

**American Medical Association (AMA) Comments On Influenza Antiviral MedKits
To The
FDA Joint Meeting of the Antiviral Drugs and Nonprescription Drugs Advisory
Committees**

(October 29, 2008)

The AMA appreciates the opportunity to comment on influenza antiviral MedKits. The AMA will present its views on the role of influenza antiviral MedKits both for pandemic planning and for seasonal influenza.

For Pandemic Planning

The AMA strongly supports the need for proper planning and preparedness for pandemic influenza. Indeed, we believe that the timely provision of antiviral therapy either for treatment or for prophylaxis of pandemic influenza is an essential part of overall pandemic preparedness. However, the AMA does not support the concept of long-term individual stockpiling of pharmaceuticals in general, and it has concerns about the use of a MedKit for individual home-stockpiling of influenza antivirals for pandemic influenza. These concerns include:

1. Long-term stockpiling in the face of an uncertain pandemic might increase the potential for misuse of the MedKit. For example, it is possible that the MedKit will be used by the public during seasonal influenza even though it is intended to be used only during a pandemic. Moreover, this could very well occur in the absence of an influenza diagnosis and appropriate counseling by a physician. This could potentially lead to selection for the survival of resistant seasonal influenza strains and/or to an increase in adverse events. Additionally, inappropriate use during seasonal influenza (such as for self-treatment of a rhinovirus infection) may also lead to decreased confidence in the effectiveness of the antiviral. Indeed, this is one of the most cited reasons why people do not seek influenza vaccination – the belief that the influenza vaccine is not effective.
2. Long-term stockpiling increases the risk for improper storage and handling of the MedKit or its unavailability when needed. For example, should the MedKit be improperly stored and handled, it is likely that its effectiveness will be compromised at the time of the pandemic outbreak. Additionally, whether the MedKit can be recovered after long-term storage and the contents used accurately during an outbreak needs to be confirmed. Finally, immediate access to the stockpiled MedKit cannot be guaranteed should people be away from their homes when a decision to use the MedKits is rendered.
3. Long-term stockpiling also raises the question of appropriate communications to, and appropriate use by, the public when the MedKit is finally used. For example, will new data on resistance actually render the MedKit useless, requiring intervention during the stockpiling duration; or will new data have resulted in new dosing requirements, for example in children? Influenza antivirals appropriately are prescription products and currently do not have the many years of post approval use and experience to guide these decisions.
4. Although beyond the scope of today's discussion, the AMA also has concerns regarding equity of access to the MedKit, the potential that physicians and other healthcare professionals would face pressure to replace the MedKits (should it be lost, used inappropriately, etc), and the potential for liability for healthcare professionals should an adverse event occur when using the MedKit, years after its issuance.

In summary, the AMA believes that the “public health preparation” that is the rationale for the development of an influenza antiviral MedKit can be achieved through other methods, including through a formal plan for pre-positioning the antiviral medications and coordination of distribution through multiple public and private networks.

For Seasonal Influenza

The AMA also questions the need for influenza antiviral MedKits for annual seasonal influenza.

The AMA believes the use of antiviral therapy during seasonal influenza should primarily occur after a diagnosis of influenza (preferably confirmed with a rapid test) has been made; a discussion between the physician and the patient takes place; and a prescription for the antiviral medication is issued. In this circumstance, the MedKit becomes simply a matter of product packaging, potentially providing a simpler, more understandable manner for a patient to start influenza antiviral therapy. The AMA strongly believes that having a MedKit stockpile available for seasonal influenza would undermine the fundamental tenet of influenza prevention – protection against infection through vaccination and other infection control techniques, such as proper hand hygiene.

The AMA appreciates this opportunity to highlight some of its concerns with the concept of home stockpiling of an influenza antiviral MedKit. Please feel free to contact me at litjen.tan@ama-assn.org for more details.