June 3, 2011

National Vaccine Program Office
c/o Kristin Goddard
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 739G.5
Washington, DC 20201

**Submitted electronically at vaccinesafetyRFI@HHS.gov

ATTN: Vaccine Safety Working Group draft white paper

Dear Ms. Goddard:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group’s (VSWG) draft white paper. IDSA would like to applaud the NVAC and members of the VSWG for their continued efforts to evaluate the federal vaccine safety system. Ensuring the use of vaccines is vital to preserving public health and protecting persons from vaccine-preventable illness. For this reason, it is imperative that the veracity of their effectiveness and safety, once it has been established, be protected.

IDSA represents more than 9,300 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education and research. Our members care for patients of all ages with serious infections, including influenza, meningitis, pneumonia, and tuberculosis; resistant infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA), *Escherichia coli* (*E. coli*), and *Salmonella*; cancer and transplant patients who have life-threatening infections caused by unusual microorganisms; food poisoning and HIV/AIDS; as well as emerging infections like the 2009 H1N1 virus and severe acute respiratory syndrome (SARS).

IDSA supports all of the recommendations put forth in the VSWG draft white paper. However, some areas could be further strengthened. IDSA’s specific recommendations are as follows:

**Recommendation 1.1 – Reaffirmation of the System Structure**

Asking the Secretary of Health and Human Services (HHS) to reaffirm HHS’ commitment to the National Childhood Vaccine Injury Act may have some benefit from a communications perspective. However, we are concerned that such a reaffirmation also could do more harm than good, by presenting the false image that vaccine safety is not currently an HHS priority or that HHS is not currently fulfilling the letter and spirit of the vaccine safety provisions.
Recommendation 2.1 – Expanded role for the ISTF
Given the membership of NVAC and its inclusion of a wide range of experts, it makes sense for the Immunization Safety Task Force (ISTF) to report directly to NVAC. This would ensure greater transparency and a more cohesive environment for information sharing.

Recommendation 3.6 – Data access
We support establishing a temporary expert committee to examine the very important issue of providing researchers responsible access to preclinical, clinical, and post-licensure vaccine safety data. While the VSWG likely is aware of the necessary cautions, IDSA would like to emphasize the importance of careful planning of such a mechanism/structure. It is imperative that vaccine safety data be utilized for scientifically sound and valid purposes.

Recommendation 4.2 – Post-licensure surveillance data considerations
It is not clear how the FDA Sentinel Project relates to the Vaccine Safety Datalink (VSD) Project. The VSD is critical to improving our assessment of vaccine safety and should be expanded. Unfortunately, none of the recommendations calls for a specific expansion of the VSD. IDSA recommends the VSWG consider such an addition.

Recommendation 8.1 – Enhanced role of the National Vaccine Advisory Committee
IDSA does not oppose the concept of enhancing NVAC’s role regarding independent, periodic review of the National Vaccine Program. However, it is unclear whether this is a necessary action or if it might potentially result in duplication of federal efforts.

Recommendation 8.2 – Relationship between ISTF and NVAC
Our comments on this recommendation mirror those made regarding Recommendation 2.1. Given the membership of NVAC and its inclusion of a wide range of experts, it makes sense to have the ISTF report directly to NVAC. This would ensure greater transparency and a more cohesive environment for information sharing.

Recommendation 8.4 – Assurance and accountability of progress in enhancing the vaccine safety system
We support Option 1: Empower NVAC to be responsible for vaccine safety assurance. Not only is this option most efficient and practical, but NVAC is also well-poised to offer the necessary expertise for the very complicated issue of vaccine safety. As a second choice, IDSA also would support establishing the fixed-tenure panel outside of HHS, if that panel were an Institute of Medicine committee—as outlined in Option 2b. This option offers both transparency and flexibility to define appropriate monitoring and reporting activities. We do not support Option 3 to create an independent agency within the Executive Branch to focus on the safety of vaccines. Under this option, there is great risk for duplication and perhaps an unnecessary use of resources.

IDSA also is pleased to have the opportunity to send a representative to the June 13, 2011 stakeholder meeting to discuss further the draft white paper. Please consider these comments in conjunction with the comments delivered at that meeting.
In closing, IDSA greatly appreciates the opportunity to comment on the draft paper. Once again, we wish to applaud the NVAC and the VSWG’s efforts to evaluate the federal vaccine safety system. Should you have any questions, please do not hesitate to contact Leslie McGorman, IDSA’s Program Officer for Public Health at 703.299.0015 or lmcgorman@idsociety.org.

Sincerely,

James M. Hughes, MD, FIDSA
President