Dear Mr. Maddux:

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. Thus we are pleased to provide brief comments regarding the “Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza” issued by the Occupational Safety & Health Administration (OSHA).

Occupational Risk Pyramid
The proposed guidance contains a scheme which recommends that employees at Very High Exposure Risk and also High Exposure Risk for pandemic influenza use respirators, while workers at Medium Exposure Risk should use facemasks. This scheme parallels prior CDC guidance. IDSA considers this scheme reasonable, providing that appropriate educational and implementation measures are followed.

Reusable or elastomeric respirators
One specific recommendation contained in this guidance relates to a recommendation of reusable or elastomeric respirators, and powered air purifying respirators (PAPRs), as an alternative to disposable respirators in the face of likely scarcity scenarios of the disposable respirators. IDSA has several concerns about this recommendation and believes these concerns preclude the large-scale use of these devices at this time. Firstly and significantly, reusable devices largely are used in industrial settings, and they are unfamiliar to many healthcare workers. Secondly, supply chain and surge manufacturing capacity of these respirators is mostly Asia-based, fragile, fragmented and short. As with disposable respirators, the supplies of reusable devices are likely to falter upon slight increase in worldwide demand. Lastly, without specific incentives in place to catalyze the purchase of the reusable devices, their high upfront cost is likely to limit actual purchase by hospitals, despite possible offsets over the course of the epidemic verses the cumulative cost of disposable devices.

As noted in the guidance, the PAPRs are impractical for many patient care activities. As an example, Los Angeles County has purchased PAPRs for its ER-
receiving hospitals solely for chemical decontamination purposes, not for patient care. At the same time we recognize that PAPRs are used by some hospitals in cases of tuberculosis and other airborne infections during high-risk exposures and they do offer higher levels of protection against airborne particulates. More extensive consideration may be needed to guide clinical and acquisition questions regarding PAPRs in the pandemic influenza context.

Shared Responsibility
The concept of ‘shared responsibility’ among federal, state, local and private parties has been proposed as a key principle governing the stockpiling of a range of critical materiel related to pandemic influenza preparedness, including the stockpiling of respirators and facemasks. IDSA separately has commented at greater length on this concept in its December 14, 2007 letter regarding the stockpiling of antiviral drugs; attached please find this letter, which was addressed to Dr. Benjamin Schwartz of the Department of Health and Human Services.

We offer a related, general comment in this context as well. IDSA notes that many hospitals rely on federal hospital preparedness funds for purchase of respirators and facemasks. We further note that in recent years these funds have been woefully inadequate to meet hospital readiness efforts including stockpiling of minimal PPE. As a result, inequalities across healthcare institutions exist and can be expected to continue. Thus, as with our December 14th letter on antivirals, IDSA recommends that the federal government take responsibility for ensuring equity in the supply of respirators and masks throughout the United States. This does not obviate the importance of continuing to urge healthcare institutions to take steps to independently acquire respirators and masks if they are so able.

IDSA appreciates the invitation to comment on the federal guidance on workplace stockpiling of respirators and facemasks for pandemic influenza. 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,

Donald Poretz, MD
IDSA President

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

cc: Carter Mecher, MD, Director for Medical Preparedness Policy, White House Homeland Security Council
Lisa Koonin, MN, MPH, Chief, Private and Public Partners Branch Division of Partnerships and Strategic Alliances National Center for Health Marketing/CoCHIS, CDC
Benjamin Schwartz, MD, Senior Science Advisor, National Vaccine Program Office, U.S. Department of Health and Human Services
December 14, 2007

Benjamin Schwartz, MD
Senior Science Advisor
National Vaccine Program Office
U.S. Department of Health and Human Services

Dear Dr. Schwartz:

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 to comment on the federal government’s draft antiviral guidance documents, which include the “Overview of Proposed Federal Guidance on Antiviral Drug Strategies and Stockpiling,” the “Proposed Guidance on Antiviral Drug Use Strategies during an Influenza Pandemic,” and the “Proposed Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic.”

