

July 15, 2008

Tevi Troy, PhD
Deputy Secretary
Office of the Deputy Secretary
Department of Health and Human Services
Room 614-G
200 Independence Avenue
Washington, DC 20201

RE: Home Stockpiling of Antivirals Proposal

Dear Dr. Troy:

Provision of timely antiviral therapy to children and adults for treatment and/or prophylaxis of pandemic influenza is a crucial component of an effective response to an influenza pandemic. We believe that the available data do not support home stockpiling of antivirals. Therefore, we are writing to express our opposition to the plan to provide the so-called *neutral guidance* - "*Information for Individuals and Families about Having Antiviral Medicines at Home in Case of Pandemic Influenza*" - to individuals for the purchase and stockpiling of influenza antiviral medications. We also wish to convey our willingness to work collaboratively to determine the most effective means to distribute, dispense and use antivirals during an influenza pandemic.

The approach of "personal responsibility" for pandemic preparedness is reasonable, appropriate, and necessary for individuals and families for certain aspects of preparedness. However, we do not believe that personal responsibility should extend to the acquisition of antivirals. Home stockpiles and the likelihood of misuse have important potential consequences for clinical health and also for public health, including impacts on drug resistance, public trust, and appropriate distribution and supply. Acquisition and distribution of critical material including antivirals during a national or regional crisis is traditionally a governmental public health function and must remain as such.

At present we are not convinced that the proposal to home stockpile antiviral drugs by individual families is an effective and safe method to preposition antiviral medications and for mitigating an influenza pandemic. Below is a list of our major concerns about the release of the neutral guidance document. These concerns derive partly from overarching considerations discussed during the past months in telephone conference calls organized by the Department of Health and Human Services and from the information presented at the June 17, 2008, meeting. At this time, we believe the results of these discussions combined with the presentations at the recent meeting, should give pause to any efforts to inform and to promote home stockpiling.

- According to presentations by the MIDAS modelers at the June 17, 2008, meeting, home stockpiling would have only a negligible effect on reducing

transmission of influenza during a pandemic. Any public health impact would at best be modest; under some models home stockpiling could actually increase the attack rate.

- Under some models, home stockpiling could hasten the emergence of resistance to antivirals.
- Home stockpiling may lead to inappropriate use of antivirals during both seasonal and pandemic influenza.
- The risk to children involves a high likelihood for medication errors. As children grow, underdosing from an earlier prescription is problematic, resulting in reduced therapeutic effectiveness and an increase in the risk of emergence of resistance during therapy of an active infection. Theoretically, such a scenario may be more likely in children due to the higher titers of virus and longer duration of shedding experienced by them with influenza infections.
- Since the ability to purchase antivirals under the neutral guidance depends entirely on financial means, the result will be maldistribution, potential inequities in protection, and other negative societal effects such as damage to public trust, especially if shortages in the public sector antiviral supply were to arise.
- The neutral guidance approach requires physicians to spend considerable time counseling people about the potential benefits and risks of home stockpiling.

The 81 million antiviral treatment regimens in the Strategic National Stockpile are designed to cover 25% of the U.S. population, but may prove inadequate. We believe that additional discussions need to be held and studies conducted to determine how best to prepare for timely mass or targeted distribution of antivirals in the face of an influenza pandemic.

We advocate for a formal plan for pre-positioning of antiviral medications and coordination of the distribution of the public stockpile with additional supplies of antiviral agents in the private sector. Such an approach would assure adequate drug availability for the treatment and prophylaxis of all for whom it would be indicated. We understand that policies and recommendations will change based on increasing availability of antiviral drugs, influenza virus resistance patterns, and new information. Alternate distribution plans, utilizing local or regional public and/or private sector sites (e.g., public health facilities and/or pharmacies), could provide effective distribution opportunities. In addition, we believe that the April 2008, Institute of Medicine publication, *Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program*, provides some important recommendations that should be considered.

In summary, our organizations do not support the issuance of neutral family guidance at this time. However, we do encourage additional discussions on a distribution and

dispensing program that includes further studies on the utility and effectiveness of the proposed MedKits. We wish to partner with the Department of Health and Human Services and other involved agencies and organizations to develop strategies that would best meet the needs of all children and families in the face of pandemic influenza. Please do not hesitate to contact, Joseph Bocchini, MD, FAAP, chair, American Academy of Pediatrics, Committee on Infectious Diseases, at 318/675-6073, if you would like to arrange further discussion with our organizations.

Sincerely,

American Academy of Family
Physicians

American Academy of Pediatrics

American Medical Association

Infectious Diseases Society of America

cc: John Tegeris, PhD