



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

October 22, 2008

Jeff Murray, M.D.
Deputy Director
Division of Antiviral Products
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Murray:

As a representative of the American Academy of Family Physicians and its 93,000 members, I would like to express concern over the proposed expanded licensure of oseltamivir, (Tamiflu®), so as to be available in a prepackaged form for home stockpiling and use in the event of an influenza pandemic.

The plan to encourage home stockpiling of a potent antiviral medication that requires a physician prescription is based on many untested assumptions and has the potential to create more harm than benefit. If implemented, it will create difficulties for physicians, other prescribers, and their patients. I will describe each of these concerns and list the questions that should be answered before any such plan proceeds. I restrict my comments to the issues that FDA should consider even though the AAFP has other concerns about the proposed home stockpiling plan.

The untested assumptions and unanswered questions about home stockpiling include those that follow. Each should be investigated before consideration of licensure of a home stockpile formulation of Tamiflu proceeds.

1. Will patients properly store and be able to retrieve the medication years after it has been obtained?
2. Will patients recall instructions for use of the medication years after they have been provided?
3. Will patients use the medication inappropriately for other viral and/or bacterial infections?
4. Will the medication be used in the recommended dose and duration by all age groups?
5. How will changing dose requirements for growing children be considered?
6. Will inappropriate use lead to oseltamivir resistance?
7. What will be the incidence of adverse drug reactions from home stockpiling and use?
8. Will patients understand the difference between post exposure prophylaxis (PEP) and chemo prevention (use of medication to prevent infection in those at risk of exposure)?
9. Does PEP prevent infection or improve outcomes if infected? If so, among what age and risk groups?
10. Can individuals accurately assess when they have been exposed to influenza?
11. Does chemo prevention prevent infection or improve outcomes if infected? Who should take it, when should they start, and how long should they take it for?

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12. If the medication is recommended for chemo prevention only for those in high risk jobs, will other members of the public adhere to this recommendation?

In light of these uncertainties the difficulties home stockpiling will create for physicians is especially questionable. The correct use of Tamiflu will require physician time to explain and will detract from other more beneficial activities such as counseling, preventive screening, immunization, and instructions on the use of other medications, all which have to occur within a limited time frame.

Physicians will be asked by patients to prescribe the medication for their family and friends, who do not have physicians, and to re-prescribe when the medication has been used inappropriately for other conditions.

The cost of the medication will present a significant barrier for some patients, creating social inequity and again creating difficulty for physicians. Some patients will have third party coverage for the medication and some will not. Some will be able to pay out of pocket and some will not. This will cause patient requests to prescribe the medication for one person using the name of another so that third party coverage can be used.

The AAFP believes that there are many measures that can be taken to reduce morbidity and mortality in an influenza pandemic. The quick and rapid use of antiviral medication in specifically defined circumstances is one of these tools. This will require collaboration and planning between physicians and public health agencies and the AAFP is eager to participate in such planning.

Sincerely,

A handwritten signature in black ink that reads "Ted Epperly M.D." The signature is written in a cursive style and is positioned below a horizontal line that extends to the left.

Ted Epperly, M.D., FAAFP
President