

Comments received by the National Vaccine Program Office from Advocacy Groups on the draft strategic National Vaccine Plan through January 30, 2009.

General Comments:

Trust for America's Health

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. The coordinating office should ensure an open and reliable communication stream within and between departments. A model to follow would be the pairing of the National Pandemic Influenza Strategy with the National Pandemic Influenza Implementation plan, which included specific roles for each federal agency and budget requests from the White House for carrying out the plan, coordinated by Homeland Security Council. 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.

Finally, it is imperative that the NVPO integrate its planning with the large infusion of federal dollars (\$750 million proposed) into immunizations proposed in the Economic Recovery and Reinvestment Act pending in Congress. These additional one-time funds, to be spent over the next 18 months, provide the NVPO with a unique opportunity to ensure that more Americans receive the recommended schedule of vaccines. In particular, the NVPO should consider asking the Secretary to use some of this new funding to provide *every* adult American with an annual influenza vaccine in 2010. This would be an excellent trial-run for a severe pandemic influenza vaccination program.

Comments on Executive Summary and Introduction:

None

Goal 1 Comments: Develop new and improved vaccines

American Federation of Teachers (Darryl Alexander)

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.

The indicators for candidate vaccines should include an assessment of work-related exposure to the disease agent in the prioritization process

Objectives 1.1– 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.

Objective 1.2.4 strategy: 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.

Families Fighting Flu

Work toward developing an improved influenza vaccine, i.e, one-time or any-time administration, longer efficacy period, longer shelf life, etc.;

Trust for America's Health

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 they represent the world's most prevalent diseases: Combined, HIV/AIDS, TB and malaria account for approximately 500 million or more illnesses annually and at least six million deaths. Worldwide, an estimated 200 million have HCV. A severe influenza pandemic could result in nearly 2 million Americans and cause hundreds of millions to die worldwide.

TFAH applauds the National Vaccine Plan's emphasis on research and development of new vaccines, especially in regards to emerging, reemerging, and biodefense-related pathogens. In the 2008 report, *Germes Go Global: Why Infectious Diseases are a Threat to America*, TFAH emphasized that financial incentives are critical to catalyze private

sector development of vaccines. **Goal 1.2** 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.

TFAH also is encouraged that the National Vaccine Plan includes a long-term strategy for expanding use and development of vaccines, similar to a recommendation included in the *Germes Go Global* report. TFAH's report expanded on this notion, however, by recommending a government-wide infectious disease research agenda in collaboration with state and local public health partners, academia, and industry. A national vaccine strategy should be just one component of this broader plan.

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

American Federation of Teachers (Darryl Alexander)

Goal 2: Indicator – develop and disseminate plans for further investigation of AEFI signs should also include specific dissemination programs for any research conducted of AEFI signs in healthcare workers and other at risk worker populations that are being encouraged to be vaccinated. This specific research will help to reassure workers in educational programs that promote their participation in vaccination programs.

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

American Federation of Teachers (Darryl Alexander)

Goal 3: The measureable indicator on training programs for all health professional schools should include content on best practices for work-related exposure prevention as well as work-site vaccination programs for vaccine-preventable diseases and assessment of their knowledge of programs.

Objective 3.3, Objective 3.4; Objective 3.6; Objective 3.7: Include NIOSH and OSHA as well as trade unions and professional associations in the delivery of information to at risk worker populations targeted for vaccination.

Every Child by Two (Amy Pisani)

This goal aims to support informed vaccine decision-making by the public, providers, and policy makers.

We recommend adding the following indicator:

- x % of the public will report receipt of official health care messages via media sources (i.e. text, email, social networking, television, Internet)

Objectives: 3.1, 3.2, 3.3, 3.4, and 3.5 - Stakeholders should include: Academia and philanthropic organizations, both of whom play a major role in reaching the public with health care messages

We support objective 3.2 - utilizing collaborations and partnerships to leverage communication efforts. Increased communication among partners is critical to our efforts to inform the public regarding the latest research and findings on vaccine safety.

