

## Preface

Written comments on the draft strategic National Vaccine Plan are featured below in a table format. Column One lists the page numbers of the Plan to which the comment refers. Column Two lists the Plan item related to the comment. Comments listed in Column Three include the organization commenting, followed by an individual (in parentheses) if one was listed. Organizations are listed by their full title on first reference and by abbreviation in all subsequent comments. Comments received from individuals list their organizational affiliation or country of origin, if available, but views expressed by individuals do not necessarily reflect the perspectives of their employer or organization. It also should be noted that comments only include those submitted by non-federal stakeholders. All comments or questions about the draft strategic National Vaccine Plan should be addressed to [NVPComments@hhs.gov](mailto:NVPComments@hhs.gov).

## Federal Framework for a National Vaccine Plan Public Comments

<b>Page</b>	<b>Item</b>	<b>Comments</b>
1-3	Title page, Table of Contents	
4	ASH Preface	
5-7	Acronyms and Abbreviations	
8-14	Executive Summary	<p><b>John Snow Incorporated (JSI) (Steinglass):</b> “Vaccine coverage surveillance” (in the text on page 9, in Figure 1 and later identical figures, and at the bottom of page 48) is an odd term. The conventional term would be “vaccine coverage monitoring.” “Surveillance” in the context of immunization programs is best reserved for the regular monitoring of disease, AEFI, genotypes, etc. “Surveillance” is so important that we use it to describe a special of monitoring of disease. We usually “monitor” quality, coverage, costs, etc.</p> <p><b>Gates Foundation (Orenstein):</b> On page 17, last paragraph – I find the wording confusing. I think the plan should take into account infectious diseases and all of their outcomes including cancers. Would the prevention of post-infectious measles encephalitis not be considered a burden to prevented, even though it is an immunological reaction to the infectious agent? What I believe you are saying is that immunomodulators, including vaccines, which may be used to prevent and treat non-infectious diseases, will not be considered. This is a better way, in my opinion, of saying that.</p>

		<p><b>Pediatric Infectious Diseases Society (PIDS) (Shulman):</b> .</p> <ul style="list-style-type: none"> <li>• 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 Vaccination Rates? As shown, the Figure implies that those making vaccine recommendations have no expected impact on Vaccination rates (or vaccination for that matter).</li> <li>• 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).</li> <li>• 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.</li> </ul> <p><b>sanofi Pasteur (Hosbach):</b> The executive summary describes the NVP goals as achieving “<u>optimal prevention</u> of infectious diseases...and <u>optimal prevention</u> of adverse reactions.” To be precise, it is difficult to suggest that adverse reactions can be prevented to the same degree that the infectious disease can be prevented. Consider using a phrase such as "while enhancing vaccine safety."</p>
15-17	Introduction	
17-18	Purpose, Perspective, and Scope <i>(Priorities are discussed here, but not explicitly identified. Suggest this is where they be cited)</i>	<p><b>Merck (Feinberg): Purpose, Perspective &amp; Scope:</b> The Plan should be aligned with Healthy People 2020 objectives, insofar as national disease outcomes are being assessed.</p> <p><b>Mayo Clinic (Poland): Purpose, Perspective &amp; Scope:</b> Importantly THE CHARTER GOAL of the NVP is to “plan for prevention of infectious diseases and adverse reactions to vaccines” [page 17], yet little solid evidence of planning for how preventing adverse reactions to vaccines is to be achieved. Absent research funding and a focus on adversomics (using the tools of genetics and molecular biology to understand genetic</p>

susceptibility to adverse reactions), this goal will not be achieved.

**JSI (Steinglass): Purpose, Perspective & Scope:** The helpful clarification at the bottom of page 17 as to why certain vaccines are excluded from this plan may highlight the need to **re-visit the mandate of the NVP beyond prevention of infectious diseases** so as not to balkanize the implementation of the overall program. But I am sure there are myriad complicated legal and political issues, of which I am unaware.

**American Dental Association (ADA) (Findley): Purpose, Perspective & 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 Geriatrics Society (AGS): Comments on priorities for the National Vaccine Plan for a ten-year period:**

Healthcare Workers

The AGS believes that healthcare workers (HCWs) should be explicitly addressed as important recipients of vaccines – this is currently not addressed in the plan. HCWs are a key target audience for education around why they should get vaccinated. This is a critical issue to prevent infection in patients, especially for the elderly and for influenza vaccine.

**Columbia University National Center for Disaster Preparedness (Columbia NCDP) (Garrett):** We appreciate the priority of ensuring a consistent supply of vaccine. It would be worth emphasizing even more the issue of safety as a priority- since we know the impact that bad PR can have for a polarizing issue such as this.

**Virginia Commonwealth University (VCU) (Hearington):** I believe the top priorities need to be the continued work on developing combination vaccines and alternate forms of vaccines (nasal sprays, oral, etc.).

I also believe that public and professional education also needs to take top priority. In my professional experience, I am finding more and more parents who are reluctant to vaccinate their children according to the recommended guidelines. A few are adamantly opposed and outright refuse to vaccinate but many more simply do not want their infants and toddlers to

	<p>receive so many injections. Those parents tend to want to "pick and choose" among the vaccines and/or devise their own schedule. I see this as a critical problem and one that can only be addressed by creating more combination vaccines and alternate vaccine forms and by educating the public not only on the safety and efficacy of the current vaccines but also on the ability of the body and the body's immune system to properly metabolize and respond to the vaccine dose. I hear over and over that vaccines aren't "pure," and listen to parents' fears regarding harmful effects of vaccines. Most do not remember just how serious vaccine-preventable diseases are and seem to fear the vaccines more than they fear the diseases. It seems, also, that some health care providers have become concerned about the numbers of injections a child receives during the first year of life. I have been surprised at the seeming lack of understanding of the rigorous testing that is employed to ensure vaccine safety and efficacy. So, education has to emerge as a number one priority.</p> <p><b>American Academy of Family Physicians (AAFP) (Schoof): Priorities</b></p> <ol style="list-style-type: none"> <li>1. Reimbursement issue (to insure a full array of vaccines can be provided in the family physicians' offices).</li> <li>2. Supply issues: Insure an adequate supply of all vaccines.</li> <li>3. Find a way to fund adult vaccines.</li> <li>4. Point of care decision tools to assist physicians with information management.</li> <li>5. Vaccine safety research to reassure the public about the safety of vaccines.</li> <li>6. Continue to protect vaccine manufacturers from groundless liability claims.</li> </ol> <p><b>Mayo Clinic (Poland): Priorities: We had better focus our priorities, time and resources on:</b></p> <ul style="list-style-type: none"> <li>• Understanding immunosenescence</li> <li>• Designing vaccines against diseases which primarily afflict the elderly</li> <li>• Improving vaccine immunogenicity and efficacy in the elderly</li> <li>• Funding vaccine delivery for all elderly</li> </ul> <p><b>SafeMinds (Wrangham): Need to Prioritize Safety within the Plan</b></p> <p>Safety should be an equal partner to the National Vaccine Plan components, which focus on new vaccine development and extending vaccine programs to the population. A "safety first" program must be designed and implemented in a manner that fully supports science, ethics, law, legal remedies, medicine, public trust, policy, business practice, funding</p>
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		<p>priorities.</p> <p><b>Australia (Horvath): Comments on the priorities for the NSVP:</b>  I agree with the current priorities and suggest the following:</p> <ul style="list-style-type: none"> <li>• One area where the NSVP could be strengthened is specific strategies and actions to improve immunisation coverage in hard to reach or high-risk groups, such as adolescents and young adults.</li> <li>• Some of these groups may be outside the school system, are more mobile and independent.</li> <li>• " This is becoming important given the development of vaccines that target these groups.</li> </ul> <p><b>National Association of Community Health Centers (NACHC) (Stevens):</b> Top Priorities for the U.S. and globally are consistent with Goal 5: increase global prevention of death and disease through safe and effective vaccination. Efforts to achieve adequate vaccination coverage for all including the uninsured serve the public health both nationally and globally.</p> <p><b>National Association of Local Boards of Health (NALBOH) (Fallon): Priorities</b></p> <ul style="list-style-type: none"> <li>• <b>Increase research into development of more combination vaccines.</b> Many providers and parents limit the number of injections given to a child during a visit. Increases the possibility of children not staying on the recommended immunization schedule. Additional combination vaccines being on the market could eliminate the need for having to give a child 4 or more injections during a visit.</li> <li>• <b>Increase the vaccine manufacturing surge capacity to assure a reliable and uninterrupted supply of vaccines.</b> If feasible, the federal government should stockpile vaccines in the event of a vaccine shortage. This is especially important in Pandemic Influenza planning.</li> <li>• <b>Increase the monitoring of the centralized vaccine distribution system the States implement.</b> There needs to be a closely monitored vaccine distribution system, both for VFC vaccines and private stock, to ensure that when there is a vaccine shortage that all providers will have access to some vaccine.</li> <li>• <b>Enhance risk communication materials targeted at the public to address vaccine safety issues.</b> Efforts need to be made to change the public's perception of the threat of a resurgence in vaccine-preventable diseases. More and more parents are questioning the need for vaccines because of the significant decrease in</li> </ul>
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		<ul style="list-style-type: none"> <li>• <b>Increase federal funding to States to enhance partnerships with the private medical sector to improve their vaccine delivery practices and immunization rates, including vaccine management plans, establishing recall/reminder systems, periodic assessment of immunization levels, etc.</b> More attention needs to be devoted to working with private sector providers in the following major areas of concern: <ul style="list-style-type: none"> <li>-Vaccine Management Plans that include vaccine storage and handling procedures, emergency vaccine retrieval and storage, vaccine incident procedures.</li> <li>-Development of patient recall/reminder systems.</li> <li>-Participation in a statewide immunization registry.</li> </ul> </li> <li>• <b>Increase federal oversight/monitoring of vaccine manufacturer facilities to lessen the possibility of manufacturing or production problems and promote good manufacturing practices (Best Practices).</b></li> <li>• <b>Increase emphasis on Adult and Adolescent immunization.</b></li> </ul> <p><b>University of Washington (Corey): Priorities</b> This list is not all-inclusive, but does define some areas of major unmet need other than HIV, TB and malaria.</p> <ul style="list-style-type: none"> <li>• Vaccines for sexually transmitted infections:</li> <li>• -T-pplidum, HSV-2 and C-trachomatis</li> <li>• CMV vaccine-this could reduce both neonatal infections leading to hearing loss and major morbidity in transplant infections.</li> <li>• Developing vaccines for viral respiratory pathogens, especially Parainfluenza-3, Human Metapneumovirus and RSV</li> <li>• Zoonotic infections</li> <li>• Infectious Disease Associated cancers</li> <li>• Other vaccines of the immunocompromised/hospitalized Host</li> </ul> <p><b>National Vaccine Advisory Committee (NVAC) Stakeholder Mtg, 2-6-09:</b> There was a consensus from participants that a clear articulation of priorities would be helpful for vaccine developers. Hopefully there would be some alignment between priorities for vaccine development and downstream recommendations for use (e.g. ACIP recommendations) which tend to trigger coverage and reimbursement.</p>
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	<ul style="list-style-type: none"> <li>• Additionally, the importance of surveillance was discussed as being important because it helps to give a clear indication of what is feasible for clinical trials. Manufacturers have to look at things from all different perspectives and there needs to be some consensus. For example, orphan areas are difficult to become internal priorities if there are no indicators that this is important externally and there are no mechanisms to move them through clinical trials and into the marketplace.</li> <li>• If there is no agreement that a disease is significant then industry needs to have an indication that there is robust surveillance in place and be ensured surveillance will continue in the various areas where they think there is a need. For example, MSRA is a top priority because the hospital and community are interested, but there is insufficient (epidemiological) data. Better data will bring the availability and interest of the individual investigators/researchers.</li> <li>• It was suggested that NVAC consider contracting with the Institute of Medicine (IOM) to develop a set of priorities; something similar to a document that was developed in the 1980's. That document looked at a variety of data, including, morbidity, technical feasibility, estimated cost, etc... It was a robust document and helped set priorities.</li> </ul> <p><b>United Kingdom, Department of Health (Salisbury): Priorities:</b> These priorities are not incorrect: the problem is how attainable they are, who has the resources to take each forward and who has the resources to coordinate all of the disparate activities.</p> <p><b>University of Iowa (Helms):</b> The draft Plan puts forward in its five broad goals and associated objectives and strategies a road map that will stimulate innovation and safety in vaccine development and improve reliability and productivity in the immunization enterprise in the US. Enhanced vaccine innovation and safety, coupled with improved reliability and productivity of the US immunization enterprise will stimulate success and progress globally.</p> <p><b>Gates Foundation (Orenstein):</b> The seriousness with which the plan is taken should be compatible with the budget devoted to each element. I recognize that budgeting by strategy or objective may be difficult. But if feasible, I think it could be helpful in determining what the real priorities are. At the moment, the plan is very comprehensive and it's difficult to see whether certain sections are more important than others. The plan implies everything is equally important.</p>
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		<p>You discuss a process for making priorities. It's not until Goal 5, that I understood that the prioritization process not only included vaccines for domestic use but vaccines for use in developing countries as well. I think this should be clarified here. Should a regular review of priorities be undertaken (e.g., every 5 years or more frequently, if needed)?</p> <p><b>Southern Nevada Health District (Sorenson) Priorities:</b></p> <ul style="list-style-type: none"> <li>• The Cost of Vaccines has not kept pace with reimbursement</li> <li>• Disease Surveillance</li> <li>• Education Strategies</li> </ul> <p><b>Nat'l Centre for Immunisation Research &amp; Surveillance (Australia):</b></p> <ul style="list-style-type: none"> <li>• Informing providers, rapidly and in a coordinated manner, is a priority. If good uptake of safe vaccines is one of the plan's (implicit) goals, providers need to be supported for two reasons: First is that providers are central to vaccine risk communication with the public. Much evidence points to the importance of providers as an information source and influence on public attitudes. Evidence from shifts in public attitudes to vaccines shows that media stories may abound but it is only once a controversy shifts the confidence of providers that we see a downturn in vaccination rates, presumably because we no longer have committed and confident providers. Second is evidence from surveys that show providers share the same general concerns about vaccines in similar proportions to the public. Hence, they are a key 'audience' in terms of effective communication. <i>Providers are the conduit for vaccine recommendations and their implementation. For every provider informed about vaccination and reassured, we inform a larger number of parents.</i> Hence this strategy is also more cost effective.</li> </ul> <p><b>Families Fighting Flu (Stein): Priorities</b></p> <ul style="list-style-type: none"> <li>• Work toward developing an improved influenza vaccine, i.e, one-time or any-time administration, longer efficacy period, longer shelf life, etc.;</li> </ul> <p><b>Trust for America's Health Priorities:</b></p> <ul style="list-style-type: none"> <li>• Globally, malaria, tuberculosis (TB) and HIV vaccines should be priorities, and would have payoffs domestically. Developing a vaccine against hepatitis C virus (HCV) also should be a priority as should increased research into a universal influenza vaccine. These are Trust for America's Health's (TFAH) priorities because</li> </ul>
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		<p><b>Hepatitis Foundation International (Dan) Priorities:</b></p> <ul style="list-style-type: none"> <li>• The top priority for the National Vaccine Plan should include education of parents, children and adult patients prior to and during vaccine visits to care providers.</li> <li>• A second priority for the National Vaccine Plan should be to educate health care providers to better educate patients prior to and during vaccination visits to clinics and doctors offices. These efforts must provide both information about vaccinations as well as communication skills, techniques to talk to patients, background education on what vaccines protect against such as liver disease caused by hepatitis B virus infection and vaccine safety concerns.</li> </ul> <p><b>PIDS (Shulman) Priorities:</b></p> <ul style="list-style-type: none"> <li>• Continue development of new vaccines, including <i>S. aureus</i>, HIV, hepatitis C, CMV, RSV, parainfluenza, and improved vaccines for influenza (including avian strains)</li> <li>• Development of an effective malaria vaccine</li> <li>• Development of an effective tuberculosis vaccine</li> <li>• Development of an HIV vaccine</li> <li>• National vaccine registry</li> <li>• Assure supply of appropriate vaccines to all ages at reasonable costs</li> <li>• Develop the infrastructure for rapid response to outbreaks of emerging or novel pathogens.</li> <li>• Polio eradication</li> <li>• Penetration of rotavirus vaccine into the developing world</li> </ul> <p><b>Bain &amp; Company, Inc. (Pasternak):</b></p> <ul style="list-style-type: none"> <li>• <i>Prioritizing strategies:</i> Assuming that the achievement of certain strategies is important independent of the overarching goals, the plan should prioritize those strategies, Currently, there are 146 different strategies proposed across the goals and objectives. It is clear that the value potential in terms of achieving the goals is not evenly distributed among these strategies, A key success factor in most endeavors is focusing on a smaller, rather than larger, number of strategies around which resources and oversight can be mobilized; otherwise, effort and oversight can become overly diffused, thereby jeopardizing the success of all proposed strategies. A prioritization should be conducted on the basis of an evidenced-driven</li> </ul>
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		<ul style="list-style-type: none"> <li>• <i>Specifying disease priorities in the plan:</i> Currently, the plan proposes a process to define a set of disease priorities to promote future vaccine development. However, establishing these priorities is of such critical importance that a process should be initiated now and completed in time to include in the final plan. The GAVI Alliance has conducted such a process for developing world priorities, and this has enabled this plan to reference specific disease targets (and associated coverage goals) in Goals of the plan.</li> </ul> <p><b>sanofi Pasteur (Hosbach):</b> Priorities: The success of the National Vaccine Plan is dependent on both public and private participation. In fact, the very success of the US national vaccine program was based upon public-private partnership and cooperation. It is critical this partnership continue to exist and does not become further fractured than it is currently perceived by those in the private sector. It will be a significant benefit to this plan that a healthy and vibrant private sector be maintained. This includes both physicians and manufacturers. In the absence of cooperation and coordination—and an appropriate balance between the public and private sectors—this plan cannot be achieved.</p> <p>As drug resistant infections such as MRSA and <i>Clostridium difficile</i> continue to rise in hospital and community settings at alarming rates, developing vaccines for these infections should be a near-term priority.</p> <ul style="list-style-type: none"> <li>• The total burden of <i>C. difficile</i> infections exceeds 500,000 cases annually, contributing to at least 15,000 deaths in the U.S. each year at a cost of \$3+ billion for treatment in hospitals.</li> <li>• Prioritizing vaccines for <i>C. difficile</i> will prove to be a realistic near-term goal that will meet an immediate medical need. <ul style="list-style-type: none"> <li>▪ It should be made clear how identified research priorities will influence CDC recommendations. Future immunization policies/recommendations need to be more predictable and better forecasted for private industry to commit large investments of resources and time in developing target vaccines.</li> <li>▪ The report should consider the establishment of systems that capture the baseline for naturally occurring events in the US population. The goal would be to establish a baseline rate for events that can be temporally associated with immunization. The objective would be to better determine whether an increase/decrease exists from an</li> </ul> </li> </ul>
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18-20	Approach to Developing the Plan	<p><b>Meningitis Vaccine Program, PATH (F. Marc Laforce) :</b> Support introduction of new vaccines as part of national vaccination programs:</p> <ul style="list-style-type: none"> <li>• Group A meningococcal conjugate vaccine in all African countries in the “meningitis belt” by 2019.;</li> <li>• <b>Note:</b> this change is being suggested because an affordable (\$US&lt; 0.50 per dose) conjugate Men A vaccine has been developed and will be introduced in meningitis belt countries beginning in 2009/2010. The strategy has been approved by WHO, UNICEF and GAVI. All meningitis belt countries should be either partially or totally covered by 2019.</li> </ul> <p><b>Merck (Feinberg):</b> Page 19, first full paragraph: Most of the indicators reflect Federal actions, rather than national ones. It may be appropriate to add indicators to assess performance of clinicians, health systems, health payers, and other stakeholders.</p> <p><b>University of Pittsburgh (Zimmerman):</b> Figure 2 – I recommend adding a “ethics review,” leading to the boxes on communication and on developing vaccine recommendations. I recommend a box about “Facilitating uptake” as a box leading to the major “vaccination” box.</p> <p><b>Trust for America’s Health: General Comments:</b></p> <ul style="list-style-type: none"> <li>• We are pleased that the NVPO is following up on the National Vaccine Plan with an implementation plan. We recommend that this plan include multiyear funding requests, identify the legislative authorities needed to achieve such strategies, and assign offices across government that will take the lead on each goal. The implementation plan should also clearly identify which office will coordinate efforts, as many goals require input and activity from different agencies and partners.</li> <li>• This implementation plan should be an evergreen document, reevaluated as the science evolves and evidence of effectiveness becomes available, and progress and results of each benchmark should be made transparent to Congress, researchers, industry, and the public.</li> </ul>

20-21	Conceptual Framework	<p><b>Fred Hutchinson Cancer Research Center (Warden):</b> <u>The plan could benefit from describing the metrics that would be used to monitor progress.</u> The plan states that "Disease prevention and enhanced vaccine safety are ultimate outcomes of a successful vaccination program"(page 20). I would like to see metrics described that would give us an indication of the success of the program in relation to disease prevention and enhanced vaccine safety. I also think that there needs to be a metric related to public attitudes about vaccines and vaccination. Clearly, great vaccines that people won't take accomplish little.</p>
21-22	National Vaccine Plan Structure	<p><b>World Health Organizations (WHO):</b> Overall well structured plan - we liked the brief situation analysis as well as the scope of the goals the plan is intended to achieve in a 10 yr horizon.</p> <p><b>Merck (Feinberg):</b> Page 21: "attitude" in first paragraph connotes a subjective nature to vaccine development; recommend deletion.</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b> <i>Clarifying the purpose of articulating specific strategies:</i> Because measurements of success will be at the "Goal" level and not at the "Strategy" level the plan should clarify expectations relative to specified strategies. Are strategies suggestions, or interchangeable alternatives for achieving the goal? Will the plan be deemed a success if an overall goal and associated indicators are achieved, but certain articulated strategies are not? If the achievement of specific strategies is deemed paramount in the overall endeavor, independent of the goal and associated indicators, they should be noted as such and metrics for tracking progress of those strategies should be developed.</p>
22-24	Monitoring and Evaluation	<p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> I find this paragraph confusing r.e. where Asst Secy sits in relation to NVPO and NVP. I may be wrong, but believe there is more than one Asst Secy and which one should be clarified. Reference could also be made to Appendix 3 where the relationship is shown.</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b> The draft plan very clearly describes goals and metrics for success, but does not describe how various stakeholders will be held accountable for achieving these goals. The plan asserts that "what gets monitored gets done/" but that is only the case when those being monitored are held accountable for</p>

		<p>achieving the outcome. One idea DHHS may consider is asking various stakeholders to make a written commitment to the aspects of the plan that they intend to actively promote. In addition, consistent with the roles and responsibilities point above, federal government agencies should be held accountable for their contributions to this plan, with separately articulated indicators associated with their performance.</p>
<p>25-27</p>	<p><b>Goal 1, Indicators, Figure</b></p>	<p><b>Columbia NCDP (Garrett):</b> For goal #1, the priorities are well thought out- especially with regards to the need for development of a vaccine capability for TB, HIV, and a more robust vaccine for seasonal influenza.</p> <ul style="list-style-type: none"> <li>Also for goal #1, there was no mention of the possibility of needing to vaccinate for “non-routine” illnesses, such as anthrax, pandemic influenza, other emerging diseases, etc. While this is likely in the domain of other Plans, it may be worth having some sort of cross-bridge information there, as much of the process will overlap if it were to become necessary to roll out.</li> </ul> <p><b>Mayo Clinic (Poland):</b> Use the new biology and the exploding advances in technology to inform and enhance our understanding of vaccine development, delivery, and safety. Nowhere does the draft plan anticipate or indicate an understanding of new technologies such as high throughput genomic sequencing, transcriptomics, adversomics, immunology and virology, mass spectrometry, etc. This is particularly egregious and noticeable in Goal 1 related to new vaccine development.</p> <ul style="list-style-type: none"> <li>In this regard a sub goal of goal 1 is to “conduct research to explore host factors...”. An important consideration has been overlooked here – the goal should include and highlight the advances coming from vaccinomics (immunogenomics and immunogenetics) as it relates to vaccine response and new vaccine development. Hence research related to understanding host genetics and population genetics is critical to achieving the aims of the draft plan.</li> </ul> <p><b>SafeMinds (Wrangham):</b> Goal 1 uses the word “safety” or “safer” several times, however, the details of the objectives make it clear that the focus is on creation of more vaccines, extending vaccines to more populations, and more effective vaccines. Safety does not appear to be a priority in Goal 1 and appears to be covered in Goal 2 of the Plan. Our input in subsequent sections describes additional components of safety, or characterizes the objectives in a more definitive manner, which we recommend incorporating into the final NVP.</p> <p><b>University of Washington (Corey):</b> There is no discussion in the document of the</p>

