January 18, 2007

U.S. Department of Health and Human Services
Room 434E
200 Independence Avenue, SW
Washington, DC 20201
Attention: Pandemic Influenza Vaccine Prioritization RFI

Re: Request for Information (RFI): Guidance for Prioritization of Pre-pandemic and Pandemic Influenza Vaccine

To Whom It May Concern:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Department of Health and Human Services’ (HHS) Request for Information (RFI) for Guidance for Prioritization of Pre-pandemic and Pandemic Influenza Vaccine (hereinafter called “Draft Guidance”). IDSA represents more than 8,500 physicians and scientists devoted to patient care, education, research, and community health in infectious diseases. Members of the Society include experts in vaccine science, hospital epidemiology, and public health. The threat of pandemic influenza is of great concern to the Society, and the evolving emergence of H5N1 avian influenza in Southeast Asia and its spread to several other continents only adds to the urgency of the situation. In 2005, IDSA’s Board of Directors established the Society’s Pandemic Influenza Task Force (PITF) to monitor potential threats and the United States’ and international responses to influenza and to issue specific recommendations to the Board. The PITF, which played a leading role in developing IDSA’s comments below, is comprised of Drs. Kathleen Neuzil (chair), David Blazes, Jeffrey Duchin, David Fedson, Kathleen Gensheimer, Frederick Hayden, Edward Janoff, Andrew Pavia, and Gregory Poland.

Recently, the PITF worked with IDSA leadership to develop a set of Pandemic and Seasonal Influenza Principles for U.S. Action. IDSA intends these principles to be informative and instructive to the Secretary of HHS and the new Assistant Secretary for Preparedness and Response as they move forward. At the core of these principles is that widespread use of a pandemic vaccine should be the central strategy for protection of human health during a pandemic event. National guidelines for prioritization of pre-pandemic and pandemic influenza vaccine are a critical component of this strategy. We have attached our principles as several relate to the information sought through HHS’s RFI on vaccine prioritization. We will refer to specific principles in addressing the questions put forth in the RFI document.
What objectives, principles, strategies, criteria, assumptions and rationales should be considered in pandemic vaccine prioritization determinations?

We agree with the stated goals of the federal response to an influenza pandemic: (1) to stop, slow, or otherwise limit the spread of the pandemic to the United States; (2) to limit the domestic spread of the pandemic and mitigate the disease, suffering, and death; and (3) to sustain infrastructure and mitigate impact to the economy and functioning of society.

The overall strategy for prioritization determinations must be based on the specific epidemiological features of the pandemic at the time it occurs. A framework for decision-making to inform vaccine prioritization should be developed that incorporates ethical principles and societal values, age-specific mortality rates, and other relevant epidemiological features.

Realizing that the features of the pandemic cannot be known in advance, we recommend that the vaccine prioritization group base their initial prioritization on a “worst-case” pandemic – similar to the 1918 pandemic. In that pandemic, mortality rates were high in healthy, middle-aged adults, in addition to the very young and the elderly. These assumptions should be clearly articulated and documented such that the public can understand the basis for the prioritization decisions. The prioritization group should consider how recommendations would change if underlying assumptions change. A secondary prioritization for a moderate pandemic should be developed. The Minnesota Pandemic Influenza Ethics Work Group prioritization framework is an excellent model for developing and communicating a prioritization scheme. (A copy of the report is attached.)

A number of factors are important to consider in prioritization of vaccines. In addition to considering risk of influenza-related mortality, other important characteristics in prioritizing groups to receive vaccine include likely response to vaccine (and therefore likelihood that group would benefit from vaccine), role of the group in society (specific examples provided below), and role of a particular group in transmitting influenza. Finally, vaccine prioritization schemes need to consider the availability of other preventive or treatment measures, such as antivirals. In addition, we strongly suggest that an explicit ethical framework be developed that will inform prioritization decisions.

What is the relative importance of the three goals described above and what are the associated implications for vaccine prioritization?

The priority should be mitigation of suffering and death while sustaining the functioning of society. Because epidemiological characteristics of influenza pandemics vary, the practical implications of the goals may vary. For example, use of vaccine to sustain infrastructure may not be relevant in certain scenarios (e.g., high mortality among children but not among working-age adults), allowing vaccine to be prioritized for prevention of disease among priority groups irrespective of whether the person works in an essential role.
Which population group(s) should have priority for receiving pre-pandemic vaccine?

This should be determined using an ethical framework to inform use of vaccine, with input from key stakeholders, and applying a clear set of assumptions. Two issues dominate here. One is the risk of vaccinating persons in the absence of a circulating pandemic strain. The other is the need for protection during the early phase of a pandemic. Priority determinations for pre-pandemic vaccines might therefore put greater emphasis on critical infrastructure personnel, key health care providers, and other essential service providers.

Which should have priority for receiving pandemic vaccine? What is the rationale?

This should be determined based upon the ethical framework adopted to guide prioritization, using a clear set of assumptions as described above, in order to achieve the stated goals of reducing mortality and suffering and maintaining functioning of society. The 2005 guidelines developed by ACIP/NVAC make a good starting point. Developing clear definitions as to what constitutes a “high risk condition”; who among those with a “high risk condition” are likely to benefit from vaccine; what services within society are truly essential; and which personnel within an “essential service” organization have essential roles are difficult but must be achieved using the best available data. The need to revise these definitions in the face of evolving data must be made explicit.