We strongly support objective 3.4.2, which seeks to maintain up-to-date, easily accessible web-based information... and 3.4.3, which seeks to utilize and evaluate new media to reach target audiences. 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.

We support increased focus on objective 3.5 which seeks to educate key decision and policy-makers about vaccines. Again ECBT conducts and will continue to conduct activities aimed at reaching this goal and encourages the role of federal agencies in this task.

Families Fighting Flu

Aggressively eliminate misconceptions and myths related to vaccine risks;

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. While it is important to continue to educate policy makers to ensure they are effective advocates and legislators, aiming simply to educate the public to make better vaccination decisions emasculates the policy making process and the policy makers themselves. Instead, trust the recommendations of the ACIP and scientific community upon which it leans and be clear in your message to consumers and medical providers. Do not overemphasize risks, but rather, promote recommended vaccinations and its empirically proven benefits. A December 2007 national poll on Children's Health conducted by C. S. Mott Children's Hospital in Michigan demonstrates the beneficial impact of communicating policy maker recommendations. The poll found that influenza vaccination rates among children age five and younger were better than in previous years, and nearly one-half of parents polled reported that the 2007-08 season was the first time they had vaccinated their children against the flu. This improvement immediately followed the ACIP's decision to expand the influenza vaccination recommendation for children from up to 23 months to five years of age.

3. 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. Consider that a survey conducted in September 2007 by the Visiting Nurse Associations of America found almost half (45%) of mothers of children under five do not get their kids vaccinated against influenza each year, and of these respondents, one-third said they did not think vaccination was necessary. People simply "don't know what they don't know." As parents of children killed by a vaccine preventable disease, we know firsthand how important vaccination is. We also believe firmly that if a parent has a true appreciation for the risks of the disease that he or she would almost always choose vaccination. Thus, we believe that measuring information dissemination by asking parents if they are satisfied with the information they have access to might be misleading. 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.

Hepatitis Foundation International (Corinna Dan)

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. This education must take place at the time of vaccination and should include information on why the vaccine is so important and the specific impact of disease on the body as well as the importance of completing vaccination series to prevent both acute and chronic diseases. There is a tremendous missed opportunity when you fail to educate patients at the time of vaccination. Kathy Schwartz, MD of Johns Hopkins Medical Center conducted a study to increase vaccination rates among homeless families and found an increase in hepatitis B vaccination rates among children when education about the importance of the liver was provided along with access to hepatitis B vaccination.

For example, the hepatitis B vaccination campaigns have failed to incorporate education and therefore patients fail to complete the series of three shots. Once informed of the importance of the liver, patients understand the rationale behind the need to complete the hepatitis B vaccine series. We have found that children and adults are more likely to complete the series if they are provided with information about the importance of the liver and the effects of hepatitis B on the liver at the time the series is initiated. Mothers who are chronically infected are not given education about preventing perinatal transmission or sexual transmission and so there is ongoing vertical transmission of hepatitis B in the US. Furthermore, parents who fear potential side effects of vaccination need this information to accept vaccination as a lifesaving tool.

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. Providers need to specifically explain the nature of the vaccine protection to engage patient compliance. This information should be provided during obstetrics visits so that parents are prepared for vaccination for hepatitis B at the time of delivery. Providers working with high risk populations, such as substance abusers, Asians and African Americans, should receive priority training. Additional specialties that should be targeted with vaccination education and training are pediatricians, adult/internal medicine doctors and family practice doctors, physician assistants, nurse practitioners, and nurses.

Trust for America's Health

Goal 3, to support informed vaccine decision-making by the public, providers, and policy-makers, reflects one of the new challenges in fighting preventable infectious diseases. 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. Culturally-specific marketing and education, partnerships with religious and community organizations, and new media should all be used to improve take-up rates. 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.

The outreach strategy should also include a goal for increasing vaccine usage among healthcare providers, who have particularly low rates of seeking seasonal influenza vaccines. In addition to education, such a goal should include working with hospitals, healthcare facilities, and public and private payers to develop incentives for healthcare professionals to become fully immunized.