	<p>mismatch that often occurs between public health priorities and the lack of commercial viability for designing and developing many vaccines, especially those of global public health importance or those perceived to have a high degree of scientific risk. This influences whether the private sector resources will be utilized to effectively develop such vaccines. There is no mention in the document of the need to develop better research structures in either non-profit research institutions or for unique public/private partnerships for the design and development of novel vaccines. There is little acknowledgement of the scientific risks in vaccine development for many important/critical disease of major economic cost and/or medical morbidity.</p> <p>The document also does not discuss liability for partially effective vaccines for diseases such as HIV, Influenza and TB; and if a rare complication occurs, how then to handle the liability issues, as the creator of these vaccines may be academic intuitions. So, somehow setting up an insurance pool to protect these institutions (not from negligence for which these institutions should have insurance, but from unanticipated rare but recognized adverse events) should be discussed in the vaccine plan.</p> <p><b>PRTM (Helming):</b> PRTM is aware that several organizations have devoted significant effort to compiling lists of threats to be addressed, and lists of vaccines (and related technologies) under development. Since each organization pursues prioritization of these efforts in accord with their own mission and their own criteria, to our knowledge there is no “Master List.”</p> <ul style="list-style-type: none"> <li>• As a first step, PRTM recommends that the NVPO undertake the development of such a Master List of Vaccine Preventable Disease targets and associated development projects. A valuable first step would be compilation of a Master List of all vaccine development, procurement, and distribution efforts underway across the Nation (and eventually, around the globe), and making such a list available to the vaccine development community.</li> <li>• A second step would be to group the development projects for same/similar vaccine targets into pipeline portfolio depictions. There would be tremendous value in sharing information nationally (globally) regarding how many vaccine candidate projects are underway for each target, and their stages of development. Such information would be an important first step in understanding gaps and possible overlaps in Vaccine development, nationally and globally.</li> <li>• A third step would be to assess the status of platform technologies that could be applied to accelerate the development of candidate vaccines, but also be applied to improve the profiles of existing vaccines to improve safety, efficacy, ease of</li> </ul>
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		<ul style="list-style-type: none"> <li>• A fourth step could be (eventually) to apply portfolio analysis and management techniques to develop consensus priorities for vaccine development, and in many cases, needed funding. For example PRTM and others have developed models which can predict rough order of magnitude cost and time estimates for a given vaccine development pipeline portfolio. Such portfolio analysis could be extended to consider how many candidates ('shots on goal') would be required to assure successful licensure of a needed vaccine, give anticipated attrition due to technical and regulatory risks. A prioritization process that ranks projects based on chances of success and pharmacoeconomic benefit allows NVPO to provide powerful perspective and guidance about projects under development and areas for further development.</li> <li>• Finally, the concept of a vaccine development portfolio could be extended to address many of the other goals cited in the National Vaccine Plan, such as investments in improving vaccine efficacy (i.e., adjuvants), surety of supply (dual sourcing), pursuit of novel technologies, research into manufacturing process development, and establishment of bioproduction capacity for needed vaccines for materials ranging from clinical trial materials to full scale production for certain needed vaccines.</li> </ul> <p><b>Wyeth (Connolly, Eyles):</b> Government incentives for research and development will continue to be important to advancing vaccine development. These incentives might range from increased support for collaborative research efforts and contracts that guarantee a specific market amount for "special vaccines", to streamlining the regulatory process without compromising safety or efficacy.</p> <ul style="list-style-type: none"> <li>• Cost estimates or funding sources for specific actions cited within the Plan such as the testing within 6 months of vaccine candidates in response to emerging infectious diseases would be helpful.</li> <li>• It is important that the public and private markets be maintained and balanced. This is important to Wyeth's ability to conduct research and development, bring new vaccine candidates to trial and ultimately to the market place. The Plan should address government strategies to ensure the privately insured children are covered through the private sector while describing enforcement procedures that ensure that Vaccines for Children purchased vaccines are directed to VFC-eligible children.</li> </ul>
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	<p><b>Task Force for Child Survival (Hinman):</b> Goal 1 – given the rapid development of genomic medicine, shouldn't there be an objective about assessing individual immunological characteristics and tailoring vaccines to match them?</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> Among these strategies, it seems that there should be something on cost effectiveness, cost utilization types of studies as part of the prioritization scheme.</p> <p><b>NVAC Stakeholder Mtg 2-6-09:</b> Overall, the participants stated this was a very technical goal and needs major re-working. There are places within Goal 1 (particularly objective 2) where objectives cannot be achieved without harmonization. It was suggested that there needs to be additional research to study the current efficacy of existing vaccines and to improve the clinical data.</p> <p><b>NVAC Discussion 2-6-09: Indicators for Goal 1 (revised)</b></p> <ul style="list-style-type: none"> <li>• Within one year, create an evidence based list of new vaccine targets to prevent infectious diseases that are high priorities for development. Strengthen the wording and link to “promises” i.e., implementation accountability and funding</li> <li>• Identify X candidate vaccines (e.g. for HIV, malaria, TB and a cross protective vaccine for Influenza) and advance Y priority vaccine candidates along the research and development pipeline including Z candidates into advanced clinical trials. -- <b>delete</b></li> </ul> <p><b>Merck (Feinberg): Goal 1</b> should also reflect the Nation's needs in biosecurity.</p> <p>Page 25, third paragraph, line 8: Change "ill" to "will."</p> <ul style="list-style-type: none"> <li>• For the prioritized list of new vaccines called for in Goal 1 to be meaningful, the agency charged with developing a prioritized list must coordinate and align with the agency responsible for addressing reimbursement issues so that a Goal-1 vaccine would readily receive reimbursement once licensed. Similarly, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) should synchronize their post-licensure safety assessments, and more clearly delineate which agency has the lead role in various assessment scenarios.</li> </ul>
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	<p><b>European CDC: Goal 1:</b>  One area of interest not mentioned in this draft is studies of the long-term immunologic memory in relationship to optimizing immunization schedules. Many of the vaccines in use today have not been in use long enough to evaluate development of life-long immunity. Cohorts to be followed long-term need to be established, please see the excellent results from the Finnish MMR-cohort that now has been followed for 25 years.</p> <p><b>Institute for Global Health (Rutherford): Vaccines for regional high-morbidity diseases.</b> With regard to vaccine development, I would ask the Committee not to forget diseases that occur regionally, such as coccidioidomycosis, histoplasmosis and Lyme disease that are not usually considered high-priority targets. Coccidioidomycosis, for instances, causes far more severe morbidity in the United States than other diseases that are considered high priorities. Internationally, <i>Neisseria meningitidis</i> type b is an obvious target for new and improved vaccines and will have domestic use, as well.</p> <p><b>Advisory Committee on Immunization Practices (ACIP) (Marcy):</b> Goal 1: I am delighted that there was mention of new adjuvants and new delivery systems. However, these goals are intended to cover 10 years of activities regarding immunization. It would seem appropriate to mention therapeutic vaccines vs infectious (e.g. Herpes group, hepatitis B, papillomavirus) and non- infectious (e.g. a variety of cancers) conditions. Perhaps, even prophylactic vaccines against non-infectious conditions (e.g. diabetes type 1, Alzheimer's, drug addiction, smoking). By well before 2019 you can be sure that Objective 1.2 will be directed to "prevent and treat infectious and non-infectious diseases"</p> <p><b>Baxter Bioscience, Vaccines (Khoury):</b> Developing <i>New and improved vaccines</i> should have well defined endpoints. For new vaccines, certain disease targets such as WNV, Lyme, Chikungunya or categories of targets such as Neglected Tropical Diseases or Newly Emerging Diseases should be specifically cited.</p> <p><b>Health Industry Distributors Association (HIDA) (Ostrand):</b> Support the development of new manufacturing and production technologies (e.g., reverse genetics, etc.) that will enable vaccines to be produced faster and in greater volume to meet both emergency preparedness needs (ex. pandemic) and expanding ACIP recommendations (261 million Americans advised to get seasonal flu vaccine in 2008-09).</p>
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		<p><b>sanofi Pasteur (Hosbach):</b> Industry should be fully and continuously engaged in the process of vaccine policy development.</p> <ul style="list-style-type: none"> <li>• Vaccine development and production is a complex and costly process that requires the commitment and agility of producers.</li> <li>• As the timeline involved in moving from initial R&amp;D to final production can be long and complex, it is important that policy makers adequately value the critical role of vaccines in promoting public health.</li> </ul> <p>Adequate funding for FDA-CBER is essential to a consistent vaccine supply and to approve new and innovative vaccines to protect public health.</p> <ul style="list-style-type: none"> <li>• CBER must have the resources necessary to conduct reviews and approvals of vaccines as quickly as possible.</li> <li>• CBER must also have resources available to examine vaccine facilities as quickly as possible and release vaccine lots in a timely manner.</li> </ul> <p><b>Novartis Vaccine Division (NVD) (Baxter):</b> There are actions the Federal government can take to ensure the vaccine enterprise is strengthened and new and improved vaccines are developed including: ensuring adequate funding for basic research; supporting advances in technology by lowering the barriers to change in the regulatory environment while simultaneously developing a predictable regulatory process; creating an evidence-based response process for managing vaccine adverse events; and clarifying recommendation criteria.</p> <ul style="list-style-type: none"> <li>• Also NVPO should evaluate how the US handles orphan vaccines.</li> </ul> <p>NVD would like to ensure that the Plan fosters innovation. NVD has identified four hurdles to innovation in the US.</p> <ul style="list-style-type: none"> <li>• Rigid regulatory processes</li> <li>• Inconsistent response to adverse events</li> <li>• Low immunization rates among adolescents and adults</li> <li>• Antiquated, Underfunded disease surveillance systems.</li> <li>• Absent from this goal is an indicator and objective to support national and global disease surveillance. The Plan should make explicit the need for adequate funding of the CDC's infectious disease surveillance activities.</li> </ul> <p>◆ <b>Indicator 1:</b> NVD believes an evidence-based list has benefits and risks and would</p>
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28	<p><b>Objective 1.1: Prioritize the needs for developing new vaccines.</b></p>	<p><b>NVAC Discussion 2-6-09:</b> Objective 1.1 (<i>Prioritize the needs for developing new vaccines</i>) Prioritize needs</p> <ul style="list-style-type: none"> <li>• Need broad consensus and support</li> <li>• Support NVPO commission appropriate body (e.g. IOM) to include all stakeholders</li> <li>• Cornerstone of the goal</li> <li>• Linkage to benefits of development of priority vaccines (e.g. addressing barriers such as regulatory approval, streamline ACIP recommendations, reimbursement)</li> </ul> <p><b>NVD (Baxter):</b> With regards to pediatric vaccines the Plan should: articulate a process for the evaluation and implementation of a new science based schedule; implement a strategy to address pragmatic challenges of pediatric vaccines prioritizing; crowded immunization schedule; the use of adjuvants; and interaction of antigens.</p> <p><b>Institute for Global Health (Rutherford): Multiple-adjuvant vaccines.</b> As a pediatrician, I would like to reinforce the need for continued development of multiple adjuvant vaccines that make office-based immunization so much easier. <b>Objective 1.1 or 1.2.</b> Explicitly add multiple-adjuvant vaccines that use existing vaccine antigens as a specific type of “new” vaccines.</p>
28	<p>1.1.1 With stakeholder input, develop, implement, and evaluate a process for prioritizing the needs for new vaccines that considers the leading causes of morbidity and mortality from infectious diseases in populations for which vaccines could be a component of an effective prevention strategy.</p>	<p><b>NVD (Baxter):</b> Agrees a successful National Plan must address vaccine development. A transparent process for prioritizing vaccines would allow industry to tailor efforts to fit country needs. The objective of developing a process to identify vaccines benefiting from improved performance characteristics would be useful for industry to determine whether or not to invest in such programs.</p> <p><b>Infectious Diseases Society of America (IDSA) (Gershon): Further articulate how NVPO will coordinate with key stakeholders in the development of certain objectives where considerable pre-existing stakeholder activity exists.</b> For instance, Strategy 1.1.1</p>

	<p>calls for development of a process to prioritize the needs for new vaccines. Presently, private sector vaccine manufacturers have their own informal prioritization schemas, which collectively represent an important “forecast” of vaccine research and development. NVPO should plan carefully for how government officials will interact with the private sector in the development of a national priority-setting process.</p> <p><b>Univ. of Washington (Corey):</b> Defining priorities for developing novel vaccines for the national vaccine plan will depend on who is in the room. I would advocate that clinicians with experience in the immunocompromised host and transplant biology be at the table, as this population consumes an increasing health care dollar and should be considered as major target populations for many novel vaccines.</p> <p><b>State University of New York, Albany (SUNY, Albany) (Bednarczyk):</b> Any indication of how consensus will be reached/tried with such a large group of stakeholders?</p> <p><b>Wyeth (Connolly, Eyles):</b> Though the plan makes reference to prioritizing vaccines based on morbidity and mortality, it does not address other criteria such as the likelihood for product development without incentives for vaccines which have little market potential or the contract demands of specific interest groups requiring that they receive the lowest global prices.</p> <p><b>American Federation of Teachers (Alexander):</b> Include the National Institute for Occupational Safety and Health (NIOSH) in the prioritization process. NIOSH has supported and/or conducted research on worker populations at risk of infectious disease exposure and could assist in the epidemiology for prioritizing needs for developing new vaccines.</p> <p><b>PATH (Elias):</b> Private philanthropies and nonprofit, nongovernmental organizations are critical partners and implementers in vaccine development. While they are referenced in several of the objectives as "non-federal stakeholders," we recommend that you consider adding them at more steps in the process so that their expertise and perspective are incorporated fully into other efforts.</p> <p><b>American Association of Colleges of Pharmacy (AACP) (Lang):</b> 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.</p>
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		<p><b>Bain &amp; Company, Inc. (Pasternak):</b> In strategy 1.1.1, a qualification should be added as it relates to a prioritization that "considers the leading causes of morbidity and mortality from infectious diseases..." This qualification should note that not only current causes, but future potential causes of morbidity and mortality should be considered in ongoing disease prioritization. For example, while invasive pneumococcal disease has been dramatically lowered among children due to the use of conjugate vaccines, continued serotype replacement may lead to the need over time for alternative technologies (e.g., universal protein vaccines). Another example would be vector-borne diseases such as dengue fever, which while not prevalent in the U.S. today are likely to become more significant health threats over time due to climate change. Vaccine development against future priorities needs to happen in the present given the long timeframe to product licensure and use.</p> <p><b>sanofi Pasteur (Hosbach):</b> Stakeholders will need to work together to accomplish goals such as advancing new delivery strategies and expediting testing of vaccine candidates in response to health threats.</p>
28	1.1.2 Conduct surveillance to continuously inform the priorities for potential new vaccines.	<p><b>SUNY, Albany (Bednarczyk):</b> Biodefense specific diseases referenced in 1.2, but not here – should be for consistency. Surveillance for diseases for which there is no vaccine only, or also for diseases with a vaccine that can be improved/modified based on disease pattern changes?</p>
28	<p><b>Objective 1.2: Support research to develop new vaccine candidates and improve current vaccines to prevent infectious diseases, particularly those determined to be priorities.</b></p>	<p><b>NVAC Discussion 2-6-09:</b> Objective 1.2 (<i>Support research to develop new vaccine candidates and improve current vaccines to prevent infectious diseases, particularly those determined to be priorities</i>)</p> <ul style="list-style-type: none"> <li>• Separate out develop new and improve current vaccines. Sensitivities were expressed about phrasing (e.g. “optimize” vs “improve” vaccines)</li> <li>• Participants felt strongly about maternal immunizations and felt there should be an indicator addressing (e.g., hold workshop to discuss barriers to developing these vaccines)</li> <li>• Needed discussion on development of vaccines where the benefit of the vaccine is not realized by the one being vaccinated.</li> </ul> <p><b>NVAC Stakeholder Mtg:</b> There was consensus from the group that the wording needs to be revised throughout objective 2 because certain words or phrases could have negative connotations or be misinterpreted as they are currently written. For example, one participant suggested that “optimize” be used instead of “enhance”. One facilitator suggested that the NVP could spell out certain terminology in the IP (e.g. what does “improve” mean) to further</p>



		<p>clarify the intention.</p> <p><b>Merck (Feinberg):</b> The United States also needs a highly responsive capability to develop new vaccine candidates rapidly, a step that must occur before clinical trials can begin. Merck and other manufacturers may be able to play a role in this regard, especially in collaboration with the US Government.</p> <p><b>SUNY, Albany (Bednarczyk):</b> This needs to be clearer with regard to which development is done for diseases w/o a current vaccine and diseases that need a newer/better vaccine.</p>
28	<p>1.2.1 Advance research and development toward new and/or improved vaccines that prevent diseases, including those that protect against emerging, re-emerging, and strategic biodefense related pathogens.</p>	<p><b>Mayo Clinic (Poland):</b> There is a science (a competency) to innovation – use it!</p> <ul style="list-style-type: none"> <li>• Old tools can't solve new problems</li> <li>• Innovation should become the “tool” by which problems are identified, framed, resourced, solved, and solutions deployed</li> <li>• Bring design thinking, the methodology of innovation, and the science of transformation into all aspects of the vaccine plan</li> </ul> <p><b>Canada Biologics (Griffiths):</b> However, it is essential to understand that significant differences may exist between vaccines used for the same indication from different manufacturers (e.g. acellular pertussis vaccines produced by different manufacturers may differ even in the number of component antigens). Furthermore, vaccines are biologics where the production process plays a critical part in product characteristics. Safety problems may not only be manufacturer but also lot associated, emphasizing the need for well established lot identification and tracking systems.</p> <p><b>NACHC (Stevens): <u>Vaccine Burden</u>:</b> As we expand the number of vaccines required the burden on the consumer is significant and it is becoming increasingly difficult to convince families to justify the number of ‘needles’ we are ordering for routine infant/toddler vaccine series. The continued development of combination vaccines makes the number of vaccines delivered more palatable.</p> <p><b>Southern Nevada Health District (Sorenson):</b> -Ability to create more combination vaccines that allow fewer injections and compress the number of visits needed to complete a series.</p>

		<p><b>Trust for America’s Health:</b> Should acknowledge that public investment, as well as philanthropic investment, may be necessary to spur research and development of vaccines, especially for emerging infections and potential pandemics where the manufacturer takes on a heavy financial risk.</p> <p><b>National Association of State Directors of Developmental Disability Services (NASDDDS) (Rolfe):</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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</li> <li>• 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 nor should we be lulled into a false sense of life time immunity.</li> <li>• 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.</li> </ul>
28	1.2.2 Conduct and support expanded vaccine research to meet medical and public health needs of specific populations including neonates, infants, the elderly, pregnant women, and immunocompromised individuals	<p><b>American Geriatrics Society (AGS):</b> The AGS recommends that the development of new and improved vaccines:</p> <ul style="list-style-type: none"> <li>• Include strategies to optimize vaccine response in frail and "old-old" populations, especially for influenza, pneumococcal and zoster vaccines.</li> <li>• In older adult populations, the AGS recommends that the development of new vaccines include a focus on their impact on functional outcomes (i.e., ADLs) in addition to traditional outcomes such as death and hospitalization.</li> <li>• The AGS recommends mandating the inclusion of older adults, particularly those</li> </ul>

29	1.2.3 Advance the science of neonatal and maternal immunization including the development of immunological models with which to study maternal immunization.	<p><b>AGS:</b> We recommend that emphasis be placed on developing combination vaccines that reduce the number of doses, whether injectable or oral, needed to completely vaccinate the vulnerable population. On the same note, we would also like to emphasize the need to develop vaccines with shorter vaccination series that reduce the total duration required to effectively vaccinate an individual. The reduction in number of vaccine dose administration and shorter vaccination series could result in higher compliance rates as well as decreased overall associated healthcare costs by reducing the number of visits. AGS is aware that the cost of developing combination vaccines and possible higher pricing as compared to the individual vaccines can be a significant barrier to the cost effectiveness of such vaccines but we believe that such an effort has great potential to result in higher compliance.</p> <ul style="list-style-type: none"> <li>• Also under this section, it should be considered that simplifying the immunization schedule in adults would greatly enhance vaccine rates. For example, FDA approved pneumococcal vaccine at age 50 (package insert), ACIP says age 65 despite efficacy in younger age groups.</li> </ul> <p><b>NVAC Stakeholder Mtg:</b> One participant favored keeping strategy 1.2.3 addressing neonatal and maternal immunizations because not having a Group B strep vaccine or pertussis vaccine for pregnant women on the market is unacceptable. There is fear of maternal immunizations and we need to address and solve these issues. We should use an emerging disease perspective when approaching these sensitive issues. There needs to be some understanding that there is value in these vaccines.</p> <p><b>BD (Dugue): (revised):</b> Develop a process that identifies current vaccines <b>and vaccine delivery systems</b> that would benefit from improved performance characteristics (effectiveness, safety, number of doses and/or delivery characteristics) and conduct and support studies to bring them to licensure.</p> <p><b>Canada Biologics (Griffiths):</b> The increasing number of combination products containing up to six components coming onto the market adds a further degree of insecurity</p>

		<p>to this situation. In a combination vaccine the failure of just one component antigen will result in the failure of the whole vaccine. Current manufacturing trends are towards very large lots, with long lead in times (7-18 months) from the start of production of a new lot, meaning that there may not be another lot ready to replace the one that failed for sometime. Furthermore, the shelf life of a combination vaccine is set by the performance of the least stable component.</p> <ul style="list-style-type: none"> <li>• Combination vaccines are affected by failure of just <b>ONE</b> component</li> <li>• Trend towards <b>very large lots</b></li> <li>• Lead in time for new antigen lot can be months (7-18 months from start of production).</li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> If these are in priority order, this should move up, since this research should be done before the research in 1.2.2.</p>
29	<p>1.2.4 Develop a process that identifies current vaccines that would benefit from improved performance characteristics (effectiveness, safety, number of doses, and/or delivery characteristics) and conduct and support studies to bring them to licensure.</p>	<p><b>JSI (Steinglass):</b> 1.2.4 and/or 1.4.1: Add “<b>vaccine packaging and presentation.</b>” In addition to formulations, there is an obvious need to work with industry on vaccine packaging and presentation (what industry calls “image”) of vaccines. The system requirements to permit smooth introduction of a new vaccine into existing vaccination programs vary considerably from the USA, where the vaccines are typically used to vaccinate a single child at a time in pediatric practices, to developing countries, where the vaccines are used at sessions serving tens of children at a time.</p> <p><b>NVD (Baxter):</b> Regarding this specific strategy, NVD disagrees with the inclusion of safety as an improved performance character. This language implies FDA approved vaccines are not safe.</p> <p><b>SUNY, Albany (Bednarczyk):</b> This is prioritization and should be in 1.1.1, not part of 1.2. Delivery is specifically addressed in 1.3.1, should be taken out of here.</p> <p><b>American Federation of Teachers (Alexander):</b> NIOSH should also be involved in research on the benefit from improved performance characteristics. Specifically NIOSH could contribute advice on protocol design for assessing efficacy in older workers. There has been some research that indicates that older nurses in at least one study did not seroconvert when vaccinated with certain Hb vaccines. NIOSH may also have some insight on what routine measures should be taken in worker populations to ascertain sero-conversion and performance in worker populations.</p>

		<b>BD (Dugue): Strategy 1.2.5 (new):</b> Support the use of single-dose manufacturer-prefilled delivery systems for current and new vaccine candidates in order to enhance vaccine performance (effectiveness, safety, number of doses, and/or delivery characteristics) and conduct and support studies to bring them to licensure.
29	<b>Objective 1.3: Support research on novel vaccine delivery methods.</b>	<b>NVAC Discussion 2-6-09:</b> Objective 1.3 ( <i>Support research on novel vaccine delivery methods</i> ) <ul style="list-style-type: none"> <li>Clarify delivery – as physical method of administering vaccines</li> </ul>
29	1.3.1 Develop and evaluate alternate delivery methods to improve the protective immune response, safety, effectiveness, and/or efficiency (e.g. number of doses) of immunization.	<p><b>BD (Dugue):</b> However, the role of new innovative vaccine delivery systems is not addressed in the draft plan. The US market has been slow to leverage the advantages of integrated prefilled vaccine delivery systems. Conventional syringes and vials remain the standard in the US, while in Europe nearly 93% of liquid vaccines are administered using a manufacturer-prefilled delivery system. As the National Vaccine Advisory Committee considers revisions to the NVP, it is critical that the plan recognize the role of novel vaccine delivery systems in improving the safety of vaccination practices, expanding access to vaccines, and extending the vaccine supply.</p> <ul style="list-style-type: none"> <li><b>(revised):</b> Develop and evaluate alternate delivery methods, <b>including integrated single dose manufacturer-prefilled delivery systems</b>, to improve the protective immune response, safety, effectiveness, and/or efficiency (e.g. number of doses) of immunization.  <i>Rationale: Studies have demonstrated distinct advantages of prefilled delivery systems that have the potential to reduce administration error and preserve vaccine supply.5,8,10,13 In addition, enhanced vaccine immune response can be achieved through alternate routes of administration14, which can be enabled by the use of manufacturer-prefilled delivery systems.</i>  <i>Furthermore, it is critical to incorporate single dose manufacturer-prefilled delivery systems earlier in the vaccine development process in order to create opportunities for increased success – reducing the need to address delivery integration issues later and capitalizing on the potential enhancement alternate delivery systems may contribute to a given vaccine candidate.</i></li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> Delivery methods are also addressed in 1.2.4 – that should be moved here.</p>

		<p><b>Southern Nevada Health District (Sorenson):</b> Delivery systems other than injection (Ex: Nasal).</p> <p><b>American Association of Occupational Health Nurses (AAOHN) (Kowalski):</b> 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.</p>
29	1.3.2 Expand knowledge of the mechanisms by which induction of protective immunity can be stimulated by immunization through mucosal surfaces and other delivery routes. Include studies to identify and mitigate host factors that decrease the effectiveness of immunizing by these routes.	<p><b>SUNY, Albany (Bednarczyk):</b> Does this include genetic classification? If so, that should be specifically addressed, so people are aware that it will be done.</p>
		<p><b>NVD (new) (Baxter):</b> Suggests adding a strategy to support increased funding for novel vaccine delivery methods.</p>
29	<b>Objective 1.4: Support development of vaccine candidates and the scientific tools needed to evaluate these candidates for licensure.</b>	<p><b>America’s Health Insurance Plans (AHIP) (Bocchino):</b> We suggest that ACIP begin to utilize cost-effectiveness or cost-benefit research conducted by independent parties (e.g. governmental organizations, or researchers without a financial stake in the outcomes of that research), rather than exclusively from vaccine manufacturers.</p> <p><b>NVAC Discussion 2-6-09:</b> Objective 1.4 (<i>Support development of vaccine candidates and the scientific tools needed to evaluate these candidates for licensure</i>)</p> <ul style="list-style-type: none"> <li>• Reorder strategies in a more logical sense and aligned with regulatory timeline</li> <li>• Clarify language – e.g., having a process for manufacturing clinical grade material i.e., contract manufacturing</li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> These seem too different to be lumped together here – makes for difficult to follow-up strategy.</p>

		<p><b>American Federation of Teachers (Alexander):</b></p> <ul style="list-style-type: none"> <li>• Target populations for candidate vaccines should include occupational groups at risk for the new or improved vaccine. For instance, poultry and livestock workers (their families and close contacts) who may be at risk for avian influenza should be identified as a priority population.</li> <li>• The indicators for candidate vaccines should include an assessment of work-related exposure to the disease agent in the prioritization process</li> </ul>
29	1.4.1 Support applied research to develop rapid and cost efficient production, and optimize formulations and stability profiles of currently available vaccines.	<b>SUNY, Albany (Bednarczyk):</b> Development of candidates and evaluation tools seem too separate to be lumped together like they are here.
29	1.4.2 Support research and development of platform technologies that are applicable to vaccine design and production.	
29	1.4.3 Improve access to appropriately designed pilot lot manufacturing facilities that produce clinical grade material for promising vaccine candidates.	<b>NVD (Baxter):</b> The tremendous private investment that is required to advance a vaccine candidate to licensure can only be sustained if the regulatory environment is sufficiently predictable and rational both to prevent unsafe or ineffective vaccines from reaching or remaining on the market and to allow licensure and ongoing distribution of safe and effective vaccines. The plan could address this situation by defining the ongoing improvement of existing vaccines as an important goal to encourage regulatory mechanisms that facilitate updating the safety and efficacy of vaccines with improvements in technology.
30	1.4.4 Improve identification of useful biomarkers and immune correlates of protection.	<p><b>SUNY, Albany (Bednarczyk):</b> Seems like it belongs, in part or in total, in objective 1.5</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b> (further identification of biomarkers and immune correlates of protection) is particularly important for encouraging the development of improved vaccines and increased supply, as this reduces the cost and timeframe for clinical development.</p>
30	1.4.5 Support translational research that accelerates the development of information that can be used in the	

	product evaluation and licensure process.	
30	1.4.6 Enhance methods and timeliness for conducting risk assessments of emerging variants or strains of vaccine-preventable disease agents, such as emerging strains of human and animal influenza virus.	
30	1.4.7 Establish and strengthen partnerships to address urgent needs in vaccine research and development	<b>SUNY, Albany (Bednarczyk):</b> Are these partnerships between different governmental agencies, or gov/non-gov entities? That should be clearer.
	1.4.8 Establish alternative development and manufacturing approaches to support licensure for those vaccines which have a limited market.	
		<b>Merck (Feinberg) (new):</b> Page 29, Strategy 1.4.9: The US Government should provide additional resources to the FDA to permit more frequent communication (e.g., early feedback, consultation during review) and more transparent review (e.g., more consultation and consistent expectations during review) with vaccine sponsors.
30	<b>Objective 1.5: Increase understanding of how the host immune system influences vaccine response.</b>	<p><b>NVAC Discussion 2-6-09:</b> Objective 1.5 (<i>Increase understanding of how the host immune system influences vaccine response</i>)</p> <ul style="list-style-type: none"> <li>Clarify this section and call out a role for genomics</li> </ul> <p><b>NVAC Stakeholder Mtg:</b> This section also needs clarity. There needs to be a distinction between innate and adaptive immune responses. There also needs to be a consensus amongst the various agencies on how they define items such as adjuvants. The group mostly suggested editorial changes to the strategies.</p> <ul style="list-style-type: none"> <li>“Host human immune system influences vaccine response” should say “host immune response determines vaccine safety and effectiveness”</li> </ul>
30	1.5.1 Expand basic and applied	<b>NVAC Stakeholder Mtg:</b>



	research on innate and adaptive immune responses to infections at different stages of life (e.g., neonate, infant, pregnancy, elderly) in order to advance the understanding of immune protection.	<ul style="list-style-type: none"> <li>It is implied that the innate and adaptive immune response. It may expand basic and applied research.</li> </ul> <p><b>American Nurses Association (ANA) (Stierle, Patton):</b> HHS should consider broadening this expansion of research to study genetic variances in immunological response based on ethnicity and race.</p>
30	1.5.2 Gain a better understanding of how induction and recall of immune memory may inform the development of vaccines that provide life-long protection.	<b>SUNY, Albany (Bednarczyk):</b> Reads more like an objective than a strategy.
30	1.5.3 Enhance research on vaccine effectiveness by continuing to support development of immunomodulators such as new adjuvants and use insights from such research to create novel vaccines and novel formulations of existing vaccines.	<p><b>Univ. of Washington (Corey):</b> A paragraph on the potential for adjuvants to improve the efficacy and lower the cost of vaccines might be mentioned.</p> <p><b>SUNY, Albany (Bednarczyk):</b> New formulations are addressed in 1.4.1</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b></p> <ul style="list-style-type: none"> <li>A strategy should be included that promotes the establishment of clear regulatory guidance on the use of novel adjuvants in vaccines. Newer adjuvants represent an important advance in vaccinology; however, a lack of clear regulatory guidance on their acceptability for various populations and situations will constrain additional innovation utilizing these tools.</li> <li>For the sake of pandemic or biodefense vaccines, should research of adjuvants be a specific goal? Similarly should research of vaccine enhancements such as stabilizing agents and alternative delivery methods that may ease administration in the developing world or in emergency use situations be specifically broken out as a goal?</li> </ul>
30	1.5.4 Expand knowledge of host related factors that impact severity of disease, and use this information to inform vaccine development.	<p><b>SUNY, Albany (Bednarczyk):</b> Similar concept to 1.5.1; may want to make the wording more similar to help convey the ideas more clearly.</p> <p><b>NVAC Stakeholder Mtg:</b></p> <ul style="list-style-type: none"> <li>Include impact vaccine response and severity of disease</li> </ul>

		<b>NVD (new) (Baxter):</b> NVD suggests add a new strategy to address the regulatory barriers for new adjuvant containing vaccines.
30	<b>Objective 1.6: Strengthen the science base for the development and licensure of safe and effective vaccines.</b>	<p><b>NVAC Discussion 2-6-09:</b> Objective 1.6 (<i>Strengthen the science base for the development and licensure of safe and effective vaccines</i>)</p> <ul style="list-style-type: none"> <li>Link this section to safety as a whole and clarify that pre-licensure safety should also inform post-licensure safety (i.e., hand off of safety information)</li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> The four strategies presented here seem to start to address indicator #4, in terms of rapid clinical testing of a vaccine, but don't fully address the idea of timeliness. It does not sync well with the listed indicators.</p>
31	1.6.1 Better characterize product safety and efficacy through research in areas including assay development, and characterization of novel cell substrates.	
31	1.6.2 Develop better animal models to study potential correlates of immune response to predict safety and efficacy in humans.	
31	1.6.3 Conduct research to inform feasible ways to provide data to support evaluation and licensure of new vaccines for biodefense related pathogens and rare diseases.	
31	1.6.4 Develop better methods for ensuring control and quality for laboratory, clinical and manufacturing practices related to developing a vaccine.	
		<b>BD (Dugue): Strategy 1.6.6 (new): Identify current and future vaccine trials where the route of administration and the single dose manufacturer-prefilled delivery system should be considered in the early phase trial design. Rationale: It is critical to</b>

		<p><i>incorporate single dose manufacturer-prefilled delivery systems earlier in the vaccine development process in order to create opportunities for increased success – reducing the need to address delivery integration issues later and capitalizing on the potential enhancement alternate delivery systems may contribute to a given vaccine candidate.</i></p>
<p>32-34</p>	<p><b>Goal 2, Indicators, and Figure</b></p>	<p><b>AGS:</b> The AGS noted that the Department of Veterans Affairs is missing from the list of groups of Research Entities suggested to receive annual report results. Since VA funding was a critical part of the support that allowed for a study of the benefits and side effects of zoster vaccine, this seems to be a significant oversight.</p> <p><b>NVD (Baxter):</b> NVD supports the inclusion of this goal to ensure the U.S. system continues to effectively meet vaccine safety needs. However, NVD cautions activities in this area to optimize safety may lead to misperception that current vaccines are not safe.</p> <p><b>NACHC (O’Fallon):</b> Goal 2 – This goal/strategy should include: Support development of registries (IIS) to enhance data collection in cases of AEFI</p> <p><b>Merck (Feinberg): Goal 2:</b></p> <ul style="list-style-type: none"> <li>• The national goal must balance speed with quality. Timely results, based on poor quality data or design, do not serve the nation’s interests. Results need to be vetted with learned intermediaries (e.g., ACIP work groups) before public release.</li> <li>• A consistent method for conducting these assessments and disseminating their results should be developed and implemented.</li> <li>• The title of Goal 2 is somewhat misleading. The safety profile of a given vaccine is an inherent characteristic that cannot be enhanced. Additional studies could allow better understanding of the safety profile, but the profile, <i>per se</i>, cannot be changed. We propose to revise the title to read "Improve the knowledge and understanding of the safety profile of vaccines to enhance vaccination practices."</li> <li>• The US Government should support EMR standards that enhance the ability to conduct effectiveness and safety studies. One objective might be to overcome potential coding biases related to healthcare provider behavior (e.g., when reimbursement rates may influence code selection).</li> <li>• The US Government should commission studies on the baseline epidemiology of AEFIs that have been associated temporally with vaccines historically (e.g., Guillain-Barré syndrome, myocarditis, unexplained death in young adults).</li> </ul>

		<ul style="list-style-type: none"> <li>• The US Government should commission systems research on ways to optimize the quality of data obtained from research using administrative databases (e.g., ability to distinguish between incident and prevalent cases of a specific event or condition).</li> </ul> <p><b>HIDA (Ostrand):</b> Increase transparency about the FDA/CBER vaccine inspection process and timelines to further bolster consumer confidence and healthcare worker (HCW) confidence in vaccine safety.</p> <p><b>sanofi Pasteur (Hosbach):</b> The original 1994 language of Goal 2, which was, “ensure the safety and effectiveness of vaccines and immunization” is preferred over the less clear revision, “Enhance the safety of vaccines and vaccination practices.”</p> <p><b>BD (Dugue): Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Goal 2 Indicators (new): By X year, vaccine administration adverse events will be reduced by X% through the use of single dose manufacturer-prefilled delivery systems.</b> <i>Rationale: Indicators that include assessment and surveillance are a laudable, and necessary first step; setting target reductions in adverse events following immunization stands to keep the Nation on track for improving vaccine safety.</i></li> <li>◆ <b>Goal 2 Indicators (new): Conduct and disseminate the results of active and passive surveillance-based assessments of current vaccine administration practices in various settings (e.g., healthcare facilities, convenient care centers and community centers).</b> <i>Rationale: Recent studies have shown that drug delivery systems have an impact on vaccine administration, including reducing risk of error that may contribute to adverse events.<sup>6,7,15</sup> A better understanding of how healthcare providers actually administer vaccines in practice (as opposed to in training) and especially in the context of emergency settings promises to reveal opportunities for improvement in training and in the engineering of, and access to, vaccine delivery systems designed to mitigate error by reducing steps required for administration.</i></li> <li>◆ <b>Goal 2 Indicators (new): Conduct or support research that examines single dose, manufacturer-prefilled delivery systems as a means of engineering safety into vaccine administration across all settings.</b> <i>Rationale: Manufacturer-prefilled delivery systems eliminate several of the steps</i></li> </ul>
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*associated with conventional syringe-and- vial administration. Simplified administration may reduce the risk of error associated with conventional nonintegrated delivery systems.*

**NVAC Discussion 2-6-09:** One area of prolonged discussion was the 4<sup>th</sup> indicator (*Conduct research to explore host factors and biological mechanisms associated with serious [adverse events following immunization] AEFIs and annually report results to the Assistant Secretary for Health, vaccine advisory committees, vaccine policy makers and other stakeholders*) and associated objectives/goals concerning genetic risk factors and biological mechanisms. There was consensus among the group that it was a very important new field of science, although there was caution against being unrealistic or over-promising. There was also support shown for reducing administration errors. The group did not propose values for Xs in the indicators.

