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SCHAKOWSKY DEMANDS FDA RESPONSE TO ILLINOIS' REQUEST TO IMPORT FLU VACCINE FROM ABROAD

SAYS ADMINISTRATOR HAS ALLOWED POLITICS TO TRUMP PUBLIC HEALTH

WASHINGTON, D.C. - U.S. Representative Jan Schakowsky today, during a hearing in the House Commerce Committee's Subcommittee on Oversight and Investigations, demanded that the FDA explain its five-month delay in responding to Illinois Governor Rod Blagojevich's request to import flu vaccine from abroad. " At a time when flu vaccine prices are up 17% Schakowsky expressed concern that despite assuring her in November of 2004 that a response would be forthcoming in a matter of weeks, the Administration is still preventing Illinois from ensuring a safe, adequate and affordable supply of the vaccine and other life-saving drugs." Below is Schakowsky's entire statement:

"Thank you, Mr. Chairman. Thirty thousand people die annually from the flu virus. Hundreds of thousands of others end up in the hospital. No American should again be asked to compromise their health because of the failures of the Bush Administration to provide sufficient doses of the flu vaccine."

"Last October, we learned that we would only have half the expected supply of influenza vaccine for the fall and winter flu season. When the Food and Drug Administration (FDA) was told of contamination at the Chiron facility, one of the largest flu vaccine producers, it failed to act in a meaningful way to address the problem or to secure additional vaccine supplies from elsewhere. We saw price gougers appear out of the woodwork to profit from a public health crisis and we saw many who would normally seek a vaccination, those at greater risks of contracting the flu, foregoing shots."

"Had FDA taken an appropriate course of action, last year's vaccine shortage and perhaps unnecessary sickness and loss of lives in the U.S. may have been avoided. None of these problems occurred in other countries where the government plays a far greater role in assuring affordable access to healthcare. In fact, in Canada, there was adequate flu vaccine supply to

sell to those Americans who were close enough to the border to go across for a shot."

"Last fall, Illinois Governor Rod Blagojevich, a leader in the fight for affordable prescription drugs and the re-importation of prescription drugs, acted to secure additional vaccine supplies for the most vulnerable people in our state. Although in the hearing we held last November the FDA indicated to me that it planned to provide a decision within two or three weeks of that time as to whether Illinois would be able to bring vaccines into the country, I understand Governor Blagojevich is still awaiting FDA authorization.

So, I want to hear more from the FDA about its response to Illinois. I want to know why, five months later, Illinois has still not been given permission by the FDA to import flu vaccines. And I want to know why, given the fact that we are still entirely relying on foreign sources to meet our flu vaccine needs, the Bush administration is still adamantly blocking Illinois' re-importation efforts of other lifesaving medications."

"The FDA allowed politics to trump public health when it undermined Gov. Blagojevich's effort to address a serious health crisis. Why would a federal health agency stall in an emergency situation like the one we faced last fall? The answer can only be because of their fear that Gov. Blagojevich's success in importing flu vaccine would provide validation for his efforts to import prescription drugs for the people of Illinois."

"Today, the Wall Street Journal highlights how many doctors, pharmacists and hospitals across the U.S. already fear another major shortage of flu shots. The Vice President of Amerinet Inc., a health-care purchasing group in St. Louis, termed the surge in orders "a feeding frenzy." Manufacturers are already charging at least 17% more for the flu shots, reflecting this rush for advance orders. According to the Wall Street Journal, "[this] shows that the vaccine-production infrastructure remains nearly as fragile and outdated as it was before last year's crisis."

"We should learn from the mistakes made last year. I would like to hear from the witnesses today, what concrete actions the Administration is taking to ensure that this same fiasco will not happen again. I want to hear what changes have been made to our nation's flu vaccine infrastructure since last year. It is clear that we need better cooperation and information sharing, not only between the manufacturers and the distributors, but also with the regulatory agencies of other countries where the manufacturing plants are located. Because we are still clearly relying on foreign sources to meet our flu vaccine needs, we need to improve monitoring of and communication with those sources. I would like to hear how the FDA and CDC will work

with state and local health officials, manufacturers and the public to improve distribution of available supply. And I want to hear how it is that, after news of massive shortages, we actually ended up with regional surpluses of the flu vaccine. That fact is especially troubling because it means many of those who needed the vaccine but did not receive it could have avoided unnecessary illness."

"At last year's hearing, I questioned the Bush Administration's attitude toward vaccine accessibility. I was disturbed by Vice President Cheney's explanation that vaccine production just isn't profitable enough for private companies. And I will ask the same question: Are the Administration's concerns for the high profits of the pharmaceutical companies to take precedence over the health of the American people?"

"I want to be able to assure my constituents that there will not be a shortage of flu vaccine in Illinois this fall. And I hope this committee will be made aware, in advance and in real time, of the status of flu vaccine production at the labs with which we contract so that the 2005-2006 flu season will not be a relapse of last year's problems."

"Thank you, Mr. Chairman."