

Testimony by

Doug Campos-Outcalt M.D.
Scientific Advisor to the American
Academy of Family Physicians

to the
FDA Joint Meeting
of the Antiviral Drugs and Nonprescription Drugs
Advisory Committees

- The AAFP agrees with the FDA assessment that the proposed storage and use of antiviral Homekits has many similarities with over the counter medication use.
- Widespread stockpiling of antiviral medication for future use at some uncertain time and under uncertain circumstances will lead to frequent medication use without direction and oversight by a trained health care professional.
- The threshold for safety and the types of studies regarding patient understanding and medication use should be similar to that for OTC medications.

The Role of Family Physicians

- Family physicians are on the front line of primary care and are a vital part of the foundation of the nation's public health infrastructure.
- Collaboration between primary care physicians and local public health departments will be essential in a future influenza pandemic to minimize community wide morbidity and mortality.

AAFP Concerns

- Areas outside FDA consideration
- Areas FDA should address

Areas Outside FDA Consideration

- Equity in availability, distribution and financial coverage for Homekits.
- Potential requests for prescriptions for other than intended purposes:
 - Relatives
 - After inappropriate use (?refills)

Areas Outside FDA Consideration

- Physician time and effort needed to discuss Homekits, which will detract from needed chronic care and effective preventive care.
- The potential for physician liability when adverse outcomes occur from home use of a medication prescribed years before.

Areas FDA Should Address:

- Will patients properly store and then find the medication years after it has been obtained?
- Will patients recall instructions for use of the medication years after they have been provided?
- Will patients use the medication inappropriately for other viral and/or bacterial infections?

- Will the medication be used at the recommended dose and duration by all age groups?
- How will changing dose requirements for growing children be considered?
- Will inappropriate use lead to antiviral drug resistance?
- What will be the incidence of adverse drug reactions from Homekit use, and how will these events be tracked?

- 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)?
- Does PEP prevent infection or improve outcomes if infected? If so, among what age and risk groups?
- Can individuals accurately assess when they have been exposed to influenza?

- 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?
- 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?

- How will patients know to request a 5 day (treatment) Homekit versus a 10 day (PEP) Homekit? Will they know the difference between these?
- What measures will be taken if viral resistance develops and the Homekits are no longer recommended?
- Will use of Homekits continue to occur after a recommendation to stop using them as been given ?

- Will use of antivirals lead to a false sense of security and less adherence to other recommended measures such as social distancing, respiratory hygiene, hand washing, immunization against seasonal influenza (or pandemic influenza should a vaccine be available), and use of face masks?
- Will the overall benefits exceed the harms?

Conclusion

- Thank you for the opportunity to raise issues we feel are important. We hope they are considered seriously.