- ◆ **Indicator 1-** Dissemination is very important (*Conduct and disseminate the results of active and passive surveillance-based safety assessments for newly recommended vaccines or for vaccines with expanded recommendations:*
  - *Within 1 year of publication in CDC's Morbidity and Mortality Weekly Report of new or revised ACIP recommendations.*
  - *Within 1 year after X million doses have been distributed)*
- ◆ **Indicator 4 -** Strategies must be developed for how to deal with this topic, which garners enormous scientific and public interest, but scientifically poses challenges. The process should be transparent of what the studies are, what the methods are, and who is doing the research.

**IDSA (Gershon): Comments on Goal 2**

**We believe the Vaccine Safety Datalink [VSD] project is a critical tool for early detection of vaccine safety concerns. However, VSD is not mentioned in Goal 2.** It is unclear whether VSD is implicit in this Goal.

- ◆ **Indicator 1:** On p.33, the first indicator, first sub-bullet suggests that safety assessments be conducted and disseminated within one year after vaccine recommendations are published in CDC's *Morbidity and Mortality Weekly Report*. VSD rapid cycle studies are critically important to assess causal relationships regarding vaccine safety. However, these studies generally take about two years to have sufficient power to detect reasonably elevated relative risks. Therefore, we recommend this time window be extended from one year to two years.

		<p><b>NVD (Baxter): Goal 2 Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 1:</b> NVD cautions that this first indicator may lead to significant amounts of data collection and production, without producing additional information helpful to safety assessments. To prevent such a scenario, the indicator needs to be targeted.</li> <li>◆ <b>Indicator 2:</b> This indicator will not lead to enhancement in the safety of vaccines and vaccination practices and as such is not supported by NVD. Signal detection does not equal evaluation.</li> <li>◆ <b>Indicator 3:</b> NVD believes the third indicator is cost prohibitive. We suggest NVPO consider tailoring the indicator.</li> <li>◆ <b>Indicator 4:</b> NVD recommends the indicator be tailored to be more achievable in the 10 year timeframe.</li> </ul> <p><b>Australia (Horvath): Goal 2 Indicators (new):</b></p> <ul style="list-style-type: none"> <li>• " By year X develop accreditation standards for various categories of immunisation providers;</li> <li>• " Y% of immunisation providers with appropriate level of accreditation by the year X.</li> </ul> <p><b>Merck (Feinberg): Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 1:</b> Consider performing assessments at several stages, such as after X million, 2X million, and 4X million doses have been administered. This approach would avoid depending only on a short-interval study that may have an inadequate comparator group (or inadequately understood baseline rates), be inadequately powered, or when reporting may be brisk and rare events may not be identified following initial introduction of the vaccine.</li> <li>◆ <b>Indicator 2:</b> This indicator should focus on the International Conference on Harmonization (ICH) end-to-end (E2E) risk management plan (RMP) for each vaccine (which addresses known risks, potential risks, unknown risks). The ICH E2E program exists as a global standard. Good pharmacovigilance practice requires sponsors to have RMPs and procedures in place to identify and investigate emerging safety signals.</li> <li>◆ <b>Indicator 3:</b> The percentages may need to vary for each of the specified cohorts.</li> <li>• Rather than stating a percentage goal, consider stating a number of lives for each</li> </ul>
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34	<b>Objective 2.1: Facilitate the</b>	<b>SUNY, Albany (Bednarczyk):</b> The four strategies in this section address vaccine safety



	<b>continuous modernization of manufacturing sciences and regulatory approaches relevant to manufacturing and inspection to enhance product and patient safety.</b>	<p>from a product quality standpoint, and not the basic risks associated with vaccines – this difference between both types of vaccine safety should be spelled out more clearly.</p> <p><b>AACP (Lang):</b> 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.</p>
34	2.1.1: Facilitate the enhancement of vaccine manufacturing sciences and quality systems, including production technologies, in process controls and testing, and identification of best practices in preventive quality systems and oversight.	
34	2.1.2: Develop, implement risk-based approaches to identify cGMP and inspection priorities.	
35	2.1.3: Support new technologies and modernization of both industry and FDA testing of product quality to better prevent and more rapidly detect potential quality or safety issues.	
35	2.1.4: Evaluate current regulations, guidance documents, policies and procedures that are relevant to manufacturing to determine enhancements that could be made to promote and enhance product safety.	<p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> This is a bit of a generic comment. Here and several other places it seems some speculation as to how this might be accomplished would be helpful. For example, what in the evaluation of manufacturing procedures would lead to changes in those procedures?</p>
		<p><b>BD (Dugue): (new): Develop a process by which single dose manufacturer-prefilled delivery systems are incorporated into the vaccine development process to ensure compatibility, optimal product quality, and patient safety.</b></p> <p><i>Rationale: Creating a standard process for integrating single dose manufacturer-prefilled delivery systems earlier in the vaccine development process allows for optimal matching of</i></p>

		<i>candidates to delivery system and leveraging of its associated advantage profile.</i>
35	<b>Objective 2.2: Enhance timely detection and evaluation of vaccine safety signals.</b>	<p><b>Association for Professionals in Infection Control and Epidemiology (APIC) (Nutty):</b> 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.</p>
35	2.2.1: Improve the effectiveness and timeliness of AEFI signal identification and assessment through coordinated use of national passive and active surveillance systems.	<p><b>NVD (Baxter):</b> To maintain public trust, adverse events and perceived adverse events must be swiftly, but appropriately addressed by the US gov't. NVD suggest the establishment of an assessment protocol that incorporates a risk/benefit analysis.</p> <p><b>SUNY, Albany (Bednarczyk):</b> What methodologies will be used to coordinate between two very different systems.</p> <p><b>Southern Nevada Health District (Sorenson):</b></p> <ul style="list-style-type: none"> <li>• Improved Surveillance for Adverse Event Reporting especially as it relates to new vaccines.</li> <li>• Better data collection system when new vaccines are introduced to monitor effectiveness and adverse event reporting in a timely manner.</li> </ul> <p><b>AACP (Lang):</b> 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, 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</p> <p><b>American Immunization Registry Association (AIRA) (Sutliff) revise:</b> Improve the effectiveness and timeliness of AEFI signal identification and assessment through coordinated use of national passive and active surveillance systems, <i>including IIS.</i></p> <p><b>NASDDDS (Rolfe):</b> Ongoing assessment of risk and adverse events while being closely</p>

		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.
35	2.2.2: Enhance collection of medical histories and biological specimens from selected persons experiencing serious AEFI reported to the Vaccine Adverse Event Reporting System (VAERS), petitioning the National Vaccine Injury Compensation Program (VICP), and available through active surveillance to enhance study of biological mechanisms and individual risk factors.	<p><b>SUNY, Albany (Bednarczyk):</b> Will these specimens be used for standard biological testing or will they also be used for genetic testing? This distinction should be more explicit.</p> <p><b>Southern Nevada Health District (Sorenson):</b> Who can report Adverse Events by use of an electronic reporting system.</p> <p><b>APIC (Nutty):</b> 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.</p> <p><b>NASDDDS (Rolfe):</b> 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.</p>
35	2.2.3: Assess lay public and professional questions and concerns about vaccine safety.	<p><b>Canada Biologics (Griffiths): Building and maintaining public confidence in vaccines and immunization.</b></p> <ul style="list-style-type: none"> <li>• Immunization programmes critically depend on a consistent supply of safe and effective vaccines.</li> <li>• The <b>consistent</b> safety/efficacy of a vaccine has long been recognized as an <b>essential element</b> of any successful immunization programme</li> <li>• Vital to maximize safety and efficacy</li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> This fits better with Goal 3 than in this Goal/Objective.</p> <p><b>APIC (Nutty):</b> Providing active surveillance to healthcare providers 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.</p>
35	2.2.4: Improve the process for assessing AEFI signals to determine which signals should be evaluated	<b>NVD (Baxter):</b> Suggest move to objective. A consistent framework for signal management that is based on risk benefit evaluation would ensure the appropriate signals are expediently evaluated without prematurely driving a vaccine off the market. It would also

	further in epidemiological and clinical studies .	improve consumer confidence in the process of AEFI evaluation.
		<b>IDSA (Gershon) (new):</b> “Increase support for the VSD project to rapidly detect and confirm signals for vaccine adverse events.”
35	<b>Objective 2.3. Improve timeliness of the evaluation of vaccine safety signals when a high priority new vaccine safety concerns emerges, a new vaccine is recommended or vaccination recommendations are expanded, and during public health emergencies as in an influenza pandemic or other mass vaccination campaign</b>	
35	2.3.1: Increase the size of the population under active surveillance for serious AEFIs that can be included in high quality, rigorously conducted epidemiological studies to test vaccine safety hypotheses.	<b>IDSA (Gershon) (revise):</b> “Increase the size of the VSD population to facilitate timely and rigorously conducted epidemiological studies of vaccine adverse events.”  <b>SUNY, Albany (Bednarczyk):</b> Increase the size of VSD or develop a new active surveillance system?
36	2.3.2: Expand collaboration with clinical, laboratory, genetic and statistical experts to conduct clinical research studies to investigate the role of host genetics in AEFI.	
36	2.3.3: Enhance capacity to monitor immunization safety in the event of a mass vaccination campaign	<b>SUNY, Albany (Bednarczyk):</b> Would this include the development of a registry of individuals who receive immunizations in a mass vaccination campaign, and can these be tied in with current IIS?

		<p><b>APIC (Nutty):</b> 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.</p> <p><b>AIRA (Sutliff) revise:</b> Enhance capacity to monitor immunization safety in the event of a mass vaccination <i>campaign by quickly aggregating the data in a state, local or regional IIS.</i></p>
36	2.3.4 Provide safety data necessary to conduct informed risk-benefit assessments for utilization of vaccines in mass vaccinations for public health emergencies.	
36	<b>Objective 2.4: Improve causality assessments of vaccines and related AEFIs.</b>	<p><b>University of Maryland (Milstien):</b> I wonder about the objective 2.4 on improving causality assessments. Although this would be desirable, I wonder if it is possible by the strategies outlined, especially for a rare AEFI with one or only a few case reports. I believe the emphasis should be on good epidemiological methods, and the strategies should say this.</p>
36	2.4.1 As appropriate, develop algorithms and assess the evidence on an individual-level for a causal relationship between certain vaccines and specific serious AEFI	<p><b>BD (Dugue): (revised):</b> As appropriate, develop algorithms and assess the evidence on an individual level for a causal relationship between certain <b>vaccine delivery systems</b>, vaccines and specific AEFI.  <i>Rationale: Recent studies have shown that vaccine delivery systems have an impact on vaccine administration, including risk of error.5 Inserting "vaccine delivery systems" in this strategy broadens the scope of the evaluation to include this known contributing factor.</i></p> <p><b>SUNY, Albany (Bednarczyk):</b> How will these be prioritized?</p>
36	2.4.2 Assess the evidence on a population-level for a causal relationship between certain vaccines and specific serious AEFI	
36	2.4.3 Regularly update the Vaccine	<p><b>SUNY, Albany (Bednarczyk):</b> Not directly related to this objective, and is already referenced in 4.7.2 where it fits better.</p>

	Injury Compensation Table based upon individual and population level causality assessments.	
36	<b>Objective 2.5: Improve scientific knowledge about the risk of vaccine adverse events and their mechanisms.</b>	
36	2.5.1 Identify host risk factors, such as previous or concurrent illness or genetic characteristics, that may be associated with increased risk for specific AEFI through basic, clinical, and epidemiological research.	
36	2.5.2 Identify the biological mechanism(s) for specific AEFI that, based upon causality assessments (Strategy 2.4.2), are likely to be causally associated with vaccination.	
36	2.5.3 Assess whether the risk of specific AEFI is increased in specific populations such as pregnant women, premature infants, elderly persons, those with immunocompromising or other medical conditions, or based on gender or racial/ethnic group.	
36	<b>Objective 2.6: Improve clinical practice to prevent, identify and manage AEFIs.</b>	<b>AACP (Lang):</b> 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

37	2.6.1 Improve training, availability of and access to vaccine safety clinical experts to provide consultation to healthcare providers and public health practitioners.	<p><b>Merck (Feinberg):</b> These professionals need not just scientific content, but also communication skill training to convey that content to their patients in an understandable way. The US Government should commission development of additional communication curricula to meet this objective.</p> <p><b>APIC (Nutty):</b> 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.</p>
37	2.6.2 Develop additional evidence-based guidelines for vaccination or re-vaccination as appropriate, for persons at increased risk for AEFI. Identify additional contraindications and precautions to vaccination, as needed.	<p><b>SUNY, Albany (Bednarczyk):</b> This seems to be part of 2.5. To stay in this objective, it should address dissemination of contraindications as part of clinical practice.</p> <p><b>APIC (Nutty):</b> 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.</p>
37	2.6.3 Reduce errors in vaccine administration (e.g., wrong vaccine, dose, injection site, or timing).	<p><b>BD (Dugue):</b> Concerns about vaccine safety have been primarily focused on drug formulation. However, adverse events have been reported due to failure of healthcare personnel to adhere to fundamental principles of infection control and aseptic technique in the administration of vaccines.</p> <p><b>NVAC Discussion 2-6-09:</b> There was strong support for efforts to reduce administration errors, including better tracking/recording.</p> <p><b>JSI (Steinglass):</b> add “<b>sharps disposal</b>”</p> <p><b>NVD (Baxter):</b> is supportive of measure to reduce errors, but recognize that careful consideration must be given to implementation. For example, if standardization in packaging is considered it may serve as an innovation deterrent and a cost prohibitive mandate on companies.</p> <p><b>AAP (Tayloe, Bocchini):</b> Another example of a way to reduce errors in vaccine administration can include the depth of injection</p> <p><b>ANA (Stierle, Patton):</b> Reducing errors in vaccine assessment and administration will</p>

		require a closer look at the increasingly complex and confusing immunization schedule as recommended by the Centers for Disease Control and Prevention. 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.
		<b>BD(Dugue): Strategy 2.6.4 (new):</b> Expand the use of single dose manufacturer-prefilled delivery systems to enhance AEFI reporting measures through vaccine traceability and reduce AEFIs related to the preparation of the vaccine for administration and the administration process.
		<b>BD (Dugue): Strategy 2.6.5 (new): Assess current vaccine administration practices and associated errors in order to identify opportunities for improvement.</b> <i>Rationale: Recent studies have shown substantial errors directly associated with the administration of vaccines. Vaccine delivery systems have an impact on vaccine administration, including risk of error.5 For this reason, the NVP should include more specific strategies that acknowledge “vaccine delivery system” as a potential contributing factor to the incidence of AEFI. Moreover, single dose manufacturer-prefilled delivery systems present opportunities for improving the traceability of vaccines and vaccinations, providing a clear mechanism for tracking quality improvement in vaccine administration.</i>
37	<b>Objective 2.7: Improve cross-cutting scientific capabilities to enhance vaccine safety and the vaccination safety system</b>	<b>NVAC Discussion 2-6-09:</b> New systems, such as electronic health records, may allow for better data transmission and integration
37	2.7.1 Enhance the immunization safety science workforce to recruit and retain additional highly trained scientists and clinicians.	
37	2.7.2 Develop additional standard case definitions for AEFI for use in immunization safety surveillance and research, vaccine safety standards such as concept definitions, standardized	<b>SUNY, Albany (Bednarczyk):</b> There also needs to be some manner to encourage use of case definitions in reporting.



	abbreviations, and standardized study designs.	
37	2.7.3 Improve laboratory, epidemiological and statistical methods used in vaccine safety research.	<p><b>SUNY, Albany (Bednarczyk):</b> This is a very broad and vague strategy – can it be broken down in to smaller, more detailed pieces.</p> <p><b>APIC (Nutt):</b> 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.</p>
		<p><b>BD (Dugue): Strategy 2.7.3 (new): Identify and support research that examines single dose manufacturer-prefilled delivery systems as a means of engineering safety into vaccine administration across all settings.</b></p> <p><i>Rationale: Studies have shown that by nature of their design, single dose manufacturer-prefilled delivery systems may mitigate considerable error potential by eliminating several of the steps associated with conventional syringe and vial administration.</i></p>
37	<b>Objective 2.8: Enhance integration and collaboration of vaccine safety activities.</b>	<p><b>IDSa (Gershon) (revise): Objective 2.8 is important, but vague.</b> We recommend rewording this to emphasize the importance of federal collaboration as follows: “Enhance timely and collaborative efforts among the federal agencies involved in vaccine safety.”</p>
37	2.8.1 Improve collaboration, such as data sharing arrangements, across agencies and departments.	<p><b>Mayo Clinic (Poland):</b> Build 21st century transformation teams (with people you never invited to the party...)</p> <ul style="list-style-type: none"> <li>• Design engineers</li> <li>• Sociologists</li> <li>• Cultural anthropologists</li> <li>• Risk communication</li> <li>• Communication experts</li> <li>• Electronic media geeks</li> <li>• “Red cell” teams for critical problem areas</li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> Should there be provisions for sharing between governmental and non-governmental entities?</p>
38	2.8.2 Improve information and data	<p><b>University of Pittsburgh (Zimmerman):</b> The discipline of vaccine ethics is treated superficially; I realize that the vaccine safety and economic objectives address ethical issues</p>

	<p>sharing with international partners (e.g., national vaccine safety programs) as consistent with ethical and human subjects protections.</p>	<p>but I believe the time has come for more formal vaccine ethics as its own discipline. Deliberative bodies often use ethics, perhaps without realizing the underlying theory and its implications. At the heart of many of the debates and problems in the vaccine world are issues of justice, autonomy, beneficence, altruism (or lack thereof), utilitarianism, and societal good versus individual freedom. The issues go beyond providing lay education but apply to deliberative bodies and government institutions. This is the most important of my suggestions and applies especially to goals 2 and 3 and could be an indicator for goal 3.</p>
		<p><b>IDSA (Gershon) (new):</b> “Assure there is independent and timely review of vaccine safety concerns to determine whether selected temporally related adverse events are causally related, and, if so, to determine risk factors for such events, and formulate a vaccine safety research agenda.”</p> <p><b>IDSA (Gershon) (new):</b> “Review the approaches used to provide independent oversight of safety issues associated with other federally-sponsored programs including transportation, blood products, and environmental concerns to identify opportunities to enhance public confidence in the vaccine safety system.”</p> <ul style="list-style-type: none"> <li>• <b>Additional strategies under 2.8 may flow from pending considerations by NVPO’s Vaccine Safety Work Group about means of enhancing integration and coordination of vaccine safety activities.</b> To note, NVPO must continue to ensure robust public input on these and other deliberations on this issue.</li> </ul>
<p>39-42</p>	<p><b>Goal 3, Indicators, and Figure</b></p>	<p><b>AHIP (Bocchino):</b> Goal #3 should be modified to include payors among listed stakeholders, thus reading: "Support informed vaccine decision-making by the public, providers, <i>payors</i>, and policy-makers."</p> <p><b>NVAC Discussion 2-6-09:</b></p> <ul style="list-style-type: none"> <li>• There needs to be a general reconsideration of who is included in the goal. There does not seem to be appropriate emphasis on professional organizations and non-governmental organizations when discussing immunization education.</li> <li>• It needs to be clear that this is not a one-step process, and that these strategies need to be on-going.</li> <li>• There seems to be a large amount of overlap with other goals, and overlap within the strategies of Goal 3, that needs to be addressed.</li> <li>• There needs to be a focus on all reasons for under-immunization, aside from just</li> </ul>

		<ul style="list-style-type: none"> <li>• Non-traditional vaccine providers must be addressed with regard to their role in immunization practices (e.g., obstetricians/gynecologists and nurse-midwives).</li> </ul> <p><b>Task Force for Child Survival (Hinman):</b> Goal 3 – given the success of the United Kingdom in assessing public attitudes and perceptions about immunizations, shouldn't there be an objective about developing a comparable system in the United States?</p> <p><b>Families Fighting Flu (Stein):</b> Focus communication efforts to encourage consumers—and especially parents responsible for the protection of children—to recognize the benefits of vaccination and why it is important to protect their families. Do not overemphasize risks, but rather, promote recommended vaccinations and its empirically proven benefits.</p> <p><b>sanofi Pasteur (Hosbach):</b> There should be a particular focus on increasing HHS/CDC communication efforts aimed at educating consumers, health-care professionals (HCP), and third party payers about the value and importance of immunization.</p> <ul style="list-style-type: none"> <li>• It is essential to reaffirm the value, importance and safety of vaccines to consumers and HCPs to drive the vaccine uptake in the U.S.</li> <li>• High and consistent consumer demand for existing vaccines has clear public health benefit and also supports a sound vaccine infrastructure.</li> </ul> <p><b>SafeMinds (Wrangham):</b> We support the Measurable Indicators of Goal 3 listed in Table 1, p11-12, and the objectives assigned to each, but believe they are once again insufficient and diminish the primary principles of informed decision-making by patients or parents. Sections of our public input provide recommendations for additional components of informed decision-making, which should be included in the final NVP.</p> <p><b>Wyeth (Connolly, Eyles):</b> The Plan should reflect a more determined and effective government strategy to refute vaccine disinformation and respond to anti-vaccine strategies that have the potential to compromise the public health.</p> <ul style="list-style-type: none"> <li>• The rationale for requiring vaccinations should be a stated strategy.</li> <li>• We suggest that a similar goal of determined and effective strategies to refute vaccine disinformation and respond to anti-vaccine strategies be added to the</li> </ul>
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		<p><b>NACHC: Additional indicators:</b></p> <ul style="list-style-type: none"> <li>• X % of health care providers will report they are satisfied with the availability of new vaccine product information and accessibility.</li> <li>• X% of health care providers will report they are satisfied with availability of older, effective and less costly single antigen vaccines when newer more costly combination vaccines emerge.</li> <li>• X% of key decision and policy makers will report they have access to costs of newly emerging vaccines along with efficacy and risk.</li> </ul> <p><b>European CDC (Jakab):</b> Another area not mentioned clearly is the identification of hard-to-reach groups and how the information about vaccines could aim to also reach these groups. In particular there are also a significant number of individuals and families around the hard-to-reach groups influenced by the hard-to-reach groups and that possibly could be reached with more in-depth information.</p> <p><b>Japan (Dr. Arita):</b> Goal 3 I would like to discuss a special establishment, Vaccine Research Institute for sub-Saharan Africa.</p> <p><b>Trust for America’s Health:</b> The benchmarks and strategies within this goal address public and clinical perceptions about vaccines, but the National Vaccine Plan does not explicitly acknowledge the need to immediately counteract a growing anti-vaccine movement. Research on messaging and public perceptions is necessary, but the Department of Health and Human Services (HHS) needs to be more proactive in changing cultural norms to urge acceptance of childhood and adult vaccinations. Misconceptions, false information, and fear continue to discourage parents from vaccinating their children and from adults from seeking products such as seasonal influenza vaccines.</p> <p><b>AACP (Lang):</b> 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</p>
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	<p>other federal agencies to evaluate communications developed within the agency for dissemination to the public.</p> <p><b>Australia (Horvath): Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers.</b>  I suggest that an additional objective could be considered under this goal, that is:</p> <ul style="list-style-type: none"> <li>• To develop an effective response to manage the influence of the anti-vaccination lobby by improving knowledge of the attitudes, methodology, the reach and impact of this group.</li> </ul> <p>Furthermore, I suggest the following:</p> <ul style="list-style-type: none"> <li>• " By year X, map drivers and barriers to immunisation uptake across geographical and social spectrums, and identify and develop measures to achieve consistent national immunisation coverage;</li> <li>• Reduce the proportion of the population who are conscientious objectors by Y% in X years.</li> </ul> <p><b>NVD (Baxter):</b>NVPO should encourage proactive government leadership in risk communication.</p> <p><b>Merck (Feinberg): Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 1:</b> The document should clearly state the initial time point to be used to calculate the "within X days" interval. The standard should be set carefully, to allow for scenarios where poorly understood situations would have to be reported before adequate guidance to the public could accompany it.</li> <li>◆ <b>Indicator 3:</b> The US Government should play an active role in providing additional culturally-appropriate educational materials (with varying levels of information content) on the benefits of vaccination in general and that of specific vaccines to the public.</li> <li>• Each of the following indicators within Goal 3 would benefit from parallel construction aligned with the Healthy People 2020 objectives, which use a target percentage increase based on a best practice, when available.</li> </ul> <p><b>SUNY, Albany (Bednarczyk): Indicator 5:</b> For consistency, indicators 2 – 5 should start with "By Y (year)" – having it at the end of the sentence may cause the timeline to get</p>
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		<p>lost.</p> <p><b>University of Pittsburgh (Zimmerman):</b> One of the critical areas for information development is point-of-care informatics-based decision support to enable clinicians to rapidly find detailed vaccine information. Global searches of vast web sites are not the answer. This applies to Goal 3 and can be an indicator.</p> <p><b>Nat’l Centre for Immunisation Research &amp; Surveillance, Australia (Leask):</b>  <b>Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 2:</b> The language of this goal depicts the public as passive recipients of information (see comment 3 above). It also assumes clinical communication fits easily into a question answer format. An alternative could be X___ % of the public will report that they are satisfied with how their health care provider <b>communicates with them</b> about the benefits and risks of vaccines by Y (year).</li> </ul> <p><b>Gates Foundation (Orenstein): Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 1:</b> On page 39, indicator 1, how do you measure “enhance communication”? Certainly, the time frames are easy to measure.</li> <li>◆ <b>Indicator 6 &amp;7:</b> On page 40, last two indicators – “all” is tough to achieve. For example, are you saying that ophthalmologists and neurosurgeons should have immunization questions on their certifying examination? I agree that is a good goal, but should it be focused on primary care providers?</li> </ul> <p><b>Univ. of Iowa Medical Center (Helms):</b> For those indicators where it applies, I would suggest setting 5 years as a time to show evidence of at least some improvement (e.g., in stakeholder-public vaccine communication). I would require the final target % to be reached no later than the assigned target date. Previously measured baseline levels (%) will be required to show progress.</p> <p><b>United Kingdom (Salisbury): Indicators and comments</b></p> <ul style="list-style-type: none"> <li>• Whilst setting process or outcome indicators for communications about immunisation are laudable, there are no criteria for what these should be and the</li> </ul>
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		<p><b>HIDA (Ostrand): Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 6:</b> We additionally recommend that education about the vaccine supply chain be incorporated into this training to help HCWs understand how vaccine reaches them and to eliminate confusion or frustration on their part that may negatively impact their desire and/or ability to immunize.</li> <li>• A continuing education credit for practicing HCWs surrounding vaccine supply chain education could also assist veteran HCWs as they schedule immunization clinics, make plans to purchase vaccine, and work to answer patient questions about vaccination timelines, safety, and security.</li> </ul>
42	<p><b>Objective 3.1: Conduct research and utilize findings in an ongoing fashion to identify communication and education needs and inform communication and education efforts.</b></p>	<p><b>JSI (Steinglass):</b> add <b>USAID</b>. USAID and its contractors are very active in the area of improving program communications.</p> <p><b>United Kingdom, Department of Health (Salisbury):</b> 3.1 p 42 – The UK does all these, and has done so for many years: these activities are invaluable.</p> <p><b>ICHS (Dang):</b> In addition, we would recommend that any development, testing of educational strategies to enable the public audiences about the risks and benefits when making immunization decisions, and assessment of the communication materials also be done in a culturally appropriate and in the language of linguistically-isolated communities (proposed strategy 3.1.3; 3.1.4; 3.1.5).</p> <p><b>Every Child by Two (Pisani):</b> Stakeholders should include: Academia and philanthropic organizations, both of whom play a major role in reaching the public with health care messages.</p>
42	<p>3.1.1 Conduct ongoing research to take a “pulse of the public” to identify knowledge, beliefs and concerns about vaccines and vaccine-preventable diseases.</p>	<p><b>Families Fighting Flu (Stein):</b> We believe the NVAC will need to monitor the percentages of consumers that do and do not vaccinate and their reasons why, and should ultimately aim for 0% of respondents to report that they did not vaccinate because they perceive vaccination to be unimportant, a hassle, too costly, or too risky.</p> <p><b>AAOHN (Kowalski):</b> Change consumer/client attitudes about vaccinations through education and re-education, information sharing, consumer stakeholders input, etc.</p>
42	<p>3.1.2 Conduct research on factors (positive influences and barriers) that</p>	<p><b>ICHS (Dang):</b> Specific to the proposed objective 3.1 of <i>improving communication and education efforts</i>, we would recommend that the proposed strategies include conducting</p>

	go into decision-making about vaccination for individuals and families, providers, and policymakers.	research that is culturally appropriate and in the language of linguistically-isolated communities (proposed strategy 3.1.2).
42	3.1.3 Develop and test educational strategies that better enable public audiences and policymakers to read, understand, and use information about vaccine risks when making immunization decisions.	<b>IDSa (Gershon): Strategy 3.1.3 implies that no educational strategies exist or they are ineffective.</b> We recommend the following wording: "Identify and review current educational strategies and, when appropriate, develop and test new interventions that would enable public audiences and policy makers to read, understand and use information about vaccine benefits and risks when making immunization decisions."
42	3.1.4 Continue to assess the effectiveness of select messages and materials in addressing information needs and concerns based on public and provider attitudes toward the benefits and risks of vaccines.	
42	3.1.5 Evaluate the effectiveness of vaccine benefit and risk communication, overall and for populations known to be at risk of under immunization, and, as needed, update communications.	<b>SUNY, Albany (Bednarczyk):</b> Does this reference only under immunization due to vaccine refusal, or also financial barriers? These need to be differentiated
42	3.1.6 Gather data to inform communications about the accessibility of vaccines (i.e., where and when to get vaccinated).	<b>JSI (Steinglass):</b> add " <b>availability</b> ". Accessibility to health facilities does not equate with availability of product and vaccination services. " <b>Acceptability</b> " could be added, as well, as services may be available but not utilized.
42	3.1.7 Gather data to inform communications activities and vaccine program managers on the direct and indirect costs of vaccination. This includes, but is not limited to, information on federal and state	<b>JSI (Steinglass):</b> add " <b>global</b> ," as USAID is involved in this.  <b>Gates Foundation (Orenstein):</b> On page 42, strategy 3.1.7 only discusses collecting information on the direct and indirect costs of vaccination. Why not benefits and costs averted?

