December 28, 2007

U.S. Department of Health and Human Services, Room 434E
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attention: Pandemic Influenza Vaccine Prioritization Guidance Comments
VIA EMAIL: Panfluvaccine@hhs.gov

To Whom It May Concern:

The Infectious Diseases Society of America (IDSA) supports the continued need for strong federal leadership as the nation builds the capacity necessary to respond to a severe influenza pandemic. We are pleased that the Department of Health and Human Services (HHS) has issued the “Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine” (“Guidance”), and we offer the following comments.

As discussed below, IDSA’s recommendations are as follows:

1) Assist state and local authorities in overcoming access barriers for vulnerable populations;
2) Establish formal review mechanism(s) to reassess prioritization across countermeasures during a pandemic;
3) Create an integrated prioritization scheme across countermeasures;
4) Establish a robust vaccine tracking system;
5) Address implementation challenges including clarification of the roles of federal and other actors; and
6) Simplify presentation of the scheme to enhance public comprehension.

Guidance Framework

The framework is essentially sound and addresses the stated program objectives, e.g., protecting essential workers, protecting those who maintain essential community services, protecting children, and protecting workers at greater risk of infection. The scheme is consistent with the importance of vaccinating essential workers in health and critical infrastructure categories, as expressed in IDSA’s January 18, 2007 reply to the Request for Information (RFI) issued by HHS.

The framework offers a laudable degree of needed detail in specifying distinct functional and demographic “target groups” within each of the four major categories. We are aware that additional work is planned to further define these target groups. IDSA would be happy to provide assistance in further defining target groups in the health care sector.

IDSA especially endorses the goal of inclusiveness reflected in the framework, e.g., the fact that all persons in the United States will be considered for vaccination as
adequate vaccine supplies become available. One component of inclusiveness is ensuring equity of access. As a cautionary note, the Guidance’s approach in defining target groups on a functional and demographic basis does not allow for a focus on vulnerable groups. Other prioritization plans such as the Minnesota Pandemic Influenza Ethics Work Group prioritization framework categorically aim to ensure access to the most vulnerable populations in order to prevent likely disparities in mortality along economic and other lines. As an adjunct to the present guidance, IDSA recommends that federal authorities encourage and aid state and local authorities in identifying and then addressing any institutional and societal barriers to reaching homeless persons, persons with disabilities, prisoners, illegal aliens and other groups not specifically identified in the present scheme.

Need for Reassessment by a Joint Panel

The Guidance anticipates the need for reassessment and potential modification of the Guidance at the time of a pandemic. Indeed, real-time reassessment of the prioritization scheme will be critical. IDSA recommends that the government rapidly and transparently develop plans for reassessment including identification of relevant tasks and the appropriate mechanism(s) to undertake these tasks.

Minimally, reassessment must incorporate information about safety and immunogenicity data for pandemic vaccine, the status of vaccine availability, epidemiologic and clinical characteristics of the emergent virus, vaccine immunogenicity data for target groups within the population, data on efficacy of dosing regimens, and information related to supply and effectiveness of antiviral drugs.

The charge of the Center for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) is to provide advice and guidance to HHS for effective control of vaccine-preventable diseases in the civilian population. Thus, the ACIP has both the expertise and experience in immunization and science to address many aspects of the above tasks. IDSA strongly supports a clear and prominent role for ACIP in ongoing development and reassessment of pandemic vaccine prioritization and use. However, additional expertise beyond ACIP, including operational, implementation and broader public health expertise, also may be required.

In its recent December 14, 2007 letter to HHS regarding the proposed antiviral guidance documents, IDSA recommended the creation of an independent panel, comprised of government and non-governmental experts, to review scientific data regarding antiviral treatment, prophylaxis and management. This was proposed in the context of a recommendation to pursue antiviral drug guidelines. (See December 14, 2007 letter, attached.) Such an independent panel may be an effective mechanism for reassessment of vaccine prioritization as well.

