyed vaccine records. Often children have to “start over” with all vaccines simply because the paper vaccine record was lost. A comparative effectiveness study of revaccination versus antibody detection testing would be helpful in determining the most cost-effective way to deal with this problem.

The Association for Professionals in Infection Control and Epidemiology (APIC – Christine Nutty, RN, MSN, CIC)

Goal 4: Ensure a stable supply of recommended vaccines, and achieve better use of existing vaccines to prevent disease, disability, and death in the United States
APIC supports efforts to improve vaccine tracking systems and to reduce financial barriers to vaccination. We encourage education of providers on business practices associated with providing immunization, including development and evaluation of employer-based immunization programs. However such efforts must also address privacy and employee rights issues. APIC agrees with the need identified in Strategy 4.1.1 to increase US licensed vaccine suppliers to have at least two suppliers of each vaccine antigen recommended for routine use. This would help to ensure a constant accessible vaccine supply, thereby preventing gaps in vaccination schedule and unprotected individuals (U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, "Invasive Haemophilus influenzae Type B Disease in Five Young Children --- Minnesota, 2008", January 30, 2009.). We also believe a target date should be added in order to expedite this very important strategy. However, additional guidance should also be in place to prioritize and provide direction on vaccine distribution during shortages or limited supplies. In addition, APIC recommends expanding references to healthcare facilities and vaccination providers to specifically include ambulatory surgery centers, rehabilitation institutions, dialysis centers and other non-traditional vaccine providers in order to broaden the scope of current vaccination practices. APIC also appreciates inclusion of Strategy 4.8.3 relating to mass vaccination activities for containment of an outbreak of a vaccine preventable disease or biological attack, and we trust that implementation will comply with the HHS Pandemic Influenza Plan.

National Association of State Directors of Developmental Disabilities Services (Linda Rolfe, Director, Washington state Division of Developmental Disabilities)

Another area of concern is the rapid deployment of new vaccines. A prime example is the HPV vaccine. Even among the health care community there are a lot of questions regarding the long term efficacy of the vaccine and the current cost burden of procuring and administering the same to a population that is hard to access (teens). The time lines for deployment have to be realistic and efforts have to be made to educate and get buy in from health care providers in order to ensure the successful deployment of the new vaccines.

Vaccine manufacturing and distribution has had its ongoing challenges. Shortage of vaccines and inability to get vaccines in the recommended age range and time frame further erodes consumer confidence. Licensing for vaccine manufacturing should not be the monopoly of one or 2 companies with an eye towards profitability and or patent protection but should have the public good in its sight. Vaccine manufacturing should be licensed to more then 3 -4 entities with strict quality control and over sight

by an independent body thereby ensuring adequate supplies even when faced with challenges such as mass disaster or contamination or recalls.

Consider developing a central vaccination database so that people can have access to their record and can give access to their healthcare professionals. Think of innovative ways to tie in this information with existing data bases and look for innovative ways of vaccine delivery – such as a vaccination clinic next to other government agencies that people visit. This way missed opportunities for vaccination can be minimized.

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

[Priorities:]

National vaccine registry

Assure supply of appropriate vaccines to all ages at reasonable costs

Develop the infrastructure for rapid response to outbreaks of emerging or novel pathogens

[Other comments:]

1. Occasionally, ACIP issues recommendations for vaccine use that are outside of the labeled indications for certain products. A recent example is the recommendation to extend the age ranges for doses of rotavirus vaccine beyond those listed in the package inserts for RotaTeq® and Rotarix®. Practitioners feel this may put them at medico-legal risk. Confusion generated by differences between the indication for vaccine use and the recommendations for vaccine use need to be addressed.

2. Develop plan for a national immunization registry that is cradle-to-grave.

Are there any goals, objectives, or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

1. Travel vaccines have a low overall impact on public health and should be de-emphasized in the plan in the interest of putting resources into areas with potentially larger impact.

Society for Adolescent Medicine (Richard E. Kreipe, MD)

One general suggestion would be to explicitly acknowledge the link between immunization and general access to health care (including access to insurance and

primary care services). This is especially relevant for young adults who are too old for VFC and often lose their coverage under SCHIP or Medicaid.

Consider more explicitly addressing the issue of health disparities through vaccination throughout this section. For example, goal 4 could read: "Ensure … and achieve better use of existing vaccines to prevent disease, disability and death *and to decrease health disparities* in the U.S."

Consider an indicator that explicitly addresses monitoring of disparities.[1] (for example, through the National Immunization Survey)

Objective 4.2.: Reduce financial and non-financial barriers to vaccination

4.2.1: Ensure that out of pocket costs for purchase and administration of all ACIP recommended vaccines for children, adolescents, and adults by publicly funded health insurance plans do not represent a significant financial barrier (i.e., Medicare, Medicaid, TRICARE, VA, FEHBP, DoD).

4.2.2 Reduce financial barriers to immunization by increasing the proportion of people with private healthcare insurance who have only minimal cost sharing for purchase, counseling, and administration of all ACIP recommended vaccines for children, adolescents, and adults (regardless of where the vaccines are administered).

Consider making these strategies more comprehensive; e.g. financial barriers to immunization should be eliminated for *all* patients, whether publicly insured, privately insured, or uninsured. This is important as each state subsidizes at varying levels, so it seems there are "geographic disparities" as well that should not exist. Young adults are among the least likely to have insurance coverage for vaccination, but are at high risk of transmitting vaccine-preventable diseases to young children as they become parents.

Objective 4.3.: Maintain and enhance the capability to monitor immunization coverage for vaccines routinely administered to infants, children, adolescents, and adults.

Consider including an additional strategy related to immunization registries and their communication with electronic medical records (EMRs). Record scattering and missed opportunities are major reasons for under-immunization in adolescents. These could be better addressed by promoting better IT infrastructure: immunization registries (for all ages, not just infants and children) and having these registries link or communicate with EMRs. Furthermore, EMRs should prompt physicians when vaccines are overdue. In addition, the importance of a national, lifetime registry cannot be understated. The ability for registries to communicate will be of great importance as immunization recommendations begin to span age groups that are increasingly mobile. The importance of this type of communication was noted during Hurricane Katrina during which millions of dollars were saved when the Louisiana and Texas registries were set up to communicate. Many vaccines are also currently being given in alternative settings. Finally, this type of comprehensive registry will also be of tremendous importance in the event of a pandemic.

1. Flannery B, Schrag S, Bennett NM, et al. Impact of childhood vaccination on racial disparities in invasive *S. pneumoniae* infections. JAMA 2004;291:2197-203.

United American Nurses, AFL-CIO (Sarah Markle-Elder)

However, we are very concerned about strategies listed under *Objective 4.5*: *Educate about, and support, health care and other vaccination providers in vaccination counseling and delivery.* Several of these strategies imply incentives for health care employers to create mandatory seasonal influenza vaccination programs. We strongly reject mandatory programs which coerce health care personnel into accepting the flu vaccine under threat of losing their jobs or any other penalty.

The strategies at issue are:

> *4.5.4 Incentivize direct health care providers, health systems, and health insurers to provide vaccines by incorporating vaccination in quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).*
>
> *4.5.8 Promote the development, implementation, and evaluation of employer-based immunization programs (including free vaccines, convenient access, education, and compliance monitoring) to increase the coverage of health-care personnel with recommended vaccines.*
>
> *4.5.9 Assess whether changes in health care facility and professional licensure and regulation can improve the safety of the health care environment by increasing vaccination rates of health care professionals.*
>
> *4.5.10 Develop and monitor policies promoting vaccination for patients and health care personnel in long-term care facilities and hospitals.*

Most concerning of all of these strategies is *4.5.9*, which indicates that individuals and/or the facilities where they work could lose their licenses if they fail to submit to annual seasonal flu vaccines. The other strategies create incentives and structures for employer-based programs. UAN is not opposed to employer-based seasonal flu programs, but we oppose programs that penalize health care workers who decline the vaccine. We maintain that such coercive programs are unnecessary, unwarranted, and counterproductive.

Mandatory flu vaccine programs are unnecessary because several studies have shown that higher health care personnel participation rates are achieved when the workers are educated about the vaccine.[i ii iii] We note that one of the major goals of the *National Vaccine Plan* is improving outreach and education to the public, providers, and policy-makers in order to support informed decision-making about vaccine benefits and risks. Nurses and other health care workers should also be afforded the opportunity to make an informed decision.

Participation rates as high as 80 percent have also been achieved by improving access for health care personnel. Factors identified in these studies include free provision of the vaccine; offering it on all shifts at convenient times and locations; and through positive and non-coercive programs such as vaccine carts, vaccine days, peer vaccination programs, gift incentives, and standing orders. Other factors include adequate allocation of staff and resources to the program and visible support by upper level management.[iv] [v] [vi] [vii] [viii] [ix]

We also note the success of voluntary hepatitis B vaccination under the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030(f)(1)). Hepatitis B infections declined by 60 percent in health care personnel from 1993 to 1999 after health care employers were required to offer the vaccine to potentially exposed workers.[x] Health care personnel are encouraged to get the vaccine but still have the option to refuse and sign a declination form.

Mandatory flu vaccination programs are unwarranted due to the variable year-to-year effectiveness of the trivalent vaccine. The estimated effectiveness in years where there is a good match is 70 to 90 percent. The effectiveness for the 2007-2008 season was estimated at 44 percent.[xi] While the flu vaccine is an important tool in the prevention of nosocomial infections, it is neither completely effective, nor is it the only one.

Lastly, mandatory flu vaccination programs are counterproductive to the long-term goal of improving health care personnel vaccination rates because they create an atmosphere of distrust. Mandatory flu vaccination programs at Virginia Mason Hospital in Seattle, Washington and Providence Hospital in Anchorage, Alaska were terminated after the registered nurse unions there contested the employers' right to implement policies affecting working conditions without negotiating.[xii] In the case of Virginia Mason Hospital, which has been cited as a successful flu vaccination program, the US Court of Appeals for the Ninth Circuit upheld an arbitrator's ruling against the hospital.[xiii] In the case of Providence Hospital, the program was stopped shortly after the Alaska Nurses Association (UAN) protested.[xiv]

UAN supports voluntary employer-provided seasonal flu vaccination programs for health care personnel. The programs should include education about the benefits of seasonal flu vaccine, side effects, and contraindications as noted by the Advisory Committee on Immunization Practices. Health care workers should be advised of their right to compensation for adverse events following immunization by the National Vaccine Injury Compensation Program.

