The United States thanks the Director-General, the Pandemic Influenza Preparedness (PIP) Framework Secretariat and the members of the PIP Framework Review Group for the opportunity to provide input. The United States maintains its commitment to global influenza preparedness and response through implementation of the PIP Framework and encourages WHO’s continued prioritization of pandemic influenza. In addition to previous written comments provided throughout the review process, the United States is providing feedback to specific findings which require further consideration and/or clarification. We look forward to the opportunity to review the Review Group’s full findings report.

The PIP Framework and the Global Influenza Surveillance and Response System (GISRS) are key components of global influenza preparedness and must continue to be a priority for World Health Organization (WHO) and Member States. While much progress has been made, several improvements should be made to continue to build upon this success. Although the PIP Framework is still relatively new, it has contributed to the following:

- Partnership Contribution resources have been distributed to 43 countries to strengthen laboratories and surveillance, burden of disease studies, regulatory capacity building, vaccine and diagnostic deployment, and risk communications.
- The number of National Influenza Centers has increased from 136 laboratories in 106 countries in 2011 to 143 laboratories in 113 countries in December 2015.
- There has been continued progress in obtaining new Standard Material Transfer Agreements 2 (SMTA-2s) from manufacturers and academic institutions (i.e. non-GISRS institutions). Manufacturers producing about 10% percent of seasonal vaccine production are now covered.
- Since 2012, manufacturers have contributed over US $80 million for pandemic preparedness. WHO has secured commitments for over 350 million doses of vaccines for countries in need in the event of a pandemic. Viruses continue to be shared to carry out critical pandemic risk assessments. Of note, although the PIP Framework states explicitly that it only covers the sharing of pandemic influenza viruses, influenza viruses are shared through the GISRS for seasonal vaccine production. Therefore, disruptions to the PIP Framework could lead to disruptions in preparedness for seasonal influenza.

Building upon these successes, the Review Group is encouraged to consider the following recommendations. The United States will provide additional recommendations at a later date.
Enhance Program Collaboration
The United States encourages greater engagement between the PIP Secretariat and other influenza program activity groups within WHO to synergize global pandemic influenza preparedness activities. Formal representation from WHO Collaborating Centers should also be considered to inform decision making and to inform resource needs, as appropriate. As technology advances and the landscape of the virus shifts, multiple stakeholders are needed to appropriately assess gaps since the last implementation plan and develop strategies for improvement.

Increase Virus and Benefit Sharing

Increase Global Specimen and Sequence Data Sharing

The United States would like the Review Group to address the need for improvements in specimen submissions globally. Increasing the number and global distribution of specimens submitted allows for better detection of novel influenza strains and informs the candidate vaccine virus selection process for both pandemic and seasonal influenza vaccines. The United States encourages support for access to genetic sequence data and management through existing databases to promote timely sharing of such data. Ensuring that the global system has the best technologies at its disposal to analyze viruses and contribute to the production of influenza vaccine remains critical. This includes the availability of tools such as human serum panels to improve the selection of seasonal and potential pandemic virus candidates.

Expedite Standard Material Transfer Agreements

The United States would like to see the PIP Secretariat conclude SMTA-2s in a timely manner, in particular with vaccine manufacturers. There has been much success in concluding Category A SMTA-2s with vaccine and antiviral manufacturers and Category C SMTA-2s with research and academic institutions. However, no Category B SMTA-2s with diagnostic manufacturers have been concluded. We recommend that the Review Group assess the total number of Categories A, B, and C SMTA-2s still needed to be concluded. Additionally, we recommend the Review Group assess an alternative benefits structure that may be appealing to diagnostic manufacturers.

Clarify Partnership Contribution

The United States would like greater clarity with how the Partnership Contribution funds are collected and used, especially at the regional and country levels. As to collection, we would like to know the relationship between the amounts collected and the quantity of vaccine manufactured by the respective partner (by dosage). As to how the funds are used, currently,
70% of funds go to preparedness activities with the following breakdown of those preparedness funds: 70% for laboratory capacity and surveillance strengthening; 10% for burden of disease studies; 10% for regulatory capacity strengthening and deployment of vaccines and medicines; and 10% for risk communication strengthening. The Review Group should identify potential overlaps in effort with other capacity building programs and initiatives, such as those associated with the Global Health Security Agenda (GHSA) and implementation of the International Health Regulations (2005) (IHR(2005)) and assess whether or not the current allocation of funds should be adjusted accordingly.

**Improve Linkages with Other Instruments**

To ensure better coordination, communication, and transparency of capacity building activities, the United States encourages the Review Group to closely assess all synergies of the PIP Framework with the Global Action Plan for Influenza Vaccines (GAP), the IHR (2005), and GHSA.

**Global Action Plan for Influenza Vaccines**

As the Global Action Plan for Influenza Vaccines (GAP) sunsets in 2016, it will be important for the GAP Secretariat and PIP Secretariat to coordinate so that aspects of the GAP can be considered in the context of the PIP Framework and efforts in advancing global influenza preparedness can be continued. Objective 1 of the GAP, which aims to increase seasonal influenza vaccine use, includes activities that assist Member States with surveillance, strengthening of national advisory committees, and promotion of equitable access. Objective 2 of the GAP aims to assist Member States with increasing vaccine production capacity. These two objectives support the strengthening of global pandemic influenza preparedness and pandemic vaccine production and uptake. These existing activities should be incorporated into the PIP Framework capacity building activities associated with the Partnership Contribution.