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

American Federation of Teachers (Darryl Alexander)

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. Specifically, the committee might benefit from a discussion on the OSHA Blood-borne Pathogen Standard (29CFR 1910.1030) as a model program for broader work-site vaccination initiatives. The standard specifically mandates that employers who have workers exposed to blood-borne pathogens develop a comprehensive prevention program that includes education, training and an opportunity to receive the Hepatitis B vaccine series *after the training* or to *sign an informed declination*. We believe that this standard offers a reasonable road map to improving vaccination rates in healthcare worker populations as well as other high exposure risk populations (corrections workers, school employees etc.).

In the best of all worlds, there would be an OSHA standard for communicable and infectious diseases that would include provisions for comprehensive prevention programs with vaccination initiatives for diseases preventable by vaccine. In the absence of a standard, guidelines for work site programs based on the OSHA approach could be extremely effective for worker populations at risk. For instance, the threat of avian influenza looms large over poultry workers and other agricultural workers who are inadvertently exposed to infected animals. Should effective vaccines for avian influenza strains become available, we would recommend using the OSHA approach. We could also use such guidelines for TB exposure in corrections and school communities (two of the most densely populated institutions in our society). If and when a better and more universal TB vaccine becomes available, a comprehensive program that included training and information for workers as well as vaccination might be an effective method for reducing general incidence of new infection in those groups.

Goal 4: **Objective 4.5:** Include all the stakeholders mentioned above.

Strategies:

4.5.1: expand knowledge regarding the value of vaccination and the program of others including school nurses

4.5.6: broaden the strategy as follows: support research to evaluate the capacity of health care employers and other employers of at risk worker groups to implement worker vaccination recommendations

4.5.8: 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.

4.5.9 This strategy is not clear. If the strategy implies mandatory vaccination as a condition of employment, we recommend that 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.

Objective 4.6: NIOSH should be involved in the development of the process for developing and evaluating immunization recommendations.

4.6.1 – Highly recommend that you include all healthcare worker unions as a stakeholder for contributing input to new immunization policies and assessing existing policies.

Objective 4.7: 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.

We recommend an additional objective in this goal: **Objective 4.10: Enhance Immunization coverage of Workers who are at risk of Acquiring Vaccine-Preventable Diseases:** As we have stressed throughout these comments not enough attention has been focused on other at risk occupational groups who could benefit from vaccination for vaccine-preventable diseases such as those in corrections and schools.

Every Child by Two (Amy Pisani)

We also feel it is necessary to prioritize Goal 4, which seeks to ensure a stable supply of recommended vaccines and achieve better use of existing vaccines. We appreciate the inclusion of language within the Indicator portion regarding the percentage of Immunization Information Systems (IIS) that will include reminder and recall systems for vaccination. 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.

ECBT strongly supports Objective 4.1 which seeks to ensure consistent and adequate availability of vaccines. Vaccine shortages in recent years have, as you know, created confusion among the public and providers, rendering children vulnerable to vaccine preventable diseases. Shortages of *Haemophilus influenzae* type b (Hib) may have been a contributing factor (along with vaccine refusal) in the recent cases of Hib in Minnesota which has resulted in the death of a child. 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.

Goal 4.2.1 – We recommend the following wording edit “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.

Goal 4.2.2. – ECBT supports 1st dollar coverage of ACIP recommended vaccines for children and adolescents. Or, if this is not feasible define “minimal cost sharing”.

ECBT supports goals 4.2.7 ad 4.2.8 to expand access to vaccinations

As stated above we support 4.3.2 to improve the completeness of IIS and EMRs to monitor vaccination coverage. 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.

We strongly support all of the objectives under 4.5, many of which coincide with the Vaccine Financing Workgroup’s recommendations. We are willing to provide our assistance in ensuring their successful completion.

Objective 4.8’s stakeholders could include philanthropic organizations, public, citizen advocacy groups

Objective 4.9 suggested Strategy: 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”.