Registered nurses are protective of their patients and mindful of their key role in infection control. However, they feel strongly that mandatory flu vaccinations are an unwarranted intrusion on their right to make decisions about their personal health.

Goal 5 Comments: Increase global prevention of death and disease through safe and effective vaccination

American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

Other outcome [indicator] consideration:
Include Hib vaccine on the list for global prevention of death and disease.

American Association of Colleges of Pharmacy (William Lang IV, MPH)

Academia, including colleges and schools of pharmacy, is increasingly involved with global partners. This involvement frequently involves students participating in patient-care initiatives in countries around the globe. The NVPO should initiate a discussion with academic institutions that provide this international learning opportunity for their health professions students to orient these programs to Goal 5 and its associated objectives. This would provide a clear direction for international cooperation and meeting the goal and objectives.

American Dental Association (John S. Findley, D.D.S.)

Goal 5. Global immunization would have the added benefit of protecting U.S. residents from exposure to diseases from visitors and immigrants. This becomes more important as global transportation becomes available to more people and with increased globalization of commerce.

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

[Priorities:]

Polio eradication

Penetration of rotavirus vaccine into the developing world

Comments on Appendices:

None

Complete Comments by Stakeholder Sector - Health Professional Associations:

American Academy of Family Physicians (Belinda K. Schoof, MHA, CPHQ)

Thank you for the opportunity to provide comments to the draft strategic National Vaccine Plan. We received the following comments:

Would urge more attention to primary care physician offices and reimbursement issues they face.

It is positive that the plan includes Objective 4.2: Reduce financial and non-financial barriers to vaccination.

Strategy 4.2.8 advocates for increased "access to vaccination at sites outside of traditional medical settings," which could be troubling for immunizations other than influenza which is so time-limited.

There is not anything about vaccine management assistance to providers, which certainly would be sensible.

Changing the advance notice of when the drug pricing publishers share vaccine manufacturer price increases would be a good strategy. This would alleviate the lag in the payers' systems in increasing the payment rates for the vaccines that had a price increase.

We would also like to share the AAFP Immunizations policy:
http://www.aafp.org/online/en/home/policy/policies/i/immunizations.html

Sincerely,

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American Academy of Pediatrics (David T. Tayloe, Jr, MD, FAAP and Joseph A. Bocchini, Jr, MD, FAAP)

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children,

adolescents, and young adults appreciates this opportunity to submit comments on the draft strategic National Vaccine Plan.

Overview:

The AAP agrees that the five broad goals of the 2008 draft of the National Vaccine Strategic Plan are appropriate. Building on the goals of the 1994 Plan, they provide the framework on which to address relevant issues related to: eliminating barriers to universal access to currently licensed vaccines in the US; improving distribution and delivery of currently available vaccines; eliminating disparities in vaccine delivery; assuring a constant, dependable vaccine supply; eliminating shortages; promoting new vaccine development and improvement of existing vaccines; vaccine safety and identification of host factors and biological mechanisms for adverse events following immunization; education of the public, providers and policy makers; enhancing communication with parents, including risk benefit communication; and developing measures to improve the public's understanding of the risks of natural infection vs. the benefits of immunization and to increase public confidence in the immunization program. The plan also appropriately includes domestic and global components. Making current vaccines available globally with the establishment of infrastructure for distribution and delivery, as well as supporting research for the development of vaccines to prevent those infectious diseases with a significant impact on global health are important components of the Plan.

The Overall Objectives and Strategies are Appropriate:

Although much has been accomplished since 1994, to meet the first part of its purpose, to "achieve optimal prevention of infectious diseases through immunization," the 2008 Plan must promptly address issues with current ACIP recommended vaccines and the vaccine infrastructure in the U.S. Some current issues severely threaten the vaccine system. Significant disparities in vaccine availability and vaccination levels exist in the United States. Goal 4: Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability, and death in the US - is critical and should be a first priority for a number of reasons, some of which include:

1. The current vaccine system is under-funded. On the public side, many states are unable to provide the funding necessary to provide all ACIP recommended vaccines to uninsured or underinsured children. In addition low Medicaid vaccine administration fees and access to FQHC for underinsured children are additional barriers. Even families with health insurance experience significant out of pocket expenses when their health insurance does not provide "first dollar" coverage for childhood vaccines.
2. Pediatricians give the majority of immunizations to children in the U.S. They are becoming increasingly frustrated. Some are considering discontinuing their participation in the immunization program for a number of reasons including the inadequacy of the supply of certain vaccines as well as inadequate reimbursement; difficulty receiving payments, especially for the more expensive

recently licensed vaccines; and different coverage rules from insurers. We also are aware that this sentiment is shared by our family physician colleagues. If primary care physicians do not participate, the immunization system in the U.S. will fail.

3. Certain target populations are not being effectively reached.
4. Vaccine shortages continue to be a significant problem. They are very disruptive and exasperating to both health care professionals and parents and potentially leave cohorts of target populations unprotected and at-risk to contract and spread vaccine-preventable diseases.
5. The AAP notes it will be important to ensure that objectives 4.2.7 and 4.2.8 do not negatively impact the medical home which is so important in the delivery of quality health care to all infants, children and adolescents. Immunizations are incorporated into routine comprehensive health visits for infants, children, and adolescents during which patients receive other essential preventive and therapeutic health services.

The AAP Offers the Following General Comments/Recommendations Summarized Below:

- Setting goals requires quality improvement cycles of data collection and change. Data collection, processing, and evaluation are just as essential to the immunization system as vaccine administration. The totality of this strategic plan would require enormous commitment of new resources. It is important to insure that as many people as possible are appropriately immunized and that the system has the necessary resources for quality improvement

- The AAP recommends expanding the language in the strategic plan to include the education of the public about the benefits of vaccines and the risks associated with vaccine refusal. The AAP recommends providing further detail in outlined initiatives and strategies to counter negative media, publications, internet, etc. which strive to negate the scientific evidence supporting the benefit of vaccines.

- How the National Vaccine Program Office (NVPO) should/would/could prioritize these goals in tight economic times with limited resources is unclear.

- The responsibility to communicate to caregivers and the public about new vaccines and safety data after substantial experience is good – the timeline for this process would be difficult to predict

- Vaccine curriculum in medical schools and primary care residencies is a good idea, and examination of knowledge in this content area is appropriate.

- Health literacy at all levels is not sufficiently explained. The AAP recommends more specific details because health literacy is such an important issue to ensure the proper delivery of vaccines to all populations.

- A nationwide immunization information system is needed. State systems are unable to communicate with other systems and thus information is not always available when needed. (4.3.2)

- The use of technology to enhance achievement of these goals could be better articulated.

- Does this plan adequately address how various credibility and Conflict of Interests issues will be managed?

- Consideration for age-specific and/or target population approaches by medical/health professional disciplines might positively influence the impact of this plan.

- Many of the indicators listed in Table 1 are likely difficult or impossible to achieve and appear to be unrealistic or artificial (just so something can be measured). Specific examples include:

    1. Getting clinical trials started within 6 months of identifying a need for a vaccine is an unrealistic expectation.
    2. Health care providers report having accurate and complete information. How will the practitioner know if she/he has complete and accurate information? Why not just say "have access to information?"
    3. Developing a certain number of vaccines in a certain number of years. This sounds nice, but is not necessarily scientifically or logistically possible to do.
    4. A six month supply in the national stockpile is insufficient to address an interruption in the manufacture of a vaccine. For example, when one of the two manufacturers of Hib vaccine suspended production and recalled recent shipments of Hib vaccine in November, 2007, the available CDC Hib vaccine stockpile plus the available production capacity of the other supplier of Hib vaccine were unable to sustain the recommended four dose schedule of Hib vaccine. This led to the suspension of the booster dose given at 12 through 15 months of age. The shortage has lasted for over a year and the earliest estimate for return to market by the manufacturer is now the second quarter of 2009. Once the suspended product is reintroduced to the market, it is not known how long it will take for supplies to be adequate to reinstate the 4th dose. Thus, the stockpile must be adequate to support the recommended vaccine schedule for much longer than a year.

- The AAP supports the strategies as noted under each defined objective. We suggest that the strategies and objectives more appropriately address the indicators in Table 1.

- The Academy encourages further review with all relevant stakeholders to reach consensus to successfully fill in the percentages in Table 1.

- The AAP recommends a focus on the development of new technologies for production of influenza vaccine and delivery of influenza vaccine annually to a large segment of the population in a short timeframe. This influenza vaccine delivery prototype could serve as a model for mass immunization campaigns (i.e., pandemic flu; avian flu).

- It will be important to address the inclusion of additional vaccines in an already crowded immunization schedule.

- Another example of a way to reduce errors in vaccine administration can include the depth of injection (2.6.3)

Other outcome considerations:

- The number (%) of providers routinely using an immunization information system.
- Elimination of immunization rate discrepancies amongst target populations.
- Include Hib vaccine on the list for global prevention of death and disease.
- Development of curriculum content to be utilized by professional schools and training programs

The AAP recognizes the efforts made to develop this draft. We believe that this carefully designed document is a significant step towards a much needed and comprehensive National Vaccine Plan. Considerable effort will be needed to discuss and develop each of these areas, set priorities, identify potential targets for candidate vaccines, and develop the capability to rapidly respond to emerging or reemerging diseases. Priorities will be set based in part on the severity of disease, populations at risk, the ability to utilize available and emerging technologies to develop vaccine candidates, and available funds.

We look forward to participating, along with other stakeholders, in the critical discussions required to develop more specific goals and indicators in the National Vaccine Plan.

