

**Congress of the United States**  
**Washington, DC 20515**

November 9, 2005

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

Dear Mike:

Thank you for participating in the House Government Reform Committee hearing "The National Pandemic Influenza Preparedness and Response Plan: Is the U.S. Ready for Avian Flu?" on November 4, 2005. We are writing to contest your stated justifications for refusing to issue a compulsory license for Tamiflu and to request, again, that you reconsider your stance.

You mentioned that issuing a compulsory license would not hasten the manufacture of Tamiflu because it is a complex manufacturing process that incorporates a step requiring an explosion hazard. There is considerable evidence showing that the manufacturing process is not prohibitively complex or dangerous.

Roche's own advertisement in several periodicals has said that they have "received more than 100 requests from different parties interested in helping us meet production challenges."<sup>1</sup> Indian generics manufacturer, Cipla has announced that they plan to start selling enough generic Tamiflu to treat 100,000 to 200,000 people by March of 2006.<sup>2</sup> News reports indicate that Thailand, Taiwan, Malaysia, and Vietnam plan to initiate production, some as soon as February 2006.<sup>3,4,5,6</sup> Taiwan appears to have made "the drug in just 18 days, not including weekends and a bank holiday, using information from publicly available documents."<sup>7</sup> They also report that Roche has admitted that it exaggerated the complexity of the manufacturing process. Ernie Prisbe, Vice President of Tamiflu inventor, Gilead Sciences, said of the Tamiflu manufacturing process, "There's nothing that overwhelming in this kind of synthesis, or that formidable, that someone couldn't do it."<sup>8</sup>

Clearly, it is feasible to ramp up production swiftly to provide for the U.S. and the entire world.

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<sup>1</sup> National Journal's CongressDailyAM, Thursday November 3, 2005, page 8

<sup>2</sup> "Is Bird Flu Drug Really So Vexing? Debating the Difficulty of Tamiflu," New York Times, November 5, 2005

<sup>3</sup> "Thailand to produce generic treatment for bird flu," ABC News, October 18, 2005

<sup>4</sup> "Malaysia, Bracing for Bird Flu, May Produce Tamiflu Locally," Bloomberg.com, November 2, 2005

<sup>5</sup> "Let others make life-saving drug, company told," Timesonline (UK), November 5, 2005

<sup>6</sup> "Roche to increase production of Tamiflu," Press-Enterprise, November 8, 2005

<sup>7</sup> "Let others make life-saving drug, company told," Timesonline (UK), November 5, 2005

<sup>8</sup> "Is Bird Flu Drug Really So Vexing? Debating the Difficulty of Tamiflu," New York Times, November 5, 2005

You also indicated that you did not wish to issue a compulsory license for Tamiflu because it would discourage pharmaceutical companies from investing in research into future anti-virals or other drugs. Please be reminded that whenever a government representative issues a compulsory license, the licensor gets a royalty in order to insure profits are not taken. Roche will undoubtedly continue to make healthy profits if a compulsory license is issued.

You further indicated that an emphasis on Tamiflu is undue since it is not our strongest defense, nor is it guaranteed to be relevant to the virus strain behind a pandemic. I agree that Tamiflu is not a silver bullet. However, to our knowledge, it is the best pharmaceutical defense we have now. Our public health infrastructure is not ready and it will take years to make it so. Until there is a better alternative, and unless we have reason to believe the drug would do more harm than good, and until our state of readiness for a pandemic is stronger, we have an obligation to do all we can to shore up our weak defenses now. Bear in mind that the shelf life of Tamiflu is five years, which means stockpiles are unlikely to go to waste.

If you are content to wait until 2007 to fill our stockpile needs, a deadline you claimed Roche would be able meet in your testimony, you are gambling with public health with the proceeds going to Roche. If the pandemic does not happen before 2007, Roche keeps their monopoly intact and the public is unharmed. If the pandemic strikes before Roche meets its promised deadline, and nothing has been done to ramp up production - like issuing a compulsory license - our stockpile will be inadequate. History will not be kind to those who could have saved lives but instead deferred to intellectual property rights.

Please reconsider your willingness to issue a compulsory license for Tamiflu.

Sincerely,



Dennis J. Kucinich  
Member of Congress



Bernard Sanders  
Member of Congress



Marion Berry  
Member of Congress