Families Fighting Flu

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. While most of the current draft plan focuses on broad vaccination efforts, both the draft and the 1994 plan also emphasize improving the success of specific disease immunization efforts such as polio, measles, and DTP3. Influenza causes more deaths every year than all other vaccine preventable diseases combined. However, influenza may be the most publically underestimated disease today. Furthermore, influenza's instability and seasonality and the relative logistical complexity of the influenza vaccination and surveillance processes have all helped to suppress influenza vaccination rates and immunization program effectiveness. The influenza references in the NVAC plans included to-date have all focused on the elderly, yet the evidence demonstrates that children, particularly those under the age of 5, are every bit as vulnerable as the elderly. Furthermore studies demonstrate that children are the group most likely to spread influenza to others, including adults. For this reason, we believe that assuring that all children receive annual influenza vaccinations be added to the plan as a stated objective. In addition, we would like to see the NVAC and its constituents:

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;

Enhance vaccine distribution to align supply with demand more accurately—both in terms of volume and timing.

Trust for America's Health

TFAH is pleased that the National Vaccine Plan acknowledges that financial and non-financial barriers to vaccines remain. Evidence of such barriers includes the remaining disparities in vaccine access among adults, the high cost of HPV vaccines. Education of providers about benefits of vaccines is important, but education paired with financial incentives and information about vaccine assistance programs for low-income or underinsured adults would be more effective. The NVPO should partner with public and private payers to ensure adequate reimbursement of clinicians (**Goal 4.5.5**) for vaccine delivery and abundant information about available assistance programs. Enhancing the effectiveness of immunization programs (**Goal 4.8**) should also include robust investment in private and public assistance programs, such as the 317 Program.

Related to the goal of stockpiling appropriate vaccines (**Goal 4.1.5**), the National Vaccine Plan should include a goal to stockpile syringes and other supplies necessary to deliver vaccines.

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

Every Child by Two (Amy Pisani)

This goal seeks to increase global prevention of death and disease through safe and effective vaccination.

Every Child By Two currently conducts limited international vaccine initiatives due to our need to prioritize vaccine safety education initiatives for the U.S. public. However, 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. Initial ECBT efforts to aid in the creation of “coalitions” in nations such as Zimbabwe and Cote D’Ivoire were met with much enthusiasm by NGOs, however these efforts were cut short due to political strife. While we do not have expertise in the area of international vaccine we thought it worth mentioning our experiences and suggest adding an objective to this end. Perhaps this would fall within objectives 5.6.5 and 5.6.7

Comments on Appendices:

None

Complete Comments by Stakeholder Sector – Advocacy Groups

American Federation of Teachers (Darryl Alexander)

On behalf of the 1.5 million members of the American Federation of Teachers, I am submitting comments on the Draft National Vaccine Plan. Our members include over 70,000 healthcare workers (primarily registered nurses, R.N.s in acute care settings) as well as teachers, school nurses, other school related personnel and public employees. The work of the National Vaccine Advisory Committee on the Draft National Vaccine Plan has just very recently come to our attention. We have not had the opportunity to thoroughly review the draft, but would like an opportunity to offer some preliminary recommendations to the committee.

We commend the committee for its work and attention to this very critical issue. We share the broad goals and objectives of the committee to improve vaccine research, development, program implementation and education.

In this letter, we offer general recommendations for the process. In addition, we have comments on the general indicators by goal. Finally we offer more specific comments on goal 4 objectives.

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. Specifically, the committee might benefit from a discussion on the OSHA Blood-borne Pathogen Standard (29CFR 1910.1030) as a model program for broader work-site vaccination initiatives. The standard specifically mandates that employers who have workers exposed to blood-borne pathogens develop a comprehensive prevention program that includes education, training and an opportunity to receive the Hepatitis B vaccine series *after the training* or to *sign an informed declination*. We believe that this standard offers a reasonable road map to improving vaccination rates in healthcare worker populations as well as other high exposure risk populations (corrections workers, school employees etc.).