	programs that offer low cost vaccines.	
		<p><b>IDSA (Gershon) (new):</b> add a strategy for studying factors obstructing utilization of programs even among those accepting of vaccine science and develop initiatives that will communicate with the public about existing immunization programs and the eligibility requirements of those programs. Increased knowledge about existing federal and state programs may serve as a positive influence on decision-making about vaccines and may increase rates of program utilization.</p> <p><b>IDSA (Gershon) (new):</b> add a strategy to conduct research into how to promote a sense of community contribution among individuals, e.g. the public health aspect of immunization, as another positive influence on decision-making about vaccines.</p> <p><b>NVD (Baxter) (new):</b> Enhance efforts to understand why individuals decline vaccines. Use information to enhance objectives in future communications efforts.</p>
42	<b>Objective 3.2: Utilize collaborations and partnerships to leverage communication efforts.</b>	<p><b>Institute for Global Health (Rutherford):</b> The list of non-federal stakeholders should include professional societies, such as the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Physicians.</p> <p><b>AARC (Myers):</b> 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.</p> <p><b>ADA (Findley):</b> The American Dental Association and its local dental societies could be valuable collaborators in enhancing communications with the general public on vaccination issues.</p> <p><b>United American Nurses (UAN) (Markle-Elder):</b> We also note that unions can assist in collaborations to educate workers as mentioned in <i>Objective 3.2</i>.</p>
42	3.2.1 Emphasize cross-agency and intra-agency collaboration to inform	

	development of communication research agendas, protocols, campaigns and messages.	
42	3.2.2 Strengthen partnerships and coalitions supporting immunization of children, adolescents, and adults.	<b>IDSA (Gershon): Strategy 3.2.2 could be strengthened by adding examples;</b> e.g. support of state-based adult immunization coalitions.
42	3.2.3 Collaborate with partners and stakeholders to communicate vaccine benefits and risks in appropriate languages, methods, and literacy levels.	<b>NVAC Discussion 2-6-09:</b> Research strategies need to address cultural appropriateness for the many varied populations they will be utilized in. The diversity of the population and differences in health literacy must be incorporated. <b>AAP (Taylor, Bocchini):</b> 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.
		<b>NVD (Baxter) (new):</b> Cultivate relationships with novel advocacy groups to promote vaccine availability and benefits.
43	<b>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.</b>	<b>Columbia NCDP (Garrett):</b> In goal #3 there are well thought out objectives to empower the public and providers to facilitate informed decision-making around the issue of vaccines. We would like to see more specific objectives around increasing the confidence of the public in the overall role for vaccines and disease prevention. We are concerned that it is so difficult for the public to get accurate information via the web and media that if the process of getting this information is not addressed, it will be nearly impossible for truly informed decision making to take place. <b>Merck (Feinberg):</b> In addition to more timely communication of "bad news," the US Government should commit to more timely communication of "good news" (e.g., shortening the gap between ACIP decisions and publication in the <i>MMWR</i> ). <b>Institute for Global Health (Rutherford):</b> I think under objective 3.3 making Important Information Forms shorter, more readable and less intimidating could be an important strategy. <b>American Federation of Teachers (Alexander): Objective 3.3, Objective 3.4; Objective 3.6; Objective 3.7:</b> Include NIOSH and OSHA as well as trade unions and professional associations in the delivery of information to at risk worker populations targeted

		<p>for vaccination.</p> <p><b>APIC (Nuttly):</b> 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.</p> <p><b>Society for Adolescent Medicine (Kreipe):</b> 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.</p> <p><b>Baxter Bioscience, Vaccines (Khoury):</b> Although the research, development and approval of new vaccines are important in furthering disease prevention, we currently have vaccines available that are underutilized. Communication of vaccine recommendations to recipients is an important issue. The availability of patient education supplied through manufacturers and through the CDC benefits the physician and health care staff in providing this education. Unfortunately the groups that are outspoken against vaccines, question vaccine safety and link vaccine use to unfounded side effects, are highly vocal and must be strongly rebutted. It is important not only for vaccine recipients to know which vaccines to get and how, but to also realize the safety and overall benefits of vaccination. It is important to communicate the truth regarding vaccines, communicate it to the public through many different channels and take an aggressive stance against the misinformation that circulates about immunizations.</p>
43	3.3.1: Enhance communication of scientific findings of vaccine safety and effectiveness studies to the public, partners, and providers in a clear, transparent and timely manner.	<p><b>Mayo Clinic (Poland):</b> The inability of the CDC to communicate vaccine recommendations in a timely manner.</p> <p><b>NVAC Discussion 2-6-09:</b> Resources and education need to be provided to the public regarding the access and evaluation of scientific literature. This education also needs to address ways in which vaccines are studied and tested, and vaccine-related supply issues.</p> <p><b>NACHC:</b> % of the public will report they have access to information that allows them to make informed vaccination decisions.” The CDC should be given funding to run public</p>

		<p>service announcements on television and through other media regarding the importance of vaccines. The myths and misinformation disseminated by the news agencies creates a sense of doubt and panic within the public that is unsubstantiated by evidence and must be dispelled within hours and days not months.</p> <p><b>Merck (Feinberg):</b> The US Government and qualified independent experts should state their conclusions about vaccine safety more forthrightly and clearly describe their advocacy position to enhance the public health benefits of vaccination appropriately, with strong, evidence-based messages understandable by the broad American public.</p> <ul style="list-style-type: none"> <li>• The US Government should develop processes to more proactively communicate reliable science on disease risks and vaccine benefits and risks to the public, in terms broadly understood by the public, to refute unsubstantiated misconceptions on vaccine safety. Such routine and repeated culturally-appropriate communication will promote educated decision making by individuals.</li> </ul> <p><b>SUNY, Albany (Bednarczyk):</b> Can there also be a strategy to educate the public about what studies can and cannot do, and what a good study is, etc.?</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> I very much agree with this. As with many of the strategies, I'm wondering how??? You allude to the use of electronic in other parts of the document, so maybe you could do that here? Are you thinking blogosphere for the public maybe??</p>
43	3.3.2: Consistently and effectively respond in a rapid and coordinated manner to emerging vaccine issues and concerns (e.g. supply, safety or public health emergencies).	
43	3.3.3: More rapidly and completely disseminate research findings through peer-reviewed journals, conferences, and partner communications to facilitate implementation of evidence-	<b>Merck (Feinberg):</b> Strategy 3.3.3: Add web-based means of dissemination.

	based strategies.	<p><b>BD (Dugue): Strategy 3.3.4 (new): Elicit private and public sector collaboration to facilitate the dissemination of research findings and general information regarding vaccine safety (e.g. formulation and delivery) and effectiveness.</b>  <i>Rationale: Private manufacturers and other entities invest significantly in the research and development of their vaccines and vaccine delivery systems. They stand ready to act in partnership with government to improve vaccine delivery and supply. Private and public collaboration allows for effective dissemination of information about vaccine safety through the entire administration process.</i></p> <p><b>NVD (Baxter) (new):</b> Enhance communication of value and benefit of vaccines, demonstrate the medical benefit provided by vaccines.</p> <p><b>NVD (Baxter) (new):</b> Enhance communication on vaccine development.</p> <p><b>Society for Adolescent Medicine (Kreipe) new:</b> Consider including an additional strategy: proactively encouraging responsible journalism and providing guidance to journalists regarding reliable and unreliable sources of vaccine information.</p>
43	<p><b>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.</b></p>	<p><b>AHIP (Bocchino):</b> Private health insurance plans currently are not listed as stakeholders in these efforts and should be, as most health insurance plans actively support these activities and promote the delivery of safe and effective high-quality health care.</p> <p><b>NVAC Discussion 2-6-09:</b> When discussing education, there needs to be an awareness of the tension around balancing informed decision making and encouraging vaccine uptake.</p> <p><b>JSI (Steinglass):</b> add “USAID.”</p> <p><b>Nat’l Centre for Immunisation Research &amp; Surveillance, Australia (Leask):</b></p> <ul style="list-style-type: none"> <li>• Tensions may arise between the explicit goal to support informed decision making and the implicit goal of maintaining high vaccination rates (as reflected in Objective 3.4 and the existence of mandates). Sometimes these can conflict, particularly when campaigns and persuasion are necessary to improve rates and no longer can claim a benign imparting of the evidence.</li> <li>• Two problems arise with this assumption. First is the assumption that those</li> </ul>

		<ul style="list-style-type: none"> <li>• The second limitation of the informed decisions model is when a vaccine risk-benefit profile reverses for an individual (e.g., OPV and VAP during a time of country-wide elimination). Then, informed individuals seeking to maximise their own utility would rationally not vaccinate, leaving the population and future generations vulnerable to disease re-introduction – a Tragedy of the Commons. What happens if this occurs with another vaccine close to elimination and no safer alternative is available? The rhetoric of informed decision making is individualistic in its assumptions. The plan, while embracing informed decision making, should make provisions for understanding and better communicating <i>population</i> benefit.</li> <li>• To address these tensions in communication to the public, role distinction may help: to give the role of persuasion to government and vaccine advocacy groups and the role of giving risk/benefit information to providers and independent organisations funded by government.</li> </ul> <p><b>Families Fighting Flu (Stein):</b> Do not let apathy of uninformed consumers cloud assessments of whether consumers are making informed decisions. Specifically, regarding Goal #4 [more appropriate for Goal 3], we are concerned that a parent apathetic towards vaccination may believe today that he or she has enough information to make an informed decision regarding vaccinating their kids, and that parent simply has decided vaccination is not important.</p> <p><b>AAP (Tayloe, Bocchini):</b> 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.</p> <p><b>Society for Adolescent Medicine (Kreipe):</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Thus, objective 3.2.3 (Collaborate with partners and stakeholders to communicate</li> </ul>
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		<p><b>Society for Adolescent Medicine (Kreipe):</b> 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.</p>
44	<p>3.4.1 Develop, implement, and evaluate a long-term strategic communications plan and program aimed at educating parents of children and adolescents about vaccine preventable diseases and the benefits and risks of vaccines.</p>	<p><b>NALBOH (Fallon):</b> Other areas include education – why vaccine is needed vs concerns about risks including autism health education at the local level; countering the perception by the public that diseases have been eradicated; and the everyday reality of the people we are most concerned about reaching – those struggling to put food on the table are not going to be thinking about vaccinations as a priority.</p> <p><b>NVD (Baxter):</b> Enabling increased transparency on immunization policy decisions will allow the public, providers and policymakers to better understand the true risks and benefits of vaccination. It will enable the public to make better informed decisions and prepare providers to effectively communicate risks and benefits to their patients. Activities need to be carefully communicated to avoid unintended consequence of raising vaccine safety concerns.</p> <p><b>IDSA (Gershon): Strategies 3.4.1 and 3.4.4 are similar and should be combined and strengthened as follows:</b> “Evaluate existing communications tools and then, as appropriate, develop, implement and evaluate a long-term strategic communications plan and program aimed at educating adults and parents of children and adolescents about vaccine-preventable diseases, the benefits and risks of vaccines and preventive healthcare visits.”</p> <p><b>NVD (Baxter):</b> Strengthen communication strategies to increase knowledge of the value of vaccines across populations.</p> <p><b>Merck (Feinberg):</b> Strategy 3.4.1 and elsewhere in the document: Change "parents" to the more inclusive "parents and caregivers."</p> <p><b>ICHS (Dang):</b> we would recommend that NPVO recognize and</p>

		<p>include the role of community health centers as the best resource to disseminate educational materials to parents and adolescents about the benefits and risks of vaccines (proposed strategy 3.4.1).</p> <p><b>Trust for America’s Health:</b> The National Vaccine Program Office (NVPO) should also partner with social assistance programs, community health centers, and emergency departments to develop outreach to uninsured and underinsured adults and families who do not have access to ongoing primary care to inform them of the need for vaccines and the vaccine assistance programs available</p>
44	3.4.2 Maintain up-to-date, easily accessible, evidence based web-based information on vaccine preventable diseases and vaccines, including benefits and risks and the basis of immunization recommendations, for all audience groups.	<p><b>ICHS (Dang):</b> Also, we would recommend that NPVO and the Vaccine For Children Program work together to offer web-based information on vaccine preventable diseases and the benefits and risks of vaccines in multi-languages (proposed strategy 3.4.2). Currently, web-based information is only available in English. In order to reach as many audience groups as possible and to make dissemination of information as convenient as possible, NPVO should present information in different languages - Vietnamese, Tagalog, Korean, Chinese, Spanish and Russian.</p>
44	3.4.3 Use and evaluate new media (such as mobile technologies and social networking), as appropriate, to reach target audiences with accurate and timely information about vaccines and to respond to emerging concerns and issues.	<p><b>Every Child by Two (Pisani):</b> In recent years ECBT has achieved much success in reaching our target population using social networking technologies and will be investigating the use of mobile technologies. We urge others to investigate this means of communicating with today’s generation of parents as well.</p>
44	3.4.4 Develop, use, and evaluate evidence-based communication tools to educate parents, adolescents, and adults about vaccine-preventable diseases, recommended vaccines, and preventive health care visits.	
44	3.4.5 Develop, implement, and evaluate interventions to increase	<p><b>IDSA (Gershon):</b> addresses the need to develop, implement, and evaluate interventions to increase knowledge of immunization among all travelers, IDSA</p>

	knowledge among all travelers about benefits and risks of immunizations before travel.	suggests specifying that “all travelers” includes several important groups at risk for vaccine-preventable diseases, e.g. immigrants’ visiting friends and relatives (VFR) and children of immigrants who travel to visit extended family in resource-poor countries.  <b>Merck (Feinberg):</b> Strategy 3.4.5: Expand to include discussion of the risks of the relevant diseases, in comparison to the immunizations.
		<b>NVD (Baxter) (new): 3.4.6.</b> Educate to improve knowledge of vaccines and vaccine-preventable diseases and understanding of basis for immunization recommendations.
44	<b>Objective 3.5: Assure that key decision and policy-makers (e.g., third-party payers, employers, legislators, community leaders, hospital administrators, health departments) receive accurate and timely information on vaccine benefits, risks, and economics, and on public and stakeholder knowledge, attitudes, and beliefs.</b>	<b>JSI (Steinglass):</b> add “USAID.”
44	3.5.1 Develop, disseminate, and evaluate business case evidence and guidance for purchasers of health care and for health plans that address the coverage of vaccines in routine health care.	
44	3.5.2 Develop, disseminate, and evaluate broad-based education of key groups (e.g., legislators, community leaders, hospital administrators, health departments) on the benefits, risks, and economics of vaccines, the basis of	<b>BD (Dugue): (revised):</b> Develop, disseminate, and evaluate broad-based education of key groups...on the benefits, risks, and economics of vaccines, the basis of immunization recommendations, vaccine policy development, and on the standards of immunization practice <b>and administration</b> . <i>Rationale: The addition of the word administration” is appropriate given that “practice” suggests decision-making standards to determine whom and when, while “administration” suggests how.</i>

	immunization recommendations, vaccine policy development, and on the standards of immunization practice.	<p><b>Mayo Clinic (Poland):</b> Devise mechanisms whereby HCWs become immunization champions. In large part this relates to requiring vaccine education and uptake among HCW's. When the majority of US HCW's refuse influenza vaccine every year it should not be surprising that they do not act as champions for the vaccine to their patients. Goal 3 speaks in part to this issue, but fails to indicate who will monitor or assess knowledge, nor the consequences for non-compliance.</p> <p><b>Educating Physicians in their Communities, American Academy of Pediatrics (EPIC) (Wishner):</b> Education – providers need to be educated based on the complexity of vaccine issues, the schedule, medical assistants immunizing, disease epidemiology, and always emerging “hot topics.” Education is also needed for the public to address the increasing number of vaccine-hesitant or refusing families.</p>
44	3.5.3 Improve capacity for public engagement initiatives at the national, state and local levels.	<b>JSI (Steinglass):</b> add “global”
		<b>Merck (Feinberg) (new):</b> A strategy should be added to this objective to inform policy-makers about the economics of vaccine manufacture, on the need to recapitalize manufacturing equipment for existing vaccines from time to time to meet evolving stringent expectations of regulators. An analogy can be found in the utility industry that periodically needs to replace capital equipment.
45	<b>Objective 3.6: Improve the knowledge of vaccines and vaccine-preventable diseases, understanding of basis for immunization recommendations, and immunization practices of all healthcare providers.</b>	<p><b>NALBOH (Fallon):</b> With additional funding, county health departments could establish an enhanced communication system with all vaccine providers in the county, regardless if they participate in the VFC Program or not, to ensure they have the most up-to-date information on vaccine-related issues, including the benefits and risks of vaccines. This would be accomplished by sending electronically sending updated information to practices, conducting site visits, conducting educational programs for provider offices and presenting at meeting of physician groups. Some of this is addressed in Objective 3.6.</p> <p><b>Merck (Feinberg):</b> Consider adding communication skills to this objective. Further, it may be useful to cross-reference the HHS Office of Minority Health's national standards for culturally and linguistically appropriate services in health care</p> <p><b>ADA (Findley):</b> Special educational programs concerning vaccines and vaccination</p>

		<p>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.</p> <p><b>ANA (Stierle):</b> 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.</p>
45	3.6.1 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, and on the standards of immunization practice.	<p><b>BD (Dugue): (revised):</b> Expand and implement training and education of immunization providers at all levels of their education on the proper use <b>and administration of vaccines</b>, the proper storage and handling of vaccines...</p> <p><i>Rationale: The addition of the word “administration” is appropriate given that “practice” suggests decision-making standards to determine whom and when, while “administration” suggests how. Well-documented errors in administration<sup>5</sup> suggest this is a critical area for focusing retraining efforts and an opportunity to utilize vaccine delivery systems that greatly reduce or eliminate the risk of error.</i></p> <p><b>NALBOH (Fallon):</b> In collaboration with the major medical associations, CDC should establish on-line training modules for physicians and office staff (nurses) on a wide variety of vaccine related topics (vaccine safety, vaccine delivery, vaccine management, assessment techniques, surveillance, etc. As an incentive, award CMEs and CEUs for successful completion.</p> <p><b>AIRA (Sutliff) revise:</b> 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, <i>and the use of IIS as a decision-support tool.</i></p>
45	3.6.2 Develop and implement educational strategies for providers on vaccine-preventable diseases, including diagnosis, modes of transmission, prevention and control,	<p><b>AAP (Taylor, Bocchini):</b></p> <ul style="list-style-type: none"> <li>• Vaccine curriculum in medical schools and primary care residencies is a good idea, and examination of knowledge in this content area is appropriate.</li> <li>• Development of curriculum content to be utilized by professional schools and training programs</li> </ul>

	and reporting requirements.	<b>AIRA (Sutliff) revise:</b> Develop and implement educational strategies for providers on vaccine-preventable diseases, including diagnosis, modes of transmission, prevention and control, reporting requirements, <i>and the use of IIS as a decision-support tool.</i>
45	3.6.3 Widely disseminate information about vaccine and vaccine use that will assist clinicians assess, report, and manage vaccine adverse events.	
45	3.6.4 Determine the most effective and efficient mechanisms to communicate to health care providers about reporting to VAERS.	<p><b>NVAC Discussion 2-6-09:</b> Education in a multitude of ways is critical, particularly to make sure that everyone in the healthcare system knows how to use VAERS to facilitate better tracking/reporting of adverse events.</p> <p><b>NACHC:</b> The Vaccine Adverse Event Reporting system is an excellent repository of non-biased research and information. This system should be given the resources to be able to communicate with/alert health professionals in a timely way about vaccine related safety issues. Using the NPI number registry [perhaps mandatory email accounts] for health professional safety service announcements is one idea.</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> For items similar to this, I assume this assessment would be by some type of survey. You might state some general way this would be approached for these types of strategies.</p> <p><b>ANA (Stierle):</b> 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.</p>
		<b>NVD (Baxter) (new): 3.6.5</b> Educate to improve knowledge of vaccines and vaccine-preventable diseases, understanding of basis for immunization recommendations, and immunization practices of all health care providers.
45	<b>Objective 3.7: Develop and disseminate communication materials, that help facilitate active and involved vaccination immunization decision-making.</b>	<b>Gates Foundation (Orenstein):</b> what is the difference between strategies 3.7.1 and 3.7.2?
45	3.7.1 Conduct research on factors that	<b>SUNY, Albany (Bednarczyk):</b> This seems to be addressed in Objective 3.1, but in

	go into decision-making about vaccination.	different terms. Can they be harmonized/combined?
45	3.7.2 Conduct research to identify the kinds of information that would support decision-making about vaccination for individuals and families, providers, and policymakers.	<p><b>SUNY, Albany (Bednarczyk):</b> This seems to be addressed in Objective 3.1, but in different terms. Can they be harmonized/combined?</p> <p><b>ANA (Stierle):</b> 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</p>
46	3.7.3 Develop evidence-based decision support tools to assist individuals, parents, and providers synthesize relevant vaccine-related information to make informed decisions regarding vaccination.	<p><b>Mayo Clinic (Poland):</b> The National Vaccine Plan (NVP) should result in a comprehensive, high-level “playbook” complete with clear goals, objectives and tactics, clear timelines, clear responsibilities and accountability; in a matrix format. We should try to conceptually emulate the same thinking, preparation, and desire (as football) to give a playbook to every Federal and state agency responsible for achieving our mission – that of delivering safe and effective vaccines to every human being.</p> <p><b>IDSA (Gershon):</b> should reference the <b>Vaccine Information Sheet (VIS)</b> and indicate the need for research on obstacles and contributing factors to VIS utilization as well as the impact of the VIS on vaccine administration.</p> <p><b>AIRA (Sutliff) revise:</b> Develop evidence-based tools <i>and use IIS</i> to assist individuals, parents, and providers in synthesizing relevant vaccine-related information to make informed decisions regarding vaccination.</p>
		<p><b>NACHC (O’Fallon) (new):</b> Add an indicator/strategy to address disparities and barriers related to accessing vaccines. This goal doesn’t seem to address any barriers to immunizations such as cost, location, culture. Identifying the barriers will be useful in the other strategies that address the development of educational strategies related to increasing immunization.</p> <p><b>SUNY, Albany (Bednarczyk):</b> Similar to strategies in 3.4 – this addresses decision making more than just getting this type of information out, but it seems a bit repetitive.</p>
47-49	<b>Goal 4, Indicators, and Figure</b>	<b>AGS:</b> The AGS suggests that adding in specific information/indicators about financial issues/barriers to immunization for older adults. We recommend adding in language such

	<p>"Achieve congruency between federal agencies that reduces financial barriers. For example, all adult vaccines recommended by the ACIP for adults age 65 and over should be covered under Medicare Part B." Currently, flu and pneumovax are, but zoster is left to part D and likely others to be developed unless we really push them.</p> <p><b>Mayo Clinic (Poland): Innovation and Transformation:</b>  The National Vaccine Plan Goal 4 draft, is, as crafted, quite good. However, it is characterized by a standing in the trees and trying to see the forest approach – that is – it is incrementalism – not visionary, transformative, and innovative. This profoundly effects the follow-on thinking about strategy, change efforts, expectations, staffing, resources, etc. This WILL NOT achieve what we should aspire to achieve. In fact, absent inspiration, innovation, and transformation in the what and how we do things, at best we will reign over “creeping incrementalism” – rather than addressing the issues surrounding national vaccine policy in a serious and transformative manner.</p> <p><b>NVD (Baxter):</b> The Plan needs to address U.S. vaccine financing challenges-vaccine reimbursements challenges in the private and public sector, and access challenges for those in need while protecting the private sector which is fuel driving vaccine innovation.</p> <p><b>NACHC (O’Fallon):</b> Goal 4 – I agree with all of these and I am glad to see support for IIS in this section and section 4.1 that addresses reducing vaccine shortages. The costs for vaccines continue to rise and evaluating the role of the federal and state government and other stakeholders (insurance companies, individuals) is a priority. The increasing costs will become more and more of a barrier in this time of shrinking resources.</p> <p><b>NALBOH (Fallon):</b> Needs to address what centralized system would be implemented to equitably distribute vaccine in the event of a vaccine shortage or delay.</p> <p><b>Merck (Feinberg): Goal 4</b> (and page 47): The term disability is used where the authors may wish to specify both disability and impairment, which are distinct constructs.</p> <p><b>PRTM (Helming): Goal 4:</b></p> <ul style="list-style-type: none"> <li>• PRTM strongly endorses investment in process development for new and existing vaccines. The pressure to push a needed <i>de novo</i> vaccine as rapidly as possible into production sometimes limits opportunities to refine manufacturing processes. One common result of immature manufacturing process development is that</li> </ul>
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		<ul style="list-style-type: none"> <li>• Finally, once a vaccine has been licensed, adoption can prove difficult. Developing plans for the rapid introduction of new vaccines is essential. Dosing regimens in parallel with other vaccines, vaccine combinations and target populations need to be considered with procurement policy, purchase guarantees, and funding allocated for routine vaccination.</li> </ul> <p><b>Wyeth (Connolly, Eyles): Goal 4 comments:</b> We believe the Plan would benefit by the addition of specific strategies that would improve coverage levels among adults, e.g. better uptake among health care professional, systematic vaccinations prior to hospital discharge and increasing access through other delivery systems such as pharmacists.</p> <ul style="list-style-type: none"> <li>• The plan might also address the value of increased use of existing vaccines to protect the public in the event of an emerging threat such as pandemic influenza.</li> </ul> <p><b>Task Force for Child Survival (Hinman):</b> the Plan does not go into any specifics about financing immunizations in this country, which is probably the biggest single issue yet to be resolved. Specific comments are:</p> <ul style="list-style-type: none"> <li>◆ Goal 4 – a major deficiency of the draft Plan is that it does not address the need for adequate reimbursement of practitioners for purchase and administration of vaccines or the need to enhance Federal support for immunizations through Section 317 and VFC (or some as-yet-unidentified mechanism). These must be addressed if the Plan is to be really useful.</li> </ul> <p><b>University of Maryland (Milstien):</b> Goal 4 seems to be several separate goals which are not necessarily conducive to being combined. Because of this, there are some strategies that are already put forward in earlier goals (communication, for example).</p>
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	<p><b>AAP (Schoof):</b></p> <ul style="list-style-type: none"> <li>• There is not anything about vaccine management assistance to providers, which certainly would be sensible.</li> <li>• 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.</li> </ul> <p><b>AAP (Tayloe, Bocchini):</b> <u>Goal 4:</u> 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:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. Certain target populations are not being effectively reached.</li> <li>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.</li> <li>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</li> </ol>
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		<ul style="list-style-type: none"> <li>• Consideration for age-specific and/or target population approaches by medical/health professional disciplines might positively influence the impact of this plan.</li> <li>• 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).</li> </ul> <p><b>APIC (Nutty):</b> 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.</p> <p><b>sanofi Pasteur (Phil Hosbach):</b> Various ways to encourage first-dollar coverage by private insurance for vaccines should be explored in greater detail. The goal is that health plans cover all ACIP recommended vaccines for all age groups. One option that should be examined is the use of tax credits and/or other financial incentives for individuals and employers.</p> <ul style="list-style-type: none"> <li>• There should continue to be an emphasis on the goal of minimizing the impact of racial disparities. <ul style="list-style-type: none"> <li>○ This issue should be made a priority and be included in the body of the Plan (currently discussed in Appendix 4) as more needs to be done on how to reach these populations.</li> <li>○ We must develop creative solutions to this problem, perhaps testing various short-term pilot projects that can potentially serve as models for implementation.</li> </ul> </li> <li>• The report should also expand its discussion about the best ways to immunize adolescents and adults. These two groups are not immunized as often as they should be immunized, and we need to focus on identifying the most effective ways to reach these populations.</li> </ul>
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	<p><b>Bain &amp; Company, Inc. (Pasternak):</b> <i>Further delineating the objectives within goal 4:</i>  While grouped together, the objectives and strategies within goal 4 are actually two distinct goals: one related to availability of vaccines (supply), and the other related to use (demand). Addressing these goals requires different strategies, and both are critically important. It is recommended that the Plan be expanded to 6 goals, and separate plans be articulated for vaccine availability and use accordingly.</p> <ul style="list-style-type: none"> <li>◆ <b>Add Indicator:</b> For supply-constrained vaccines, an indicator should be added that pertains to the absolute level of bulk manufacturing capacity that is increased relative to current levels for U.S. licensed products / facilities.</li> <li>◆ <b>Add Indicator:</b> An indicator should be added that pertains to the proportion of vaccine expenditures that are reimbursed through private and public health plans. Minimizing out-of-pocket requirements by individuals is essential to maintaining high immunization rates, as the individual transaction decision between patient and provider suboptimizes the public good. Consistent with this point, Strategy 4.2.2 is of particular importance in the plan.</li> <li>◆ <b>Add Strategy:</b> Another strategy to consider is the development and communication of supply contingency plans by vaccine manufacturers in the event of supply disruptions.</li> <li>◆ <b>Add Strategy:</b> A strategy should be included that promotes the adherence of the VICP to evidenced-based decision-making. As illustrated by the Hannah Poling case, compensation decisions that are based purely on a "biologic plausibility" standard, even if scientific and clinical evidence suggest otherwise, undermines public confidence in our immunization program.</li> </ul> <p><b>Society for Adolescent Medicine (Kreipe):</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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 <i>and to decrease health disparities</i> in the U.S."</li> </ul>
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		<p>◆ <b>Add Indicator:</b> Consider an indicator that explicitly addresses monitoring of disparities.<sup>1</sup> (for example, through the National Immunization Survey)</p> <p><b>University of Pittsburgh (Zimmerman):</b> Appropriately, the plan addresses the economic issues at the local level; this should stay as some clinicians are leaving vaccine delivery due to the economic burden. The percentage of primary care clinicians who provide vaccines could be an indicator for goal 4.</p> <p><b>BD (Dugue): Goal 4 Indicator #1 (revised):</b> The United States will have 6 months' supply of all vaccines <b>and vaccine delivery systems</b> appropriate to stockpile. <i>Rationale: Vaccines require a delivery method in order to be introduced into the body. As a result, as the Nation works to achieve adequate vaccine supply, it is critical that a corresponding capacity of "vaccine delivery systems" is also established.</i></p> <p><b>NACHC: Additional indicators:</b>  -X% of health care providers will report no barriers to obtaining older, less costly and effective single antigen vaccines when newer highly costly combination vaccines emerge.</p> <p><b>NVAC Discussion 2-6-09:</b> Indicator 1 and Strategy 4.1.5 Assuring equality of vaccine supply for each sector—to include BOTH public and private.</p> <p>Underserved Populations:</p> <ul style="list-style-type: none"> <li>• Gap of underinsured children.</li> <li>• Adolescents</li> <li>• Some adults</li> <li>• How to reach underserved groups:</li> </ul> <p>-Community organizations, employers, churches. Ensure providers have systems to reach these underserved populations.  -Provide culturally sensitive education and outreach materials.  - Indicator 2 seemed to be too weak an indicator, i.e., measures perception, not reality:</p> <ol style="list-style-type: none"> <li>a. Qualitative, not quantitative</li> <li>b. Doesn't include providers' barriers</li> </ol> <p>◆ <b>"Indicator 2</b> – Reduce financial and non-financial barriers to access immunization services, such as cost, availability, and language, by Y (year) so that:</p>
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--\_X\_% of parents of infants and children report no barriers to immunization;  
--\_X\_% of parents of adolescents report no barriers to immunization; and  
--\_X\_% of adults report no barriers to immunization.”