IDSA recommends consideration of a single, joint panel that is carefully constituted to address new data and information about vaccination as well as antiviral treatment and prophylaxis. The joint panel could function as a working group of existing, federally approved committees such as ACIP, the National Vaccine Advisory Committee, or the new National Biodefense Science Board, and would require a clear charge and authority. The panel also could address any pre-pandemic vaccination efforts; relevant information may include efficacy data and information about pre-pandemic vaccination efforts until that point.
Harmonization and Integration of Prioritization Efforts

IDSA further recommends the federal government take steps to create, harmonize and integrate prioritization schemes across essential medical countermeasures for pandemic influenza. Minimally, this integration would help avoid administration of both pandemic vaccine and prolonged antiviral prophylaxis to the same populations or persons. Such a scheme could incorporate a plan for prioritizing pre-pandemic vaccine as well. Pre-pandemic vaccine administration may affect pandemic vaccination, and vaccine availability will affect administration of antiviral drugs. These considerations may belong in a national pandemic vaccine strategy document or in a joint, harmonized prioritization guidance document.

A harmonized and integrated prioritization strategy would improve the ability of a joint review panel to reassess countermeasure prioritization. For instance, in the case that emergent vaccine data indicate low immunogenicity for elderly or children, the panel could adjust the relative priority of antivirals and vaccine for these groups.

Implementation and Vaccine Tracking

Effective implementation is of paramount importance, and we are pleased to learn that CDC along with state and local personnel will begin coordinating a process to develop an implementation plan. IDSA’s January 18, 2007 reply to HHS’ RFI addressed many issues of allocation, access to data, information transparency and monitoring. These concerns remain important to the implementation process going forward. The January 18th letter also called for a comprehensive real-time countermeasure tracking system to be developed and tested to measure distribution, uptake, and efficacy at the federal, regional, and local levels. Notably one step toward this aim is the Countermeasure and Response Administration program operated by CDC, which offers the opportunity for states to track doses administered, by individuals and priority group. We recommend consideration of ways to integrate dose tracking with tracking of distribution and efficacy.

Another issue of particular importance is the logistical challenge of identifying persons who meet the eligibility criteria and distributing vaccine to them. Many of the criteria included in the Guidance cannot be readily and reliably established, inviting fraud and inequitable access. An implementation plan must address how vaccinators will confirm criteria of “high risk” or “household contact” in a crisis when medical or other records may not be available and when people desperate for vaccine may misrepresent their risk status. Likewise, prioritizing vaccine to persons who work in essential service and critical infrastructure organizations poses practical logistical challenges. Equally important considerations include:

- clarifying the allowable identity of vaccinators, e.g. whether this may include non-healthcare personnel;
- identifying how vaccinators or decision-makers will move from one tier to the next;
- clarifying how the safety, integrity and transportation of vaccine will be assured, including measures to reduce the illegal sale or trade of pandemic vaccine; and
- clarifying how federal and other entities will assure consistency in policy application and prioritization at the local, state, and regional levels.
Simplification of the Presentation

Finally, IDSA is concerned about the complexity of the prioritization scheme and the potential for confusion. It is difficult to follow the varied references to “target groups,” “categories,” “levels” and “tiers.” Significant difficulties were experienced in recent efforts to communicate a simpler approach for prioritization during a vaccine shortage. To avoid similar confusion, IDSA recommends efforts be taken to improve and simplify the terminology, graphics and narrative in the Guidance and in any implementation materials that follow. The expertise of design engineers may be helpful. Both the Minnesota prioritization framework and the Canadian Pandemic Influenza Plan serve as excellent models for communicating a prioritization scheme.

IDSA appreciates the invitation to comment on the “Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine,” and we would be happy to assist further on these important efforts. Should you have any questions, please feel free to contact Julie Hantman, MPH, IDSA’s Senior Program Officer for Public Health at jhantman@idsociety.org or (703) 299-0015.

Sincerely,

[Signature]

Donald Poretz, MD
IDSA President

Attached:  
IDSA letter to Dr. Benjamin Schwartz, Department of Health and Human Services, December 14, 2007
IDSA letter to Department of Health and Human Services, January 18, 2007

cc:  Benjamin Schwartz, MD, Senior Science Advisor, National Vaccine Program Office, U.S. Department of Health and Human Services  
Secretary Michael Leavitt, Department of Health and Human Services  
Bruce Gellin, MD, MPH, Director, National Vaccine Program Office, HHS  
Anne Schuchat, MD, Director, National Center for Immunization and Respiratory Diseases, CDC  
RADM W. Craig Vanderwagen, MD, Assistant Secretary for Public Health Emergency Preparedness, HHS