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the most densely populated institutions in our society). If and when a better and more universal TB vaccine becomes available, a comprehensive program that included training and information for workers as well as vaccination might be an effective method for reducing general incidence of new infection in those groups.

Here are some specific comments in that vein on the measurable indicators and objectives by goal:

Goal 1: Develop new and improved vaccines

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.

The indicators for candidate vaccines should include an assessment of work-related exposure to the disease agent in the prioritization process

Objectives 1.1– 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.

Objective 1.2.4 strategy: 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.

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Goal 3: The measurable indicator on training programs for all health professional schools should include content on best practices for work-related exposure prevention as well as work-site vaccination programs for vaccine-preventable diseases and assessment of their knowledge of programs.

Objective 3.3, Objective 3.4; Objective 3.6; Objective 3.7: Include NIOSH and OSHA as well as trade unions and professional associations in the delivery of information to at risk worker populations targeted for vaccination.

Goal 4: **Objective 4.5:** Include all the stakeholders mentioned above.

Strategies:

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We encourage the committee to invite the occupational health and safety professionals of the public health community to participate in the process of development of the national vaccine program. We believe that our collective experience of work site programs may help in the broadening of the program.

Thank you for the opportunity to submit comments. If other opportunities arise, we will be happy to submit more detailed comments as well as documentation.

Sincerely,

Darryl Alexander
Program Director
AFT Health and Safety Program

Every Child by Two (Amy Pisani)

Every Child By Two would like to thank the committee for requesting our input into the Draft National Vaccine Plan, which we have reviewed in detail. We are very impressed with the thoughtful and detailed consideration of national priorities that are incorporated into the draft plan and have only a few additions and comments to provide to the committee at this time. We will be attending the meeting in February where the plan will be discussed in further detail. As we gain a broader understanding of the priorities and goals of the plan we will provide public comment if needed.

As you may be aware, Every Child By Two (ECBT) was founded in 1991 to raise parental awareness about the critical importance of timely immunization, foster establishment of a systematic method to locate and immunize children and provide convenient access to immunization services into the future.

Our efforts to educate parents about timely immunizations have become increasingly complicated in recent years due to the prevalence of misinformation regarding the safety of vaccines within television and print media and via the Internet. In response to this, we have focused much of our efforts in recent years on public education campaigns. We have reached out to policy makers, parents, journalists and television producers about the critical importance of following the recommended immunization schedules. We have developed a campaign that seeks to provide the public with access to credible scientific information on which to base their healthcare decisions and we have disseminated public service announcements nationwide which have been viewed by millions of Americans. Public education efforts are of paramount importance to ensure the timely immunization of every child and we strongly support prioritization of Goal 3 within the plan.

We also continue our efforts to foster systematic methods to locate children and reduce barriers to access. We work with coalitions and health department personnel at the both the city and state levels on numerous initiatives aimed at raising and maintaining immunization rates. Our experiences in the states have provided us much insight into the complexity of the immunization delivery systems and the barriers faced by families throughout the nation. To this end we strongly support national efforts to remedy the looming vaccine financing crisis, which threatens to dismantle our immunization program. Therefore, we also recommend high prioritization of Goal 4 and provide specific comments below.

Goal 3

This goal aims to support informed vaccine decision-making by the public, providers, and policy makers.

We recommend adding the following indicator:

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Objectives: 3.1, 3.2, 3.3, 3.4, and 3.5 - Stakeholders should include: Academia and philanthropic organizations, both of whom play a major role in reaching the public with health care messages

We support objective 3.2 - utilizing collaborations and partnerships to leverage communication efforts. Increased communication among partners is critical to our efforts to inform the public regarding the latest research and findings on vaccine safety.

We strongly support objective 3.4.2, which seeks to maintain up-to-date, easily accessible web-based information... and 3.4.3, which seeks to utilize and evaluate new media to reach target audiences. 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.

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Goal 4

We also feel it is necessary to prioritize Goal 4, which seeks to ensure a stable supply of recommended vaccines and achieve better use of existing vaccines. We appreciate the inclusion of language within the Indicator portion regarding the percentage of Immunization Information Systems (IIS) that will include reminder and recall systems for vaccination. 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.