**Australia (Horvath): Goal 4 Indicators (new):**

- Within X years, develop effective vaccine industry policy to assure sustainable vaccine supply;
- Within X years, develop immunisation program delivery standards, e.g. cold chain standards to minimise wastage and improve quality.

**IDSA (Gershon): Comments on Goal 4**

- The Introduction should cite the recent changes in the adult immunization schedule, to emphasize the opportunity for addressing adult vaccine preventable diseases.
- Add an indicator involving heightened utilization or coverage levels for specific eligibility-based programs such as the Vaccines for Children program or Medicare program.

**NVD (Baxter): Indicators:**

- ◆ **Indicator 1:** During a recent NVAC meeting CDC indicated they are considering scaling back the definition of populations which would be served by the pediatric stockpile to VFC eligible children. NVD cautions that this policy would create inequality in care limiting access to the insured during a shortage.
- ◆ **Indicator 2:** NVD would like to know how the baseline and tracking of these percentages will be established.
- ◆ **Indicator 6:** NVD suggests the Plan include an evaluation strategy on expanding vaccines currently excluded from NVIC such as vaccines targeted at adults only.

**Merck (Feinberg): Indicators:**

- ◆ **Indicator 1:** Criteria to define "appropriate to stockpile" should be developed and applied to all vaccines. Some vaccines require more than 6 months to manufacture a single lot, so the inventory level should be developed in an informed manner, recognizing the cycle time for manufacture. This indicator should be reconciled with efforts of the CDC Stockpile Working Group, which endeavors to rationalize

		<ul style="list-style-type: none"> <li>◆ <b>Indicator 2:</b> Merck supports the goal of access to affordable health insurance with vaccination benefits for all. Merck believes this is best attained by strengthening the existing public- and private-sector collaboration on vaccine access and financing that has generally enabled high rates of vaccination, especially for children. Strengthening the system requires recognition of the value of vaccination, adequate fiscal appropriations by governments and private-sector stakeholders (e.g., employers, insurers) to provide sufficient resources for vaccine purchase and administration, and increased attention and resources devoted to adult immunization. Because there are numerous barriers to an optimal system, any solutions will need to be comprehensive to have the desired effect.</li> <li>• Other barriers to evaluate include logistical issues (e.g., distance from or transportation to a vaccination provider), societal (e.g., healthcare-delivery models that do not prioritize vaccinations programs), and cultural issues (e.g., attitudes toward vaccination).</li> <li>◆ <b>Indicator 3:</b> These are important indicators; it is essential that they address disparities evident based on ethnicity or age. Considering, for example, that pneumococcal 23-valent vaccination levels among adults have plateaued since 2002, considerable extra effort will be needed to reach 2020 goals. Progress toward the Healthy People 2020 goals is the key outcome measure, not the process measures of the preceding indicators.</li> <li>◆ <b>Indicator 4:</b> Progress may be more precisely measured by changing the denominator to "lives served by systems."</li> <li>◆ <b>Indicator 5:</b> We recommend this indicator encompass all States, not just a fraction of them.</li> <li>◆ <b>Indicator 6:</b> Consider moving this indicator to Goal 3.</li> <li>• If no update to the VIT was needed after X years, which federal official would certify this determination?</li> <li>◆ <b>Merck (Feinberg) Add indicator:</b> An indicator should be added to enhance the mutual recognition of manufacturing-facility inspectors of certain countries, to avoid diverting industrial resources on redundant inspections. Such mutual recognition should manifest as streamlined, uniform regulatory review with more transparent review guidelines and standards, in a way that does not compromise safety.</li> </ul>
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		<ul style="list-style-type: none"> <li>◆ <b>Add indicator:</b> An indicator should be added to assess the number of lives (both children and adults) covered by electronic immunization records.</li> <li>◆ <b>Add indicator:</b> The US Government should add an indicator to assess and reduce the degree to which the supply chain for imported vaccines (or their components) is vulnerable to disruption overseas in the event of a global or multinational emergency.</li> </ul> <p><b>SUNY, Albany (Bednarczyk): Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 4:</b> Do we want a straight proportion of systems addressed, or a proportion of the population covered by these systems? You can have a large number of IIS, but if they are all small population states, the service isn't as widespread.</li> <li>◆ <b>Indicator 5:</b> Seems related to Objective 4.4, but there isn't a direct link to look at disease outcomes following ACIP recommendations in this objective.</li> </ul> <p><b>United Kingdom, Department of Health (Salisbury): Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 2:</b> It is clearly desirable that there should be reductions in financial and non-financial barriers to access to immunisation, but setting such a percentage reduction to X% is subjective without linkage to an outcome criterion. Reducing financial barriers to immunisation is going to require either cheaper vaccines or more support to subsidise manufacturers' prices. Are additional funds going to be available and by what means will these be requirements be assessed and taken forward?</li> <li>◆ <b>Indicator 3:</b> Although there will be vaccine coverage target levels established in the Healthy People 2020 programme, there are no indications within the document about how coverage rates will be increased or poor performance identified and addressed. There is an implicit assumption that coverage improvements will follow these targets but that may not be the case.</li> <li>◆ <b>Indicator 5:</b> I note the intention to have surveillance implemented in X% of states within Y years after an ACIP recommendation. But in the case of a new vaccine or vaccination programme adaptation, surveillance should be in place before implementation not after.</li> </ul>
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	<p><b>Former ACIP member (Abramson): Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 2:</b> I think that we should specifically state that 100% of infants and children should report no barriers to immunization (if the 100% is not agreed to by the group writing the National Vaccine Plan then we should at least note that a very high minimum percentage that should be achieved in every state [&gt;90% in every state]).</li> </ul> <p><b>ACIP (Marcy): Indicators:</b> Goal 4: In a recent survey of pediatricians and family physicians, barriers to HPV vaccination were primarily financial, including lack of insurance coverage (47%-64%); lack of adequate reimbursement (38%-52%), up- front costs for purchase of vaccine (3%-44%). There should be a sentence: " __X__% of providers report no barrier to immunization"</p> <p><b>AAP (Tayloe, Bocchini): Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 1:</b> A six month supply in the national stockpile is insufficient to address an interruption in the manufacture of a vaccine. 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 4<sup>th</sup> dose. Thus, the stockpile must be adequate to support the recommended vaccine schedule for much longer than a year.</li> <li>◆ <b>Add Indicator:</b> The number (%) of providers routinely using an immunization information system.</li> <li>◆ <b>Add Indicator:</b> Elimination of immunization rate discrepancies amongst target populations.</li> </ul> <p><b>AAOHN (Kowalski): Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 1:</b> 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.</li> <li>• Rotate the 6 months supply of stockpile vaccines and provide to public health facilities for administration, as applicable.</li> </ul>
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49	<p><b>Objective 4.1: Ensure consistent and adequate availability of vaccines for the United States.</b></p>	<p><b>BD (Dugue):</b> Ensure consistent and adequate availability of vaccines <b>and vaccine delivery systems</b> for the United States.  <i>Rationale: Vaccines require a delivery method in order to be introduced into the body. Adding “vaccine delivery systems” to this objective demonstrates the Nation’s understanding that vaccines and vaccine delivery systems are recognized as two distinct components of the NVP. Worldwide, two primary types of vaccine delivery are in use – a nonintegrated delivery system in which the vaccine is stored in a single dose or multi-dose vial and a separate disposable syringe is required to withdraw and administer the vaccine; and an integrated delivery system in which the single dose prefilled container is the delivery system. Manufacturer-prefilled delivery systems fall into the latter category. Conventional vials of vaccine require sterilizing swabs to clean the vial stopper, two needles – one for withdrawal of vaccine from vial and one for injection – and a sterile syringe.</i></p> <p><b>NVAC Discussion 2-6-09:</b> One comment concerning FDA having adequate resources to ensure adequate vaccine supply.</p> <p><b>Canada Biologics (Griffiths):</b> Ensuring a reliable supply of vaccines used in routine</p>

	<p>immunization programmes, especially those used in children, is important (objective 4.1). Failure to administer some scheduled doses due to supply issues, with possible impact on long term protection, may lead to disease outbreaks many years hence (eg mumps in young adults) if no catch up campaigns are undertaken.</p> <p><b>JSI (Steinglass):</b> Goal 4 (page 47) and objective 4.1 specifically states “in the USA,” yet USAID is mentioned as a collaborator on many of the strategies. The content of these strategies is indeed appropriate for USAID (4.2, 4.3, 4.4, 4.5, 4.6), as the plan has appropriately indicated; it is just that “in the USA” does not work in the wording of the goal itself or of several of the objectives.</p> <p><b>NVD (Baxter):</b> The objectives under this strategy span beyond the US to an international effort and venture into private industry activities. It is not clear how these strategies could be successfully implemented.</p> <p><b>PRTM (Helming):</b> In a final point regarding stable supply, manufacturing volume goals for vaccines must be tightly aligned with the goals of informed decision-making by the public, providers, and policy-makers. Capital investments in manufacturing capacity will be recouped by vaccine uptake. Accurate supply and demand forecasting will be essential to efficient manufacturing business models. Market assurance in some form through vaccine purchase commitments (by all potential buyers) over a 10-15 year time horizon will be essential, so that manufacturers can justify and maintain necessary manufacturing capital.</p> <p><b>University of Maryland (Milstien):</b> Objective 4.1 on vaccine availability relies on a number of strategies including vaccine stockpiles. It seems to me that stockpiles are not the best way to address this issue, and the other strategies should be promoted to the exclusion of this one. In addition, the best way to reduce vaccine shortages would be to lower the barriers to licensure of fully safe and effective vaccines that are manufactured in other countries including those outside of the US and Europe. This could be a major focus that could also greatly improve the global vaccine supply situation.</p> <p><b>Institute for Global Health (Rutherford): Objective 4.1.</b> The lack of market-based solutions to improving the number of vaccine manufacturers is pretty glaring. I do not have a specific recommendation other than it should be considered by the Committee. If there is no way to incentivize private-sector manufacturers and make this market more attractive for</p>
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		investment, should we be moving toward a government-base manufacturing system, as other countries have done (e.g., Mexico and Brazil)?
49	4.1.1 Increase US licensed vaccine suppliers to have at least two suppliers of each vaccine antigen recommended for routine use by infants, children, adolescents and adults.	<p><b>NVD (Baxter):</b> NVD welcomes expanding the definition of stockpiled vaccines beyond pediatric to ensure supply is available for lifesaving adult and travel vaccines. NVD cautions requiring a 6-month supply to do business in the U.S. may deter entrants. NVD suggests additional evaluation prior to implementation to ensure this requirement would not delay access to lifesaving vaccines. Stabilize vaccine supply by maintaining a full pediatric stockpile for ACIP recommended vaccines and creating a stockpile mechanism for other life saving vaccines.</p> <p><b>Merck (Feinberg):</b> Strategy 4.1.1: Insert at beginning of sentence "While maintaining high quality and licensure standards..." Further, we suggest changing "two suppliers" to "two sources of supply" (which could be satisfied by a single sponsor) to more readily achieve the desired goal. Another option would be to stockpile bulk vaccine substance, which generally tends to have a longer shelf life than packaged product.</p> <p><b>Wyeth (Connolly, Eyles):</b> Though the goal to have at least two manufacturers for every vaccine is laudable, it should be made clear that this will not come at the cost of vaccine efficacy and safety. Achieving this goal also does not in itself prevent vaccine shortages.</p> <p>Not referenced are strategies to ensure sustainable and adequate funding for the purchase and supply of vaccines and program operations, differentiating between the budget needs and issues of the public and private health care sectors. It is important to know if the 6 month vaccine stockpile will cover all children or only a sub-set of children.</p> <p><b>Southern Nevada Health District (Sorenson):</b> We have had too many shortages of vaccine and interruptions in the Vaccination Schedule.</p> <p><b>Every Child by Two (Pisani):</b> Every effort should be made to ensure the successful completion of Objective 4.1.1. to increase US licensed vaccine suppliers to have at least two suppliers of each vaccine antigen.</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> Great idea, but how is this expected to be accomplished? Some speculation should probably be made if possible.</p>

		<p><b>APIC (Nutty):</b> 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.</p> <p><b>NASDDDS (Rolfe):</b> 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 than 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.</p>
49	4.1.2 Promote development of high quality harmonized vaccine standards internationally.	<p><b>Merck (Feinberg):</b> US Government efforts to harmonize recommended vaccination schedules among countries would facilitate vaccine development.</p> <ul style="list-style-type: none"> <li>• Please clarify which vaccine standards need to be harmonized. Presumably these are production standards.</li> </ul>
49	4.1.3 Improve product quality and availability through better manufacturing sciences, through communication and training in best practices and through better manufacturing and production oversight.	<p><b>Mayo Clinic (Poland):</b> Accept, promote, embrace, and require outside review of major governmental entities responsible for vaccines in the US</p> <ul style="list-style-type: none"> <li>• Peer-review is the best known antidote to innovation dementia, poor science, poor decision-making, political agendas, biases, etc.</li> </ul>
50	4.1.4 Improve vaccine ordering, distribution and tracking systems for routine use, for public health emergencies, and for management of supply disruptions.	<p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> Perhaps it might be suggested that some use of electronic tracking systems be used here. That could include download of EMR data in some situations.</p>
50	4.1.5 Optimize use, and content, and distribution of vaccine stockpiles.	<p><b>Trust for America’s Health:</b> Related to the goal of stockpiling appropriate vaccines (<b>Goal 4.1.5</b>), the National Vaccine Plan should include a goal to stockpile syringes and other supplies necessary to deliver vaccines.</p>
50	4.1.6 Improve the development, communication, and tracking of adherence to recommended changes in	

	vaccine use during national vaccine shortages.	
50	4.1.7 Enhance support for international regulatory information sharing and collaboration.	<b>SUNY, Albany (Bednarczyk):</b> This seems very similar to 4.1.2, and should possibly be moved up to be closer to this strategy.
		<b>BD (Dugue): Strategy 4.1.7 (new): Expand vaccine availability and supply through the use of integrated single dose manufacturer-prefilled delivery systems due to their reduced overfill requirements when compared to nonintegrated systems.</b> <i>Rationale: Prefilled delivery systems have the advantage of reducing vaccine waste when compared to vaccines administered with a conventional syringe and vials that wastes ten times the amount of vaccine.</i>
50	<b>Objective 4.2: Reduce financial and non-financial barriers to vaccination.</b>	<b>NVAC Discussion 2-6-09:</b> Emphasize role for employers in Objective 4.2. (Reduce financial and non-financial barriers to vaccination)  <b>IDSa (Gershon): should be strengthened from “Reduce” to “Eliminate financial and non-financial barriers to vaccination,” and strategies should be specified for different populations.</b> For instance, this may include strengthening the medical home for childhood vaccination, and increasing administration fees. <ul style="list-style-type: none"> <li>Consider adding strategies under Objectives 4.2 and 4.4 regarding coverage of immigrants and other historically-underserved populations.</li> </ul> <b>NAACHO:</b> Finally, no ambitious plan for improving immunization coverage will be realistic without a clear-eyed recognition of the expanded resources that will be needed to achieve its objectives. Section 317 funding is wholly inadequate for expansion of local programs, and Vaccines for Children funding is unavailable for local health departments to serve underinsured children. Indeed, most local health departments are finding that they must reduce their efforts, rather than expand them, as growing program costs and demands generated by outbreaks of vaccine-preventable disease outstrip the resources that are available simply to maintain existing coverage rates.  <b>NACHC:</b> A combined effort to expand financial coverage for vaccines and the institution of reliable and mandatory electronic vaccine registries is needed.

	<p><b>NVD (Baxter):</b> suggest the NVPO consider including strategies here which support the September 2008 NVAC report on child and adolescent financing. NVD suggests an established process for evaluating the financial and non-financial barriers to immunization should be the first strategy under this objective and therefore recommends moving 4.2.3 to 4.2.1.</p> <p><b>University of Pittsburgh (Zimmerman):</b> A greater emphasis on overcoming barriers to vaccine delivery at the local level would improve the document (e.g., methods to increase vaccination rates such as standing orders).</p> <p><b>Former ACIP member (Abramson):</b></p> <ul style="list-style-type: none"> <li>• The basic issue is that I do not believe that we can achieve many of the goals that are outlined in this plan if we continue the present system that results in vaccines being prioritized on a state by state basis.</li> <li>• “The AAP shares the NVAC's stated goal that every child and adolescent should receive all ACIP-recommended vaccines without financial barriers. The AAP believes that the best way to accomplish this goal is to develop a national vaccine program that does not depend on our current incremental approach.</li> <li>• An immunization program that is national in scope is needed to ensure that all children get all ACIP-recommended vaccines. This immunization program could be part of a comprehensive national healthcare program for all children (e.g., Medikids). Alternatively, if a Medikids type program does not become reality than a national immunization program could be developed that is a partnership between the federal and private sector.</li> </ul> <p><b>ICHS (Dang):</b> Removing financial barriers to immunization, either by ensuring that out of pocket expenses are not cost prohibitive or by improving the supplies of vaccines so that shortages do not occur, will go a long way in promoting the benefits of immunizations.</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> This whole group of strategies feel almost like objectives in and of themselves to me. That is so because to change these things or implement them as strategies takes such a huge policy shift in the U.S. Much of this is health care finance related and the Stakeholders are in a position to be advocates at best. The purpose stated in the strategies is correct and should be here, but how this gets accomplished needs some careful thought.</p>
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		<p><b>AACP (Lang):</b> 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.</p> <p><b>ANA (Stierle, Patton):</b> 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.</p> <p><b>HIDA (Ostrand):</b> Adequate production, distribution, and stockpiles of certain existing vaccines could be bolstered by financial support from the government via increased reimbursement for providers who purchase these vaccines, as well as by guaranteed purchases by government to incentivize distributors and manufacturers who currently produce and or buy/distribute vaccine that is not utilized and/or returned due to lack of public interest in preventative immunizations.</p>
50	<p>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).</p>	<p><b>Merck (Feinberg):</b> Strategy 4.2.1: Insert "required" in front of "by publicly funded health insurance plans..." to complete the thought.</p> <p><b>Every Child by Two (Pisani) revise:</b> "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 (strike out "a significant" and replace with "any") financial barrier.</p> <p><b>Society for Adolescent Medicine (Kreipe):</b> Consider making these strategies (4.2.1 and 4.2.2) more comprehensive; e.g. financial barriers to immunization should be eliminated for <i>all</i> 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</p>



		<p>coverage for vaccination, but are at high risk of transmitting vaccine-preventable diseases to young children as they become parents.</p> <p><b>sanofi Pasteur (Phil Hosbach):</b> Reimbursement for the costs of vaccines as well as related administration costs must be prompt and adequate. This would serve as great incentive to ensure increased coverage rates across the nation.</p> <ul style="list-style-type: none"> <li>• In addition, greater attention should be paid to Medicaid payment rates. Medicaid payment rates vary by state with some states reimbursing well below the cost for vaccine administration. These admin fees are paid to VFC providers and could result in a decline in private physician enrollment in the VFC program.</li> </ul>
50	4.2.2 Reduce financial barriers to immunization by increasing the proportion of people with private healthcare insurance who have 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).	<p><b>AHIP (Bocchino):</b> AHIP and its member plans support initiatives that reduce the financial barriers to the administration of all ACIP-recommended vaccines for children, adolescents, and adults (regardless of where the vaccines are administered) by increasing the proportion of people with private health insurance and expanding public programs.</p> <p><b>NALBOH (Fallon):</b> Objective 4.2.2 discusses eliminating cost as a barrier to immunization. Private providers can not administer the following state-supplied vaccines (under the VFC <i>Plus</i> Program) to those children who have health insurance which does not include vaccine coverage – varicella, pneumococcal, meningococcal, HPV and influenza. This presents a problem.</p> <p><b>Every Child by Two (Pisani):</b> ECBT supports 1<sup>st</sup> dollar coverage of ACIP recommended vaccines for children and adolescents. Or, if this is not feasible define “minimal cost sharing”.</p>
50	4.2.3 Identify and regularly monitor financial and non-financial barriers (e.g., vaccine availability and language) to receipt of ACIP recommended vaccines for children, adolescents, and adults, and regularly publicize the findings.	<p><b>AHIP (Bocchino): General Comments:</b> Private health insurance plans play an active role in improving immunization rates by identifying and removing barriers that may prevent their members (more than 200 million Americans) from receiving appropriate ACIP-recommended vaccines. Improving immunization rates is accomplished through provider and member education, numerous innovative quality improvement initiatives and collaboration with other stakeholders who recognize the importance of immunizations. AHIP and its member plans generally support the Draft Plan, as well as many of the objectives and strategies specified. However, many of the non-financial contributions of private health insurance plans remain unrecognized and the details of how goals and objectives will be implemented remain unclear. Thus, we are raising concerns that policy options that may be</p>

		<p>pursued under the Plan could have unintended consequences such as weakening the nation's immunization system.</p> <p><b>NVD (Baxter):</b> Address non-financial barriers to access in the adolescent and adult populations by designing objectives and implementing programs which increase focus on innovative delivery of vaccines utilizing alternative sites and new delivery methods.</p>
50	4.2.4 Strengthen the ability of States to purchase and expand access to ACIP recommended vaccines for people who qualify for publicly supported vaccinations.	<p><b>NVD (Baxter):</b> Suggest that this is vague and requests that NVPO provide clarity on what would be done to strengthen states and suggest the action item would be the more appropriate strategy under this objective (i.e. "strengthen states ability to purchase....by...").</p> <p><b>ICHS (Dang):</b> we recommend that the NPVO strengthen Washington State's ability to purchase and expand access to recommended vaccines (proposed strategy 4.2.4). Currently, Washington State's Universal Childhood Vaccine Program is under threat of elimination due to projected budget deficit of \$6 billion. Without the Universal Childhood Vaccine Program, children who are uninsured, underinsured, or who do not qualify under the federal Vaccine for Children program may not receive the recommended vaccinations. We would recommend that the NPVO consider adopting a universal childhood vaccination policy as a long-term goal.</p> <p><b>Southern Nevada Health District (Sorenson):</b> Allow large metropolitan areas to be directly funded or address "earmarks" to give them more direct access to vaccine and operational support. Their needs are often very different than other small communities in a State.</p>
50	4.2.5 Develop, implement, and evaluate strategies to reduce the financial burden on vaccination providers for purchase of initial and ongoing vaccine inventories.	<p><b>AHIP (Bocchino):</b> We support efforts to strengthen access to publicly-purchased vaccines for qualified individuals, and to ensure that reimbursement for vaccine administration can be based on evidence from methodologically sound, rigorous studies. As many vaccine providers administer vaccines to patients covered by both public and private payors, we recommend that CPT codes and their modifiers be structured to identify the source of the vaccine (i.e. through the Vaccines for Children program or a private source) to promote accurate reimbursement claim submissions.</p> <p><b>Mayo Clinic (Poland):</b> Create a comprehensive and seamless "birth to death" vaccine funding and delivery mechanism.</p> <p><b>NVD (Baxter):</b> The Plan should seek to ensure adequate funding of basic vaccines-</p>

		<p>related research in the federal budget and a distribution of that funding within the NIH and other agencies that ensures long term innovation.</p> <p><b>Merck (Feinberg):</b> Strategy 4.2.5: Insert "and storage" after "for purchase..." to complete the context</p> <p><b>EPIC (Wishner):</b> Simplify the process of ordering and obtaining reimbursement for vaccines. To me, this implies universal purchase for all recommended vaccines for all ages. Work with the pharmas to get them to give better pricing given the increase in quantity purchased.</p> <p><b>AAFP (Schoof):</b> Would urge more attention to primary care physician offices and reimbursement issues they face.</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b> (reducing financial burden on vaccination providers) is of particular importance, as increasingly unfavorable financial implications are becoming a growing impediment for vaccine availability among providers. The strategy should promote harmonized provider economics at acceptable levels.</p>
50	4.2.6 Enhance public sector infrastructure to support and sustain adult immunization activities.	<p><b>IDSA (Gershon):</b> <b>We believe the NVP has a major opportunity to articulate specific strategies for increasing adult immunization coverage rates.</b> Therefore, we would substitute and also expand on Strategy 4.2.6 as follows:</p> <ul style="list-style-type: none"> <li>• In place of 4.2.6, we recommend the following: "Encourage and support the development and implementation of a plan to finance and deliver adult immunizations through the public sector by enhancing the Section 317 Program to provide separate funding for adult vaccine purchase and infrastructure."</li> </ul> <p><b>NVD (Baxter):</b> suggests greater specificity would clarify the intent.</p> <p><b>Trust for America's Health:</b> The NVPO should consider asking the Secretary to use some of this new funding to provide <b>every</b> adult American with an annual influenza vaccine in 2010. This would be an excellent trial-run for a severe pandemic influenza vaccination program.</p>
51	4.2.7 Expand access to vaccination at medical care sites for children,	<p><b>NVD (Baxter):</b> requests increased specificity on this strategy.</p>

	adolescents, and adults.	
51	4.2.8 Expand access to vaccination at sites outside of traditional medical settings.	<p><b>AHIP (Bocchino):</b> AHIP and its member health insurance plans support efforts to expand access to vaccination at sites outside of the traditional physician office setting (e.g. convenience clinics, pharmacies, public health departments, non-traditional physician offices, etc.)</p> <p><b>NACHC:</b> To achieve adequate vaccination coverage the points of care need to be expanded. Nothing illustrates this challenge more than the new directive to <b>annually</b> vaccinate all children 6 months to 18 years with the influenza vaccine. Our clinics and primary care facilities simply cannot complete this task within the few short months the flu vaccine is available each year. Mass school based vaccine clinics and designated after hours 'influenza' clinics may address the issue but the preservation the medical home should be considered a priority as well.</p> <p><b>NVD (Baxter):</b> believes that increase specificity is required and suggests the inclusion of strategy components to address the current issues related to access at alternative sites including, among others; reimbursement for vaccines, obtaining VFC enrollment status outside traditional settings and ensuring medical home is informed of vaccination.</p> <p><b>EPIC (Wishner):</b> Influenza vaccine – the current system does not facilitate or even allow implementation of the current recommendations. The VFC influenza vaccine distribution needs drastic improvement!!! Alternate methods of administration, such as school-based clinics and administration by specialists, needs to be facilitated, encouraged, and funded. Work with school nurses – public health nurses can not do it all - and provide vaccine.</p> <p><b>AAFP (Schoof):</b> 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.</p> <p><b>ADA (Findley):</b> Private dental offices, dental schools and other dental facilities could easily be used as vaccination sites, especially during emergencies.</p>
		<p><b>BD (Dugue): Strategy 4.2.9 (new): Reduce access barriers to vaccination in alternate sites and for diverse and health-disparate populations by simplifying training for administration through providing ready-to-use delivery systems, removing steps to assemble, and assuring dose accuracy.</b></p>