Sincerely,

David T. Tayloe, Jr, MD, FAAP
President

Joseph A. Bocchini, Jr, MD, FAAP
Chair, Committee on Infectious Diseases

American Association of Colleges of Pharmacy (William Lang IV, MPH)

The American Association of Colleges of Pharmacy (AACP) staff was guided in our response to your request for input on the 2008 draft strategic National Vaccine Plan by members of our Section of Teachers of Pharmacy Practice. We appreciate the opportunity to provide our input.

In general, AACP commends the National Vaccine Program Office (NVPO) for updating the 1994 strategic plan and support the draft goals and indicators established in the 2008 draft strategic National Vaccine Plan.

In particular, we are pleased that the plan recognizes the role that community-based vaccinators (including pharmacist), in addition to physicians, can play in increasing immunization rates of all patient populations. Increasing immunization rates was included as a goal of Healthy People 2010 and anticipated to remain an important goal in the development of Healthy People 2020. Colleges and schools of pharmacy provide immunization education and training to students through the professional curriculum and to practicing pharmacists through continuing education. Many of our institutions use the Centers for Disease Control and Prevention (CDC) - approved immunization training program or use the CDC approved program as a template for creating their own program. Educating a healthcare professional with strong communication skills is an important aspect of the professional curriculum in recognition that patients and consumers need assistance in translating information aimed at providing them a greater opportunity to participate in their care.

AACP and its members also appreciate that the plan includes "academia" as a non-federal stakeholder member responsible and capable of assisting the NPVO in achieving the five goals and nearly all the associated objectives. We encourage you to consider including academia as a non-federal stakeholder in meeting all the goal objectives especially those that include evaluation and research elements. Faculty at our nation's colleges and schools of pharmacy regularly work with a broad range of federal agencies to help them develop, implement, and evaluate patient and consumer communications such as those recommended in this strategic plan. Academic pharmacy is involved with the translation of new knowledge into clinical practice supported by the Agency for Healthcare Research and Quality (AHRQ) DeCIDE network and the National Institutes of Health (NIH) Clinical and Translational Science Awards programs. Our members have worked with the Food and Drug Administration (FDA) to determine the impact of prescription drug labeling on adherence. We recommend that the research agenda that can be constructed from this strategic plan be discussed with appropriate individuals and harmonized with ongoing efforts within AHRQ, FDA, CDC and NIH.

Comments on input requests listed in the Dear Colleague letter:

- Should the plan be fully achievable, aspirational, or a combination of the two?

While the plan is substantial in its scope, given appropriate resources to support the infrastructure necessary to generate the appropriate responses to the goals, through participation of federal and non-federal stakeholders, this plan could be fully achievable. HHS leadership should be engaged and fully committed to the need for appropriate resources to fully accomplish the plan. The five goals are well stated and the associated objectives could be met through current research and infrastructure available to academia. We again recommend the NVPO working with other federal agencies to harmonize research components of the draft plan.

- What recommendations can you offer for the numeric targets for the indicators?

At this time we are not able to assist with addressing the numeric targets. We would recommend that Healthy People 2010 and the National Health and Nutrition Examination Survey, among other federal data resources, be mined to create proxy measures for stakeholder consideration as a starting point.

- Please comment on the overall vaccine and immunization enterprise.

AACP members of the Section of Teachers of Pharmacy Practice indicate that "we have many excellent old and new vaccines, that are generally very safe compared to other products in the pharmaceutical arsenal. It is lack of access to these vaccines, even for those who desire to be vaccinated, that is currently the largest barrier hindering optimal immunization rates. Access problems do include potential lack of an adequate and stable supply of virtually all vaccines (especially if demand reflected the size of the true target populations). However, for most vaccines, the supply is generally sufficient for the current demand."

AACP recommends that the NVPO consider creating federal support for collaborative research initiatives that build upon the knowledge and skills of faculty researchers across professions as one approach for development of new vaccines. This is an approach utilized by the FDA through its support of the National Institute of Pharmaceutical Technology and Education (NIPTE). The development of new vaccines can be a low priority for private industry due to start up costs and low return on investment, especially for vaccines with targeted at a small population. Public private partnerships like NIPTE offer the opportunity for new product and manufacturing approaches to be developed as well as improvements to existing product manufacturing.

- How should accountability of non-federal stakeholders that are part of the plan be described?

Accountability would be described after non-federal stakeholders are asked to participate within specific activities related to goal, objective, or strategy attainment. Without agreed to frameworks of participation accountability can neither be described nor evaluated.

Specific comments related to Goals:

- Goal 1: Develop new and improved vaccines

Academic pharmacy can assist the NVPO with prioritizing the needs for new vaccines since our faculty are involved with this type of analysis for other biomedical entities.

Academic pharmacy and the students they educate form a significant network of community-based healthcare professionals able to conduct surveillance activities that can inform prioritization.

Pharmacy faculty, supported by federal grant funding, already are providing insight into new biomedical interventions. Federal grant funding for vaccine development would garner interest from the academy and may be an approach toward creation of new vaccines that may initially have a low return on investment, thus making the endeavor less favorable to private industry. Federal extra-mural grant funding could also be focused on specific patient populations such as pediatrics and older adults.

Pharmacy faculty are capable and currently engaged in comparative effectiveness research providing a ready research infrastructure for comparing/determining effectiveness and safety of vaccines.

Pharmacy faculty, collaborating across institutions, are currently at work to improve the manufacturing process of pharmaceuticals. This approach of collaborative, interprofessional research should be encouraged and recommended throughout Goal 1 Objective 1.3 and throughout the entirety of the plan.

- Goal 2: Enhance the safety of vaccines and vaccination practices

As mentioned above, pharmacy faculty, collaborating across institutions, are currently at work to improve the manufacturing process of pharmaceuticals. This approach would help meet Goal 2 Objective 2.1.

Academic pharmacy and the students they educate form a significant network of community-based healthcare professionals able to conduct surveillance activities that can inform prioritization. This network includes nearly 12,000 students dispersed throughout the healthcare system from one end of its continuum to the other. This network, supported and reinforced by licensed healthcare providers offers a practice-based research network that can detect trends in real time and help create active surveillance systems and enhance timely detection and evaluation of vaccine safety signals outlined in Goal 2 Objective 2.2

This same opportunity for the creation of a practice-based research network utilizing students and educators would readily address the concerns, new and emerging, regarding vaccine safety and surveillance identified in Goal 2 Objectives 2.3, 2.4, and 2.5.

Assessment of health professions education curriculum for contemporary competencies is a regular endeavor of academic pharmacy. The NVPO should consider convening or creating an advisory group of health professions educators with the aim of ensuring that health professions education curricula continually are updated to reflect current scientific evidence. This would assist the NVPO in addressing Goal 2 Objective 2.6

This same advisory group approach should be considered for Goal 2 Objective 2.7 and 2.8

- Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers

AACP is concerned that academia is not included as a non-federal stakeholder within Goal 3 Objectives 3.1, 3.2, 3.3 and 3.4.
Academia can assist the NVPO with meeting the stated objectives through research and evaluation of communication approaches and other activities developed to address these objectives. As mentioned earlier, faculty at colleges and schools of pharmacy work with other federal agencies to evaluate communications developed within the agency for dissemination to the public.

The plan does recognize academia as a non-federal stakeholder in Goal 3 Objective 3.6, but should be included in Objective 3.7

- Goal 4: Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States

AACP recommends that the NVPO consider creating federal support for collaborative research initiatives that build upon the knowledge and skills of faculty researchers across professions and institutions. This is an approach utilized by the FDA through its support of the National Institute of Pharmaceutical Technology and Education (NIPTE). The development of new vaccines can be a low priority for private industry due to start up costs and low return on investment, especially for vaccines with targeted at a small population. Public private partnerships like NIPTE offer the opportunity for new product and manufacturing approaches to be developed as well as improvements to existing product manufacturing.

Objective 4.2 may be addressed through provision of vaccines through student-lead organizations. Student pharmacists are extremely effective and more flexible than practicing providers when you consider increasing access to vaccine provision and are not dependent on reimbursement for service provision. Student organizations at health professions institutions, including pharmacy, are a ready resource, with a proven track record of vaccine delivery across the country.

Please consider earlier comments regarding the development and support of practice-based research networks that utilize the experiential learning requirements of pharmacy education as an effective model for addressing Goal 4 Objective 4.3 and 4.4

Utilize the skills or pharmacy faculty in creating and assessing curricula for improving provider counseling and delivery in addressing Goal 4 Objective 4.5.

Similarly, pharmacy faculty should be included in any entity NVPO creates to address Goal 4 Objective 4.6

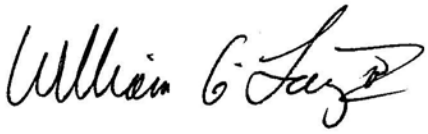
The translation of research into practice can be supported by ensuring the education of healthcare professionals includes the necessary critical thinking and communication skills to address the strategies listed in Goal 4 Objective 4.7.

- Goal 5: Increase global prevention of death and disease through safe and effective vaccination

Academia, including colleges and schools of pharmacy, is increasingly involved with global partners. This involvement frequently involves students participating in patient-care initiatives in countries around the globe. The NVPO should initiate a discussion with academic institutions that provide this international learning opportunity for their health professions students to orient these programs to Goal 5 and its associated objectives. This would provide a clear direction for international cooperation and meeting the goal and objectives.

Thank you for your interest in the input of the American Association of Colleges of Pharmacy. We look forward to working with you as you continue to refine the 2008 strategic plan and place it into action. Please do not hesitate to contact Will Lang (wlang@aacp.org) if you have questions or need additional information.

Sincerely,



William Lang IV, MPH
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American Association of Occupational Health Nurses, Inc. (Richard J. Kowalski, RN, MSA, COHN-S)

The American Association of Occupational Health Nurses, Inc. (AAOHN) is the national association representing the specialty practice of occupational and environmental health nursing, committed to create a positive economic impact through worker health and well being leading to optimal performance. As an organization supportive of population-based health care within a prevention and health promotion framework, AAOHN appreciates the invitation and opportunity to provide input into the draft strategic National Vaccine plan.