IDSA applauds the intense federal interest and commitment in determining appropriate strategies for antiviral treatment and prophylaxis of the United States population in the event of a pandemic. However, the time frame provided for public comment has made it difficult for us to undertake a thorough examination of the implications of the guidances. We believe these complicated issues require careful discussion before priorities can be established. Nonetheless, we offer the following comments on the draft antiviral guidance documents and on their implementation.

THE ANTIVIRAL STRATEGY GUIDANCE DOCUMENTS

Guidance Assumptions
IDSA recognizes that the strategies outlined in the federal antiviral guidance must remain dynamic, allowing room for change as new information becomes available. Guidance must be evidence-based and reflect ethical principles and the latest science.

Planning frameworks must be based on a range of reasonable assumptions. The antiviral guidance is based on the assumptions that community mitigation measures, absent antiviral post-exposure prophylaxis, will reduce the attack rate in a pandemic by one-half; the pandemic will be severe; that the supply of antiviral agents will not change in a way that would make fewer courses of antiviral drug available.

IDSA is concerned about the uncertainties underlying each of these assumptions. Most notably, the guidance reflects a new critical assumption that community mitigation strategies will reduce the attack rate in a pandemic.
by one-half, reducing the illness attack rate to 15 percent of the population with commensurate reductions in pandemic mortality. The basis for this core assumption should be clarified and clearly referenced in the antiviral guidance. The implications of this assumption on the estimate on antiviral drug strategy should be discussed.

In addition, the antiviral guidance document assumes a severe pandemic and an abundant supply of antivirals. It does not address strategies in the event of development of viral resistance to stockpiled drugs, the implications of higher or lower pandemic attack and case-fatality rates, or the potential, as suggested by some investigators, that the dose and/or duration of therapy might need to be higher than currently assumed.

Therefore, we recommend that consideration be given to the following:

- Develop antiviral drug guidelines for a moderate pandemic scenario (analogous to the pandemic vaccine use guidance) and account for varying degrees of antiviral drug availability;
- Assess the possible dramatic impact on strategy should the dose or duration of antiviral drugs be greater than currently assumed;
- Anticipate how much antiviral drug will be stockpiled for pandemic use and indicate how the growing size of the stockpile will affect priorities;
- Incorporate results of additional studies determining pediatric dosing and strategy for children; and
- Discuss the impact of vaccine availability on antiviral drug use guidance.

Similar to the pandemic vaccine guidance, federal antiviral guidance should be based on estimates across a range of assumptions. IDSA recommends adding an appendix to the guidance, outlining a set of assumptions that provides the foundation for the antiviral guidance.

Additional Surveillance and Data Review Mechanism
To maintain credibility, trust and responsiveness, a transparent mechanism should be in place to allow for prompt review of scientific data on the efficacy and effectiveness of antiviral treatment, antiviral resistance data, adverse effects, and optimal dosing and prophylactic use. This would allow timely modifications to the recommendations. IDSA suggests an independent panel, comprised of government and non-governmental experts, to function in this capacity.

The Use of Antiviral Prophylaxis
Given the current level of knowledge, IDSA recommends that the national guidance assure a sufficient supply of antivirals for the extended prophylaxis of health care workers and essential emergency personnel for the duration of a pandemic. We recognize that it will be important to have a consistent and uniform approach for prophylaxis of health care workers nationwide. Therefore, we recommend developing detailed federal guidance on the prophylactic use of antivirals for the health care sector and essential emergency personnel. The document should discuss risks and potential benefits — antiviral safety, how they should be administered, and how their use should be monitored for efficacy and safety. It should include a prioritization scheme for when drug supplies are limited.
In the current draft antiviral guidance, there is minimal attention to prioritization. We think that it is highly unlikely that there will be adequate supplies to achieve all of the goals of prophylaxis. The document should provide a much more explicit rationale and strategy for prioritization.

