## Congress of the United States Washington, DC 20515

October 26, 2005

Michael Leavitt Secretary Department of Health and Human Services 200 Independence Avenue, SW Washington, D.C. 20201-0004

## Dear Secretary Leavitt:

As experts assert that the likelihood of a global avian flu pandemic is extremely high, it is more important than ever that we make our health our top priority. A keystone of our defenses against an outbreak will be two anti-viral drugs called Tamiflu and Relenza. Both enjoy patent protection, which means that the patent holders have the ability to limit the manufacture of their respective drugs to their own company or contractors.

Last year, we were reminded of the perils of relying on a small number of entities to manufacture drugs that comprise our flu safety net. Chiron was forced to scrap half of the U.S. flu vaccine supply when their manufacturing facility failed to meet safety standards. And yet, at the cusp of a potentially far more devastating avian flu epidemic, we are about to repeat our mistake.

Furthermore, when a company holds a patent monopoly, they can control world supply. For example, Roche is not taking the necessary steps to meet world demand for Tamiflu. Klaus Stohr of the World Health Organization's (WHO) Global Influenza Programme has said it will take 10 years for Roche to adequately supply world demand for Tamiflu stockpiles. The U.S. currently has stockpiles for less than 1% of the American population. The WHO recommends stockpiles for 40% of the population. Roche has now announced twice that they will enter into negotiations with generics manufacturers to license Tamiflu to them. But if Roche sets fees too high, generics will not have sufficient incentive to make the drug. In addition, they have indicated they will not allow generics to supply the U.S., making their efforts inapplicable to our stockpiling efforts.

Compromising our pharmaceutical defenses against the avian flu is neither prudent nor necessary. The U.S. government has the authority to issue compulsory licenses specifically because of circumstances like these (28 USC 1498). If manufacturing licenses are issued, other qualified entities would also be able to manufacture the drug and the patent holder would be compensated. Indeed, such licenses have been issued in the past under far less urgent circumstances.

Many experts, including the Director General of Taiwan's Centre for Disease Control, Kou Hsusung, say that generic companies can profitably manufacture the drug despite the complexity of

the manufacturing process. In their desperation to meet their county's demand, a major Indian drug company recently announced they had reverse engineered Tamiflu and expect to begin sales by January of 2006.

Compromising public health in order to preserve patent monopoly rights is inexcusable. We strongly urge you to immediately issue a compulsory license for Tamiflu and Relenza so that generic manufacturers can get to work shoring up our defense against avian flu.

Sincerely,

Dennis J. Kucinich

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Member of Congress

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