Vaccines are not just to protect the individual receiving the vaccination, but society (direct protection of the majority provides indirect protection of others-*herd immunity*). Vaccine-preventable disease levels are at or near record lows and the number of vaccines for preventable diseases have increased. On the flip side, the number of individuals receiving vaccines have declined, possibly related to fear of adverse effects, cost, access to provider, number of vaccines required per site (arm, thigh) or visit, age, etc., and the number of emerging infectious disease exposures and vaccine-preventable disease outbreaks have increased, e.g., measles, mumps, etc. As a global society, exposure to

infectious diseases must be considered a significant U.S. as well as a world health issue, e.g., international travel and increase potential for exposure, importation of food, in appropriate use of antibiotics, access to health resources and environmental changes, e.g., hurricanes.

The last Vaccine Plan was developed fifteen years ago (1994). Many of the challenges for disease prevention and vaccine enhancements in 1994 are still relevant today. Success will be influenced by financial factors and non-financial factors, i.e., attitude toward vaccination, vaccine safety and vaccination effectiveness as well as key immunization stakeholders. These key stakeholders should not be limited to federal (CDC, USAID) or international (WHO), but professional organizations and agencies (administrators of vaccines), consumers (recipients of vaccines) and global immunization trends must be considered.

Given the length of the current document and complexity of the objectives, success of the plan will be challenging, but achievable. AAOHN supports the document with the following recommendations**:**

- The plan should be fluid because emerging diseases are constantly changing and/or mutating.
- Research is imperative and should not be limited to just U.S. public and private stakeholders but have a global collaboration and exchange.
- With current vaccine fears and biases, continued research is needed to explore host factors related to adverse effects and failures at different stages in life, e.g., infancy, adolescence, pregnancy, elderly, etc. as well as those associated with workplace exposures, genomic characteristics and/or biomarkers immune responses/indicators.
- Confidentiality needs to be maintained due to the perceived implications of genomic and biomarkers personal information misuse.
- To maintain a stable supply of recommended vaccines, do not limit manufacturers to production of one vaccine but have multiple vaccine manufacturers to prevent the occurrence of vaccine shortage, e.g., influenza.
- To achieve better use of existing vaccines:
    - Rotate the 6 months supply of stockpile vaccines and provide to public health facilities for administration, as applicable.
    - Implement or re-implement the electronic health records (increase information access to avoid missed opportunities) and the recall system, both of which were discussed 15 years ago.
    - Change consumer/client attitudes about vaccinations through education and re-education, information sharing, consumer stakeholders input, etc.

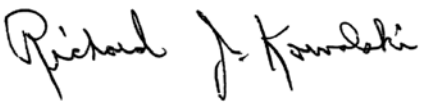
AAOHN supports public and private, national and global collaboration to leverage communication, education and research on vaccine use, indication, adverse effects, etc. as well as to leverage legislation and financial support. However, vaccine research should investigate other routes of vaccine administration as well as the continued efforts to combine vaccines and decrease the number of associated adverse events. Although

genetic testing is a possible alternative to decreasing adverse effects, there are legal and ethical implications.

The goal of the plan is to eradicate, eliminate or control infectious, vaccine preventable diseases. As the primary health care provider for workers, worker populations, employers and community groups, occupational and environmental health nurses (OHNs) are in the unique position to influence the development and implementation of a workplace vaccine plan and workforce vaccine rates. As a member of the health and safety team or as the workplace licensed health care professional, the OHN facilitates the operation of the annual flu program, administration of required vaccines and meds for travel and other work related requirements, administration of the disaster preparedness plan, health education to influence best health options for workers and their families and prevention of worker exposure, which impacts worker absenteeism and productivity, and community health and economy.

AAOHN appreciates the opportunity to have provided comments to the Department of Health and Human Services and the National Vaccine Program Office on the draft *National Vaccine Plan.* We would welcome the opportunity to work with the Department in the future.

Sincerely,



Richard J. Kowalski, RN, MSA, COHN-S
President

American Association of Respiratory Care (Timothy R. Myers, BS, RRT-NPS)

The American Association for Respiratory Care (AARC) is a professional organization representing 48,000 respiratory therapists who treat high-risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis. We appreciate the opportunity to comment on the National Vaccine Plan and to become an active stakeholder in assisting the National Vaccine Program Office in its efforts to achieve the goals and objectives of the plan.

You have specifically asked for input on four broad areas for the plan: 1) priorities over the next 10 years, 2) comments on the plan's goals, objective and strategies; 3) indicators and suggested target estimates; and 4) stakeholders' roles in the plan. Since much of the plan focuses on issues that are outside our areas of expertise, our comments focus primarily on the last item, stakeholders' roles. The AARC is best positioned to assist with Goal 3: "Support informed vaccine decision-making by the public, providers and policy-makers." Therefore, our comments below focus on the objectives and strategies contained within that goal. With respect to specific vaccines, the two that are of interest to our organization are the flu and pneumococcal vaccines.

1. Which stakeholders should have responsibility for enacting the objectives and strategies listed in the draft Plan?

We concur with the list of stakeholders that have been identified in the plan for Goal 3. However, while it may be assumed that patient advocacy groups, or patient information organizations (PIOs), are included among the term "the public", we believe it is important to make a distinction that recognizes the important roles these groups play in reaching a vast audience who can benefit from the goals and objectives outlined in the National Vaccine Plan. We recommend adding these types of organizations to the list of non-Federal stakeholders.

2. Identify roles your organization can play in the Plan.

Respiratory therapists (RTs) serve in a variety of venues and this gives our professional members access to patients and health care professionals in many different types of settings. Some examples include acute care hospitals, hospital outpatient settings, sleep disorder centers and diagnostic laboratories, rehabilitation facilities, skilled nursing facilities, patients' homes, physicians' offices, wellness centers and convalescent and retirement centers.

Given the growing number of individuals with chronic illnesses, the RTs' education, training and expertise in clinical conditions such as asthma, chronic obstructive pulmonary disease (COPD), and lung disease, also makes them uniquely positioned to expand their role into the disease management arena where coordinated care among various health delivery systems and communications about prevention and self-managed care are important aspects of the program.

Overall, RTs are professional providers of quality health care to all age groups in hospitals, alternate sites and in the home. As a professional organization, the AARC has numerous resources and tools that our members can use to assist in carrying out some of the objectives and strategies outlined in Goal 3 of the National Vaccine Plan. We see the AARC's role as a stakeholder taking on a variety of initiatives:

- Improving our grassroots efforts at the local level. Our state societies have websites and newsletters and state conferences where the AARC can request state societies to assume the task of generating interest in the value of vaccines and the need for immunizations. RTs and their state societies are already working together on pandemic flu/mass casualty/disaster planning.

- Using our section chiefs and "list servs" to enhance the delivery of timely, accurate and transparent information about the risks and benefits of vaccines and the vaccine program. The AARC has numerous specialty sections that provide an e-mail message list, monthly e-newsletters, quarterly bulletins and a specialty section website for those RTs who practice in a particular area of respiratory care. Some examples of

these specialties include adult acute care, continuing care/rehabilitation, home care, long-term care, neonatal-pediatrics, sleep, and diagnostics.

- Partnering with organizations like the COPD and Alpha 1 Foundations, the Asthma & Allergy Foundation of America, the Pulmonary Education and Research Foundation (PERF) and others to promote the vaccine program. The AARC works closely with a number of patient organizations on a regular basis in an effort to coordinate our activities that share a common interest.

- Using the AARC.org web site and YourLungHealth.com to frequently remind health care professionals and patients about the value of the vaccine program. The AARC website is designed to provide valuable information not only to our RTs but a vast majority of the public and health care community who are interested in gaining a better understanding of respiratory illnesses, accessing evidence-based literature and clinical practice guidelines, or keeping up to date on the latest developments and regulatory activities that impact those who treat or suffer from respiratory illnesses. The YourLungHealth web site is aimed at providing similar information to the patient population. This year, in collaboration with the CDC and the National Vaccine Program Office, we used these websites to stress the value getting a flu shot.

- Publishing articles in our magazine, AARC Times, to increase awareness of vaccine preventable diseases and the benefits and risks of flu and pneumococcal vaccines. The AARC Times is a monthly magazine that is available to our members and the professional health care community. We can offer a valuable service to our readers through continuing education on the importance of the goals and objectives identified in the National Vaccine Plan.

- Enhancing our public relations guide book to reach targeted audiences with timely and accurate information about the risks and benefits of the flu and pneumococcal vaccines so they can make informed decisions. As members of AARC, our RTs have access to multiple resources to assist them in developing local public relations campaigns. For example, we provide guidance and categories to assist them in writing press releases, replying to press inquiries, developing fact sheets on a number of relevant topics, and triggering other publicity ideas. Our audiences include the AARC Leadership, patients and lay caregivers, the general public, the health care community, employers, payers, government, educators, industry and competitors.

- Developing information on the benefits and risks of getting vaccinated from the perspective of the respiratory therapists. The benefits and risks of vaccinations is a perennial topic for health care providers and patients. Our RTs can play an important role in educating a broad sector of the health care community about the flu and pneumococcal vaccine from the vantage point of treating patients with respiratory illnesses.

- Updating our human resources survey to include questions around the vaccine program. Every five years, the AARC conducts a survey of its members to gather

important statistics on a number of topics. The survey will be conducted this year and for the first time we have included questions that will enable us to track immunization rates among RTs in order to measure success in improving the rate of flu vaccines among health care workers as part of the Healthy People 2010 initiative. In the future, we can use this tool to incorporate questions that will provide pertinent information about expanding the knowledge base of those who are served by our RTs as to the benefits and risks of being vaccinated or immunized against the flu and/or pneumonia.

We appreciate the opportunity to work with the National Vaccine Program Office and others in meeting the goals and objectives of the National Vaccine Plan, especially in support of informed vaccine decision-making by the public, providers and policy-makers. Should you have any questions or need to contact us in the future, feel free to call our Executive Director, Sam Giordano at 972-243-2272 or e-mail at giordano@aarc.org.

