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

General Comments:

PATH (Christopher J. Elias, MD, MPH)

"…, 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."

Comments on Executive Summary and Introduction:

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

[Page 23, paragraph 2:]
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.

Goal 1 Comments: Develop new and improved vaccines

PATH (Christopher J. Elias, MD, MPH)

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.

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

[Page 28, Goal 1:]
Among these strategies, it seems that there should be something on cost effectiveness, cost utilization types of studies as part of the prioritization scheme.

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

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

Goal 2:

- By X year, X % of infants, children, adolescents, adults, and pregnant women will be under active surveillance for AEFIs

"… this sounds great, but active surveillance, really?? I've looked downstream in the document and don't see mention of how this might be accomplished. It seems that some idea of how this would be done would be worth mentioning

[Page 32, Goal 2:]
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[Page 35, Goal 2, Strategy 2.1.4: Strategy 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.]

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?

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

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

[Page 43, Goal 3, Strategy 3.3.1: Enhance communication of scientific findings about vaccine safety and effectiveness studies to the public, partners, and providers in a clear, transparent and timely manner.]

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??

[Page 45, Goal 3, Strategy 3.6.4: Determine the most effective and efficient mechanisms to communicate to health care providers about reporting to VAERS.]

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.

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

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

[Page 49, Goal 4, Strategy 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.]

Great idea, but how is this expected to be accomplished? Some speculation should probably be made if possible.

[Page 50, Goal 4, Strategy 4.1.4: Improve vaccine ordering, distribution and tracking systems for routine use, for public health emergencies, and for management of supply disruptions.]

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.

[Page 50, Goal 4, Strategies under Objective 4.2: Reduce financial and non-financial barriers to vaccination.]

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.

[Page 51, Goal 4, Strategy 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.]

Absolutely right. My question here is whether there is anything that can be said as to how this will actually happen.

[Page 52, Goal 4, Strategies 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)., and

4.5.2 Improve counseling and referral of patients for immunization by healthcare providers who do not offer immunization services.]

How should be speculated on for 4.5.1 and 4.5.2.

[Page 53, Goal 4, Objective 4.6: Maintain a strong, science-based, transparent process for developing and evaluating immunization recommendations.]

For all of these in 4.6 I think speculation as to how would help.

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

PATH (Christopher J. Elias, MD, MPH)

While the plan states that it is not intended to focus on vaccines for diseases with "non-infectious outcomes," we were surprised not to see the human papilloma virus (HPV) vaccine listed alongside meningococcal, rotavirus, and pneumococcal vaccines. HPV is a sexually transmitted disease (STD) that contributes to approximately 250,000 lives lost among women each year, with most deaths occurring in the developing world. The exclusion of HPV vaccine, attributed to statute's current definition, suggests a need for a waiver to the current statute, or a formal revision of the statute, to bring it up to date with modern vaccination options. We recommend that you add HPV to the list of vaccines that should receive support for introduction.

The need for a sufficient supply of affordable vaccines in the developing world must compel us to look at innovative and creative methods of manufacturing new products. 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.

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.

In addition to these broader recommendations, I have attached a document that includes specific edits to the draft vaccine plan that we have collected from several groups working on vaccine development and delivery at PATH. I understand that you may have already received some of these edits directly from staff, but we thought it might be helpful to receive them all in one document as well.

PATH Suggested Edits to Draft Strategic National Vaccine Plan [suggested edits are in bold type]

Goals Indicators (Pg. 13)

Support introduction of new vaccines as part of national vaccination programs:

• **Group A meningococcal conjugate vaccine** in all African countries in the "meningitis belt" by **2019;**

Note: This change is being suggested because an affordable ($US< 0.50 per dose) conjugate Men A vaccine has been developed and will be introduced in meningitis belt countries beginning in 200912010. The strategy has been approved by WHO, UNICEF,

and GA VI. All meningitis belt countries should be either partially or totally covered by 2019.

Goals Indicators (Pg. 57)

• Transmission of wild polio virus will be eradicated by Y (year).

• Mortality from measles will be reduced by X% by Y (year) compared with a X (year) baseline.