		<i>Rationale: Manufacturer-prefilled delivery systems, in easy-to-use self-storage units, simplify administration and, as is the case with prefilled syringes, minimize waste<sup>10</sup>, reduce the risk of error<sup>3,15</sup> and save time<sup>8</sup> – all critical considerations, especially in formerly underserved populations and during a mass immunization effort.</i>
		<p><b>IDSA (Gershon) (new):</b> “Develop an entitlement program that ensures provision of all ACIP-recommended immunizations to uninsured or underinsured adults. Toward this end, hold a stakeholder meeting and/or launch other supportive efforts to better understand the benefits and pitfalls of this approach, including the commissioning a study (IOM or otherwise).”</p> <p><b>IDSA (Gershon) (new):</b> “Reduce the financial barriers to healthcare providers giving adult vaccination by working to ensure adequate levels of vaccine administration fees across payors for adults.”</p> <p><b>IDSA (Gershon) (new):</b> “Require that all ACIP-recommended adult immunizations be covered under Medicare Part B for Medicare-eligible recipients.”</p>
		<b>Merck (Feinberg) (new):</b> Add a strategy that calls for support to the existing system of private-sector vaccine providers, providing them the tangible and intangible resources needed to sustain this form of vaccine delivery.
51	<b>Objective 4.3: Maintain and enhance the capacity to monitor immunization coverage for vaccines routinely administered to infants, children, adolescents, and adults.</b>	<p><b>AHIP (Bocchino):</b> We believe that the federal government should take the lead in defining the standards for both public and private EHR systems as identified in Objective 4.3, as previous attempts to develop a standardized system have resulted in fragmented efforts and delays with small physician practices reluctant to purchase systems that may not be compatible with future standards. Such systems should be “opt-out” for vaccines, allow two-way immediate data exchange, maximize support of physician decision-making with regard to appropriate delivery of ACIP-recommended vaccines, include reminder / recall systems, assist with inventory management and be the basis for reporting of quality indicators on immunization.</p> <p><b>NACCHO:</b> Strategy #1 is to monitor vaccination coverage among children of vaccines recommended for routine use by ACIP/CDC at the national level and state levels and at the urban area Section 317 grantees. Strategies #2 and #3 recommends similar coverage monitoring for adolescents and adults but eliminates Section 317 grantees.</p> <ul style="list-style-type: none"> <li>• We strongly urge expansion of these strategies in two respects. First, it essential</li> </ul>

		<p>that such monitoring activity include samples adequate to determine coverage levels by race and ethnicity. We are gravely concerned about disparities in coverage among these populations and coverage levels are not always available based on sample size.</p> <ul style="list-style-type: none"> <li>• Second, restricting local monitoring to 317 grantees eliminates or it entirely leaves out many large areas, particularly large urban areas, where coverage levels may deviate significantly from those found at the state level. As methodologies for sampling and coverage monitoring evolve, it is essential that valid data for monitoring immunization coverage in cities, large urban counties, and metropolitan areas also be obtained. Such data will identify coverage gaps and disparities that would otherwise be unidentified and enable monitoring of progress in ameliorating them.</li> </ul> <p><b>NVD (Baxter):</b> These strategies need to be integrated with patient electronic records. Immunizations are a small part of that initiative but could help drive it.</p> <p><b>NASDDDS (Rolfe):</b> 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.</p>
51	<p>4.3.1 Identify, implement, and evaluate cost-effective and rapid methods for assessing vaccination coverage:</p> <ol style="list-style-type: none"> <li>a. among children, adolescents, adults overall and by State, immunization grantee, and within states and grantees;</li> <li>b. among persons in key population subgroups (e.g., racial/ethnic groups, pregnant women, healthcare</li> </ol>	<p><b>NACCHO: Objective 4.4</b> Achieve immunization coverage targets for infants and children. <b>Objective 4.5</b> Achieve immunization coverage targets for adolescents 11-21 years of age.</p> <ul style="list-style-type: none"> <li>• These objectives and the strategies associated with them should explicitly address racial and ethnic disparities in childhood and adolescent immunization status. We believe that such disparities exist and urge a national strategy to identify and address the barriers that confront these populations in obtaining immunizations.</li> <li>• Improving immunization coverage will require innovative approaches at the local level.</li> </ul> <p><b>United Kingdom (Salisbury):</b> What criteria could be used to assess cost-effectiveness in methods for assessing vaccination coverage? What would be value for money in different methodologies?</p> <p><b>AIRA (Sutliff) revise:</b> : Identify, implement, and evaluate cost-effective and rapid</p>

	<p>workers); and</p> <p>c. by type of vaccination financing (e.g., VFC, other public sector program, private sector).</p>	<p>methods, <i>such as the use of IIS</i>, for assessing vaccination coverage:</p>
51	<p>4.3.2 Improve the completeness and use of Immunization Information Systems (IIS) and electronic medical records (EMR) to monitor vaccination coverage.</p>	<p><b>AGS:</b> Although the information regarding immunization status of an individual is maintained by various entities at various levels, AGS suggests development of a centralized National Vaccine Registry containing information on the vaccination status of individuals. We believe that this should be updated regularly and properly maintained. It must be easily accessible to healthcare agencies and to providers. This will help avoid duplicate or missed vaccinations, especially in the elderly, in which relevant information is often lost during transition from one healthcare setting to the other. This registry can be further extended to collaborate and share information with international regulatory agencies on multilateral and bilateral basis to create a positive environment for vaccine use. This will enhance the safety of vaccines and vaccination practices as well as support informed vaccine decision-making by the public, providers, and policy-makers, and extends to goals 2, 3 and 5. We understand that such a registry would have to be organized in a way that was consistent with HIPPA and that this would be significant undertaking.</p> <p><b>AHIP (Bocchino):</b> Developing the capability to administer vaccines “regardless of location” poses logistical challenges, and such a capability would require a national immunization information system (IIS, or immunization registry) that tracks vaccines and the doses patients receive across multiple jurisdictions, and is interoperable with electronic and personal health records (EHR and PHR) (Strategies 4.3.1 and 4.3.2). A system that tracks the administration of ACIP-recommended vaccines should not be dependent upon providers or patients, but rather should draw upon the efficiency and immediacy allowed by IIS. AHIP member health plans, through IISs that are linked with personal and electronic health records, are actively engaged in the enhanced tracking of administered vaccines.</p> <p><b>Mayo Clinic (Poland):</b> a seamless virtual matrix organization of Federal, State, local, and DoD organizations responsible for vaccine delivery. From this should develop a system for coordination of goals and objectives across agencies. The current system does not work, results in waste, and is not informed or agile enough to anticipate and respond to serious barriers (examples: funding mechanisms for vaccine deliver, the anti-vaccine culture, others)</p>

	<p><b>NVAC Discussion 2-6-09:</b> Improve immunization information systems (IIS), including:</p> <ul style="list-style-type: none"> <li>• Record keeping, accountability, recall, tracking.</li> <li>• The current indicator for these systems is too limited; eg. All states should have a functioning registry.</li> <li>• Emphasize the need to include an accurate transfer of vaccine information from the provider to the IIS and support the committee that is looking at this.</li> </ul> <p><b>Southern Nevada Health District (Sorenson):</b> More and better development of Immunization Registries</p> <p><b>EPIC (Wishner):</b> Immunization registries – hold states and other project areas accountable for immunization registry performance, i.e., Pennsylvania. I see how useful the Philadelphia KIDS registry is and do not understand how the PA state SIIS registry remains so dysfunctional.</p> <p><b>Every Child by Two (Pisani):</b></p> <ul style="list-style-type: none"> <li>• We request that the committee consider additional areas where IIS can be utilized and prioritize the expeditious development of IIS and universal usage of IIS by private providers. For instance, IISs can be utilized to enhance vaccine safety surveillance, track mass vaccination efforts, assist in vaccine recalls, and ensure proper use of government-funded vaccines.</li> <li>• We believe this should be highly prioritized as millions of tax payer dollars have been spent on the development of IIS to date and EMR technology is at the forefront of the new administration’s agenda.</li> </ul> <p><b>AIRA (Sutliff):</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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</li> </ul>
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		<p><b>AAP (Taylor, Bocchini):</b> 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.</p> <p><b>AAOHN (Kowalski):</b> 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.</p> <p><b>PIDS (Shulman):</b> Develop plan for a national immunization registry that is cradle-to-grave.</p> <p><b>sanofi Pasteur (Phil Hosbach):</b> There should be a more detailed discussion in the Plan of the use of Immunization Information Systems (IIS) and electronic medical records (EMR).</p> <ul style="list-style-type: none"> <li>• A comprehensive survey on the status of registries across the nation should be undertaken.</li> <li>• There needs to be interoperability of registry systems across the country as well as integration of registries with any health information record systems being used.</li> <li>• Key features of value to “on the ground” vaccinators (e.g., ability to generate reminder/recalls, quick identification of vaccine gaps for individual patients) should be part of registry systems.</li> <li>• Additional funding for such systems could be provided through grants and contracts to state and local agencies and other non-profit entities.</li> </ul>
		<p><b>AIRA (Sutliff) new:</b> 4.3.3 Support and encourage electronic medical records (EMR) vendors to develop interfaces to seamlessly exchange immunization data with IIS.</p> <p><b>Society for Adolescent Medicine (Kreipe) new:</b> 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</p>

		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.
51	<b>Objective 4.4: Enhance tracking of vaccine preventable diseases and monitoring of the effectiveness of licensed vaccines.</b>	<p><b>AHIP (Bocchino):</b> AHIP and member health insurance plans, through electronic and personal health records (EHR and PHR) and registries, are actively engaged in the enhanced tracking of vaccine preventable diseases.</p> <p><b>NVD (Baxter):</b> recommends expanding EIN to be sufficiently robust and flexible to serve all anticipated effectiveness measurement needs, rather than ad hoc systems.</p> <p><b>Institute for Global Health (Rutherford): Objective 4.4.</b> This is an important objective and one that rests fairly squarely on the shoulders of state and local health departments. I would encourage that a new strategy be added that discusses improved federal funding for state and local surveillance and outbreak response.</p>
51	4.4.1 Strengthen epidemiologic and laboratory methods and tools to diagnose vaccine-preventable diseases and characterize the impact of vaccination coverage on relevant clinical outcomes.	<b>Pediatric Dengue Vaccine Initiative (Letson):</b> Absolutely right. My question here is whether there is anything that can be said as to how this will actually happen.
51	4.4.2 Monitor circulating strains of relevant vaccine-preventable pathogens.	
52	4.4.3 Monitor ongoing disease burden and determine epidemiologic and clinical characteristics of cases of relevant vaccine-preventable diseases.	
52	4.4.4 Conduct studies to assess vaccine effectiveness and indirect (community or herd) protection.	<b>IDSA (Gershon): Expand Strategy 4.4.4 to read:</b> "Conduct studies to assess vaccine effectiveness and indirect (community or herd) protection. <i>Develop and maintain capacity to rapidly estimate the effectiveness of pandemic and pre-pandemic influenza vaccines.</i> "
52	4.4.5 Monitor long-term protection	<b>Merck (Feinberg):</b> Change "Monitor" to "Conduct studies to assess..."

	from vaccines administered to infants, children, adolescents, and adults.	
52	4.4.6 Assure rapid and comprehensive identification, investigation, and control of vaccine preventable disease outbreaks.	
		<b>Merck (Feinberg) (new):</b> Support the development and implementation of a web-based reportable disease notification system.
52	<b>Objective 4.5: Educate about, and support, healthcare and other vaccination providers in vaccination counseling and delivery.</b>	<p><b>NVD (Baxter):</b> suggests adding a strategy to include immunization training within medical, nursing and pharmacist school curriculum.</p> <p><b>AACP (Lang):</b> Utilize the skills or pharmacy faculty in creating and assessing curricula for improving provider counseling and delivery in addressing Goal 4 Objective 4.5.</p> <p><b>UAN (Markle-Elder):</b> 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.</p>
52	4.5.1 Expand knowledge regarding the value of vaccination, the vaccination program, and vaccine administration by traditional healthcare providers, medical and nursing trainees, and other vaccinators (e.g., pharmacists, community vaccinators).	<p><b>JSI (Steinglass):</b> what about also <b>using them (e.g., pharmacists) to provide services</b>, not just increase their knowledge?</p> <p><b>American Federation of Teachers (Alexander):</b> include school nurses</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> How should be speculated on for 4.5.1 and 4.5.2.</p>
52	4.5.2 Improve counseling and referral of patients for immunization by healthcare providers who do not offer immunization services.	
52	4.5.3 Promote and support educational and technical assistance to improve	<b>AHIP (Bocchino):</b> We also support efforts to help vaccine providers reduce the overhead costs associated with administering vaccines by promoting educational and technical

	business practices associated with providing immunizations.	assistance to improve business practices associated with providing immunizations through the appropriate medical society. Many plans already offer educational and technical materials for health care providers on preventive care, as well as information on accurate coding and billing practices to ensure rapid reimbursement for immunization as well as other services.
52	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).	<p><b>AHIP (Bocchino):</b> We also support the development of innovative payment arrangements that incentivize health care providers with respect to vaccines and note that private health insurance plans are in a better position than other stakeholders are to develop the appropriate incentives for reimbursement.</p> <p><b>AIRA (Sutliff) revise:</b> : Incentivize direct health care providers, health systems, and health insurers to provide vaccines by incorporating vaccination <i>and use of IIS in</i> quality assessment programs (e.g., HEDIS, Quality Measures and Pay for Performance programs).</p>
52	4.5.5 Ensure appropriate reimbursement for vaccine counseling and administration by providers under public sector and private health plans.	<p><b>AHIP (Bocchino):</b> Better tools and data are need to help providers individually determine, in the context of their particular circumstances, “appropriate” fees for vaccine counseling and administration under public sector and private health plans. We would oppose, however, an attempt to impose a specific “appropriate” reimbursement level or formulation on individual market participants, whose circumstances may vary.</p> <p><b>NVAC Discussion 2-6-09:</b> Ensure adequate payment of providers for vaccinations services including</p> <ul style="list-style-type: none"> <li>• Counseling</li> <li>• Vaccine storage and handling</li> <li>• Vaccine administration</li> </ul> <p><b>Southern Nevada Health District (Sorenson):</b> Pay for education and counseling about vaccine and not just the cost of vaccines.</p> <p><b>Trust for America’s Health:</b> The NVPO should partner with public and private payers to ensure adequate reimbursement of clinicians (<b>Goal 4.5.5</b>) for vaccine delivery and abundant information about available assistance programs.</p>
52	4.5.6 Support research to evaluate the capacity (accommodating the increased	<b>American Federation of Teachers (Alexander) revised:</b> support research to evaluate the capacity of health care employers and other employers of at risk worker groups

	number of patient visits required to receive recommended vaccines) of health care providers to implement childhood, adolescent, and adult vaccination recommendations.	to implement worker vaccination recommendations
53	4.5.7 Develop, implement, and evaluate communication tools as part of comprehensive programs to ensure health care professionals are appropriately immunized with recommended vaccines.	<p><b>NVAC Discussion 2-6-09:</b> Healthcare provider vaccination- a priority. But group was divided on role of mandates.</p> <p><b>ADA (Findley):</b> 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.</p> <p><b>ANA (Stierle, Patton):</b> 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.</p>
53	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.	<p><b>Merck (Feinberg):</b> Strategy 4.5.8 and elsewhere in document: Change "compliance" to "adherence"</p> <p><b>American Federation of Teachers (Alexander) revised:</b> broaden the strategy to include the employer programs of other high risk worker groups (corrections, schools etc.). Also the promotion of comprehensive health and safety program plans that integrate vaccination should be included in the strategy.</p> <p><b>UAN (Markle-Elder):</b> 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.</p>
53	4.5.9 Assess whether changes in health care facility and professional licensure	<b>American Federation of Teachers (Alexander):</b> This strategy is not clear. If the strategy implies mandatory vaccination as a condition of employment, we recommend that

	<p>and regulation can improve the safety of the health care environment by increasing vaccination rates of health care professionals.</p>	<p>the committee revisit this strategy and rescind any recommendation for mandatory vaccination as a condition of licensure. Clearly there is a need for research on why healthcare workers are not responding to annual vaccination programs. We believe that, in part, health care workers are not receptive because of the lack of good, comprehensive education and training programs on influenza and the benefits to them as well as patients of their participation in a vaccination program. Again we recommend an OSHA approach where the vaccination program becomes a part of a comprehensive exposure prevention program as vehicle for increasing participation.</p> <p><b>ANA (Stierle, Patton):</b> 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.</p> <p><b>UAN (Markle-Elder):</b> 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.</p>
53	<p>4.5.10 Develop and monitor policies promoting vaccination for patients and health care personnel in long-term care facilities and hospitals.</p>	<p><b>ANA (Stierle, Patton):</b> 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.</p>
		<p><b>AIRA (Sutliff) new:</b> 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.</p>
		<p><b>BD (Dugue): Strategy 4.5.11 (new): Assess current vaccine administration practices among healthcare and other vaccination providers to identify barriers to efficiency, safety and convenience.</b>  <i>Rationale: Studies show that vaccine delivery systems have an impact on administration. With a trend to offer vaccines in less-traditional settings, greater vigilance and easier-to-use,</i></p>

		<i>lower-risk delivery systems may be required to ensure safety.</i>
53	<b>Objective 4.6: Maintain a strong, science-based, transparent process for developing and evaluating of immunization recommendations.</b>	<p><b>University of Maryland (Milstien):</b> Objective 4.6 is very important, and I wonder, given US experience with this, if it would not be useful to add a strategy to help other countries with this objective as well – the NVP could learn and it could help the supply situation as new vaccine uptake increases.</p> <p><b>American Federation of Teachers (Alexander):</b> NIOSH should be involved in the development of the process for developing and evaluating immunization recommendations.</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> For all of these in 4.6 I think speculation as to how would help.</p> <p><b>AACP (Lang):</b> Pharmacy faculty should be included in any entity NVPO creates to address Goal 4 Objective 4.6</p>
53	4.6.1 Obtain broad-based input from the public and stakeholders contributing to new immunization policies and to assessment of existing policies.	<p><b>American Federation of Teachers (Alexander):</b> Highly recommend that you include all healthcare worker unions as a stakeholder for contributing input to new immunization policies and assessing existing policies.</p> <p><b>ANA (Stierle, Patton):</b> 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.</p>
53	4.6.2 Support and strengthen immunization advisory committees at the state and national levels.	<p><b>JSI (Steinglass):</b> add “country”, since this is the WHO plan?</p> <p><b>SUNY, Albany (Bernarczyk):</b> Very broad statement – any specifics on how to support and strengthen?</p> <p><b>ANA (Stierle, Patton):</b> 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</p>

		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.
53	4.6.3 Assess the impact of new vaccines and vaccine recommendations on the overall immunization schedule, including programmatic implementation, safety, and efficacy.	<p><b>BD (Dugue): (revised):</b> Assess the impact of new vaccines, <b>vaccine delivery systems</b> and vaccine recommendations on the overall immunization schedule, including programmatic implementation, safety and efficacy.  <i>Rationale: Given the role of “vaccine delivery systems” in increasing efficacy<sup>14</sup>, reducing risks<sup>5</sup>, minimizing waste<sup>10</sup>, saving time<sup>8</sup> and increasing cost efficiency<sup>8, 10, 13</sup>, these systems, and specifically single dose manufacturer-prefilled delivery systems, should be considered as a relevant factor in the immunization schedule.</i></p> <p><b>SUNY, Albany (Bernarczyk):</b> Safety is addressed in Goal 2</p>
53	4.6.4 Evaluate the cost-effectiveness of proposed and existing immunization recommendations.	<p><b>ANA (Stierle, Patton):</b> 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.</p>
		<p><b>AIRA (Sutliff) new:</b> 4.6.5 Leverage the data available through population-based IIS to evaluate the impact and implementation of new and existing immunization recommendations.</p>
53	<b>Objective 4.7: Strengthen the Vaccine Injury Compensation Program (VICP) and Public Readiness and Emergency Preparedness (PREP) Act compensation fund.</b>	<p><b>NVD (Baxter):</b> agrees a level of evidence should be established to add new syndromes to the injuries table.</p> <p><b>American Federation of Teachers (Alexander):</b> Non-federal stakeholders should include healthcare unions. Many of us were struck by the gaps in protection in the Vaccine Injury Compensation Program (VICP) when the last administration was heavily promoting small pox vaccination for nurses and other healthcare workers in preparation for a bioterrorism attack. The initiative was especially troubling given the primitive nature of the vaccinia inoculums and the risk of AEFI.</p> <p><b>AACP (Lang):</b> The translation of research into practice can be supported by ensuring the education of healthcare professionals includes the necessary critical thinking and</p>



		communication skills to address the strategies listed in Goal 4 Objective 4.7.
54	4.7.1 Increase knowledge about the VICP and PREP act among all stakeholders.	<b>Wyeth (Connolly, Eyles):</b> We believe the Plan should go well beyond a strategy to “increase knowledge about the VICP.” The NVP should make it clear that NVPO and sister agencies are committed to safety in the design of vaccines and the FDA approved designs are viewed as the best balance of safety and effectiveness concerns. It should also address the need for tort reform that further reduces liability risks when the manufacturer is not malfeasant.
54	4.7.2 Assure the program is responsive to evolving science, including regularly updating the Vaccine Injury Table.	<b>sanofi Pasteur (Hosbach):</b> When considering modifications to the Vaccine Injury Table of VICP, it is essential that any changes be based on sound, science-based evidence; failure to do so can generate unfounded concerns.
54	4.7.3 Continue to ensure fair and efficient compensation.	
54	4.7.4 Examine alternative approaches for adjudication of claims for illnesses not included in the Vaccine Injury Table (and seek Federal legislation as necessary).	
54	<b>Objective 4.8: Enhance the effectiveness of state and federal immunization programs.</b>	<p><b>Institute for Global Health (Rutherford): Objective 4.8.</b> I would specifically include local health agencies in the wording of the objective, i.e., “Enhance the effectiveness of <i>local</i>, state and federal immunization programs.”</p> <p><b>Every Child by Two (Pisani):</b> stakeholders could include philanthropic organizations, public, citizen advocacy groups</p> <p><b>Trust for America’s Health:</b> Enhancing the effectiveness of immunization programs (<b>Goal 4.8</b>) should also include robust investment in private and public assistance programs, such as the 317 Program.</p>
54	4.8.1 Implement, monitor, and evaluate evidence-based interventions designed to raise and sustain high vaccination coverage in children, adolescents, and	

	adults.	
54	4.8.2 Monitor and evaluate the impact of state immunization laws including daycare, school, and college prematriculation requirements, the role of exemptions to them, insurance mandates, and immunization information systems requirements.	<p><b>AHIP (Bocchino):</b> AHIP and its member plans agree that it is important to monitor and evaluate the impact of state immunization laws including childcare, school, and college pre-matriculation requirements, the role of exemptions, insurance mandates, and immunization information systems requirements (Objective 4.8.2). As we have indicated already, we oppose any objectives or strategies that would, directly or indirectly, lead to a legislative or regulatory scenario in which private health insurers or purchasers of health insurance are compelled to include specific benefits in health insurance products.</p> <p><b>Merck (Feinberg):</b> Strategy 4.8.2: Insert "and regulations" after "state immunization laws..." Insert "pre-school," after "childcare...."</p>
54	4.8.3 Prepare, practice, and evaluate mass vaccination activities for containment of an outbreak of a vaccine-preventable disease, for a biological attack, for the critical workforce in advance of an influenza pandemic, and for the entire population, prior to and during, an influenza pandemic.	<p><b>ADA (Findley):</b> 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.</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b> As it relates to pandemic influenza specifically, much progress has been made by the federal government to ensure adequate availability of supply through vaccine stockpiles and surge capacity. However, delivery remains a key bottleneck that if not addressed will mitigate progress that has been made from a supply perspective.</p>
		<b>NVD (Baxter) (new):</b> Suggest the addition of a new strategy under this objective to support adequate funding for immunization programs.
54	<b>Objective 4.9: Enhance Immunization Coverage of International Travelers Who Are at Risk of Acquiring Vaccine-Preventable Diseases.</b>	<p><b>IDSA (Gershon):</b> Strengthen Objective 4.9 on immunization coverage of travelers by including specific strategies.</p> <p><b>PIDS (Shulman) delete:</b> 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.</p>
55	4.9.1 Define the populations at risk for acquiring international travel-related vaccine-preventable diseases, and identify and address barriers to their	

	receiving immunizations.	
55	4.9.2 Implement and evaluate activities to enhance immunization coverage among travelers.	<b>AIRA (Sutliff) revise:</b> Implement and evaluate activities, <i>such as the use of international certificate of immunization produced by IIS</i> , to enhance immunization coverage among travelers.
		<b>Every Child by Two (Pisani) new:</b> Determine whether health plan coverage of travel vaccines is sufficient and if not, does this act as a barrier to receipt of vaccines? Determine whether there is sufficient access to travel vaccines via private provider offices and public clinics and if not determine methods to alleviate barriers i.e. increase number of “travel vaccine clinics”.
56-58	<b>Goal 5, Indicators, and Figure</b>	<p><b>Meningitis Vaccine Program, PATH (F. Marc Laforce):</b> Support introduction of new vaccines as part of national vaccination programs:</p> <ul style="list-style-type: none"> <li>• Group A meningococcal conjugate vaccine in all African countries in the “meningitis belt” by 2019.</li> <li>• <b>Note:</b> this change is being suggested because an affordable (\$US&lt; 0.50 per dose) conjugate Men A vaccine has been developed and will be introduced in meningitis belt countries beginning in 2009/2010. The strategy has been approved by WHO, UNICEF and GAVI. All meningitis belt countries should be either partially or totally covered by 2019.</li> </ul> <p><b>AHIP (Bocchino):</b> Goal #5, as it is currently stated, is unclear as to how it relates to disease prevention and immunization in the United States and, therefore, why it is in the scope of a U.S. National Vaccine Plan. While this goal is important from a global perspective, especially in light of diseases that do not respect geographic boundaries, the Strategic Plan does not explicitly state why it is important that U.S. vaccination activities to be coordinated with global immunization efforts (e.g. to reduce exposure to communicable diseases for travelers entering and leaving the United State, and/or to improve international relations).</p> <p><b>Columbia NCDP (Garrett):</b> While the need to think globally is contained in the plan, we did not get the sense that it is a priority- the international parts of the plan still read like an issue that is “over there” as opposed to our issues “over here.” Existing and emerging diseases have great potential to disrespect political boundaries as we know, so this really is just one fight. The more that the Plan can break down barriers to a seamless international</p>