Timothy R. Myers, BS, RRT-NPS
President

American Dental Association (John S. Findley, D.D.S.)

The American Dental Association (ADA) is pleased to comment on the U.S. Department of Health and Human Services' (HHS) draft National Vaccine Plan. These comments are offered in response to your Federal Register notice of January 14, 2009 (74 FR 2076).

- ***Purpose, Perspective, and Scope.*** Mention is made of emergency preparedness in this plan and other plans. It might be wise to address this subject in more detail, since not all agencies may have easy access to "other HHS strategic plans" or would think of consulting other plans beyond this plan.

- ***Goal 5.*** Global immunization would have the added benefit of protecting U.S. residents from exposure to diseases from visitors and immigrants. This becomes more important as global transportation becomes available to more people and with increased globalization of commerce.

- ***Objective 3.2.*** The American Dental Association and its local dental societies could be valuable collaborators in enhancing communications with the general public on vaccination issues. People generally see their dentist regularly rather than episodically, as they do with other health care providers. This concept of the importance of preventing disease is a basic tenet of dental practice, so dental personnel could be enthusiastic proponents.

- ***Objective 3.6.*** Special educational programs concerning vaccines and vaccination programs should be made available to dentists (like the smallpox materials sent out to all dentists by the Centers for Disease Control and Prevention) for their use.

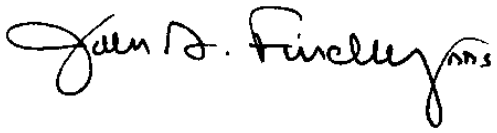
- ***Strategy 4.2.8.*** Private dental offices, dental schools and other dental facilities could easily be used as vaccination sites, especially during emergencies.

- ***Strategies 4.5.7-10.*** These strategies should be emphasized for dental personnel and the families of dental personnel to be priority vaccine recipients, since they will be particularly vulnerable to infection spreading, especially in the event of a bioterrorism event.

- ***Strategy 4.8.3.*** Dentistry should be included in these exercises and in planning for mass vaccination activities. This is a valuable asset that should not be overlooked. Mention in this or another section would be helpful to draw attention to the value of dental personnel in this area.

Dentistry's role in mass vaccinations is new and evolving. We appreciate the opportunity to comment on your work and applaud your efforts to include a role for dentistry in the final plan. If you have any questions or would like additional information, please contact Dr. Albert Guay at 312-440-2844 or guaya@ada.org.

Sincerely,



John S. Findley, D.D.S.
President

American Immunization Registration Association (Cindy Sutliff)

The American Immunization Registry Association (AIRA) is a membership organization that promotes the development and implementation of immunization information systems (IIS), also known as immunization registries, as an important tool in preventing and controlling vaccine preventable diseases. The organization provides a forum through which IIS programs, interested organizations and individuals and communities combine efforts, share knowledge and promote activities to advance IIS and immunization programs. The State, Local, and Regional IIS programs are broadly represented in AIRA's membership.
By collecting or receiving identifiable health or other information, public health can report on disease, injury, and vital events such as birth or death. Collecting and receiving this information also helps them conduct public health surveillance, public health investigations, and public health interventions. The results of such activities are that

public health can better prevent or control disease, injury, or disability.
To achieve some of these public health purposes, public health is interested in fostering the ability to consolidate an individual's immunization record, more easily access immunization information for individuals or a population, and more easily securely exchange individual and population immunization data between private and public health organizations and population-based immunization information systems (IIS).
As such, AIRA wishes to take this opportunity for public comment on the Draft Strategic National Vaccine Plan. We have divided our responses into two areas: General recommendations and recommendations for modifications to specific wording in the draft. Therefore, AIRA makes the following recommendations:

General Recommendations

1. The draft plan should include the fact that IIS provide the capability to develop and maintain an accurate and complete consolidated record of an individual's immunizations, and also provide the ability to securely access and exchange those records.
2. Public health must be able to conduct surveillance and assess immunization coverage for at-risk populations. The draft plan should mention that this is a critical capability for public health and that IIS provide this capability.
3. The draft plan often uses the terms IIS and EMR in the same sentence in a way that does not distinguish between the roles of these two tools (for example, in section 4.3.2). IIS store and provide population information, aggregating data about groups, while EMRs are clinical tools used in a provider practice to collect and provide individual patient information. The plan should distinguish between the roles of each when mentioning them together.

Specific Wording Changes

Section 2.2.1

Current: Improve the effectiveness and timeliness of AEFI signal identification and assessment through coordinated use of national passive and active surveillance systems.
Recommended Wording: Improve the effectiveness and timeliness of AEFI signal identification and assessment through coordinated use of national passive and active surveillance systems, including IIS.

Section 2.3.3

Current: Enhance capacity to monitor immunization safety in the event of a mass vaccination campaign.
Recommended Wording: Enhance capacity to monitor immunization safety in the event of a mass vaccination campaign by quickly aggregating the data in a state, local or regional IIS.

Section 3.6.1

Current: Expand and implement training and education of immunization providers at all levels of their education on the proper use of vaccines, the proper storage and handling of vaccines, the basis of immunization recommendations, vaccine safety, and on the standards of immunization practice.

Recommended Wording: Expand and implement training and education of immunization providers at all levels of their education on the proper use of vaccines, the proper storage and handling of vaccines, the basis of immunization recommendations, vaccine safety, on the standards of immunization practice, and the use of IIS as a decision-support tool.

Section 3.6.2
Current: Develop and implement educational strategies for providers on vaccine preventable diseases, including diagnosis, modes of transmission, prevention and control, and reporting requirements.
Recommended Wording: Develop and implement educational strategies for providers on vaccine-preventable diseases, including diagnosis, modes of transmission, prevention and control, reporting requirements, and the use of IIS as a decision-support tool.

Section 3.7.3
Current: Develop evidence-based tools to assist individuals, parents, and providers synthesize relevant vaccine-related information to make informed decisions regarding vaccination.
Recommended Wording: Develop evidence-based tools and use IIS to assist individuals, parents, and providers in synthesizing relevant vaccine-related information to make informed decisions regarding vaccination.

Section 4.3.1
Current: Identify, implement, and evaluate cost-effective and rapid methods for assessing vaccination coverage:
a. among children, adolescents, adults overall and by State, immunization grantee, and within states and grantees;
b. among persons in key population subgroups (e.g., racial/ethnic groups, pregnant women, healthcare workers); and
c. by type of vaccination financing (e.g., VFC, other public sector program, private sector).
Recommended Wording: Identify, implement, and evaluate cost-effective and rapid methods, such as the use of IIS, for assessing vaccination coverage:
a. among children, adolescents, adults overall and by State, immunization grantee, and within states and grantees;
b. among persons in key population subgroups (e.g., racial/ethnic groups, pregnant women, healthcare workers); and
c. by type of vaccination financing (e.g., VFC, other public sector program, private sector).

Section 4.3
Recommended Additional Sub-section:
4.3.3 Support and encourage electronic medical records (EMR) vendors to develop interfaces to seamlessly exchange immunization data with IIS.

Section 4.5.4
Current: Incentivize direct health care providers, health systems, and health insurers to

provide vaccines by incorporating vaccination in quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).
Recommended Wording: Incentivize direct health care providers, health systems, and health insurers to provide vaccines by incorporating vaccination and use of IIS in quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).

Section 4.5
Recommended Additional Sub-section:
4.5.11 Promote using IIS as a decision-support tool to identify the appropriate timing of vaccines so providers administer them when needed. Promote use of IIS as an educational tool that provides feedback to providers about administered vaccinations being invalid due to improper timing.

Section 4.6
Recommended Additional Sub-section:
4.6.5 Leverage the data available through population-based IIS to evaluate the impact and implementation of new and existing immunization recommendations.

Section 4.9.2
Current: Implement and evaluate activities to enhance immunization coverage among travelers.
Recommended Wording: Implement and evaluate activities, such as the use of international certificate of immunization produced by IIS, to enhance immunization coverage among travelers.

For more information about AIRA's responses, please contact:
Cindy Sutliff
Executive Director, AIRA
Email: csutliff@health.nyc.gov
Phone: 212-676-2325

American Nurses Association (Linda J. Stierle, MSN, RN, NEA-BC and Rebecca M. Patton, MSN, RN, CNOR)

The American Nurses Association (ANA) welcomes the opportunity to comment on the Department of Health and Human Services' proposed National Vaccine Plan to set strategic national goals concerning immunization research, development, safety, practices, and policies over the next ten years.

ANA represents the interests of the nation's 2.9 million registered nurses (RNs), the single largest group of health care professionals in the United States. The association represents RNs in all roles and practice settings, through its constituent member nurses associations and 23 organizational affiliates. ANA members include registered nurses

and Advanced Practice Registered Nurses (APRNs).

ANA supports efforts to enhance vaccine education, access, and safety, as immunizations are a cornerstone in preventative health care, and represent important public health and safety measures in controlling and preventing infectious diseases.

ANA is pleased to offer comments to your specific questions as listed in your email, as well as offer comments on your proposed objectives and strategies in the plan.

ANA suggests a top priority for vaccines and immunization enterprise in the United States should be making vaccination a federal priority in decreasing disease burden, and increasing vaccination levels in children, adults and the elderly. To achieve this, the Department of Health and Human Services (HHS) should take the lead in providing funding to vaccine programs targeting adults and the elderly to decrease the financial barriers to vaccination, and to create more opportunities for adults to be vaccinated in the public sector (pertinent to Objective 4.2). Such a program might resemble the eligibility criteria of the Vaccines For Children (VFC) program, a program that has proved successful in providing vaccines for under-insured and uninsured children younger than 19 years of age.

Secondly, HHS should prioritize the strengthening of public confidence in vaccine safety. Anti-vaccine sentiments have become more prominent in the media, as outspoken celebrities and other vaccine opponent groups have gained attention and support from some in the public, prompting fears and suspicions of vaccines and vaccine safety. Unfortunately, the government's efforts to reassure the public of vaccine safety have been met with skepticism for various reasons. A priority for HHS should be to seek out more champions for vaccination from the private sector. In addition, greater transparency in the processes of vaccine licensure and practices approval could be beneficial in increasing the public's confidence in and understanding of the decision making, and decrease suspicion that political or economic factors enter into these processes (pertinent to Objective 3.7).

