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Legislative Fact Sheet
Colorado and Tamiflu Stockpiling for Pandemic Preparedness

A pandemic is a global disease outbreak. A flu pandemic occurs when a new influenza virus emerges for which people have little or no immunity, and for which there is no vaccine. The disease spreads easily person-to-person, causes serious illness, and can sweep across the country and around the world in very short time. Avian (bird) flu is caused by influenza A viruses that occur naturally among birds. H5N1 is an avian flu strain that has been circulating widely in birds in other countries. Since 2003, a growing number of human H5N1 influenza A cases have been reported in Asia, Europe, and Africa. More than half of the people infected with the H5N1 virus have died. Nearly 100% of these cases have been caused by exposure only to infected poultry. There has been no sustained human-to-human transmission of the disease, but the concern is that H5N1 could evolve into a virus capable of human-to-human transmission. No H5N1 cases in birds or humans have been reported in North or South America. To date there have been 357 human cases worldwide over the past 4 years.

Background

- In 2006, the U.S. Department of Health and Human Services (HHS) began stockpiling treatment courses of the antiviral drugs zanamivir (Relenza®) from GlaxoSmithKline and oseltamivir phosphate (Tamiflu®) from Roche. HHS's goal is to acquire sufficient quantities of antiviral drugs to treat 25% of the U.S. population. An added goal of these purchases is to stimulate development of expanded domestic production capacity sufficient to accommodate subsequent needs through normal commercial transactions.
- HHS has purchased enough antivirals to treat 15% or 44 million people of the U.S. population. This stockpile will be federally maintained through the Strategic National Stockpile. Colorado's allotment is 677,699 courses.
- HHS recommended states purchase additional antivirals at a federally subsidized rate to treat 10% of their state's population. HHS agreed to subsidize 25% of state purchases. Colorado's allotment available for purchase is 477,470 at a cost of just over $7,000,000.
- CDPHE has opted to not participate in this program due to cost, lack of scientific evidence of antiviral effectiveness during a pandemic and because Colorado's federal allotment of 677,699 will cover: all hospitalized patents, all high risk patients who get the flu and seek care, all essential service workers (first responders, medical care providers, food workers, law enforcement, fire fighters, etc.) who get the flu and seek care and at least eight weeks of continuous prophylaxis for all health care workers taking care of flu patients.
- The Governor's Expert Emergency Epidemic Response Committee, the Colorado Medical Society, the Public Health Directors of Colorado and the Colorado Association of Public Health Leaders support this decision. HHS has also gone on record in saying that antiviral stockpiling does not equal preparedness.

Problem

Colorado is being asked to participate in a program with several limiting factors:

- **High Costs**
  The federal government only pays 25 percent of the cost to purchase an antiviral stockpile. That means that Colorado will be expected to come up with 7 million dollars to pay for this stockpile.
- **Uncertain effectiveness for unknown virus**
  Since we do not know what a pandemic virus will actually be, we also do not know what antiviral medications, if any, will work best if at all. We also do not know if antiviral medication will be the best approach to preventing the spread of disease, since we cannot identify a pandemic virus. Much of the data and recommendations are based on the use of antivirals with seasonal flu.
- **Possible side effects**
  In 2006, reports indicated that "People with the flu, particularly children, may be at increased risk of self-injury and confusion shortly after taking Tamiflu and should be closely monitored for signs of unusual behavior". FDA has issued a warning on Tamiflu about serious adverse effects associated with use in children.
- **Expiration dates**
  Antiviral medications have a limited shelf life. Tamiflu has a shelf life for only five years. The federal Shelf-Life Extension Program could extend this for another two years.
- **Unreasonable regulations**
  States are not allowed to rotate the stock of medicines to ensure that the stockpile would be available indefinitely. Colorado had been negotiating with a big health care provider to host the storage site and rotate the stockpile, so the medication would not expire all at once and be thrown away, but the federal government would not permit this arrangement. The stockpile would need to be discarded at the end of its shelf life. Further, states cannot use the stockpile for any other purpose. If an outbreak of H5N1 occurred in poultry, Colorado could not use this stockpile to provide treatment or prophylaxis to poultry workers who may have to cull sick birds.
- **Ecological impacts**
  At the seven-year expiration, disposal of mass quantities of antiviral medications could cause other problems. Scientists who study the effects of drugs on our environment predict that wild birds will develop drug-resistant strains of influenza if they are exposed to antiviral medication waste by-products in our water sources. It is also possible that up to 80 percent of the active chemicals in Tamiflu remain in our wastewater, due to the amount that is excreted by the human body and the way that the chemicals breakdown after disposal.
- **Seasonal Flu resistance**
  Reports of seasonal flu resistance to Tamiflu are increasing every year and could significantly impact any role in mitigating flu pandemic. As of February 1, 2008, nine countries in Europe reported more evidence that one of the three types of seasonal influenza viruses is showing resistance to Tamiflu and said this represents the first clear sign that the resistant variant can spread, and there is evidence of emerging resistance in the United States. It is very possible that resistance in a pandemic flu strain would emerge very quickly making the drug useless. There are already strains of the bird flu virus that show Tamiflu resistance.

Recommendations

- Colorado has spent most of their effort and funds around planning with local public health agencies, hospitals, businesses, schools and universities, law enforcement and communities. Focus of this planning has been education, personal and business preparedness, mass vaccination efforts and "social distancing". Modeling has shown that implementing social distancing measures may reduce mortality by 72%.
- Vaccine technology is advancing quickly so Colorado has focused planning and exercises around preparing for how to vaccinate the public when vaccine becomes available.
- We are not recommending using scarce state resources to purchase a stockpile of a medication of unknown effectiveness for an event with uncertain timing and severity. We believe resources are better spent on preparedness planning.

CDPHE experts are available to brief any member of the General Assembly who requests additional information.

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