ECBT strongly supports Objective 4.1 which seeks to ensure consistent and adequate availability of vaccines. Vaccine shortages in recent years have, as you know, created confusion among the public and providers, rendering children vulnerable to vaccine preventable diseases. Shortages of *Haemophilus influenzae* type b (Hib) may have been a contributing factor (along with vaccine refusal) in the recent cases of Hib in Minnesota which has resulted in the death of a child. 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.

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ECBT supports goals 4.2.7 ad 4.2.8 to expand access to vaccinations

As stated above we support 4.3.2 to improve the completeness of IIS and EMRs to monitor vaccination coverage. 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.

We strongly support all of the objectives under 4.5, many of which coincide with the Vaccine Financing Workgroup’s recommendations. We are willing to provide our assistance in ensuring their successful completion.

Objective 4.8’s stakeholders could include philanthropic organizations, public, citizen advocacy groups

Objective 4.9 suggested Strategy: 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”.

Goal 5

This goal seeks to increase global prevention of death and disease through safe and effective vaccination.

Every Child By Two currently conducts limited international vaccine initiatives due to our need to prioritize vaccine safety education initiatives for the U.S. public. However, 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. Initial ECBT efforts to aid in the creation of “coalitions” in nations such as Zimbabwe and Cote D’Ivoire were met with much enthusiasm by NGOs, however these efforts were cut short due to political strife. While we do not have expertise in the area of international vaccine we thought it worth mentioning our experiences and suggest adding an objective to this end. Perhaps this would fall within objectives 5.6.5 and 5.6.7

Again, thank you for allowing us to comment on this National Vaccine Plan.

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Families Fighting Flu

Thank you for inviting Families Fighting Flu (FFF) to comment on the draft NVAC strategic plan. We applaud the NVAC for developing such an ambitious and well-thought plan, and we are hopeful that the momentum created by the 1994 plan continues. We have four requests for the NVAC to consider as it finalizes the current plan:

1. 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. While most of the current draft plan focuses on broad vaccination efforts, both the draft and the 1994 plan also emphasize improving the success of specific disease immunization efforts such as polio, measles, and DTP3. Influenza causes more deaths every year than all other vaccine preventable diseases combined. However, influenza may be the most publically underestimated disease today. Furthermore, influenza’s instability and seasonality and the relative logistical complexity of the influenza vaccination and surveillance processes have all helped to suppress influenza vaccination rates and immunization program effectiveness. The influenza references in the NVAC plans included to-date have all focused on the elderly, yet the evidence demonstrates that children, particularly those under the age of 5, are every bit as vulnerable as the elderly. Furthermore studies demonstrate that children are the group most likely to spread influenza to others, including adults. For this reason, we believe that assuring that all children receive annual influenza vaccinations be added to the plan as a stated objective. In addition, we would like to see the NVAC and its constituents:

- a. 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;
- b. Work toward developing an improved influenza vaccine, i.e, one-time or any-time administration, longer efficacy period, longer shelf life, etc.;
- c. Aggressively eliminate misconceptions and myths related to vaccine risks;
- d. Enhance vaccine distribution to align supply with demand more accurately—both in terms of volume and timing.

2. 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. While it is important to continue to educate policy makers to ensure they are effective advocates and legislators, aiming simply to educate the public to make better vaccination decisions emasculates the policy making process and the policy makers themselves. Instead, trust the recommendations of the ACIP and scientific community upon which it leans and be clear in your message to consumers and medical providers. Do not overemphasize risks, but rather, promote recommended vaccinations and its empirically proven benefits. A December 2007 national poll on Children’s Health conducted by C. S. Mott Children’s Hospital in Michigan demonstrates the beneficial impact of communicating policy maker recommendations. The poll found that influenza vaccination rates among children age five and younger were better than in previous years, and nearly one-half of parents polled reported that the 2007-08 season was the first time they had vaccinated their children against the flu. This improvement immediately followed the ACIP’s decision to expand the influenza vaccination recommendation for children from up to 23 months to five years of age.