In terms of the specific goals and strategies, ANA provides the following comments:

Strategy 1.5.1 (Page 30) – HHS should consider broadening this expansion of research to study genetic variances in immunological response based on ethnicity and race.

Strategy 2.6.3 (Page 37) - Reducing errors in vaccine assessment and administration will require a closer look at the increasingly complex and confusing immunization schedule as recommended by the Centers for Disease Control and Prevention. In the past 10 years, a host of vaccines have been added to the schedule, with varying indications for age and number of doses. It is quite difficult for many health care providers to stay current on the immunization schedule, and to decipher patient vaccine records and make vaccine recommendations in accordance with that schedule. Simplification of the schedule is one way to reduce errors from incorrect assessments of vaccine records. This may require HHS to work with vaccine developers to encourage vaccine products that require less

boosting to achieve effective immunological response. Another is federal financial support for states to develop and implement immunization registries that provide vaccine assessments and recommendations.

Strategy 3.6.4 (Page 45) - Health care providers should allow and encourage the public to report to VAERS on their own, and this information should be clear on federally produced vaccine information statements.

Strategy 4.5.7 (Page 53) - ANA has developed influenza vaccination campaigns for nurses. If HHS seeks a model for communication tools as part of a comprehensive program to ensure health care professionals are appropriately immunized, we would be happy to provide these tools for your use and reference.

Strategy 4.5.9 (Page 53) - ANA discourages changing professional licensure requirements to increase vaccination rates in health care providers. A focus on licensure would actually neglect the population of unlicensed health care providers that provide routine patient care, such as patient care technicians and nursing assistants, and would not encompass the spectrum of health care providers that would benefit from vaccination.

Strategy 4.5.10 (Page 53) - ANA has a Position Statement opposing health care facility policies that mandate certain vaccines for health care workers. ANA supports health care vaccination. However, vaccination should be an informed choice of the individual and not a requirement for employment.

Strategy 4.6.1 (Page 53) – In order to ensure transparency of the decision-making processes of various federal immunization committees such as the Advisory Council on Immunization Practices, there should be increased public access to these and other pertinent proceedings. This can significantly increase broad-based support for current and future policies.

Strategy 4.6.2. (Page 53) - In order to strengthen federal vaccine decision-making and advisory committees, ANA strongly encourages diversifying membership to include representatives from the entire spectrum of health care practice beyond medical doctors. Advisory committees on vaccines often lack the voices and input of nurse representatives, even though RNs and APRNs provide the bulk of immunization services in both private practice and public health. Because of the strong role that nurses play in public education and patient advocacy, excluding nurses from participation in these important bodies is also detrimental to the patient population. HHS should take advantage of the strong link between nurses and their patients, and enlist the nursing profession in the task of encouraging the public to adhere to vaccination recommendations and policies.

Strategy 4.6.4 (Page 53) - In considering the cost-effectiveness of current immunization recommendations, HHS should include the cost of revaccination due to lost or destroyed vaccine records. Often children have to “start over” with all vaccines simply because the paper vaccine record was lost. A comparative effectiveness study of revaccination

versus antibody detection testing would be helpful in determining the most cost-effective way to deal with this problem.

ANA looks forward to being a beneficial stakeholder in the implementation of the National Vaccine Plan. Specifically, ANA sees the nursing profession as an integral and key player in the effort to achieve the objectives laid out in the description of Goal 3. In clinical practice, nurses are involved in almost every phase and strategy of the plan, as nurses' practice in the diverse areas of health care research, education, service delivery, policy, and public outreach.

ANA appreciates the opportunity to comment on this proposal. We sincerely hope that these comments are helpful. Should you have any questions or would like to discuss these comments further, please contact Katie Brewer, RN, MSN, via e-mail at katie.brewer@ana.org, or via telephone at (301) 628-5043.

Sincerely,

Linda J. Stierle, MSN, RN, NEA-BC
Chief Executive Officer
American Nurses Association

Rebecca M. Patton, MSN, RN, CNOR
President
American Nurses Association

The Association for Professionals in Infection Control and Epidemiology (APIC – Christine Nutty, RN, MSN, CIC)

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide input to the draft Strategic National Vaccine Plan. APIC is a nonprofit, multi-disciplinary, international organization representing 12,000 infection preventionists, whose mission is to improve health and promote safety by reducing the risks of infection and adverse outcomes in patients and healthcare personnel. APIC agrees with the purpose of the National Vaccine Plan (NVP) to promote achievement of the National Vaccine Program mission to prevent infectious diseases and reduce adverse reactions to vaccines by providing strategic direction and promoting coordinated implementation by vaccine and immunization enterprise stakeholders. We agree with the value of incorporating a ten-year horizon in order to balance a strategic vision while also allowing for adjustments that will be needed to integrate changing circumstances and new opportunities. We also support promoting accountability and flexibility through an annual monitoring process.

We would also like to provide input into some of the goals, objectives and strategies on which we have some expertise.

Goal 2: Enhance the safety of vaccines and vaccination practices

APIC encourages efforts to improve public perceptions about vaccine safety, and efforts to improve reporting of adverse events from immunization (AEFI) and reduce errors in administration of vaccines via training, education and engineering controls. We also advocate improved methods of monitoring vaccine safety, especially in the event of a mass vaccination campaign, which would involve using an improved process for reporting adverse events. In addition, APIC supports ongoing research and surveillance to monitor changing trends resulting from current vaccine use.

APIC supports Objective 2.2 to enhance timely detection and evaluation of vaccine safety signals; however, we have some concerns about possible under usage of the Vaccine Adverse Event Reporting System (VAERS). Since hospitalized patients often receive the pneumococcal/influenza vaccine shortly before discharge, the vaccine provider may not be aware of AEFIs that may occur post-discharge and events may go unreported. We recommend more specific suggestions on how active surveillance would be implemented. Some options might include follow-up phone calls, return visits to offices or vaccine providers, or surveys mailed to patients. We also recommend adding to Strategy 2.2.2 that information gleaned through active surveillance be reported back to healthcare professionals in a timely manner. This could facilitate Strategy 2.2.3, to assess lay public and professional questions and concerns about vaccine safety. In addition, we suggest expanding the term "lay public" to include community vaccine groups, particularly those who oppose vaccination.

To implement Strategy 2.3.3, we believe that involving healthcare systems in the reporting process could help enhance capacity to monitor immunization safety in the event of an influenza pandemic or other mass vaccination campaign.

Objective 2.6, to improve clinical practice to prevent, identify and manage AEFIs, is especially important. APIC welcomes the opportunity to assist in improving training and communications on vaccine safety and administration, as identified in Strategy 2.6.1, and we believe this will help in implementing Strategy 2.6.3 to reduce errors. We agree with the need, identified in Strategy 2.6.2, to develop additional evidence-based guidelines for vaccination or revaccination for persons at increased risk of AEFI. We are especially concerned about dated and conflicting evidence regarding revaccination of children with reactions to diphtheria, pertussis, and tetanus vaccines. We also agree with Strategy 2.7.3 to improve laboratory, epidemiological and statistical methods used in vaccine safety research. However, we believe that identifying the gaps in current methods and research is an essential first step, and we recommend adding language identifying this to Strategy 2.7.3.

Goal 3: Support informed vaccine decision-making by the public, providers, and policymakers

APIC agrees that timely and accurate information is essential to improving vaccine delivery and safety. We support enhanced communications with healthcare professionals concerning the perceived benefits and risks of vaccines and improved dissemination of research findings to facilitate implementation of evidence-based strategies. APIC stands ready to partner with the Centers for Disease Control and Prevention (CDC) in distribution of vaccine information to our members and is willing to collaborate in educational initiatives.

Goal 4: Ensure a stable supply of recommended vaccines, and achieve better use of existing vaccines to prevent disease, disability, and death in the United States
APIC supports efforts to improve vaccine tracking systems and to reduce financial barriers to vaccination. We encourage education of providers on business practices associated with providing immunization, including development and evaluation of employer-based immunization programs. However such efforts must also address privacy and employee rights issues. APIC agrees with the need identified in Strategy 4.1.1 to increase US licensed vaccine suppliers to have at least two suppliers of each vaccine antigen recommended for routine use. This would help to ensure a constant accessible vaccine supply, thereby preventing gaps in vaccination schedule and unprotected individuals (U.S. Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, "Invasive Haemophilus influenzae Type B Disease in Five Young Children --- Minnesota, 2008", January 30, 2009.). We also believe a target date should be added in order to expedite this very important strategy. However, additional guidance should also be in place to prioritize and provide direction on vaccine distribution during shortages or limited supplies. In addition, APIC recommends expanding references to healthcare facilities and vaccination providers to specifically include ambulatory surgery centers, rehabilitation institutions, dialysis centers and other non-traditional vaccine providers in order to broaden the scope of current vaccination practices. APIC also appreciates inclusion of Strategy 4.8.3 relating to mass vaccination activities for containment of an outbreak of a vaccine preventable disease or biological attack, and we trust that implementation will comply with the HHS Pandemic Influenza Plan.

Thank you again for the opportunity to participate in updating the Strategic National Vaccine Plan. We look forward to continuing to provide assistance to HHS as the plan develops.

Sincerely,
Christine Nutty, RN, MSN, CIC
2009 APIC President

National Association of State Directors of Developmental Disabilities Services (Linda Rolfe, Director, Washington state Division of Developmental Disabilities)

Thank you for the opportunity to comment. I asked for help from one of our pediatric consultants in WA and we provide the following feedback.