• 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).

• Support introduction of new vaccines as part of national vaccination programs:

• **Group A meningococcal conjugate vaccine** in all African countries in the "meningitis belt" by **2019;**

• Rotavirus vaccine in X countries by Y (year); and

• Pneumococcal conjugate vaccine in Z countries by Y (year).

• X countries establish immunization advisory committees by Y (year) that make evidence based decisions on adding new vaccines to the routine program and monitor program quality, vaccination coverage, and vaccine safety.

• 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), **safety boxes. and sufficient capacity to treat resulting shams and other infectious waste** for all immunizations.

Objective 5.2 (Pg. 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, monitoring, and program evaluation.

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, **safety boxes. and final waste treatment systems.**

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.

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).

Objective 5.3 (Pg. 60)

5.3.3 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 **safe delivery of** new vaccines into routine programs.

5.3.4 Conduct post-licensure evaluations of the impact of new vaccines on immunization programs, disease patterns, and the occurrence of AEFI.

***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)**

Objective 5.5 (Pg. 61)

5.5.4 Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines and related **safe injection and waste management** technologies.

Objective 5.6 (Pg. 62)

5.6.5 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 **and their delivery systems.**

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

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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.

[Page 58, Goal 5, Strategies under Objective 5.1.: Improve global surveillance for VPDs and strengthen health information systems to monitor vaccine coverage, effectiveness, and safety.]

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.

Comments on Appendices:

Pediatric Dengue Vaccine Initiative (William Letson)

[Comments copied from insertions in a copy of the draft Plan:]

- [Page 63, Appendix 1: Vaccine-type invasive pneumococcal disease has been reduced by 92% in all ages.]

This is true and good. It might be beyond the point, but it has become clear that there is an increase in non vaccine serotypes in many locales now. That might be acknowledged.

Complete Comments by Stakeholder Sector – Global Partners

PATH (Christopher J. Elias, MD, MPH)

On behalf of PATH, I would like to commend you and the rest of the staff at the National Vaccine Program at the United States Department of Health and Human Services for the thorough job you have done developing the most recent draft of the strategic National Vaccine Plan. While including quite a bit of complex information, the document remains both well structured and highly accessible.

As a nonprofit organization dedicated to improving global health, we applaud the strong emphasis in the document on the use of vaccines to prevent global diseases and appreciate the opportunity to provide recommendations for its further development. We were also pleased at the recognition of the imperative of pandemic preparedness. Additionally, the plan's recognition of the need to support decision making in developing countries for the planning of introduction of new vaccines is a critically important component that we were glad to see included.

After reviewing the draft plan, there are several specific recommendations that we would like to offer for consideration:

1. While the plan states that it is not intended to focus on vaccines for diseases with "non-infectious outcomes," we were surprised not to see the human papilloma virus (HPV) vaccine listed alongside meningococcal, rotavirus, and pneumococcal vaccines. HPV is a sexually transmitted disease (STD) that contributes to approximately 250,000 lives lost among women each year, with most deaths occurring in the developing world. The exclusion of HPV vaccine, attributed to statute's current definition, suggests a need for a waiver to the current statute, or a formal revision of the statute, to bring it up to date with modern vaccination options. We recommend that you add HPV to the list of vaccines that should receive support for introduction.

2. The need for a sufficient supply of affordable vaccines in the developing world must compel us to look at innovative and creative methods of manufacturing new products. 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.

3. 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.

4. 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.

5. In addition to these broader recommendations, I have attached a document that includes specific edits to the draft vaccine plan that we have collected from several groups working on vaccine development and delivery at PATH. I understand that you may have already received some of these edits directly from staff, but we thought it might be helpful to receive them all in one document as well.

6. Finally, 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.

Again, many thanks for the opportunity to provide our thoughts and recommendations. Please do not hesitate to contact me or Rachel Wilson, PATH's director of policy and advocacy (rwilson@path.org), at any point in the future should you have any questions about these recommendations or require additional information.

Christopher J. Elias, MD, MPH President and CEO

PATH Suggested Edits to Draft Strategic National Vaccine Plan [suggested edits are in bold type]

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