3. Do not let apathy of uninformed consumers cloud assessments of whether consumers are making informed decisions. Specifically, regarding Goal #4, 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. Consider that a survey conducted in September 2007 by the Visiting Nurse Associations of America found almost half (45%) of mothers of children under five do not get their kids vaccinated against influenza each year, and of these respondents, one-third said they did not think vaccination was necessary. People simply “don’t know what they don’t know.” As parents of children killed by a vaccine preventable disease, we know firsthand how important vaccination is. We also believe firmly that if a parent has a true appreciation for the risks of the disease that he or she would almost always choose vaccination. Thus, we believe that measuring information dissemination by asking parents if they are satisfied with the information they have access to might be misleading. 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.

4. Look to FFF to enhance advocacy efforts. We, as parents, understand firsthand the consequences of not vaccinating our children. We also know that parents, caregivers, medical providers, and policy makers, if given the benefit of our perspective in addition to scientific studies from respected organizations, will clearly recognize the importance of vaccination and how the benefits outweigh current costs, hassles, and perceived risks.

FFF's organizational objectives are to:

a. Reduce the number of childhood hospitalizations (more than 20,000 under age five) and deaths (more than 400 over last five flu seasons) caused by influenza each year by educating people about the importance of annual influenza vaccination in children; and

b. Increase the number of children vaccinated annually against influenza.

FFF is already an accomplished advocacy organization, and though both our funding and resources are limited, we are rich in personal experience. Thus, we hope to be able to work with larger groups and lend our stories to their communication and advocacy efforts to maximize both reach and effectiveness. We ask the NVAC, as plan developers, administrators, and facilitators, to help FFF and to support these efforts by ensuring stakeholders assigned with communications responsibility are encouraged to leverage FFF. The NVAC and its supporting organizations face great challenges in implementing the current plan, and we appreciate that our requests will likely add to the complexities of these challenges. However, we believe that these issues are critical to the success of the NVAC's charter and intentions, and we look forward to working with the NVAC and its other constituents to continue to develop the nation's vaccination program and protect our society, ourselves, and our children.

Sincerely,

Gary D. Stein

Founding Board Member

Families Fighting Flu, Inc.

Father of Jessica Stein (1997-2002)

Families Fighting Flu, Inc. Executive Committee

Richard Kanowitz

Father of Amanda Kanowitz

Joe Lastinger

Father of Emily Lastinger

Doris Stein

Mother of Jessica Stein

Families Fighting Flu, Inc. Board of Directors

Rick Cerett

Grandfather of Marques Jackson

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Mother of Amanda Kanowitz
Jennifer Lastinger
Mother of Emily Lastinger

Diane McGowan
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Daena Nicholas
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Gary Palmer
Father of Breanne Palmer

John Vittas
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Hepatitis Foundation International (Corinna Dan)

National Vaccine Plan Comments from:
The Hepatitis Foundation International

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. This education must take place at the time of vaccination and should include information on why the vaccine is so important and the specific impact of disease on the body as well as the importance of completing vaccination series to prevent both acute and chronic diseases. There is a tremendous missed opportunity when you fail to educate patients at the time of vaccination. Kathy Schwartz, MD of Johns Hopkins Medical Center conducted a study to increase vaccination rates among homeless families and found an

increase in hepatitis B vaccination rates among children when education about the importance of the liver was provided along with access to hepatitis B vaccination.

For example, the hepatitis B vaccination campaigns have failed to incorporate education and therefore patients fail to complete the series of three shots. Once informed of the importance of the liver, patients understand the rationale behind the need to complete the hepatitis B vaccine series. We have found that children and adults are more likely to complete the series if they are provided with information about the importance of the liver and the effects of hepatitis B on the liver at the time the series is initiated. Mothers who are chronically infected are not given education about preventing perinatal transmission or sexual transmission and so there is ongoing vertical transmission of hepatitis B in the US. Furthermore, parents who fear potential side effects of vaccination need this information to accept vaccination as a lifesaving tool.