1. While the 5 goals outlined in the strategic plan are broad with a 10 year horizon in mind, we have certain concerns about with administration and buy in from the consumer as new vaccines are developed. We would hope that there would also be an added focus on developing combination vaccines, studying their efficacy and possible synergistic effects and development of herd immunity as we move forward with the strategic plan. There is growing resistance from families to the

administration of multiple vaccines especially in infants and children, despite efforts by providers to educate them on its benefits. Mostly the resistance does not appear to be to the vaccine itself but to the number of pokes the child has to endure to receive the multiple vaccines.

2. As we move forward with developing new vaccines – the burden of disease has to be factored in to the equation. Some diseases although debilitating affect only a very small segment of society
3. Another area of concern is the rapid deployment of new vaccines. A prime example is the HPV vaccine. Even among the health care community there are a lot of questions regarding the long term efficacy of the vaccine and the current cost burden of procuring and administering the same to a population that is hard to access (teens). The time lines for deployment have to be realistic and efforts have to be made to educate and get buy in from health care providers in order to ensure the successful deployment of the new vaccines.
4. In our enthusiasm to develop new vaccines , the existing vaccines should not be forgotten. These vaccines have to be studied for new ways of delivery, effects on recall of immune memory and efforts should be made continuously to retain immunogenicity in the vaccinated population and they nor we should be lulled into a false sense of life time immunity.
5. Vaccine manufacturing and distribution has had its ongoing challenges. Shortage of vaccines and inability to get vaccines in the recommended age range and time frame further erodes consumer confidence. Licensing for vaccine manufacturing should not be the monopoly of one or 2 companies with an eye towards profitability and or patent protection but should have the public good in its sight. Vaccine manufacturing should be licensed to more then 3 -4 entities with strict quality control and over sight by an independent body thereby ensuring adequate supplies even when faced with challenges such as mass disaster or contamination or recalls.
6. Ongoing assessment of risk and adverse events while being closely monitored, this information should be disseminated proactively to the providers who administer these vaccines for early detection of potential problems and education of the consumer.
7. Bring more transparency to the decision making process by involving both the providers and consumers on a large scale, utilizing newer technology to solicit input in a timely and effective manner. This promotes empowerment and buy in which is crucial for the success of the program.
8. Consider developing a central vaccination database so that people can have access to their record and can give access to their healthcare professionals. Think of innovative ways to tie in this information with existing data bases and look for innovative ways of vaccine delivery – such as a vaccination clinic next to other government agencies that people visit. This way missed opportunities for vaccination can be minimized.
9. Minimize the efforts of lobbyists and private interest groups to influence the decision making process. While their input may be valuable from a funding stand point, a credible independent body free of such biases should be the prime analyst and decision maker.

10. Although vaccines have made major contributions on the world stage in terms of reducing disease burden and mortality, resistant organisms are a constantly evolving threat and development of more synthetic vaccines has to be explored aggressively. This process may reduce manufacturing time as well decrease the costs of vaccines, thereby ensuring affordability.

Linda Rolfe, Director
Division of Developmental Disabilities

Pediatric Infectious Diseases Society (Stanford T. Shulman, MD)

On behalf of the Pediatric Infectious Diseases Society (PIDS), I am writing to provide PIDS' comments to the draft strategic National Vaccine Plan. Members of the Clinical Affairs and Public Policy Committees, as well as the Vaccine Advocacy Task Force have reviewed the Plan and have collectively provided the following comments:

Comments from conference call participants:
1. Occasionally, ACIP issues recommendations for vaccine use that are outside of the labeled indications for certain products. A recent example is the recommendation to extend the age ranges for doses of rotavirus vaccine beyond those listed in the package inserts for RotaTeq® and Rotarix®. Practitioners feel this may put them at medico-legal risk. Confusion generated by differences between the indication for vaccine use and the recommendations for vaccine us need to be addressed.

2. PIDS recommends developing a plan for a national immunization registry that is cradle-to-grave for all civilians.

3. PIDS recommends studying the impact of current communication tools such as Vaccine Information Statements (VIS) before developing new tools.

4. PIDS agrees with the need for at least 2 licensed vaccine suppliers in the US for each vaccine. However, it is important to assure that manufacturers supply vaccine **for all ages** for each vaccine. Manufacturers should, when appropriate for specific diseases, be required to test vaccines in all appropriate age groups. For example, new candidate influenza vaccines should be tested in all age groups, including infants and the elderly.

5. Travel vaccines have a low overall impact on public health and should be de-emphasized in the plan in the interest of putting resources into areas with potentially larger impact.

6. Communication between agencies involved in vaccine supply issues and among other stakeholders should be further developed and funding should be made available to support such efforts.

7. PIDS has some concerns about the Overview of the vaccine and immunization enterprise as shown in Figure 1.

a.) Should the "Develop vaccine recommendations" box have some relationship, either a direct relationship with an indicator arrow to High Vaccination Rates, or indirectly through an arrow from "Develop vaccine recommendations" to Vaccination (adult, adolescent, and childhood) then an arrow to High Vaccinations Rates? As shown, the Figure implies that those making vaccine recommendations have no expected impact on Vaccination rates (or vaccination for that matter).

b.) Similarly, the "Develop vaccine recommendations" box, should have both a forward and backward arrow with the Communication and Education Strategies box. The Communication and Education Strategies box should also have bidirectional arrows to/from Attitudes about Vaccinations, given all the emphasis recently on bidirectional communication between patients/parents and providers (and other stakeholders).

c.) As shown in the Figure, "Development of vaccine recommendations" is a completely separate portion of the vaccine and immunization enterprise. Perhaps this issue, as drawn, is correct and may be part of the continuing issue patients, parents and providers are experiencing (or perceived to be experiencing) with vaccine acceptance and usage in the U.S. If there is meant to be meaningful "feedback" it needs to be shown in the Figure.

Comments on priorities for the National Vaccine Plan for a ten-year period:
What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally?

1. US
   a. National vaccine registry
   b. Improved public education on safety and efficacy of vaccines to counter disinformation and myths
   c. Assure supply of appropriate vaccines to all ages at reasonable costs
   d. Continue development of new vaccines, including *S. aureus*, HIV, hepatitis C, CMV, RSV, parainfluenza, and improved vaccines for influenza (including avian strains)
   e. Develop the infrastructure for rapid response to outbreaks of emerging or novel pathogens

2. Global
   a. Polio eradication
   b. Penetration of rotavirus vaccine into the developing world
   c. Development of an effective malaria vaccine
   d. Development of an effective tuberculosis vaccine
   e. Development of an HIV vaccine

Why are those priorities important to you?

1. US
    a. A national registry would facilitate universal coverage and timeliness of vaccination and would provide a database for studies of vaccine delivery
    b. Vaccination myths threaten public health. Providers are unable to effectively address public concerns in the course of routine immunization visits.
    c. Vaccine shortages threaten public health.
    d. These diseases continue to produce much mortality and morbidity, and therapy is often expensive of ineffective.
    e. Pandemic or emerging pathogens are a threat to public health
2. Global
    a. This seems an achievable target
    b. Rotavirus causes approximately 600,000 annual deaths, the vast majority of which are in developing countries
    c., d. e. – these diseases remain extensive and lethal in impact

Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:

Comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns.

1. Occasionally, ACIP issues recommendations for vaccine use that are outside of the labeled indications for certain products. A recent example is the recommendation to extend the age ranges for doses of rotavirus vaccine beyond those listed in the package inserts for RotaTeq® and Rotarix®. Practitioners feel this may put them at medico-legal risk. Confusion generated by differences between the indication for vaccine use and the recommendations for vaccine use need to be addressed.

2. Develop plan for a national immunization registry that is cradle-to-grave.

3. The agenda should include the development of strategies to better capture post marketing vaccine adverse effects. This would assure that recipients, regardless of location, race, and socioeconomic status, would be adequate represented.

Are there any goals, objectives, or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

1. Travel vaccines have a low overall impact on public health and should be de-emphasized in the plan in the interest of putting resources into areas with potentially larger impact.

Comments on stakeholders' roles in the National Vaccine Plan:
Identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organizations can play in the Plan.

PIDS members, if requested or solicited, would be interested in evaluating VIS and other evidence-based tools to assist patients, parents and providers in synthesizing relevant vaccine related information and make informed decisions.

Please accept these comments as a means to help in your effort to update the existing National Vaccine Plan. In addition, PIDS would like to be involved by actively participating in future revisions of the Plan. Should you have any questions, please contact Christy Phillips, Executive Director at (703) 299-9865. Thank you for your efforts to ensure better health care for infants, adolescents, and adults.

Sincerely,
Stanford T. Shulman, MD
President

Society for Adolescent Medicine (Richard E. Kreipe, MD)

1. GENERAL COMMENTS

This is a clear and comprehensive document that reflects both the priorities and the policy statements of the Society for Adolescent Medicine. We were pleased that adolescent vaccination issues were addressed throughout the document.

One general suggestion would be to explicitly acknowledge the link between immunization and general access to health care (including access to insurance and primary care services). This is especially relevant for young adults who are too old for VFC and often lose their coverage under SCHIP or Medicaid.

2. SPECIFIC COMMENTS

Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers

Indicators – first bullet: By Y (year), enhance communication with stakeholders and the public to more rapidly inform them (within _X_ days) about urgent and high-priority vaccine and vaccine-preventable disease issues (e.g., outbreaks, supply shortages, vaccine safety concerns).
While it is critical for the public to be able to access information about vaccine safety concerns, it is just as critical for them to have information about the high quality and safety of existing vaccines. Communicating only information about safety concerns may be misleading and be picked up by the media, only reinforcing the media bias toward concerns about vaccine safety. Thus, in the first bulleted indicator, we would suggest including communication about vaccine quality and safety as well as vaccine safety concerns. This will help ensure the plan is proactive as well as reactive. This is consistent with objective 3.3.1.

Indicators – second bullet: _X___ % of the public will report that they are satisfied with how their health care provider answers their questions about the benefits and risks of vaccines by Y (year).
This is a passive indicator that essentially depends upon the "consumer" knowing about product availability. It seems that a more critical component is making sure providers are discussing the availability of the vaccine, noting the fact that there is a national recommendation for vaccination, and answering questions about vaccination. There are providers who are not routinely discussing immunizations with patients, especially if they do not feel the vaccines are appropriate. We would suggest a measure that ensures that patients are being made aware of the availability of nationally recommended vaccines as well as the important information associated with those vaccines.