	<p>agenda to fight disease, the better. This is a great start.</p> <p><b>Mayo Clinic (Poland):</b> I am skeptical of Goal 5 – rather I believe the plan should focus intensely on our internal issues that are under our direct control. Goal 5 is more credibly a goal that CDC/WHO should undertake.</p> <p><b>JSI (Steinglass): Goal 5 comments</b></p> <ul style="list-style-type: none"> <li>• Goal 5, paragraph 1: needs editing so it does not sound like you are trying to <b>reduce</b> (!) under-1 measles coverage.</li> <li>• Goal 5, paragraph 2, line 2 and Goal 5 indicators: if <b>sustainability</b> is a goal, as it should be, then consider that at least some indicators should reflect achievement over time and not just single-year achievement. For example, the proportion of countries in any given year that have not only achieved but also <b>sustained infant DTP3 coverage of 80% or higher (or perhaps a lower threshold) EACH year for the past three years.</b></li> <li>• Page 57, para starting with “Figure 7,” lines 8-11. There is a curious lack of any mention to vaccination itself. Suggest adding “<b>designing vaccination delivery strategies</b>” to the list.</li> </ul> <p><b>NVAC Discussion 2-6-09:</b> There was consensus among the group on the need for global health goal in the National Vaccine Plan</p> <ul style="list-style-type: none"> <li>• The group recommended increasing communication regarding the relevance of global health to U.S. citizenry</li> <li>• The plan should work out the tension between “achievable” and “aspirational”—and in that context, address the leadership role of the U.S. (federal or national?).</li> <li>• The plan reflects U.S. support for globally agreed-to goals</li> <li>• Incorporate the importance of sustainability of goals throughout plan</li> <li>• The plan should incorporate recognition that our commitment to global health should reflect our foreign policy interests; there should be greater communication between foreign policy and global health stakeholders</li> <li>• The National Vaccine Plan should better identify all potential partners and stakeholders in global health (e.g., academic organizations, non-governmental organizations [NGOs], professional associations, and manufacturers) and should</li> </ul>
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		<ul style="list-style-type: none"> <li>• Ensure that content is cross-referenced, so that relevant partners and initiatives are recognized throughout the plan</li> </ul> <p><b>NACHC:</b> Relatively “new” vaccine initiatives such as the pediatric Hepatitis B series should become part of routine pediatric immunization programs in those countries where Hepatitis B is endemic. Similarly, as other innovative vaccines e.g. HPV [Gardasil] are made available to the public every effort should be made to close the divide between developed and under developed countries in terms of access to valuable preventive medicine.</p> <p><b>Merck (Feinberg) Goal 5:</b></p> <ul style="list-style-type: none"> <li>• The US Government should support investment in cold-chain management and vaccine thermostability.</li> <li>• Countries should be encouraged to develop comprehensive adult immunization programs that should include influenza and pneumococcal infection as target vaccine-preventable diseases.</li> <li>• The US Government should collaborate more with US-based industry in its efforts to improve global health.</li> </ul> <p><b>Japan (Dr. Arita) Goal 5 comments:</b></p> <ul style="list-style-type: none"> <li>• Here, I would like to propose, we must do something for eliminating HIV and malaria which are the cause of the disasters in people of sub-Saharan Africa. There, in many countries, the life span went down to 30 to 40 of age and 90% of world death caused by the two diseases occurring exclusively there. What about to plan and set up special international intuition ( for instance, Sub-Saharan Vaccine Research Institute) in Accra or Johannesburg. It will focus on RD and if possible the production, for the purpose of introduction of vaccines for elimination of HIV and malaria in 800 million population there.</li> </ul> <p><b>Gates Foundation (Bates):</b> the plan references GAVI’s role and importance. However, GAVI is not listed as a “non-federal stakeholder” under any of the specific objectives or in Appendix 3 (p.71) that lists stakeholders. This may be because GAVI is a partnership and not an agency. However, it is a primary vaccine delivery platform on which the U.S. relies and specifically funds through an embedded earmark in the State/Foreign Ops appropriations bill. It is likely that GAVI will play a central role in the implementation of the</p>
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	<p>U.S.' global immunization strategy.</p> <p><b>ACIP (Finger):</b> There is an error on page 56. I think you meant to say we were supposed to reduce the proportion of 1 year-old children UNIMMUNIZED against measles by two thirds.</p> <p><b>Task Force for Child Survival (Hinman):</b> Goal 5 – although adding a goal on global immunizations is a great thing, why isn't HPV vaccine listed as a specific vaccine to be addressed? Also, why isn't GAVI listed as an important stakeholder?</p> <p><b>ACIP (Marcy): Goal 5:</b> Any discussion of international vaccine development should at least mention Tb and malaria vaccine development, even if the major financial support seems to come from Bill and Melinda Gates.</p> <p><b>Institute for Global Health (Rutherford):</b> Goal 5 is missing a sure thing. I would strongly encourage the inclusion of <i>Haemophilus influenzae</i> type b vaccine, a vaccine that we know works and has virtually eliminated this disease in the United States, to the list of indicators under the fourth bullet.</p> <p><b>Southern Nevada Health District (Sorenson):</b> Provide more assistance to large urban areas that have a regular influx of transient and foreign born individuals into their communities.</p> <p><b>AACP (Lang):</b> 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.</p> <p><b>ADA (Findley):</b> 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</p>
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	<p>globalization of commerce.</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b> Continued support of HIV vaccine development should be an explicit strategy, and one which also applies to Goal 5, given the long time horizon of this plan. Federal government agencies have a critical role to play in supporting "push" strategies that are necessary to continue HIV vaccine development efforts, as market forces alone will not be sufficient to drive adequate private sector investment due to the tremendous technological obstacles and resulting high candidate failure rates.</p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 6:</b> As it relates to the last indicator (X countries enhance injection safety by Y year), promoting the use of auto-disable syringes and other safety injection approaches should be balanced with the cost implications and resulting impact on affordability, which constrains overall utilization of vaccines. This consideration should be factored into the final language of the indicator.</li> </ul> <p><b>sanofi Pasteur (Hosbach):</b></p> <ul style="list-style-type: none"> <li>• Dengue is another major global health concern and should be included in the language of the plan alongside HIV, tuberculosis and malaria</li> <li>• How does the U.S. propose to influence other countries in achieving higher immunization rates per Goal 5? How will percentages and timeframe be determined? What national resources will be available to achieve these global objectives?</li> </ul> <p><b>WHO: Goal 5 Indicators:</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 2</b> "Mortality from measles will be reduced by X% by Y (year) compared with an X (year) baseline" could be reviewed. Indeed, in the next 10 yr, we anticipate that all regions will have moved towards a 'measles elimination' goal (zero incidence vs zero mortality)</li> <li>◆ <b>Indicator 3</b> "X% of countries will achieve DTP3 vaccination coverage of 90% or greater nationally (and 80% or greater in each country's district) by Y (year)" : we already remove the second part from our list of indicators in WHO since it is difficult to have data to measure both in a reliable manner.</li> </ul> <p><b>IDSA (Gershon):</b> On page 57, the first indicator seeks to set a year by which wild</p>
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	<p><b>polio virus will be eradicated.</b> The global community now acknowledges the effort will take longer than expected. As no fixed target year is broadly accepted elsewhere, it is problematic for a date to appear in a U.S. plan.</p> <ul style="list-style-type: none"> <li>• Throughout this goal, the Global Alliance for Vaccines and Immunization (GAVI) should be added as a non-federal stakeholder.</li> </ul> <p><b>Australia (Horvath): Goal 5 Indicator (new):</b></p> <ul style="list-style-type: none"> <li>• Within X years, collaborate with international funding organisations to develop accountability models and standards to improve efficiency and effectiveness of immunization program delivery in developing countries.</li> </ul> <p><b>NVD (Baxter):</b> suggests an objective to support the challenges of low-middle income countries be added.</p> <ul style="list-style-type: none"> <li>◆ <b>Indicators:</b> believes the indicators under this goal are not mirroring the objectives outlined. It is unclear how the indicators were chosen and how the Plan will lead to successful implementation of the indicators. Suggests these indicators, objectives and strategies must be designed collaboratively with global governmental and non-governmental stakeholder input to ensure alignment, enhance output and reduce uncoordinated or duplicative efforts.</li> <li>◆ <b>Indicator 1-3:</b> recommends NVPO align proposed disease reduction indicators with strategies and goals already in place through-Millennium Development Goal, GAVI, UNICEF, etc.</li> <li>◆ <b>Indicator 4:</b> suggests tailoring to specifically reference conjugate meningococcal vaccine.</li> <li>◆ <b>Indicator 5:</b> suggests establishing a metric of X countries establishing immunization advisory committees, and requiring this metric to incorporate assessment submetrics. Suggests adding an objective which would gather information on advisory committees.</li> <li>◆ <b>New indicator:</b> Assess vaccine wastage due to storage conditions assess vaccine wastage due to excessive heat or cold and reduce wastage by X percent.</li> </ul> <p><b>Merck (Feinberg): Indicators:</b></p> <ul style="list-style-type: none"> <li>• <i>Haemophilus influenzae</i> type b, hepatitis B, human papillomavirus, and perhaps</li> </ul>
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		<p>other diseases should be added to the indicators.</p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 4:</b> The list should be prioritized based on public health need. A mechanism should be provided to augment this list, perhaps by linking it to other vaccines provided via Expanded Programme on Immunization (EPI) or an Accelerated Development and Introduction Plan (ADIP)- or GAVI-like process.</li> <li>• The US Government should increase its collaboration with international organizations like GAVI and engage in innovative mechanisms to sponsor vaccine development (eg, Advanced Market Commitments, International Finance Facility for Immunization).</li> <li>• Merck is willing to work with the US Government on evaluating potential incentives for manufacturers to build capacity to allow these goals to be met more readily. Merck has already committed itself to contributing to vaccine solutions for the developing world.</li> <li>◆ <b>Indicator 5:</b> This indicator might be actualized by means of US scientific and technical support to X countries.</li> <li>◆ <b>Indicator 6:</b> The benefits and risks of individual devices such as those named need to be carefully analyzed, including assessment of practicality of their use, to avoid unintended consequences.</li> <li>• "All immunizations" may not be an appropriate goal and is not the US standard.</li> </ul> <p><b>SUNY, Albany (Bernarczyk): Indicators 2:</b> This is the only indicator that uses a % difference from a baseline value – can it just reference a specific reduction as all other indicators do?</p> <p><b>Wyeth (Connolly, Eyles):</b> A key need is to establish different philanthropic programs and vaccine prices based on the economic circumstances of each country. Wyeth is concerned that vaccine contracting policies of certain organizations may be significant hurdles to global immunization programs.</p> <ul style="list-style-type: none"> <li>• Add objective: An objective should be added to develop a process to more accurately estimate vaccine demand for different country markets, as this is directly linked to a goal of assurance of adequate and sustainable vaccine supply.</li> </ul> <p><b>European CDC (Jakab):</b> Also the indicators under goal 5 are of great interest to us; polio eradication, measles elimination, increased coverage of DTP, establishing Advisory Committees in more countries and enhance injection safety. ECDC will specifically focus the</p>
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VPD-work certainly for 2009 but probably also for the coming years on supporting the work by WHO EURO on measles and rubella immunization in the European region and increase coverage to all childhood vaccines.

**Former member of ACIP (Abramson): Indicators**

- ◆ **Indicator 4:** I think that influenza vaccine should be added (I was recently appointed as a member of the WHO Strategic Advisory Group of Experts and have now become aware that the topic of influenza vaccine has moved up on the list of vaccines to be considered for global introduction). It is less clear to me that HPV vaccine can be introduced within the time frame of this plan, but I wanted to make sure that the decision not to include it in this bullet was made after careful consideration.

**University of Maryland (Milstien): Indicators**

- ◆ **Indicator 1:** Although it is understood that this is a plan that involves stakeholders, and their actions are to be held accountable, the NVP is going a little far to consider that the activities of all countries can be included and monitored in the plan. For example, the target "Transmission of wild polio virus will be eradicated by Y year" -- even WHO has difficulty with that one, and they have a little bit more jurisdiction over national vaccine programs around the world than NVP does. It would be more useful to include targets that indicate the work that HHS can do that would assist polio eradication, such as training, laboratory support, epidemiological support, defining standards, etc. This fact is noted on p56, so why is this difficulty then ignored?

**Gates Foundation (Orenstein): Indicators**

- ◆ **Indicator 1:** I understand the desire to have a year by which polio will be eradicated. But that is running counter to what is now going on with the effort, which is basically saying it may take longer than expected but we need to achieve the goal. The problem is we have failed to meet a number of milestones including the original year 2000 and Rotary's 2005. Can we just say polio will be eradicated and then one can look at any given timeframe as to whether the goal has been achieved or not? In the absence of a global date, I think it is problematic for a date to appear in a US plan.

	<p><b>PATH (Elias): Indicators and comments</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 4:</b> we were surprised not to see the human papilloma virus (HPV) vaccine listed alongside meningococcal, rotavirus, and pneumococcal vaccines. We recommend that you add HPV to the list of vaccines that should receive support for introduction.</li> <li>◆ <b>Indicator 4 subbullet: Group A meningococcal conjugate vaccine</b> in all African countries in the "meningitis belt" by <b>2019</b>;</li> </ul> <p>Note: This change is being suggested because an affordable (\$US&lt; 0.50 per dose) conjugate Men A vaccine has been developed and will be introduced in meningitis belt countries beginning in 2009/2010. The strategy has been approved by WHO, UNICEF, and GA VI. All meningitis belt countries should be either partially or totally covered by 2019.</p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 6:</b> X countries enhance injection safety by Y (year) through the use of auto-disable syringes or other safe injection devices (e.g., needle free delivery), <b>safety boxes, and sufficient capacity to treat resulting sharps and other infectious waste</b> for all immunizations.</li> <li>• We recommend that you include recommendations for US partnerships with vaccine manufacturers in emerging countries to develop and/or manufacture new vaccines, particularly as we plan to meet the tremendous need that will face us should an influenza pandemic threaten the people of the world.</li> <li>• We suggest that the importance of supporting pandemic preparedness also be explicitly included in Goal 5. In particular, we suggest objectives to support pandemic preparedness overseas, foster global manufacturing capacity, and contribute to global needle stockpiles.</li> </ul> <p><b>Pediatric Dengue Vaccine Initiative (Letson): Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 4:</b> I might consider Hib here. I know it is hard to document the magnitude of the problem in much of the world. That is probably more related to free use of antibiotics than absence of disease. For a good deal of the developing world, cholera and typhoid might also be considered here.</li> </ul> <p><b>AAP(Tayloe, Bocchini): Indicators</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 4:</b> Include Hib vaccine on the list for global prevention of death and disease</li> </ul>
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		<p><b>Baxter Bioscience, Vaccines (Khoury): Indicators and comments</b></p> <ul style="list-style-type: none"> <li>◆ <b>Indicator 4:</b> Should additional pathogens be listed in the goal indicators for Goal 5?</li> <li>• In order to facilitate research impacting the developing world perhaps a plan to offer regulatory incentives and commercial protection above and beyond the traditional commercial product.</li> <li>• How will harmonization through international regulatory groups be attained? What will be the indicator that this has occurred?</li> </ul>
58	<b>Objective 5.1: Improve global surveillance for VPDs and strengthen health information systems to monitor vaccine coverage, effectiveness, and safety.</b>	<p><b>NVD (Baxter):</b> Recommend that vaccine industry be included in the implementation phase of this objective.</p> <p><b>Pediatric Dengue Vaccine Initiative (Letson):</b> Good stuff. I think this would be strengthened by some suggestion as to how this is accomplished. Goal 5 is, of course, is more out of the control of the U.S. Stakeholders, but not altogether.</p>
58	5.1.1 Achieve sustainable WHO certification quality surveillance for eradication targeted VPDs.	
58	5.1.2 Expand and improve surveillance systems for all current VPDs and for diseases for which vaccine introduction is being considered.	<p><b>NVD (Baxter):</b> Inclusion of this goal in the Plan highlights the role that the U.S. vaccine enterprise can play in helping reduce the burden of vaccine-preventable diseases in these countries.</p> <p><b>SUNY, Albany (Bernarczyk):</b> Does this address only country-specific surveillance systems or does it also look at cross-border systems (e.g., WHO)?</p>
58	5.1.3 Strengthen all levels of global laboratory networks (including national, regional, and global reference laboratories) to sustain and improve VPD diagnosis in order to establish baseline disease burden, detect outbreaks, and monitor the impact of new vaccines.	<p><b>Bain &amp; Company, Inc. (Pasternak):</b> is particularly important. A major constraining factor to policy recommendations, vaccine development and demand for vaccines among developing world countries is the lack of good epidemiological data. For example, while diarrheal disease is known to be a serious health problem in sub-Saharan Africa, the contribution of the Rotavirus pathogen specifically is not well understood, and thus uptake of Rotavirus vaccines has been (and will continue to be) slow to occur.</p>

59	5.1.4 Enhance assessments of emerging variants or strains of vaccine-preventable disease agents.	
59	5.1.5 Develop new diagnostic tests, tools and procedures to improve both field-based and laboratory confirmation of diagnoses.	
59	5.1.6 Improve coverage monitoring of vaccines and other health services linked with the vaccination program and the use of information at district and local levels.	<b>IDSA (Gershon) (revise):</b> “Improve the measurement of immunization coverage to assure it accurately reflects population immunity levels induced by vaccination and improve the use of such information at district and local levels.”
59	5.1.7 Introduce and improve programs that monitor the occurrence of AEFI.	
59	<b>Objective 5.2: Improve and sustain immunization programs that deliver vaccines safely and effectively as a component of healthcare delivery systems and promote opportunities to link immunization delivery with other priority health interventions, where appropriate.</b>	<p><b>JSI (Steinglass):</b> Objective 5.2, line 2: Add “safely, effectively, <b>efficiently and equitably</b>”</p> <p><b>NVD (Baxter):</b> suggest specific strategies that address, injection safety, cold chain and logistics issues.</p> <p><b>Gates Foundation (Bates):</b> I appreciate Objective 5.2 which encourages the link between immunization delivery and other priority health interventions. I do wonder, however, how so many activities – e.g., surveillance, laboratory networks, economic studies – will be resourced given the U.S.’ limited immunization-specific bilateral and multilateral funding. I assume those details will be addressed in the implementation plan that follows this strategic plan.</p>
59	5.2.1 Provide support to countries and partners to strengthen key components of immunization program management and implementation, including epidemiological analysis, comprehensive planning, vaccine distribution and administration,	<b>JSI (Steinglass):</b> “vaccine distribution” doesn’t quite do justice to “ <b>vaccine forecasting, ordering, storage, and distribution</b> ” (see 4.1.4 for the fuller description used there)

	monitoring, and program evaluation.	
59	5.2.2 Provide technical support to countries to introduce, sustain, and monitor recommended safe injection practices for all vaccinations, including the use of auto disable syringes or needle-free devices.	<p><b>JSI (Steinglass):</b> add “..safe injection and <b>Disposal..</b>”</p> <p><b>PATH (Elias) revise:</b> Provide technical support to countries to introduce, sustain, and monitor recommended safe injection practices for all vaccinations, including the use of auto disable syringes or needle-free devices, <b>safety boxes. and final waste treatment systems.</b></p>
59	5.2.3 Support linking delivery of immunization and other health services in ways that do not jeopardize immunization coverage, and develop standardized methods for monitoring and evaluating the efficiency, effectiveness and impact of combined interventions to improve coverage and public health.	
59	5.2.4 Encourage establishment of programs, as appropriate, for vaccination beyond the traditional infant target age groups (e.g., among older children, adolescents and adults)	<p><b>NALBOH (Fallon):</b> Under Goal 5, objective 5.2, Strategy 5.2.4, CDC needs to provide States with additional funding to support the establishment of an effective adult immunization initiative.</p>
		<p><b>BD (Dugue): Strategy 5.2.5 (new): Reduce access barriers to vaccination and enable wider distribution of vaccines to countries by simplifying training for administration through providing ready-to-use delivery systems, removing steps to assemble, and assuring dose accuracy.</b></p> <p><i>Rationale: Manufacturer-prefilled delivery systems, in easy-to-use self-storage units, simplify administration and, as is the case with prefilled syringes, minimize waste, reduce the risk of error and save time – all critical considerations, especially in formerly underserved populations.</i></p>
59	<b>Objective 5.3: Support introduction and availability of new and under-utilized vaccines to prevent diseases</b>	<p><b>Meningitis Vaccine Program, PATH (F. Marc Laforce) :</b> Consider adding a new 5.3.5 Support the introduction of the new meningococcal A conjugate vaccine in African meningitis belt countries. (important for USAID and CDC support).</p>

	<b>of public health importance.</b>	<p><b>JSI (Steinglass):</b> “availability” is only part of the challenge. Add “availability and <b>use</b>.”</p> <p><b>NVD (Baxter):</b> suggests the addition of a strategy to facilitate the regulatory process for these vaccines.</p>
60	5.3.1 Collaborate with global organizations and partners to accelerate the clinical testing and licensure, where appropriate, in developing countries of vaccines already licensed in developed countries.	<p><b>Canada Biologics (Griffiths):</b> Strategy 5.3.1 proposes collaboration with global organizations and partners to accelerate clinical testing and licensing, where appropriate, in developing countries of vaccines already licensed in developed countries. However, it is likely that some vaccines will be tailor made either for specific regions or countries and will be clinically tested and licensed directly in developing country settings (eg clade specific HIV vaccine, conjugate pneumococcal vaccines with regional compositions). Such vaccines may be produced either by the major pharmaceutical manufacturers or, increasingly, by developing country vaccine manufacturers. Vaccines from either source may not be subject to clinical evaluation nor licensing in a developed country.</p>
60	5.3.2 Strengthen country capacity to make informed decisions on introduction of new vaccines based on evaluation of epidemiology, financial sustainability, safety, and programmatic considerations.	
60	5.3.3 Support the integration of new and under-utilized vaccine into each GAVI-eligible country’s multi-year national plan of action and provide training and logistical support necessary to successfully incorporate new vaccines into routine programs.	<p><b>PATH (Elias) revise:</b> Support the integration of new and under-utilized vaccine into each GA VI-eligible country's multi-year national plan of action and provide training and logistical support necessary to successfully incorporate <b>safe delivery of</b> new vaccines into routine programs.</p>
60	5.3.4 Conduct post-licensure evaluations of the impact of new vaccines on immunization programs,	<p><b>SUNY, Albany (Bernarczyk):</b> This should be with the global safety strategies such as those in 5.1.7</p>

	disease patterns, and the occurrence of AEFI.	
		<p><b>IDSA (Gershon) (new):</b> “Evaluate standard metrics that may be used in assessing whether new and improved vaccines represent a cost-effective investment.” One might look at cost per disability-adjusted life year (DALY) averted as a potential standard, or years of potential life lost, or other measures.</p> <p><b>IDSA (Gershon) (new):</b> “Collect critical data on health burden, expected impact of vaccines on that burden, and relevant costs in enough countries to assure globally-derived estimates are accurate and assist individual country decision makers in making evidence-based policy decisions.”</p> <p><b>JSI (Steinglass) (new): Add a new strategy 5.3.5:</b> Collaborate with global organizations and partners and vaccine producers early in the design and manufacturing processes, so that vaccines will be presented and packaged for smooth introduction into low- and middle-income country immunization programs.</p> <p><b>Gates Foundation (Orenstein):</b> How about under objective 5.3, adding in a strategy: “Evaluate standard metrics to be used in assessing whether new and improved vaccines represent a cost-effective investment”? In this way, one might look at cost/DALY averted as a potential standard or years of potential life lost.</p> <p><b>PATH (Elias) new:</b> Consider adding a new 5.3.5: Support the introduction of the new meningococcal A conjugate vaccine in African meningitis belt countries. (Important for USAID and CDC support)</p>
60	<b>Objective 5.4: Improve communication of research-based and culturally and linguistically appropriate information about the benefits and risks of vaccines to the public, providers, and policy-makers.</b>	<b>NVD (Baxter):</b> While economic studies are important tools to support decision-makers, the assessment of the value of vaccination programs must include more than economic studies. This is not articulated in the strategies supporting this objective.
60	5.4.1 Support appropriate economic	<b>Bain &amp; Company, Inc. (Pasternak):</b> The language of Strategy 5.4.1 (Support appropriate economic studies to inform the understanding....among key decision an policy-



	studies to inform the understanding of the costs and benefits of immunization among key decision and policy-makers.	makers) should be broadened. Federal and Non-federal stakeholders should support evidenced-based (economic and otherwise) policy decision-making by international actors.
60	5.4.2 Develop and support capabilities to communicate vaccine risks and to respond to emerging vaccine safety issues and concerns to the public, providers, and other stakeholders in a clear, transparent and timely manner.	<b>Merck (Feinberg):</b> Strategy 5.4.2: Insert "culturally appropriate," after "transparent..."
60	5.4.3 Provide assistance in determining the most effective and efficient mechanisms to communicate with health care providers about reporting on AEFI; evaluate providers' knowledge and adherence to recommendations to prevent AEFI; and improve and assess adherence to these recommendations.	
60	5.4.4 Assist countries to develop, implement and assess comprehensive evidence-based communication plans to increase provider and public awareness of vaccine preventable diseases and promote immunization recommendations, especially among populations at risk of under-immunization.	
61	5.4.5 Assist countries to develop and implement sustainable communication research to gather timely and reliable	

	data from the public and providers on knowledge, attitudes and beliefs about the benefits and risks of vaccines.	
61	5.4.6 Provide technical assistance and training to behavioral and communications scientists and promote their participation on Technical Advisory Groups.	<p><b>JSI (Steinglass):</b> This one sounds awkwardly written and particularly narrow, relative to other strategies.</p> <p><b>Merck (Feinberg):</b> Strategy 5.4.6: Insert "and professionals" after "scientists..."</p>
61	<b>Objective 5.5: Support the development of regulatory environments and manufacturing capabilities that facilitate access to safe and effective vaccines in all countries.</b>	<p><b>NVD (Baxter):</b> suggest a new strategy to expand regional registration capabilities to support countries that do not have country specific registration resources.</p>
61	5.5.1 Promote and support the efforts of the World Health Organization to develop and harmonize international standards and norms to assure the quality, safety and efficacy of vaccines and to provide a predictable environment for vaccine development.	<p><b>SUNY, Albany (Bernarczyk):</b> International harmonization is addressed in 4.1.2, related to US supply. If these should both be kept in, there needs to be a clearer explanation why.</p>
61	5.5.2 Promote and support the efforts of the World Health Organization to improve regulatory capacity in countries with limited infrastructures to assure vaccine quality, evaluate new vaccines when appropriate and assure that clinical trials are conducted in accordance with Good Clinical Practices.	<p><b>NVD (Baxter):</b> NVD cautions a single solution approach to global standards and norms to assure vaccine quality, evaluate new vaccines when appropriate and assure that clinical trials are conducted in accordance with Good Clinical Practices could have the unintended consequence of decreasing access to vaccines in emerging markets. A single approach may raise barriers to the licensure and production of vaccines particularly if EMEA/CBER guidelines form the basis of these standards and norms.</p> <p><b>Canada Biologics (Griffiths):</b> The promotion and support of the efforts of the WHO to improve regulatory capacity in key developing countries, usually those with vaccine production capabilities, is thus very important and may not be quite the same as Strategy 5.5.2 which appears to deal with regulatory capacity in countries with more limited</p>

		<p>infrastructures, possibly those of the newly established African Vaccine Regulators Forum.</p> <p><b>SUNY, Albany (Bernarczyk):</b> International regulatory harmonization is addressed in 4.1.7, related to US supply. If these should both be kept in, there needs to be a clearer explanation why.</p>
61	5.5.3 Support efforts to harmonize international vaccine licensing regulations.	<p><b>SUNY, Albany (Bernarczyk):</b> International regulatory harmonization is addressed in 4.1.7, related to US supply. If these should both be kept in, there need to be a clearer explanation why.</p>
61	5.5.4 Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines and related technologies.	<p><b>JSI (Steinglass):</b> here you could add “effective vaccines <b>PRESENTED AND PACKAGED FOR SMOOTH INTRODUCTION INTO EXSTING VACCINATION PROGRAMS...</b>”</p> <p><b>Merck (Feinberg):</b> Insert ", in accordance with current Good Manufacturing Practices" at end of sentence (to mimic Strategy 5.5.2).</p> <p><b>Wyeth (Connolly, Eyles):</b> The provision of “technical assistance to developing country vaccine manufacturers” needs clarification regarding potential incentives as well as measures to ensure consistent quality, safety and effectiveness of vaccines.</p> <p><b>PATH (Elias) revise:</b> Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines and related <b>safe injection and waste management</b> technologies.</p>
61	<b>Objective 5.6: Build and strengthen multilateral and bilateral partnerships and other collaborative efforts to support global immunization and eradication programs</b>	<p><b>NVD (Baxter):</b> Strategies under this objective need to be more specific and evidence based. The strategies are too general.</p>
62	5.6.1 Participate in establishing global immunizations, priorities, goals and objectives and provide technical assistance at global, regional, and national forums.	<p><b>JSI (Steinglass):</b> add national <b>AND SUB-NATIONAL LEVELS</b>”</p>

62	5.6.2 Strengthen international collaborations for basic and applied research, especially onsite research in disease endemic areas or those with the greatest burden of disease.	
62	5.6.3 Work with global partners to establish an international system that facilitates rapid response to emerging infections through the development of vaccine reference strains and candidate vaccines.	
62	5.6.4 Contribute to development and implementation of a research agenda establishing the scientific basis for VPD eradication/elimination; identifying optimal vaccination approaches; and developing strategies to minimize risks in the post-eradication period.	<p><b>Canada Biologics (Griffiths):</b> Strategy 5.6.3 indicates a need to work with global partners to establish an international system that facilitates rapid response to emerging infections through the development of vaccine reference strains and candidate vaccines. It is also vital to ensure that adequate regulatory mechanisms are in place to deal with vaccines for rapidly emerging infections (eg pandemic influenza, SARS) where timelines may not allow for the normal product development cycle ( ie phase I II III clinical studies) . Mechanisms for greater international regulatory collaboration and work sharing in the event of regional or global involvement are critical.</p> <ul style="list-style-type: none"> <li>• Rapid timelines in the face of rapidly emerging epidemic/pandemic</li> <li>• Clinical evaluation for safety/efficacy difficult in absence/low level disease or if infection remains focal in nature</li> <li>• <b>Not possible to follow routine regulatory process</b></li> <li>• Need to facilitate the necessary regulatory process</li> <li>• Closer interaction between manufacturers and regulatory authorities from early stage of product development</li> <li>• <b>International dimension important, if global issue.</b></li> </ul> <p><b>JSI (Steinglass):</b> “identifying optimal vaccination approaches” should not be limited just to eradication/elimination approaches. Shouldn’t there similarly be a strategy related to contributing to development, implementation and research on <b>identifying vaccination approaches and strategies for the routine vaccination program?</b></p>
62	5.6.5 Build and strengthen bilateral and multilateral partnerships and other	<b>BD (Dugue): (revised):</b> Work with global partners to secure and maintain adequate stockpiles/strategic

	<p>collaborative efforts to support availability, access, sustainable financing, and use of current, underutilized, and new vaccines.</p>	<p>reserves of vaccines <b>and vaccine delivery systems</b> to maintain uninterrupted supply, for emergency response to outbreaks, and for special purposes.  <i>Rationale: To have an adequate supply of vaccines without an accompanying adequate supply of the required delivery system will lead to an insufficient response capacity. The addition of “vaccine delivery systems” to this strategy demonstrates the Nation’s understanding that vaccines and vaccine delivery systems are two separate components of the NVP. Moreover, the need to add “vaccine delivery systems” in the context of stockpiling for pandemics or bioterror events is even more critical due to the ability of novel delivery systems – such as single dose manufacturer-prefilled delivery systems – to minimize waste, save time, increase cost efficiency, optimize efficacy and reduce risks inherent in nonintegrated delivery systems.</i></p> <p><b>Every Child by Two (Amy Pisani):</b> Our prior experiences in Africa and our initial membership in the Measles Initiative led us to understand that there is a lack of coordination among NGOs that could be remedied with training and counsel by U.S. counterparts.</p> <p><b>PATH (Elias) revise:</b> Build and strengthen bilateral and multilateral partnerships and other collaborative efforts to support availability, access, sustainable financing, and use of current, underutilized, and new vaccines <b>and their delivery systems.</b></p>
62	<p>5.6.6 Work with global partners to secure and maintain adequate stockpiles/strategic reserves of vaccines to maintain uninterrupted supply, for emergency response to outbreaks, and for special purposes.</p>	<p><b>SUNY, Albany (Bernarczyk):</b> Does this reference US outbreaks, international outbreaks, or both?</p>
	<p>5.6.7 Work with global partners to develop a global advocacy agenda and create a positive environment for vaccine use.</p>	<p><b>SUNY, Albany (Bernarczyk):</b> What does this mean?</p> <p><b>Gates Foundation (Bates):</b> One could argue that Activity 5.6.7 (develop a global advocacy agenda) could be an explicit objective, since many of the activities that would emerge from the agenda – resource mobilization, political will, public awareness – will be critical to the success of the other Goal 5 objectives and activities. Assuming that the global agenda will remain an activity rather than a full objective, you may make the point that this component is a significant undertaking whose resource requirement does not convey as written. I would encourage the later implementation plan to provide some sense of priority among these many important activities.</p>