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. Providers need to specifically explain the nature of the vaccine protection to engage patient compliance. This information should be provided during obstetrics visits so that parents are prepared for vaccination for hepatitis B at the time of delivery. Providers working with high risk populations, such as substance abusers, Asians and African Americans, should receive priority training. Additional specialties that should be targeted with vaccination education and training are pediatricians, adult/internal medicine doctors and family practice doctors, physician assistants, nurse practitioners, and nurses.

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Trust for America's Health

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(1) Comments on priorities for the National Vaccine Plan for a ten-year period: What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you?

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 they represent the world's most prevalent diseases: Combined, HIV/AIDS, TB and malaria account for approximately 500 million or more illnesses annually and at least six million deaths. Worldwide, an estimated 200 million have HCV. A severe influenza pandemic could result in nearly 2 million Americans and cause hundreds of millions to die worldwide.

(2) Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period: Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Goal 1 – Research

TFAH applauds the National Vaccine Plan's emphasis on research and development of new vaccines, especially in regards to emerging, reemerging, and biodefense-related pathogens. In the 2008 report, *Germs Go Global: Why Infectious Diseases are a Threat to America*, TFAH emphasized that financial incentives are critical to catalyze private sector development of vaccines. **Goal 1.2** 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.

Goal 3 – Education and Outreach

Goal 3, to support informed vaccine decision-making by the public, providers, and policy-makers, reflects one of the new challenges in fighting preventable infectious diseases. 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. Culturally-specific marketing and education, partnerships with religious and community organizations, and new media should all be used to improve take-up rates. 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.

The outreach strategy should also include a goal for increasing vaccine usage among healthcare providers, who have particularly low rates of seeking seasonal influenza vaccines. In addition to education, such a goal should include working with hospitals, healthcare facilities, and public and private payers to develop incentives for healthcare professionals to become fully immunized.

Goal 4 – Improve Supply and Access

TFAH is pleased that the National Vaccine Plan acknowledges that financial and non-financial barriers to vaccines remain. Evidence of such barriers includes the remaining disparities in vaccine access among adults, the high cost of HPV vaccines. Education of providers about benefits of vaccines is important, but education paired with financial incentives and information about vaccine assistance programs for low-income or underinsured adults would be more effective. The NVPO should partner with public and private payers to ensure adequate reimbursement of clinicians (**Goal 4.5.5**) for vaccine delivery and abundant information about available assistance programs. Enhancing the effectiveness of immunization programs (**Goal 4.8**) should also include robust investment in private and public assistance programs, such as the 317 Program.

Related to the goal of stockpiling appropriate vaccines (**Goal 4.1.5**), the National Vaccine Plan should include a goal to stockpile syringes and other supplies necessary to deliver vaccines.

Multi-year Planning and Implementation

TFAH also is encouraged that the National Vaccine Plan includes a long-term strategy for expanding use and development of vaccines, similar to a recommendation included in the *Germs Go Global* report. TFAH's report expanded on this notion, however, by recommending a government-wide infectious disease research agenda in collaboration with state and local public health partners, academia, and industry. A national vaccine strategy should be just one component of this broader plan.

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. The coordinating office should ensure an open and reliable communication stream within and between departments. A model to follow would be the pairing of the National Pandemic Influenza Strategy with the National Pandemic Influenza Implementation plan, which included specific roles for each federal agency and budget requests from the White House for carrying out the plan, coordinated by Homeland Security Council. 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.

Finally, it is imperative that the NVPO integrate its planning with the large infusion of federal dollars (\$750 million proposed) into immunizations proposed in the Economic Recovery and Reinvestment Act pending in Congress. These additional one-time funds, to be spent over the next 18 months, provide the NVPO with a unique opportunity to ensure that more Americans receive the recommended schedule of vaccines. In particular, the NVPO should consider asking the Secretary to use some of this new funding to provide *every* adult American with an annual influenza vaccine in 2010. This would be an excellent trial-run for a severe pandemic influenza vaccination program.