Indicators – general comment. Finally, all indicators seem to assume that immunizations will be delivered by traditional health care providers. The use of alternative sites is growing; it would be helpful to consider rewording indicators or creating new indicators that take this trend into account (what type of certification will be required, is there a minimum standard for those who immunize). This is addressed in part in a later objective, but these indicators could also incorporate the reality that not only office-based physicians are providing vaccination.

Objective 3.3.: Enhance delivery of timely, accurate, and transparent information to public audiences and key intermediaries (such as media) about what is known and unknown about the benefits and risks of vaccines and the vaccination program.
Consider including an additional strategy: proactively encouraging responsible journalism and providing guidance to journalists regarding reliable and unreliable sources of vaccine information.

Objective 3.4.: Increase public awareness of vaccine preventable diseases, and benefits and risks of vaccines and immunization, especially among populations at risk of under immunization.
Despite the phrase "especially among populations at risk of under immunization," there are no specific strategies that address these populations. Consider including a

strategy to enhance access to information and education among minority, low-income populations at risk for under-immunization. Culturally appropriate educational efforts will be important. Thus, objective 3.2.3 (Collaborate with partners and stakeholders to communicate vaccine benefits and risks in appropriate languages, methods, and literacy levels) may be more appropriate here than where it is currently.

In addition, within the enumerated strategies listed, it is important to expand the role of public service announcements on television. These are trusted methods of communication via a very accessible medium. They do not require the ability to read – which is critical – and, when done well, are extremely effective.

It will also be important to include in this objective taking a more active role in addressing misinformation about vaccine public safety. The new cases of Hib deaths reinforce the need for a more aggressive approach to the misunderstandings that have led to personal belief exemptions. This is the explicit role of those who know and understand the data.

Goal 4: Ensure stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the U.S.

General comments
Consider more explicitly addressing the issue of health disparities through vaccination throughout this section. For example, goal 4 could read: "Ensure … and achieve better use of existing vaccines to prevent disease, disability and death and to decrease health disparities in the U.S."

Consider an indicator that explicitly addresses monitoring of disparities.[1] (for example, through the National Immunization Survey)

Objective 4.2.: Reduce financial and non-financial barriers to vaccination

4.2.1: Ensure that out of pocket costs for purchase and administration of all ACIP recommended vaccines for children, adolescents, and adults by publicly funded health insurance plans do not represent a significant financial barrier (i.e., Medicare, Medicaid, TRICARE, VA, FEHBP, DoD).
4.2.2 Reduce financial barriers to immunization by increasing the proportion of people with private healthcare insurance who have only minimal cost sharing for purchase, counseling, and administration of all ACIP recommended vaccines for children, adolescents, and adults (regardless of where the vaccines are administered).
Consider making these strategies more comprehensive; e.g. financial barriers to immunization should be eliminated for all patients, whether publicly insured, privately insured, or uninsured. This is important as each state subsidizes at varying levels, so it seems there are "geographic disparities" as well that should not exist. Young adults are among the least likely to have insurance coverage for vaccination, but are at high risk of transmitting vaccine-preventable diseases to young children as they become parents.

Objective 4.3.: Maintain and enhance the capability to monitor immunization coverage for vaccines routinely administered to infants, children, adolescents, and adults.
Consider including an additional strategy related to immunization registries and their communication with electronic medical records (EMRs). Record scattering and missed opportunities are major reasons for under-immunization in adolescents. These could be better addressed by promoting better IT infrastructure: immunization registries (for all ages, not just infants and children) and having these registries link or communicate with EMRs. Furthermore, EMRs should prompt physicians when vaccines are overdue. In addition, the importance of a national, lifetime registry cannot be understated. The ability for registries to communicate will be of great importance as immunization recommendations begin to span age groups that are increasingly mobile. The importance of this type of communication was noted during Hurricane Katrina during which millions of dollars were saved when the Louisiana and Texas registries were set up to communicate. Many vaccines are also currently being given in alternative settings. Finally, this type of comprehensive registry will also be of tremendous importance in the event of a pandemic.

1. Flannery B, Schrag S, Bennett NM, et al. Impact of childhood vaccination on racial disparities in invasive S. pneumoniae infections. JAMA 2004;291:2197-203.

United American Nurses, AFL-CIO (Sarah Markle-Elder)

I am writing to provide comments on the draft *National Vaccine Plan* on behalf of the United American Nurses, AFL-CIO (UAN). UAN represents 45,000 registered nurses working in direct patient care throughout the United States. Registered nurses recognize the critical role they play in the prevention of infectious disease. We therefore appreciate the opportunity to give feedback as stakeholders.

UAN supports the goals of the plan, particularly *Goal 3*, supporting informed vaccine decision-making by the public, providers, and policy-makers. We note the need for "accurate, timely, transparent, complete, and audience-appropriate information" as discussed in *Goal 3* so that all populations at risk are educated about the benefits and risks of infectious disease vaccinations.

Included in this are the objectives to add vaccine education to the curricula of professional schools, training programs, and certifying examinations as described in the *Goal 3 Indicators*. Health care workers can be trained during their preparatory education and in continuing education settings. We also note that unions can assist in collaborations to educate workers as mentioned in *Objective 3.2*.

However, we are very concerned about strategies listed under *Objective 4.5*: *Educate about, and support, health care and other vaccination providers in vaccination*

counseling and delivery. Several of these strategies imply incentives for health care employers to create mandatory seasonal influenza vaccination programs. We strongly reject mandatory programs which coerce health care personnel into accepting the flu vaccine under threat of losing their jobs or any other penalty.

The strategies at issue are:

> *4.5.4 Incentivize direct health care providers, health systems, and health insurers to provide vaccines by incorporating vaccination in quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).*
>
> *4.5.8 Promote the development, implementation, and evaluation of employer-based immunization programs (including free vaccines, convenient access, education, and compliance monitoring) to increase the coverage of health-care personnel with recommended vaccines.*
>
> *4.5.9 Assess whether changes in health care facility and professional licensure and regulation can improve the safety of the health care environment by increasing vaccination rates of health care professionals.*
>
> *4.5.10 Develop and monitor policies promoting vaccination for patients and health care personnel in long-term care facilities and hospitals.*

Most concerning of all of these strategies is *4.5.9*, which indicates that individuals and/or the facilities where they work could lose their licenses if they fail to submit to annual seasonal flu vaccines. The other strategies create incentives and structures for employer-based programs. UAN is not opposed to employer-based seasonal flu programs, but we oppose programs that penalize health care workers who decline the vaccine. We maintain that such coercive programs are unnecessary, unwarranted, and counterproductive.

Mandatory flu vaccine programs are unnecessary because several studies have shown that higher health care personnel participation rates are achieved when the workers are educated about the vaccine.[xv] [xvi] [xvii] We note that one of the major goals of the *National Vaccine Plan* is improving outreach and education to the public, providers, and policy-makers in order to support informed decision-making about vaccine benefits and risks. Nurses and other health care workers should also be afforded the opportunity to make an informed decision.

Participation rates as high as 80 percent have also been achieved by improving access for health care personnel. Factors identified in these studies include free provision of the vaccine; offering it on all shifts at convenient times and locations; and through positive and non-coercive programs such as vaccine carts, vaccine days, peer vaccination programs, gift incentives, and standing orders. Other factors include adequate allocation of staff and resources to the program and visible support by upper level management.[xviii] [xix] [xx] [xxi] [xxii] [xxiii]

We also note the success of voluntary hepatitis B vaccination under the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030(f)(1)). Hepatitis B infections

declined by 60 percent in health care personnel from 1993 to 1999 after health care employers were required to offer the vaccine to potentially exposed workers.[xxiv] Health care personnel are encouraged to get the vaccine but still have the option to refuse and sign a declination form.

Mandatory flu vaccination programs are unwarranted due to the variable year-to-year effectiveness of the trivalent vaccine. The estimated effectiveness in years where there is a good match is 70 to 90 percent. The effectiveness for the 2007-2008 season was estimated at 44 percent.[xxv] While the flu vaccine is an important tool in the prevention of nosocomial infections, it is neither completely effective, nor is it the only one.

Lastly, mandatory flu vaccination programs are counterproductive to the long-term goal of improving health care personnel vaccination rates because they create an atmosphere of distrust. Mandatory flu vaccination programs at Virginia Mason Hospital in Seattle, Washington and Providence Hospital in Anchorage, Alaska were terminated after the registered nurse unions there contested the employers' right to implement policies affecting working conditions without negotiating.[xxvi] In the case of Virginia Mason Hospital, which has been cited as a successful flu vaccination program, the US Court of Appeals for the Ninth Circuit upheld an arbitrator's ruling against the hospital.[xxvii] In the case of Providence Hospital, the program was stopped shortly after the Alaska Nurses Association (UAN) protested.[xxviii]

UAN supports voluntary employer-provided seasonal flu vaccination programs for health care personnel. The programs should include education about the benefits of seasonal flu vaccine, side effects, and contraindications as noted by the Advisory Committee on Immunization Practices. Health care workers should be advised of their right to compensation for adverse events following immunization by the National Vaccine Injury Compensation Program.

Registered nurses are protective of their patients and mindful of their key role in infection control. However, they feel strongly that mandatory flu vaccinations are an unwarranted intrusion on their right to make decisions about their personal health.

Thank you for the opportunity to make these comments. I look forward to meeting with you on February 6.

Sincerely,

Sara Markle-Elder

Sara Markle-Elder
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United American Nurses, AFL-CIO

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[xviii] Ibid.
[xix] Hospitals take their best shot at the flu: 'best practices' share winning strategies. *Hosp Empl Health*. 2008, 27(9); 99-101.
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[xxii] Stone EG, Morton SC, Hulscher ME, et al. Interventions that increase use of adult immunization and cancer screening services: a meta-analysis. *Ann Intern Med*. 2002; 136:641-51.
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