52-55	<p><b>Appendix 1. Anticipated outcomes from the 1994 National Vaccine Plan and the extent to which each has been achieved at the time the Federal Framework for a National Vaccine Plan was drafted in 2008</b></p>	<p><b>Merck (Feinberg):</b> Appendix, on Pneumococcal Vaccination: Revise last bullet that inaccurately characterizes the benefits of adult vaccination of pneumococcal vaccination (with polysaccharide vaccine)</p> <ul style="list-style-type: none"> <li>Appendix in row with heading “Some vaccines requiring multiple doses...”: Suggest the wording “has not affected access to immunization” be removed or softened in light of publications describing better vaccination coverage with use of combination vaccines (Marshall GS et al. Pediatric Infect Dis J 2007; 26 (6):496-500.</li> <li>In line with above, also do not agree that no evidence of cost effectiveness for combination vaccines.</li> </ul> <p><b>Gates Foundation (Orenstein):</b> I would urge you to include in an appendix, the legislation establishing the National Vaccine Program (NVP). The plan had nothing to do with any benefits to our program. No resources were associated with it. The original legislation had certain amounts that were authorized to be appropriated but never were. It would be interesting to adjust those amounts for today’s dollars and look at the gap between authorization and appropriation.</p> <p>On page 64, is that a 68% reduction in measles cases or in estimated measles deaths? It’s not clear whether that is from 1994 or some other period. In fact for a number of the items in this appendix, it is not clear what time frame, both beginning and ending, the data refer to.</p>
56-58	<p><b>Appendix 2: IOM committee recommendations from the June 11, 2008 letter report “Initial Guidance for an Update of the National Vaccine Plan: A Letter Report to the National Vaccine Program Office” and National Vaccine Program Office responses</b></p>	<p><b>AHIP (Bocchino):</b> AHIP and its member health insurance plans support an evidence-based approach to the development of routine vaccine recommendations that considers both clinical- and cost-benefit analyses. AHIP is pleased to participate in ACIP’s process of developing recommendations (i.e. through our liaison to ACIP), and we applaud the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices’ (ACIP) efforts to incorporate cost-effectiveness into its recommendations. Data from AHIP’s recent survey on the immunization practices and policies of health insurance plans indicate that private health insurance plans base vaccine coverage almost universally on ACIP recommendations.</p>
59-61	<p><b>Appendix 3: Key Stakeholders In the United States National Vaccine</b></p>	<p><b>AGS: Professional Medical Societies</b></p> <ul style="list-style-type: none"> <li>The AGS suggests that the Professional Medical Societies be expanded to state:</li> </ul>

<p><b>System</b></p>	<p>societies representing the health professions, local and national Infection Control Societies such as the Society for Healthcare Epidemiology of America and the Association for Practitioners of Infection Control and Epidemiology, and organizations representing health care settings such as the Association of Homes and Services for the Aging.</p> <p><b>BD (Dugue):</b> Given the impact that delivery systems have on vaccine administration, safety, efficiency and supply preservation, the medical technology industry should be included as a non-federal stakeholder in all appropriate plan goals and objectives.</p> <p><b>NALBOH (Fallon):</b> Add to the Stakeholders list – child care facilities and colleges/universities.</p> <p><b>American Federation of Teachers (Alexander):</b> We recommend that the committee more thoroughly investigate the potential role of occupational health and safety vaccination program approaches as a key component of improving over-all vaccination program efficacy. The National Institute for Occupational Safety and Health as well as the Occupational Safety and Health Administration would be excellent agencies to consult on vaccine programs especially in healthcare and other institutions where workers are likely to be exposed to infectious diseases preventable by vaccine.</p> <p><b>AAOHN (Kowalski):</b></p> <ul style="list-style-type: none"> <li>• Key stakeholders should not be limited to federal (CDC, USAID) or international (WHO), <u>but</u> professional organizations and agencies (administrators of vaccines), consumers (recipients of vaccines) and global immunization trends must be considered.</li> <li>• 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.</li> </ul> <p><b>AARC (Myers): Stakeholder’s Role</b></p> <ul style="list-style-type: none"> <li>• <u>Improving our grassroots efforts at the local level.</u> Our state societies have websites and newsletters and state conferences where the AARC can request state societies to</li> </ul>
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		<p>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.</p> <ul style="list-style-type: none"> <li>• <u>Using our section chiefs and “list serves” to enhance the delivery of timely, accurate and transparent information about the risks and benefits of vaccines and the vaccine program.</u> 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.</li> <li>• <u>Partnering with organizations like the COPD and Alpha 1 Foundations, the Asthma &amp; Allergy Foundation of America, the Pulmonary Education and Research Foundation (PERF) and others to promote the vaccine program.</u></li> <li>• <u>Using the AARC.org web site and YourLungHealth.com to frequently remind health care professionals and patients about the value of the vaccine program.</u> 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.</li> <li>• <u>Publishing articles in our magazine, AARC Times, to increase awareness of vaccine preventable diseases and the benefits and risks of flu and pneumococcal vaccines.</u> The AARC Times is a monthly magazine that is available to our members and the professional health care community.</li> <li>• <u>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.</u> 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.</li> <li>• <u>Developing information on the benefits and risks of getting vaccinated from the perspective of the respiratory therapists.</u> 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</li> </ul>
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		<ul style="list-style-type: none"> <li>• <u>Updating our human resources survey to include questions around the vaccine program.</u> Every five years, the AARC conducts a survey of its members to gather important statistics on a number of topics. 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.</li> </ul> <p><b>sanofi Pasteur (Hosbach):</b> We think it is important to strengthen the number and expertise of FDA staff that are knowledgeable about vaccine issues. There are relatively few experts dedicated to the study of vaccines, and a number of these are involved in clinical research with manufacturers. Perhaps there needs to be a way to more effectively utilize these experts, with full disclosure of their activity and transparency throughout the process. They are among the most knowledgeable observers, but often their views are not solicited or included in the policy debate.</p> <p>Private enterprise, particularly larger corporations, should be encouraged to view themselves as immunization stakeholders and often as immunization providers.</p> <ul style="list-style-type: none"> <li>• Good preventive care, including immunizations, helps keep employees healthy and “on the job.”</li> <li>• Workplaces can also provide a convenient channel for efficient vaccine delivery and greater emphasis should be placed on this in the report.</li> </ul>
62-70	<p><b>Appendix 4: Roles and Responsibilities of Department of Health and Human Services Agencies and Offices, and other federal Departments in the Federal Framework for a National Vaccine Plan</b></p>	<p><b>NACHC: Comments on stakeholders’ roles in the NVP:</b> Numerous stakeholders impact all of these goals, however the vaccine manufacturers need to address the issue of the high cost of new combination vaccines, the reduction of elimination of suitable less expensive vaccines and if this doesn’t occur then other stakeholders would need to weigh in on the issue.</p> <p><b>National Association of Chain Drug Stores (NACDS) (Khani): Comments on stakeholders’ roles in the NVP</b></p> <ul style="list-style-type: none"> <li>• Community pharmacies and pharmacists are the most accessible healthcare providers. Patients should have access to the most appropriate cost-effective medications to treat their particular medical conditions and should be able to choose where to obtain their prescription medications and pharmacy services, such as immunizations.</li> </ul>

- The practice of pharmacy has made great strides to expand beyond traditional dispensing of prescription medications and related devices to the provision of pharmacy-delivered services, including preventive offerings such as immunizations.

**NACHC: Stevens Comments on stakeholders' roles in the NVP**

- **Insurance companies:** pressure should be placed upon insurance companies to fully cover preventive medicine such as mandatory/required vaccinations. Insured parties should earn incentives for obtaining vaccinations as these put the insured party and the greater public at less risk for costly infectious diseases.
- **Traveler's health:** evaluate accelerated dosing plans for Hep A vaccines as most traveler's are unlikely to seek out Hep A vaccination 6 months prior to travel. On line airline purchase tickets for overseas travel should be linked to a website, perhaps the CDC, where a potential traveler can insert their destination and a spread sheet of the recommended prophylactic meds and necessary vaccines needed prior to travel is generated along with a link to local travel vaccine clinics.
- **Federally Qualified Health Centers:** Health professionals within these centers could be given incentives to link with school based nursing units to institute vaccine catch-up clinics at school grounds and/or at their clinic base. Incentivize these clinics for the total number of vaccines they administer not the percentage of coverage per patient. Our patients have chaotic lives and are often lost to follow up or change health providers; every encounter is considered an opportunity for catch-up vaccination so although this is the case a chart review might show that 45% of the patients have not been fully vaccinated. Additional burdens to the health care system are: vaccine shortages and manpower needs. As nurses are the primary administrators of vaccination, more time needs to be allotted for them to carry out this duty to ensure safe administration and proper documentation. Proper reimbursement for this activity would allow centers to hire the additional support staff they need.

**NACHC (O'Fallon): Comments on stakeholders' roles in the NVP**

- The state immunization programs should also be stakeholder. These groups implement the federal guidelines and work closely with the costs, other stakeholder, providers, and families.

	<p><b>Australia (Horvath): Comments on stakeholder roles</b>  General comments: the role of the following stakeholders in forming and shaping public attitude towards immunisation should not be underestimated:</p> <ul style="list-style-type: none"> <li>• The role of schools/educational system, churches and other faith-based institutions needs to be explored and developed;</li> <li>• The role of the anti-vaccination lobby should be acknowledged and managed.</li> </ul> <p><b>European CDC (Jakab): Comments on stakeholders' roles</b></p> <ul style="list-style-type: none"> <li>• As mentioned above safety issue are of highest priority at the ECDC and we hope to establish Immunization Information Systems enabling us to in collaboration with Member States develop Database Linked Safety systems at least in a few of the MS, preferably with a good geographical distribution. Europe has a long tradition in using combination vaccines and with the now increasing number of vaccines being used together with the established combination vaccines active surveillance of safety is necessary. A global collaboration on vaccination safety would be most welcome. ECDC, together with the European Commission is also discussing the possibility to support the GAVI in order to improve his international commitment in the field of immunisation.</li> </ul> <p><b>United Kingdom (Salisbury): Comments on stakeholders' roles</b></p> <ul style="list-style-type: none"> <li>• Please 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 organization can play in the Plan.</li> <li>• My concern is not the roles and responsibilities of individual agencies or stakeholders but the identification of how this project will be managed and by whom.</li> </ul> <p><b>Univ. of Iowa (Helms):</b> A centralized oversight process should be developed to identify which and how Federal/Non-Federal stakeholders will take the operational lead to organize and oversee data collection for Goals. I think the NVPO/NVAC could be wisely used to oversee and assure progress. NVPO/NVAC could also develop a centralized process to assemble and present periodic Plan progress reports.</p> <p><b>Bain &amp; Company, Inc. (Pasternak):</b></p>
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		<ul style="list-style-type: none"> <li>• The role of federal government agencies (and especially DHHS) in achieving the 5 goals should be clearly articulated for two reasons: 1) most of the stakeholders outside of the federal government represent a fragmented group of constituents (e.g., industry, providers, academia, public) and thus achieving their alignment around specific strategies will be less feasible than doing so by the federal government; 2) while input is being sought from the full range of stakeholders, the final decision on the elements of the plan rests with DHHS; thus its committed role in executing the proposed strategies and achieving the stated goals is important to articulate and appropriate to expect.</li> <li>• Better definition of the roles and responsible government agency would be helpful to the reader. A table that describes pathogen, research area, and which stage of support or funding will be helpful for industry to better target areas for research. Currently there does not seem to be definitive delineations on priorities between the different government agencies, and little detail on transfer of programs during the development process. It is encouraging that one of the targets for the new plan is to facilitate better communication and teamwork between government organizations and with the industry.</li> </ul>
71-72	<b>Appendix 5: HHS Agency and Other Federal Department Strategic Plans relevant to the Federal Framework for a National Vaccine Plan</b>	
	<b>General Comments</b>	<p><b>NACHC:</b> I am not clear on where the issue of opening up the VFC underinsured category to all VFC health care providers resides.</p> <p><b>Mayo Clinic (Poland):</b> We have a serious set of issues, many of which are not acknowledged within the document. I have called these the “The Six P’s”. These issues need to be both acknowledged and used to inform new policy:</p> <ul style="list-style-type: none"> <li>• Providers uninformed about vaccines</li> <li>• Public health and governmental authorities disconnected from patients and delivery of vaccines</li> <li>• Payers with a short-term focus</li> <li>• Pharma with an agenda</li> <li>• Politicians ignorant of public health needs</li> <li>• Parochialism throughout the system</li> </ul>

		<p>-Switch the method and focus of thinking and design of the system from Federal agencies to a focus on patients and their educational needs. “Patient-Centered Focus and Design”. IN this regard consider developing an “<u>Immunization Innovation Council</u>” populated by scientists, laypersons, psychologists, scientists, cultural anthropologists, engineers, and others to provide important advice and council, as well as representing different points of view.</p> <p>-Fund and require CDC, FDA, NVPO to design RFP/RFA/BAA’s that map to vaccine priority areas that need transformative change</p> <p style="text-align: center;"><b>The Future</b></p> <p>A new golden era of personalized “Predictive Vaccinology” whereby we:</p> <ul style="list-style-type: none"> <li>• <b>Abandon a “one size and dose fits all vaccine approach”</b></li> <li>• <b>Predict whether to give a vaccine based on likelihood of response</b></li> <li>• <b>Predict the likelihood of a significant adverse event to a vaccine</b></li> <li>• <b>Predict the number of doses likely to be needed to induce a response to a vaccine (HBV and measles examples)</b></li> <li>• <b>Design/develop new vaccines</b></li> </ul> <p><b>PRTM (Helming):</b> Further insight would be attainable through additional steps including:</p> <ul style="list-style-type: none"> <li>• Grouping projects by similar vaccine targets</li> <li>• Assessing platform and enabling technologies that can accelerate development of candidate vaccines</li> <li>• Applying portfolio analysis and management techniques to develop consensus priorities</li> </ul> <p><b>NVD (Baxter):</b> Research: A successful 10year strategy will require a non risk-averse, ambitious and aggressive scientific research and development program that delivers the next generation of vaccines.</p> <p><b>NVAC Discussion 2-6-09:</b> <u>General Comments:</u></p> <p>The National Vaccine Plan needs to have a broader, more comprehensive public education</p>
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		<p>campaign section. For example, CDC could develop a campaign discussing the value of vaccines because they are considered a credible source.</p> <p>-One participant felt that more money could be spent on vaccine safety to increase the confidence in consumers to vaccinate and therefore increase uptake of vaccines. Increased uptake is an important public health goal and would also be important to manufacturers (increased market). The participant asked vaccine manufacturers to speak to a point raised at the Institute of Medicine's expert committee meeting on February 2, 2009 on the National Vaccine Plan's Goal 3: Support informed vaccine decision-making by the public, providers, and policy-makers. The participant asked for clarification from industry as to the discrepancy between money spent by CDC on vaccine safety research (said to be \$20 million) and monies spent on vaccine promotion (said to be \$300 billion). The participant asked for a discussion on why, given the importance and need for increased money for safety research (as discussed at the earlier IOM meeting) more money is spent on communication for vaccine promotion versus safety.</p> <p>- Adults need to be included in the equation because of the importance of adult immunization. Also, adults in non-traditional settings (long-term care, institutionalized adults) need to be addressed.</p> <p><b>Australia (Horvath): General comments:</b></p> <ul style="list-style-type: none"> <li>• As global polio eradication ties in with the Global Polio Eradication Initiative, we would support this.</li> <li>• Reducing deaths from measles will require attention to improving the vaccination rates with MMR, and not only in developing countries.</li> <li>• It is commendable to improve dTpa coverage, however it should be noted that the Pa (pertussis) component needs booster doses to retain immunity.</li> <li>• The introduction of rotavirus vaccination will hopefully occur in African and other developing nations as it is the second largest cause of morbidity in children (after pneumonia).</li> <li>• Support for evidence based decisions on adding new vaccines to routine programs, as well as the monitoring of program quality, vaccination coverage and safety.</li> <li>• No new vaccines to be added to routine programs without support for appropriate surveillance both to monitor outcomes( reductions in notifications of that disease) as well as any unintended adverse events.</li> <li>• Suggest targeting measles polio and rotavirus globally as well as meningococcal disease in Africa.</li> </ul>
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		<p><b>Comments on the goals, objectives, and strategies:</b>  I agree with the existing goals and suggest the following:</p> <ul style="list-style-type: none"> <li>• A goal worthy of further consideration is improving accessibility and affordability of vaccines.</li> <li>• The increasing cost of new vaccines, if not effectively addressed could price vaccines out of the reach of those with the greatest need.</li> <li>• Affordability will be an important issue for vaccines targeting groups who might not consider immunisation a priority.</li> <li>• You may also wish to consider that a specific goal, objective and strategy be developed and implemented to ensure vaccine manufacturers are more efficient and produce vaccines at affordable prices. This is important given that the majority of the vaccine manufacturers are US-based and determine global vaccine prices, and Goal 5 refers to increased global prevention of death and disease through safe and effective vaccination. For example, without the activities of non-governmental and international organisations funding the purchase of vaccines in developing countries, immunization programs in these countries would be minimal.</li> </ul> <p><b>IDSA (Gershon):</b>  <b><u>Comments regarding the pending Implementation Plan</u></b>  <u>To assure the NVP's maximal impact, it is critically important that the Implementation Plan:</u></p> <p><b>1) Specify government lead(s) for each goal, with a primary lead specified where relevant.</b></p> <p><b>2) Include multi-year funding targets for each goal and objective.</b></p> <p><b>3) Require all federal agencies to consistently reference the NVP in their immunization-related initiatives, articulating all federal immunization-related programs and funding requests as vehicles for achieving the NVP's goals and objectives.</b> Requiring federal agencies to reference the NVP will build the Plan's credibility while also raising awareness within Congress of the importance of federal immunization activities. Also, if federal agencies consistently tie programs and initiatives to the NVP, this may aid bench-marking.</p> <p><b>4) Further articulate how NVPO will coordinate with key stakeholders in the development of certain objectives where considerable pre-existing stakeholder activity exists.</b> For instance, Strategy 1.1.1 calls for development of a process to prioritize</p>
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	<p>the needs for new vaccines. Presently, private sector vaccine manufacturers have their own informal prioritization schemas, which collectively represent an important “forecast” of vaccine research and development. NVPO should plan carefully for how government officials will interact with the private sector in the development of a national priority-setting process.</p> <p><b>JSI (Steinglass):</b> Page 71: <b>international organizations:</b> you could add a bullet “other technical organizations” to account for the stakeholders who provide technical assistance to other countries such as JSI, PATH, Hopkins, etc. You could add World Bank to the WHO, UNICEF line.</p> <p><b>NVD (Baxter):</b> The goals, objectives and strategies outlined in the Plan require significant funding allocations; however funding is not addressed in the Plan. NVD strongly suggest NVPO consider the financing aspect of the Plan and include suggestions on how funding, such as increase to Section 317 and CBER’s budget can be achieved.</p> <p>Overall, NVD suggests the Plan could be strengthened by focusing on objectives and strategies that:</p> <ul style="list-style-type: none"> <li>• Support regulatory processes which are flexible enough to allow innovation and predictable enough to ensure safe vaccines are brought to the market as quickly as possible.</li> <li>• Support and sustain increased federally-funded basic research to assure continued scientific advances which can contribute to development of new vaccines.</li> <li>• Simplify and improve finance and reimbursement mechanisms to increase vaccine choice, increase vaccination rates and address coverage gaps for individuals ineligible for vaccine access within existing programs.</li> </ul> <p><b>Merck (Feinberg): General comments:</b>  We provide the following general comments on the entire list of goals and indicators:</p> <ul style="list-style-type: none"> <li>• We strongly recommend that the plan provide a detailed implementation plan for the goals and indicators enumerated in the table below and in the plan. The implementation plan should specify agencies with lead responsibility for achieving the goal or sub-goals. In other words, the plan should provide a level of detail more granular than that specified on pages 28 to 61 of the document. Such a level of detail informs clearer thinking that should facilitate successful actualization of the indicators.</li> </ul>
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		<ul style="list-style-type: none"> <li>In addition, we recommend that the detailed implementation plan should integrate specific tasks for federal state and local agencies. The plan should also explicitly call on the agencies to collaborate to achieve the goals and indicators of the Plan.</li> </ul> <p><b>France (Didier Houssein):</b> The main current project concerns the elaboration of a national strategy to improve the individual and collective vaccine protection.</p> <p>The committee decided to direct the reflection on 3 axes close to some of general or operational objectives of the US plan:</p> <ol style="list-style-type: none"> <li>to improve data on vaccinations: in France, the difficulties concern more the collect of data on the vaccination coverage (delay for the data on children and the lack for those on adults) than on the side effects of vaccines (good organisation of the pharmacovigilance system and implementation of risk management plan for new recommended vaccines (against pneumocoques and HPV vaccine));</li> <li>to develop promotion of vaccinations (information, trainings and communication) for health professionals;</li> <li>to ease access to vaccination (from various aspects : geographical, budgetary, socio-cultural viewpoints and availability of vaccines).</li> </ol> <ul style="list-style-type: none"> <li>Various actions have already been conducted and first of all, it should be established a picture of what have already been done for these proposals in the 5 coming years.</li> <li>Move from mandatory vaccinations towards recommended vaccinations ;</li> <li>Evolution of recommendations on target populations, from general population to more specific groups;</li> <li>Willingness to make expertise more multi-disciplinary oriented, with the development of public health and societal approach (health economists, public health specialists, sociologists) ;</li> <li>Concern about experts' conflicts of interests : <ul style="list-style-type: none"> <li>with pharmaceutical companies, including a follow-up and a more in-depth control of public statements of interest,</li> <li>with competent authorities : recommendations from experts (HCSP) are published, whatever the subsequent ministerial decision.</li> </ul> </li> </ul> <p><b>Fred Hutchinson Cancer Research Center (Warden): I would change the order</b></p>
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		<p>_____ . I would make goal number two "enhance the safety of vaccines and vaccination practices" into goal number one. I would make goal number three "support informed vaccine decision making by the public providers and policymakers" into goal number two and I would make goal number one "develop new and improved vaccines" into goal number three. Since this document is likely to have a political as well as a planning dimension, it would seem best to acknowledge the concerns of the many people who are worried about vaccination and vaccines. I doubt that this modification would actually result in changes in the way the plan was administered, but might improve its acceptance by more of the general public.</p> <p><b>The government should develop a dedicated vaccine testing infrastructure</b> that is experienced in vaccine evaluation and clinical trial management related to vaccines. Similar to the HIV Vaccine Trials Network sponsored by the NIH and dedicated to the testing of AIDS vaccines, this type of infrastructure would provide the public a level of transparency and accountability related to the results of clinical trials and other vaccine testing. It would also reduce the up front costs to vaccine developers and manufacturers, as well as provide incentives for their continued work in vaccinology.</p> <p><b>Univ. of Iowa (Dr. Helms):</b> I believe the presentation of the broad goals of the Plan would better facilitate public understanding and support if the current order of goals were changed to the following order:</p> <ol style="list-style-type: none"> <li>1) Support informed vaccine decision making, etc.,</li> <li>2) Ensure a stable supply, etc.,</li> <li>3) Enhance safety, etc.,</li> <li>4) Develop new and improved vaccines,</li> <li>5) Increase global prevention of disease, etc.</li> </ol> <p><b>University of Pittsburgh (Zimmerman):</b> Academia could be a stakeholder in a wider range of the objectives.</p> <p><b>United Kingdom, Department of Health (Salisbury):</b></p> <ul style="list-style-type: none"> <li>• This is an extraordinarily ambitious set of goals and targets. What resources are going to be set aside? Even monitoring these multiple targets and outcomes is going to be hugely labour intensive, even if no new funds are provided for the</li> </ul>
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		<p>activities themselves. These are laudable objectives but there are no indications of how the resources are going to be identified and mobilised to achieve these goals.</p> <ul style="list-style-type: none"> <li>I am uncomfortable with much of the language used within this table and within the body of the text. In many of the targets, there are insensitivities about the role of the US as opposed to that of national governments or other international agencies, and there are numerous instances where the achievement of the goal is outside of the US' ability to deliver the outcome. Certainly, the US can contribute greatly, and already does so, but it is not appropriate for the US to define what indicators or outcomes should be in place in other countries. The outcomes that are being sought are appropriate – I would suggest the use of alternative language.</li> </ul> <p><b>Japan (Dr. Arita):</b></p> <ul style="list-style-type: none"> <li>From my experience in the smallpox eradication, namely the past" evidence oriented program." The critical evidence in polio has been that 75 to 85 % of polio cases were all in the age group of under 35 months, in other words, if you develop the herd immunity in children age group under three years, we can expect 80% reduction of the global incidence.</li> <li>Now for polio eradication,. why not we concentrate the OPV campaign in the age group, 0 to 34 months, specifically, the first three immunizations, up 14 months, instead of saying too broadly," children under five years". To do this , I would like to refer to the recommendation done by USAID in 1988 when the global PE started as shown below:</li> </ul> <ol style="list-style-type: none"> <li>OPV vaccination ; Birth as early as possible. usually BCG vaccination coverage has been the highest among EPI vaccines in Africa and Asia</li> <li>OPV vaccination ; 6 weeks with DPT</li> <li>OPV vaccination ; 10 weeks with DPT</li> <li>OPV vaccination ; 14 weeks with DPT</li> </ol> <p><b>ACIP (former member) (Finger):</b></p> <ul style="list-style-type: none"> <li>The action steps are very general in nature, and I think this must be by design. For</li> </ul>
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instance, there is not a lot of detail about such things as specific vaccine safety research projects, specific enhancements to VPD surveillance, and specific plans to move the IIS system ahead from where it is now, including communication of information from the IISs between the states. I assume these kinds of specifics will come later in other documents.

**NCIRS, Australia ( Leask):**

- **Comment 1**  
There could be more linkage between the goals and objectives. At present it is not clear which objective relates to which goal or how they are related.
- **Comment 2**  
There are also multiple objectives. These could be thematically condensed to make the plan more manageable.

**University of Maryland (Milstien):**

- Nowhere do I see any indication that the vaccine plan is going to be concerned with vaccine logistics, especially vaccine thermostability and the cold chain, which can affect vaccine safety, efficacy, and coverage. When was the last time there was a general cold chain review in the US? How will vaccines that are quite temperature sensitive, like rotavirus vaccines, be handled? How will vaccine administrators be able to handle new vaccines with differing characteristics? Why does the vaccine industry in the US place so little emphasis on basic thermostability characteristics?
- It is not particularly clear from the plan, who will assure the monitoring of implementation of the plan? Is it to be done only by the individual stakeholders, and/or by NVP and/or by some outside body such as the IOM? How is this to be done? How frequently? This needs to be clearly understood and agreed, or in fact there is no need to have a plan.
- Your plan suffers from the fact that what you are calling “Indicators” are not indicators. In most cases they are targets, although in some cases they are activities or strategies. An indicator would be, for example, “number of new candidate vaccines identified,” or the “existence of an updated Vaccine Table.” To be able to develop an implementation plan, the strategic plan needs to be clear, consistent, and able to be monitored.

**Gates Foundation (Orenstein):** the plan offered nothing to me in competing for

	<p>resources within my agency. For example, an initiative to help meet Healthy People objectives could help in supporting the fact that we were attempting to achieve a national goal and gave some advantages against those with initiatives not mentioned in Healthy People. Thus, it would be important to get some language in the implementation phase that any vaccine-related initiative would be judged against the plan.</p> <p><b>Institute for Global Health (Rutherford):</b> I thought the report was very well done but noted that there were no numeric targets that appeared in Table 1 or elsewhere in the report. I assume these are currently being debated. Secondly, I applaud the use of the Institute of Medicine report to guide many of the goals, objectives and strategies of the report; I think it provides an extra layer of credibility. Thirdly, I also strongly applaud the inclusion of Goal 5 and think that internationally is where substantial benefits can be achieved in the relatively short term using products that are already on the shelf. Fourthly, while I realize prevention of infectious diseases in non-human animals is beyond the scope of this report, I would suggest including it somewhere near page 17 where other disclaimers appear.</p> <p><b>Families Fighting Flu (Stein):</b></p> <ul style="list-style-type: none"> <li>• Add objectives or goals to the plan that focus specifically on eradication of influenza, enhancing the influenza vaccination program, increasing influenza vaccination rates, and ultimately protecting our nation’s children from the perils of influenza.</li> <li>• Ensure that Healthy People 2020 specifies childhood and universal influenza vaccination targets so that in aiming to reach or exceed these targets, the NVAC plan will be improving influenza vaccination penetration;</li> <li>• Enhance vaccine distribution to align supply with demand more accurately—both in terms of volume and timing.</li> </ul> <p><b>PATH (Elias):</b> given that vaccine research and development is ever-changing and quickly evolving, we would strongly recommend that the National Vaccine Plan be updated on a regular basis, with a new strategy planned in five year's time. Furthermore, a report midway through the timeframe of this plan on the progress in achieving the stated goals and objectives would go a long way in assessing US success, modifying our activities accordingly, and planning for the development of the next strategic plan.</p> <p><b>AAP (Tayloe, Bocchini):</b></p>
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		<ul style="list-style-type: none"> <li>• 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</li> <li>• How the National Vaccine Program Office (NVPO) should/would/could prioritize these goals in tight economic times with limited resources is unclear.</li> <li>• The use of technology to enhance achievement of these goals could be better articulated.</li> <li>• Does this plan adequately address how various credibility and Conflict of Interests issues will be managed?</li> <li>• 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).</li> <li>• 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.</li> <li>• The Academy encourages further review with all relevant stakeholders to reach consensus to successfully fill in the percentages in Table 1.</li> </ul> <p><b>AACP (Lang):</b></p> <ul style="list-style-type: none"> <li>• Should the plan be fully achievable, aspirational, or a combination of the two? 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.</li> <li>• 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.</li> <li>• Please comment on the overall vaccine and immunization enterprise. AACP recommends that the NVPO consider creating federal support for collaborative research initiatives that build upon the knowledge and skills of faculty researchers</li> </ul>
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- 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.

**AAOHN (Kowalski):**

- 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.

**PIDS (Shulman):**

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.

**HIDA (Ostrand):** The current prioritization of Goals 1-5 is appropriate. However, given the less than optimal utilization by healthcare workers of some vaccines (ex. influenza) it may be prudent to move 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*) to the Goal #1 position. By doing this, and by tackling the underutilization of existing vaccines, we can better ensure that the effort expended in developing new vaccines is maximized.