If the decision is made to use post-exposure prophylaxis in conjunction with the voluntary quarantine of cases, the evidence supporting its use for household contacts should be examined more closely. In addition, practical aspects of beginning post-exposure prophylaxis of household contacts within 24 hours of exposure to the index case must be addressed, including accurate diagnosis of the index case, identifying who should determine the need for prophylaxis and ensuring prompt drug delivery when the health care system may be overwhelmed.

IMPLEMENTING THE ANTIVIRAL STRATEGIES GUIDANCE

In the original planning document, HHS envisaged an antiviral stockpile large enough to treat 25 percent of the U.S. population. However, procurement has been slow; the federal portion is 72 percent complete, whereas state purchases are only 36 percent complete. Funding to complete both stockpiles, particularly the state portion, is uncertain. States vary in their willingness to purchase their antiviral allotments, and many states do not have sufficient resources. There appears to be little enthusiasm among state public health officials and legislatures to purchase additional supplies of antivirals beyond current targets.

Shared Responsibility

IDSA agrees in principle with the concept of shared responsibility among federal, state, local, and private parties, but in practice this approach to an antiviral strategy is not realistic and will lead to fragmented, unequal, and ultimately unsuccessful implementation. We strongly recommend that the federal government ensure equity of the antiviral supply throughout the United States so that all individuals have equal access to antiviral drugs regardless of the state or locality in which they live.

Inequalities in access to antiviral stockpiles exist, and will be greatly exacerbated during expansion, unless specific attention is paid to equity. We cannot build an equitable strategy for antiviral treatment and prophylaxis on a foundation that is already unequal. Therefore, IDSA suggests that the federal government first focus on creating consistency among state antiviral stockpiles for treatment and secondly, focus on establishing stockpiles intended for the prophylaxis of the health care sector and essential emergency personnel.

The states and municipalities have the enormous responsibility to distribute and track antiviral drugs. However, they have varying ability to purchase additional stockpiles. We feel that the responsibility of the Federal Government is to assure that all Americans will have equal access to antivirals based on the priority schemes. It is not acceptable that one’s access depends on the state in which one lives or the institution for whom one works.

Health Care Institution Stockpiles

As stated earlier, IDSA strongly supports extended antiviral prophylaxis for health care workers for the duration of a pandemic. Because of logistical issues and concerns about eminent domain, many health care institutions have already chosen not to stockpile antiviral agents out of fear of incurring expenses without clear benefit. In addition, many institutions that wish to purchase antivirals do not have the funds to do so.
The federal government should provide resources to either purchase or subsidize antiviral agents for health care institutions. IDSA suggests that the federal government work with the appropriate health care system stakeholders to define optimal stockpiling strategies and mechanisms, including where and how the antivirals will be stored, shelf life extension, how storage will be paid for, and how the antivirals will be delivered when they are needed.

**Operations Research**
Although the commissioning of the Institute of Medicine report clearly recognizes the importance of pre-positioning, distribution, and dispensing, there is a real need for additional research in these areas that will contribute to a detailed plan for implementing the antiviral recommendations, including specifics on the logistics of storage, distribution, administration, monitoring effectiveness, and ongoing evaluation of all aspects of antiviral use during a pandemic.

Again, we appreciate the invitation to comment on the federal antiviral strategies guidance for pandemic influenza. 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) 299-1216.

Sincerely,

Donald Poretz, MD  
IDSA President

cc: Carter Mecher, MD, Director for Medical Preparedness Policy, White House Homeland Security Council  
RADM W. Craig Vanderwagen, MD, Assistant Secretary for Public Health Emergency Preparedness, HHS  
Bruce Gellin, MD, MPH, Director, National Vaccine Program Office, HHS  
Lisa Koonin, MN, MPH, Chief, Private and Public Partners Branch Division of Partnerships and Strategic Alliances National Center for Health Marketing/CoCHIS, CDC