In our principles document, IDSA emphasizes that the U.S. must preserve medical readiness by ensuring that medical workers and public health workers who are involved in direct patient contact and other support services essential for direct patient care, including vaccinators, are able to perform their duties during an influenza pandemic. Other groups that might be prioritized highly based on their role in society include high-level government officials; vaccine and antiviral manufacturers and others essential to manufacturing and critical support; public safety workers including police, fire, 911 dispatchers, and correctional facility staff; utility workers essential for maintenance of power, water, and sewage system functioning; transportation workers transporting fuel, water, food, and medical supplies as well as public transportation; telecommunications/IT workers to maintain essential network operations and maintenance; emergency response and public health workers critical to pandemic response; and mortuary workers. Criteria for determining which persons working in these occupations are eligible for vaccine are needed.

How can fairness, equity, efficiency, and related principles be reflected in the determination of priority groupings for receipt of pre-pandemic or pandemic vaccine?

As stated above, the process for determining priority groups must be inclusive and transparent, and the assumptions and rationale behind all priority decisions need to be clearly articulated. The resulting ethical framework developed by an expert panel should subsequently undergo stakeholder and public review and comment. Issues such as the relative importance of preventing death among the elderly compared to children and
younger adults can only be made with broader input. Once the plan is developed, public education is essential.

In addition, a scheme that incorporates consideration of years of life lost, or years of quality life lost should be considered. The life-cycle ranking proposal of Emanuel and Wertheimer provides a good starting point for developing an ethical framework for prioritization of limited potentially life-saving resources. (“Who should get influenza vaccine when not all can?” Science, 12 May 2006).

*For priority groups, how should vaccine be allocated, distributed, and administered? Who (federal, state or local authorities) should determine when and how the vaccine is distributed and administered?*

As stated in our principles document, detailed vaccine (and antiviral) distribution templates should be provided by the federal government and distributed for each state and locality to adapt. The scientific and ethical issues involved in preparedness and response will be essentially the same in all parts of the United States; the logistics will vary. As such, we believe it is critical to develop a single national standard that all localities can apply. The standard should reflect a broad consensus, and should be periodically revised as the facts and evidence change. Some adaptation to fit local circumstances may be necessary, but multiple, independent standards that are potentially conflicting would be problematic. Countermeasure prioritization and distribution plans should be re-visited and updated according to the prevailing pandemic situation and as vaccine and antiviral production capacity increases. A comprehensive real-time countermeasure tracking system should be developed and tested to measure distribution, uptake, and efficacy at the federal, regional, and local levels. Ultimately, the prioritization scheme should be practical and easy to apply in the field. Barriers to access, such as requiring individuals to pay for the vaccine, must be removed.

One option is that vaccine be allocated to states and local health jurisdictions based on the estimated population meeting eligibility criteria in that jurisdiction. Arrangements should be made in advance and should clearly authorize local public health agencies to direct distribution. State and local agencies must have necessary access to data on vaccine supply. In order to maintain the trust of providers and the public, it is critical that information about distribution and allocation of vaccine be transparent at the federal, state, and local levels and be readily accessible to both public health practitioners and the public in real time. Problems with the current vaccine distribution system demonstrate the discord that can result.

Even with the clear delineation of priority groups, the logistics of identifying persons who meet criteria and distributing vaccine to them pose formidable challenges. Vaccine prioritization must correspond to practical, objective, and clear eligibility criteria that are easy to apply in the field at the local level. A prioritization scheme that includes criteria that cannot be readily and reliably established invites fraud and inequitable access. For example, criteria that require health care and public health workers to administer vaccine
based on medical risk factors (e.g. history of chronic medical conditions) may be very difficult to implement in a crisis when medical 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.

Criteria for release of vaccine by federal authorities should be agreed upon in advance with state and local stakeholders. Ideally, administration of vaccine should be done by public health personnel and health care providers and healthcare facilities. Limited supplies may make it impossible to distribute vaccine to small health care facilities, clinics, and offices. Administration of vaccine must be closely monitored to assure accountability and use in accordance with guidelines.

Finally, for a pandemic influenza vaccination program to succeed, national, regional, and local public health agencies’ capacities to manage large-scale public health emergencies must be bolstered. These improvements must be sustainable and not contingent on one-time or unreliable resources. Annual influenza vaccine distribution should be used as an opportunity to test vaccine protocols and distribution plans. Many of the preparatory activities necessary to implement a prioritization plan at the state and local level require certainty that on-going funding is assured. Long-term investments in this area will have collateral benefits in defending against other biological agents.

Given IDSA’s expertise in pandemic and seasonal influenza and pandemic preparedness policy, we would be more than happy to offer our experts to serve on the vaccine prioritization group and welcome other opportunities to participate in the prioritization process. We look forward to working with you to see this critical pandemic preparedness keystone actualized to ensure the widespread use of available vaccine during a pandemic event.

Should you have any questions, please feel free to contact Beth Rada, MS, IDSA’s program officer for science and research at brada@idsociety.org or (703) 299-0200 x1216.

Sincerely,

Martin J. Blaser, MD
IDSA Immediate Past-President