



Tamiflu May Not Be Reliable Bird Flu Protection, DHS Official Warns

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By Todd Zwillich

WebMD

The antiviral drug being hurriedly stockpiled by governments worldwide may not be reliable protection against bird flu, a U.S. preparedness official warned Tuesday.

Experts have long said that Tamiflu is not a cure for bird flu, but the drug could help slow the severity or spread of the disease in the event of a human pandemic. Governments have rushed to order stocks, prompting a worldwide run on the drug and criticism of its manufacturer for apparent refusal to share its patent with generic drugmakers.

But even that assessment may be overly optimistic, Michael Osterholm, MD, told reporters Tuesday. Osterholm is associate director of the National Center for Food Protection and Defense within the Department of Homeland Security.

Questions of Effectiveness

"I believe that antiviral drugs really represent a tool, a limited tool," said Osterholm, who is also director of the Center for Infectious Disease Research and Policy at the University of Minnesota. "What we don't know is if Tamiflu will work."

Tamiflu and drugs like it can mitigate flu severity and slow disease spread if taken within 48 hours of symptoms. The drug has been shown to have some effectiveness against H5N1, the virus strain that has sickened more than 120 people and killed more than 60 in Southeast Asia.

Once it enters the body, H5N1 replicates more rapidly and penetrates a wider range of lung cells than do other more common flu viruses. The aggressive infection sets off a rapid and massive release of chemicals that then turn on the immune system to destroy it.

When Should Tamiflu Be Taken?

Experts call the chemical release a "cytokine storm." One key but unanswered question about the drug is whether it needs to be given earlier or in higher-than-usual doses to stave off the dangerous "storm."

"Frankly we just don't know," Osterholm said.

Limited animal studies have suggested that Tamiflu must be given before infection in order to be effective, he said. That could greatly reduce Tamiflu's usefulness in an epidemic because the drug would have to be given long before any evidence of sickness.

The U.S. has announced plans to increase its Tamiflu stores from 2 million to more 20 million treatment courses. The drug is on back order from Swiss manufacturer Roche as dozens of other governments have requested the drug.

"It's being sold right now as almost the Cipro of post-9/11," said Osterholm, referring to mass purchases of the antibiotic ciprofloxacin after mailed anthrax attacks killed five people in the fall of 2001.

Roche Responds

In a statement Tuesday, William M. Burns, CEO of Roche's pharmaceuticals division, said Tamiflu was effective.

"Tamiflu is designed to be active against all clinically relevant influenza viruses, and key international research groups have demonstrated, using animal models of influenza, that Tamiflu is effective against the avian H5N1 strain circulating in the Far East."

The company has fallen under criticism from lawmakers and some governments for refusing to suspend its patent so that generic drug makers could help fill stockpile orders.

One Indian company, Cipla, announced last week that it would go ahead with plans to manufacture a Tamiflu copy whether or not Roche gives it a license.

Meanwhile, one lawmaker increased pressure on Roche Tuesday by calling on the company to allow up to five U.S. generic manufacturers to make emergency supplies of the drug within the next 30 days. Sen. Charles Schumer (D-N.Y.) said he would ask the Bush administration to use emergency powers to suspend the company's patent if it does not license the drug by that time.

Roche spokesman Terrence Hurley told WebMD in an email that the company has not refused any official requests to sublicense Tamiflu. "To date, we have been approached by just one country in the Far East and are having conversations with them right now," he said.

"That is not near good enough. Roche has responsibilities to the world," Schumer told reporters.

By [Todd Zwillich](#), reviewed by Louise Chang, MD

SOURCES: Michael Osterholm, MD, director, Center for Infectious Disease Research and Policy, University of Minnesota, associate director, National Center for Food Protection and Defense, U.S. Dept. of Homeland Security. Sen. Charles Schumer, (D-N.Y.). William M. Burns, CEO, Roche Pharmaceuticals Division. Terrence Hurley, spokesman, Roche.

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